

Maternal Child Health for American Indians & Alaska Natives

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# Cesarean delivery in Native American women:

Are low rates explained by practices common to the Indian Health Service?

BACKGROUND: Studying populations with low cesarean delivery rates can identify strategies for reducing unnecessary cesareans in other patient populations. Native American women have among the lowest cesarean delivery rates of all United States populations, yet few studies have focused on Native Americans. The study purpose was to determine the rate and risk factors for cesarean delivery in a Native American population.

METHODS: We used a case-control design nested within a cohort of Native American live births, >/= 35 weeks of gestation (n = 789), occurring at an Indian Health Service hospital during 1996-1999. Data were abstracted from the labor and delivery logbook, the hospital's primary source of birth certificate data. Univariate and multivariate analyses examined demographic, prenatal, obstetric, intrapartum, and fetal factors associated with cesarean versus vaginal delivery.

RESULTS: The total cesarean rate was 9.6 percent (95% CI 7.2-12.0). Nulliparity, a medical diagnosis, malpresentation, induction, labor length > 12.1 hours, arrested labor, fetal distress, meconium, and gestations < 37 weeks were each significantly associated with cesarean delivery in unadjusted analyses. The final multivariate model included a significant interaction between induction and arrested labor (p < 0.001); the effect of arrested labor was far greater among induced (OR 161.9) than

noninduced (OR 6.0) labors. Other factors significantly associated with cesarean delivery in the final logistic model were an obstetrician labor attendant (OR 2.4; p = 0.02) and presence of meconium (OR 2.3; p = 0.03).

CONCLUSIONS: Despite a higher prevalence of medical risk factors for cesarean delivery, the rate at this hospital was well below New Mexico (16.4%, all races) and national (21.2%, all races) cesarean rates for 1998. Medical and practice-related factors were the only observed independent correlates of cesarean delivery. Implementation of institutional and practitioner policies common to the Indian Health Service may reduce cesarean deliveries in other populations.

Mahoney SF, Malcoe LH. Cesarean delivery in Native American women: are low rates explained by practices common to the Indian health service? Birth. 2005 Sep;32(3):170-8.

#### **OB/GYN CCC Editorial**

I have always marveled at what great patients AI/AN women are to practice medicine with. I assumed our patient's many favorable obstetric traits were in part genetic and part cultural, plus a degree of genetic homogeneity.

Sheila Mahoney and her colleagues became aware of the low cesarean delivery rates in the IHS and she felt that it would be good to look at possible reasons in a systematic way. This

(continued on page 19)

#### THIS MONTH

#### Also on-line....

This publication is a digest of the monthly Obstetrics and Gynecology Chief Clinical Consultant's Newsletter which is available on the Internet at www.ihs.gov/MedicalPrograms/MCH/M/OBGYN01.cfm
You are welcome to subscribe to the listserv and receive reminders about this service. If you have any

I am looking forward to hearing from you.

questions, please contact

me at nmurphy@scf.cc.

NEIL J. Murphy

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

### **IHS Child Health Notes**

#### September 2005

"You don't have to be unfair to be tough." Barney Frank, US Congressman

#### **Articles of Interest**

American Indian and Alaska Native Children: Findings From the Base Year of the Early Childhood Longitudinal Study, Birth Cohort (ECLS-B)

This E.D. TAB provides descriptive information about American Indian and Alaska Native (AIAN) children born in the United States in 2001. It presents information on characteristics of their families, on children's mental and physical skills, on children's first experiences in childcare, on the fathers of these children, and on their prenatal care. The report profiles data from a nationally representative sample of children at about 9 months of age both overall, and for various subgroups (i.e., male and female, AIAN children living in different types of families, AIAN children living in poverty). This report tells us that about one-third of AIAN children live in poverty (34 percent), about one-third live in households where the mother has less than a high school education (34 percent); three-quarters live in households with two parents, and about 1 in 10 (11percent) were born to teen-aged mothers. Nonetheless, AIAN children at about 9 months of age do not perform significantly differently from the general population of children in terms of early mental and physical skills, such as exploring objects in play, babbling, eye-hand coordination and pre-walking skills.

#### **Editorial Comment**

The National Center for Education Statistics is within the Department of Education. They have the ambitious task of completing a longitudinal study of early childhood development. The birth cohort is from 2001 and involves a sampling of all races and ethnic groups. New reports are expected every few years. This report provides a wealth of data about AI/AN infants that can be used for reference.

I would like to welcome two new contributors to our child health notes. Dr. Rosalyn Singleton of Anchorage, Alaska, will be providing a monthly update on vaccinations and pediatric infectious disease issues. Dr. Douglas Esposito from Fort Defiance, AZ, will provide a monthly review on new articles relating to AI/AN health problems. I expect they will add knowledge and breadth, and possibly wit, to these pages. Please let me know if there are other topics you would like to see discussed in these pages by our consultants..

"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

Pertussis Prevention: What's in the Forecast?

Although DTaP vaccine has nearly eliminated diphtheria and tetanus in the US, pertussis infections increased dramatically, from a low of 1,020 cases in 1976 to more than 19,000 cases in 2004 – a 40 year high. Approximately 36% of the cases occur in adolescents; however, 90% of pertussis deaths occur in young infants who are often exposed to pertussis from older siblings. The pertussis immunity induced by early childhood vaccinations wanes after about 6 years, leaving adolescents and adults susceptible to pertussis.

In 2005 two companies received FDA licensure of Tdap vaccines. BOOSTRIX® (GlaxoSmithKline) is licensed for 10-18 year olds while Adacel® (Sanofi Pasteur) is licensed for persons 11 to 64 years of age. The Tdap vaccines have the same amount of tetanus and diphtheria toxoid as Td and with 1/4 the amount of the pertussis antigens found in DTaP vaccines. Both vaccines elicit superior immune responses to that seen in children with DTaP and similar adverse events to currently available Td vaccine. In June 2005 the ACIP recommended that adolescents 11-18 years of age be given a single Tdap in place of the Td booster. The full recommendations and VFC coverage will be published in the next few months. The ACIP expects to phase in adult Tdap indications over the next few years. Tdap has been added to the RPMS Immunization Table, and Tdap will forecast in adolescents 11-18 years of age in the next Immunization package version (Winter 2005).

#### Recent literature on American Indian/ **Alaskan Native Health**

#### Doug Esposito, MD

Outcome evaluation of a public health approach to suicide prevention in an American Indian Tribal Nation Am J Public Health. 2005;95(7):1238-44.

#### **Highlights**

- Evaluation of a 15 year community-based mental health intervention targeting adolescent suicide on a rural New Mexico Athabaskan Tribal Nation.
- Target population was primarily aged 10-19 years, but 20-24 year olds were targeted as well later on in the project.
- Other targets included broad-based community education and awareness of suicide, in addition to other related behaviors (child abuse and neglect, family violence, trauma, and alcohol and substance abuse).

(Child Health Notes, continued on page 5)

### From Your Colleagues

#### Meera Ramesh, Bethel, Alaska

#### Diabetes prevention and control - Prenatal program

The Bethel Diabetes prevention and control program has four clinical diabetes educators in a four tiered rural health care delivery system. Diabetes educators collaborate with the hospital OB and prenatal departments, the village clinic CHA/P's and the Alaska Native Medical Center. Educators provide the initial education and follow-up on a weekly basis, and through out the pregnancy to maintain a consistent relationship. Weekly glucose reports are collected via all communication means, from patients with class A1, and A2 prenatal diabetes. Reports are reviewed with the prenatal case manager and at the high risk OB committee. The committee addresses all issues such as hypertension, pre-eclampsia, glucose control, tobacco cessation and other maternal morbidities. All prenatal patients are required to enter the Bethel pre-maternal home at 36 weeks gestation. The diabetes registry tracks all prenatal diabetes patients. Data is entered into the RPMS system, and reports can be retrieved through Q-Man and other report generating systems. Random chart audits track key outcomes such as high birth weight, delivery problems and other prenatal difficulties. Tracking of long-term infant and maternal outcomes is being planned. Past audits have proven good outcomes for those patients followed by the diabetes program. All CHA/P's have access to the Advanced Diabetes Training classes so that they may be a resource to their villages. Meera Ramesh, MS, RD, LD, CDE, Director, Community Health and Wellness Yukon-Kuskokwim Health Corporation. Questions? Judith.Thierry@ihs.gov

#### Judy Thierry, HQE

### Maternal Morbidity in American Indian and Alaska Native Women, 2002–2004

PURPOSE: Maternal morbidity, defined as a condition that results from or is aggravated by pregnancy, is a significant economic and public health burden in the United States. The most common morbidities reported in recent studies include preterm labor, genitourinary complications, hemorrhage, and hypertensive disorders. However, few studies have reported data specific for American Indian and Alaska Native (AI/AN) women. The purpose of our analysis was to examine maternal morbidity in AI/AN women present at delivery hospitalizations using a population-based design.

METHODS: Using the Indian Health Service (IHS) National Patient Information Reporting System, we analyzed aggregated data from five IHS medical centers from July 2002 through June 2004. Delivery hospitalizations were identified by the ICD-9 code V27 listed in any of the 15 diagnosis fields. Maternal morbidity was identified by ICD-9 codes 640-677 listed in any diagnosis fields. All analyses were performed using SPSS version 12.0.

RESULTS: Overall, 6,761 deliveries were performed at the IHS medical centers during our study period. The average age of AI/AN women who delivered was 25.5 years, with the youngest being 13 years and the oldest being 47 years. The most common complication was gestational diabetes occurring in 7.4% of women. Pregnancy-related hypertension was reported in 5.3% of women and 2.3% of women experienced genitourinary infections.

CONCLUSIONS: AI/AN women who delivered at these five medical centers had higher rates of some maternal morbidity compared to women in the general population. Our findings stress the need for continual surveillance and etiologic research to understand the elevated health risk among these women. From Stephen J. Bacak, Judy Thierry, Myra Tucker, Edna Paisano 17th Annual Research Conference, Indian Health Service For further information:

Stephen J. Bacak, MPH at sb897694@ohio.edu

#### **OB/GYN CCC Editorial**

This is a major step forward to help the Indian Health system better plan clinical programs and resource allocation. Clearly, there is significant work to be done to improve the health care status of AI/AN pregnant woman. This data should be a lightening rod for us to improve our perinatal care for AI/AN women.

The process of analyzing this data set is open to each of the Indian Health system Areas. One would simply need to contact Judy Thierry\* to participate in analyzing the data from your area. The possibilities are quite open ended.

Here a just few comments from Chris Carey M.D. Chairman of the ACOG Committee on American Indian Affairs "...What about mentioning preterm labor/preterm birth or hemorrhage in the AN/AI population? You list them as most common in the general population. Were their rates lower? As you know, some reports show lower rates of preterm birth in AI/AN populations and lower infant mortality, but that may be due to mis-classification as Caucasian race. What about stillbirths and neonatal deaths?..."

\*Please contact Judy Thierry to analyze similar data in your Area, Judith.Thierry@ihs.gov

**Domestic** 

Violence

#### Patients May Prefer That Physicians Ask About Family Conflict

CONCLUSION: Most patients are open to discussions about family conflict with their physicians. The skills they recommend to physicians are well within the domain of family medicine training.

Burge SK, et al Patients' advice to physicians about intervening in family conflict. Ann Fam Med. 2005 May-Jun;3(3):248-54.

### **Hot Topics**

#### **Obstetrics**

# The 4P's Plus screen for substance use in pregnancy: clinical application and outcomes

CONCLUSION: The 4P's Plus identifies not only those pregnant women whose drinking or drug use is at a high enough level to impair daily functioning, but provides an opportunity for early intervention for the much larger group of women whose pregnancies are at risk from relatively small amounts of substance use. Chasnoff IJ, et al The 4P's Plus screen for substance use in pregnancy: clinical application and outcomes. J Perinatol. 2005 Jun;25(6):368-74.

## Misoprostol: Effective and safe treatment option in term premature rupture of membranes

CONCLUSION: Misoprostol is an effective and safe agent for induction of labor in women with term premature rupture of membranes. When compared with oxytocin, the risk of contraction abnormalities and the rate of maternal and neonatal complications were similar among the 2 groups.

Lin MG et al Misoprostol for Labor Induction in Women With Term Premature Rupture of Membranes: A Meta-Analysis.

### Progesterone therapy ameliorates other risk factors in previous preterm delivery

CONCLUSION: The use of 17alpha-hydroxyprogesterone caproate in women with a previous preterm delivery reduces the overall risk of preterm delivery and changes the epidemiology of risk factors for recurrent preterm delivery. In particular, these data suggest that 17alpha-hydroxyprogesterone caproate reduces the risk of a history of more than 1 preterm delivery.

Meis PJ, et al Does Progesterone Treatment Influence Risk Factors for Recurrent Preterm Delivery? Obstet Gynecol. 2005 Sep;106(3):557-561

### Meperidine for Dystocia During First Stage of Labor: Limit Use

CONCLUSION: Because of the absence of any benefits in patients with dystocia in labor and the presence of harmful effects on neonatal outcomes, meperidine should not be used during labor for this specific indication.

Sosa CG, et al. Meperidine for dystocia during the first stage of labor: a randomized controlled trail. Am J Obstet Gynecol October 2004;191:1212-8.

## Compressive sutures of the uterus are effective in postpartum bleeding: Case Series

OBJECTIVE: To demonstrate the usefulness of a new method of applying compressive sutures to treat postpartum bleeding secondary to uterine atony.

METHODS: Multiple sutures were applied longitudinally and transversally around the uterus of 7 women with postpartum uterine atony and postpartum bleeding. Results: The procedure was successful in all cases. Conclusion: Compressive sutures of the uterus were effective in treating uterine atony with postpartum bleeding. Level of Evidence: III.

Pereira A, et al Compressive uterine sutures to treat postpartum bleeding secondary to uterine atony. Obstet Gynecol. 2005 Sep;106(3):569-72.

#### Gynecology

### PID: Outpatient treatment was as effective in preventing reproductive morbidity

CONCLUSION: Among all women and subgroups of women with mild-to-moderate PID, there were no differences in reproductive outcomes after randomization to inpatient or outpatient treatment. Level of Evidence: I. Ness RB, et al Effectiveness of Treatment Strategies of Some Women With Pelvic Inflammatory Disease: A Randomized Trial. Obstet Gynecol. 2005 Sep;106(3):573-580. Child Health

#### Adolescents Prefer Honesty and Patient-Centered Care

CONCLUSIONS: Participants rated aspects of interpersonal care (especially honesty, attention to pain, and items related to respect) as most important in their judgments of quality. As in most previous studies of adults, technical aspects of care were also rated highly, suggesting that adolescents understand and value both scientific and interpersonal aspects of care.

Britto MT, et al. Health care preferences and priorities of adolescents with chronic illnesses. Pediatrics November 2004;114:1272-80.

#### School-based dental sealant program manual now available online

SEAL AMERICA: The Prevention Invention, a how-to manual for establishing a schoolbased dental sealant program, is now available online. The manual was first developed in 1995 by the American Association of Community Dental Programs in cooperation with the Association of State and Territorial Dental Directors, the Health Resources and Services Administration's Maternal and Child Health Bureau, and the Centers for Disease Control and Prevention's Division of Oral Health. www.mchoralhealth.org/Seal

#### Chronic disease and Illness

#### One Third of Deaths From GI Bleeding **Due to NSAIDs**

CONCLUSION: Mortality rates associated with either major upper or lower GI events are similar but upper GI events were more frequent. Deaths attributed to NSAID/ASA use were high but previous reports may have provided an overestimate and one-third of them can be due to low-dose aspirin use.

Lanas A, et al A nationwide study of mortality associated with hospital admission due to severe gastrointestinal events and those associated with nonsteroidal antiinflammatory drug use.Am J Gastroenterol. 2005 Aug;100(8):1685-93.

#### (Child Health Notes, continued from page 2)

- A reduction in suicide attempts and gestures, but not successful suicides, was steadily documented over the course of the evaluation period (1988-2002).
- Durability of effect of the intervention was seen as the target population aged; i.e. reductions in suicidality generalized to older non-intervention age groups over time as intervention subjects advanced into the older age groups.
- The investigators attribute the success of the program to its integrated comprehensive community-based public health approach.
- Substantial growth in mental health services available to the target community were achieved over time, and were likely a large part of the success of the project.

#### **Editorial Comment**

Suicide is the second leading cause of death for American Indians and Alaska Natives (AI/AN) age 15-24 years, and represents one of the most pressing health problems faced by AI/AN communities today. AI/AN suicide rates are more than twice those suffered by the general population. Unfortunately, mental health and related services for the most vulnerable segments of our population are significantly under funded, and therefore, limited.

The authors report on a successful public health-oriented suicide prevention program conducted on an American Indian reservation. It appears that their success was in part attributable to a significant bolstering of the mental health services available to the target community. It will be a challenge for most of us who work with AI/AN populations to replicate these successes due to the difficulty of achieving similar expansions in mental health services under the current environment of extraordinary under funding.

#### **Pediatric Locums Service**

The AAP Committee on Native American Child Health has developed a web site to help IHS and 638 contract sites find pediatric locums. The web site has on line form you can fill out describing your locums needs and which will be posted for AAP members.

www.aap.org/nach

In addition, the AAP is interested in helping site find pediatricians to fill permanent vacancies. Contact AAP staff member Sunnah Kim at 847-434-4729

#### **Breastfeeding**

#### Glyburide nor glipizide compatible with breast-feeding

CONCLUSIONS: Neither glyburide nor glipizide were detected in breast milk, and hypoglycemia was not observed in the three nursing infants. Both agents, at the doses tested, appear to be compatible with breastfeeding.

Feig DS, et al Transfer of glyburide and glipizide into breast milk. Diabetes Care. 2005 Aug;28(8):1851-5.

#### **Features**

#### **American Family Physician**

### Cochrane for Clinicians—Putting Evidence into Practice: Short-Acting Insulin Analogues vs.

#### **Human Insulin for Diabetes**

CLINICAL SCENARIO: A 63-year-old woman has poor control of her type 2 diabetes with oral medications alone. You decide to discuss insulin therapy with her.

CLINICAL QUESTION: Are short-acting insulin analogues (lispro, aspart) better than regular insulin for controlling blood sugar levels, reducing A1C levels, and preventing long-term complications of diabetes?

EVIDENCE-BASED ANSWER: For patients with type 2 diabetes, regular insulin and short-acting insulin analogues are equally effective in the treatment of diabetes and in lowering A1C levels. For patients with type 1 diabetes, short-acting analogues produce a slightly greater reduction of A1C levels than regular insulin. Regular insulin and short-acting insulin cause hypoglycemia at similar rates. No studies have compared the effects of regular insulin and insulin analogues on the long-term complications of diabetes

#### Room Air vs. Oxygen for Resuscitating Infants at Birth

CLINICAL QUESTION: Does using 100 percent oxygen for neonatal resuscitation increase morbidity and mortality?

EVIDENCE-BASED ANSWER: Based on limited evidence, it appears that mortality is lower in infants resuscitated with room air than in those given 100 percent oxygen. However, these results should be treated with caution because one fourth

of studies used back-up supplementary oxygen.

PRACTICE POINTERS: Because excessive oxygen can increase free radical levels and decrease cerebral blood flow, it is thought that it may increase ischemic injury. Many deliveries occur outside of hospitals, where access to oxygen supplementation is limited. In hospital deliveries, early cord clamping often is performed to bring the newborn closer to an oxygen source for resuscitation. Delayed cord clamping has been shown to be beneficial in preterm infants to allow perfusion after delivery.

Tan and colleagues reviewed the literature to determine whether neonatal resuscitation with room air improves outcomes compared with 100 percent oxygen. They found five randomized and quasirandomized studies including 1,302 infants in total. A reduction in death rate was evident for infants resuscitated with room air (number needed to treat = 20). One study found that infants given room air had better five-minute Apgar scores; however, the difference was small and there were no significant differences in 10-minute Apgar scores or rates of grade 2 or 3 hypoxic ischemic encephalopathy. Another meta-analysis came to similar conclusions.

Based on current evidence, 100 percent oxygen should be used with caution during neonatal resuscitation. Routine use of oxygen should not supersede interventions with known benefit such as delayed cord clamping. Evidence supports the routine use of room air.

Tan A, et al. Air versus oxygen for resuscitation of infants at birth. Cochrane Database Syst Rev 2005;(2):CD002273.

#### **Family Planning**

### EC in adolescents: No compromise of family planning or increased sexual behavior

Conclusion: Young adolescents with improved access to EC used the method more frequently when needed, but did not compromise their use of routine contraception nor increase their sexual risk behavior. Level of Evidence: I.

Harper CC et a; The effect of increased access to emergency contraception among young adolescents. Obstet Gynecol. 2005 Sep;106(3):483-91.

#### **OB/GYN CCC Editorial**

These Level I data confirm other studies that the use of EC in adolescents is not associated with a compromise in the use of routine contraception, nor an increase their sexual risk behavior. I trust our federal regulatory agencies to rely on scientific data solely to make decisions on medication availability.

#### Emergency Contraception for adolescents, American Academy of Pediatrics

"...Although adolescent birth rates have declined in the past 10 years, unintended teen pregnancy and the associated negative consequences of adolescent pregnancy remain important public health concerns. Adolescent birth rates in the United States are much higher than rates in other developed countries. Emergency contraception has the potential to significantly reduce teen pregnancy rates and this will similarly reduce the abortion rate."

#### **Recognizing Elaine Locke:**

#### Key Contributor to Improvements in AI/AN Women's Health for 35 years

On April 1, 2005 Ms. Elaine Locke celebrated her 35th anniversary with the American College of Obstetricians & Gynecologists. Elaine began her tenure with the College in the Government Relations department. Ms. Locke having grown up in the Bemidji area of MN always had an interest in American Indian issues. Ms. Locke maintained that interest in her early years at the College and turned that interest into a more active role in 1980 when she began to be the full time staff person for the ACOG Indian projects.\*

The College recognized Ms. Locke's dedication to ACOG and to the improvement of AI / AN women's health with a celebration at the ACOG offices in Washington, DC. Ms. Locke was presented with a certificate of appreciation and a substantial gift. The American Indian Affairs Committee also celebrated Ms. Locke's long tenure and dedication at the Indian breakfast at this year's ACM in San Francisco. The committee presented Ms. Locke with a lovely vase and the committee vice chair presented her with a Navajo purse that her parents had bought on their honeymoon. The celebration continued in Denver at the ACOG/IHS postgraduate course where the faculty presented Ms. Locke with a beautiful Navajo rug as well as shared pictures of Ms. Locke on various site visits and at different ACOG/IHS Denver courses. 35 years of service is certainly noteworthy and we look forward to sharing many more with Ms. Locke.

- \* A few of those projects include:
- · ACOG /IHS Postgraduate Course on Obstetric, Neonatal, and Gynecologic Care
- ACOG Fellows in Service Program
- ACOG Committee on American Indian Affairs –see for many activities
- Annual IHS Area Site Visits
- Liaison Relationship—AAP, Committee on Native American Child Health (CONACH)

#### **OB/GYN CCC Editorial**

I took the ACOG/IHS Postgraduate Course in Denver in 1985 as a Family Physician when I started working in Indian Health in Bethel, Alaska, so I have only benefited from Elaine's hard work for a mere 20 years. Given my short tenure of a mere 20 years, I thought I would see if there might be a slightly longer term perspective or two on Elaine's contributions....

#### From William H.J. Haffner, M.D., OB/GYN Senior Clinician, IHS, 1981-1994

"Thirty-five years devoted to making a difference in health for all women and twenty-five of these years specifically devoted to Indian women's health! Elaine, in ways seen and most often unseen, has had an impact at ACOG and in the IHS on the lives of countless women through her tireless commitment, constant networking, and very thoughtful personal persuasion!

Thank you, Elaine "

Captain, USPHS (Retired)

Professor of Obstetrics and Gynecology

Former Chair of the OB/GYN Department, F. Edward Hebert School of Medicine

Uniformed Services University in Bethesda, MD

#### From Alan Waxman, M.D. OB/GYN Chief Clinical Consultant, IHS, 1994 - 2000

"Elaine has one of the most organized minds of anyone I've ever worked with. She is able to juggle numerous projects, anticipate future deadlines, and find key players no matter where they might be. I've often gotten messages from Elaine while working at remote clinics barely on the map. Her meticulous attention to detail has kept her very complex projects for ACOG and IHS running seamlessly."

Associate Professor, University of New Mexico IHS Breast and Cervical Cancer Control Program Consultant IHS 1976-200 primarily at Gallup Indian Medical Center

#### **ACOG**

#### Management of abnormal cervical cytology and histology —Summary of Recommendations

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

· Women with ASC cytology results may undergo immediate colposcopy, triage to colposcopy by high-risk HPV DNA testing, or repeat cytology screening at 6 and 12 months. Triage to colposcopy should occur after positive HPV test results or ASC or higher-grade diagnosis. Women with ASC who test negative

for HPV or whose HPV status is unknown and test negative for abnormalities using colposcopy should have a repeat cytology test in 1 year.

- Most women with ASC who are HPV positive or women with ASC-H, LSIL, or HSIL test results should undergo colposcopy.
- For women with an ASC HPV-positive test result or ASC-H or LSIL cytology result and a negative initial colposcopy or a histologic result of CIN 1, optimal follow-up is repeat cervical cytology tests (not screening) at 6 and 12 months or an HPV test at 12

- months; a repeat colposcopy is indicated for a cytology result of ASC or higher-grade abnormality or a positive high-risk HPV test.
- The recommendation for follow-up of untreated CIN 1 includes cytology tests at 6 and 12 months with colposcopy for an ASC or higher-grade result, or a single HPV test at 12 months, with colposcopy if the test result is positive.

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

- Endocervical sampling using a brush or curette may be undertaken as part of the evaluation of ASC and LSIL cytology results and should be considered as part of the evaluation of AGC, AIS, and HSIL cytology results.
- Endocervical sampling is recommended at the time of an unsatisfactory colposcopy or if ablative treatment is contemplated.
- Endocervical sampling is not indicated in pregnancy.
- Endometrial sampling is indicated in women with atypical endometrial cells and in all women aged 35 years or older who have AGC cytology results, as well as in women younger than 35 years with abnormal bleeding, morbid obesity, oligomenorrhea, or clinical results suggesting endometrial cancer.
- Women with HSIL cytology results and negative or unsatisfactory colposcopy results should undergo excision unless they are pregnant or adolescent.
- Women with AGC favor neoplasia or AIS cytology results and negative or unsatisfactory colposcopy results should undergo excision unless they are pregnant. A colposcopic examination negative for abnormalities after two AGC-NOS cytology results is also an indication for excision in the absence of pregnancy.
- Pregnant women with CIN 2 or CIN 3 may undergo follow-up with colposcopy during each trimester and should be reevaluated with cytology and colposcopy examinations at 6–12 weeks postpartum or thereafter. Treatment of CIN 2 and CIN 3 in pregnancy is not indicated.
- Women with CIN 2 or CIN 3 should be treated (in the absence of pregnancy) with excision or ablation. Management of CIN 2 in adolescents may be individualized.
- Women treated for CIN 2 or CIN 3 with a positive margin on excision may be followed by repeat cytology testing, including endocervical sampling every 6 months for 2 years or HPV DNA testing at 6 months; if these test results are negative, annual screening may be reestablished.
- Women with a cervical biopsy diagnosis of AIS should undergo excision to exclude invasive cancer. Cold-knife conization is recommended to preserve specimen orientation and permit optimal interpretation of histology and margin status.
- After treatment of CIN 2 or CIN 3, women may be monitored with cytology screening three to four times at 6-month intervals or undergo a single HPV test at 6 months before returning to annual follow-up.

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

- Colposcopic examination during pregnancy should have as its primary goal the exclusion of invasive cancer. Excisions in pregnant women should be considered only if a lesion detected at colposcopy is suggestive of invasive cancer.
- Cervical cytology screening lacking endocervical cells may
  be repeated in 1 year when testing was performed for routine
  screening. Cytology screening performed for a specific indication (ie, AGC follow-up or posttreatment follow-up after LEEP
  with a positive margin) may need to be repeated.
- Adolescents with ASC who are HPV positive or with LSIL results may be monitored with repeat cytology tests at 6 and 12 months or a single HPV test at 12 months, with colposcopy for a cytology result of ASC or higher-grade abnormality or a positive HPV test result.
- After treatment of AIS, when future fertility is desired and cervical conization margins are clear, conservative follow-up may be undertaken with cytology and endocervical sampling every 6 months.
- Women should not be treated with ablative therapy unless endocervical sampling test results are negative for abnormalities and the lesion seen and histologically evaluated explains the cytologic finding.
- In the absence of other indications for hysterectomy, excisional or ablative therapy for CIN 2 or CIN 3 is preferred.

Management of abnormal cervical cytology and histology.

ACOG Practice Bulletin No. 66. American College of Obstetricians and Gynecologists. Obstet Gynecol 2005;106:645–64.

#### **Obesity in Pregnancy**

ABSTRACT: One third of adult women in the United States are obese. During pregnancy, obese women are at increased risk for several adverse perinatal outcomes, including anesthetic, perioperative, and other maternal and fetal complications. Obstetricians should provide preconception counseling and education about the possible complications and should encourage obese patients to undertake a weight reduction program before attempting pregnancy. Obstetricians also should address prenatal and peripartum care considerations that may be especially relevant for obese patients, including those who have undergone bariatric surgery.

Obesity in pregnancy. ACOG Committee Opinion No. 315. American College of Obstetricians and Gynecologists. Obstet Gynecol 2005;106:671–5

### The Importance of Preconception Care in the Continuum of Women's Health Care

ABSTRACT: The goal of preconception care is to reduce the risk of adverse health effects for the woman, fetus, or neonate by optimizing the woman's health and knowledge before planning and conceiving a pregnancy. Because reproductive capacity

spans almost four decades for most women, optimizing women's health before and between pregnancies is an ongoing process that requires access to and the full participation of all segments of the health care system. The importance of preconception care in the continuum of women's health care. ACOG Committee Opinion No. 313. American College of Obstetricians and Gynecologists. Obstet Gynecol 2005;106:665-6

#### Meningococcal Vaccination for **Adolescents**

ABSTRACT: Every year in the United States, approximately 1,400-2,800 individuals are infected with meningococcal disease. The Advisory Committee on Immunization Practices (ACIP) to the Centers for Disease Control and Prevention (CDC) released recommendations in early 2005 to reduce the incidence of meningococcal disease during adolescence and young adulthood. To achieve this goal, routine vaccination of preadolescents with meningococcal conjugate vaccine (MCV4) is now recommended. For adolescents who have not received

MCV4, the CDC now recommends vaccination before entry into high school, at approximately 15 years of age. The American College of Obstetricians and Gynecologists supports these recommendations and encourages all health care providers caring for adolescent and young adult patients to provide meningococcal vaccination with MCV4 when appropriate. This includes vaccination of college freshmen who live in dormitories. Pregnant women may be vaccinated with meningococcal polysaccharide vaccine (MPSV4) as indicated. Health care providers also are encouraged to discuss meningococcal vaccination with patients whose children have reached preadolescence, adolescence, or young adulthood and to increase awareness of the signs and symptoms of meningococcal disease.

Meningococcal vaccination for adolescents. ACOG Committee Opinion No. 314. American College of Obstetricians and Gynecologists. Obstet Gynecol 2005;106:667-9

#### Case Managers Corner\*

#### Wouldn't it be nice if there was more distance education available to nurses?

Here is just two possibilities. Can you think of others?

A: For separate reasons, schools of nursing and public television stations are finding it a matter of mutual interest to work together in the production of distance education content for college nursing students in their communities. The advent of digital television (DTV) broadcasting has given these distance education partnerships new capabilities for reaching more potential students. In this article, I review one innovative collaboration between several nursing education programs and a public broadcasting service member station in South Texas. In this pilot project, nursing faculty were trained in television production techniques and became producers of DTV instructional video material. This case study demonstrates a number of ways in which nursing distance education programs can benefit by designing and delivering course

material via digital broadcasting. It also highlights several difficulties that should be considered by distance educators prior to embarking on DTV curriculum development projects. Whitmore BA. Nursing distance education at the dawn of digital broadcasting: a case study in collaboration. J Nurs Educ. 2005 Aug;44(8):351-6.

B: You can obtain free online CEUs on obstetric topics from the Indian Health system. Just go to the Perinatology Corner and pick from any, or all, of the modules. They can be completed from home or at work.

#### Perinatology Corner:

www.ihs.gov/MedicalPrograms/MCH/M/ MCHpericrnr.asp

\*In lieu of a Case Manager submission, Reynaldo Espera, from ANMC Labor and Delivery submitted the above.

respera@anmc.org

#### **AHRQ**

#### **AHRQ Research Activities** Relevant to the American Indian and Alaska Native Community

AHRQ released a new program brief titled AHRQ Research and Other Activities Relevant to American Indians and Alaska Natives. AHRQ research topics include examining organizational factors influencing rural health care providers, reducing disparities in the American Indian/Alaska Native population, developing electronic data systems for Primary Care Practicebased Research Networks (PBRNs), and implementing AHRQ's Put Prevention Into Practice program. AHRQ funds research that enhances the health services research infrastructure and knowledge base, while building relationships with other Federal agencies.

A print copy is available by sending an e-mail to ahrqpubs@ahrq.gov

#### **Elder Care News**

### Cancer screening in elderly patients: a framework for individualized decision making

Considerable uncertainty exists about the use of cancer screening tests in older people, as illustrated by the different age cutoffs recommended by various guideline panels. We suggest that a framework to guide individualized cancer screening decisions in older patients may be more useful to the practicing clinician than age guidelines. Like many medical decisions, cancer screening decisions require weighing quantitative information, such as risk of cancer death and likelihood of beneficial and adverse screening outcomes, as well as qualitative factors, such as individual patients' values and preferences.

Our framework first anchors decisions through quantitative estimates of life expectancy, risk of cancer death, and screening outcomes based on published data. Potential benefits of screening are presented as the number needed to screen to prevent 1 cancer-specific death, based on the estimated life expectancy during which a patient will be screened. Estimates reveal substantial variability in the likelihood of benefit for patients of similar ages with varying life expectancies. In fact, patients with life expectancies of less than 5 years are unlikely to derive any survival benefit from cancer screening.

We also consider the likelihood of potential harm from screening according to patient factors and test characteristics. Some of the greatest harms of screening occur by detecting cancers that would never have become clinically significant. This becomes more likely as life expectancy decreases. Finally, since many cancer screening decisions in older adults cannot be answered solely by quantitative estimates of benefits and harms, considering the estimated outcomes according to the patient's own values and preferences is the final step for making informed screening decisions.

Walter LC, Covinsky KE. Cancer screening in elderly patients: a framework for individualized decision making. JAMA. 2001 Jun 6;285(21):2750-6.

#### Comment: Bruce Finke, Elder Care Director, IHS

The following are paraphrased thoughts in response to the Mandelblatt JS, et al article, 'Toward optimal screening strategies for older women: Should cost matter the most?' and the subsequent comments in the August CCC Corner\*

My read of this piece is that life expectancy remains the dominant consideration in whether or not to recommend mammography for elderly women. I very much like the approach of Walter and Covinsky (attached) which this article references. It gives a way of thinking (and talking with patients) about the competing mortality and the potential benefit of screening.

For example, a very healthy 80 year old (in the highest quartile of life expectancy - 13 years) has a risk of dying of breast cancer that is higher than a very unhealthy 50 year old (in the lowest

quartile of life expectancy—24.5 years). Since I would generally recommend a mammogram to 50 year olds unless they are actively dying, I would also recommend it to the active, vigorous 80 year old. We still have to assess the patient, think about co-morbid conditions and assess relative life expectancy, but it gives us data about the likelihood that screening will benefit the patient.

I'm not sure that the cost projections in this article are all that useful. For one thing, I really have no way of assessing their accuracy. There are an awful lot of assumptions in play. And of course they don't help us to work with individuals.

I am not philosophically opposed to using cost as a factor in understanding the value of a screening test or of screening a particular population - I think we have the obligation to identify ways to use the limited resources we have available in our health system to greatest benefit for the largest number of people. But we have not, generally, applied these kinds of calculations to population-specific decisions about screening in the Indian health system. Breast cancer screening in the Southwest is a good example. Because the incidence of breast cancer in this population is substantially lower than that of the US All Races, it's likely that cost / benefit ratio is somewhat different that used to decide that screening on a population-wide basis makes sense.

But we don't have the data or the research capacity to develop those kinds of analyses and I think that it is just fine to go with nationally derived recommendations.

BOTTOM LINE: The Mandelblatt JS, et al article may not be relevant. Please take a good look at the Walter and Covinsky article (above) and see if that doesn't seem useful to your patients and your practice.

\*Toward optimal screening strategies for older women: Should cost matter the most? See August CCC Corner



# CCC CORNER

4320 Diplomacy Drive, Anchorage, AK 99508 Tel: (907) 729-3154 Fax: (907) 729-3172

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We are looking forward to hearing from you.

First Name	Last Name	(MD, RN, CNM, etc)	Organization or Facility	Mailing Address

#### **Medical Mystery Tour**

### Overbooked clinic and next patient with chronic pelvic pain

J. D. is 25 year old gravida 4, para 1, 0,2,1 who presents to the outpatient clinic for follow-up of pelvic pain and vaginal bleeding and is scheduled to receive methotrexate. The patient initially presented to the emergency department (ED) 6 days ago and had followed up there again last Friday night. The patient had been told to follow-up in outpatient clinic on Monday.

The patient had some vaginal spotting 5-6 weeks prior, but it was not like her normal menses. Prior to that time the patient had a history of irregular menstrual cycles, so she was not sure of her exact previous cycles.

The patient's obstetric history is significant for one term vaginal delivery of a 3,565 gram male, one ectopic pregnancy treated with laparoscopic salpingectomy, and one ectopic pregnancy treated successfully with single dose methotrexate. Those events occurred at another Service Unit and the records are felt to be in transit, as the patient had signed a release of information when her pregnancy test first became positive 2 weeks ago.

#### Other history included:

- a case of cervical chlymadia trachomatis at 18 years of age treated with azithromycin
- one case of presumed pelvic inflammatory disease treated as an outpatient with:
  - -- Ceftriaxone 250 mg IM in a single dose, Doxycycline 100 mg orally twice a day for 14 days and
  - -- Metronidazole 500 mg orally twice a day for 14 days.
- new relationship with a partner who is interested in having a large family

PHYSICAL EXAM: BP 126/76, P 88, RR 16, Weight 147 lbs., Height 66 inches, Body Surface Area 1.76 m2

Exam confirmed mild pelvic discomfort, right side greater than left; small amount of recent vaginal bleeding from a closed and long cervix; otherwise unremarkable

LABORATORY EVALUATION: Blood type B positive, hemoglobin 11.2, urinalysis negative.

#### QUANTITATIVE HCG

6 days prior 850

4 days prior 1400 54% increase

2 day prior 2142 53% increase

IMAGING STUDIES: Pelvic ultrasound performed 2 days prior revealed a 3 cm right adnexal structure thought to be a possible an ovarian cystic structure with complex elements or a curved hydrosalpinx. The structure had the appearance of a donut. The radiologist's dictation stated that the study was consis-

tent with a hydrosalpinx or corpus luteum cyst, but that ectopic pregnancy needed to be considered clinically. There was also indistinct intrauterine contents not unlike a gestational sac, but no distinct fetal pole or yolk sac. The radiologist could not rule out a pseudosac. The radiologist's DRAFT report suggested appropriate medical / surgical intervention depending the patient's condition.

The patient's chart was not found due to her recent visits to the ED, hence the ED clinical notes were not available. The lab values had been pulled up on the RPMS system. The patient said the ED physician told her that her HCG levels were not increasing appropriately for a normal pregnancy.

The patient needed to get back to work to her new job at a large box-like retail outlet nearby as soon as possible. She said as this was another ectopic pregnancy, that she would prefer repeating a course of single dose methotrexate, just like last time. This patient was the first of two overbooked patients at 1:00 PM as the clinic was trying to maintain its 3rd next available statistics for improved patient access. Both overbooked patients were in rooms and the 1:15 PM was being checked for an evaluation of chronic pelvic pain and need for a narcotic refill.

The patient said that ED provider told her that you would know what dose of methotrexate to prescribe in this particular situation. She said she heard the ED physician was concerned that her HCG had not increased by 66% during the previous serial 2 day intervals. She said the ED physician said that you might want to call a specialist to find out, because this was her third ectopic pregnancy.

### What dose of methotrexate would you prescribe to this patient?

#### **MCH Alert**

#### Adolescent pregnancy prevention

The supplement to the September 2005 issue of the Journal of Adolescent Health identifies and highlights some of the lessons learned from eight years of investment in the Community Coalition Partnership Program, a 13-community demonstration program aimed at preventing adolescent pregnancy that was funded by the Centers for Disease Control and Prevention (CDC) from 1995 through 2003.

#### Menopause Management

#### **AHRQ Releases Evidence Report on Managing** Menopause-Related Symptoms

The Agency for Healthcare Research and Quality (AHRQ) has released the results of a systematic review on managing menopause-related symptoms.

By definition, menopause is the permanent cessation of menses caused by reduced ovarian hormone secretion. Menopause usually occurs in women 40 to 58 years of age, and it may take several years to fully transition from onset to completion. During this time, many women experience symptoms that can cause reduced quality of life.

Common menopause-related symptoms include:

- Hot flashes
- Vaginal dryness
- Sleep disturbance
- Mood symptoms
- Cognitive disturbances
- · Somatic complaints
- · Urinary complaints
- · Uterine bleeding

Many therapies exist to manage these symptoms, including hormone therapy, antidepressants and other drugs, behavioral interventions, and complementary and alternative medicine.

The AHRQ evidence report evaluates the benefits and harms of common interventions to relieve menopause-related symptoms. The review included American women who were going through menopause and who presented with at least one of the above symptoms. A technical expert panel, which was made up of experts and clinicians in the field, and expert reviewers provided input for this review.

#### Managing Menopausal Symptoms—estrogen

Estrogen was the most consistently effective intervention for vasomotor symptoms. The therapy also helped manage urogenital symptoms, along with sleep, mood, sexual, and quality-of-life outcomes compared with placebo. The most common adverse effects of estrogen therapy were breast tenderness and uterine bleeding.

#### testosterone and estrogen

The reviewers found few trials evaluating testosterone therapy. However, one trial showed no difference between combination testosterone and estrogen therapy and estrogen therapy alone for hot flashes, vaginal dryness, or sleep problems. The results of two trials showed that testosterone and estrogen therapy improved sexual symptoms better than estrogen alone or placebo. However, women receiving combination therapy had significantly more incidences of acne and hirsutism compared with those in

the estrogen-only group.

#### progestin

Trials showed varying results regarding progestin in the management of vasomotor symptoms.

#### tibolone

A few trials of fair to good quality showed that tibolone (Livial) helped manage vasomotor symptoms, sleep, and somatic complaints compared with placebo. Tibolone was similar to estrogen in the management of some symptoms. Patients treated with tibolone experienced more uterine bleeding, body pain, weight gain, and headaches compared with patients who were treated with placebo.

#### soy isoflavones and other alternative therapies

Although results varied and more research is needed, alternative therapies were beneficial in managing some nonvasomotor symptoms.

CONCLUSION: Trials evaluating therapies for the management of menopause-related symptoms were conclusive only for estrogen in the management of vasomotor and urogenital symptoms. After further research, other therapies may demonstrate beneficial results.

LIMITATIONS: The trials included in this evidence review had the following limitations:

- Highly selected, small sample groups
- Short duration
- Inadequate reporting of loss to follow-up, maintenance of comparable groups, contamination, methods of analysis, and
- Some nonstandardized and nonvalidated measures and outcomes
- Unclear inclusion and exclusion criteria
- Industry sponsorship

Evidence Report/Technology Assessment No. 120, "Management of Menopause-Related Symptoms,"

#### **Perinatology Picks**

#### George Gilson, MFM

### First trimester prenatal genetic screening: Is it ready for 'Prime Time' at your facility?

A PROVIDER WRITES: "I have been reading a lot recently about first trimester nuchal translucency (NT) measurement as a screening tool for fetal Down syndrome. I already do all our OB ultrasounds and have been doing US for over 7 years. I am excited to try NT. My question is this: If I do this screening on women I am dating anyways, should I be offering this screening to all our patients? How about just the high-risk women? Do you have to do the biochemical screen as well?"

REPLY: First trimester screening for fetal aneuploidy by means of measurement of the nuchal translucency (NT) combined with biochemical testing (PAPP-A and free beta HCG) is being requested more and more by our patients. There is a narrow window when this testing may be done (11 weeks 0 days to 13 weeks 6 days), so accurate dating is critical. The advantages of first trimester screening are an earlier and more accurate answer for our patients who are concerned about this issue. The detection rate (sensitivity) of the combined NT + PAPP-A (pregnancy associated plasma protein A) and "free beta" (not our usual bHCG pregnancy test) approaches 90%, with a low false positive rate (FPR) of about 3%, in the best studies.

"In the best studies" is a key phrase here. NT measurement is not an easy skill that can be casually acquired by any sonographer. The median normal value of the NT is just under 1 mm, so it must be obtained in a very defined and strict fashion. A certification process, and an ongoing quality assurance program, are necessary to assure that we have the skills on which our clients can rely in order to make major decisions about their pregnancy. In order to become certified you must first take a one-day didactic course and pass a written exam (not too hard). You must then acquire a set of your own images which must be sent to the certifying body, followed by a video documenting how you obtained the images. This process may take up to a year. More images must then be submitted annually for quality assurance and renewal of certification. The images are judged strictly and it requires quite a while for most applicants to accumulate a certifiable number of images. Most of our facilities will probably require referral to a quality center for this exam at this time.

The NT measurement alone only has a sensitivity of about 75%, with a FPR that approaches 20%, so it must be combined with the biochemical panel. Medicaid and most insurance pay for these tests, but our patients without a payment source must pay out of pocket, about \$95. It is nevertheless probably the most cost-effective test, because the low rate of false positives allows us to avoid a lot of unnecessary referrals, invasive procedures, and parental anxiety.

Another issue is whether you are able to readily provide referral for chorionic villus sampling (CVS) if the screening results are positive. Are you able to counsel the parents appropriately about the details and the risks of this costly invasive procedure? Or does the patient want to wait until 15 weeks and have amniocentesis? Since less than half of board-certified maternal-fetal medicine (MFM) specialists include CVS in their practice, do you have a qualified specialist in your area to whom you can refer? The ability to provide adequate counseling, referral, and follow up is critical before your practice embarks on this screening scheme. (See the attached abstract detailing some of the ethical issues involved in referring or not referring.)

Patients who have had first trimester screening probably should not go on to have second trimester screening (triple or quad screening) because it will result in many more false positives (the majority of the cases will already have been detected in the first trimester). There is a testing scheme called "integrated screening" which "integrates" the results of both the first and second trimester screening to give a final answer. This actually has the best detection and the lowest false positive rate, BUT, the lab must correct the patient's second trimester risk with her new first trimester risk in order to give an accurate answer and avoid a high FPR. Unlike in the U.K., where this strategy has been extensively studied and developed, most labs in the U.S. are not set up to "integrate" results in this fashion at the present time.

That brings up the issue of second trimester testing for fetal open neural tube defects (ONTD). First trimester testing does not address that issue. While the maternal serum alpha fetoprotein (AFP), collected between 15 and 20 weeks, can detect 65% of fetal ONTD and abdominal wall defects, it is currently available only in a "package" as the "triple screen" or the "quad screen" where it is able to generate a software program-derived risk assessment. It is not available as a single test for ONTD, and, "you don't want to know" the other values that may now give you a high false positive rate for Down syndrome! You can get around this problem by omitting second trimester serum screening and doing a second trimester anatomic scan (over 90% sensitivity for ONTD), but, for most of us, this may require another costly referral

As you can see, "the in's and out's" of implementing first trimester screening at the present time are formidable. The laboratory logistics have not quite caught up with the studies, or the patient demand. While first trimester screening is preferred by clients, and eventually will probably become the test of choice for women who present early enough, it currently entails multiple barriers for most of us, and is not yet "ready for prime-time". Unlike "Nike", you can't "just do it"! This situation will certainly be evolving over time. ACOG originally called first trimester

- screening "investigational", but has now stated that it is "an option" if the following criteria can be met:
- 1. Appropriate ultrasound training and ongoing quality monitoring programs are in place.
- 2. Sufficient information and resources are available to provide comprehensive counseling to women regarding the different screening options and limitations of these tests.
- 3. Access to an appropriate diagnostic test is available when screening test results are positive.

Our goal now should be to try to meet those standards in our practice settings. Yes, we've implemented this option in Anchorage, but it has been "a process". I hope that answers the questions you've raised and will help you make the best decision for your service unit. Please read the accompanying abstracts to further your understanding of some of these issues. Stay tuned for further developments!

Prospective first-trimester screening for trisomy 21 in 30,564 pregnancies.

CONCLUSION: The most effective method of screening for chromosomal defects is by first-trimester fetal NT and maternal serum biochemistry.

Avgidou K, et al Prospective first-trimester screening for trisomy 21 in 30,564 pregnancies. Am J Obstet Gynecol. 2005 Jun;192(6):1761-7.

#### Implementation of first-trimester risk assessment for trisomy 21: ethical considerations

The performance and evaluation of first-trimester risk assessment should meet standards of scientific and ethical excellence. Scientific standards are well understood. Ethical standards are less well understood. On the basis of the ethical concept of the physician as fiduciary, and the ethical principles of respect for autonomy, beneficence, and justice, we show that the obstetrician has an ethical obligation to routinely offer pregnant women first-trimester risk assessment in high quality centers. We conclude that ethics is an essential dimension of implementation of first-trimester risk assessment for trisomy 21. Chervenak FA, McCullough LB. Implementation of first-trimester risk assessment for trisomy 21: ethical considerations. Am J Obstet Gynecol. 2005 Jun;192(6):1777-81.

#### **OB/GYN CCC Editorial**

The 'process' Dr. Gilson describes above has taken years at our Indian Health system facility and is very dependent on excellent personnel who are willing to make a long term commitment. The 'process' requires extra education, training, and an ongoing effort at quality assurance documentation from the whole team. Anywhere along that timeline, personnel turnover can jeopardize all your previous efforts.

#### ACOG Comm. Opinion No 296 states:

Although first-trimester screening for Down syndrome and trisomy 18 is an option, it should be offered only if the following criteria can be met:

- 1. Appropriate ultrasound training and ongoing quality monitoring programs are in place.
- 2. Sufficient information and resources are available to provide comprehensive counseling to women regarding the different screening options and limitations of these tests.
- 3. Access to an appropriate diagnostic test is available when screening test results are positive.

If nothing else, you facility should be using the second trimester serum 'quad' screen, as opposed to the former 'triple' screen. Here a few resources to help you evaluate the steps in this process.

First-trimester screening for fetal aneuploidy. ACOG Committee Opinion No. 296. American College of Obstetricians and Gynecologists. Obstet Gynecol 2004;104:215-17

#### **Prenatal Genetic Screening** —Serum and Ultrasound

Perinatology Corner Module (free CME or just a great resource) www.ihs.gov/MedicalPrograms/MCH/M/TM01.cfm

#### Fetal Medicine Foundation Certification

www.fetalmedicine.com/nuchal.htm

#### **Osteoporosis**

#### Osteoporosis Prevention in Postmenopausal Women

CONCLUSION: We observed significant reductions in the incidence of vertebral fractures with hormone replacement therapy, etidronate, and calcitonin, and significant improvements in bone mineral density with hormone replacement therapy and calcitonin.

Ishida Y, Kawai S. Comparative efficacy of hormone replacement therapy, etidronate, calcitonin, alfacalcidol, and vitamin K in postmenopausal women with osteoporosis: The Yamaguchi Osteoporosis Prevention Study. Am J Med. 2004 Oct 15;117(8):549-55.

#### Navajo News

### Contraception, the 'Patch', and reports of adverse events including death

A number of articles have appeared in various news media over the past year reporting deaths associated with use of the contraceptive patch. The Association of Reproductive Health Professionals (ARHP) concludes that the articles that have been reviewed are biased and unfortunate, misrepresenting the available data and presenting a skewed picture of adverse events attributable to the contraceptive patch in particular, and medications in general. To assist ARHP member clinicians who may face questions from their clients about the patch—and contraception—as a result of these news reports, the organization has prepared some evidence-based talking points on this subject.

#### ARHP Talking Points

- The patch has been used by approximately five million women in the United States since it became available in 2002.
- Deaths among young women because of medical problems such as blood clots and heart attacks are very rare, and they are also very rare among young women using contraceptive hormones.
- Taking oral contraceptives or using hormonal contraceptive patches slightly increases the risk of cardiovascular problems especially for women over 35 who smoke.
- The rate for cardiovascular problems estimated for women using the patch is in the range that has been reported for other hormonal contraceptives such as oral contraceptives [see Contraceptive Technology Table 9-4, p. 230].
- Health risks for patch users are essentially the same as risks for women using other hormonal contraceptives.
- In context, risks for death associated with other common activities such as driving an automobile (1 in 5,900) or continuing a pregnancy to term (1 in 10,000) are significantly higher than risks associated with use of hormonal contraceptives.
- The risk of death associated with pregnancy—a common outcome among women who don't use contraception—is far higher than the risk of death associated with using contraceptive pills or the patch. Pregnancy-related deaths, including those at delivery, stillbirth, and ectopic pregnancy, claim the lives of two to three U.S. women every day—with 13 deaths reported for every 100,000 live births in 1999.
- Possible adverse drug reports are submitted voluntarily to FDA
  by clinicians in the U.S. and are intended to provide a means to
  identify rare medical problems that had not been anticipated
  in the clinical studies undertaken for FDA drug approval. Serious
  medical events are reported whether or not there is a clear
  "cause and effect" connection to the drug. For any medication
  that is widely used, therefore, at least some deaths are bound
  to occur and be reported.

BACKGROUND: As of May, 2005, Ortho Evra has been safely used by more than five million women worldwide since introduction in 2002. While adverse events and patient concerns should be taken seriously, there is no reason for alarm at this time. Evra is as safe as oral contraceptives and NuvaRing for healthy reproductive age women with no contraindications to combined hormonal contraception. As you are aware, each Evra patch delivers a daily dose of 150 mcg of norelgestromin (the active metabolite of norgestimate) and 20 mcg of ethinyl estradiol (per 24 hours). This dose is considered equivalent to a 35 mcg oral contraceptive, although comparing oral delivery and transdermal delivery is difficult.

If one only looks at fatal pulmonary embolus, and if the 16 deaths mentioned above are directly attributable to Evra, which they aren't, this number of deaths, though unfortunate, is less than the number of expected deaths from pulmonary embolism among users of combined hormonal oral contraceptives (from which we would extrapolate expected number of deaths from Evra). Total woman-years of exposure to Ortho Evra are 4.1 million woman years. The absolute risk of death from pulmonary embolism in current oral contraceptive users is estimated at 1 per 100,000 woman years<sup>a</sup>. This would translate into 41 expected deaths from pulmonary embolism, not 16.

To further place this into context, 16 deaths during 4.1 million woman years of use translates into a rate of 0.39 per 100,000 woman years. The expected death rate from Viagara is 6 per 100,000 prescriptions. The risk of dying from continuing a pregnancy beyond 20 weeks is 10.7 per 100,000 live births<sup>b</sup>.

In addition, among women who do not use OCs, do not smoke nor have any other cardiovascular risk factors, total incidence of stroke and acute myocardial infarction is estimated at 1 to 2 events per 100,000 woman years in those ages 20-24 years<sup>c</sup>. Much of this incidence among non-smokers, not using oral contraceptives is attributable to ischemic and hemorrhagic stroke which are expected at a rate of 1.9 per 100,000 woman years for ages 20 to 24; 3.4 per 100,000 woman years for ages 30 to 34; and 6.2 per 100,000 woman years for ages 40 to 44<sup>d</sup>. Corresponding expected ischemic and hemorrhagic stroke per 100,000 woman years among non-smoking oral contraceptive users are 2.2 for ages 20 to 24; 3.9 for ages 30-34; and 11.7 for ages 40-444.

EXTRAPOLATING FROM THIS DATA: The expected number of ischemic and hemorrhagic strokes during 4.1 million years of Evra use is 90, if all users were non-smokers and in age group 20-24; 160 if all users were non-smokers and in age group 30-34; and 480, if all users were non-smokers and in the age group 40 to 44. Without a breakdown of age, one only can say that the expected number of strokes is between 90 and 160 for women ages 20 to 34 using Evra, if all Evra users were non-

smokers. As expected ischemic and hemorrhagic stroke incidence is higher among older oral contraceptive users who smoke. Incidence rates for ischemic and hemorrhagic stroke range from 5.6 per 100,000 woman years for smokers ages 20-24 to 102 per 100,000 woman years for women ages 30 to 344.

No medication is without risk. No medical procedure is without risk. No pregnancy is without risk. As with any health care decision, a balancing of individual risks and benefits is required. Healthy reproductive age women with no contraindications to combined hormonal contraception who want Ortho Evra should be encouraged to try this method, and if already using this method, women should not be discouraged from using it.

- <sup>a</sup> Goldhaber SZ. Pulmonary embolism. Lancet 2004;363:1295-1305.
- <sup>b</sup> Chang J, Elam-Evans LK, Berg CJ, Herndon J, Flowers L, Seed KA, et al. Pregnancy-Related Mortality Surveillance - United States, 1991-1999.

Surveillance Summaries, February 21, 2003. MMWR 2003;52(No SS-2):1-8.

- <sup>c</sup> Farley TMM, Meirik O, Chang CL, Poulter NR. Combined oral contraceptives, smoking, and cardiovascular risk. J Epidemiol Community Health 1998;52:775-785.
- <sup>d</sup> World Health Organization. Cardiovascular Disease and Steroid Hormone Contraception. Report of a WHO Scientific Group. Geneva 1998; WHO Technical Report Series 877.

#### **OB/GYN CCC Editorial**

Based upon the information available now it is reasonable to say that re: CV problems nothing unexpected is occurring. The number of serious adverse events reported for Evra is within the range of what is expected for oral contraceptives. The rates for Evra are not lower—they should be comparable and based upon the information we have, that appears to be the case.

#### **Midwives Corner** Amy Doughty, Zuni

#### Centering Pregnancy— **Group Prenatal Care**

October 21 & 22, 2005 Zuni, New Mexico

We are excited to offer this exciting training in Zuni. Contact Amy.Doughty@ihs.gov

#### Oklahoma Perspective

#### **Greggory Woitte—Hastings Indian Medical Center**

#### Electronic Health Record for care of women and children

As many of you are aware, technology is becoming very pervasive in our lives. Cell phones, pagers, PDAs, laptops are all part of our daily existence. I can remember what it was like without these advances but can't imagine going back. Electronic health records (EHR) is one of those technologies. Here at Hastings Indian Medical Center, we began to implement a change from written documentation to EHR over a year ago. At that time, three physicians were chosen to begin training and utilization of the new system. I was the OB/GYN that was to begin using the system. Initially, I quickly discovered as did my pediatric counterpart that this system was not designed for the OB or pediatric population. In fact, EHR is an older version of a system used in the VA hospitals (not many pediatric or OB patients there). So we had to adapt. I created various templates, that we use for our daily visits but we still had to continue to use the OB flow sheet to maintain continuity in the system. I understand that one of the future updates will include a flow sheet, but that it is a ways away.

Despite the pitfalls in the system and setbacks that we have had in the year, I have a difficult time reverting to the old pen and paper system. I find that the computer reminds me to ask things from my patients that I might have forgotten to ask in the 15 minute appointment. I am told that the documentation has improved drastically, not to mention the legibility. EHR is not a panacea, and it had a rough start but, it has a lot of potential to become one of those technologies.

#### **OB/GYN CCC Editorial comment:**

The Office of information Technology is working to develop standardized national pediatric and OB templates that will be available for use with the EHR as well as PCC+, hopefully by the end of 2005.

Contact Theresa.Cullen@ihs.gov with questions.

#### Primary Care Discussion Forum—November 1, 2005 Morbidity and Mortality Rounds—Web Based

#### Rectal bleeding: Is it hemorrhoids?

- 40 year old American Indian female presents to a remote ambulatory care clinic with intermittent blood in her stool for the last 3 months.
- She has had chronic constipation.
- She believes that the blood is due to her hemorrhoids.

#### Goals of Web Based Morbidity and Mortality Rounds in Indian Health

- Create a forum to discuss primary care M&M cases within the I/T/U settings
- · Cases will create a forum to discuss quality of care and patient safety
- · Recognize and discuss the unique and ubiquitous constraints within the Indian Health system

#### **AFP**

#### Intensive Diet-Behavior-**Physical Activity Program** for Obesity in Children

CLINICAL QUESTION: Can a specific program of diet and exercise result in sustained weight loss in children?

BOTTOM LINE: An intensive three-month program of dietary counseling, a hypocaloric diet, and structured exercise can cause weight loss in children that is sustained over one year. More important, the program seemed to increase the amount of exercise the children performed, and this increase was sustained after the intervention was discontinued.

(Level of Evidence: 2b) www.aafp.org/afp/20050801/ tips/7.html

#### **STD Corner**

Laura Shelby, STD Director, IHS

#### Screening for sexually transmitted diseases in non-traditional settings: a personal view

We conducted a literature search to review studies that presented quantitative data on sexually transmitted disease (STD) screening in non-traditional settings in the United States. We examined the studies for evidence of the feasibility of screening, population size reached, acceptability, yield, and potential for contributing to STD control. We found 17 studies in jails, eight in emergency room, five in schools

and 15 in other community settings. Jail-based and emergency room-based STD screenings have the highest yields and the largest numbers screened and thus hold significant promise as settings for routine STD screening. More research needs to be done in school and community settings to better identify their potential. Cohen DA, et al Screening for sexually transmitted diseases in non-traditional settings: a personal view Int J STD AIDS. 2005 Aug;16(8):521-7.

#### **AFP**

#### NSAIDs Alone or with Opioids as Therapy for **Cancer Pain: Cochrane for Clinicians**

CLINICAL SCENARIO: A 70-year-old woman is diagnosed with malignant melanoma that has metastasized to the liver and lungs. She has begun to experience abdominal pain, which you attribute to the liver metastases. She wants to know what you recommend for pain management.

CLINICAL QUESTION: What is the most effective therapy for the management of cancer pain?

EVIDENCE-BASED ANSWER: Shortterm trials indicate that cancer pain can be reduced with the use of nonsteroidal antiinflammatory drugs (NSAIDs) as initial mono-

therapy. NSAIDs combined with opioids can result in slight short-term improvement in pain compared with either agent alone. Long-term efficacy and safety of NSAIDs for cancer pain have not been established.

www.aafp.org/afp/20050801/cochrane.html#c1

#### Methamphetamine in Indian Country: Good Resources

In follow-up to the recent Primary Care Discussion Forum, the methamphetamine power point presentations at the site below should be reviewed, even if you do not deal with patients using meth, or think you are not seeing them.

The demographics for those entering into treatment should be reviewed to give a clear picture of the multifactor demographic, exposure history including abuse, sexual abuse, other drugs,. And while the age of treatment is in the 30's for both men and women the lifetime history is telling. Billings is one of the treatment centers so does contribute to the AI/AN demographics though all of the sites have enrolled AI/AN clients.

www.methamphetamine.org/presentations.htm

www.methamphetamine.org

#### Clustering of fast food restaurants around schools

Although fast-food restaurants are located throughout the city, they are clustered in areas within a short walking distance from schools. Fast-food consumption has increased dramatically over the past several decades and may be an important contributor to the rise in the prevalence of obesity in children and adolescents. The neighborhood food environment is a relatively new concept in public health research, and methods for defining, characterizing, and quantifying the food environment are still under development.

• The median distance from any school to the nearest fast-food restaurant was 0.5 km, indicating that students in half the city's schools

need to walk little more than 5 minutes to reach a fast-food restaurant.

- Nearly 80% of schools had at least one fastfood restaurant within 800 m (approximately a 10-minute walk).
- · There was statistically significant clustering of fast-food restaurants within 1.5 km of schools located within areas of the city outside downtown.

Austin SB, Melly SJ, Sanchez BN, et al. 2005. Clustering of fast-food restaurants around schools: A novel application of spatial statistics to the study of food environments. American Journal of Public Health 95(9):1575-1581.

#### (Cesarean delivery..., continued from page 1)

article joins the growing body of literature that raises issues about the ability of AI/AN women to maintain both low rates of cesarean delivery and stable perinatal morbidity / mortality. This trend continues while the US all races cesarean delivery rate has significantly increased with no corresponding improvement in perinatal morbidity/mortality.

#### References on related topics include:

Do all hospitals need cesarean delivery capability? Leeman(s): Outcome based study: Zuni, New Mexico

Native American Community with a 7% Cesarean Delivery Rate. Leeman(s): What explains the low rate in Zuni?

#### Here is some background on the lead author

Sheila Mahoney is a commissioned officer in the USPHS. Sheila joined the PHS directly from nurse-midwifery school in 1990 and went to Gallup, where she worked for 4 years as a nurse- midwife. She transferred to Santa Fe in 1994 and was there until 2003. The work was completed as part of her MPH thesis which she obtained at the University of New Mexico in 2002. Sheila transferred to the NIH in 2003 to become more involved in health research. Sheila works on the Gynecology Consult Service for the NIH and is involved in the fibroid and endometriosis trials. Unfortunately there is no obstetrics which she sorely feels the lack of. mahoneys@mail.nih.gov

#### FDA Director of the Office of Women's **Health resigns**

Our federal regulatory agencies should use scientific evidence to weigh evidence, rather than rely on other factors. The FDA Director of the Office of Women's Health resigned recently to call attention to need to return to a science based regulatory system. See details at:

www.chron.com/cs/CDA/ ssistory.mpl/editorial/3339516

From Guttmacher —on Plan B or Emergency contraception:

www.guttmacher.org/ media/supp/ec121702.html

By the way, IHS National Supply and Support Center purchases all methods of FDA approved contraception, including emergency contraception. An article will be forthcoming in the IHS Primary Care Provider. Also please see Family Planning (in Features section) EC in adolescents: No

compromise of family planning or increased sexual behavior

#### **Start Planning Now**

### National Indian Health Board: Youth and Tradition—Our Greatest Resources

- October 16-19, 2005
- Phoenix, AZ
- Distinguished presenters and informative workshops
- www.nihb.org/staticpages/index.php?pa ge=200403301344379533

#### **Centering Pregnancy**

#### —Group Prenatal Care

- October 21-22, 2005
- Zuni, NM
- Contact Amy.Doughty@ihs.gov

#### Advances in Indian Health, 6th Annual

- May 2-6, 2006
- Albuquerque, NM
- Save the dates brochure
- www.ihs.gov/MedicalPrograms/MCH/M/ CN01.cfm#May06

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Some of the Articles Inside Ob/Gyn & Pediatrics CCC Corner

September 2005

#### Abstracts of the Month

• Cesarean delivery in Native American women

#### **IHS Child Health Notes**

- Findings From the Base Year of the Early Childhood Longitudinal Study, Birth Cohort (ECLS-B)
- Pertussis Prevention: What's in the Forecast?
- Outcome evaluation of a public health approach to suicide prevention in an American Indian Tribal Nation.

#### From Your Colleagues

- Meera Ramesh, Bethel, Alaska—Diabetes prevention and control Prenatal program 3
- Judy Thierry, HQE—Maternal Morbidity in American Indian and Alaska Native Women, 2002–2004

#### **Hot Topics**

- The 4P's Plus screen for substance use in pregnancy: clinical application and outcomes
- PID: Outpatient treatment was as effective in preventing reproductive morbidity
- One Third of Deaths From GI Bleeding Due to NSAIDs

#### **Features**

- American Family Physician—Cochrane for Clinicians—Putting Evidence into Practice
- Family Planning—EC in adolescents: No compromise of family planning or increased sexual behavior
- Recognizing Elaine Locke—Key Contributor to Improvements in AI/AN Women's Health for 35 years
- ACOG—Management of abnormal cervical cytology and histology —Summary of Recommendations
- Elder Care News—Cancer screening in elderly patients: a framework for individualized decision making
- Menopause Management—AHRQ Releases Evidence Report on Managing Menopause-Related Symptoms
- Perinatology Picks—First trimester prenatal genetic screening: Is it ready for 'Prime Time' at your facility?
- Navajo News—Contraception, the 'Patch', and reports of adverse events including death