



The University of Vermont
VACCINE TESTING CENTER

Information for Study Volunteers receiving the NIH Tetravalent Dengue Vaccine

January 2018

Summary: Recent news has highlighted concerns about a dengue vaccine made by the company Sanofi Pasteur and called Dengvaxia[®]. This is not the same vaccine as the one we are studying.

Concerns about that vaccine relate to observations of people living in areas where Dengue viruses exist and only among those who have received the Dengvaxia[®] vaccine. New studies have shown that people living in areas where dengue exists who have never had dengue infection, who are then vaccinated with Dengvaxia[®], are at higher risk for developing illness due to the dengue viruses or being hospitalized for dengue after vaccination.

On the other hand, when someone who has been previously infected with dengue is vaccinated with Dengvaxia[®], they appear to be protected against future dengue illnesses.

As a result of this data, the manufacturer (Sanofi Pasteur) announced it was changing the labeling on the vaccine to limit its use to people with previous exposure to dengue virus.

Detailed information: There are 4 different serotypes, or strains, of dengue. They are known as dengue 1, dengue 2, dengue 3 and dengue 4. Infection with one serotype provides long-lived immunity or protection to that particular serotype and protection against the other 3 that diminishes over time. After the short-lived protection to the other 3 serotypes wanes, it may predispose individuals to a more severe form of dengue if they are infected with one of these other 3 serotypes.

For this reason, a successful dengue vaccine needs to provide a well-balanced response to all 4 of the dengue serotypes. One of the concerns has been that if a vaccine does not provide a well-balanced response, it may put vaccine recipients at risk of more severe disease if they are infected with dengue following vaccination. For example, if a vaccine provided a very strong response to dengue 4 but a much smaller response against dengue 1, 2, or 3, then infection with dengue 1, 2, or 3 after vaccination might lead to more severe disease. This appears to be what is observed with Dengvaxia[®].

What does this mean for the current Dengue Vaccine trial at UVM?

It is important to note that the National Institutes of Health (NIH) dengue vaccine currently being studied here at UVM is a different vaccine than Sanofi Pasteur's Dengvaxia®. There are several differences between the two vaccines, which may contribute to the findings with Dengvaxia:

- 1) The Sanofi vaccine is built on a “backbone” of another vaccine for Yellow Fever and therefore may not contain sufficient dengue components for a complete immune response. The NIH (UVM) vaccine only contained dengue components.
- 2) The NIH vaccine appears to foster a far more balanced response to dengue 1-4 (all four serotypes), which is hoped to avoid the risk of dengue disease following vaccination.

Who Can I talk to if I have questions?

- 1) You can call the Vaccine Testing Center at 802-656-0013 to speak to a study team member.