MotherToBaby Launches New Observational Study of Mepolizumab (Nucala®) in Pregnancy

BRENTWOOD, TN – MotherToBaby Pregnancy Studies, conducted by the Organization of Teratology Information Specialists (OTIS), has launched a new observational study of mepolizumab (Nucala®) in pregnancy, a new medication for the treatment of severe asthma. This study aims to provide crucial information on the safety of this medication in pregnancy by following asthmatic women during their pregnancy and following their child up to one year of age. Given that untreated asthma can put both the mother and pregnancy at risk, the need for rigorous and ongoing research of new medications and their effects during pregnancy becomes vitally important. This study will expand efforts to better understand safety of asthma medications in pregnancy

Mepolizumab (Nucala®), launched by GlaxoSmithKline (GSK) in November 2015, was the first IL-5 inhibitor approved by the U.S. Food and Drug Administration (FDA) for as an add-on treatment for severe asthma with an eosinophilic phenotype. Similar to inhaled steroids, mepolizumab provides a preventative approach to asthma control; it is thought to act by inhibiting interleukin 5 (IL-5), a group of proteins and signal molecules produced by white blood cells. This may decrease inflammation in the lungs and the number of subsequent severe asthma attacks in persons with eosinophilic asthma. Mepolizumab is administered as an injection under the skin (subcutaneously) once every 4 weeks. It is not intended to treat active asthma symptoms.

“We know that asthma in pregnancy, especially poorly controlled asthma, is associated with higher rates of pregnancy complications, like placental problems, premature delivery, and low birth weight. With this reality, it is especially important that a woman’s asthma be carefully managed prior to and during a pregnancy,” said Christina Chambers, PhD, MPH, MotherToBaby Pregnancy’s Studies lead investigator and world-renowned perinatal epidemiologist at UC San Diego. “Yet medications that are newly approved by the FDA have little to no information about how safe they are for a pregnant woman and her developing baby. Our research aims to fill this critical gap.”

In addition to mepolizumab, MotherToBaby Pregnancy Studies are also enrolling pregnant women who are using other medications for the treatment of their asthma including, but not limited to albuterol, formoterol, salmeterol, and/or inhaled steroids, as well as pregnant women who do not have asthma. These studies are coordinated by the University of California, San Diego, and are in collaboration with the American Academy of Allergy, Asthma & Immunology as part of the Vaccines and Medications in Pregnancy Surveillance System (VAMPSS).

Women who are pregnant and who reside in the U.S. or Canada may be eligible to participate. Participants are not asked to take or alter any medications, do not need to travel, and are not asked to make any changes to their normal routine.

To join or for more information on MotherToBaby Pregnancy Studies, call toll-free 877.311.8972, visit MotherToBaby.org or email MotherToBaby@ucsd.edu.

If you are pregnant or planning a pregnancy and have questions about asthma and the medications used to treat asthma in pregnancy, MotherToBaby Fact Sheets are available in both English and Spanish and can be downloaded for free. MotherToBaby experts are also available to provide free personalized risk assessments via phone, email, text, or live-chat.

More about MotherToBaby

MotherToBaby is the nation’s leading authority and most trusted source of evidence-based information on the safety of medications and other exposures during pregnancy and while breastfeeding.

The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) Office of Women’s Health have recognized OTIS and MotherToBaby as a recommended resource for information on exposures during pregnancy and lactation.

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A statement issued by the MotherToBaby Public Affairs Committee

Recently, the issue of lead in drinking water has become a topic of great concern nationally. While there is much news coverage of this issue and of the experts working toward ensuring that these communities have safe drinking water,

there has been very little data reported or resources identified specifically for women who are pregnant or breastfeeding.

Here is what we do know: Lead can get into your body through the gut if you swallow or inhale tiny particles of paint chips, medications, soil, water, or other items that contain lead. Because lead is naturally found in many places in the environment, most people have small amounts of lead in their blood and do not usually experience problems. When a person is exposed to lead over a long period of time or at a high level, the body will store lead in the bones and teeth. Lead can stay in the bones and teeth for many years. During pregnancy and breastfeeding, lead can leave bone and move back into the bloodstream. A blood lead test can be done to see how much lead is present in the blood. Although most people will have some lead in their blood, levels greater than 10 micrograms per deciliter (µg/dl) indicate that there is some exposure at home or in the workplace that needs to be addressed. While there is no clear safe level of lead in the body, the goal is to have the lowest level possible. Women who had exposure to lead in the past should have levels checked before and during pregnancy. The Centers for Disease Control and Prevention recommend that public health actions (such as a search for the source of the lead) be initiated when blood lead levels are above 5 µg/dL. Lead can cross into the baby starting at about the 12th week of pregnancy. The amount of lead in the blood of the mother and baby are almost the same, as are the levels in breast milk. Lead may also be found in infant formulas prepared at home, particularly if the local water supply contains high levels of lead. A mother should not stop breastfeeding unless her blood lead levels are above 5 µg/dL. Be sure to talk to your health-care provider about all your choices for breastfeeding.

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Pregnancy

***MotherToBaby Creates Zika Fact Sheets, Launches New Media** (Scroll down for additional resources, video)*

BRENTWOOD, TN – As information surrounding the Zika virus continues to evolve, MotherToBaby, a service of the international non-profit Organization of Teratology Information Specialists (OTIS), unveils new tools to bring the most accurate, evidence-based information to pregnant and breastfeeding women. Easy-to-understand fact sheets regarding Zika, as well as insect repellant use during pregnancy, are now available on www.MotherToBaby.org. Additionally, teratogen information specialists (experts trained in the field of birth defects) have begun taking questions about exposures from the general public and health care providers beyond its traditional telephone line – through private, live chat, text messaging and e-mail.

MotherToBaby, a suggested resource by many agencies including the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration's (FDA) Office of Women's Health, recognizes the urgent need for providing pregnant women, those planning a pregnancy, as well as breastfeeding moms with the most up-to-date information about the Zika virus and other potential causes of preventable birth defects. MotherToBaby is an official supporter of World Birth Defects Day, which is recognized by more than 50 international organizations each year on March 3rd.

"With the information and research about Zika changing on an almost daily basis, it can be confusing and, potentially, cause unnecessary anxiety for a pregnant woman," said Stephen Braddock, MD, incoming president of MotherToBaby who serves as the Director of Medical Genetics at Saint Louis University. "That's why MotherToBaby's specifically-trained teratogen experts are here to sift through and interpret the evolving Zika-related research, putting it into perspective so a woman can make informed health decisions in collaboration with her health care provider," added Dr. Braddock.

The challenges of staying up-to-date on the changing Zika information are lessened since OTIS, the professional society which provides the MotherToBaby service, includes members and researchers currently in the thick of the Zika outbreak. Lavinia Schuler-Faccini, PhD, lead author of one of the first ground-breaking studies to examine the association between the Zika virus in pregnant women and microcephaly (small head and brain) in their babies, is part of the MotherToBaby/OTIS network. Dr. Schuler-Faccini is President of the Brazilian Society of Medical Genetics (Sociedade Brasileira de Genetica Medica).

"Being based in Brazil, one of the countries where Zika has been declared an 'outbreak,' has allowed me to communicate the very latest research to my American colleagues," said Dr. Schuler-Faccini. "For example, I was able to provide region-specific information where infected mosquitos are currently located to a worried American traveler who had contacted MotherToBaby," she added.

More about Zika
On February 1, 2016 the World Health Organization (WHO) declared a global public health emergency over Zika virus, due to its suspected ability to cause microcephaly in unborn babies. Zika virus was first identified in Africa in 1947. In 2013, there were outbreaks in islands in the Pacific, and now outbreaks are being reported in many Central and South American countries. Isolated cases have also been reported in the U.S. in people who have recently traveled to South American countries, and in Puerto Rico, over the last few weeks. Additionally, just last week, federal health officials reported strong evidence that more than a dozen people have caught the virus through sexual transmission.

About MotherToBaby
MotherToBaby provides free, evidence-based, personalized risk assessments, education and counseling regarding the effects of exposures during pregnancy and while breastfeeding. Examples of exposures include the Zika virus, prescription and over-the-counter medications, alcohol, tobacco, illicit drugs, vaccines, beauty products, herbal supplements, chemicals and more. The public, as well as health care providers, can be connected with a MotherToBaby expert through its traditional toll-free phone line, 866-626-6847, via text message at 855-999-3525, or through live chat and email on www.MotherToBaby.org.

More than 100,000 women and their health care providers seek information about birth defects prevention from

MotherToBaby every year. MotherToBaby has been able to launch new outreach efforts to reach underserved populations and launch new communication technologies through a cooperative agreement with the U.S. Health Resources and Services Administration.

About World Birth Defects Day
Along with more than 50 birth defects-related organizations around the world, MotherToBaby is helping to raise awareness of this critical global issue by participating in World Birth Defects Day, which is observed yearly on March 3. The commemorative day not only helps to raise awareness of the problem of birth defects, but also the importance of improving prevention strategies and research that will ultimately lead to fewer birth defects and a healthier society.

More Resources

- **Health care providers interested in viewing the recording of a National Society for Genetic Counselors joint webinar on research surrounding Zika, click here.**
- **MotherToBaby's Dee Quinn, MS, CGC provides the latest Zika research on "*The Vibrant Gene*" program:**
- **MotherToBaby's Public Affairs Committee has also issued an official statement about the Zika virus, which can be read here.**
- **Our sister society, the Teratology Society, has recently published a blog looking closely at the science needed to learn more about Zika as well. Read its latest *Birth Defects Insights* blog here.**

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Media Contact: Nicole Chavez, 619-368-3259, nchavez@MotherToBaby.org. Interviews in Spanish can also be arranged.

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By Kiran Thanigasalam, BPharm, MPH, MotherSafe (MotherToBaby's Australian partner)

As Birth Defects Prevention Month came to a close last month, I thought it was crucial I keep the momentum going by talking about Iodine with every patient I come across as a pharmacist and counselor. Why? When planning for baby, you and your prenatal vitamin need to be on the same team when it comes to health. While there may be no "i" in team, there is an "i" in both iodine and iron. When the topic of iodine supplementation is raised with pregnant women, I can tell you that a lot of women confuse iodine with iron when searching for the perfect prenatal vitamin.

What is iodine?

Iodine is a naturally-occurring trace element which is vital for thyroid function. It is an essential component of the thyroid hormones T4 and T3. Some common food sources include seaweed, fish, egg and iodized salt.

Misconception
The total recommended daily intake in pregnancy ranges from 220 micrograms (U.S. RDA) to 250 micrograms (W.H.O, Unicef, ICCIDD). While many women report that they have "tested within normal limits for everything" and have a balanced diet, the American Thyroid Association, American Academy of Pediatrics and the Endocrine Society recommend a prenatal supplement of at least 150 micrograms of elemental iodine per day for every pregnant woman. This recommendation assumes that the woman is also getting 70-100 micrograms of iodine in her daily diet.
The only exceptions to this recommendation are women with pre-existing thyroid conditions such as Graves' disease who have been advised by their treating specialists to avoid iodine supplements.

Dietary iodine intake in the US has generally been considered adequate since the fortification of table salt and other foods. However, since routinely testing iodine concentrations in urine is not practical and since supplementation is cheap, safe and effective, the preventative approach of a one-size-fits-all supplement in pregnancy provides peace of mind – especially for at-risk groups like vegetarians or those who do not consume dairy products or iodized salt.

Getting enough iodine is *crucial* for a developing baby's brain and skeleton.
In its most extreme form, iodine deficiency can result in maternal goiter (a condition in which the thyroid gland becomes enlarged), miscarriage and stillbirth. However an underactive thyroid gland in the mother, even if she is not having any symptoms, can cause the baby to have neurodevelopmental problems such as a reduced IQ.

Clearly, not all prenatal vitamins are the same.
A 2009 paper published in the New England Journal of Medicine surveyed 223 prenatal multivitamins marketed in the United States and found that only 51% contained iodine, and 37% of those products contained kelp as the iodine source. Unfortunately, wide variations in the iodine content of kelp make this an unreliable choice of supplement. Potassium iodide is preferred.

As a result, it is crucial to check that the prenatal vitamin you are contemplating buying contains not only folic acid (which is important to prevent birth defects of the spine, called neural tube defects), but also iodine at the recommended amount and in the right form. Here's to a winning team when it comes to iodine and health for you and baby!

MotherSafe

About the Author
Kiran Thanigasalam, BPharm MPH, is a pharmacist and teratogen information specialist at MotherToBaby's international affiliate, MotherSafe, which is based at the Royal Hospital for Women, Randwick in Australia.

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THE TERATOLOGY SOCIETY

Birth Defects Insights

a blog by our partners at the Teratology Society

By Sarah Običan, OBGYN, Teratology Society Council Member and member of the MotherToBaby Board of Directors

See Dr. Obican's blog on Linkedin and share it with your professional networks here

Where should I even begin? As a physician, I'm concerned. As a scientist, I'm concerned. As a woman in her childbearing years, I'm concerned. While

the vast majority of babies are born healthy and free of birth defects, the prevalence of certain birth defects are on the rise and the bottom line is – it's concerning.

Just in the past few days, new evidence of increasing rates of gastroschisis has emerged. Gastroschisis is a serious birth defect where the intestines and sometimes other organs poke through an opening in the abdomen near the belly button. We don't understand why this birth defect occurs. There's only one consistent risk factor identified in studies – moms who are younger are more likely to have a baby with this problem. But in recent years, the rate of this problem has been increasing and we don't know why.

How about antidepressants during pregnancy? That's always a hot button issue that seems to gain a lot of press attention, from jumping to conclusions of its potential link to autism, to premature birth and everything in between. ***We still do not have concrete answers.*** What we do have is mounting evidence of the growing use of antidepressants among childbearing women. According to a study published just last week, about 15 percent of women aged 15–44 years filled at least one prescription for an antidepressant in a single year. Since much is not known about the safety of antidepressants in pregnancy, coupled with the known fact that about half of pregnancies are unplanned, research on the effects of antidepressants during pregnancy needs to be prioritized so women and their doctors have the information they need to make informed choices.

And then there's Zika. It's on the nightly news. It's a discussion around the water cooler. It's real and appears to not be going away anytime soon, especially as women all over the world prep to travel and cheer on their home countries in this Summer Olympic games in Brazil. The association between Zika virus during a woman's pregnancy and microcephaly in her baby is rapidly evolving. Microcephaly is a life-threatening neurodevelopmental birth defect characterized by an affected infant's smaller-than-normal head.

Science is Hope

As a Council member of the Teratology Society, a society of scientists dedicated to researching birth defects and developmentally-mediated disorders, and Board member of the Organization of Teratology Information Specialist's (OTIS) MotherToBaby program, it goes without saying that I look forward to our annual conferences. One of the advantages of the conferences, held jointly, is that they bring together experts from many fields. Some are laboratory scientists who do genetic studies, others do animal research, some focus on epidemiology studies, while others see patients and talk to parents. All these smart minds at the same meeting — both in the formal meeting rooms and in the conversations that happen in the hallway between sessions — can come up with new ideas on how to tackle these important issues causing so much concern. These are groups that don't get the opportunity to exchange ideas on a regular basis. Submit your research abstract online **(deadline: February 15th)**, take part in our annual meeting, and visit www.Teratology.org

I hope that by having the leaders in the studies on Zika virus from Brazil and the United States presenting to our group of researchers leads to an improved understanding of this association and improved care for mothers and their babies. I hope that by bringing the world's leaders on antidepressant research together in one session will lead to new ways to study its use in pregnancy. I hope our scientists help answer that young mom left wondering what she could have done differently to avoid having her baby deal with the complications of gastroschisis. Bottom line – From hope comes motivation, which, as scientists, can lead to answers. Join the hope.

Scientists interested or are already involved in research related to topics mentioned in this blog are encouraged to join the Teratology Society, the premier source for cutting-edge research and authoritative information related to birth defects and developmentally-mediated disorders, as well as the Organization of Teratology Information Specialists (OTIS), the non-profit society that provides the MotherToBaby service. Members include those specializing in cell and molecular biology, developmental biology and toxicology, reproduction and endocrinology, epidemiology, nutritional biochemistry, and genetics, as well as the clinical disciplines of prenatal medicine, pediatrics, obstetrics, neonatology, medical genetics, and teratogen risk counseling. The Teratology Society publishes the scientific journal, Birth Defects Research. Learn more at www.Teratology.org.
Find the Teratology Society on Linkedin
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About The Author
Sarah G. Obican, MD, is an OBGYN, Maternal Fetal Medicine specialist at the University of South Florida. She's currently a Councilor of the Teratology Society. She's also on the Board of Directors of the Teratology Society's sister organization, MotherToBaby, which provides evidence-based answers to questions about exposures during pregnancy and breastfeeding.