

NEWS RELEASE

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FOR IMMEDIATE RELEASE

LESSONS FROM FLU SEASONS PAST: RISK OF SERIOUS FLU-RELATED SICKNESS FAR OUTPACES RISK OF INJECTABLE VACCINE IN PREGNANT WOMEN

Pregnant women who catch the flu are at serious risk for flu-related complications, including death, and that risk far outweighs the risk of possible side effects from injectable vaccines containing killed virus, according to an extensive review of published research and data from previous flu seasons.

The review, a collaboration among scientists from the Johns Hopkins Children's Center, Emory University and Cincinnati Children's Hospital, and published online Oct. 22 in the American Journal of Obstetrics & Gynecology, found substantial and persistent evidence of high complication risk among pregnant women -- both healthy ones and those with underlying medical conditions -- infected with the flu virus, while confirming vaccine safety. The findings, researchers say, solidify existing CDC recommendations that make pregnant women the highest-priority group to receive both the H1N1 and seasonal flu vaccines.

"The lessons learned from flu outbreaks in the distant and not-too-distant past are clear and so are the messages," says lead investigator Pranita Tamma, M.D., an infectious disease specialist at the Johns Hopkins Children's Center. "If you are an expectant mother, get vaccinated. If you are a physician caring for pregnant women, urge your patients to get vaccinated."

Because even healthy pregnant women end up in the hospital with preventable flu complications -- some devastating and some fatal -- at a rate far higher than that of other adults, and because of the proven effectiveness and overall safety record of flu vaccines, all pregnant women should consider getting vaccinated to prevent complications in both the expectant mother and her offspring, researchers say.

"Healthcare providers will play a key role in women's decisions about whether or not to be vaccinated against H1N1," says study senior investigator Saad Omer, M.B.B.S., M.P.H. Ph.D., of Emory University.

"There is substantial evidence that vaccination is not only safe for pregnant women but that it is critical for protecting women and their infants against serious complications from the flu. Physicians and other providers should talk about risks and benefits with their patients and help alleviate any unfounded fears."

Even though there are still no published data on the safety of the new H1N1 vaccine, experts believe it to be just as safe as the seasonal flu vaccine, Johns Hopkins' Tamma says, because "the H1N1 vaccine is manufactured in the same rigorous way as the seasonal flu vaccines and we expect it to have a very similar safety profile as the other flu vaccines."

In their extensive review of data from three past flu pandemics and 11 published research studies on vaccine safety outcomes over 44 years, the researchers found no increased risk of either maternal complications or bad fetal results from the inactivated (injection) flu vaccine.

Researchers point out that even though study after study has found no link between the vaccine stabilizer thimerosal and autism, thimerosal-free injectable versions of the flu vaccine are available for those who have lingering concerns.

In their review, researchers say four studies have found evidence that antibodies protective against the flu, developed by the mother after vaccination, cross the placenta and transfer some protection to the fetus that lasts up to six months after birth.

Because pregnancy causes a variety of changes in the body, most notably decreased lung capacity, along with increased cardiac output and oxygen consumption, it puts pregnant women at high risk for complications. In addition, parts of the mother's immune system are selectively suppressed, a process that offers essential protection to the fetus, but decreases the mother's ability to fight off infection.

Other findings in the review:

In the first four months of the H1N1 flu outbreak this spring,

- pregnant women were hospitalized at four times the rate of other healthy adults infected with the virus, according to the CDC.
- Pregnant women made up 13 percent of all H1N1 deaths during that period, and most of the women who died were previously healthy.
- Pregnant women do not get infected with the flu more often than other adults, but they develop more serious complications and more often.
- Pregnant women with underlying conditions such as asthma or diabetes are at even higher risk for complications.
- During the 1918 Spanish flu pandemic, of the 1,350 flu-infected pregnant women who were studied, half developed pneumonia, and more than half of those who did so died, with most deaths occurring during the third trimester.
- During the 1957 pandemic, nearly half of all women of childbearing age who died of the flu were pregnant.
- Eleven clinical studies closely followed pregnant women and/or their fetuses after vaccination and found no evidence of harmful side effects in either the mother or the fetus.
- The Vaccine Adverse Event Reporting System database, a national repository of self-reports of adverse vaccine effects, showed 26 reports of adverse effects between 2000 and 2003, a period during which 2 million pregnant women were vaccinated against the flu. Of the 26 reports, six had to do with wrongly administered vaccine without any negative consequences; nine reports described brief injection site tenderness; eight involved systemic symptoms, such as malaise and fever; and three were miscarriages. Investigators point out that these are self-reported events and do not establish any evidence of cause and effect either with respect to either miscarriage or side effects.

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