

# eNeonatal Review

Jointly Presented by The Johns Hopkins University School of Medicine and The Institute for Johns Hopkins Nursing

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## December 2006 VOLUME 4, NUMBER 4

### In this issue...

Since its inception in 1987, the Neonatal Resuscitation Program of the American Academy of Pediatrics and the American Heart Association has had the goal of ensuring that there is someone in attendance at every delivery whose only responsibility is to care for the newly born infant. Although the first set of guidelines upon which the specific steps in the NRP were based were developed largely by extrapolation from the adult literature on resuscitation and from empiric evidence, subsequent versions of the guidelines have been based, as much as possible, on conclusions drawn from an evaluation of the relevant literature. The most recent set of NRP guidelines, published in November, 2005, resulted from a 3-year literature review process by an international committee of experts (the neonatal section of the International Liaison Committee on Resuscitation, ILCOR) to arrive at consensus recommendations for neonatal resuscitation practice.

In this issue — in a departure from our usual format — we provide an overview of the evidence evaluation process used to inform the development and revision of NRP practice guidelines as published in the new AAP/AHA Neonatal Resuscitation Program textbook, and take an in-depth look at three significant changes in practice that resulted from the most recent ILCOR review.

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#### Guest Faculty Disclosure:

Faculty Disclosure: No relationship with commercial supporters.

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## Learning Objectives

The Johns Hopkins University School of Medicine and The Institute for Johns Hopkins Nursing take responsibility for the content, quality, and scientific integrity of this CME/CE activity.

**At the conclusion of this activity, participants should be able to:**

- Describe the evidence review process used to develop new NRP guidelines
- Discuss the results of recent studies regarding the use of 100% oxygen during neonatal resuscitation
- Identify the recommended doses of intravenous and endotracheal epinephrine during neonatal resuscitation

## Commentary

In 2006, the Neonatal Resuscitation Program of the American Academy of Pediatrics and the American Heart Association published the fifth edition of the Textbook of Neonatal Resuscitation, containing updated treatment recommendations based on recent changes in practice guidelines. The evidence review process that resulted in these changes in guidelines for neonatal resuscitation took place over a three year period starting in 2003, when members of the neonatal section of the International Liaison Committee on Resuscitation (ILCOR) began discussing possible revision. Reviewers identified the relevant literature for their assigned topics by searching multiple databases, reference lists from pertinent recent publications, and their own files, and reviewed the most significant articles from each source. The evidence was assigned a level based on the type of study described (LOE, defined in Table 1), and the quality of each study was categorized. Studies were then grouped by whether they supported or refuted the treatment recommendation being reviewed.

**Table 1**

**Definitions of Levels of Evidence**

LEVEL OF EVIDENCE	DEFINITION
Level 1	Randomized clinical trials or meta-analyses of multiple clinical trials with substantial treatment effects
Level 2	Randomized clinical trials with smaller or less significant treatment effects
Level 3	Prospective, controlled, non-randomized, cohort studies
Level 4	Historic, non-randomized, cohort or case-control studies
Level 5	Case series: patients compiled in serial fashion, lacking a control group
Level 6	Animal studies or mechanical model studies
Level 7	Extrapolations from existing data collected for other purposes, theoretical analyses
Level 8	Rational conjecture (common sense); common practices accepted before evidence-based guidelines

After several preliminary meetings and much lively discussion, all of the reviewers met in January 2005 as part of the Consensus 2005 meeting organized by the American Heart Association. At that meeting, both a Consensus on Science statement and a treatment recommendation were developed for each topic based on a synthesis of the evidence evaluated by the reviewers and the input of all of the ILCOR members. Treatment recommendations were classified based on the strength of the evidence (see Table 2). These statements were published in *Circulation* in November 2005 and in *Pediatrics* in May 2006<sup>[1,2]</sup>. The members of the NRP steering committee then met in October 2005 to develop specific recommendations for the AAP/AHA NRP, and these changes were then incorporated into the fifth edition of the NRP textbook, released in April 2006. A summary of major changes to the guidelines can be viewed at [www.aap.org/nrp](http://www.aap.org/nrp).

**Table 2**

**Classes of Recommendations**

CLASS	CLINICAL DEFINITION	REQUIRED LEVEL OF EVIDENCE
<b>Class I</b> <i>Definitely recommended.</i> Definitive, excellent evidence provides support	Always acceptable, safe <ul style="list-style-type: none"> <li>• Definitely useful</li> <li>• Proven in both efficacy &amp; effectiveness</li> <li>• Must be used in the intended manner for proper clinical indications.</li> </ul>	One or more Level 1 studies are present (with rare exceptions) <ul style="list-style-type: none"> <li>• Study results consistently positive and compelling</li> </ul>
<b>Class II</b> <i>Acceptable and useful</i>	Safe, acceptable <ul style="list-style-type: none"> <li>• Clinically useful</li> <li>• Not yet confirmed definitively</li> </ul>	Most evidence is positive <ul style="list-style-type: none"> <li>• Level 1 studies are absent, or inconsistent, or lack power</li> <li>• No evidence of harm</li> </ul>
<b>Class IIa</b> <i>Acceptable and useful</i> Good evidence provides support	<ul style="list-style-type: none"> <li>• Clinically useful</li> <li>• Considered treatments of choice</li> </ul>	<ul style="list-style-type: none"> <li>• Generally higher levels of evidence</li> <li>• Results are consistently positive</li> </ul>
<b>Class IIb</b> <i>Acceptable and useful</i> Fair evidence provides support	<ul style="list-style-type: none"> <li>• Clinically useful</li> <li>• Considered optional or alternative treatments</li> </ul>	<ul style="list-style-type: none"> <li>• Generally lower or intermediate levels of evidence</li> <li>• Generally, but not consistently, positive results</li> </ul>
<b>Class III</b> <i>Not acceptable, not useful, may be harmful</i>	Unacceptable <ul style="list-style-type: none"> <li>• Not useful clinically</li> <li>• May be harmful.</li> </ul>	No positive high level data <ul style="list-style-type: none"> <li>• Some studies suggest or confirm harm.</li> </ul>

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**INTRAPARTUM SUCTIONING FOR PREVENTION OF MECONIUM ASPIRATION SYNDROME**

Carson BS, Losey RW, Bowes WA Jr, Simmons MA. **Combined obstetric and pediatric approach to prevent meconium aspiration syndrome.** Am J Obstet Gynecol 1976; 126: 712-5.

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Vain, N.E.; Szyld, E.G.; Prudent, L.M. et al. **Oropharyngeal and nasopharyngeal suctioning of meconium-stained neonates before delivery of their shoulders: multicentre, randomised controlled trial.** Lancet 2004; 364:597-602.

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Since the mid-1970s, obstetricians have been performing intrapartum suctioning of infants born to mothers with meconium-stained amniotic fluid (MSAF), i.e., interrupting the process of parturition after delivery of the baby’s head in order to suction the naso- and oro-pharynx. The study by Carson et al<sup>[3]</sup> (LOE 3) describing the use of both intrapartum suctioning and selective postpartum endotracheal intubation and suctioning as a practice that reduced the incidence of meconium aspiration syndrome contributed significantly to the widespread use of intrapartum suctioning. However, subsequent studies (e.g., Falciglia et al,<sup>[6]</sup> LOE 4) called into question the value of intrapartum suctioning and suggested that the incidence of meconium aspiration syndrome was not altered by postpartum management because most cases occurred in utero.

Carson’s 1976 study determined the incidence and severity of meconium aspiration syndrome in infants born to mothers with MSAF before and after instituting both intrapartum pharyngeal suctioning and visualization of the vocal cords after delivery with intubation if meconium was seen. Although the authors stated that the incidence of MAS was “significantly reduced”, the p-value was 0.07, which does not meet the general definition of p<0.05 to establish a significant difference. In addition, several infants were not treated according to group

assignment. Based on these results, the use of intrapartum pharyngeal suctioning by obstetricians became a standard practice.

In a 2004 randomized, double-blinded controlled trial performed in 11 centers in Argentina and one in the United States, Vain et al randomized 1263 infants born to mothers with MSAF to receive intrapartum suctioning and 1251 infants who were not suctioned before delivery of the chest; all infants then received standard treatment (i.e., tracheal intubation and suctioning only if not vigorous after delivery). The primary outcome evaluated was incidence of meconium aspiration syndrome, and no difference was observed between the two groups. In addition, there were no differences in the need for supplemental oxygen or mechanical ventilation, mortality, or length of hospital stay. The authors concluded that there was no benefit to intrapartum suctioning in the prevention of meconium aspiration syndrome (LOE 1).

Based on the limitations of the Carson study and the strength of Vain's multicenter trial, the ILCOR review concluded that there is no apparent benefit to intrapartum suctioning; therefore, the practice is no longer recommended in routine management of infants born to mothers with MSAF. It is important to note that the randomized, controlled trial did not find evidence of harmful effects of intrapartum suctioning, although it was not designed to specifically investigate this issue. Thus, there may be situations in which intrapartum oropharyngeal suctioning may be performed.

## USE OF SUPPLEMENTARY OXYGEN DURING DELIVERY ROOM RESUSCITATION

Saugstad OD, Rootwelt T, Aalen O. **Resuscitation of asphyxiated newborn infants with room air or oxygen: an international controlled trial: The Resair 2 study.** *Pediatrics* 1998; 102:1-7.

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Vento M, Asensi M, Sastre J, et al. **Resuscitation with room air instead of 100% oxygen prevents oxidative stress in moderately asphyxiated term neonates.** *Pediatrics* 2001; 107: 642-7.

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Since 1987, the NRP has recommended the use of 100% oxygen during all resuscitations. Empiric evidence as well as data from studies of perinatal physiology suggested that 100% oxygen would facilitate the postnatal fall in pulmonary artery pressure, thus assisting with the transition from fetal to newborn circulation in those newly-born infants who manifested signs of abnormal transition after delivery. However, some investigators have hypothesized that the use of 100% oxygen could increase oxidative stress in an already compromised infant and, therefore, could exacerbate post-asphyxial injury. Over the past 15 years, a number of animal studies and several clinical trials<sup>[15,19,23]</sup> have examined the question of whether newborns could be successfully resuscitated after a perinatal insult by using 21% oxygen rather than 100% oxygen and, further, whether use of 21% oxygen might even improve outcomes after resuscitation.

Studies in newborn animal models (LOE 6) have, in general, found that the rates of successful resuscitation from an imposed asphyxial insult were equivalent regardless of the FiO<sub>2</sub> used for resuscitation. Investigation of short-term outcomes (most <7 days) in most cases did demonstrate increases in biochemical markers of oxidative stress as well as alterations in neurotransmitter release and cerebral blood flow response in those animals that were resuscitated with 100% oxygen<sup>[7,8,16,17]</sup>. Conversely, several studies found potentially adverse short-term biochemical changes in animals resuscitated with room air compared to those in which 100% oxygen was used<sup>[20,21]</sup>.

Extrapolation of the results of these animal studies to the clinical situation is complicated by a number of limitations. First, several different models were used to mimic changes associated with perinatal asphyxia. Second, no animal studies have been conducted to examine long-term outcomes, i.e., at weeks to months of age. Perhaps most important, virtually all of the studies were performed in animals that were several hours old or older, and therefore had already successfully transitioned to extrauterine life before being subjected to the insult. Thus, the question of whether the use of 100% oxygen has particular benefits when pulmonary artery pressures are still high, as they are just after birth, was not addressed by these studies. However, based on the success of resuscitation with 21% oxygen in animals, several clinical trials were carried out examining the use of 21% oxygen for resuscitation in newly born infants.

In 1998, Saugstad et al reported on a total of 609 newly born infants (from 10 centers) with asphyxia (defined as apnea or gasping at birth with heart rate <80 bpm), who were resuscitated with 21% oxygen on even dates and 100% oxygen on odd dates (not a true randomization procedure). Infants who did not respond after 90 seconds of resuscitation were switched over from the initial gas to the "other" gas. The primary outcome measure was death within the first 7 days and/or diagnosis of hypoxic-ischemic encephalopathy. A number of

secondary outcomes were also investigated, including Apgar score at 5 minutes, heart rate at 90 seconds, and duration of resuscitation. The investigators found no significant difference in the primary outcome measure between the two groups; in addition, no differences were found in heart rate at 60 or 90 seconds after delivery or median 5-minute Apgar scores, or median time to first breath. However, infants resuscitated using 21% oxygen had a significantly shorter median time to first breath. Of note is the fact that equal numbers of infants were switched from room air to oxygen and from oxygen to room air due to perceived lack of response (LOE 2).

In the 2001 Vento et al report, term neonates with "perinatal asphyxia" were randomized to be resuscitated with either 21% or 100% oxygen; caregivers were blinded with regard to the identity of the resuscitation gas. Primary outcomes were Apgar scores at 1, 5, and 10 minutes, time to first cry, and time to regular respiration. In addition, a number of indices of oxidative stress were measured in blood at delivery, 72 hours postnatal age, and 28 days postnatal age. The authors found no differences in Apgar scores between the two groups. Time to first cry and time to sustained respiratory pattern were significantly shorter in the group resuscitated with 21% oxygen. The reduced-to-oxidized glutathione ratio at 28 days was no different from control in the 21% group, while it was significantly lower in the 100% oxygen group, suggesting that the latter group had experienced sustained oxidative stress (LOE 2).

In these studies, as well as several others<sup>[15,24]</sup> (LOE 2) comparing the effects of using 21% and 100% oxygenation for resuscitation in the delivery room, no significant difference in mortality rates was observed between the two treatments. In addition, on follow-up at 18-24 months postnatal age<sup>[18]</sup>, Saugstad et al found no difference in outcomes. Two meta-analyses of the same five clinical trials<sup>[5,22]</sup> (LOE 7) found minimal differences in outcome measures between the two treatment groups; however, in the 2004 paper<sup>[5]</sup> the authors concluded that mortality rate was significantly decreased in the 21% oxygen group, while the 2005 paper<sup>[22]</sup> concluded that there were insufficient data to recommend the use of either 21% or 100% oxygen for resuscitation of infants with perinatal asphyxia.

Overall, the results of the clinical studies suggest that resuscitation with 21% oxygen is as effective as, and might even be superior to, resuscitation with 100% oxygen. However, unresolved issues regarding study design, subject enrollment and randomization, diagnoses in those infants who died, and the number of severely asphyxiated infants included in each study group confounded interpretation of the clinical trials. As a result, the NRP recommendation that 100% oxygen be used when positive-pressure ventilation is required or in the presence of central cyanosis was not changed. Because the evidence suggests that 21% may be as effective as 100% oxygen, however, the 2005 guidelines also state that individual providers may take the option of starting with less than 100% oxygen. No evidence is available to support a recommendation for using a specific oxygen concentration between 21% and 100% at present. If an oxygen concentration <100% is used to initiate resuscitation, crossover to 100% oxygen is recommended if there is no improvement in 90 seconds. This time point was chosen because it was used in the clinical trials that included a crossover design<sup>[15,23]</sup>; however, there have been no studies to determine the optimum timing for changing the oxygen concentration during resuscitation if an appropriate response (i.e., increasing heart rate) is not observed with the initial oxygen concentration.

## USE OF EPINEPHRINE DURING DELIVERY ROOM RESUSCITATION

Crespo SG, Schoffstall JM, Fuhs LR, Spivey WH. **Comparison of two doses of endotracheal epinephrine in a cardiac arrest model.** Ann Emerg Med 1991; 20:230-4.

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Kleinman, ME, Oh, W. and Stonestreet, B.S. **Comparison of intravenous and endotracheal epinephrine during cardiopulmonary resuscitation in newborn piglets.** Crit Care Med. 1999 27:2748-54.

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Ralston, SH, Tacker WA, Showen L et al. **Endotracheal versus intravenous epinephrine during electromechanical dissociation with CPR in dogs.** Ann Emerg Med. 1985; 14:1044-8.

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Previously, the recommended dose of epinephrine was 0.1 to 0.3 ml/kg of a 1:10,000 solution (0.01 to 0.03 mg/kg), given via either the endotracheal tube or intravenous access, typically via an umbilical venous catheter. Because endotracheal access is generally available before intravenous access during resuscitation,

the endotracheal route was recommended for initial doses. However, the 2005 Consensus on Science was that published studies in adult cardiac arrest patients<sup>[13,14]</sup> found that endotracheal administration of epinephrine was of little or no benefit in restoring cardiac function. In addition, both animal<sup>[4,10-12]</sup> (LOE 6) and human<sup>[9]</sup> (LOE 2) studies demonstrated that endotracheal epinephrine administration was associated with increased blood epinephrine concentrations and/or an effect on cardiovascular variables only when given at approximately 10 times the previously recommended dose of 0.01-0.03 mg/kg.

In 1991, using an adult pig model of ventricular fibrillation followed by external cardiac compressions, Crespo et al tested the effects of two different doses of epinephrine given via the endotracheal tube on plasma epinephrine levels and blood pressure. Animals that received 0.01 mg/kg (i.e., the previously recommended dose) via the endotracheal tube had no increase in plasma epinephrine levels. Animals treated with 0.1 mg/kg (i.e., 10x the previously recommended dose) had significantly higher plasma epinephrine levels than pigs who received no exogenous epinephrine or 0.01 mg/kg; however, the investigators found no significant increase in blood pressure associated with the higher epinephrine levels.

In Kleinman & Stonestreet's 1991 study, radiolabeled epinephrine (0.01 mg/kg) or placebo was administered to newborn piglets via intracardiac, intravenous, or endotracheal route during resuscitation after ventricular fibrillation-induced cardiac arrest. The authors reported that intravascular epinephrine administration was associated with increased plasma epinephrine levels and increased carotid blood pressure, but that endotracheal administration was not associated with an increase in either epinephrine level or blood pressure.

In 1985, using an adult dog model of cardiac arrest due to electromechanical dissociation, Ralston et al determined dose-response curves for intravenous and intratracheal epinephrine. Outcomes did not differ significantly between the animals assigned to the two routes of administration, but the median effective dose of endotracheal epinephrine was approximately 10 times higher than the median effective dose for intravenous epinephrine (0.13 mg/kg compared to 0.014 mg/kg, respectively).

As is apparent from these studies and others, there are no data from randomized clinical studies in newly born infants. Most of the animal studies must also be interpreted cautiously because they were carried out in older animals and/or used a model, such as ventricular fibrillation, that produces cardiac arrest via a mechanism not usually encountered in the newborn. The few studies in newborn animals used animals that were already being ventilated and oxygenated or were hypoxic but not in frank cardiac arrest. In spite of these limitations, the consensus reached by the members of the neonatal ILCOR was that, given the lack of data to support the efficacy of endotracheal administration of epinephrine during resuscitation in newly born infants, the intravenous route is the optimal route of administration. Because there are limited data suggesting that doses of epinephrine 10 times higher than the intravenous dose might be effective if given via the endotracheal tube, the administration of one dose of epinephrine via the endotracheal tube at a higher dose (up to 0.1 mg/kg) than the intravenous dose could be considered while intravenous access is being obtained. However, there are no data that establish the safety or efficacy of this dose in newly born infants. Data in the adult and pediatric populations suggest that higher doses of intravenous epinephrine are associated with poorer outcomes after resuscitation; therefore, the use of epinephrine doses greater than 0.03 mg/kg IV is not recommended, and care must be taken to ensure that a dose of epinephrine prepared for endotracheal administration is not inadvertently administered via the intravenous route.

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## Ask the Authors

### LAST MONTH'S Q & A December 2006 - Volume 4 - Issue 4

In our December 2006 issue, we overviewed the development and revision of the NRP practice guidelines as published in the new AAP/AHA Neonatal Resuscitation Program textbook. Based on those data, the eNeonatal Review Team asked the December faculty a few questions:



Commentary & Reviews:  
**Jane E. McGowan, M.D.**

Professor of Pediatrics  
Drexel University  
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### The eNeonatal Review Team asked the December faculty a few questions.



Since Vain et al showed no decrease in the incidence of meconium aspiration syndrome after Intrapartum suctioning of the oropharynx, does this mean that obstetricians should never perform Intrapartum suctioning?



The current recommendation states that "routine" Intrapartum suctioning is not recommended. There may be circumstances where there is material in the oropharynx that could cause mechanical obstruction during the baby's first breaths, and brief suctioning with a bulb syringe may be useful in such cases. However, delaying delivery for prolonged suctioning and/ or suctioning vigorously enough to cause vagally-mediated bradycardia is not indicated whether or not meconium is present.



If I do not choose to use 100% oxygen for resuscitation, what oxygen concentration should I start with?

**A** Unfortunately, there are no published data comparing the outcome of resuscitation using specific oxygen concentrations between 21% and 100%, although such studies are in progress. Thus, it is up to the individual practitioner to select an oxygen concentration that he/she deems appropriate for use during resuscitation of the newly-born infant. The most important aspect of resuscitation, regardless of the initial FiO<sub>2</sub> used, is the ongoing evaluation of the response of the infant to resuscitative efforts. Thus, if the infant's heart rate and/or respiratory effort do not improve after initiation of positive-pressure ventilation, regardless of oxygen concentration, further steps must be undertaken to achieve the desired response.

**Q** Can I give more than one dose of endotracheal epinephrine during a resuscitation?

**A** As stated in the 5th edition of the Textbook of Neonatal Resuscitation, there are no studies demonstrating that administration of endotracheal administration of epinephrine at currently used doses has any effect on heart rate or blood pressure during neonatal resuscitation. Thus, if epinephrine administration is indicated, efforts should be directed at obtaining vascular access via one of several routes as described in the textbook. Obtaining vascular access should take priority over drawing up and administering multiple doses of epinephrine via the endotracheal tube as it is unlikely that subsequent doses will have any effect if there was no response to the initial dose.

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##### **Nurses**

The Institute for Johns Hopkins Nursing is accredited as provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.

##### **Respiratory Therapists**

Respiratory Therapists should [visit this page](#) to confirm that AMA PRA category 1 credit is accepted toward fulfillment of RT requirements.

#### **Credit Designations · [back to top](#)**

##### **Physicians**

The Johns Hopkins University School of Medicine designates this educational activity for a maximum of 1.0 *AMA PRA Category 1 Credit(s)*<sup>™</sup>. Physicians should only claim credit commensurate with the extent of their participation in the activity.

##### **Nurses**

This 1.0 contact hour (for each eNewsletter or a maximum of 6 contact hours for all twelve eNewsletters) Educational Activity (Provider Directed/Learner Paced) is provided by The Institute for Johns Hopkins Nursing.

##### **Respiratory Therapists**

Respiratory Therapists should [visit this page](#) to confirm that your state will accept the CE Credits gained through this program.

#### **Target Audience · [back to top](#)**

This activity has been developed for Neonatologists, NICU Nurses and Respiratory Therapists working with Neonatal patients. There are no fees or prerequisites for this activity.

#### **Learning Objectives · [back to top](#)**

At the conclusion of this activity, participants should be able to:

- Describe the evidence review process used to develop new NRP guidelines
- Discuss the results of recent studies regarding the use of 100% oxygen during neonatal resuscitation
- Identify the recommended doses of intravenous and endotracheal epinephrine during neonatal resuscitation

#### **Statement of Responsibility · [back to top](#)**

The Johns Hopkins University School of Medicine and The Institute for Johns Hopkins Nursing takes responsibility for the content, quality, and scientific integrity of this CME/CNE activity.

#### **Faculty Disclosure Policy Affecting CE Activities · [back to top](#)**

As providers accredited by the Accreditation Council for Continuing Medical Education and American Nursing Credentialing Center's Commission of Accreditation, it is the policy of The Johns Hopkins University School of Medicine and The Institute of Johns Hopkins Nursing to require the disclosure of the existence of any significant financial interest or any other relationship a faculty member or a provider has with the manufacturer(s) of any commercial product(s) discussed in an education presentation. The presenting faculty reported the following:

- Dr. Noguee has indicated a financial relationship of grant/research support with Forest Laboratories and has received an honorarium from Forest Laboratories.
- Dr. Lawson has indicated a financial relationship of grant/research support from the NIH. He also receives financial/material support from Nature Publishing Group as the Editor of the Journal of Perinatology.
- Dr. Lehmann has indicated a financial relationship in the form of honorarium from the Eclipsys Corporation.

All other faculty have indicated that they have not received financial support for consultation, research, or evaluation, nor have financial interests relevant to this e-Newsletter.

**Unlabelled/Unapproved Uses · [back to top](#)**

The use of antiretroviral drugs for the indication of prevention of transmission of HIV to the infant is discussed. This is not a labeled indication for these agents.

**Disclaimer Statement · [back to top](#)**

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**Internet CE Policy · [back to top](#)**

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