

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

Ralph E. Kauffman, MD, Chairman  
William Banner, Jr, MD  
Jeffrey L. Blumer, MD  
Richard L. Gorman, MD  
George H. Lambert, MD  
Wayne Snodgrass, MD

Liaison Representatives

Donald R. Bennett, MD, PhD, American Medical Association  
Jose F. Cordero, MD, MPH, Centers for Disease Control  
Sharon Dooley, MD, American College of Obstetricians and Gynecologists  
Sam A. Lucata, MD, National Health and Welfare, Health Protection Branch, Canada  
Robert Peterson, MD, Canadian Paediatric Society  
John C. Petricciani, MD, Pharmaceutical Manufacturers' Association

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.

PEDIATRICS (ISSN 0031 4005). Copyright © 1990 by the American Academy of Pediatrics.

Gloria Troendle, MD, Food and Drug  
Administration  
Sumner J. Yaffe, MD, National Institute of  
Child Health and Human Development

AAP Section Liaison  
Cheston M. Berlin, MD, Section on Clinical  
Pharmacology

Consultants  
Mary Ellen Mortensen, MD  
Anthony R. Temple, MD

#### REFERENCES

1. American Academy of Pediatrics, Committee on Drugs. Emergency drug doses for infants and children and naloxone use in newborns: clarification. *Pediatrics*. 1989;83:803
2. Weiner PC, Hogg MIJ, Rosen M. Effects of naloxone on pethidine-induced neonatal depression. *Br Med J*. 1977;2:228-231
3. Chernick V, Manfreda J, DeBooy V, et al. Clinical trial of naloxone in birth asphyxia. *J Pediatr*. 1988;113:519-525
4. Tenebein M. Continuous naloxone infusion for opiate poisoning in infancy. *J Pediatr*. 1984;105:645-648
5. Stile LI, Fort M, Wurbruger RJ, et al. The pharmacokinetics of naloxone in the premature newborn. *Dev Pharmacol Ther*. 1987;10:454-459
6. Welles B, Belfrage P, de Chateau P. Effects of naloxone on newborn infant behavior after maternal analgesia with pethidine during labor. *Acta Obstet Gynecol Scand*. 1984;63:617-619
7. Fischer CG, Cook DR. The respiratory and narcotic antagonistic effects of naloxone in infants. *Anesth Analg*. 1974;53:849-852
8. Brice JEH, Moreland TA, Walker CHM. Effects of pethidine and its antagonists on the newborn. *Arch Dis Child*. 1979;54:356-361
9. Evans JM, Hogg MIJ, Rosen M. Reversal of narcotic depression in the neonate by naloxone. *Br Med J*. 1976;2:1098-1100
10. Gerhardt T, Bancalari E, Cohen H, et al. Use of naloxone to reverse narcotic respiratory depression in the newborn infant. *J Pediatr*. 1977;90:1009-1012
11. Bloom RS, Cropley C, eds. *Textbook of Neonatal Resuscitation*. Dallas, TX: American Heart Association/American Academy of Pediatrics; 1987.

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

Committee on Drugs  
*Pediatrics* 1990;86;484

**Updated Information &  
Services**

including high resolution figures, can be found at:  
<http://pediatrics.aappublications.org/content/86/3/484>

**Permissions & Licensing**

Information about reproducing this article in parts (figures, tables) or in its  
entirety can be found online at:  
<http://www.aappublications.org/site/misc/Permissions.xhtml>

**Reprints**

Information about ordering reprints can be found online:  
<http://www.aappublications.org/site/misc/reprints.xhtml>

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®



# PEDIATRICS®

OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

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

Committee on Drugs  
*Pediatrics* 1990;86;484

The online version of this article, along with updated information and services, is located on the World Wide Web at:

<http://pediatrics.aappublications.org/content/86/3/484>

Pediatrics is the official journal of the American Academy of Pediatrics. A monthly publication, it has been published continuously since 1948. Pediatrics is owned, published, and trademarked by the American Academy of Pediatrics, 345 Park Avenue, Itasca, Illinois, 60143. Copyright © 1990 by the American Academy of Pediatrics. All rights reserved. Print ISSN: 1073-0397.

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®

