Vaccines: Research to Market

1. New vaccines are rigorously/extensively tested in the lab before clinical trials.
2. Vaccine trials on people are regulated by the FDA to ensure the safety of the volunteers. There are three phases of clinical trials. Vaccines are tested on adult volunteers first. Each phase includes more volunteers to simulate a broader population of possible recipients.
3. A vaccine is licensed by the FDA only if it is safe, effective and the benefits outweigh the risks.
4. A batch of vaccines is called a lot. Lots of vaccines are released to the public after the FDA reviews the testing done by the manufacturer. Each lot must be tested by the manufacturer to make sure it is safe, pure and potent. The FDA inspects manufacturers to ensure quality and safety.

Vaccines: Getting on the U.S. Recommended Immunization Schedule

1. The Advisory Council on Immunization Practices (ACIP), which includes child health experts from the National Association of Pediatric Nurse Practitioners (NAPNAP), the American Academy of Pediatrics (AAP) and the American Academy of Family Physicians (AAFP), reviews all the available data from the clinical trials and other studies to make recommendations for a vaccine’s use relevant to age and disease prevention.
2. A vaccine is added to the immunization schedule after the ACIP recommendations are reviewed and approved by the CDC Director.

Vaccines: Continuous Monitoring

1. Once added to the schedule, safety and risks versus benefits are continually monitored by the FDA & CDC through:
   a. The Vaccine Adverse Event Reporting System [VAERS]
   b. The Vaccine Safety Datalink [VSD]
2. Safety monitoring may show that a recommendation for a vaccine may need to change.
3. Continual monitoring of vaccines ensures the vaccine supply remains safe and effective.