

PEDIATRIC VACCINE STOCKPILES WHAT IS THE PUBLIC HEALTH ISSUE?

In 2001-2004, the US experienced shortages of vaccines against eight diseases prevented through routine vaccination of children and adolescents. This situation led the Advisory Committee on Immunization Practices, the American Academy of Pediatrics, and the American Academy of Family Physicians to recommend deferral of certain vaccinations and to set priorities for high-risk patients until vaccine supplies returned to normal. While necessary to address supply concerns, these deferrals place children at an increased risk to infectious diseases that are otherwise preventable.

Vaccine stockpiles, first developed by CDC in 1983, can be used to interrupt disease outbreak situations and amelio¬rate short-term production problems, which are likely to occur from time to time. The pediatric vaccine stockpiles use dynamic inventory systems in which vaccine stock is rotated; as older vaccines are rotated into the market for use, fresh doses of vaccines enter the stockpiles. Stockpiles do not currently exist for all recommended childhood vaccines. In light of recent vaccine shortages and increased concerns about an influenza pandemic or bioterrorism event, expansion of CDC's stockpiles has become a pressing public health need.

CDC has been working to acquire a six-month national supply of all recommended childhood vaccines for use in case of supply disruptions or outbreaks of vaccine-preventable diseases. Completion of the stockpile purchases will take time because the vaccine manufacturing capacity is limited. CDC is currently working with each manufacturer to jointly identify potential opportunities for CDC to purchase additional vaccines for the pediatric vaccine stockpile. CDC continues to work with each manufacturer to maintain and manage their storage and maintenance contracts which provide guidance regarding the maintenance of each vaccine in the stockpiles.

WHAT HAS CDC ACCOMPLISHED?

The Department of Health and Human Services' Office of General Counsel reviewed the legal authority of the *Omnibus Reconciliation Act* (OBRA) of 1993 legislation and confirmed the Secretary's authority under current law to build Vaccines for Children (VFC) program stockpiles equal to the amount needed for the U.S. pediatric population for 6 months of routinely recommended vaccines. In 2003, CDC began purchasing vaccine for expanded national pediatric stockpiles with the \$172 million of VFC funds apportioned for the stockpile. CDC has purchased 6-month stockpiles of measles, mumps, rubella (MMR), varicella, and inactivated polio (IPV) vaccines. CDC has also purchased partial stockpiles of hepatitis B, hepatitis A, pneumococcal conjugate (PCV), *Haemophilus influenzae type b* (Hib), hepatitis B, diphtheria, tetanus and acellular pertussis vaccines, a combination vaccine containing DTaP, IPV, and hepatitis B, rotavirus, and a combination vaccine containing hepatitis B and Hib. CDC plans to continue purchasing those vaccines and others, including new and combination vaccines, for the stockpiles.

With input from key stakeholders, CDC is committed to its strategic plan to purchase additional vaccine for the national pediatric vaccine stockpile program. The plan addresses the Government Accountability Office's (GAO) recommendations about the number of doses needed nationally, vaccine form (e.g., bulk, filled, labeled, packaged), storage location, and maintenance.

WHAT ARE THE NEXT STEPS

CDC is continuing to buy vaccine for the stockpile. Consideration is being given to the correct composition of the stockpile, so that vaccines are available as needed.

February 2007