

Committee on Drugs

**Naloxone Dosage and Route of Administration  
for Infants and Children: Addendum to  
Emergency Drug Doses for  
Infants and Children**

The following addendum from the Committee on Drugs was prepared in response to numerous requests for reference material or rationale to support the dosage of naloxone for infants and children<sup>1</sup> currently recommended by the Committee on Drugs.

The currently recommended dose of naloxone is 0.1 mg/kg for infants and children from birth to 5 years of age or 20 kg of body weight. Children older than 5 years of age or weighing more than 20 kg may be given 2.0 mg. These doses may be repeated as needed to maintain opiate reversal.<sup>1</sup> The higher dose recommendation is based, in part, on a concern that 0.01 mg/kg, currently recommended in approved labeling, may not provide optimal opiate reversal in some infants.<sup>2</sup> In addition, it is intended to simplify naloxone dosing and provide greater probability of optimal opiate reversal in most patients.

Because doses as high as 0.4 mg/kg have been administered to newborns without ill effect,<sup>3</sup> it is felt that the higher dose poses no increased risk. Naloxone doses ranging from 0.005 to 0.4 mg/kg have been reported in the pediatric literature.<sup>2-10</sup> Individual doses up to 0.4 mg/kg<sup>3</sup> and constant intravenous infusion of 0.16 mg/kg/h for 5 days<sup>4</sup> have not been associated with naloxone-related adverse effects. The average half-life of naloxone in premature newborns is 70 minutes.<sup>5</sup>

The Committee's naloxone dosing recommendation has been incorporated recently into the joint American Heart Association (AHA)/American Academy of Pediatrics (AAP) textbook on neonatal resuscitation<sup>11</sup> and the accompanying test mate-

rials. However, a discrepancy persists between the routes of administration recommended by the Committee and the routes of administration recommended in the AHA/AAP neonatal resuscitation guidelines. The AHA/AAP neonatal resuscitation guidelines suggest that naloxone be administered intravenously, intramuscularly, subcutaneously, or intratracheally. The Committee has recommended the intravenous and intratracheal routes consistently. Although there are no well-controlled studies in infants and children directly comparing the intravenous and intratracheal vs intramuscular or subcutaneous routes of administration, the Committee's recommendation is based on a concern that absorption of intramuscularly or subcutaneously injected medication may be erratic and/or delayed in the patient who is hypotensive, hypoperfused, and/or peripherally vasoconstricted.

COMMITTEE ON DRUGS, 1989-1990

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The recommendations in this statement do not indicate an exclusive course of treatment or procedure to be followed. Variations, taking into account individual circumstances, may be appropriate.

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