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VACCINE SHORTAGES TRIGGER EXCLUSION EXEMPTIONS

LIKE THE REST OF THE NATION, Oregon is currently experiencing shortages of tetanus-diphtheria vaccine (“adult” Td, for persons ≥ 7 years of age), 7-valent pneumococcal conjugate vaccine (PCV7), varicella vaccine, and Comvax® (*Haemophilus influenzae* type b (Hib)/hepatitis B vaccine). Comvax® will be in short supply at least through March 2002, and the other shortages are expected to continue through mid-year. Spot shortages of additional vaccines are probable through the summer of 2002.

Today’s supply problems are multifactorial, complex, and different for each vaccine. The issues include manufacturer withdrawal from the market, difficulty in complying with good manufacturing practices established by the Food and Drug Administration, and insufficient reserve vaccine supplies.

The Advisory Committee on Immunization Practices (ACIP) has issued revised recommendations to optimize use of tetanus-diphtheria (Td) vaccine, pneumococcal conjugate (PCV7) vaccine and diphtheria-tetanus-acellular pertussis (DTaP) vaccine until supplies are adequate. This issue of *CD Summary* reviews these recommendations and the effect of the vaccine shortages on the upcoming school and day-care immunization exclusion cycle.

TETANUS-DIPHTHERIA

The shortage of Td vaccine spotted more than a year ago^{2,3} was not improved by Wyeth Lederle’s withdrawal from this

particular market. Fortunately, this shortage does not affect children <7 years old, because instead of Td, they should receive DTaP or pediatric DT vaccine. For everyone ≥ 7 years old, Td vaccine administration should be prioritized as follows (highest to lowest):^{1,2,3}

1. persons traveling to a country where the risk for diphtheria is high (Table);
2. persons requiring tetanus vaccination for prophylaxis in wound management;
3. persons who have received fewer than 3 doses of any vaccine containing tetanus and diphtheria toxoids;
4. pregnant women and persons at occupational risk for tetanus-prone injuries who have not been vaccinated with Td within the preceding 10 years.

DTaP

While the ACIP has recommended deferral of doses 4 and 5, Oregon providers should not defer, at least through February. CDC has guaranteed Oregon adequate supply to cover school exclusions.

PNEUMOCOCCAL CONJUGATE

Provider demand for PCV7 has been much greater than anticipated. Normally, we wouldn’t complain about such zeal, but it has apparently surprised the manufacturer and strained the vaccine supply. Adding to the shortfall have been several “manufacturing difficulties” that have thwarted production at full capacity for the past several months.⁴

The guiding principles for administering PCV7 during this shortage are:

- decrease the number of doses administered to each healthy infant. (The main efficacy trial for PCV7 found even a single dose to provide substantial protection.⁵)
- All providers (regardless of their own supply) should reduce their PCV7 use, because otherwise, there won’t be enough for the high-risk kids. Specific recommendations are as follows:
 - for *high-risk* children <5 years of age, the vaccination schedule recommended by ACIP in October 2000 should be followed.⁶ The high-risk group includes children with sickle-cell disease and other hemoglobinopathies; anatomic asplenia; chronic disease including chronic cardiac or pulmonary disease and diabetes mellitus; cerebrospinal fluid leak; HIV infection; immunocompromising conditions; immunosuppressive chemotherapy or long-term systemic corticosteroids use; and those who have received a solid organ transplant;
 - for *healthy* infants and children <24 months old, modify the vaccination schedule based on estimates of your own vaccine supply and on the age at which vaccination is initiated, as indicated in the Table (*verso*).

Keep a list of children for whom conjugate vaccine has been deferred so that it can be administered when the supply is adequate.

VARICELLA

Although ACIP has not issued revised recommendations regarding this vaccine, it is currently in very short supply in Oregon.

WHAT ABOUT SCHOOL REQUIREMENTS?

Oregon law requires a passel of immunizations for children attending school or day care.⁷ However, to assure that children are not denied attendance at school or day care because of vaccine-supply problems,

Countries with high risk for diphtheria^{1,2,3}

Africa	Algeria, Egypt, and sub-Saharan Africa (Angola, Benin, Burkina Faso, Burundi, Cameroon, Cape Verde, Central African Republic, Chad, Comoros, Congo, Cote d’Ivoire and the Democratic Republic of Congo)
Americas	Brazil, Dominican Republic, Ecuador and Haiti
Asia/Oceania	Afghanistan, Bangladesh, Cambodia, China, India, Indonesia, Iran, Iraq, Laos, Mongolia, Myanmar, Nepal, Pakistan, Philippines, Syria, Thailand, Turkey, Vietnam and Yemen
Europe	Albania and all countries of the former Soviet Union (Armenia, Azerbaijan, Belarus, Estonia, Georgia, Kazakhstan, Kyrgyz Republic, Latvia, Lithuania, Moldova, Tajikistan, Turkmenistan, Ukraine and Uzbekistan)



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Oregon State Public Health Officer Dr. Grant Higginson has temporarily suspended requirements for *Td* and *Varicella* vaccines; requirements for other vaccines retain their force, and children without legally-allowable exemptions who lack documentation of tetanus-diphtheria, polio, measles/mumps/rubella (MMR), hepatitis B, or Hib vaccination will be excluded. (PCV7 is not an issue, because, although recommended, it is not currently required for day care.)

For the duration, we ask for your continued diligent attention to the following:

- maintain contact with your Vaccines For Children representative if you experience any vaccine shortages. We have been able to avert many deferrals by trading and borrowing vaccine in each community. We can only do that if we hear from you;
- continue to immunize every child due

for vaccines, with each currently recommended vaccine that you have in stock. Remember to use the modified schedules included here.

For questions about the review/exclusion cycle, please contact: Amanda Timmons, School Law Coordinator: 503/731-4564.

If unable to reach Amanda, please call: Lorraine Duncan, Immunization Program Manager: 503/731-4135, or Mimi Luther, VFC/Vaccine Manager: 503/731-4267.

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3. CDC. Deferral of routine booster doses of tetanus and diphtheria toxoids for adolescents and adults. *MMWR* 2001;50(20):418,427.
4. CDC. ACIP votes to temporarily revise recommendations for PCV7 and to continue previous DTaP recommendations [press release]. December 7, 2001. At <http://www.cdc.gov/nip/news/shortages/pneumo-and-dtap.htm>.
5. Black S, Shinefield H, Fireman B, et al. Efficacy, safety and immunogenicity of heptavalent pneumococcal conjugate vaccine in children. Northern California Kaiser Permanente Vaccine Study Center Group. *Pediatr Infect Dis J*. 2000;19:187-955.
6. CDC. Pneumococcal conjugate vaccine use in a setting of vaccine shortage: updated recommendations of the Advisory Committee on Immunization Practices. *MMWR* 2001;50:1140-1142. At <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5050a4.htm> or (same CDC prefix) [mmwr/PDF/wk/mm5050.pdf](http://www.cdc.gov/mmwr/PDF/wk/mm5050.pdf) (see page 12) and <http://www.cdc.gov/nip/news/shortages/pneumo-and-dtap.htm>.
7. Oregon Administrative Rules 333-050-0010-0120.

ACIP recommendations—PCV7 vaccination⁶

Age of first PCV7 vaccination	No shortage*	Moderate shortage (shortfall estimated at <25%)	Severe shortage (shortfall estimated at ≥25%)
<6 months	2, 4, 6, and 12-15 months	2, 4, and 6 months (defer 4 th dose)	2 doses at 2-month interval in 1 st 6 months of life (defer 3 rd and 4 th doses)
7-11 months	2 doses at 2-month interval; 12-15 month dose	2 doses at 2-month interval; 12-15 month dose	2 doses at 2-month interval (defer 3 rd dose)
12-23 months	2 doses at 2-month interval	2 doses at 2-month interval	1 dose (defer 2 nd dose)
24 months	1 dose should be considered	No vaccination	No vaccination
Reduction in vaccine doses used		21%	46%

The "no shortage" column is given for reference, but at this time, there is insufficient vaccine to follow these original recommendations for healthy children <2years old