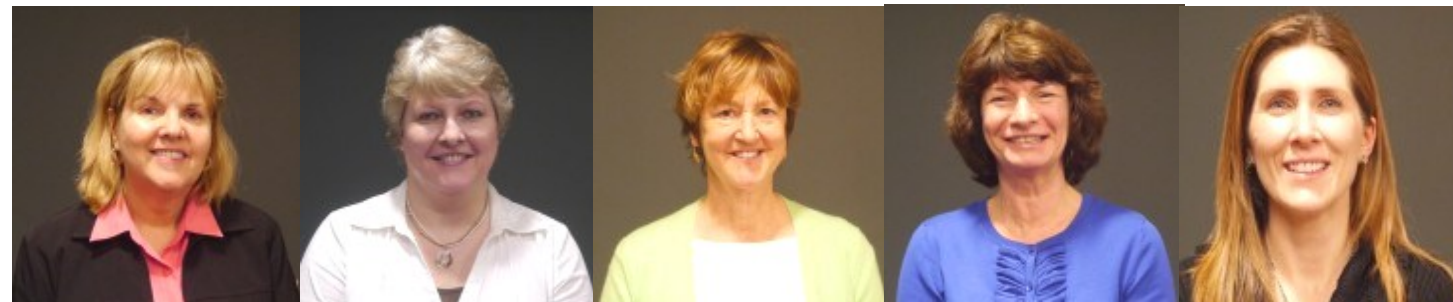


## Meet Our Nurse Interviewers



Clare Coughlin, RN    Laurie Cincotta, RN    Susan Littlefield, RN    Kathy Sheehan, RN    Moira Quinn, RN

### What have you learned from moms you interview?

*Clare:* Despite the busy demands of work and parenthood, most of the mothers we contact are eager to participate in order to help other families. Each and every day, I am reminded of their generosity and their tremendous resilience—often in the face of adversity. It is a privilege to talk with them about their pregnancies.

*Moira:* I am consistently amazed and impressed by the generosity of the women who participate in our study. I have learned that, regardless of their individual circumstances, the number of women who are willing to give their time and share their experiences to benefit others is inspiring.

### Why is this job important to you?

*Kathy:* The research we are conducting is so extremely important in helping future mothers make critical health care choices even before they become pregnant. It may also put some mothers minds at ease with regards to certain exposures, such as flu vaccine use during pregnancy.

*Susan:* Time after time, mothers tell me that they are glad to have the chance to help so that future moms may not have to go through what they have just experienced. I consider myself very lucky to have the chance to work with these women, and to be part of a nationwide effort to find out more about the cause of birth defects.

*Clare:* Simply put, to improve the health of infants and pregnant women. Despite well-wishers telling me otherwise, I recall pregnancy as a stressful time in my life. Although my kids are older now, I remember worrying about all sorts of things that might impact the health of my baby. It would have been reassuring and helpful to know about the latest research findings in these areas.

### What would you like the moms you interview to know?

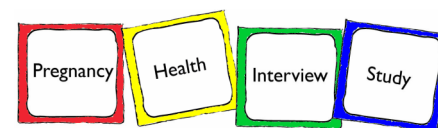
*Laurie:* The success of this research depends directly on the thousands of women who have shared their time and experiences. Each woman's pregnancy is unique and each experience is important to our research. One individual's

participation does make a difference. By participating, women are helping to improve the health of pregnant women and babies.

*Kathy:* All of the nurse interviewers are mothers who have experienced the “juggling” routines involving caring for children, working, and other responsibilities. We know how valuable “free time” is, and we will bend over backwards to accommodate their schedules. Mothers who were initially reluctant to be interviewed will later tell me that they are glad they participated and hope the information will help future mothers have healthy pregnancies. □

## More Study Results

Over the years, we have published over 130 articles in medical journals. This newsletter shares a few highlights from recent and significant publications. It is not possible to list all findings here but we wanted to give you an idea of how your participation helps other families. For more detail about our study results please visit our website at: [sites.bu.edu/phis](http://sites.bu.edu/phis)



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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 this 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 47,000 women in the past 37 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 vaccines, over-the-counter medicines, vitamins, and herbal products. Results of our research, which are published in major medical journals, have added to what we know about 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 involved in this important public health effort recognize that the success of our research 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**  
Professor of Epidemiology and Pediatrics at Boston University

### Antihistamine Use During Pregnancy

Antihistamines are a group of medications that are used to treat various conditions, including allergies and nausea and vomiting. Some antihistamines require a prescription, but most are available over-the-counter (OTC), and both prescription and OTC antihistamines are often used by women during pregnancy. Until recently, little information was available to women and their health care providers on the possible risks and relative safety of these medications in pregnancy, particularly when it came to specific birth defects.

Based on interviews with tens of thousands of new mothers, we have added important new information for many of these medicines. We studied antihistamines that had been suggested in earlier studies to increase risks of certain defects, and we also studied other possible risks that might not have been identified in the past. Where there was sufficient information in the study data, we found no evidence to support suggestions of risk that had been found in earlier studies. In considering possible risks that had not been identified by others, we found very few suggestions that any given medicine might be linked to an increase risk of a specific birth defect, and though these few deserve further research attention, these findings may have also been due to chance. □

### Use of Macrolide Antibiotics During Pregnancy

Macrolides are a type of antibiotic (examples include erythromycin, clarithromycin and azithromycin) commonly prescribed for use during pregnancy. Prior studies have reported increased risks of congenital heart defects (CHD) and pyloric stenosis (PS) in infants whose mothers used these medications during pregnancy. We examined this issue using data from the Slone Pregnancy Health Interview Study from 1994 through 2008. We identified 4132 infants with CHD, 735 infants with PS and 6952 infants without any malformations. Interviews with the mothers of these infants provided detailed information on medications taken during pregnancy.

Overall, we found no evidence of a link between maternal use of macrolide antibiotics during pregnancy and infants born with CHD or PS. In addition, we did not find any evidence for concerns about increased risks of other birth defects following maternal use of macrolides during pregnancy. However, as with all medications in pregnancy, women should talk with their health care provider about the risks and benefits of taking these antibiotics during pregnancy. □



## The Folic Acid Story

When our study began 37 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 multi-vitamin 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 multi-vitamin 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. □

## Completing Your Participation

After the telephone interview there is one more important step to complete your participation:

Each woman is asked to sign and return a medical record release form for her child and a vaccine release for herself if she reported in her interview that she received any vaccines in pregnancy.

### Medical Record release (blue form):

To have confidence that our data are correct and to be sure that our findings are accepted by other scientists and health care providers, 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 study participant. We also need a medical record to document that infants without any problems were healthy at birth.

Scientific standards require that we confirm any conditions present from the child's medical record whenever possible. Some conditions are complex 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.

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

### Vaccine Record release (green form)

If you reported receiving a vaccine while you were pregnant, we ask you to sign and return the green release form so we can request a copy of your vaccine record from your health care provider or wherever you received the vaccine. This allows us to know exactly which vaccine you received.

*If you have not returned these forms yet, please do so now so our records will be complete. We have enclosed copies for your convenience. All you have to do is sign and date them and return them in the postage paid envelope. Please call your nurse interviewer if you have any questions about these forms.* □

## Use of decongestants during pregnancy and the risk of birth defects

Over-the-counter (OTC) decongestants, like Sudafed, are some of the most commonly used medications during pregnancy. Because they are available without prescription, they are widely thought to be safe by healthcare providers and pregnant women, but their safety with respect to specific birth defects is unclear. Previous studies suggested that taking OTC decongestants during early pregnancy increases the risk of several birth defects. We studied this issue using interview data from mothers of 12,734 infants born with malformations and 7,606 infants without malformations.

Overall, we found that taking OTC decongestants during early pregnancy was linked to a few specific birth defects, such as a heart problem called endocardial cushion defect, ear defects, and pyloric stenosis. Given that decongestants are commonly taken during pregnancy, there is continuing need for more studies to better understand the risks and safety of these medications during pregnancy in relation to birth defects. As is the case with prescription drugs, women who are pregnant or planning to become pregnant should talk with their health care provider about the risks and benefits of using these drugs during pregnancy. □

## Why Study Flu and Other Vaccines? H1N1 Vaccine Results

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.

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 flu 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. 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 continue to send us vaccine release forms, since they are critical in helping us learn more about this important public health topic.

Other new vaccines have also recently become available, and we will study their safety as well. We will continue to collect information on vaccine use in pregnancy and analyze it in the future. □

We recently published reassuring evidence that H1N1 flu vaccine is relatively safe during pregnancy. Together with our colleagues at UC San Diego and in collaboration with the American Academy of Allergy Asthma and Immunology, we studied H1N1 ("swine flu") vaccine given in pregnancy.

This national effort was launched shortly after the H1N1 outbreak in 2009. Despite the recommendation that all pregnant women should get a flu shot, it is estimated fewer than 50-percent of women actually do. Researchers say that's because women are concerned about the possible effects of the shot on the developing baby.

We interviewed 4,191 mothers from four regional centers in the U.S. who had either delivered a baby with one of 41 specific birth defects or delivered an infant without defects.

We compared the use of the flu vaccine in the two groups during the 2009 – 2011 seasons. Dr. Carol Louik, ScD, lead investigator on the study said, "We found no evidence of an increase in risk for the most commonly-occurring specific major birth defects, which were the focus of the study, if a woman received the flu shot in pregnancy. Concerns about the risk of specific birth defects was a critical question that has not been considered very much until now, and our findings are reassuring." □

