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Quadrivalent HPV:
Final ACIP Recommendations
—with comments by Amy Groom

Recommendations for Routine Use and Catch-Up

Routine Vaccination of Females Aged 11–12 Years

ACIP recommends routine vaccination of females aged 11–12 years with 3 doses of quadrivalent HPV vaccine. The vaccination series can be started as young as age 9 years.

Catch-Up Vaccination of Females Aged 13–26 Years

Vaccination also is recommended for females aged 13–26 years who have not been previously vaccinated or who have not completed the full series. Ideally, vaccine should be administered before potential exposure to HPV through sexual contact; however, females who might have already been exposed to HPV should be vaccinated. Sexually active females who have not been infected with any of the HPV vaccine types would receive full benefit from vaccination. Vaccination would provide less benefit to females if they have already been infected with one or more of the four vaccine HPV types. However, it is not possible for a clinician to assess the extent to which sexually active persons would benefit from vaccination, and the risk for HPV infection might continue as long as persons are sexually active. Pap testing and screening for HPV DNA or HPV antibody are not needed before vaccination at any age.

Recommended Schedule

Quadrivalent HPV vaccine is administered in a 3-dose schedule. The second and third doses should be administered 2 and 6 months after the first dose.

Minimum Dosing Intervals and Management of Persons Who Were Incorrectly Vaccinated

The minimum interval between the first and second doses of vaccine is 4 weeks. The minimum recommended interval between the second and third doses of vaccine is 12 weeks. Inadequate doses of quadrivalent HPV vaccine or vaccine doses received after a shorter-than-recommended dosing interval should be readministered.

Interrupted Vaccine Schedules

If the quadrivalent HPV vaccine schedule is interrupted, the vaccine series does not need to be restarted. If the series is interrupted after the first dose, the second dose should be administered as soon as possible, and the second and third doses should be separated by an interval of at least 12 weeks. If only the third dose is delayed, it should be administered as soon as possible.

Simultaneous Administration with Other Vaccines

Although no data exist on administration of quadrivalent HPV vaccine with vaccines other than hepatitis B vaccine, quadrivalent HPV vaccine is not a live vaccine and has no components that adversely impact safety or efficacy of other vaccinations. Quadrivalent HPV vaccine can be administered at the same visit as other age appropriate vaccines, such as the Tdap and quadrivalent meningococcal conjugate (MCV_4) vaccines. Administering all indicated vaccines together at a single visit increases the likelihood that adolescents and young adults will receive each of the vaccines on schedule. Each vaccine

(continued on page 14)

THIS MONTH

2007 Native Women's Health and MCH Conference

Interested in the latest program/clinical updates? You should attend the Native Women's Health and MCH Conference in Albuquerque, August 15–17, 2007. This meeting is triennial. It has internationally known speakers and benchmarks, e. g., Institute for Healthcare Improvement.
nmurphy@scf.cc

This is different from than the ACOG/IHS Postgraduate course, held every September in Denver to rave reviews. The Denver meeting is an excellent 4.5 day primer on basic obstetrics, gynecology, and neonatal care, plus a clinical update.
YMalloy@acog.org

Also on-line....

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

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

IHS Child Health Notes

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

Quote of the month

"Our capability to prevent and treat disease seems to exceed our willingness to apply our interventions."
—C. Everett Koop, Former Surgeon General of the United States

Articles of Interest

Double burden of iron deficiency in infancy and low socioeconomic status: a longitudinal analysis of cognitive test scores to age 19 years.

Arch Pediatr Adolesc Med. 2006 Nov;160(11):1108-13.

Middle class Costa Rican infants who had chronic iron deficiency had lower cognitive scores than their counterparts with normal iron stores. This gap was not reduced by later supplementation of iron stores in childhood. The gap in cognitive performance persisted even when these children were followed out to 19 years of age. The difference in cognitive performance was even greater when low income Costa Rican infants with iron deficiency were compared to their counterparts with sufficient iron. In low income children who were iron deficient, the gap in cognitive performance actually increased over time even if their iron stores were repleted in early childhood. These results suggest the value or preventing iron deficiency in infancy.

Editorial Comment

Some things can't be undone. Congenital hypothyroidism will result in permanent cognitive deficits unless treated by 3 weeks of age; later, adequate treatment cannot fully reverse this injury. The article above suggests that iron deficiency in infancy may have permanent cognitive effects that cannot be reversed with later iron therapy.

Every effort to prevent iron deficiency should be made. Breastfed infants should receive iron fortified cereal starting at 4 months of age. If there is any concern that a breastfed infant is not receiving sufficient iron they should receive iron supplements. These are most easily given as iron drops at 1 mg/kg/d of elemental iron beginning at 6 months of age and until 12 months. Breastfed pre-term and low birth weight infants should be supplemented with elemental iron at 2mg/kg/d beginning at 1 month of age and until 12 months of age. Non breastfeeding infants should receive only iron fortified formula.

All infants should be screened for iron deficiency anemia at 9 months. This is earlier than the previous recommendation to screen at 12 months but will allow for earlier detection of anemia and earlier iron repletion if needed.

Recent literature on American Indian/ Alaskan Native Health

Doug Esposito, MD

Editorial Comment

Please forgive me, but this month I would like to diverge a little from my usual M.O. I would like to take a short journey away from Indian Country and travel the literature specifically related to the foreign country. Of course, many of the same health and socioeconomic issues facing the developing world are in force in Indian Country, so it won't be such an exotic vacation after all. Anyway, I promise to ultimately make a point that is relevant to Indian child health, so please bear with me.

The February 2007 issue of the American Journal of Public Health is devoted to the topic of international child health priorities. There are several really interesting and timely entries that are worth exploring. There is even an article entitled "Changing the Child Labor Laws for Agriculture: Impact on Injury,"1 a topic once very near and dear to my own heart. Unfortunately, I cannot really link its relevance to Indian child health, so I will simply mention it in passing. Also, for anyone interested in understanding a piece of the insanity that controls public health policy making in this country, you should have a look at "Paternalism and Its Disconnects: Motorcycle Helmet Laws, Libertarian Values, and Public Health."2 OK Doug, time to move on!

The opening editorial introduces this topical issue by laying out an important argument.3 Victora states "It is widely known that 10% of the world's expenditure in health research is for the conditions accounting for 90% of the global burden of disease," the so-called "10/90 gap in funding." Of course, this funding scheme makes no rational sense when one considers that "two thirds of the more than 10 million annual deaths in children could be prevented by universal coverage with off-the-shelf, low-cost interventions." The bottom line? We are not spending enough to develop efficient and effective systems of health care delivery and heath system access/utilization, much to the detriment of child survival and the public health. For a more detailed mathematical discussion of this topic, the reader is referred to Leroy et al, "Current Priorities in Health Research Funding and Lack of Impact on the Number of Child Deaths per Year."4

To bring the topic home, Wolf discusses related issues in "Potential Health and Economic Consequences of Misplaced Priorities" in JAMA.5 He makes the argument that policy decisions should be based on principles of public health more than is the tendency in contemporary America.

So, what does this all mean for us? I knew you would ask that question. The reader might remember my comments in the December 2006 issue of the IHS Child Health Notes.6 In that issue, I reviewed an article reporting the preliminary results of a study of a paraprofessional home visitation program designed to improve outcomes for Native American children born to adolescent mothers.7 The preliminary effectiveness of this model, I said, challenges us to rethink the longstanding model of public health nursing as it is practiced in the IHS and consider how a paraprofessional model might be incorporated into our programs. Needless to say, a multitude of barriers exist that deter innovation when it comes to how health and preventive services are delivered, not the least of which is funding.

In speaking to the authors of this paper, they describe that very few grants are available to fund either new models of service delivery or methods to improve what already exists. Of course, billions of dollars are available out there to investigate new technologies: "...of the scarce research funds aimed at reducing child mortality, 97% were directed at the development of new technologies, such as drugs, vaccines, or laboratory diagnostics. Only 3% were spent on operational research to determine how to best deliver existing interventions to mothers and children who need them most."3 Are you surprised to learn that there appears to be a "10/90 gap in funding" issue in the United States, too?

References:

1. Marlenga B, Berg RL, Linneman JG, et al. Changing the child labor laws for agriculture: impact on injury. Am J Public Health. 20007;97(2):276-82.

2. Jones MM, Bayer R. Paternalism and its discontents: motorcycle helmet laws, libertarian values, and public health. Am J Public Health. 2007;97(2):208-17.

3. Victora C. Editor's choice: addressing international child health priorities. Am J Public Health. 2007;97(2): 203. 4. Leroy JL, Habicht JP, Pelto G, et al. Current priorities in health research funding and lack of impact on the number of child deaths per year. Am J Public Health. 2007;97(2):219-23.

5. Woolf SH. Potential health and economic consequences of misplaced priorities. JAMA. 2007;297(5):523-6.

6. IHS Child Health Notes, December 2006.

7. Barlow A, Varipatis-Baker E, Speakman A, et al. Home-visiting intervention to improve child care among American Indian adolescent mothers: a randomized trial. Arch Pediatr Adolesc Med. 2006;160(11):1101-7.

MCH Headlines

Judy Thierry HQE

The Magic of Play

Child care involves PLAY. Parenting involves play.

For those of you working directly or indirectly with day care programs, in child care settings, Early and Head Start programs you will find this short news article "the Magic of Play" interesting and possibly something you want to begin in your projects and programs. Cuidando los Niños a non-profit in Albuquerque, NM serves children of homeless families as they reenter community. The program meets the needs of the children while their mother is also supported in seeking housing, work and educational and social services. Their article links the child play and parent 'play' and interaction into a meaningful approach and intervention.

www.cuidandolosninos.org/home.html

Hot Topics

Obstetrics

Prenatal HIV Screening Saves Lives: We need to do better

by Brigg Reilley and Scott Giberson

Current national standards of care for prenatal care specifically recommend that all pregnant women be routinely screened for a variety of diseases for which early detection is critical for the mother and/or the child. Routine screening includes tests for HIV, syphilis, gonorrhea, chlamydia, and hepatitis B surface antigen. Furthermore, the Centers for Disease Control and Prevention (CDC) recently expanded recommendations for HIV screening so that more persons will be aware of their HIV status. Screening based on risk factors alone is no longer recommended for HIV (1, 2).

IHS considers prenatal HIV screening an important indicator of the quality of care provided by the Agency. As a result, HIV screening during prenatal care is one of the core Government Performance and Results Act (GPRA) measurements, and the IHS goal is to reach 100%. Nationally, IHS facilities have a collective prenatal HIV screening rate of 65%. For the most recent year, GPRA statistics show that levels of prenatal HIV care range by Area range from 17% to 84%. Although many facilities screen for HIV appropriately, there is room for improvement.

Editorial Comment

Site visits made by the IHS Division of Epidemiology and Disease Prevention to IHS clinical units have revealed some of the explanations for inconsistency in reported prenatal HIV screening rates. While the results are still preliminary, some patterns are emerging. In general, if the service unit has a screening rate <80%, there is generally a systemic clinical or data gap, often one that may be easily identified and fixed. If these gaps are addressed, the reported screening rates have the potential to increase substantially:

Clinical:

- Not using "opt-out" HIV testing. Opt-out means that HIV screening is treated like other routine infectious disease screenings, such as syphilis. A consent form for HIV testing is no longer recommended or required by CDC. (However, you must check with state regulations for specific testing requirements). Some service units in fact now ask prenatal patients to sign refusals if they wish to forgo HIV testing, so it is clear to the mother what risk she is taking for her and her baby if she has undetected HIV.
- Responsibility for performing HIV testing. Some small clinics simply do an HCG test, followed by basic metabolic blood work, and then refer the woman elsewhere for prenatal care. However, GPRA considers a service unit 'responsible' for HIV testing if a pregnant woman is seen more than once during pregnancy. Small clinics with the highest GPRA rates assume responsibility for the entire prenatal infectious disease screening, including HIV, and have integrated prenatal testing into a single prenatal lab panel.
- Transfer of patients. Women will often be referred from one clinic to another. Smaller clinics may assume that labs were done at the larger facility and vice versa, but sometimes, in reality, neither facility has ordered the test. This is a troublesome finding because it is a lost opportunity for prenatal care.
- Not testing. Some providers still decide whether or not to test a woman based on risk factor assessment. This strategy is no longer standard of care. In addition, some providers have extremely high refusal rates. Others have expressed a lack of time and that patients need to see an HIV counselor before testing. All of these perceived obstacles can be worked out. However, at some facilities, these difficulties persist.

Data:

- Not entering historical data. Again, if a woman has more than one visit during her pregnancy, we should know her HIV serostatus. If the test has been done at another facility, either prior to or after her appointments at your facility, GPRA finds the service unit responsible for obtaining and entering the HIV test.
- Not entering reference lab data. If the test is done by an outside lab, and the lab is not linked to RPMS, the service unit does not get 'credit' for the test unless it is entered. Some low GPRA rates are tied to lab slips not being entered in RPMS.

Other

The barriers to higher GPRA rates are mainly service unit-based, rather than patient-based. Patient-based difficulties are harder to resolve. Some women arrive very late in pregnancy (although rapid HIV tests can still be used). Some women never return after two appointments. Admittedly, these cases are difficult to follow up, although some reviewed charts showed multiple attempts by determined PHNs. While these types of patients can be the most challenging, they may also be the most important patients to screen for HIV.

How can we identify what is going wrong in our facility?

Run a simple patient list of women who are pregnant but not screened for HIV (Brigg Reilley, in the Division of Epidemiology and Disease Prevention, can email the program commands to anyone interested, courtesy of Audrey Lynch at PIMC). A quick chart review should reveal if the service unit has clinical gaps, data gaps, or both. If problems of the type we have discussed here are solved, the service unit can enjoy immediate improvement in GPRA rates for prenatal screening.

References Online

Features

Breastfeeding

Suzan Murphy, PIMC

Inquiring families want to know—what about breastfeeding and….

Is it okay if the mom smokes or chews tobacco and breastfeeds?

According to American Academy of Pediatrics, the risk benefit of breastfeeding outweighs the potential risk of tobacco metabolites in the mother's milk. The greater concern is that the baby not be exposed to second hand smoke.

Can a mom still breastfeed if she has pierced nipples?

La Leche League reports that body piercing, including nipple piercing has been a common practice throughout history. There have not been problems reported that are specifically associated with breastfeeding and pierced nipples. General recommendations include keeping the area clean and removing nipple jewelry before allowing the baby to breastfeed. Also, nipple piercing while breastfeeding is probably not feasible due to the 3 month or longer healing time required.

Can moms drink alcohol and breastfeed?

Yes and maybe. Numerous professional sources including Thomas W. Hale, R.Ph. Ph.D., University of Texas (author of Medication and Mother's Milk), American College of Nurse-Midwives, and American Academy of Pediatrics agree that moderate and occasional consumption of alcohol is usually compatible with breastfeeding.

Important considerations are:

- The baby's age
- A newborn has an immature liver and will take longer to metabolize any of the alcohol that gets into the mom's milk.
- Moms body size
- A larger mother can metabolize alcohol more quickly than a smaller mom.
- Amount of alcohol consumed
- Most sources report that waiting 2 hours for every drink (12 oz beer, 5 oz wine, 1 standard drink—including 1 shot of spirits such as vodka, whiskey, rum, tequila, etc) or until the mother feels neurologically normal, is a reasonable waiting period.
- A helpful calculator for how long alcohol takes to be metabolized can be found online.

Please note that moms do not need to pump to get rid of the alcohol. A mom's milk is a dynamic fluid, the milk and alcohol are not trapped. A mom's liver will metabolize the alcohol in the breastmilk like the alcohol in her blood stream.

What about caffeine?

American College of Nurse-Midwives provides a well documented and succinct recommendation.

Though dietary caffeine appears in breast milk, nursing mothers can safely consume small amounts of caffeine without passing on a significant amount to the baby. Higher caffeine amounts could potentially cause problems such as poor sleeping, nervousness, irritability, and poor feeding, so limiting your caffeine intake makes sense.

Caffeine tends to build up in babies' systems because their bodies cannot get rid of it very easily. Try using decaffeinated coffee and tea, and avoid colas and other carbonated drinks that have added caffeine. The American Academy of Pediatrics recommends that nursing women limit consumption to the caffeine equivalent of 1 to 3 cups of coffee per day.

If you have other asked/unasked questions (and answers) about breastfeeding, please send them to:
suzan.murphy@ihs.gov for the future articles.

From Your Colleagues

Stephen W. Heath, Albuquerque

When Things Go Wrong: Responding to Adverse Events

A Consensus Statement of the Harvard Hospitals. Burlington, Massachusetts: Massachusetts Coalition for the Prevention of Medical Errors. This consensus paper of the Harvard-affiliated hospitals proposes a full disclosure when adverse events or medical errors occur, including an apology to the patient. The paper represents the collaborative effort of a group of clinicians, risk managers, and patients participating from several Harvard teaching hospitals and the Risk Management Foundation.

Stephen.Heath@ihs.gov

OB/GYN CCC Editorial

Another reason to attend the Native Women's Health and MCH Conference

As the Program is rather extensive, if you didn't have enough reasons already, Stephen Heath will present on the nuances of systematic error and its effect on Risk Management in Indian Health. The Conference will be in Albuquerque, NM August 15- 17, 2007. The theme of the meeting is "Improve the System: Improve the Outcome" so it will explore how we can all work together to raise the AI/AN health status to the highest possible status. The meeting is only every 3 years, so you and a team from your facility should try your best to attend.

International Health Update

Claire Wendland, Madison, WI

Testing New Drugs on the World's Poorest Patients

In the film The Constant Gardener, based on the novel by John LeCarré, the protagonist battles representatives of a nefarious pharmaceutical company intent on concealing evidence of unethical medical research on impoverished African subjects. Though fictional, the film and book film drew public attention to a real and growing phenomenon in which wealthy pharmaceutical corporations farm out basic medical research to so-called "CROs" (contract research organizations). In order to secure the large numbers of human test subjects required to meet the gold standard criteria for drug approval demanded by the FDA–the randomized placebo-controlled double-blind trial–the CROs turn to economically vulnerable populations. Increasingly, they look beyond the domestic poor to international settings where signing up for a research protocol may provide the patient's best (or only) chance of receiving medical care. In an era in which drugs are one of the most lucrative businesses around, human research subjects have thus become a hot international commodity.

For those who are interested in the facts behind the popular fiction, a recent book by investigative journalist Sonia Shah explores the phenomenon of international clinical drug trials at some length. In The Body Hunters, Shah details the factors driving US-based pharmaceutical companies, unable to find sufficient numbers of enrollees at home, to outsource their drug trials to countries like India, South Africa, and the former Soviet Socialist Republics. Here, she argues, wealthy corporations benefit from a combination of less restrictive regulatory environments and more desperate patient populations, the end result of which is larger enrollments in their trials. While much of this ground has been trodden before–one could plausibly argue that she makes very little original contribution to the discussion–Shah does a commendable job of consolidating a wide and unwieldy range of academic, historical and journalistic investigations in a readable, largely balanced, and engagingly written book.

In a PLoS Medicine piece, Trudo Lemmens and Paul Miller explore a related issue: financial compensation of physicians who recruit patients from their practices to join clinical trials. Though their legal status remains murky, explicit "finders fees" are clearly prohibited by most professional medical ethical codes (including that of the AMA). Nonetheless, various recruitment incentives have been designed to wiggle through loopholes in these various professional codes, with the net effect of insuring that "patients have become de facto market products," as Lemmens and Miller put it. Like Shah, these authors believe that institutional review boards have proved inadequate to the task of protecting vulnerable populations from the powerful vested interests of big pharma. The authors call for a rethinking of national and international regulations to prevent "jurisdiction shopping," in which companies scout the world for those countries with the most favorable (or least onerous) legal and financial climate for patient recruitment. The globalization of biomedicine and the increasing interpenetration of medicine and industry are combining to ensure that formerly distinct borders–geopolitical, professional, disciplinary–are increasingly fluid, arbitrary, and manipulable. Whose interests will be served and how the vulnerable will be protected in the context of these shifting alliances and opportunities are questions of urgent and ongoing importance to all of us.

Shah S. The Body Hunters: Testing New Drugs on the World's Poorest Patients. New York: The New Press, 2006

Lemmens T, Miller PB. Regulating the market in human research participants. PLoS Medicine 3(8):e330, August 2006

Medical Mystery Tour

Prolonged second stage with an epidural

Let's review last month's case briefly … a primigravida at 41 3/7 weeks with a history of polycystic ovarian syndrome, a 41 lb. weight gain, a known female infant, and one abnormal result on a 3 hour glucose tolerance test had a prolonged second stage with epidural anesthesia. Exam had revealed an estimated fetal weight of "9 + lbs". Her temperature rose to 100.6 F and she was started on intravenous gentamicin and ampicillin. Stage I was desultory after misoprostol cervical ripening and required pitocin augmentation.

As Stage II neared 4 hours—including time to 'labor down'—the risks and benefits of vacuum assistance were discussed with the patient and it was agreed to proceed. The vacuum extractor was placed during 3 contractions. Subsequently, the fetal presenting part descended to +3/5 with the scalp visible without pushing. The fetal heart tones were reassuring throughout. The patient is noticeably beginning to tire and subjectively seems to be pushing less effectively.

What would you have done at that point?

- Allow the patient to push for 30 minutes more and re-evaluate
- Notify the OR team and discuss cesarean delivery
- Wait for the epidural to completely wear off
- Apply the vacuum for a second trial
- Add clindamycin
- Other....

Let's take a 'time out' here

A valid argument could be made for virtually all the above choices. Assuming a reassuring fetal tracing there is no magic to a certain numerical length of Stage II, especially if the patient did not have a strong sensation throughout and was allowed to 'labor down' with an epidural. If you choose that course be sure your documentation reflects that the patient was not actively pushing during that period. On the other hand, the delivery provider should be aware that the patient has developed several risk factors that make a successful vaginal delivery fraught with potential difficulty.

The one exception would the choice to reapply the vacuum for a second trial. Before we explore that option though, perhaps we may want to re-explore the use of the vacuum the first time. This patient had several risk factors that predispose patients to a possible shoulder dystocia.

Risk factors for shoulder dystocia

- Fetal macrosomia
- Glucose Intolerance
- Operative vaginal delivery
- History of shoulder dystocia
- Labor abnormalities
- Postterm pregnancy
- Male fetal gender
- Obesity and high weight gain
- Advanced maternal age
- Shoulder-pelvis disproportion

Shoulder dystocia is best defined as the need for additional obstetric maneuvers to effect delivery of the fetal shoulders at the time of vaginal delivery. It occurs in 0.2 to 3 percent of all births and represents an obstetric emergency. Shoulder dystocias can be anticipated only rarely, as many occur in the absence of identifiable risk factors. Therefore, all obstetric care providers must be prepared to recognize a shoulder dystocia immediately and proceed through an orderly sequence of steps to effect delivery in a timely manner and minimize risk to the mother and fetus. It should be noted, however, that permanent birth injury, and even fetal death, can result in cases of shoulder dystocia that are appropriately identified and managed.

This patient has the majority of the above risk factors. Let us explore a two of the more salient aspects:

One abnormal glucose tolerance test result:

This condition is often overlooked, but is associated with macrosomia. Women with one abnormal value on the oral GTT demonstrate fasting insulin concentrations and insulin resistance comparable to that of women with GDM, and they are more likely to deliver a macrosomic infant than women without GDM or women with GDM that is treated. The management of these patients is controversial. Some have recommended that they be treated the same as women who meet standard criteria for GDM, others have not considered further intervention or recommended repeating the oral GTT in four weeks . Studies have shown that treatment of women with one abnormal GTT value decreases the risk of a macrosomic infant and is cost-effective.

Operative vaginal delivery:

Operative vaginal delivery is a risk factor for shoulder dystocia. It is not known whether shoulder dystocia is a result of instrument-aided descent of the fetus or is the underlying reason the fetus has not descended naturally. In a classic study, the combination of macrosomia (defined as birth weight greater than 4000 g), prolonged second stage, and midpelvic operative delivery was associated with a 21 percent incidence of shoulder dystocia. By comparison, when only prolonged second stage and midpelvic operative delivery were present, the risk fell to 4.57 percent and was 0.16 percent in the absence of these risk factors. One review concluded that instrumental delivery was the intrapartum risk factor most associated with permanent brachial plexus injury.

While operative vaginal delivery is just one of many risk factors, it represents a 'sin of commission'. In many cases one never knows exactly what will / will not occur without prior intervention in a rare event like shoulder dystocia. On the other hand, if one has performed an operative vaginal delivery, then right or wrong, all the subsequent events are viewed within the purview of that action. Hence, it becomes a post hoc assumption that the fetus was 'pulled' into the shoulder dystocia.

Back to our case

In this case, the vacuum extractor was re-applied for 3 more applications of traction which brought the presenting part to crowning shortly followed by the 'turtle sign'. Gentle traction, McRoberts, and nuchal cord release x2 were performed without success. A procto-episotomy was performed without success, followed by the Woods screw maneuver without success. Attention was then paid to the posterior arm and delivery was accomplished after a total of 2 minutes on the perineum. The parturient was taken to the OR for a 4th degree laceration repair. The patient notes continued fecal incontinence at this writing.

The infant had good cord pH(s), but Apgars of 2/5. The infant was admitted to the special care nursery for one day after resuscitation in the labor suite due to hypotension and ventilation requirements. The infant weighted slightly more than 9 pounds and had a fractured clavicle. The infant was discharged in stable condition after one subsequent day in the step down unit. There were no neurologic deficits and the child has done well in well child care.

In retrospect, the actual shoulder dystocia was handled quite well. Perhaps there was an element of being 'lucky not good', though. In Quality Improvement terms, this probably represents a 'near miss'.

In either case, I submit that if you have what is very likely a macrosomic infant with a prolonged labor, that you not perform operative vaginal delivery.

In addition, I strongly suggest that when you do attend a macrosomic delivery, that you encourage the fetus to 'deliver through'. In other words, once the fetus is in the final expulsive effort, that you continue the downward momentum until the anterior shoulder is visible, e. g., do not stop the downward progress to suction the oropharynx.

In regard to operative vaginal delivery in this setting, it is perhaps best to remember the Latin phrase Primum non nocere "First, do no harm".

References: Online

Midwives Corner

Lisa Allee, CNM, Chinle

Being Present

Pembroke and Pembroke have written an article that is a must-read for all of us that attend women in pregnancy, labor and birth, and, actually, it is highly relevant in the provision of any kind of health care. It is essential reading for the student who needs to learn the art and not just the technical science of what we do and it will remind experienced providers of the human contact we must strive to achieve even on the busiest day. I highly recommend that you read the entire article (if you can not get the full text through PubMed please contact me and I will email it to you) but here are a few of the juiciest morsels.

"Presence involves an offering of self (Scoppo, 2003). In being present to the other, one generously makes available one's personal resources. To be present as a midwife is to be open, available and receptive to the needs and preferences of the woman (Berg et al., 1996; Lundberg, 2004)."

"A caring presence involves creating an environment of trust and security."

The authors present a discussion of spirituality, which is a clear reminder that our work is not about us and our egos—it is about being with the other.

"The spiritual person identifies making meaning out of one's existence on earth as a central human task. The journey into meaning usually involves self-transcendence. To be spiritual is to break through the confining and limiting grip of egoism. Egotistic persons are locked up inside themselves; they have little or no capacity to reach out to others and to the world around them. Overcoming selfish tendencies in order to help others is central in an authentic spirituality."

Next they present two concepts that make presence possible—responsibility and availability. The discussion of responsibility is based on Buber's work: "He is talking about 'responsiveness', about the ability to respond to the other person and her needs and aspirations. For Buber responsibility is a deep capacity to respond to the claims others make on us. It requires an acute awareness of the other through which she becomes present in her wholeness and uniqueness."

"In order to be genuinely responsive to a woman, it is necessary to include oneself in her inner world. That is, one must discover precisely what it is that she needs and values. Women ask to be sensitively listened to. Further they ask that the midwife approach them with a respect for their uniqueness."

The authors discuss availability in terms of receptivity and being open and "porous" or permeable to the communication from others. They also discuss hospitality as pivotal and present a fascinating picture of midwife as host: "Hospitality plays a vitally important role in engaging on a personal, friendly level with women. We need to ask, however, whether or not it is appropriate to refer to a midwife as a host. Many would rather have it that the midwife is the invited guest (Leap, 2000; Kenedy, 2003). The primary actor in the birthing experience is the woman. She invites others to be with her as she gives birth. There is still a place, we contend, for the appellation 'host' in relation to the midwife's role. It is clearly wrong to refer to him or her as host of the birthing process. To speak of him or her as host in the context of the relationship he or she shares with the woman is, however, not only appropriate but also illuminating. It is illuminating because it reminds us that the midwife is called upon to mentally establish an open space that will be filled by the woman's needs and preferences. To be available to the woman involves listening to her and following her lead through the process of childbirth (Lundgren, 2004). Midwives need a certain 'incohesion' in order to be truly receptive. If they fill their internal spaces with their own commitments and preferences, there is no place for the woman to make contact."

Read this article. It's important.

The spirituality of presence in midwifery care. Pembroke, NF, Pembroke, JJ Midwifery 2007 Feb

Navajo News

Jean Howe, Chinle

New ACOG recommendations challenging for rural IHS sites—a plea for sharing strategies to meet national standards in the face of limited resources…

One new challenge facing Navajo Area prenatal providers, and probably many others providing care to pregnant women at rural sites throughout IHS, is what to do about all the new options for prenatal genetic screening. ACOG recently issued Practice Bulletin No. 77, Screening for Fetal Chromosomal Abnormalities, which reviews the tests currently available and acknowledges how confusing this area has become. You know you're in a difficult situation when ACOG includes a section entitled, "With so many Down syndrome screening tests available, how do I decide which tests to offer?"

Before one wades through the array of available tests, it seems important to acknowledge a couple of new guiding principles that we are being asked to incorporate into our practice:

1.) It's not just about age any more. Although the risk of Down syndrome and other chromosome abnormalities increase with age for individual women, most Down syndrome babies are born to young women. It has become the standard of care to offer prenatal screening for chromosome abnormalities to all women as part of routine prenatal care.

2.) It's not just about second trimester screening anymore. There are now well-established methods of first trimester screening. We need to figure out how to make these testing options available to our patients.

Other principles haven't changed at all. Our job as providers is to

share information about screening options and offer non-directive counseling. It is still the woman's choice to decide what (if any) tests she would like to have done and her right to decline testing altogether. Some women seek information to consider termination of pregnancy, others to make special preparations before the birth of a baby with additional needs. Also, because of the distance to tertiary care facilities, some infants may benefit from prenatal diagnosis that allows planned deliveries in urban centers with additional resources.

There are several markers that can be used to calculate a risk for Down syndrome. One relatively new test is the nuchal translucency measurement (NT), a measure of the thickness of the fluid collection at the back of the fetal neck in the first trimester. To be used for calculating Down syndrome risk, NT measurements must be performed by certified sonographers with special training and ongoing monitoring. Optimal NT measurements are obtained at 12-13 weeks although the test may be performed from 10 4/7 to 13 6/7 weeks. Not all patients sent for NT testing will be able to have images successfully obtained. Serum first trimester measurements include PAPP-A (pregnancy-associated plasma protein A) and total or free β hCG. Second trimester serum markers include MSAFP (maternal serum alpha-fetoprotein), hCG, and unconjugated estriol which are used in calculation of a "triple screen"; with the addition of inhibin A this becomes a "quad screen". The main focus of this testing has become the identification of Down syndrome although some of these markers are also used in the identification of other conditions, including trisomy 18 and open neural tube defects.

The ACOG Practice Bulletin provides much detail about the different screening tests, their detection rates, and their false positive rates. One relevant comparison for any facility still doing second trimester triple screen testing is the improved detection of Down syndrome with the change to Quad screening (from <70% to over 80%). ACOG answers the question about how to choose with several considerations, including the following:

"...If nuchal translucency measurement is not available or cannot be obtained in an individual patient, a reasonable approach is to offer serum integrated screening [with a detection rate of 85-88%] to patients who present early and second-trimester screening to those who present later."

This still leaves a great deal of work to be done. A review of the tests available through our contracted laboratory provider fails to identify any test options that combine first and second trimester serum testing but do not also rely on NT measurements. And as NT measurements are only available at tertiary care facilities several hours away, this just isn't a realistic option for wholesale screening for our rural facility, especially given the narrow window of dates when testing can be done. So, for our site, and some other sites in Navajo, we've transitioned to Quad screening but haven't resolved the first trimester dilemma. If you work at a rural site and have successfully addressed this problem, we'd like to hear from you. Also, if anyone has found or created a culturally sensitive patient education brochure about prenatal genetic screening, please share!

OB/GYN CCC Editorial comment:
Let's begin a dialogue

I want to thank Jean Howe for bringing up this issue, as it is a major concern nationwide. Various suggestions have included that we adapt a serum screening strategy whereby we only refer the women who have abnormal results. Each Area would need to negotiate with their lab, or find a new lab, e. g., is the lab able to integrate the NTD results? The PAPP-A and free bHCG can be done at 10-13 wks if the patient comes early enough. If so, then perform the quad screen at 15-20 and integrate the results, or refer if there is an abnormal 1st trimester result. Patients who come later can get a quad screen, and refer those with abnormal results if they so wish.

Let us know how your Area has solved this emerging problem. nmurphy@scf.cc

Oklahoma Perspective

Greggory Woitte–Hastings Indian Medical Center

Cesarean Delivery on Maternal Request

It was in June of last year when I last wrote about the NIH Consensus conference on Cesarean Delivery on Maternal Request (CDMR). Over the past year there has been several articles written on the subject. The most recent of which is published in the New England Journal of Medicine by Ecker and Frigoletto (excerpted below).

Here at Hasting's Indian Medical Center, we are beginning to explore this issue through journal clubs and dialogue. We have had more patients recently requesting Cesarean Delivery over the past year. A review of the NIH Consensus conference points out that most of the evidence is weak or non-existent to support planned vaginal or cesarean delivery. Moderate quality evidence is available for only three outcome variables (postpartum hemorrhage, maternal length of stay, and neonatal respiratory morbidity). .

ACOG sent out a news release on May 9, 2006 after the NIH consensus conference. In it they point out that more research is needed and that CDMR is not recommended for women planning on having several children due to the risks of placenta previa and placenta accreta increasing with each cesarean delivery. In addition, Dr. Zinberg, Deputy Executive Vice President of ACOG states "ACOG continues to review all of the issues surrounding maternal-request cesarean, but at this time our position is that cesareans should be performed for medical reasons."

A number of the articles written have pointed out ACOG's position that a cesarean delivery on maternal request can be ethically justified at times. In ACOG's "Surgery and Patient Choice: The Ethics of Decision Making," ACOG states that "In the

absence of significant data on the risks and benefits of cesarean delivery, the burden of proof should fall on those who are advocates for a change in policy in support of elective cesarean delivery (ie, the replacement of a natural process with a major surgical procedure."

As many of the articles and editorials written over the past year have pointed out, caution should be used when a patient requests a cesarean delivery. Moving slowly in the absence of good evidence is a prudent option. While support for a women's choice is without question of paramount importance, performing cesarean deliveries on maternal request may ultimately lead to a violation of the Hippocratic Oath to do no harm.

OB/GYN CCC Editorial comment:
Looking for sanity in the ever increasing cesarean delivery rate

Ecker and Frigoletto state the key question centers on both the number needed to treat to avoid one adverse neonatal outcome and the level of risk that is currently considered acceptable. As practicing obstetricians, we find that the risk that women are now willing to assume in exchange for a measure of potential benefit, especially for the neonate, has changed: for many, the level of risk of an adverse outcome that was tolerated in the past to avoid cesarean delivery is no longer acceptable, and the threshold number needed to treat has thus been reset.

In the face of the resulting continued increase in cesarean deliveries, our obligation as providers is to educate patients about the tradeoffs entailed in choosing a particular course or intervention and to ensure that their choices are congruent with their own philosophy, plans, and tolerance of risk. In areas in which there is still uncertainty, we must organize clinical trials that will produce the data we require for counseling patients. For the moment, however, few of the relevant factors seem likely to change, and the cesarean rate can be predicted to continue its climb.

The March 2006 National Institutes of Health (NIH) State-of-the-Science Conference report concluded that there was a need for research that explicitly compared outcomes of planned cesarean delivery with outcomes of planned vaginal delivery. Declercq et al examines 6 years of data from a population-based linked data system to create a refined measure identifying women with planned cesareans and planned vaginal births and comparing maternal outcomes and costs associated with these two options.

1.) planned cesarean increases complications and re-hospitalizations and
2.) planned cesarean increases cost

Kennare R, et al just reported that after the first cesarean, the risks increase in next pregnancy. Specifically, cesarean delivery is associated with increased risks for adverse obstetric and perinatal outcomes in the subsequent birth. However, some risks may be due to confounding factors related to the indication for the first cesarean.

Dr. Woitte reminds us to do no harm. Declercq et al and Kennare R, et al findings suggest that planned primary cesareans are not without immediate health consequences for mothers and financial implications for society. Clinicians should be aware of the increased risk for maternal re-hospitalization after cesarean deliveries to low-risk mothers when counseling women about their choices.

References: Online

Gynecology

Surgery versus medical therapy for heavy menstrual bleeding

AUTHORS' CONCLUSIONS: Surgery, especially hysterectomy, reduces menstrual bleeding at one year more than medical treatments but LNG-IUS appears equally effective in improving quality of life. The evidence for longer term comparisons is weak and inconsistent. Oral medication suits a minority of women long term.

Marjoribanks J; Lethaby A; Farquhar C Surgery versus medical therapy for heavy menstrual bleeding. Cochrane Database Syst Rev. 2006; (2):CD003855

Osteoporosis

Bisphosphonate Related Osteonecrosis of the Jaws (BRONJ)

M. Winkler DDS, MS and K. Martin DDS

In the mid 1800s, English matchstick factory workers started presenting with horrific jaw bone exposures and infections which led to disfigurements and sometimes death. This was before the advent of antibiotics and most of these patients received copper and surgery for their plight–with less than desirable results. Eventually, this disease process became linked to the white phosphorus used in the matchstick making industry.(Hellstein)

Currently, oral and maxillofacial surgeons and dentists are seeing a revival of this type of presentation from IV and oral bisphosphonate drugs. Our current pathogenesis has only been linked to drugs which contain nitrogen side chains: zolendronic acid, pamidronate, risedronate, ibandronate, and alendronate. Rates are now reported to be 6-7% with Zolendronic acid, 4+% with Pamidronate, and <1% with Alendronate. Early inconsistencies in terminol-

ogy and diagnosis have probably led to a lower report of the actual incidence. Another compounding factor is current literature remains at level 3 studies only. We lack any randomized controlled trials/prospective studies. Consequently, our understanding of pathogenesis, progression, treatment, and identification of risk factors (steroid therapy, hormone replacement, age, clinical and radiographic presentation) is sorely lacking. Reports of this type of osteonecrosis are significantly increasing. The two major initial case reports on BRONJ in 2003 and 2004 have more than doubled their original number of patients.(Marx and Ruggiero)

Pathogenesis of this disease has not yet been identified, but the preponderance of evidence and response to treatments suggests a metabolic origin rather than vascular etiology. Especially considering hyperbaric oxygen treatments are not effective in treating this disease (unlike patients with osteoradionecrosis or osteomyelitis). These drugs are diffused through out the jaws and not just a focal area like osteomyelitis or a slightly larger area like osteoradionecrosis. There is NO such thing as debriding until we find healthy bone. This type of osteonecrosis (consider the bisphosphonate bone response like osteopetrosis) has only been shown in the jaws with one exception involving the auditory canal in a patient with maxillary BRONJ.(Polizzotto) It is believed this is due to the well vascularized jaw structures and significantly higher bone turnover of the jaws compared to the long bones, especially in areas of tooth extractions/implant. (Hughes et al., Rogers et al., Rodan et al., Stepan et al., Strewler) Couple this with the unique anatomy of the oral environment: significant bony prominences, exceptionally thin mucosa tissue covering (<1mm in some areas), and constant exposure to trauma (eating, habits, etc.) …And yes, a potato chip can do you in!

Please realize bisphosphonates are phenomenal drugs and have been and will continue to be a keystone treatment for osteoporosis and certain malignancies, but for people with bad habits, in particular bristle allergies, these drugs pose exponentially more problems. This is where bad habits catch up to people. Studies have shown >80% of inciting events (induction of osteonecrosis) have been linked to previous dentoalveolar surgeries, e.g., extractions, etc.(Durie et al) SO, if you have patients in their 50s who still are not orally stable (poor-fair oral hygiene) and require treatments like extractions–this is exactly the type of patient whose bad habits will be a factor. There are spontaneous inductions noted in both IV and oral bisphosphonates, but the incidence is significantly higher in IV forms compared to orals. BRONJ appears to be potency related with zolendronic acid the highest in vitro potency and alendronate the lowest.(O'connell) Usually the incidence begins after 2-3 years of use with these drugs.(Durie et al.) Realize the risk of BRONJ increases with time. With the long half lives of these drugs (alendronate, the weakest drug, is greater than 10 years) the incidence of osteonecrosis is unlikely to decrease with time, even if the drug(s) have been discontinued. Bottomline for bisphosphonates: if you need it, you need it!

Some general treatment recommendations include:

- PATIENT EDUCATION! Stress what to look for and regular dental care Discussion with patients: risks, benefits, and options
- Visual Inspection of oral cavity by ALL providers at each visit, note key areas
- Routine dental exams—yes, I realize access to care is a problem
- An ounce of prevention is truly worth more than a pound of jaw bone

Hopefully as more information is elucidated and patient education grows we will better tailor our bisphosphonate therapies (nitrogen vs. non-nitrogen side chain drugs, loading vs. maintenance dosing, drug holidays?) and prevent what can be an exceedingly frustrating and unrewarding disease to manage.

Reference: Online

Perinatology Picks

George Gilson, MFM, ANMC

What is the best management plan for the woman with suspected preterm labor?

As is well known, the incidence of preterm birth (PTB) is increasing in the United States, and is currently approaching 13% of all births. Of importance to us, the incidence of PTB in

Child Health

Newborn male circumcision: Improved outcomes with pediatric hospitalists

In 2004, the Department of Obstetrics and Gynecology at the University of Michigan decided to stop offering routine circumcision for specialty and disciplinary, logistic, and educational reasons. The Pediatric Hospitalist Service assumed responsibility for the procedures and the educational process with resultant patient and staff satisfaction, educational, logistical and economic benefits.

Johnson TR et al Why and how a department of obstetrics and gynecology stopped doing routine newborn male circumcision. Obstet Gynecol. 2007 Mar;109(3):750-2.

Women's Health Headlines

Carolyn Aoyama, HQE

Can you dispense birth control agents to minors without parental consent?

If you work in South Dakota, we have clarification on IHS policy as it relates to State law in the prescription and dispensing of contraceptives and contraceptive devices to minors thanks to Mary Lynn Eaglestaff.

OB/GYN CCC Editorial

Encourage family communication first. IHS honors State laws

Here is a common question:

I am seeking input regarding I.H.S. policy for parental consent when providing pregnancy-related, STD, and family planning services to minors. I looked it up on the I.H.S. Manual which seems to imply that state and local regulations apply. As a federal facility, are we bound by applicable state law in these matters or does I.H.S. have a federal policy which supersedes state law?

The first answer is always to encourage complete communication within the family. In the meantime, yes, the IHS honors State laws and regulations.

Native American women is actually slightly higher than that of the general population. So, when one of our clients comes in with preterm contractions, and may be in true preterm labor, what is the best management plan for her?

First, I'd like to review a few salient points about deciding if this is the real thing. Is she really in true preterm labor and at risk of an imminent preterm birth? It's often not that easy to decide. The **fetal fibronectin test (fFN)**, while not the greatest test in our armamentarium, may be quite helpful as a triage tool. If your patient must be transferred a long distance for tertiary care, the fFN is quite cost-effective, and will pay for itself many times over compared to a costly transport and hospitalization. The negative predictive value of the fFN approaches 98%. If the test is negative, it is very unlikely that this woman with preterm contractions is actually going to deliver in the next 7-14 days. The positive predictive value of the test is not so great, only 12-15%, but it does "up the ante", and make you more likely to consider transport.

The fFN only requires a 15 second sample taken from the posterior fornix, and the currently available rapid test will provide an answer in less than 2 hours. Remember, blood, amniotic fluid, semen, and lubricant gel, will all make the test positive, so it will not be helpful to you in those situations. **Remember to collect the fFN before you do your digital exam!** If you find that there is advanced cervical dilation, you can toss the sample. However, if, as is common, there are contractions, but minimal cervical change, the test can be quite helpful in your decision-making and management.

Another helpful maneuver to decide if the woman who has preterm contractions, but an unimpressive cervical exam, is actually in true preterm labor, is to do "**one-shot terbutaline triage**". While beta agonists like terbutaline are not currently thought to have a satisfactory risk-benefit profile to qualify them as primary agents for tocolysis, they may be helpful to sort out the clinical picture just described. A single subcutaneous injection of terbutaline 0.25 mg will usually ameliorate preterm contractions in women not destined to actually deliver early. Contrary to widespread opinion, **intravenous fluid boluses are NOT effective at stopping preterm contractions**, and may be dangerous if given too energetically.

So, let's say that despite the single shot terbutaline, your client has persistent contractions, and her cervix has gone from fingertip to 1-2 cm over 2 hours of observation. Her fFN returns positive. You decide this is the real thing, and make plans for hospitalization or transport. What tocolytic agent is best for her? Actually, none of the currently available tocolytics are ideal. Likewise, none of the available tocolytic agents are FDA approved for this indication, they are currently all "off-label" use. Their main purpose at this time is to try to buy 48 hours for the administration of **corticosteroids for fetal lung maturation**. So, if you think this is real preterm labor and that this fetus is at considerable risk of PTB, your first maneuver should be to start steroids. Betamethasone 12 mg intramuscularly for 2 doses at 24 hour intervals (over 48 hours) is probably the best choice. If not available, dexamethasone 6mg intramuscularly every 12 hours x4 doses (over 48 hours) is also fine. **Steroids are probably the most important, and most evidence-based, intervention at this time as regards improving ultimate perinatal outcome.**

Is antibiotic therapy appropriate for this patient? There is no evidence that antibiotics are of any benefit for idiopathic preterm labor (i.e., no evidence of overt chorioamnionitis or urinary tract infection). In the situation of preterm premature rupture of membranes without labor however, antibiotics are appropriate, but I won´t discuss that situation here. However, antibiotics are indicated in idiopathic preterm labor as **prophylaxis for group B streptococcus (GBS)** carriage. When you collect your fFN, you should also take a rectovaginal culture for GBS and begin empiric treatment with penicillin or ampicillin (or cefazolin or clindamycin if there is a history of penicillin allergy). This should be continued for 48 hours until the culture is back. Antibiotics may be stopped if the culture is negative or if labor has stopped.

In order to allow time for steroids, which tocolytic is best? As noted above, **beta agonists**, such as terbutaline and ritodrine (the latter no longer manufactured), when used at the doses needed to stop contractions, have prominent cardiovascular side effects. They carry a

significant risk of pulmonary edema, especially combined with over vigorous intravenous hydration. **Beta agonists can no longer be recommended as first line tocolytic agents.**

Likewise, despite overwhelming evidence of its lack of efficacy, **magnesium sulfate** ($MgSO_4$) tocolysis remains a North American anomaly. Cochrane reviews have found it to be an ineffective tocolytic (no significant benefit in preventing preterm birth compared to placebo). Moreover, the risk of total pediatric mortality was significantly higher for infants exposed to $MgSO_4$ (RR = 2.8, CI 1.2-6.6). It also has quite unpleasant maternal side effects and requires an intravenous drip that is cumbersome during transport. **$MgSO_4$ should no longer be used as a tocolytic.**

How about another calcium channel blocker such as **nifedipine**, the popular anti-hypertensive? Several meta-analyses have found them to be superior to beta agonists, and considerably safer. Unfortunately, none of the individual randomized are sufficiently powered (the largest had only 95 patients enrolled), and none of them compared nifedipine to placebo or no treatment.

Calcium channel blockers achieve tocolysis by blocking myometrial L-type voltage dependent calcium channels. They also block them in vascular smooth muscle and myocardium. They have been associated with headache, flushing, hypotension, secondary fetal distress, pulmonary edema (especially in combination with beta agonists), and myocardial infarction These adverse effects were most prominent in women with multiple gestation, preterm labor associated with infection, and women with underlying cardiovascular disease.

Dosage regimens have not been standardized, and are based on regimens designed to treat hypertension. A reasonable protocol would be to give 20 mg orally initially, and repeat in 30 minutes if no effect. Thereafter, 20 mg orally every 6 hours for 48 hours (maximum dose 160 mg) may be given. Maintenance tocolysis with the extended release forms of the drug have been shown to neither decrease the recurrence of preterm labor, nor improve perinatal outcomes. **I would consider nifedipine to be a second line tocolytic agent.**

The next agents available are the non-steroidal anti-inflammatory agents, of which **indomethacin** is the best studied. These agents are cyclo-oxygenase inhibitors and block prostaglandin synthesis in the myometrium. The randomized controlled trials also lack power, but those available demonstrate efficacy compared to placebo. Indomethacin is essentially free of maternal side effects. Several retrospective reports from the early 1990's called attention to an increased incidence of necrotizing enterocolitis, intraventricular hemorrhage, constriction of the ductus arteriosus, and oligohydramnios in infants treated in utero with this agent. These adverse effects became non-significant however when multivariate analysis corrected for gestational age, and have not been found to be significant in the prospective studies. NSAIDs do constrict the ductus, especially in fetuses over 32 weeks, but this effect is reversed when the drug is stopped, and is uncommon when administration is limited to 48 hours. A cost-benefit analysis has clearly demonstrated an improvement in perinatal outcomes with use versus non-use of indomethacin. The regimen recommended is a loading dose of 100 mg orally, followed by 50 mg orally every 6 hours, not to exceed 400 mg in 48 hours. **Based on the evidence for its safety and efficacy, I would consider indomethacin to be the best first line tocolytic agent.**

Another drug in this class is **ketorolac**, which we have found to be very effective in our population. We use an initial dose of 30 mg intravenously or intramuscularly, and then give 30 mg IV every 6 hours over 48 hours, not to exceed 240 mg. Because it is given parenterally, its effect is usually immediate, probably contributing to our seeing a high success rate with its use. We have seen one case of significant oligohydramnios, and one case of maternal oliguria (in a woman with chronic hypertension and mildly increased creatinine), both of which resolved without sequelae after stopping therapy. There is only one published study of this agent that I was able to find; it involved 88 women and compared ketorolac to $MgSO_4$ (where it was superior). At this time its use cannot be considered an evidence-based recommendation.

In conclusion, as long as the etiology of "idiopathic" preterm remains cryptic, we are reduced to using interventions that are suboptimal. Nevertheless, attempts at an accurate diagnosis, use of steroids when indicated, and use of indomethacin or nifedipine as our "best bet" tocolytics, will hopefully be the most efficacious way to help us reduce the incidence of preterm birth and poor perinatal outcomes in our population.

References: Online

should be administered using a separate syringe at a different anatomic site.

Cervical Cancer Screening Among Vaccinated Females

Cervical cancer screening recommendations have not changed for females who receive HPV vaccine. HPV types in the vaccine are responsible for approximately 70% of cervical cancers; females who are vaccinated could subsequently be infected with a carcinogenic HPV type for which the quadrivalent vaccine does not provide protection. Furthermore, those who were sexually active before vaccination could have been infected with a vaccine type HPV before vaccination. Health-care providers administering quadrivalent HPV vaccine should educate women about the importance of cervical cancer screening.

Groups for Which Vaccine is Not Licensed

Vaccination of Females Aged <9 Years and >26 Years

Quadrivalent HPV vaccine is not licensed for use among females aged <9 years or those aged >26 years. Studies are ongoing among females aged >26 years. No studies are under way among children aged <9 years.

Special Situations Among Females Aged 9–26 Years

Equivocal or Abnormal Pap Test or Known HPV Infection

Females who have an equivocal or abnormal Pap test could be infected with any of approximately 40 high-risk or low-risk genital HPV types. Such females are unlikely to be infected with all four HPV vaccine types, and they might not be infected with any HPV vaccine type. Vaccination would provide protection against infection with HPV vaccine types not already acquired. With increasing severity of Pap test findings, the likelihood of infection with HPV 16 or 18 increases and the benefit of vaccination would decrease. Women should be advised that results from clinical trials do not indicate the vaccine will have any therapeutic effect on existing HPV infection or cervical lesions.

Females who have a positive HC2 High-Risk test conducted in conjunction with a Pap test could have infection with any of 13 high-risk types. This assay does not identify specific HPV types, and testing for specific HPV types is not conducted routinely in clinical practice. Women with a positive HC2 High-Risk test might not have been infected with any of the four HPV vaccine types. Vaccination would provide protection against infection with HPV vaccine types not already acquired. However, women should be advised that results from clinical trials do not indicate the vaccine will have any therapeutic effect on existing HPV infection or cervical lesions.

Genital Warts

A history of genital warts or clinically evident genital warts indicates infection with HPV, most often type 6 or 11. However, these females might not have infection with both HPV 6 and 11 or infection with HPV 16 or 18. Vaccination would provide protection against infection with HPV vaccine types not already acquired. However, females should be advised that results from clinical trials do not indicate the vaccine will have any therapeutic effect on existing HPV infection or genital warts.

Lactating Women

Lactating women can receive HPV vaccine.

Immunocompromised Persons

Because quadrivalent HPV vaccine is a noninfectious vaccine, it can be administered to females who are immunosuppressed as a result of disease or medications. However, the immune response and vaccine efficacy might be less than that in persons who are immunocompetent.

Vaccination During Pregnancy

Quadrivalent HPV vaccine is not recommended for use in pregnancy. The vaccine has not been causally associated with adverse outcomes of pregnancy or adverse events in the developing fetus. However, data on vaccination during pregnancy are limited. Until additional information is available, initiation of the vaccine series should be delayed until after completion of the pregnancy. If a woman is found to be pregnant after initiating the vaccination series, the remainder of the 3-dose regimen should be delayed until after completion of the pregnancy. If a vaccine dose has been administered during pregnancy, no intervention is needed. A vaccine in pregnancy registry has been established; patients and health-care providers should report any exposure to quadrivalent HPV vaccine during pregnancy (telephone: 800-986-8999).

Editorial comment: Amy Groom, Steve Holve, and Ros Singleton

Strategy for a Successful HPV Vaccine Rollout in Indian Country

The Advisory Committee on Immunization Practices (ACIP) recommends that the human papillomavirus (HPV) vaccine be routinely administered to females 11–12 years of age, with catch up vaccination for women 13–26 years. This vaccine is available at no charge through the Vaccines for Children program for all VFC-eligible women 9–18 years, per the VFC resolution.

The quadrivalent HPV vaccine is remarkably effective. In studies, the vaccine was 100% effective in preventing carcinoma in situ (CIN) 2/3 from 16/18 which are associated with 70% of cervical cancer, but this success comes at a cost. In the private sector, the vaccine costs $120 per dose or $360/person for a complete series of three vaccinations. IHS and tribal sites that are eligible and order through the VA Pharmaceutical Prime Vendor (PPV) can get the vaccine at $84.17/dose.

While the quadrivalent HPV vaccine was placed on the CDC federal contract in October of 2005, and is currently available through VFC in most states, some states have been delayed in the roll out of the vaccine or have had to restrict access to the vaccine to certain age groups due to limitations in VFC and state funds. Eventually coverage with HPV vaccine for all VFC eligible female patients 9–18 years of age should be available.

IHS recommends implementation of the full ACIP recommendation, targeting females 11–12 year olds with routine vaccination, and catch up vaccination for 13–18 or 13–26 year olds where possible. In states where HPV vaccine is not yet available for 11–18 year olds due to limits in supply and/or funding, IHS recommends the following:

1. Target girls 11–12 years old and 17–18 years old with HPV vaccine starting this summer and fall. This will capture older girls who will lose their VFC eligibility if we don't try to immunize them this year.
2. Ensure that each state has reliable numbers of the IHS female user population 9–18 years of age. This may assist states in lobbying the CDC for additional funds for HPV vaccine which should ultimately allow for full implementation of the ACIP recommendation for VFC-eligible patients seen by IHS and tribal facilities.
3. If a state is unable or unwilling to provide vaccine to at least the 11–1 2 year olds and 17–18 year olds, than consideration should be given for the agency to approach the CDC about increasing funding to ensure that AI/AN girls receive the HPV vaccine to which they are entitled by statute.

In order to vaccinate women 19–26 years old, the following strategies may help to offset the cost:

Medicaid: If Medicaid covers HPV vaccine for this age group in your state, contact your billing department to see how to bill for this vaccine. If you have a single fee for Medicaid visits, you may be able to schedule vaccinations with a billable provider (e.g. physician, nurse practitioner, physician assistant or midwife; not a nurse only visit) which may allow clinics to recover the cost of this immunization. The Alaska Native Medical Center (ANMC) in Anchorage has come up with a method to bill Medicaid by writing a prescription for HPV vaccine so that it can be billed separate from the clinic visit.

Merck Vaccine Patient Assistance Program (PAP): The Merck PAP allows patients over age 19 years who meet certain income and insurance coverage criteria to obtain HPV vaccine for free. Sites purchase some vaccine up front, and for patients who are approved by the Merck program, the vaccine is replaced by Merck to the dispensing pharmacy on a quarterly basis. The applicant must apply from a facility that is not 'wholly owned and operated by the government'. Hence, all tribal and urban facilities would qualify, plus those IHS facilities that receive additional funding, other than federal funding, e. g., grants, contracts, private funding, etc. If you are in doubt whether your facility qualifies, please contact (800) 293-3881 toll free 8:00 AM–8:00 PM EST Monday–Friday. If your facility does not qualify, then the patient could apply from a different facility, e. g., private, or semi-governmental clinic.

The application process is straightforward. Sites usually hear within the hour if the application is approved, though it can take up to 4 hours.

References: Online

Domestic Violence

Rachel Locker

Violence Threatens the Health of Pregnant Women and Newborns

CONCLUSION: Women experiencing intimate partner violence both prior to and during pregnancy are at risk for multiple poor maternal and infant health outcomes, suggesting prenatal risks to children from mothers' abusive partners.

Silverman JG et al Intimate partner violence victimization prior to and during pregnancy among women residing in 26 U.S. states: associations with maternal and neonatal health. Am J Obstet Gynecol. 2006 Jul;195(1):140-8.

SAVE THE DATES

Advances in Indian Health

- May 1–4, 2007
- Albuquerque, NM
- 26 credits
  http://hsc.unm.edu/cme/2007Web/AIH/AIH2007Index.shtml

2007 IHS APN/PA Meeting

- May 21–25, 2007
- Scottsdale, AZ
- Nearly 20 hours of credit
  www.ihs.gov/MedicalPrograms/clinicalSupportCenter/training.cfm#paapn

Native Women's Health and MCH Conference

- August 15–17, 2007
- Albuquerque, NM
- DRAFT Brochure
  www.ihs.gov/MedicalPrograms/MCH/F/CN01.cfm#Aug07
- Contact nmurphy@scf.cc

Abstract of the Month

- Quadrivalent HPV: Final ACIP Recommendations —with comments by Amy Groom

IHS Child Health Notes

- Double burden of iron deficiency in infancy and low socioeconomic status: a longitudinal analysis of cognitive test scores to age 19 years.
- Recent literature on American Indian/Alaskan Native Health

Hot Topics

- Obstetrics—Prenatal HIV Screening Saves Lives: We need to do better

From Your Colleagues

- Stephen W. Heath, Albuquerque—When Things Go Wrong: Responding to Adverse Events

Features

- Breastfeeding—Inquiring families want to know—what about breastfeeding and....
- International Health Update—Testing New Drugs on the World's Poorest Patients
- Medical Mystery Tour—Prolonged second stage with an epidural
- Midwives Corner—Being Present
- Navajo News—New ACOG recommendations challenging for rural IHS sites
- Oklahoma Perspective—Cesarean Delivery on Maternal Request
- Gynecology—Surgery versus medical therapy for heavy menstrual bleeding
- Osteoporosis —Bisphosphonate Related Osteonecrosis of the Jaws (BRONJ)
- Perinatology Picks—What is the best management plan for the woman with suspected preterm labor?
- Child Health—Newborn male circumcision: Improved outcomes with pediatric hospitalists
- Women's Health Headlines—Can you dispense birth control agents to minors without parental consent?

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