The purpose of this statement is to update previous information and recommendations provided by the Committee for the use of Haemophilus influenzae type b conjugate vaccines in view of the licensure of a new product. Our initial recommendations concerned the use of PRP-D, a vaccine consisting of the capsular polysaccharide of H influenzae type b conjugated to diphtheria toxoid, which was licensed for use in December 1987.

On December 22, 1988, a second conjugate vaccine was licensed by the US Food and Drug Administration for the prevention of infections caused by H influenzae type b in children 18 months of age or older. This newly licensed vaccine is a conjugate of H influenzae type b capsular oligosaccharide and a nontoxic mutant diphtheria toxin protein molecule called CRM197. The official designation of this vaccine is “Haemophilus b conjugate vaccine (diphtheria CRM197 protein conjugate)” and it is often referred to as HbOC.

No serious adverse reactions have been reported in clinical trials to date. Among 265 infants in the United States between 16 and 23 months of age who received HbOC, 7.2% had temperatures exceeding 38°C, 1.5% had erythema and warmth at the injection site, and 0.8% had localized swelling. Like PRP-D, HbOC is more immunogenic in 18-month-old children than are the unconjugated polysaccharide vaccines (PRP). Among 212 HbOC recipients in the study, the geometric mean antcapsular antibody concentration 1 month after immunization was 13.11 μg/mL. Moreover, 98.1% of these infants had an antibody concentration in excess of 1 μg/mL, a concentration associated with protection in a Finnish field trial of unconjugated PRP. Thus, although no efficacy study has been performed with HbOC in children 18 months or older, the decision to license HbOC (and PRP-D before it) was based on the enhanced immunogenicity of this vaccine at this age compared with the response elicited by unconjugated PRP.

RECOMMENDATIONS
1. The Committee continues to recommend that all children receive a single dose of a H influenzae type b conjugate vaccine at 18 months of age. At this point, the Committee considers that the cost, safety, indications, and inferred efficacy at this age are likely to be equivalent for PRP-D and HbOC, the two conjugate vaccines currently licensed. Thus, reference is made to previous recommendations regarding the use of PRP-D in which either HbOC or PRP-D may be used.
2. Children immunized with PRP-D or HbOC need not be immunized with other H influenzae type b vaccines.
3. There are no known contraindications to simultaneous administration of HbOC and polio vaccines (inactivated polio vaccine or oral polio vaccine), measles-mumps-rubella, or diphtheria-tetanus-pertussis, although information regarding the safety and serologic interactions of these vaccine combinations awaits publication of data from ongoing clinical trials.
4. Efficacy trials involving these and other conjugate vaccines in infants younger than 18 months of age are in progress. It is hoped that one or more of these vaccines will prove effective in younger
infants and that their use in young infants can be recommended in the future.

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