

University of Maryland Medical Center

The University of Maryland Medical Center is listed as part of the National Institutes of Health (NIH) Vaccine Trials Network and that have been included in trials of Flu vaccine, HIV Vaccine, Avian Flu Vaccine,

The University of Maryland information from its own site:<http://www.umm.edu/pediatrics/research.html>

Center for Vaccine Development

Back in 1974, Myron Levine, M.D., and Richard Hornick, M.D., established the Clinical Research Center for Vaccine Development at the University of Maryland Medical Center. In 1976, because of its expanded work-scope and size, the Clinical Research Center was renamed the Center for Vaccine Development (CVD).

The CVD rapidly became an international leader in vaccine research. It has earned a reputation for the genetic engineering of new vaccine candidates against cholera, typhoid fever, shigellosis and malaria, as well as for the innovative clinical evaluation of a variety of new vaccines.

The CVD is unique in that it incorporates within it the full range of vaccinology activities. It initiates basic laboratory science programs to generate new vaccine candidates and follows those candidates through clinical evaluation, field studies and, finally, public policy analysis.

The Center is dedicated to controlling infectious diseases that afflict children and adults throughout the United States and in developing countries. The Center is involved in projects to control cholera, typhoid fever, malaria, shigellosis, E. coli diarrheal disease and invasive infections (such as meningitis) caused by Haemophilus influenzae type b, pneumococcus and meningococcus. The CVD maintains field units in Chile and Mali, which help it to fulfill its mission in developing countries.

In 2000, the CVD received a \$20.4 million, five-year grant from the Bill and Melinda Gates Foundation to develop a "stealth" measles vaccine. This vaccine is being designed to protect infants in sub-Saharan Africa and other developing regions of the world who are at high risk of developing severe or fatal measles, but who are too young to receive the current measles vaccine.

Despite the fact that there already exists a measles vaccine, about 900,000 infants and young children continue to die each year from measles in developing countries, particularly in sub-Saharan Africa. One of the reasons for this is that, based on World Health Organization recommendations, the current measles vaccine should not be given to infants younger than 9 months of age.

The period from about 4 to 8 months of age, however, represents a high-risk period for infants in developing countries, where measles is common and the chance of exposure is high. When measles is contracted during this young age, the disease is often severe. Up to 20 percent of exposed infants may suffer fatal outcomes.

CVD researchers think that it may be possible to successfully protect infants younger than 9 months of age using a new vaccine that applies advances in biotechnology. Instead of injecting the measles vaccine, researchers prefer administering DNA vaccines and "live vector" vaccines via mucosal surfaces -- either orally or by nose drops.

As Director of the Center for Vaccine Development and lead investigator of the Stealth Measles Vaccine Project, Levine is directing the effort to develop a mucosally delivered measles vaccine. Levine and a team of researchers are preparing for early clinical trials of the new vaccine to be conducted in Mali and Mozambique. It will take a collaboration of genetic engineers, immunologists, epidemiologists and clinical vaccine specialists from several different medical organizations around the world to complete the trials.

WHAT ARE THE VACCINES FOR MEASLES, MUMPS, AND RUBELLA?

Before the vaccine became available, about 56,000 cases of rubella occurred annually in the US. *Rubella (German Measles)*. When rubella, commonly known as German measles, infects children or adults, it causes a mild illness that includes a rash, enlarged lymph nodes, and sometimes a fever.

Side Effects of Live Measles Mumps-Rubella (MMR) Vaccines

Common side effects from the MMR vaccination include fever, rash, and joint pain. Children are more likely to experience such side effects from the second dose (at 10 to 12 years) than from the first (at four to six years).

Fever. About 5% to 15% of people who are vaccinated with any live measles virus vaccine develop a fever of 103 degrees or greater, usually between five and 15 days after the vaccination. It usually lasts one or two days but can persist up to five days. In very young children, seizures can occur from high fever eight to 14 days after vaccination, but they are rare and almost never have any long-term effects.

Swollen Glands. The live-mumps vaccine can cause mild swelling in the glands that are situated near the ears.

Joint Pain. Up to 25% of women have joint pain one to three weeks after a vaccination with a live-rubella virus; it lasts for one day to three weeks. Such pain does not usually interrupt daily activities. Rarely, it recurs or becomes persistent.

Allergic Reaction. People who have known anaphylactic allergies (very severe reactions) to eggs or to neomycin are at high risk for a severe allergic response to the MMR vaccine. People with allergies that do not cause anaphylactic shock to these substances are not at higher risk for a serious allergic reaction to the vaccine. Mild allergic reactions may occur in some people, including rash and itching. A rash occurs in about 5% of people who are vaccinated with a live-measles vaccine. A live-mumps vaccination has caused rash and itching, but these symptoms are usually mild.

Interaction with Tuberculosis Test. The live-measles vaccine may interfere with a tuberculosis test, so the two should be administered at least four to six weeks apart. No evidence exists that the vaccine has an adverse effect on tuberculosis itself.

Mild Infection. One study suggests that a mild form of measles that has no symptoms may develop in previously immunized people who are exposed to the virus, although this mild infection may not be significant.

Severe Side Effects. Much controversy has arisen over severe side effects of the MMR. This is of great concern since the evidence of any serious problems is very weak and studies refuting them tend to be stronger. It should be noted that in 2000, measles caused about a million deaths in children in countries where the vaccine is not used.

Researchers have confirmed that MMR can cause a rare bleeding disorder called idiopathic thrombocytopenic purpura (ITP). This can cause a purple bruise-like discolorations that can spread across the body, nosebleeds, or tiny red spots. It is nearly always mild and temporary. The risk for this is about one in 22,300 doses. (The risk is much higher with the actual infections, particularly rubella.)

There have been a few reports of encephalitis (inflammation in the brain) associated with the live-measles vaccine, although the incidence of these events is no higher in immunized children than in nonimmunized children. (Encephalitis is extremely rare in either case).

Much publicity has centered on a possible link between the MMR vaccine, which was introduced in 1988, and a variant of autism that includes inflammatory bowel disease (IBD) and impaired behavioral development. Such findings have been rigorously reviewed and refuted in a number of well-conducted studies. Of special note was a 2002 analysis of vaccinations records of children with autism, with or without behavioral problems and gastrointestinal disorders who were born between 1979 and 1998. It found no higher incidence in autism during those years. (Reports of symptoms related to autism did increase after widespread publicity of this supposed side effect.) In the study, there was a link between impaired behavioral development and bowel problems, but they were not related to the vaccine.