NATIONAL COUNCIL OF CHIEF CLINICAL CONSULTANTS

CCC CORNER

Focus on the Health of American Indian and Alaska Native Women and Children

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VariZIG™ replaces VZIG

Varicella Prophylaxis for high risk persons (including pregnancy)

On October 27, 2004, the Advisory Committee on Immunization Practices (ACIP) was informed by the only U.S.-licensed manufacturer of varicella zoster immune globulin (VZIG) (Massachusetts Public Health Biologic Laboratories, Boston, Massachusetts) that the company had discontinued production of VZIG. The supply of the licensed VZIG product is now nearly depleted. In February 2006, an investigational (not licensed) VZIG product, VariZIG™ (Cangene Corporation, Winnipeg, Canada) became available under an investigational new drug application (IND) submitted to the Food and Drug Administration (FDA). This product can be requested from the sole authorized U.S. distributor, FFF Enterprises (Temecula, California), for patients who have been exposed to varicella and who are at increased risk for severe disease and complications.

The investigational VariZIG™, similar to licensed VZIG, is a purified human immune globulin preparation made from plasma containing high levels of anti-varicella antibodies (immunoglobulin class G [IgG]). Unlike the previous product, the investigational product is lyophilized. When properly reconstituted, VariZIG™ is approximately a 5% solution of IgG that can be administered intramuscularly.

As with any product used under IND, patients must be informed of potential risks and benefits and must give informed consent before receiving the product.

Indications for Use of Investigational VariZIG™

Patients without evidence of immunity to varicella (i.e., without history of disease or age-appropriate vaccination) who are at high risk for severe disease and complications, who have been exposed to varicella, and from whom informed consent has been obtained, are eligible to receive the IND application product under an expanded access protocol. The patient groups recommended by ACIP to receive VariZIG™ include the following:

- Pregnant women.
- Immunocompromised patients.
- Neonates whose mothers have signs and symptoms of varicella around the time of delivery (i.e., 5 days before to 2 days after).
- Premature infants born at >28 weeks of gestation who are exposed during the neonatal period and whose mothers do not have evidence of immunity.
- Premature infants born at <28 weeks of gestation or who weigh <1,000 g at birth and were exposed during the neonatal period, regardless of maternal history of varicella disease or vaccination.

Varicella vaccine was recommended in 1999 for postexposure prophylaxis of other persons without evidence of varicella immunity and who have no contraindications to vaccination (2). The vaccine should be administered preferably within 96 hours and possibly up to

(continued on page 15)

THIS MONTH

"Solstice" is derived from two Latin words: "sol" meaning sun, and "sistere," to cause to stand still. This is because, as the summer solstice approaches, the noonday sun rises higher and higher in the sky on each successive day. On the day of the solstice, it rises an imperceptible amount, compared to the day before. In this sense, it "stands still."

Also on-line....

This is a digest of the monthly Chief Clinical Consultant's Newsletter, available on the Internet at:
www.ihs.gov/MedicalPrograms/MCH/M/OBGYN01.cfm

The official publication of the National Council of Chief Clinical Consultants

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

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

IHS Child Health Notes

June 2006

"It doesn't matter if the cat is black or white as long as it catches mice."
—Deng Hsaio P'ing 1904–1997

"Science is facts; just as houses are made of stone, so is science made of facts; but a pile of stones is not a house and a collection of facts is not necessarily science." —Henri Poincare (1854-1912)

Articles of Interest

A randomized, controlled trial of removable splinting versus casting for wrist buckle fractures in children. Pediatrics. 2006 Mar;117(3):691-7.

Wrist buckle fractures are commonly seen in pediatric patients in both emergency departments and pediatric clinics. The standard treatment in the United States is to place these children in a short arm cast for 2 to 4 weeks. In Britain many patients are placed in a removable splint.

This study was a randomized controlled trial for children 6 to 15 years of age with a buckle fracture of the wrist. Patients received either a short arm cast or a removable plaster splint for three weeks. There was no difference in pain our fracture healing. Children with the splint had better physical functioning and less difficulty with activities of daily living at 2 and 3 weeks post injury.

Editorial Comment

Buckle wrist fractures are commonly seen and treated by primary care physicians in the Indian Health Service if for no other reason than few of our rural clinics have easy access to orthopedists. This study confirms what most people knew intuitively; that these fractures heal promptly. This study also confirmed what many of us knew from experience; that these fractures heal so rapidly in children that many patients will remove their own casts off before 3 weeks and never return for follow-up. In this study 40% of children had stopped wearing their splint most of the time by 14 days and by 20 days almost 85% had stopped wearing their splint. If both treatments are equal we should use the least restrictive choice. A commercially available preformed splint would likely work as well as a plaster splint and be much quicker in a busy clinic.

Screening for developmental dysplasia of the hip: recommendation statement.

Pediatrics. 2006 Mar;117(3):898-902.

Screening ultrasounds of the hip in newborns were going to make unrecognized developmental dysplasia of the hip (DDH) a thing of the past. It hasn't worked out that way.

The United States Preventive Services Task Force looked at the risk/benefits of screening tests for DDH. They felt that screening ultrasounds have a high false positive rate. Surprisingly, they also found there was not sufficient evidence to recommend physical exam screening for DDH given the high rate of spontaneous resolution of DDH in well infants. There is no controlled trial demonstrating better outcomes in a population screened for DDH.

Editorial Comment

The American Academy of Pediatrics and the Academy of Family Practice continue to recommend physical exam screening for DDH. It seems prudent to perform a physical exam of the hips at well child visits until 6 months of age.

Infectious Disease Updates.

Rosalyn Singleton, MD, MPH

Mumps Outbreak hits the Midwest

Through May 10th 3,268 mumps cases have been reported to CDC from 12 states in the United State's largest mumps outbreak in years. The outbreak started in Iowa in Dec. 2005. The strain of mumps virus is the same one that has caused an ongoing outbreak in the United Kingdom. The majority of the cases are in 2-dose MMR recipients and the predominant age group is 18-24 years. This isn't unusual since mumps is occurring in a highly vaccinated population. About 80% of persons who have received 1 MMR dose can be considered protected and 90% after 2 doses. Since no vaccine is 100 percent efficacious, most cases of disease in a highly vaccinated population will happen in individuals that have been vaccinated.

The main outbreak control measure is immunization of persons not fully vaccinated. In an outbreak, fully vaccinated is defined as 2 doses of MMR for persons aged 1-49 years and 1 dose of MMR vaccine for persons aged 50 years and older. During an outbreak, health-care facilities should consider recommending 2 doses of MMR vaccine to unvaccinated health-care workers born before 1957 who do not have other evidence of mumps immunity.

So far, Wisconsin sites in the Bemidji Area are the main IHS sites affected by this outbreak. CDC recommends that a blood specimen for IgM, and buccal swab and/or urine for culture or PCR be collected from all patients with clinical features compatible with mumps. Isolation procedures consist of droplet precautions for 9 days after onset of parotitis. Daily updates on this outbreak are available on the CDC website at:
www.cdc.gov/nip/diseases/mumps/default.htm

Recent literature on American Indian/ Alaskan Native Health

Doug Esposito, MD, MPH

A Nationwide Population-Based Study Identifying Health Disparities Between American Indians/Alaska Natives and the General Populations Living in Select Urban Counties.

Summary

The authors report results of a study designed to assess the health status of the urban American Indian/Alaska Native population served by urban Indian health organizations (UIHOs). Data from the 2000 US census and the National Center for Health Statistics were used.

As you might imagine, health data collected on a national level demonstrates significant disparities for AI/AN groups as compared to the general US population. This is true for the urban as well as for the general AI/AN population. The authors also document significant disparities in socioeconomic status. They show that AI/AN people living in UIHO areas are about twice as likely to be poor, unemployed, and to not have a college education. Rates of AI/AN children living in poverty were found to be highest; almost twice that of the comparison groups and approximately 10 percent higher than adult AI/ANs. It was found that approximately 20% of the 400,000 AI/AN births happening nationwide between 1991 and 2000 occurred in urban areas covered by UIHOs. Other interesting and important statistics are reported in this article, and should be accessed directly by any interested individuals.

Some study findings were not easily explained, and require additional investigation. Lower rates of low birth weight were found for both urban and nationwide AI/AN populations than for the comparison groups. However, rates of prematurity were slightly higher. The authors suggest that this is perhaps somehow related to higher rates of diabetes among AI/AN groups, but such a statement seems a little "premature" to me! Additionally, the birth rate for AI/ANs living in UIHO service areas was about one fourth that of the general US population, although the birth rate for the general AI/AN population nationwide was similar to that of the general US comparison group. The authors posit that this could be due to mobility factors of the maternal AI/AN population at large, whereby deliveries are occurring outside of the UIHO area of residence. Are these women moving back to Reservations to have their babies?

The authors make several suggestions that they believe would result in reductions in health disparities. They contend that disparities in access to care are paramount to the plight of the urban AI/AN population. Other studies have definitively documented that urban AI/ANs are less frequently insured and less frequent users of primary health care. Under funding of urban Indian health programs also appears to be important. The authors point out that "...although UIHOs are the primary health care venue for urban American Indians/Alaska Natives, who represent 60% of the nationwide AIAN population, IHS allocations for these organizations represent 1% of the total IHS budget." They call for urgently needed leadership "to refocus and unify the system into a more cohesive and coherent national health care initiative" to address a "fragmented and decentralized" urban AI/AN health system.

Finally, data collection on urban AI/AN populations is problematic. Difficulties exist due to racial misclassification and a lack of a formal mechanism to track urban AI/AN health statistics and demographics. The authors suggest that the adoption of standardized racial classification schemes would help to more accurately track the needs of this underserved population. Further research in a number of areas, of course, is needed.

American Journal of Public Health 2006 March 29

Editorial Comment

Relatively few studies exist documenting the health status of urban AI/ANs, even though as many as 60% of the Native American population nationwide reside in urban areas. The results of the current study mirror findings from other studies of urban AI/AN children, some of which are listed below. The plight of the urban Indian is an important issue, only made worse by the apparent continuing migration of AI/AN people to urban centers and the continued dissolution of funding for AI/AN health programs. Achieving the goal of eliminating health disparities by the year 2010 as set forth in Healthy People 2010 is appearing more and more of an impossibility to this writer. What do you think?

Additional Reading

Perinatal and infant health among rural and urban American Indians/Alaska Natives. Am J Public Health. 2002 Sep;92(9):1491-7.

Disparities in infant health among American Indians and Alaska natives in US metropolitan areas. Pediatrics. 2002 Apr;109(4):627-33.

Health status of urban American Indians and Alaska Natives. A population-based study. JAMA. 1994 Mar 16;271(11):845-50.

Measuring disparity among American Indians and Alaska Natives; who's counting whom? Med Care. 2003;41(5):579-81.

From Your Colleagues

Steve Heath, Albuquerque

Risk Management and Medical Liability, 2nd Edition, Indian Health

The Second Edition of the IHS publication, *Risk Management and Medical Liability, A Manual for Indian Health Service and Tribal Health Care Professionals*, by Stephen W. Heath, MD, MPH has been posted on the IHS website at the National Council of Chief Clinical Consultants (NC4) homepage. The button labeled "Credentials/Risk Management" will take you to Manual site.

This current edition of the Manual describes the medical malpractice tort claim process changes that have taken place, updates data on tort claims, describes the IHS role in National Practitioner Data Bank reporting, and provides additional risk management guidance for local programs and health care professionals. It has been posted on the IHS website to allow access to as many individuals as possible. Users are encouraged to print the Manual for hard-copy use, if desired.

www.ihs.gov/NonMedicalPrograms/nc4/Documents/RM2_a.pdf

Donald Clark, Albuquerque

What is the rate of preterm birth in Native Americans?

Native Americans have the second highest rate of preterm birth, as per Peristats from March of Dimes. During 2001-2003 (average) in the United States, preterm birth rates were highest for black infants (17.7%), followed by Native Americans (13.2%), Hispanics (11.6%), whites (11.0%) and Asians (10.4%).

OB/GYN CCC Editorial

The Peristats is a great resource provided the March of Dimes. You can create your own search by various geographic or other demographic parameters. Go to the link below create your own queries to see its many dimensions.

www.marchofdimes.com/peristats/default.aspx

In addition, as the AI/AN population has high rates of tobacco use, the additional information on periodontal disease may let us to better sculpt our effort to improve the AI/AN infant, neonatal, and postneonatal deaths and mortality rates.

Judy Thierry, HQE

Achievements in Public Health: Reduction in Perinatal Transmission of HIV Infection

Implementation of recommendations for universal prenatal HIV testing, ARV prophylaxis, elective cesarean delivery, and avoidance of breastfeeding has resulted in a 95% decrease in the number of perinatal AIDS cases in the United States since 1992 and a decline in the risk for perinatal HIV transmission from an HIV-infected mother to less than 2%. However, barriers to the elimination of perinatal HIV infection remain, as the number of HIV infections continues to rise among women, and health-care services are not universally accessed by women in need of these services. Finally, the success in reducing perinatal HIV transmission observed in the United States contrasts with the situations in poorer countries, particularly in sub-Saharan Africa, where perinatal HIV transmission remains largely unabated. Continued success in the United States and reduction of perinatal HIV transmission in areas where such transmission remains common will require sustained commitment to prevention of HIV infection among women and to treatment for women affected by HIV/AIDS.

Achievements in Public Health: Reduction in Perinatal Transmission of HIV Infection—United States, 1985—2005 MMWR June 2, 2006 / 55(21);592-597

Editorial Comment: George J. Gilson, MD

Since the first pediatric cases of HIV were reported in the early 80's, significant progress has occurred in the prevention of vertical transmission of the infection in the United States. Prior to the era of anti-retroviral therapy (ARV), perinatal transmission was as high as 30%, but is currently under 2 per cent. Nevertheless, transmission continues to occur, mostly to infants who are born to women who have had no prenatal care (16%), or who have had prenatal care, but who have not been tested (26%), or who had been recognized as infected, but who had not been adequately treated (41% had not received zidovudine during labor). These are the areas where we should be able to make improvements in our care. Utilization of the "opt-out" approach to prenatal HIV screening, testing with the rapid, point of care, "OraQuick" test in labor for women with undocumented HIV status, and re-testing in the third trimester of high-risk women (history of a sexually transmitted infection or illicit drug use in the current pregnancy, or women from high prevalence areas), are all areas where the primary provider can play an important role in reducing transmission. Increased awareness among women of the need for testing, and case management to insure adequate prenatal care and adherence to ARV treatment for women identified as infected, are also crucial in preventing new infant infections. HIV infection in women is increasing rapidly, currently accounting for over a quarter of the total cases in the United States, and underscores the need for increased vigilance on the part of all of us who care for pregnant clients.

Hot Topics:

Obstetrics

Incontinence not correlated with vaginal delivery

Incontinence is a common problem for postmenopausal women, but that no difference in prevalence or severity could be demonstrated between parous and nulliparous sisters. Conversely, familial factors appear to be highly significant predictors of urinary incontinence. The authors suggest that the current focus on delivery in the etiology of incontinence is inappropriate and that research and preventive efforts be directed toward understanding familial factors.

CONCLUSION: Vaginal birth does not seem to be associated with urinary incontinence in postmenopausal women. Considering the high concordance in continence status between sister pairs, and considering that the majority of parous women are continent, an underlying familial predisposition toward the development of urinary incontinence may be present.

Concordance of Continence Status Within Sister Pairs

Incontinence in nulliparous sister	None (%)	Parous sister present (%)	Total (%)
None	47 (32.87)	28 (19.58)	75 (52.45)
Present	25 (17.48)	43 (30.07)	68 (47.55)
Total	72 (50.35)	71 (49.65)	143 (100.00)

note: Seven sister pairs, in each of which one of the sisters had incontinence unrelated to stress or urge, were not included in this table.

Adapted with permission from Buchsbaum GM, Duecy EE, Kerr LA, Huang LS, Guzick DS. Urinary incontinence in nulliparous women and their parous sisters. Obset Gynecol 2005;106:1256.

Buchsbaum GM, et al. Urinary incontinence in nulliparous women and their parous sisters. Obset Gynecol December 2005;106:1253-8.

OB/GYN CCC Editorial

Do we inject a bias toward cesarean delivery based on future incontinence?

Buchsbaum et al have raised serious questions about the argument that there is a direct correlation between vaginal delivery and future incontinence.

According to Wu et al, nearly two thirds of obstetricians support elective cesarean delivery for this reason. Combined with the current backlash against vaginal birth after cesarean delivery, the cesarean delivery rate seems set to spiral beyond the current 30 percent unless the debate can be refocused on scientific evidence of the net benefit for mothers.

Wu JM, Hundley AF, Visco AG. Elective primary cesarean delivery: attitudes of urogynecology and maternal-fetal medicine specialists. Obstet Gynecol 2005;105:301-6

Serious maternal morbidity increases with increasing number of cesarean deliveries

CONCLUSION: Because serious maternal morbidity increases progressively with increasing number of cesarean deliveries, the number of intended pregnancies should be considered during counseling regarding elective repeat cesarean operation versus a trial of labor and when debating the merits of elective primary cesarean delivery. LEVEL OF EVIDENCE: II-2

Silver, RM et al Maternal Morbidity Associated With Multiple Repeat Cesarean Deliveries. Obstetrics & Gynecology 2006;107:1226-1232

Improve the systems against maternal mortality from hemorrhage

CONCLUSION: Despite a significant increase in major obstetric hemorrhage cases, we found improved outcomes and fewer maternal deaths after implementing systemic approaches to improve patient safety. Attention to improving the hospital systems necessary for the care of women at risk for major obstetric hemorrhage is important in the effort to decrease maternal mortality from hemorrhage.

Skupski DW, et al Improving hospital systems for the care of women with major obstetric hemorrhage.

OB/GYN CCC Editorial

Are you current with your Advanced Life Support in Obstetrics (ALSO) Course?

Please take this opportunity to double check if your ALSO status is current. If you haven't taken the ALSO Course in the last 5 years, or feel you need a refresher, then please contact the ALSO office. **www.aafp.org/online/en/home/cme/aafpcourses/clinicalcourses/also.html**

Gynecology

FDA Licenses Vaccine for Prevention of Cervical Cancer in Females Caused by Human Papillomavirus

The Food and Drug Administration (FDA) announced the approval of Gardasil, the first vaccine developed to prevent cervical cancer, precancerous genital lesions and genital warts due to human papillomavirus (HPV) types 6, 11, 16 and 18. The vaccine is approved for use in females 9-26 years of age. Gardasil was evaluated and approved in six months under FDA's priority review process—a process for products with potential to provide significant health benefits.

The vaccine is effective against HPV types 16 and 18, which cause approximately 70 percent of cervical cancers and against HPV types 6 and 11, which cause approximately 90 percent of genital warts.

Gardasil is a recombinant vaccine (contains no live virus) that is given as three injections over a six-month period. Immunization with Gardasil is expected to prevent most cases of cervical cancer due to HPV types included in the vaccine. However, ➔

➔ females are not protected if they have been infected with that HPV type(s) prior to vaccination, indicating the importance of immunization before potential exposure to the virus. Also, Gardasil does not protect against less common HPV types not included in the vaccine, thus routine and regular pap screening remain critically important to detect precancerous changes in the cervix to allow treatment before cervical cancer develops.

The results showed that in women who had not already been infected, Gardasil was nearly 100 percent effective in preventing precancerous cervical lesions, precancerous vaginal and vulvar lesions, and genital warts caused by infection with the HPV types against which the vaccine is directed.

The studies also evaluated whether the vaccine can protect women already infected with some HPV types included in the vaccine from developing diseases related to those viruses. The results show that the vaccine is only effective when given prior to infection.

Two studies were also performed to measure the immune response to the vaccine among younger females aged 9-15 years. Their immune response was as good as that found in 16-26 year olds, indicating that the vaccine should have similar effectiveness when used in the 9-15 year age group.

The safety of the vaccine was evaluated in approximately 11,000 individuals. Most adverse experiences in study participants who received Gardasil included mild or moderate local reactions, such as pain or tenderness at the site of injection.

OB/GYN CCC Editorial

Rapid Approval Marks Major Advancement in Public Health

This is the biggest news in Women's Health since the advent of the pap smear.

While FDA approval is important, perhaps most important, programmatically, is when and how the Merck vaccine gets approved for roll out by the Advisory Committee on Immunization Practices (ACIP).

The ACIP meeting is due to occur in late June and it is really there that more of the salient details will arise"

Will it be indicated universally or just for high risk groups?

- If universally, then it will qualify for the Vaccines For Children (VFC) program approval and be essentially free to Natives through the State Immunization program
- If for high risk groups only, then it will be difficult to get broad acceptance, plus we would likely have to pay for it

As this would be the third new vaccine for adolescents in as many years (Read as: Expensive - approximately $120 each times 3 doses), the HPV vaccine will run into some stiff competition for limited State Immunization funding with acellular DPTa and Menactra (meningitis).

Typically ACIP rolls out new vaccines the first of the calendar year…hence January 2007 is the most likely roll out guess at this point

Each Indian Health site needs to be mindful that this vaccine is limited to only two of the major cancer causing subtypes, e. g., 16 and 18. In Alaska Natives our rates of 16 and 18 are somewhat similar to the national statistics, but we actually had a very high rate of multiple infections, e.g., subtypes not covered by either the Merck or GSK vaccines. It is for that reason one probably need to think along the lines of long term immunogenicity studies in your population to monitor its effect over time.

Similar studies and similar programmatic follow-up were very helpful during the Hep B vaccine national roll out. In addition, the Merck vaccine has not particularly well studied in minority patients to date.

This will be important because we need our patients with abnormal paps to become the local champions for this vaccine in their conversations with their adolescent daughters and sisters. Though we need to emphasize this is a 'Cancer' vaccine, there still will be some questions about the effect of a possible STI vaccine in a pre-pubescent girls. This is especially important to do asap because a possible ultimate rollout in 5- 6 months is really a short time line for something like this.

So……based on these and other issues, you may want to consider first maximizing patient education to facilitate the roll out (based on local focus group developed materials), hopefully in the near term, e. g., the cancer preventing nature of this vaccine should be emphasized vs this is not primarily an STI preventing vaccine—with subsequent implications on sexual behavior in pre-teen girls. See Fact Sheet below

Human Papilloma Virus Vaccine Fact Sheet

This fact sheet on Human Papilloma Virus (HPV) vaccines provides questions and answers about HPV and HPV vaccines, which may be available soon. http://www.cdc.gov/std/hpv/STD-Fact-HPV-Vaccine.htm

Overlap repair of obstetric anal sphincter injury: Decrease in fecal incontinence

CONCLUSION: Primary overlap repair of the external anal sphincter is associated with a significantly lower incidence of fecal incontinence, urgency, and perineal pain. When symptoms do develop, they appear to remain unchanged or deteriorate in the end-to-end group but improve in the overlap group. LEVEL OF EVIDENCE: I

Fernando RJ et al Repair Techniques for Obstetric Anal Sphincter Injuries A Randomized Controlled Trial. Obstetrics & Gynecology 2006;107:1261-1268

Child Health

Co-occurring maternal conditions and behavior problems in children

Our study suggests that, by 3 years of age, there is already evidence of the effect of adverse childhood experiences, occurring in this study in the form of parental mental health problems, substance use, and domestic violence. ➔

➔

The authors found that

- The risk of behavior problems in 3-year-olds increased with the number of categories—mental health, substance use, and domestic violence—in which the mother reported a condition in the year after delivery.
- The graded increase in risk was independent of sociodemographic and prenatal factors, as well as measures of paternal mental health and substance use in the year after delivery.

The authors conclude that "to play their most useful role, health care providers might wish to consider the health and well-being of the family, the social unit involved in the transfer of health between generations, rather than limiting their focus to the individual patient or to a particular developmental period."

Whitaker RC, Orzol SM, Kahn RS. 2006. Maternal mental health, substance use, and domestic violence in the year after delivery and subsequent behavior problems in children at age 3 years. Archives of General Psychiatry 63(5):551-560.

Maternal cholestasis is significantly associated with RDS in the newborn

RESULTS: The incidence of RDS in newborns from cholestatic pregnancies was twice that the reference population (28.6% vs 14%). The multivariate analysis showed that the risk of RDS in these newborns was approximately 2.5 times higher than in control infants. Within the ICP group, maternal and neonatal bile acid levels of infants affected by RDS were not significantly higher than those of healthy infants. The multivariate analysis showed that a low gestational age was the most important risk factor, but the probability of respiratory distress syndrome also increased by 2 per thousand for every additional micromole of the interaction term "neonatal by maternal bile acids level." CONCLUSIONS: Maternal ICP is significantly associated with the occurrence of RDS in the newborn. We hypothesize that bile acids can produce surfactant depletion in the alveoli reverting the reaction of phospholipase A2. This hypothesis could potentially be confirmed by bronchoalveolar lavage study.

Zecca E et al Intrahepatic cholestasis of pregnancy and neonatal respiratory distress syndrome. Pediatrics. 2006 May;117(5):1669-72.

OB/GYN CCC Editorial

The incidence of intrahepatic cholestasis of pregnancy may also be elevated in certain AI/AN women.

Our preliminary survey shows a high prevalence (3.9 %) of IHCP in pregnant Alaska Native women.

Q. Is cholestasis in pregnancy significant in American Indians and Alaska Natives?

A. Yes, cholestasis can be associated with infant mortality and maternal discomfort.

See link: **www.ihs.gov/medicalprograms/mch/m/documents/cholestas4206.doc**

Chronic disease and Illness

Group visits: Promising approach to chronic care management for the motivated patient

RESULTS: Although the heterogeneity of the studies presented renders the assessment of this care model problematic, there is sufficient data to support the effectiveness of group visits in improving patient and physician satisfaction, quality of care, quality of life, and in decreasing emergency department and specialist visits.

CONCLUSION: Group visits are a promising approach to chronic care management for the motivated patient. Future research may benefit, however, from abandoning old nomenclatures and clearly defining the structure, processes of care, content of visits, and appropriate outcome measures.

Jaber R et al Group visits: a qualitative review of current research. J Am Board Fam Med. 2006 May-Jun;19(3):276-90.

Depression Relapse in Pregnancy High When Medication Stopped

CLINICAL QUESTION: What is the risk of relapse of major depression in women who discontinue their antidepressant medication while pregnant?

BOTTOM LINE: Nearly 50 percent of women currently receiving antidepressant medication will experience a relapse of major depression during pregnancy. The risk is highest for those discontinuing their medication. It is likely that this study sample consists of patients with a higher severity of illness than those found in a routine community practice, so the findings may not generalize to other settings. (Level of Evidence: 1b)

Cohen LS, et al. Relapse of major depression during pregnancy in women who maintain or discontinue antidepressant treatment. JAMA February 1, 2006;295:499-507.

Determining Eligibility for Gastric Bypass Surgery

Case Scenario: I have a 65-year-old patient with a body mass index (BMI) close to 50 kg per m2. Her weight dramatically affects her quality of life. She uses a wheelchair and has difficulty getting around. Her weight also has affected her health: she has congestive heart failure, sleep apnea, and pulmonary hypertension. A thallium stress test has shown that she has minimal coronary artery disease. The patient has been unable to lose weight with diet and exercise. I thought she was an acceptable candidate for gastric bypass surgery, and I referred her to a surgeon to discuss this option. But soon afterward, my patient returned to my office devastated. The surgeon had informed her that she was not a candidate for gastric bypass surgery because of her age.

Should this patient be allowed to have the surgery? Should I try to find another surgeon who is willing to perform the risky procedure? What are the ethical implications of allocating an expensive resource such as gastric bypass surgery?

See discussion:

www.aafp.org/afp/20060501/curbside.html

Features

Breastfeeding

Suzan Murphy, PIMC

Early breastfeeding choice, GDM, and BMI

When a mother has diabetes during pregnancy, she has more to worry about. Among other diabetes related concerns, her baby has a greater risk for being large for gestational age, developing type 2 diabetes at an early age. Also, studies indicate that if are babies born large for gestational age, they are likely to stay over weight or obese as they grow.

But there is hope that more children born to mothers with gestational diabetes mellitus (GDM) can avoid early childhood obesity and its risk of later adult obesity, and so possibly diabetes. A study by Schaefer-Graf et al in Germany found that early feeding choice could change risk of overweight for children from mothers with GDM.

During 1995-2000, 2000 women with GDM were cared for at the Vivantes Medical Center in Berlin, Germany. Later, many returned for follow-up, including 354 children (54% males, 46% females) who were included in this study. The mean age was 5.4 + 1.6 years, 28.4% were overweight. Overweight prevalence by feeding choice was:

- Children not breastfed 37.3%.
- Children breastfed up to 3 months 32.5%
- Children breastfed more than 3 months 22.0%

The impact of breastfeeding as a preventive measure was maintained after adjusting for confounding factors such as parental obesity and high birth weight. The authors concluded that "the risk of childhood overweight may be reduced by 40-50% when breastfeeding is >3 months."

For more information about this study, please see the complete article by Schaefer-Graf UM et al, Association of Breast-feeding and Early Childhood Overweight in Children From Mothers With Gestational Diabetes Mellitus, Diabetes Care, Vol:29, Number 5, May 2006, pp 1105-1007.

Domestic Violence

DV is 4 times more common than breast cancer: Its morbidity and mortality cannot be ignored

The present investigation focusing on intimate partner violence [IPV] prevalence in a cohort of insured, employed, educated, English-speaking U.S. women provides new knowledge on the high prevalence, several dimensions of chronicity, severity, and interrelatedness of IPV types.

The authors found that

- Over 14% of the women reported IPV of any type in the past 5 years, and 7.9% in the past year.
- Many women reported more than one IPV type. For example, among the

138 women with physical abuse (not sexual) in the past 5 years, 28 (20.3%) experienced physical abuse only, while 79.7% also experienced other types of IPV. Of the 138 women reporting physical abuse, 84 (60.9%) experienced a total of two to three types of IPV, and 26 (18.8%) experience four to five types.

- Between 10% and 21% (depending on IPV type) of the women who reported IPV reported abuse by two or more partners.
- The proportion of women with IPV rating it as moderately to extremely violent was 61% for physical violence, 45% for sexual intercourse, 36% for forced sexual contact, 63% for fear due to a partner's threats or anger, and 31% for controlling behavior.
- IPV risk was higher among younger women, women with lower incomes, women with less education, women who were single mothers, and women who had been exposed to any form of abuse as a child or who had witnessed IPV as a child.

From the present work, a picture emerges of both physical and non-physical IPV as very common, chronic, intergenerational, and present in highly overlapping forms. A cause of major morbidity and mortality, which is fourfold more common than breast cancer, cannot be ignored.

Thompson RS, Bonomi AE, Anderson M, et al. 2006. Intimate partner violence: Prevalence, types, and chronicity in adult women. American Journal of Preventive Medicine 30(6):447-457.

ACOG

Use of Hormonal Contraception in Women With Coexisting Medical Conditions, Practice Bulletin, No. 73

Summary of Recommendations and Conclusions

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

- A history of benign breast disease or a positive family history of breast cancer should not be regarded as contraindications to oral contraceptive use.
- Combination oral contraceptives are safe for women with mild lupus who do not have antiphospholipid antibodies.
- Combination contraceptives are not recommended for women with a documented history of unexplained venous thromboembolism or venous thromboembolism associated with pregnancy or exogenous estrogen use, unless they are taking anticoagulants.
- Combination oral contraceptives should be prescribed with caution, if ever, to women who are older than 35 years and are smokers.
- Use of the levonorgestrel intrauterine system is appropriate for women with diabetes without retinopathy, nephropathy, or other vascular complications.

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

- Healthy, nonsmoking women doing well on a combination contraceptive can continue their method until the ages of 50–55 years, after weighing the risks and benefits.
- Progestin-only oral contraceptives and DMPA can be initiated safely at 6 weeks postpartum in lactating women and immediately postpartum in nonbreastfeeding women.
- Combination contraceptives are not recommended as the first choice for breastfeeding women because of the possible negative impact of contraceptive doses of estrogen on lactation. However, use of combination contraceptives by well-nourished breastfeeding women does not appear to result in infant development problems; therefore, their use can be considered once milk flow is well established.
- Women with well-controlled and monitored hypertension who are aged 35 years or younger are appropriate candidates for a trial of combination contraceptives, provided they are otherwise healthy, show no evidence of end-organ vascular disease, and do not smoke.
- The use of combination contraceptives by women with diabetes should be limited to such women who do not smoke, are younger than 35 years, and are otherwise healthy with no evidence of hypertension, nephropathy, retinopathy, or other vascular disease.
- The use of combination contraceptives may be considered for women with migraine headaches if they do not have focal neurologic signs, do not smoke, are otherwise healthy, and are younger than 35 years. Although cerebrovascular events rarely occur among women with migraines who use combination oral contraceptives, the impact of a stroke is so devastating that clinicians should consider the use of progestin-only, intrauterine, or barrier contraceptives in this setting.
- Because of the increased risk of venous thrombotic embolism, combination contraceptives should be used with caution in women older than 35 years who are obese.
- In women with depressive disorders, symptoms do not appear to worsen with use of hormonal methods of contraception.
- If oral contraceptives are continued before major surgery, heparin prophylaxis should be considered.

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

- Most women with controlled dyslipidemia can use combination oral contraceptives formulated with 35 mcg or less of estrogen. In women with uncontrolled LDL cholesterol greater than 160 mg/dL, a triglyceride level greater than 250 mg/dL, or multiple additional risk factors for coronary artery disease, alternative contraceptives should be considered.
- Depot medroxyprogesterone acetate has noncontraceptive benefits and is appropriate for women with sickle cell disease.
- Progestin-only contraceptives may be appropriate for women with coronary artery disease, congestive heart failure, or cerebrovascular disease. However, combination contraceptives are contraindicated in these women.
- Short- or long-term use of DMPA in healthy women should not be considered an indication for DXA or other tests that assess bone mineral density. In adolescents, the advantages of DMPA likely outweigh the theoretical safety concerns regarding bone mineral density and fractures. However, in the absence of long-term data in this population, consideration of long-term use should be individualized.

Use of hormonal contraception in women with coexisting medical conditions. ACOG Practice Bulletin No. 73. American College of Obstetricians and Gynecologists. Obstet Gynecol 2006:107:1453–72.

Patient-Requested Cesarean Update: Cesareans should be performed for medical reasons

Here is an excerpt from an ACOG Press Release

…Both Dr. Zinberg and Dr. D'Alton stress that women who request cesarean delivery in the absence of any medical indication should be counseled on the risks associated with cesarean, including a higher risk of infection, adhesions (painful scar tissue under the skin), pulmonary embolisms (blood clots), complications from the use of anesthesia, and the potential need for future cesareans, which entail additional risk. They also pointed out that the decision to perform a CDMR should be carefully individualized and consistent with ethical principles. "There is also a growing concern of the increased risk of babies born before 39 weeks of gestation; therefore, CDMR should not be performed prior to 39 weeks of gestation or without verification of lung maturity," says Dr. Zinberg.

Osteoporosis

Calcium Plus Vitamin D for Fracture Prevention: POEM

Clinical Question: Does supplementation with 1,000 mg of calcium and 400 IU of vitamin D reduce the risk of fracture in healthy women?

Bottom Line: The ability of a small dose of calcium and vitamin D to prevent fractures in healthy community-dwelling women is modest at best. This study used a relatively low dose of vitamin D (less than the 700 to 800 IU found most beneficial in previous studies), and the patients were generally at low risk of fracture. Perhaps that explains the discordance of these findings with the bulk of the literature on this topic. (Level of Evidence: 1b)

Jackson RD, et al., for the Women's Health Initiative Investigators. Calcium plus vitamin D supplementation and the risk of fractures [Published correction appears in N Engl J Med 2006;354:1102]. N Engl J Med February 16, 2006;354:669-83.

Family Planning

Refusals by pharmacists to dispense emergency contraception: a critique

Over the past several months, numerous instances have been reported in the United States media of pharmacists refusing to fill prescriptions written for emergency postcoital contraceptives. These pharmacists have asserted a "professional right of conscience" not to participate in what they interpret as an immoral act. In this commentary, we examine this assertion and conclude that it is not justifiable, for the following reasons:

1) postcoital contraception does not interfere with an implanted pregnancy and, therefore, does not cause an abortion;

2) because pharmacists do not control the therapeutic decision to prescribe medication but only exercise supervisory control over its dispensation, they do not possess the "professional right" to refuse to fill a legitimate prescription;

3) even if one were to grant pharmacists the "professional right" not to dispense prescriptions based on their own personal values and opinions, pharmacists "at the counter" lack the fundamental prerequisites necessary for making clinically sound ethical decisions, that is, they do not have access to the patient's complete medical background or the patient's own ethical preferences, have not discussed relevant quality-of-life issues with the patient, and do not understand the context in which the patient's clinical problem is occurring. We conclude that a policy that allows pharmacists to dispense or not dispense medications to patients on the basis of their personal values and opinions is inimical to the public welfare and should not be permitted.

Wall LL, Brown D. Refusals by pharmacists to dispense emergency contraception: a critique. Obstet Gynecol. 2006 May;107(5):1148-51.

Discussion needed:

Reasons why women discontinue oral contraception

RESULTS: Most women who reported having discontinued OCs did so because of medical side effects, and most had switched to less effective methods. Among OC users, 26.4% had sexual intercourse on days they missed pills just before or after their placebo week. Nonadherence did not differ by socioeconomic factors or obesity.

CONCLUSION: Clinicians may need to encourage their patients to discuss their reasons for wanting to discontinue the use of an effective contraceptive method and assist them with their concerns or to switch to other effective methods to protect themselves from unintended pregnancy.

Huber LR, et al Contraceptive use and discontinuation: findings from the contraceptive history, initiation, and choice study. Am J Obstet Gynecol. 2006 May;194(5):1290-5

Office of Women's Health, CDC

Recommendations to Improve Preconception Health and Health Care —United States

This report provides recommendations to improve both preconception health and care. The goal of these recommendations is to improve the health of women and couples, before conception of a first or subsequent pregnancy. The recommendations focus on changes in consumer knowledge, clinical practice, public health programs, health-care financing, and data and research activities. Each recommendation is accompanied by a series of specific action steps and, when implemented, can yield results within 2-5 years. Based on implementation of the recommendations, improvements in access to care, continuity of care, risk screening, appropriate delivery of interventions, and changes in health behaviors of men and women of childbearing age are expected to occur.

Preconception Care website

www.cdc.gov/ncbddd/preconception/default.htm

Medical Mystery Tour

Copious post operative mucous secretions

A 60 year old female presented to her primary care provider with lower abdominal discomfort. The patient did not complain of increasing weight or abdominal girth, and noted no change in her appetite. The patient was s/p vaginal hysterectomy for a history of irregular bleeding with normal pap smears. Imaging studies revealed a complex cystic pelvic mass with no evidence of ascites. Other medical issues included hypertension, controlled with oral medication, and smoking one pack a day of tobacco without current respiratory symptoms. The patient was well nourished had no previous history of abdominal surgery.

The patient underwent a staging laparotomy that revealed bilateral hydrosalpinges, and was otherwise without complications. On post op day one, the patient was afebrile and tolerated an advancing diet, but had coarse breath sounds. On the second day post-op the patient developed increased mucous production and had periods of desaturation. Examination revealed rhonchi and continued coarse breath sounds. Chest X-ray revealed complete opacification of the left hemithorax. The patient was transferred to the Intensive Care Unit and received an urgent bronchoscopy and was found to have tenacious mucous plugging. Her left lung was easily reinflated. The patient rapidly improved and was returned to the medical surgical ward the following day. The patient continued to produce copious mucous secretions and she received vigorous pulmonary toilet with bronchodilators and incentive spirometry.

On the day the following the bronchoscopy the patient was noted to have several small fatty spots between her midline staples, but she was otherwise tolerating an advancing diet, voiding, and had bowel movements. It was felt the prolapsed subcutaneous fat was a result of the patient's coughing due to the copious secretions. On the fourth postoperative day, there was no wound discharge. In fact the subcutaneous fat was becoming dehydrated so moist gauze was placed on the wound to facilitate replacement of the slightly prolapsed subcutaneous fat the next day. The patient was prepared for discharge on the fifth post-operative day and it was elected to remove the staples, replace the slightly prolapsed subcutaneous fat and then place steristrips over the otherwise clean and dry incision. In anticipation of discharge the patient was encouraged to stop smoking and the nature of chronic obstructive pulmonary was discussed with the patient.

Can you think of any further discharge or wound care instructions you would give this patient?

Stay tuned to next month's CCCC Newsletter for the rest of the story

STD Corner

Lori de Ravello, National IHS STD Program

HIV Testing and Additional Analysis of National Survey on HIV/AIDS

The Centers for Disease Control and Prevention (CDC)'s reported plans to recommend routine HIV testing for patients in health care settings will mark a major change in the way HIV testing is conducted in the United States and is intended to increase testing nationwide. Given that an estimated one in four of the more than one million people living with HIV/AIDS in the U.S. do not know they are infected, increased testing could help more people learn they are HIV positive, linking them to necessary care and services and leading to reduced risk behaviors. In order to help inform discussions about expanded testing, the Kaiser Family Foundation is releasing additional data from its "2006 Survey of Americans on HIV/AIDS"

These two new reports are based on subsets of the full survey.

www.kff.org/kaiserpolls/pomr050806pkg.cfm

STD Corner

Social Networks Testing: Strategy for Identifying Persons with Undiagnosed HIV Infection

One strategy for reaching and providing HIV CTR to persons with undiagnosed HIV infection is the use of social networks. Enlisting HIV-positive or high-risk HIV-negative persons (i.e., recruiters) to encourage people in their network (i.e., network associates) to be tested for HIV may provide an efficient and effective route to accessing individuals who are infected, or at very high risk for becoming infected, with HIV and linking them to services. The social network approach has proven to be a viable recruitment strategy for reaching people beyond current partners.

www.cdc.gov/hiv/resources/guidelines/snt/index.htm

ACOG

Noncontraceptive Uses of the Levonorgestrel Intrauterine System, Committee Opinion

ABSTRACT: The levonorgestrel intrauterine system, approved for contraceptive use for up to 5 years, also has noncontraceptive uses. It appears to reduce menstrual bleeding significantly in women with idiopathic menorrhagia. Current studies suggest that menopausal hormone therapy regimens combining the levonorgestrel intrauterine system with estradiol are effective in reducing climacteric symptoms and in inducing amenorrhea in most women after 1 year. Further studies are required before this device can be recommended as a treatment for endometriosis-associated pelvic pain, hyperplasia, or endometrial adenocarcinoma, or as adjuvant therapy with tamoxifen.

Noncontraceptive uses of the levonorgestrel intrauterine system. ACOG Committee Opinion No. 337. American College of Obstetricians and Gynecologists. Obstet Gynecol 2006;107:1479–82.

Midwives Corner

Lisa Allee, CNM

Empowering women to find the power of birth is of great value

The effect of labor pain relief medication on neonatal suckling and breastfeeding duration.

This study by Jan Riordan and colleagues is unique in that they had a true control group of women who delivered without any pain medication. Previous studies had compared groups of women with different types of medications. They also used a tool to assess breastfeeding specifically, whereas other studies used tools that assessed general neonatal behaviors. The study was prospective, multisite, and involved 129 mother-baby dyads with vaginal births at term, 29% of which occurred after unmedicated labors and 71% had some form of pain medication. The results showed significant differences in breastfeeding ability between the non-medicated group and those receiving pain medications. The babies who were not exposed to any pain medication had significantly higher scores, meaning more vigorous and effective suckling, than the other three groups. The IV-analgesia-only group and the epidural-only group had similar scores, significantly lower than the non-med group, and the IV and epidural group had the lowest scores. The results did not show a difference in duration of breastfeeding, but the dyads with low scores weaned earlier than those with medium or high scores.

The authors conclude that pain medication during labor, including epidurals (and I think we can easily extrapolate to intrathecals) clearly hinder breastfeeding. They make the following points for consideration in clinical care:

- Nonpharmacological comfort measures are effective and do not compromise early neonatal suckling and breastfeeding.
- Informed consent includes telling women that their infant's ability to breastfeed is diminished with IV analgesics and epidurals (intrathecals.)
- If epidurals (intrathecals) are used, it appears the best choice is medication that does not include a narcotic.
- Breastfeeding mothers who have had pain medication during labor may become discouraged and babies with poor breastfeeding behaviors are at greater risk for dehydration, jaundice, and poor weight gain.

Riordan J, Gross A, Angeron J, Krumwiede B, Melin J. 2000. The Effect of Labor Pain Relief Medication on Neonatal Suckling and Breastfeeding Duration. Journal of Human Lactation 16(1): 7-12

Editorial comment: Lisa Allee, CNM

I find this article to be yet another affirmation that empowering women to find the power of birth is of great value. When we teach, support, encourage, cajole, advocate, and do whatever else is necessary to assist women through the intense, life-altering experience of labor and birth without using narcotics, there are profound benefits for the woman, the baby, and, with this article, society when you consider the far-reaching effects of breastfeeding success. This article also points out that when women do use narcotics during labor that we must be very attentive to breastfeeding support initially and ongoing.

Primary Care Discussion Forum—September 1, 2006

Palliative Medicine's Role in the Continuity of Care

Moderator: Tim Domer, M.D.

- Management of acute vs chronic pain
- Quality of Life in chronic illness
- The meaning of "Code Status"
- Preparing for a "Good Death"
- End-of-Life Care as part of Continuity of Care and Prevention

Navajo News

Kathleen Harner, Chinle

Methamphetamine abuse among women on Navajo (Part 3 of 4)

Phoenix Indian Medical Center (PIMC) has developed a program designed specifically for the special needs of substance abusers and women with mental health disorders. Their goal was to: protect the unborn from toxic drug exposure, assist the mother in successfully abstaining from drugs and alcohol, and to prevent repeat pregnancies with drug affected newborns. Beginning in October of 2003, the midwives at PIMC staff a "Special Care Clinic" devoted to pregnant drug users, victims of domestic violence and women with mental health disorders. The clinic meets one afternoon a week and has longer appointments than the normal prenatal care visits. Social workers and substance abuse counselors are in the clinic and available for same time appointments. At the first prenatal care visit problems are identified, a routine prenatal workup and sexually transmitted disease (STD) testing is performed. If substance abuse is identified it is discussed thoroughly and a drug contract is created and the patient is asked to sign it. A urine drug screen (UDS) is obtained if the patient agrees.

PIMC has created a wide network of referrals for the women in their "Special Care Clinic". These include Mental Health, Public Health Nursing, Home Health, Case Management and some Community Support Groups (e.g. Twelve Step Programs). Social services and substance abuse counseling are as accessible as possible because they are in the clinic with the midwives. The patient sees the same counselor and midwife at each visit whenever practical. The patient need never explain the purpose of her visit to the admitting clerk, which avoids embarrassment. A UDS is obtained at each visit if the patient has agreed and the drug contract is signed at each visit as well. Patients are seen weekly if needed and otherwise are on a routine prenatal care schedule.

Patients receive gifts and incentives for participating in the "Special Care Clinic". At each visit the pregnant woman is given a gift for herself and her baby. These gifts include make-up, hair care products, inexpensive jewelry and lotions for the mother. Baby gifts are blankets, clothing, pacifiers, and baby picture frames. Patients seem to particularly like the "Fetus Models" of a 12-week fetus. When a patient has had three negative UDS in a row she is rewarded with a $15.00 gift certificate for Wal-Mart, Target or Food City. If she tests positive for drugs there is no punitive action but she is usually seen more frequently.

If a patient is abusing MA heavily, residential treatment is offered. If she is positive for drugs, in addition to her weekly visit with the midwife and mental health counselor she also sees the social worker two or more times a week. Once several drug screens have been negative, she may be seen on a weekly schedule.

As of January 15, 2005 the program had been operating for 15 months. Over ninety women participated with a total of 275 midwife visits. Their diagnosis included substance abuse, anxiety/depressive disorders, bipolar disease, homelessness, severe congenital anomalies incompatible with life and domestic violence. Some patients are still lost to follow up. Many are drug free or have only occasional lapses. The midwives and patients are happy with the program. At PIMC every success is celebrated.

The PIMC program uses contingency management very effectively in their program. Contingency management (CM) treatments are based on a simple behavioral principle, if a behavior is reinforced or rewarded it is more likely to occur in the future. Reinforcement of good behaviors such as negative urine screens and attending prenatal or therapy appointments encourage women to stay abstinent. Rewards need not be large to be effective.

Cognitive behavioral therapy (CBT) has been widely used for treating cocaine abusers. CBT attempts to help patients recognize, avoid and cope with problematic behaviors associated with substance abuse. It has many advantages over other more traditional therapies such as twelve step programs and traditional psychotherapy. It is a short-term therapy that creates skills the patient can use after therapy is over. It has been studied extensively in clinical trials and has been proven very effective. It is flexible and can be individualized and it is compatible with other treatments.

MA abuse among women of childbearing age is a complicated problem. Using a multifaceted and multidisciplinary approach to helping pregnant women stop abusing MA provides the best opportunity for success.

Hunter, F What we did about Prenatal Substance Abuse Special Care clinic. A Power Point presentation 2005.

Kathleen Harner: kathleen.harner@tcimc.ihs.gov

Next Month: The 'drop in' meth abusing gravida

Perinatology Picks

George Gilson, MFM, ANMC

Cesarean delivery rate: Continues to increase without improving population outcomes

Attempts to define, or enforce, an "ideal" cesarean delivery rate are futile, and should be abandoned. The cesarean rate is a consequence of individual value-laden clinical decisions, and is not amenable to the methods of evidence-based medicine. The influence of academic authority figures on the cesarean rate in the US is placed in historic context. Like other population health indices, the cesarean deliver rate is an indirect result of American public policy during the last century. Without major changes in the way health and maternity care are delivered in the US, the rate will continue to increase without improving population outcomes.

An RCT requires a hypothesis that is testable in the real world: it should be simple, specific, and stated in advance. On those grounds, there is no direct way to test the hypothesis that there is an ideal cesarean delivery rate. Because the cesarean rate is calculated post-hoc, it is also impossible to design a prospective trial comparing specific cesarean rates. Conceptually, one might set up a large RCT with multiple arms, each having a different proportion of women by intended method of delivery, e. g., 100% elective cesarean versus 0% planned vaginal birth, 80/20, 50/50, etc. For specified outcome variables, an ideal cesarean rate could then be estimated retrospectively. It is clear that the ideal rate will depend on which women are studied, and how much weight is given to maternal versus fetal morbidity—all subjective criteria.

Cyr RM. Myth of the ideal cesarean section rate: commentary and historic perspective. Am J Obstet Gynecol. 2006 Apr;194(4):932-6.

OB/GYN CCC Editorial

Patient-choice vaginal delivery?

As Dr. Gilson points out the rapidly increasing cesarean rate does not improve commonly measured patient outcomes. Zweifler et al confirm that trend in this 1996 through 2002 California study of the Birth Statistical Master Files were used to identify 386,232 California residents who previously gave birth by cesarean delivery and had a singleton birth planned in a California hospital. (Results below). *See also the Oklahoma Perspective, page 15.*

Here is an excerpt from a Reflection by Dr. Larry Leeman and Dr. Lauren Plante from the May/June Annals of Family Medicine:

Patient-choice cesarean delivery is increasing in the United States. The American College of Obstetricians and Gynecologists supports this option, citing ethical premises of autonomy and informed consent, despite a lack of evidence for its safety. This increase in patient-choice cesarean delivery occurs during a time when women with a breech-presenting fetus or a previous cesarean deliver have fewer choices as to vaginal birth. Patient-choice cesarean delivery may become widely disseminated before the potential risks to women and their children have been well analyzed. The growing pressure for cesarean delivery in the absence of a medical indication may ultimately result in a decrease of women's childbirth options. Advocacy of patient-choice requires preserving vaginal birth options as well as cesarean delivery.

Leeman LM, Plante LA. Patient-choice vaginal delivery? Ann Fam Med. 2006 May-Jun;4(3):265-8

Vaginal delivery of singleton fetuses in breech presentation at term remains a safe option

RESULTS: Cesarean delivery was planned for 5579 women (68.8%) and vaginal delivery for 2526 (31.2%). Of the women with planned vaginal deliveries, 1796 delivered vaginally (71.0%). The rate of the combined neonatal outcome measure was low in the overall population (1.59%; 95% CI [1.33-1.89]) and in the planned vaginal delivery group (1.60%; 95% CI [1.14-2.17]). It did not differ significantly between the planned vaginal and cesarean delivery groups (unadjusted odds ratio = 1.10, 95% CI [0.75-1.61]), even after controlling for confounding variables (adjusted odds ratio = 1.40, 95% CI [0.89-2.23]).

CONCLUSION: In places where planned vaginal delivery is a common practice and when strict criteria are met before and during labor, planned vaginal delivery of singleton fetuses in breech presentation at term remains a safe option that can be offered to women.

Goffinet F, et al Is planned vaginal delivery for breech presentation at term still an option? Results of an observational prospective survey in France and Belgium. Am J Obstet Gynecol. 2006 Apr;194(4):1002-11.

Glyburide and insulin: Equally efficient for treatment of GDM in all levels of severity

STUDY DESIGN: In a secondary analysis of our previous randomized study, 404 women were analyzed. The association among glyburide dose, severity of GDM, and selected maternal and neonatal factors was evaluated. Severity levels of GDM were stratified by fasting plasma glucose (FPG) from the oral glucose tolerance test (OGTT). Infants with birth weight at or above the 90th percentile were considered large-for-gestational age (LGA). Macrosomia was defined as birth weight > or =4000 g. Well-controlled was defined as mean blood glucose < or =95 mg/dL. The association between glyburide- and insulin-treated patients by severity of GDM and neonatal outcome was evaluated.

CONCLUSION: Glyburide and insulin are equally efficient for treatment of GDM in all levels of disease severity. Achieving the established level of glycemic control, not the mode of pharmacologic therapy, is the key to improving the outcome in GDM

Langer O et al Insulin and glyburide therapy: dosage, severity level of gestational diabetes, and pregnancy outcome. Am J Obstet Gynecol. 2005 Jan;192(1):134-9.

Oklahoma Perspective

Greggory Woitte—Hastings Indian Medical Center

Elective Cesarean Delivery

When asked the question in your office about an elective primary cesarean delivery, how do you respond? Do you defer to the patient's right to determine her birthing method or do you respond that you don't perform one without an indication? As the media popularizes elective cesareans for the famous, where do we stand as a profession? The NIH convened a consensus conference March 27-29, 2006 to review the available evidence.

Here is a summary of their conclusions:

Cesarean deliveries without medical or obstetrical indications are on the rise and a component of this is due to elective maternal request.

Insufficient evidence to fully evaluate

There is insufficient evidence to evaluate fully the benefits and risks of cesarean delivery on maternal request as compared to planned vaginal delivery, and more research is needed.

Until quality evidence becomes available, any decision to perform a cesarean delivery on maternal request should be carefully individualized and consistent with ethical principles.

Given that the risks of placenta previa and accreta rise with each cesarean delivery, cesarean delivery on maternal request is not recommended for women desiring several children.

Cesarean delivery on maternal request should not be performed prior to 39 weeks of gestation or without verification of lung maturity, because of the significant danger of neonatal respiratory complications.

Maternal request for cesarean delivery should not be motivated by unavailability of effective pain management. Efforts must be made to assure availability of pain management services for all women.

NIH or another appropriate Federal agency should establish and maintain a Web site to provide up-to-date information on the benefits and risks of all modes of delivery.

http://consensus.nih.gov/2006/2006CesareanSOS027html.htm

Nurses Corner

Sandra Haldane, HQE

SANE/SAFE training and capacity

Dear nursing colleagues:

I am gathering information on IHS and tribal capacity to conduct sexual assault examinations for adults and children. Specifically, I need to know which IHS and tribal facilities currently have a trained forensic nurse examiner on staff.

Please send me the following information:

- For each area, which hospitals and health centers have one or more nurses or APNs trained to perform a forensic examination and which do not?
- Please let me know if SANE or SAFE training has been offered in the past year, and where

Thank you very much for your help in getting me this information!

Carolyn Aoyama,
Carolyn.Aoyama@ihs.gov

(VariZIG™ replaces VZIG…, continued from page 1)

120 hours postexposure. If illness occurs, with or without postexposure vaccination, antiviral treatment (e.g., acyclovir) can be considered for adolescents and adults.

Editorial Comment:

Rosalyn Singleton MD

Varicella Prophylaxis for high risk persons: VariZIG™ replaces VZIG

Varicella Zoster Immune Globulin (VZIG) is no longer available. A similar product, VariZIG™ (Cangene) is available under an investigational new drug application (IND) with the FDA. VariZIG™ can be used for patients without evidence of varicella immunity who have been exposed to chicken pox and are at high risk for severe disease and complications, including: immunocompromised patients, neonates whose mothers have chicken pox around the time of deliver, certain premature infants in the neonatal period, and pregnant women. These groups have contraindications to Varicella vaccine.

VariZIG™ must be given within 96 hours of exposure. A protocol under the IND has been approved by a Central IRB which allows use of VariZIG™ on a case by case basis using the Central IRB approval as long as your institution and local IRB allow that. Providers who identify a patient can call FFF Enterprises 800-843-7477 for the necessary forms. FFF will send VariZIG™ by next day air.

SAVE THE DATES

IHS/ACOG Obstetric, Neonatal, and Gynecologic Care Course

* September 17–21, 2006
* Denver, CO
* Contact YMalloy@acog.org or call Yvonne Malloy at 202-863-2580
* Neonatal Resuscitation Program available
* Brochure www.ihs.gov/MedicalPrograms/MCH/F/documents/ACOG_06brochR1_1.pdf

2007 Indian Health MCH and Women's Health National Conference

* August 15–17, 2007
* Albuquerque, NM
* For anyone involved in care of women and children
* Internationally recognized speakers
* Save the dates. Details to follow

Special Note

HPV vaccine approved by the FDA: Public Health Approval Marks Major Achievement in Public Health.

See **Hot Topics, Gynecology** on pages 5–6 for more information.

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Summer Solstice~

People around the world have observed spiritual and religious seasonal days of celebration during the month of June. Most have been religious holy days which are linked in some way to the summer solstice.

On this day, typically JUN-21, the daytime hours are at a maximum in the Northern hemisphere, and night time is at a minimum. It is officially the first day of summer. It is also referred to as Midsummer because it is roughly the middle of the growing season throughout much of Europe.

In pre-historic times, summer was a joyous time of the year for those Aboriginal people who lived in the northern latitudes. The snow had disappeared; the ground had thawed out; warm temperatures had returned; flowers were blooming; leaves had returned to the deciduous trees. Some herbs could be harvested, for medicinal and other uses. Food was easier to find. The crops had already been planted and would be harvested in the months to come. Although many months of warm/hot weather remained before the fall, they noticed that the days were beginning to shorten, so that the return of the cold season was inevitable.

—More about the significance of the Solstice season to indigenous peoples in the coming months.