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NEW DRUG INFORMATION, and other related stuff ...

ACEI use in PREGNANCY

A recent study published in the *New England Journal of Medicine (NEJM)* includes disquieting results of an increased risk of congenital malformations associated with using angiotensin converting enzyme inhibitors (ACEIs) in the first trimester of pregnancy. The current package inserts list the pregnancy category for ACEIs as C (1st trimester) and D (2nd/3rd trimester).¹ In addition, the package inserts of all ACEIs contain a boxed warning noting the risk of injury or even death to the fetus when used in the 2nd or 3rd trimester of pregnancy. The *NEJM* study included 29,507 infants enrolled in the Tennessee Medicaid program.² Of the 29,507 patients, 209 infants had been exposed to an ACEI. Results of the study included that infants exposed to ACEIs were at an increased risk for malformations; cardiovascular and central nervous system malformations displayed clinical significance. The authors concluded that use of an ACEI during

the first trimester is not safe and should be avoided. Due to the timing of this information and lack of conclusive evidence, the FDA does not plan on changing the pregnancy category of ACEIs at this time but stresses the importance of considering these findings when discussing medication use in pregnancy.³

1. Zestril[®] [package insert]. Wilmington, DE:AstraZeneca Pharmaceuticals. June 2005.

2. Arobogast PG, Cooper WO, Dudley JA, Dyer S, Gideon PS, Hall K, et al. Major congenital malformations after first-trimester exposure to ACE inhibitors. N Engl J Med. 2006;354(23):2443-2451.



3. U.S. Food and Drug Administration [homepage on the Internet]. [updated 2006 June 7; cited 2006 June 16]. Angiotensin-Converting Enzyme Inhibitor (ACE inhibitor) Drugs and Pregnancy; [about 3 screens]. Available from: http://www.fda.gov/cder/drug/infopage/ace_inhibitors/default.htm

ABOUT GROUP B STREP- What you should know...

- *What is it?* Group B streptococcus (GBS) is a type of bacteria found in the vagina and/or lower intestine of 10-35% of healthy women. GBS is part of the normal flora in the human body and normally does not cause problems unless it invades the body. This rarely occurs and is known as "GBS disease".¹
- *Who is affected*? 15,000-18,000 newborns and adults in the U.S. contract serious GBS disease each year. One half of all GBS occurs in newborns and is acquired during birth.¹
- *How common is it in newborns?* 8,000 babies in the U.S. contract GBS disease each year; 800 may die from it and 20% of the babies who survive GBS-related meningitis are handicapped.¹
- *Symptoms:* Problems with temperature regulation, grunting sounds, seizures, breathing difficulties, stiffness, limpness, refusal to feed with the majority of these occurring during the 1st week of life¹
- *Screening:* Every pregnant woman should be screened for GBS at 35-37 weeks of pregnancy. The test involves collecting a swab from the lower vagina and rectum and culturing the sample. Results are usually available in three days.^{1,2}
- *If results are positive*: This just means that a patient is colonized with GBS. It does not mean that she has GBS disease or that her baby will become ill. A positive test means that a woman and her doctor need to plan for labor and delivery with this test in mind.¹
- *Risks factors for developing GBS disease*: (+) culture at 35-37 weeks, having a previous baby with GBS infection, labor or membrane rupture before 37 weeks, black race, young maternal age^{1,2}
- *Prevention:* IV antibiotics during labor and delivery to women who are GBS positive (Penicillin G 5 million units IV initially, then 2.5 million units IV q 4 hours until delivery); cesarean sections are not likely to prevent GBS; no vaccine is available at this time²
- 1. About Group B Strep Association [Homepage on the internet]. Chapel Hill, NC: Group B Association online. [cited 2006 June 16]. Available from: <u>http://www.groupbstrep.org/info0.html</u>
- 2. Centers for Disease Control and Prevention. Prevention of Perinatal Group B Streptococcal Disease. MMWR 2002;51(No. RR-11):1-28.

FROM THE MEDICAL LITERATURE ...

Testing negative for GBS...its impact on clinical decisions...A retrospective review was conducted on all cases of culture-proven early-onset GBS disease (EOGBS) from 1997-2003 at the Brigham and Women's Hospital in Boston; 25 cases of EOGBS were identified out of 67,260 infants. Surprisingly, the majority of GBS were found in infants whose mother had tested GBS negative. The author concluded that the previous negative test may have influenced the decision to not administer antibiotics during labor and thus increased the risk of GBS infection in the infant. Since GBS colonization varies with pregnancy, it is imperative to be more cautious when pregnant women present in labor. Approximately 30% of 1000 cases of EOGBS per year result from false-negatives. This study suggest that prompt intrapartum antibiotic treatment of women with signs of an infection involving the chorion, amnion, and amniotic fluid, regardless of GBS-screening results, is necessary. It may be feasible to screen when presented for delivery. Eichenwald EC, Madoff LC, Puopolo KM. Early onset group B streptococcal disease in the era of maternal screening. Pediatrics. 2005;115:1240-6

The Jesse Cause- Are you familiar?



The **Jesse Cause** was founded by Chris and Shelene Keith, whose son Jesse was born with GBS. He suffered from meningitis, sepsis, and hydrocephalus. This resulted in three brain surgeries. The Jesse Cause

hopes to spare other families from the effects of GBS. To learn more about the Jesse Cause and GBS, visit <u>www.thejessecause.org</u>. This website will provide you with information about GBS, stories of surviviors, prevention methods, and signs/symptoms to look for...

FROM THE LAY LITERATURE about medicine ...

Gestational diabetes? The American Diabetes Association provides helpful information

regarding gestational diabetes. gestational diabetes brings This website provides of gestational diabetes to the 4% of all pregnant women will to about 135,000 cases per year experiences gestational diabetes



For many patients, the thought of concern and worry to their pregnancy. information ranging from the definition possible long term risks. For example, develop gestational diabetes (equivalent in the U.S.). Also, if a woman in one pregnancy, her risk of

experiencing it again in a future pregnancy is about 66%. For additional information regarding gestational diabetes, visit: <u>http://www.diabetes.org/gestational-diabetes.jsp</u>. To calculate your diabetes risk, visit: <u>http://www.diabetes.org/risk-test.jsp?WTLPromo=allaboutdiabetes_risktest&vms=203442192959</u>

SUMMER SAFETY...



Miserable in the heat?!?!? Summer heat can exacerbate discomfort due to hormonal fluctuations, extra body weight, and other physical changes associated with pregnancy. Heat can be dangerous for you and your baby if you become overheated, dehydrated, or develop hyperthermia (heat cramps, heat exhaustion, and heatstroke). Although a pregnant woman carries extra fluid, it does not protect the baby from dehydration. It may actually contribute to dehydration due to shifts of fluid out of the cells and into the

extracellular spaces, causing edema. Dehydration can be dangerous during pregnancy because it can cause tachycardia in the baby and increase the risk of preterm labor. Preterm labor risk increases because dehydration decreases the blood volume which increases the concentration of oxytocin. Also, your baby is always 2 degrees warmer than you and cannot sweat to lower his body temperature. Be vigilant!!

Tips to protect you and your baby from dehydration:

- Drink 8-10 glasses of water per day and eat lighter meals
- Limit time outdoors
- Wear lightweight, loose-fitting clothes when outdoors
- Wear sunscreen of at least SPF 15

Pregnancy Weekly [Homepage on the internet]. c2000-2006 [cited 2006 June 16]. Available from: <u>http://www.pregnancyweekly.com/pregnancy_health_fitness/hot_summer_safety.htm</u>

For more information on Pregnancy Care/Concerns check out these helpful resources...

- The **March of Dimes** is an organization established to help prevent birth defects, premature births, and infant mortality. To learn more about the organization and the available resources to healthcare providers visit: <u>http://www.marchofdimes.com/</u>
- Fetal and neonatal risks...*Drugs in Pregnancy and Lactation* includes pregnancy categories, fetus risk summaries, and breastfeeding summaries. Further references are cited as additional sources for each drug. To learn more, refer to: Briggs, GC, Freeman



RK, Yaffe SJ. Drugs in pregnancy and lactation. 7th ed. Philadelphia: Lippincott Williams & Wilkins; 2005.

• **Drugs and Lactation** ... **LactMed**, from the National Library of Medicine, is a Webbased collection of 450 drug records on maternal drug levels in breast milk, drug levels in infants' blood, potential effects of drug ingestion on breastfeeding infants, and alternate drugs to consider. The database was developed by Philip O. Anderson, Pharm.D., FASHP, under the guidance of a scientific review panel. It is fully referenced and indicates the date last updated. <u>http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?LACT</u>

Reviews and References of Note...

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Important Dates in July:



- Independence Day- 4th
- Alzheimer's Awareness Week- 2nd-8th
- Sickle Cell Awareness Day- 4th
- National Transplant Week- 9th-15th



"A hundred years from now, it will not matter what my bank-account was, the sort of house I lived in, or the make of car I drove. But the world may be different, because I was important in the life of a child." - Author Unknown

An electronic bulletin of drug and health-related news highlights, a service of ... Auburn University, Harrison School of Pharmacy, Drug Information Center
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