Why Do We Need a Copy of Your Child's Medical Record?

To have confidence that our data are correct and to be sure that our findings are accepted by doctors and others, we need to document the exact diagnoses for all of the infants in our study. We need to know the precise medical terminology so we can make sure we correctly classify each diagnosis. Even when parents know the exact term, scientific standards require that we can also document the diagnosis from the child's medical record. The same applies to children who do not have birth defects—we need to have confirmation from the child's medical record to meet strict scientific standards about the conditions we are studying. Some conditions are complicated and the medical terms can be confusing. Various tests, surgical reports, echocardiograms, x-rays or even lab results help us code medical conditions correctly.

It can often take a while to diagnose some conditions, and a baby may be seen at more than one health care facility during his/her first year of life. For example, a baby with a heart defect may be transferred right away to a hospital for intensive care or a baby with a cleft lip may have the lip surgically repaired several weeks after birth. This is why it's important for us to review records from all hospitals where the baby was seen, and in some cases your child's pediatrician record.

The medical record authorization form you complete and return allows us to obtain a copy your child's record. This authorization is only valid for a specific time period after birth. All information that would identify you or your child is removed when we receive the record. We value the trust you place in us and we follow strict rules for protecting your privacy and confidentiality. If you have any questions about this, please call us.□

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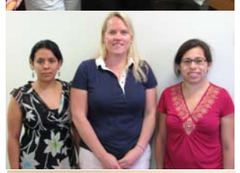

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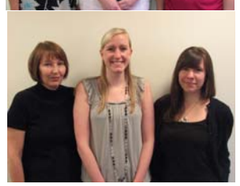

Paula Wilder
Lindsay Andrus
Nicole Gonzalez

Not pictured: Joan Shander

Hirschsprung Disease Research

Hirschsprung disease is a congenital condition in which certain nerve cells are missing from a part of the large bowel. The absence of these nerves can cause intestinal blockage. If the condition is severe, the newborn may fail to pass meconium or stool and may vomit.

Hirschsprung disease occurs in about 1 in 5000 births, and causes about 25% of all cases of newborn intestinal obstruction. It occurs in males more often than in females, and occurs more often in conditions such as Down syndrome.

Dr. Robert Heuckeroth, a pediatric gastroenterologist at Washington University in St. Louis, has been studying Hirschsprung disease in his laboratory for many years. Together, we are learning more about genetic and non-genetic factors (such as nutrition) that may be important in the development of the intestinal tract. Using the interview information collected in our study, we hope our research will lead us to better understand and perhaps even help prevent Hirschsprung disease. □

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Research News

A Word of Thanks from our Principal Investigator

We would like to express our deepest appreciation to each of the families who participated in the study. We know how busy family life can be and we value the time and effort you took to be part of our research. Your generosity has been what has helped us interview over 39,000 women in the past 34 years. Thank you!

A major goal of our study is to learn more about the safety of medications taken by pregnant women. Though women take a wide variety of medications in pregnancy, we know very little about how those medicines might affect the infant. This lack of information can make a pregnant woman terribly anxious about whether a needed medicine is safe for her baby.

To learn as much as we can, our study focuses not only on prescription medicines, but also on over-the-counter medicines, vitamins, and herbal products. Results of our research, which are published in major medical journals, have supported the safety of some products and the risks of others, and as we interview more and more women about their pregnancies, we will have even greater opportunities to answer important questions.

All of us who have devoted our careers to this important public health effort recognize that the success of this research effort depends directly on the tens of thousands of women who have contributed their experiences to the study. They have repeatedly told us that they participate in the study for one simple reason—to improve the health of women and babies in the future. We believe that our study's contributions over the years clearly show that their participation really does make a difference! □

Allen A. Mitchell, MD

Study Results

Over the years, we have published over 100 articles in medical journals. It would be impossible to list all the study findings here, but we want to share highlights of a few of them in this newsletter to give you an idea of how your participation helps other families. For more detailed information about our study results, please visit our website at www.bu.edu/slone/phis. □

Study Nuts and Bolts

Women who participate in this study come from the metropolitan areas of Boston, Philadelphia, and San Diego, as well as the states of Rhode Island, Delaware, New York and southern New Hampshire. They are mothers of babies with a wide range of birth defects, mothers of babies with no birth problems at all, and women who have had a pregnancy loss.

After completing the study interview, each woman is asked to sign and return a medical record release form. This is very important, because it helps us to be sure that the information we gather about the medical diagnoses of each baby is complete and accurate and that the results of our study are correct.

All information we receive is kept strictly confidential. In addition, we remove all names, addresses, phone numbers and any other identifying information from all study data, including all medical records we receive. Preserving your confidentiality is a priority for us. □

In This Issue...

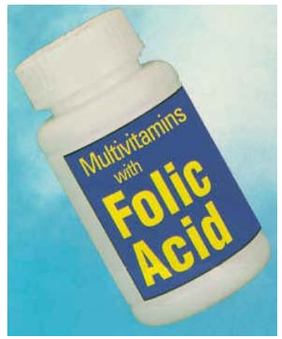
The Folic Acid Story

When our study began 34 years ago, we didn't think that any medicine or vitamin could actually *reduce* the risk of a birth defect. To our delight, we were wrong! Researchers had suggested that folic acid taken around the time a woman became pregnant might reduce the risk of a baby being born with neural tube defects, such as spina bifida. We studied this possibility carefully in our own study data, and in 1993 we found that women who took a multivitamin containing folic acid around the time they became pregnant reduced the risk of neural tube defects by about half—a dramatic effect, and one that has been shown in most other studies as well. In addition, our study was the first to show that the amount of folic acid (0.4mg or 400 mcg) contained in a standard multivitamin was enough to produce this effect.

Because of the clear benefit of folic acid in reducing risks of neural tube defects, we have studied whether it might reduce the risks of other birth defects as well, and we found that it might also lower risks for heart defects, cleft lip and palate, and urinary tract defects. It's now recommended that women who might become pregnant make sure they take enough folic acid (0.4mg) each day, either by eating lots of foods that contain folic acid or by taking a daily multivitamin. Getting enough folic acid from a normal diet can be difficult, so the government now requires that this vitamin be added to most flour, corn meal, pasta, and breakfast cereals.

When we looked at the dietary information women provided us during their interviews, we found that eating flour and cereal grains fortified with folic acid still didn't provide enough folic acid for most women. These results reinforced expert advice that the best way to get enough folic acid to reduce the risk of certain birth defects is to take a daily multivitamin that contains folic acid. Since folic acid has this benefit only if it's taken around the time of conception, and since about half of all pregnancies are unplanned, it's important for all women of childbearing potential to be taking a daily vitamin that contains folic acid.

Next, we looked at our data to see how many women knew about the need for folic acid and how many took a folic acid-containing multivitamin around the time of conception. By the late 1990's, we found that half the women we interviewed knew that folic acid could help prevent birth defects. In recent years our data show that almost 40% of women take a multivitamin containing folic acid. This means that 60% of women are not taking folic acid. Women with lower incomes and less education, along with women who hadn't planned on becoming pregnant, were less likely to know about the benefit of folic acid and were also less likely to be taking it. This information is helping to improve public education efforts designed to increase the number of women taking folic acid around the time of pregnancy. □



Risk Factors for Persistent Pulmonary Hypertension of the Newborn

Persistent pulmonary hypertension of the newborn (PPHN) is a rare but very serious condition in which a newborn baby has unusually high blood pressure in the arteries of the lung. While advances have reduced deaths and other complications in these babies, it would be helpful to know before delivery which babies might be at risk for PPHN so medical care could be made available immediately—and it would be even better if we could predict factors that might reduce the risk of developing PPHN in the first place.

In a major study of PPHN, we found that babies with this condition were more often delivered by Cesarean section, were unusually large, and more often born to mothers who were overweight or had diabetes or asthma. We also found that PPHN was more common among mothers who took certain antidepressant medications (called "SSRIs") in the second half of pregnancy. These factors may not cause PPHN, but knowing them can help doctors anticipate which women might have a higher risk of delivering a baby with PPHN. □

Vaccines Given in Pregnancy

Vaccines provide protection against many serious illnesses. While we usually think of vaccines as something given to children, important new vaccines have been developed in the last few years, many of which are intended for adults. The best known new vaccine is the H1N1 vaccine, also known as the "swine flu" vaccine. Federal officials estimate that from April 2009 to January 2010, approximately 57 million cases of H1N1 occurred in the United States. Even though the illness was not always as serious as had been feared, there were almost 12,000 deaths due to H1N1. For a number of reasons, pregnant women are particularly at risk for influenza being severe and even fatal. They are considered one of the highest risk groups to receive the vaccine and certain medications that may help prevent or reduce the severity of flu, whether it is the "usual" seasonal flu or the more widespread and potentially much more serious "pandemic" flu, such as swine flu. Still, because of concerns about possible effects on their fetus, many pregnant women worry about whether they should receive any vaccine during pregnancy.

Flu vaccine safety is generally well-established, though there is agreement that we should collect more information on its use in pregnancy. Our study has helped to estimate how many women are following the recommendation to receive the seasonal flu vaccine while pregnant, and we are actively collecting information on the H1N1 vaccine as well. A major focus of our study is to provide more information on the safety of all flu vaccines. To do this, we need to know the specific type of flu vaccine a woman received. We thank all our study participants who sent us vaccine release forms, since they are critical in helping us get this important information.

Other new vaccines have also recently become available, and we will study their safety as well.

If you had a vaccine while pregnant, we ask that you sign a release form so we can request a copy of your vaccine record from your health care provider. This allows us to know exactly which vaccine you received and when in your pregnancy it was given. If you have not yet returned the form, please do so now; if you have any questions, please contact us at 617-734-6006.

We will continue to collect information on vaccine use in pregnancy and analyze it in the future. Thank you for helping us learn more about this important public health topic. □

Asthma and Pregnancy

One special focus of our study is to evaluate the safety of medicines used to treat asthma in pregnant women. This is important because asthma is the most common chronic medical problem that requires pregnant women to take prescription medicines. We know that many pregnant women worry about whether their asthma medicines will harm the fetus and, because of this concern, some might even stop or decrease use of these asthma medicines during pregnancy. At the same time, we also know that poorly controlled asthma may harm the fetus. This situation makes it very important to learn more about asthma medications in pregnancy.

Today there are many medicines available to treat asthma, but little is known about their safety when taken during pregnancy. By collecting information about the various medicines women take to control their asthma, we hope to be able to learn whether they pose a risk to the fetus and if so, which ones might be safer. In addition, the information women provide about the severity of their asthma, both before the pregnancy began as well as during pregnancy, will help us understand the effect of asthma itself on the fetus. By gathering details about both asthma and the medicines women use to treat it, we hope to improve our understanding of the most effective and safest ways to treat asthma during pregnancy. □

Congenital Problems in Baby Boys

A diagnosis that is hard for us to confirm is a condition called undescended testicle(s). The medical term for this is cryptorchidism. As a baby boy grows inside his mother's womb, his testicles typically form inside his abdomen and move down (descend) into the scrotum shortly before birth. But in some cases, that move or descent does not occur or is not complete, and the baby is born with a condition known as undescended testicles (or cryptorchidism).

Cryptorchidism is the most common genital abnormality in boys, affecting approximately 30% of baby boys born prematurely and about 4% born at term. In about half of the babies, the undescended testicles move down or descend on their own by the time the boy reaches 6 months of age. If descent doesn't happen by then, the baby is evaluated for possible treatment by a urologist.

Hypospadias is another male birth defect, but this one affects the penis. Normally, the tube that carries urine from the bladder (called the urethra) opens at the tip of the penis, but in hypospadias, the opening is somewhere else along the penis, usually on the underside. The opening can occur anywhere from just below the end of the penis to the scrotum. Hypospadias is a rare disorder, affecting only about 1 out of 250 live male births.

We hope to learn more about these and all sorts of other birth defects, and we thank you for sharing your pregnancy histories and your medical records with us! Please call us if you have any questions or concerns.□