



## What sort of testing goes on before and after a vaccine is given to a child?

MARK SAWYER, MD: Vaccines are tested very extensively before they even reach the marketplace. Clinical trials are done in the population for which the vaccine is intended to be used and usually hundreds, if not thousands, of people are studied.

PAUL A. OFFIT, MD: So for example, the rotavirus vaccines—and there are two currently that are being distributed—were tested in more than 60,000 children for each of the vaccines. It took 20 years to develop those vaccines. So those vaccines have been in children for a long time, and the safety testing is quite extensive. A typical development program for a vaccine costs about a billion dollars.

There is a vaccine to prevent a common cause of cervical cancer, called the human papilloma virus vaccine that was tested in 30,000 women for seven years before it was ever licensed. I think drugs never undergo that kind of scrutiny. Vaccines really are held to a very high standard of safety. That's why they cost so much to develop. But again, they're given to healthy people so they should be held to that high level.

MARK SAWYER, MD: But perhaps even more important than that, and something I think a lot of people don't know, is *after* a vaccine is already on the market, it continues to be studied. And that way we can find very rare side effects from a vaccine because we only see those after millions and millions of people get the vaccine.

PAUL A. OFFIT, MD: There are a couple ways in which we monitor safety. One is something called the Vaccine Adverse Events Reporting System, or VAERS, whereby people who get a vaccine—the doctors or nurses or the person themselves or the parent—can report any possible side effect. And that raises the question of whether or not the vaccine could have actually caused it. And then to *test* that question, to answer that question, there's something called the Vaccine Safety Data Link, which is this computerized network of people who receive vaccines or don't receive vaccines, so you can really very quickly test whether or not there's a problem.