



THE VOICE

for Women & Families

The First Cancer Vaccine

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National Research Center for Women & Families

We are dedicated to improving the health and safety of women, children, and families by using research to develop more effective programs and policies.

Join us for our Mother's Day Foremother Awards!

CFC # 11967

Since the Food and Drug Administration (FDA) approved Gardasil in 2006, the world's first cancer vaccine has attracted a great deal of public debate.

Gardasil vaccine protects girls and women, ages 9 through 26, from the two types of human papillomavirus (HPV) infection that are responsible for 70% of cervical cancer cases. Since the vaccine is not effective against the types of HPV that cause approximately 30% of cervical cancers, vaccinated women and girls will still need Pap smears to help detect cervical cancer in its early stages, when treatment is most effective.

Gardasil also provides immunity to two types of HPV that cause about 90% of all genital warts.

Is this vaccine a breakthrough in the war on cancer, or mostly hype? The National Research Center (NRC) for Women & Families has examined the research, scrutinized the role of the FDA, and is helping women, parents, the media, and policy makers understand what is known and not known about the risks and benefits of this vaccine.

HPV is a group of more than 120 viruses, some of which cause cervical cancer and genital warts. About 30 types of HPV spread through sexual contact greatly increase the risk of cancers around the anus and the genitals in males and females.

Many of the approximately 6 million Americans who are infected with genital HPV each year have no symptoms and do not even know that they are infected. Dr. Janet Phoenix, NRC's Policy Research Director, explains that most HPV infections are short-term. Women with persistent infections are more likely to develop cervical cancer. "In the United States, genital HPV infections cause more than 10,000 cases of cervical cancer per year and kill approximately 3,700 women. Throughout the world, HPV kills 288,000 women each year," Dr. Phoenix points out.

Who is Protected?

Dr. Diane Harper, a professor at Dartmouth Medical School, conducted the studies of the HPV vaccine that are the basis of the FDA's decision to approve Gardasil. A member of our National Research Network, Dr. Harper explained to us how HPV is spread and why the vaccine is just as important for girls as for women.

Dr. Harper tells us that the chances of HPV infection increase every time a woman has genital contact, even if there is no sexual intercourse, and that women are at risk of exposure to HPV throughout their entire life. "All it takes is skin-to-skin contact with an infected partner to acquire it, even if that partner is wearing a condom," she explains. "If a woman already is infected with one of the four types

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FDA Passes the Buck on Breast Implants

The FDA approved silicone gel breast implants for the first time in November, but only for women who are 22 or older. Because of serious concerns about safety, the FDA is requiring implant makers to study 80,000 women with breast implants for 10 years.

Previous studies evaluated women with breast implants for only 3 years. FDA's newly required studies are intended to determine longer-term safety.

The National Research Center (NRC) for Women & Families has been at the forefront of health and consumer groups urging the FDA to require better safety studies. "The FDA bowed to industry pressure to approve the implants despite all the concerns about long-term safety," says NRC president Dr. Diana Zuckerman. "Instead of making sure implants are safe before they approved them, they are leaving it up to women and their doctors to weigh the risks and benefits."

The FDA admits that most silicone implants leak for years without a woman or her plastic surgeon realizing it. Since silicone can leak into the lymph nodes under the arms, and from there to the lungs, liver, or other organs, the FDA warns women that they need to undergo breast MRIs three years after getting silicone gel breast implants, and every other year after that. MRIs are 86% accurate at determining if there is a rupture or leak in the breast implant. The FDA states that broken silicone gel implants should be removed as soon as possible. Women with saline breast implants do not need MRIs to detect rupture because saline implants deflate when they break.

The FDA decided that breast implants are "reasonably safe" for

most women for the 3 years that were studied. That does not mean safe for everyone. FDA scientists said that most women have at least one serious complication within 3 years of silicone or saline implants.

Complications to Expect?

Breast pain, breast hardness, and numbness in the nipple are common complications that may last for years, and may never go away.

One of the most serious complications is toxic shock syndrome, with several medical journal articles documenting patients who died or had gangrene as a result of breast augmentation surgery. These are rare.

"Every week we hear from women who want to have their leaking implants removed and can't afford to do so."

--Renee Carter, M.D.

One in three breast augmentation patients needs additional surgery within 5 years after implants, and most women will need surgery to remove a broken implant within 10 years. Implant problems are even more likely for breast cancer patients, with almost half needing additional surgery within 3 years.

Breast augmentation may interfere with breastfeeding. Unfortunately, no studies has been conducted to determine if a leaking implant could harm a nursing infant.

Do Breast Implants Cause Cancer?

Breast implants do not cause breast cancer, but they interfere with mammography. Mammograms can't see through breast implants, and research indicates they will miss the tumors of half of the augmented women who have breast cancer. And, according to a study by FDA scientists, mammograms can cause implants to rupture.

Researchers at the National Cancer Institute found that women with breast augmentation are more likely to die of brain cancer or lung cancer than other plastic surgery patients. Research is needed to find out if implants can cause these cancers.

Financial Implications

Most women pay \$4,000-6,000 for their first augmentation surgery with saline implants, and about \$1,000 more for silicone gel implants. But, the long-term costs are much higher.

Health insurance will not pay for breast augmentation or for MRIs needed to check for rupture. Most will not pay for any medical problems resulting from augmentation.

"Every week we hear from women who want to have their leaking implants removed and can't afford to do so," says Dr. Renee Carter, NRC's Medical Advisor. "Many women pay for breast augmentation on an installment plan or loan. Implants are especially risky for them, because they might still be paying off their augmentation surgery when serious implant problems arise. It often costs more to get implants removed than to have them put in, and many of these women just can't afford it."

Next Steps

NRC is working with the National Women's Health Network, Our Bodies Ourselves, NOW, African American Women in Touch, support groups for cancer patients and implant patients, other health and consumer organizations, and Congress to make sure the FDA requires better research and helps women understand all the risks.

Cancer Vaccine, *from page 1*

of HPV in the vaccine, getting the vaccine will still provide good protection from the other three types, although not from the one type that she was already exposed to."

HPV is so common that 80% of U.S. women are expected to have had an infection by the time they are 50 years old. Unlike diseases such as mumps or measles, people exposed to HPV do not necessarily build immunity. As a result, a woman can get the same HPV infection many times in her life.

Like most cancers, cervical cancer usually takes at least 15-20 years to develop, unless a person has a compromised immune system. Long after a woman has stopped being sexually active, or has been in a monogamous relationship, she can still get cervical cancer from HPV.

Women who did not have a Pap smear in the last 3 years before diagnosis with cervical cancer are more likely to die from the disease. Since the vaccine doesn't protect against all the kinds of HPV that cause cervical cancer, all women will still need Pap smears.

The U.S. Advisory Committee on Immunization Practices recommends that the vaccine be given routinely to all girls ages 11 and 12. Young girls are most likely to benefit from the vaccine, because they are less likely to have previously been exposed to HPV. The vaccine was not tested in women over 26, but there is some evidence that it may be less effective for women in their mid-20's and older. Research is needed to understand whether the vaccine has much benefit for these "older women" whether they have been sexually active or not.

Gardasil has been studied in clinical trials lasting only 5 years, so the long-term effectiveness and safety is

also unknown. Dr. Harper and other experts think it is likely that patients will need at least one booster shot for longer-lasting HPV prevention.

Unfortunately, Gardasil is expensive, consisting of three shots over a six-month period, costing about \$360. If the vaccine is given to 12-year-old girls and lasts only 5-10 years, they will need at least one booster to protect them through what is likely to be their most sexually active years. Girls and women who are uninsured or less affluent are unlikely to be able to afford to protect themselves from HPV, cervical cancer, and genital warts for their entire lives unless the cost is reduced dramatically.

Next Steps

Research has shown that immunizations required for school attendance are the most effective way to ensure widespread use of vaccines. That is why a policy that requires the HPV vaccine to be mandatory would be the best way to ensure that most girls are protected. It is up to each state to decide whether or not to require the HPV vaccine for school enrollment.

Mandatory requirements are controversial. Some parents and policy makers believe that giving young girls protection against sexually transmitted diseases results in girls becoming more sexually active. However, there are no studies that support these concerns.

Gardasil has the potential to save women's lives, but we don't know how many lives will actually be saved or how much life-long protection will cost. The vaccine needs to be studied for many more years to ensure that the vaccine is safe and effective over the long-term. Public health advocates agree it needs to be more affordable to be widely used.

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Can Policy Changes Reduce Kids' Obesity?

Childhood obesity is a major public health problem. Can Uncle Sam help parents help their children to lose weight?

Eating and exercise at home and with family is crucial, but what our children eat and how much they weigh is also influenced by what they do when they are not at home and not with their family. Many different policies -- at schools, in our communities, in restaurants, and elsewhere -- are also influential. Can changes in laws help parents and communities decrease obesity among their children? Is that likely to happen this year?

With a generous planning grant from the Robert Wood Johnson Foundation, NRC for Women & Families interviewed 36 Congressional staff members in the U.S. House of Representatives and U.S. Senate to ask them about childhood obesity issues and policy proposals on a national level. We discussed a wide range of policies that directly or indirectly could influence childhood obesity.

Many Congressional staff support laws that could directly influence what children eat, by providing useful information or healthier options in federal food programs. Some of the policies that attracted considerable support include:

- Funding model **obesity prevention projects** in communities where obesity is most common, such as low-income neighborhoods
- Requiring calorie information on **fast-food packaging**
- Reducing calories in the **School Breakfast and Lunch Program**
- Updating standards on other foods sold in schools, such as **school**

stores, vending machines, at extra-curricular activities or fundraisers



- Reducing calories in the **Food Stamp Program**

- Changes in the **Women, Infant, and Children (WIC) food program** for low-income mothers and their children, aimed at reducing calories (for example, providing low-fat milk and cheeses, and more fresh fruit and vegetables)

Harder Sells

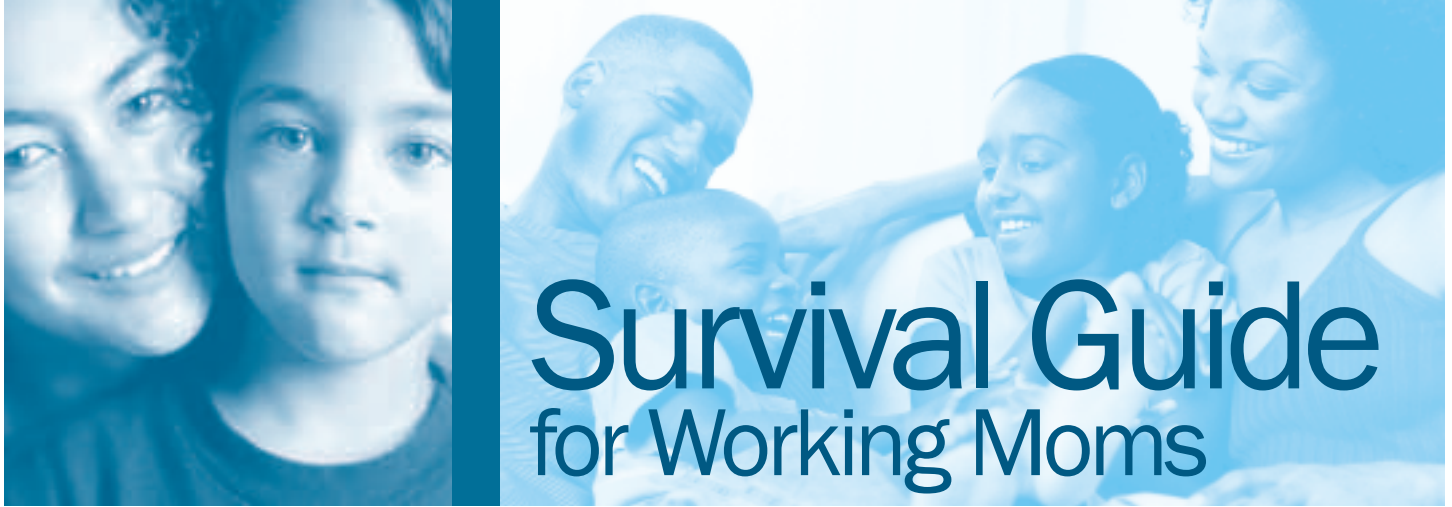
Congressional staff showed less enthusiasm for restricting advertising of fast food or junk food on children's TV programs, mainly because of concern about free speech. There was also less support for requiring that public schools mandate a minimum number of hours per month of physical education classes or recess, because the No Child Left Behind law has already put a great strain on many public schools.

What Would Work?

Nobody knows how effective public policy changes would be, but there is good reason to believe that they could help reduce childhood obesity. For example, removing high calorie drinks and snack foods from school vending machines could lower calorie consumption by at least 100 calories each week for every year a child spends in school. That could prevent a child from gaining several pounds every year. Even at 1-2 pounds per year, that would prevent children from gaining 12-24 pounds during their school years.

Would having calories listed on fast food packages influence eating habits? Ideally, that information should be on the menu, so that it influences what you order. In reality, it would be difficult to fit calorie information on the wall menus in fast food restaurants. If you've already bought a 600-calorie burger, 500-calorie bag of fries, and 300-calorie drink, chances are that seeing that information on your food packaging won't stop you from eating your meal. But, you may be less likely to go back for your free drink refill or dessert, and may be less likely to go back for the same fattening combo for at least a few days.

Keeping our kids a healthy weight requires a combination of more exercise and healthier choices of meals and snacks. Parents need to do a better job of limiting junk food and encouraging exercise, but for most families, the 6 hours that kids spend at school each day needs to be part of the strategy. Many parents would appreciate helpful policies and programs that encourage their children to eat healthier foods and get more exercise, and reduce high-calorie temptations during the school day.



Survival Guide for Working Moms

Are you getting enough sleep? Are your kids?

When it is time to get up in the morning, do you beg yourself for another 5 minutes? Do other family members need repeated coaxing to get out of bed? This morning ritual is not much fun, but the bigger issue is whether you and other family members are getting enough sleep to be productive and healthy, and avoid accidents.

How much is enough?

Many adults get 7 hours of sleep each night, and they think that is enough. But, research shows that your work performance, driving, ability to cope with stress, patience with your kids and co-workers — just about every aspect of your daily life — is harmed because 7 hours is simply not enough sleep to do your best. Just one more hour of sleep each night would mean you are less likely to lose your temper, less likely to have a car accident, and less likely to make a mistake at work.

If you're not sure if you need more sleep, here's a clue: people who have enough sleep at night do not nap during the day, even during a boring lecture or TV program.

Between the ages of 10 and 17, kids stay up later each night, but they have to get up earlier because middle school and high school schedules start earlier than elementary schools. According to Mary Carskadon, a researcher from Brown University, one in four high school students report 6.5 hours of sleep or less on average, but they really need more than 9 hours of sleep.

How does she know? In one study, when given no cues about what time it was, 10-year olds slept 9 hours and 20 minutes each night and woke up naturally. As the children got older, and their "biological rhythms" changed, they were more alert at night but still slept for the same amount of time, and they struggled to stay awake during the day.



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(continued from previous page) Sleeping late on weekends helps children and adults make up for their lack of sleep during the week, but it can also make it more difficult to go to sleep on Sunday night. It's like changing time zones every week. Sleep experts recommend keeping your weekend sleep schedule no more than 2 hours different from your weekday sleep schedule. For example, if you need to get up at 7 am during the week, get up by 9 am on weekends.

So, how do we make sure that we get enough sleep?

Many teens and adults depend on caffeine, nicotine, and other stimulants to stay awake. Colas have caffeine, but some sodas, such as Mountain Dew and Red Bull, have even more. By the end of the day, many children and adults are wide awake. They go to sleep too late and then need caffeine the next morning – starting the cycle all over again.

Parents need to set consistent rules about caffeine consumption and about bedtime. Avoid caffeine for at least 5 hours before bedtime – more, if possible. Take TVs and computers out of your child's bedroom if you want to control when they go to bed. If you enforce these rules with young children, it will be easier to maintain the rules as your child grows up. And it also helps to enforce the rules every day. Every time you give in just makes your children more likely to test those limits when you least want them to.

How does lack of sleep affect us?

Learning

Students are less able to pay attention or remember what they are learning in school when they do not get enough sleep. That's true for what you learn at work, too.

Safety

Lack of sleep has a similar effect as alcohol on judgment, reaction time, and driving skill. And as with alcohol, the teen or adult who is impaired from lack of sleep may not realize it. In fact, many of us who do not get enough sleep experience "sleep attacks" – unintentionally falling asleep for a few seconds. Sleep attacks might mean you miss some information if you're sitting in class or watching TV. They can be fatal if you are driving.

Smoking, Drinking, and Drugs

The impaired judgment that can cause car accidents also can result in making bad choices. As we all know, children can be easily swayed

by peer pressure, and lack of sleep makes them even less able to "just say no" or think ahead about negative consequences.

Conflicts with Family and Friends

Tired babies are cranky, and research shows that tired teens and adults are, too. This can contribute to constant tension and arguments between children and other family members, as well as road rage, gang fights, family violence, and other serious problems.

David Dinges, a professor at the University of Pennsylvania, conducted a study that allowed adults to sleep only 6 hours per night. He found that after a week the adults in the study were just as impaired as adults getting 8 hours of sleep per night who had gone without sleep for 48 hours straight. Since teens need more sleep than adults, Dinges believes that teens would be even more impaired.



“Every time you give in just makes your children more likely to test those limits when you least want them to.”

Will Children's Health Insurance Survive?

The State Children's Health Insurance Program (SCHIP) provides health care coverage to 6 million children who would be otherwise uninsured. It is due to expire at the end of September 2007.

SCHIP was signed into law by President Clinton in 1997 to provide federal funds to help states insure children whose family incomes are too high for Medicaid but too low to afford private health insurance. About 9 million children who are eligible for SCHIP coverage remain uninsured.

The program is very popular, but 14 states -- Alaska, Georgia, Illinois, Iowa, Maine, Maryland, Massachusetts, Minnesota, Mississippi, Missouri, Nebraska, New Jersey, Rhode Island and Wisconsin -- lack the federal funding to continue the current coverage through September 30, 2007. Approximately \$900 million more is needed to continue the program at the current levels for one more year. Last year, Congress passed a temporary fix to help the states that were most in need, but those funds will only last until May 2007.

In January, President Bush proposed major cuts in the SCHIP Program, starting in October 2007.

New bills have been proposed to protect or expand the program. In January 2007, Sen. Jay Rockefeller (WV) introduced S.401, the Keep Children Covered Act of 2007. This bill will eliminate the predicted shortfall in funds for this year. A joint bipartisan effort authored by U.S. Representatives Rahm Emanuel (IL), Jim Ramstad (MN), Mike Ross (AR), Ray LaHood (IL), Allyson Schwartz (FL), and Carol Shea-Porter (NH), titled the *Healthy Kids Act*, was announced in February. This law would increase children's access to

affordable health care, offer state incentives to make SCHIP more efficient, and provide families that



are not eligible for Medicaid or SCHIP with a Healthy Savings Tax Credit that can be used to purchase health coverage for their children. Sen. John Kerry (MA) and Rep. Henry Waxman (CA) have proposed bills, S. 95 and HR. 1111, respectively, which will amend sections of the Social Security Act to ensure universal healthcare coverage for all uninsured children. All the bills would make insurance more available for children, and vary in costs and strategies used.

NRC for Women & Families is working with other public health organizations to support efforts to expand the program to include more children. We point to evidence that this program works: children are more likely to receive needed preventive services. For information on how to contact your Congressional representatives to urge their support for this vital health program, see our web site, www.center4research.org, in the section on "Making a Difference."

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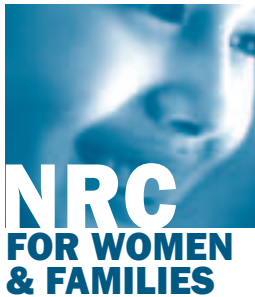
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