



Volume 11 / Issue 12  
December 2016

## Table of Contents

### Antimicrobial Management of Neonates Born to Mother with a Diagnosis of Chorioamnionitis

By Kamlesh K. Jha, MBBS, MD, FAAP; Pragma Jha (Student); Shruti Trehan, MBBS, MD, FAAP; Shilpa Singh, MBBS, MD, FAAP; Laetitia Satmboliou, MD, FAAP; Romeen Lavani, MBBS, MD, FAAP; Stephen Co, MD, FAAP  
Page 1

### Upcoming Medical Meetings

Page 5

### Autopilot Non-Invasive Ventilation

By Michael Narvey, MD  
Page 7

### Have You Googled Yourself Lately? Shaping Your Online Presence - Social and Mobile Media for the Neonatologist

By Clara H. Song, MD  
Page 10

### Clinical Trials

Page 11

### Medical News, Products and Information

Page 13

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ISSN: 1932-7137 (online)  
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## Antimicrobial Management of Neonates Born to Mother with a Diagnosis of Chorioamnionitis

By Kamlesh K. Jha, MBBS, MD, FAAP; Pragma Jha (Student); Shruti Trehan, MBBS, MD, FAAP; Shilpa Singh, MBBS, MD, FAAP; Laetitia Satmboliou, MD, FAAP; Romeen Lavani, MBBS, MD, FAAP; Stephen Co, MD, FAAP

### Introduction

Early Onset Neonatal Sepsis (EOS) continues to be a serious problem associated with neonatal mortality and morbidity. The sepsis-associated death rates per 100,000 live births have declined because of the intrapartum antibiotic prophylaxis in pregnant women during labor and delivery. Chorioamnionitis remains a huge risk factor for Early Onset Neonatal Sepsis; it increases the risk of early onset neonatal sepsis by 6%-10%. Proven EOS mortality remains as high as 30% in developed countries and 60% in developing countries.<sup>1-3</sup> There is no agreement amongst the national guidelines on treating neonates born to mothers with clinical diagnosis of Chorioamnionitis.<sup>4-7</sup> The purpose of this guideline is to provide an evidence-based approach to managing neonates born to mothers with clinical diagnosis of Chorioamnionitis.

### Neonate Less Than 34 Weeks:

#### Symptomatic or Asymptomatic:

1. Labs: CBC BCX ( blood culture) immediately after birth.
2. Antibiotics:

#### If baby received Ampicillin during intrapartum period:

- Begin with IV Ampicillin + IV Cefotaxime.
- If initial CBC does not reveal low ANC (absolute neutrophil count) or Bandemia and if spinal tap is performed and the values are normal for age, discontinue Cefotaxime and start on Gentamicin.
- If 72-hour BCX is negative and neonate is asymptomatic, discontinue antibiotics.
- If 72-hour culture is negative, but neonate remains symptomatic,

continuation of antibiotics should be at the attending physician's discretion.

#### If baby did not receive Ampicillin during intrapartum period:

- IV Ampicillin + Gentamicin.
- If 72-hour BCX is negative and neonate is asymptomatic, discontinue antibiotics.
- If 72-hour culture is negative, but neonate remains symptomatic, duration of antibiotics should be at the attending physician's discretion.

Neonate More Than 34 Weeks	
Symptomatic	Asymptomatic
CBC BCX @birth	BCX @ birth
IV Ampicillin + Gentamicin	CBC @ 6 hour
If baby did not receive Ampicillin during intrapartum period: IV Gentamicin + IV Ampicillin	If baby becomes symptomatic any time before the 6 <sup>th</sup> hr: start on IV antibiotics.
If baby received Ampicillin during intrapartum period: IV Ampicillin + IV Cefotaxime	If baby remains asymptomatic, but 6 <sup>th</sup> hr CBC ANC is below 1500 and/or IT ratio > than 0.25 +baby received antibiotics during intrapartum period: start on IV antibiotics.
	If baby remains asymptomatic and 6 <sup>th</sup> hour CBC is normal, continue to observe.

#### Why Give Cefotaxime If Baby Received Ampicillin During Intrapartum Period?

Joseph et al<sup>15</sup> has shown that Ampicillin-resistant E. coli was isolated from 92% of infected neonates whose mothers received Ampicillin during the intrapartum period; whereas, only in 18% of infected

## EVIDENCE-BASED WEBINAR

# Early Inhaled Nitric Oxide and Progression of Hypoxic Respiratory Failure (HRF)

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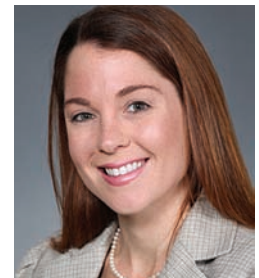
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- Optimizing oxygenation in HRF
- Evidence for the earlier use of inhaled nitric oxide in the treatment of HRF



**Satyan Lakshminrusimha, MD**  
Chief, Division of Neonatology  
Women and Children's  
Hospital of Buffalo



**Ashley Darcy Mahoney, PhD, NNP-BC**  
Neonatal Nurse Practitioner,  
South Dade Neonatology  
Assistant Professor,  
Emory University School of Nursing

### Indication

INOMAX is indicated to improve oxygenation and reduce the need for extracorporeal membrane oxygenation in term and near-term (>34 weeks gestation) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension in conjunction with ventilatory support and other appropriate agents.

### Important Safety Information

- INOMAX is contraindicated in the treatment of neonates dependent on right-to-left shunting of blood.
- Abrupt discontinuation of INOMAX may lead to increasing pulmonary artery pressure and worsening oxygenation.
- Methemoglobinemia and NO<sub>2</sub> levels are dose dependent. Nitric oxide donor compounds may have an additive effect with INOMAX on the risk of developing methemoglobinemia. Nitrogen dioxide may cause airway inflammation and damage to lung tissues.
- In patients with pre-existing left ventricular dysfunction, INOMAX may increase pulmonary capillary wedge pressure leading to pulmonary edema.
- Monitor for PaO<sub>2</sub>, inspired NO<sub>2</sub>, and methemoglobin during INOMAX administration.
- INOMAX must be administered using a calibrated INOMax DS<sub>IR</sub><sup>®</sup> Nitric Oxide Delivery System operated by trained personnel. Only validated ventilator systems should be used in conjunction with INOMAX.

**Please see Brief Summary of Prescribing Information on adjacent page.**



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# INOmax<sup>®</sup> (nitric oxide gas)

## Brief Summary of Prescribing Information

### INDICATIONS AND USAGE

#### Treatment of Hypoxic Respiratory Failure

INOmax<sup>®</sup> is indicated to improve oxygenation and reduce the need for extracorporeal membrane oxygenation in term and near-term (>34 weeks) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension in conjunction with ventilator support and other appropriate agents.

### CONTRAINDICATIONS

INOmax is contraindicated in neonates dependent on right-to-left shunting of blood.

### WARNINGS AND PRECAUTIONS

#### Rebound Pulmonary Hypertension Syndrome following Abrupt Discontinuation

Wean from INOmax. Abrupt discontinuation of INOmax may lead to worsening oxygenation and increasing pulmonary artery pressure, i.e., Rebound Pulmonary Hypertension Syndrome. Signs and symptoms of Rebound Pulmonary Hypertension Syndrome include hypoxemia, systemic hypotension, bradycardia, and decreased cardiac output. If Rebound Pulmonary Hypertension occurs, reinstate INOmax therapy immediately.

#### Hypoxemia from Methemoglobinemia

Nitric oxide combines with hemoglobin to form methemoglobin, which does not transport oxygen. Methemoglobin levels increase with the dose of INOmax; it can take 8 hours or more before steady-state methemoglobin levels are attained. Monitor methemoglobin and adjust the dose of INOmax to optimize oxygenation.

If methemoglobin levels do not resolve with decrease in dose or discontinuation of INOmax, additional therapy may be warranted to treat methemoglobinemia.

#### Airway Injury from Nitrogen Dioxide

Nitrogen dioxide (NO<sub>2</sub>) forms in gas mixtures containing NO and O<sub>2</sub>. Nitrogen dioxide may cause airway inflammation and damage to lung tissues.

If there is an unexpected change in NO<sub>2</sub> concentration, or if the NO<sub>2</sub> concentration reaches 3 ppm when measured in the breathing circuit, then the delivery system should be assessed in accordance with the Nitric Oxide Delivery System O&M Manual troubleshooting section, and the NO<sub>2</sub> analyzer should be recalibrated. The dose of INOmax and/or FiO<sub>2</sub> should be adjusted as appropriate.

#### Worsening Heart Failure

Patients with left ventricular dysfunction treated with INOmax may experience pulmonary edema, increased pulmonary capillary wedge pressure, worsening of left ventricular dysfunction, systemic hypotension, bradycardia and cardiac arrest. Discontinue INOmax while providing symptomatic care.

### ADVERSE REACTIONS

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. The adverse reaction information from the clinical studies does, however, provide a basis for identifying the adverse events that appear to be related to drug use and for approximating rates.

Controlled studies have included 325 patients on INOmax doses of 5 to 80 ppm and 251 patients on placebo. Total mortality in the pooled trials was 11% on placebo and 9% on INOmax, a result adequate to exclude INOmax mortality being more than 40% worse than placebo.

In both the NINOS and CINRGI studies, the duration of hospitalization was similar in INOmax and placebo-treated groups.

From all controlled studies, at least 6 months of follow-up is available for 278 patients who received INOmax and 212 patients who received placebo. Among these patients, there was no evidence of an adverse effect of treatment on the need for rehospitalization, special medical services, pulmonary disease, or neurological sequelae.

In the NINOS study, treatment groups were similar with respect to the incidence and severity of intracranial hemorrhage, Grade IV hemorrhage, periventricular leukomalacia, cerebral infarction, seizures requiring anticonvulsant therapy, pulmonary hemorrhage, or gastrointestinal hemorrhage.

In CINRGI, the only adverse reaction (>2% higher incidence on INOmax than on placebo) was hypotension (14% vs. 11%).

Based upon post-marketing experience, accidental exposure to nitric oxide for inhalation in hospital staff has been associated with chest discomfort, dizziness, dry throat, dyspnea, and headache.

### DRUG INTERACTIONS

#### Nitric Oxide Donor Agents

Nitric oxide donor agents such as prilocaine, sodium nitroprusside and nitroglycerine may increase the risk of developing methemoglobinemia.

### OVERDOSAGE

Overdosage with INOmax is manifest by elevations in methemoglobin and pulmonary toxicities associated with inspired NO<sub>2</sub>. Elevated NO<sub>2</sub> may cause acute lung injury. Elevations in methemoglobin reduce the oxygen delivery capacity of the circulation. In clinical studies, NO<sub>2</sub> levels >3 ppm or methemoglobin levels >7% were treated by reducing the dose of, or discontinuing, INOmax.

Methemoglobinemia that does not resolve after reduction or discontinuation of therapy can be treated with intravenous vitamin C, intravenous methylene blue, or blood transfusion, based upon the clinical situation.

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**“Joseph et al<sup>15</sup> has shown that Ampicillin-resistant *E. coli* was isolated from 92% of infected neonates whose mothers received Ampicillin during the intrapartum period; whereas, only in 18% of infected neonates whose mothers were not treated by Ampicillin were Ampicillin-resistant *E. coli* isolated.”**

neonates whose mothers were not treated by Ampicillin were Ampicillin-resistant *E. coli* isolated.

**Spinal Tap Should Be Done in the Following Scenario:<sup>4</sup>**

1. Any neonate with positive blood culture.
2. Any neonate whose clinical course or lab data strongly suggests bacterial sepsis.
3. Neonates who worsen with initial antibiotics treatment.

**Duration of Antibiotics:**

1. BCX positive, but negative CSF (cerebrospinal fluid): 14<sup>th</sup> day,
2. Positive CSF culture: 21 days or 2 weeks after negative CSF culture, whichever is longer.

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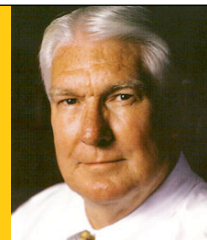
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### Upcoming Medical Meetings

**NEO - The Conference for Neonatology**  
Feb. 23-26, 2017; Orlando, FL USA  
[www.neoconference.com](http://www.neoconference.com)

**30<sup>th</sup> Annual Gravens Conference on the Physical and Developmental Environment of the High Risk Infant, in Collaboration with the March of Dimes**  
Mar. 1-4, 2017; Clearwater Beach, FL USA  
[www.tinyurl.com/GravensConference](http://www.tinyurl.com/GravensConference)

**NPA 38<sup>th</sup> Annual Conference - Perinatal Mental Health: Advocating for the Health and Wellbeing of Families**  
Mar. 9-11, 2017; Atlanta, GA USA  
[www.nationalperinatal.org](http://www.nationalperinatal.org)

**NeoHeart: Cardiovascular Management of the Neonate**  
Mar. 22-25, 2017; San Diego, CA USA  
[choc.org/neoheart](http://choc.org/neoheart)

**14<sup>th</sup> National Advanced Practice Neonatal Nurses Conference**  
Apr. 19-27, 2017; Waikiki Beach, HI USA  
[www.academyonline.org](http://www.academyonline.org)

**1<sup>st</sup> World Congress on Maternal Fetal Neonatal Medicine**  
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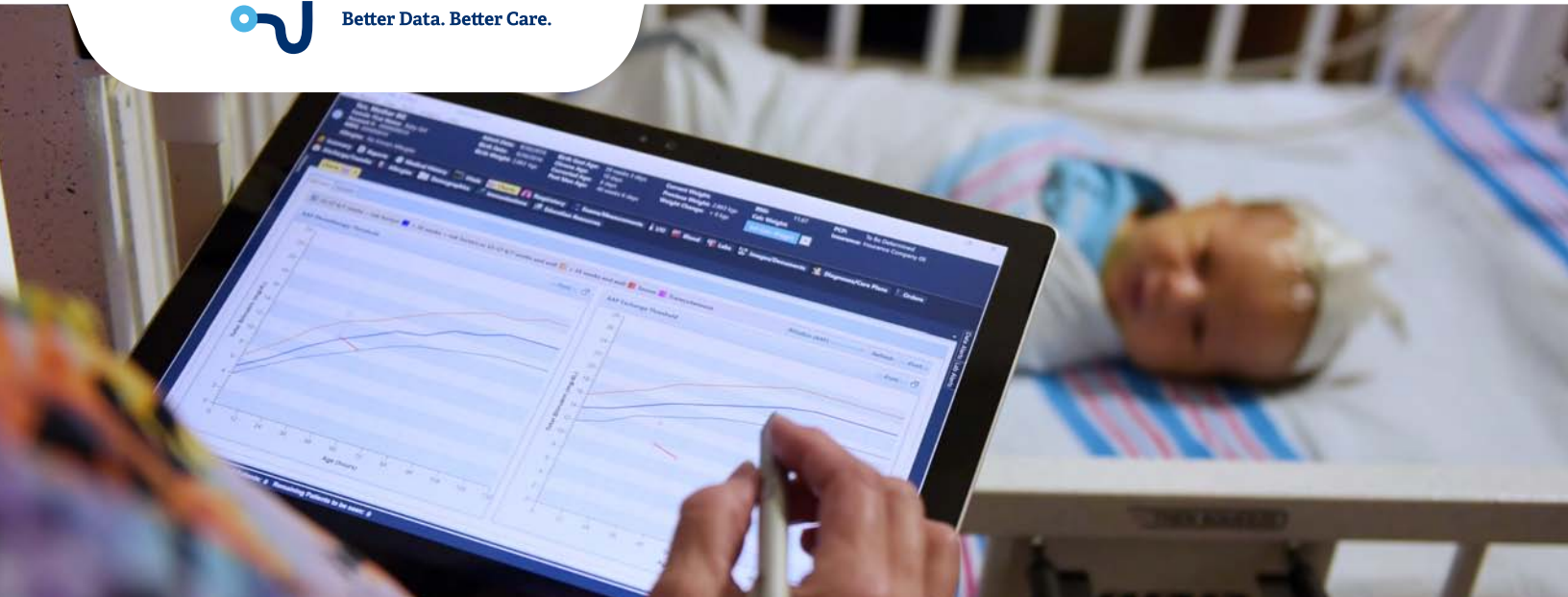
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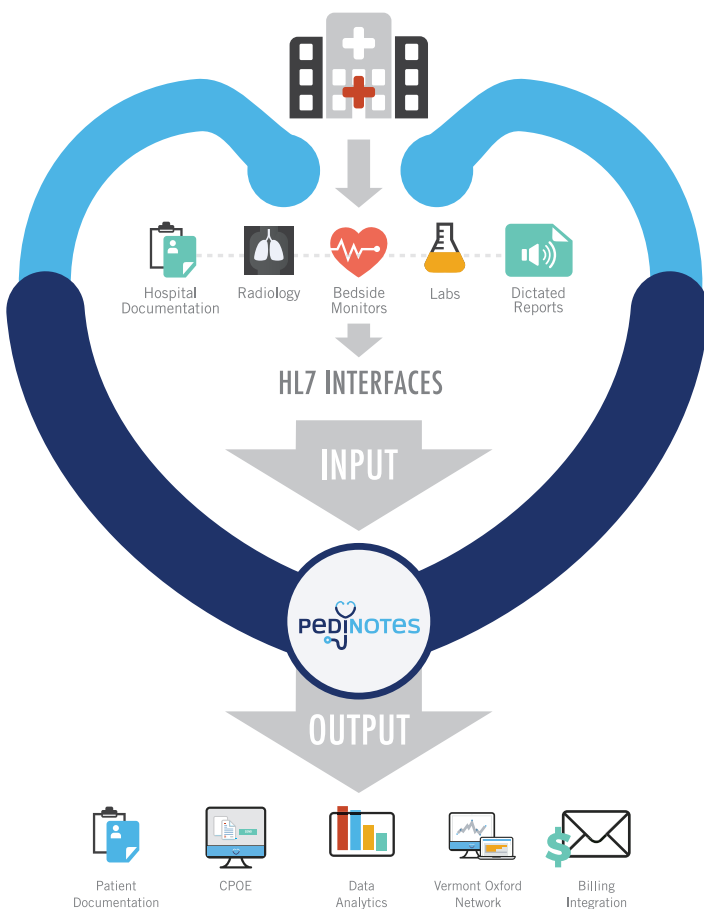
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# Autopilot Non-Invasive Ventilation

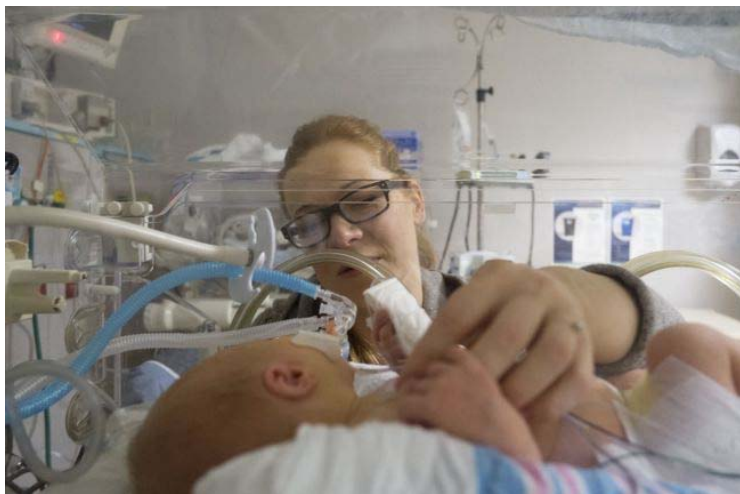
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Originally Published on:

All Things Neonatal

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I had a chance recently to drive a Tesla Model S with autopilot. Taking the car out on a fairly deserted road near my home, I flicked the lever twice to activate the autopilot feature and put my hands behind my head while the vehicle took me where I wanted to go. As I cruised down the road with the wheel automatically turning with the curves in the road and the car speeding up or slowing down based on traffic and speed limit notices, I couldn't help but think of how such technology could be applied to medicine. How far away could the self-driving ventilator or CPAP (Continuous Positive Airway Pressure) device be from development?



I have written about automatic saturation adjustments in a previous post, but this referred to those patients on mechanical ventilation. "Automatic adjustments of  $\text{FiO}_2$ : Ready for Prime Time?" Why is this goal so important to attain? The reasoning lies in the current design trends in modern NICUs (Neonatology Intensive Care Units). We are in the middle of a large movement towards Single Patient Room NICUs that have many benefits such as privacy, which may lead to enhanced breastfeeding rates and increased parental visitation. The downside, having spoken to people in centres where such designs are already in place, is the challenge nursing faces when given multiple assignments of babies on  $\text{O}_2$ . If you have to go from room to room and a baby is known to be labile in their  $\text{O}_2$  saturations, it is human nature to turn the  $\text{O}_2$  up a little more than you otherwise would to give yourself a "cushion" while you are out of the room. I really don't fault people in this circumstance, but it does pose the question as to whether in a few years we will see a rise in oxygen-related tissue injury such as CLD or ROP from such practice. In the previous post I wrote about babies who are ventilated, but these infants will often be one-to-one nursed, so the tendency to overshoot the  $\text{O}_2$  requirements may be less than the baby on non-invasive ventilation.

## A System for Controlling $\text{O}_2$ Automatically for Infants on Non-Invasive Ventilation

This month in Archives, Dr. Dargaville and colleagues in Australia provide two papers, the first demonstrating the validation of the mathematical algorithm that they developed to control  $\text{O}_2$ , and a second, a clinical report outlining how well the system actually performed on patients. The theoretical paper, "Development and preclinical testing of an adaptive algorithm for automated control of inspired oxygen in the preterm infant," is a challenge to comprehend, although it validates the approach in the end, while the clinical paper, "Clinical evaluation of a novel adaptive algorithm for automated control of oxygen therapy in preterm infants on non-invasive respiratory support," at least for me, was easier to digest.

The study was really a Proof-of-Concept (POC) with 20 preterm infants (mean GA 27.5 weeks, 8 days of age on average) included, who each underwent two hours of manual control by nursing to keep saturations between 90-94% and then 4 hours of automated control (sats 91% – 95%), then back to manual for two hours. The slightly shifted ranges were required due to the way in which midpoint saturations are calculated. The essential setup was a computer equipped with an algorithm to make adjustments in  $\text{FiO}_2$  using an output to a motor that would adjust the  $\text{O}_2$  blender and then provide feedback from an  $\text{O}_2$  saturation monitor back to the computer.

The system was equipped with an override to allow nursing to adjust in the event of poor signal or lack of response to the automatic adjustment.

The results, though, demonstrate that the system works and, moreover, that does a very good job! The average percentage of



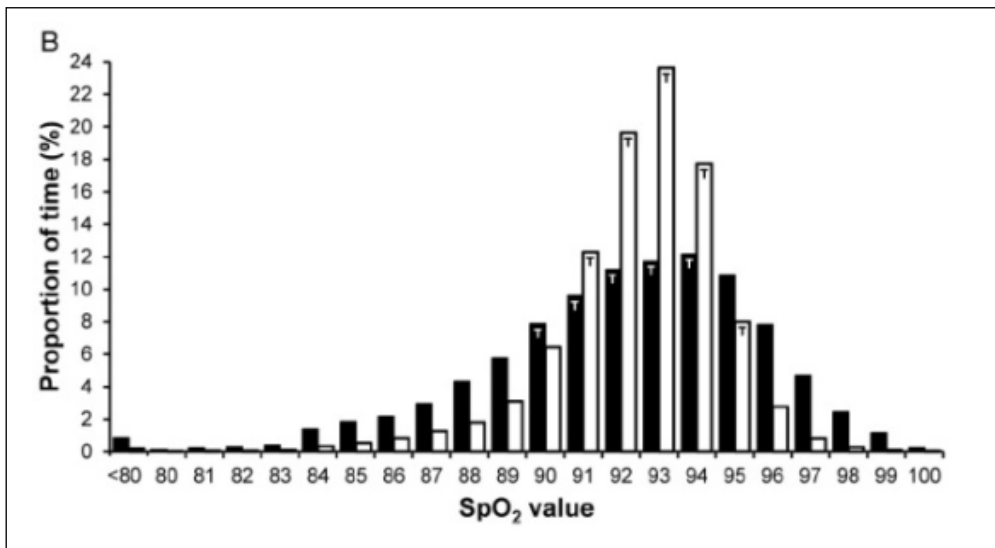
## PROGRESS IN PERINATAL CARDIOLOGY

Detection and Management of Fetal Congenital Heart Disease

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time that the saturations were in the target range were significantly better with automated control (81% automated, 56% manual). As well as depicted in the above figure, the

***“From the above quote from the paper, it is clear that automated control works to keep the saturation goal through roughly 7X the number of adjustments than nursing makes per hour. It is hard to keep up with that pace when you have multiple assignments, but that is what you need I suppose! The use of the auto-setting here reduced the amount of nursing interventions to adjust FiO<sub>2</sub> by 90% and yields tighter control of O<sub>2</sub> saturations”***

amount of time spent in both hypoxic and hyperoxic ranges was considerable with manual control, but non-existent on either tail with automated control (defined as <85% or >98%, where black bars are manual control and white automatic).

From the above figure, you can see that the amount of time the patients are in target range is much higher with automatic control, but is this simply because in addition to automatic control, nurses are “grabbing the wheel,” and augmenting the system here? Not at all.

“During manual control epochs, FiO<sub>2</sub> adjustments of at least 1% were made 2.3 (1.3–3.4) times/hour by bedside staff. During automated control, the minimum alteration to FiO<sub>2</sub> of 0.5% was being actuated by the servomotor frequently (9.9 alterations/min overall), and changes to measured FiO<sub>2</sub> of at least 1% occurred at a frequency of 64 (49–98) /hour. When in automated control, a total of 18 manual adjustments were made in all 20 recordings (0.24 adjustments/hour), a reduction by 90% from the rate of manual adjustments observed during manual control (2.3/hour).”

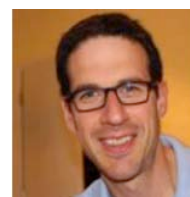
From the above quote from the paper, it is clear that automated control works to keep the saturation goal through roughly 7X the number of adjustments than nursing makes per hour. It is hard to keep up with that pace when you have multiple assignments, but that is what you need I suppose! The use of the auto-setting here reduced the

amount of nursing interventions to adjust FiO<sub>2</sub> by 90% and yields tighter control of O<sub>2</sub> saturations.

### Dare to Dream

Self-driving oxygen administration is coming, and POC needs to be developed, and soon, into a commercial solution. The risk of O<sub>2</sub> damage to developing tissues is too great not to bring this technology forward to the masses. As we prepare to move into a new institution, I sincerely hope that this solution arrives in time, but regardless, I know our nurses and RRTs will do their best, as they always do until such a device comes along. When it does, imagine all of the time that could be devoted to other areas of care once we are able to move away from the non-invasive device!

NT



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# 3 BIG THINGS



**HATHAWAY**  
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In nearly 20 years of successfully matching great physicians with great opportunities, I've learned that the right physician placement depends on three primary factors – location, work life and money!

**LOCATION:** Believe it or not, location drives most physician job opportunity decisions, but people often end up in the wrong places for the wrong reasons – the placement doesn't last and they must start their search all over again after a year or so. Conversely, often the best locations are places that people rarely think of, but which offer the lifestyle and family considerations that are at the core of what people are truly looking for.

**WORK LIFE:** Work life is arguably the most complex consideration to evaluate. Do you like the people you are (or will be) working with? Do they inspire you to do your best? Does the organization appreciate you and your contribution? Are you happy there? Do you look forward to starting work each day?

**MONEY:** Contrary to popular belief, money should never be the primary consideration. Money is always important and if it isn't sufficient it will kill the deal – but money is too often used by employers to mask weakness in other areas of consideration. That might be alright if it offsets location, for example - but money alone is a poor trade-off for the ongoing misery of a bad work life.

Of course, this is just a summary of these three considerations – there is more to it as you drill down on each of these areas and evaluate opportunities. If you would like some personalized help finding a great physician practice, please contact me at [mike@hathawayhealthcare.com](mailto:mike@hathawayhealthcare.com) or 954-603-1192.

I look forward to helping you!

Sincerely,

Mike Hathaway

**Hathaway Healthcare Executives**

Ph: 954-603-1192 • Fx: 954-482-4890

# Have You Googled Yourself Lately? Shaping Your Online Presence - Social and Mobile Media for the Neonatologist

By Clara H. Song, MD

“Social & Mobile Media for the Neonatologist” by Dr. Song, is a periodic column in *Neonatology Today*. Dr. Song created and moderates the social media outlets for the American Academy of Pediatrics, Section on Neonatal-Perinatal Pediatrics, as well as the NICU at the Children’s Hospital at OU Medical Center. She holds workshops and speaks regionally and nationally on the topic of social communication for the healthcare professional, including: the AAP Perinatal Section Spring meeting, yearly, and the 2011 *NEO: The Conference for Neonatology*.

Last month on October 24, 2016, the *New York Times* printed a two-page spread of some of the tweets from Republican presidential nominee Donald Trump since announcing his candidacy last year. Only the insulting tweets made the cut; perhaps, that was “All the News that was Fit to Print,” as their motto is. It was actually a print version of the digital tab of the ongoing tweets that were particularly inflammatory. There were even rumors that Mr. Trump had subsequently relinquished control of his Twitter account to his campaign manager, but these rumors were later found to be untrue.

I am writing this article on the eve of Election Day. Tomorrow, we will have a new POTUS. I am on the edge of my seat with anticipation with what tomorrow will bring. For so many reasons, this has been a fascinating campaign year... and nearly every moment has been chronicled on social media. The *Twittersphere* has been bustling with banter from all sorts of media coverage and real-time play-by-play of events. This social media generation has the potential to capture every word, smile and smirk in less than 140-characters. Amid the excitement and anticipation, my thoughts wander back to the article’s subheading about how our next potential President may be one who “has made personal insults and attacks a part of his campaign.”

Let’s not just focus on the election, or on a particular candidate. What can we learn from this specific example, as healthcare professionals, educators, researchers, scientists, neonatologists? I don’t imagine that many of us are up tweeting at all hours, but do we really know if others are tweeting about us? Should we be checking our web reputation? “I don’t have a web reputation,” you say. Well, you might not think so. However, you may already be online and not even know it. Have you Googled yourself lately? Your hospital affiliation may have created your public professional profile. A positive or, even, angry comment from family or staff member may have left comments about you or your group on Facebook. You may want to know what is being said about you and your work. Communication now is real-time and online; it is virtual and social. I’ve said it before, social media is like rock & roll - it’s here to stay, so let’s just rock along with it. That being said, you should be the one in control of your profile and your message -- no one else.

A quick online self-search of “Clara Song, MD” reveals pages on the Google search engine of various profile professional websites with images and location maps, aside from presentations and articles. I have actually reviewed only a few of these sites, such as: the OU Medicine Pediatrics Find a Doctor homepage, LinkedIn and Doximity. The others are physician profiling sites such as: Health Grades, WebMD Physician Directory, vials.com and HIPAASpace.com. These websites amass physician information for “comparison” and “verification” and allow for physician rating. Though not user-owned or user-created, these profiles can be user-managed. These sites typically have options that allow for the physician to claim the profile and update the information. What these sites lack is the ability to add information to or manipulate their template.

Healthcare social media influencer, Dr. Kevin Pho of KevinMD.com, recommends maintaining accounts on sites for professionals, like LinkedIn, and the physician-only site, Doximity. Shape your profile to reflect your message and the values for which you stand. You may decide you want your profile to simply reflect the facts so that you are reachable for your colleagues and patients, so serial fact-checking of your multiple public profiles will be important. You may, however, take it another step and want to create a platform for advocacy or have an educational message for your families from which the general public can also benefit.

Remember the 4 P’s: Public, Privacy, Professional, Permanent. Presume your web profile is public, and Google yourself to confirm this. Check your privacy settings. Online profiles are typically set to be at their most sharable and ‘social’ (i.e. public). So, reviewing privacy settings and policies will clarify who is able to access your information and media. Present your professional self in the virtual world as you would your professional life on both your personal and work-affiliated platforms. There is ‘Vegas Rule’ in the web. Online content is permanent. It can be deleted and temporarily lost, but always found if sought after hard enough.

Twitter is the ultimate social media example of the First Amendment. It is fast-paced, immediate and interactive digital expression. It also has an excellent and precise memory. *The New York Times* piece from October is yesterday’s news, as they say, but it was tweeted and retweeted multiple times. As such, it will forever live in the searchable Twitter cloud. With the freedom of speech and opinion, comes responsibility, especially for those of us caring for the most vulnerable patients without a voice of their own. We not only represent our own selves, but our profession and each other. So check what’s out there. You may already be out there, and not know it. Take control of your own reputation and message.

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NT

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# Clinical Trials (from clinicaltrials.gov)

## Impact of Deprivation on Hospital Care Efficiency in Paediatrics

*This study is currently recruiting participants*

**Sponsor:** Assistance Publique - Hôpitaux de Paris

**ClinicalTrials.gov Identifier:** NCT02617251

**Last verified:** August 2016

### Purpose:

Many studies have shown that deprived patients, in particular, consumed more healthcare resources than non-deprived patients, in particular in terms of increased length of stay (LOS) and readmission rates, which has an impact on hospital efficiency and the healthcare system as a whole. There are many types of indicators available to assess deprivation in a hospital setting and French decision makers are currently using reliance on public aids to allocate additional funding to hospitals, based on the percentage of deprived patients they admit. However there are limits to this method: it only assesses one dimension of deprivation, the target population often does not know about the existence of those aids, and they have a clear threshold effect. An alternative solution is to use ecological deprivation indices which are obtained by aggregating different variables measured at a specific time and place, i.e. the patient's place of residence at the time of care. One such index, the FDep, was developed specifically in France, although others, such as the Carstairs index and the European deprivation index also exist.

The primary objective of this study is to study the association between deprivation, measured by the FDep, and hospital care efficiency in paediatric and neonatology patients, measured by the difference between patient LOS and the national average LOS of their diagnosis-related group, DRG). The secondary objectives are to carry out a budget impact analysis on the impact of deprivation for hospitals with a paediatric or neonatology ward, to study: the association between deprivation and readmission at 15 days, to study the relation between FDep and the currently used deprivation indicators, and to assess the added value of the FDep compared to those indicators and whether or not it should be used in routine practice.

In order to do so, an exhaustive retrospective study using the French hospital claims database will be carried out for the years 2012-2014. Deprivation indices will be calculated based on patients' postcode. The primary endpoint will be calculated using the national LOS present in the French national cost study. Similarly, the budget impact will look at the difference between production costs derived from the national cost study after adjusting for LOS and the statutory health insurance's tariffs, which will allow us to assess whether a hospital stay is associated with a gain, a loss or is budget-neutral for the hospital. Readmissions at 15 days will be identified through record linkage.

Descriptive analyses will summarise both hospital and patient characteristics. Uni- and bivariate analyses will be carried out by

focusing of the variables of interest (e.g. average deprivation index by legal status of the hospital, mean LOS depending on the number of paediatric beds etc.). The deprivation index will be divided into quantiles as is the norm and the endpoints will be assessed for each of those quantiles. An ANOVA (or a Kruskal-Wallis test if the ANOVA hypotheses are not met) will test whether the results differ between each quantile. For readmission rates, a Chi<sup>2</sup> test will be performed.

In order to study the association between deprivation and the endpoints, the investigators will model each endpoint using as the main explanatory variable the deprivation index. Three main types of explanatory variables will be added to the model: patient characteristics (age, sex, severity level etc.), hospital characteristics (legal status, size, number of full-time equivalent etc.) and environment/context characteristics (number of paediatricians for 1,000 inhabitants, rural vs. urban area etc.).

In order to assess the added benefit of using the deprivation index vs. the current indicators, a sub-cohort will be constructed in Paris teaching hospitals (AP-HP) as, unfortunately, whether the patient receives public aids is not present in the hospital claim database but is available only at the local level. The investigators will look at the distribution of patients with public aids in each quantile of the deprivation index and run the previous models using the two types of indicators one after the other and comparing the statistical performance of each pair of models.

**Condition:** Deprivation

**Intervention:** Other: None

**Study Type:** Observational

**Study Design:** Observational Model: Ecologic or Community

**Time Perspective:** Retrospective

**Primary Outcome Measures:**

Hospital stay duration for participants [Time Frame: 30 months]  
[Designated as safety issue: No]

**Estimated Enrollment:** 3,500,000

**Study Start Date:** April 2015

**Estimated Study Completion Date:** December 2017

**Estimated Primary Completion Date:** December 2017 (Final data collection date for primary outcome measure)

**Eligibility:**

**Ages Eligible for Study:** Child, Adult, Senior

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**Genders Eligible for Study:** Both

**Accepts Healthy Volunteers:** No

**Sampling Method:** Non-Probability Sample

**Study Population:** Hospitalization in neonatology and pediatrics

**Inclusion Criteria:**

**Neonatology Population**

- Hospital stay present in the national hospital claims database in 2012-2014
- With a DRG and/or principal diagnosis related to neonatology
- In a hospital with a neonatology ward (including ICU)
- Age <28 days

**Paediatric Population**

- Hospital stay present in the national hospital claim database in 2012-2014
- In a hospital with at least one paediatric department
- Age < 15 years old
- After exclusion of the neonatology stays previously identified

**Exclusion Criteria:**

- Day admissions
- Stays with error codes

**Contacts and Locations:** Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below.

**Contacts:**

Contact: Jean-Claude Carel, MD, PhD  
+33140 034105  
[jean-claude.carel@aphp.fr](mailto:jean-claude.carel@aphp.fr)

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**Locations:**

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Recruiting  
Paris, France, 75019  
Contact: Jean-Claude Carel, MD, PhD  
+33140 034105  
[jean-claude.carel@rdb.aphp.fr](mailto:jean-claude.carel@rdb.aphp.fr)

**NT**

For up-to-date information visit: [www.clinicaltrials.gov](http://www.clinicaltrials.gov) and refer to this study by its ClinicalTrials.gov identifier: NCT02617251



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- Optionally, a picture of the author(s) may be submitted.
- No abstract should be submitted.
- The main text of the article should be written in informal style using grammatically correct English. The final manuscript may be between 400-4,000 words, and contain pictures, graphs, charts and tables. Accepted manuscripts are often published within 1-3 months of receipt. Abbreviations which are commonplace in pediatric cardiology or in the lay literature may be used.
- Comprehensive references are not required. We recommend that you provide only the most important and relevant references using the standard format.
- Figures should be submitted separately as individual separate electronic files. Numbered figure captions should be included in the main Word file after the references. Captions should be brief.
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# Medical News, Products & Information

Compiled and Reviewed by Tony Carlson,  
Senior Editor

## Blood Test May Help Identify Fetal Alcohol Spectrum Disorders, Research Shows

Newswise — Researchers at the Texas A&M College of Medicine, the University of California San Diego School of Medicine and the Omni-Net Birth Defects Prevention Program in Ukraine have identified a blood test that may help predict how severely a baby will be affected by alcohol exposure during pregnancy, according to a study published in the journal *PLOS ONE*. The findings could facilitate early intervention to improve the health of infants and children who were prenatally exposed to alcohol.

Fetal Alcohol Syndrome is a severe form of a spectrum of mental and physical disabilities, called Fetal Alcohol Spectrum Disorders (FASD), that can affect children's development with long-lasting consequences. In the United States and Western Europe, it is estimated that 2% to 5% of school-age children are affected by FASD. In some parts of the world, that number is even higher. Children and adults affected by FASD may have a range of symptoms, from physical changes like a small head and subtle differences in the face, to learning difficulties and behavioral issues.

Despite widespread prevention guidelines, drinking during pregnancy still occurs. This is partly because about half of pregnancies in the United States are unplanned, and therefore, many women might not realize that they need to stop consuming alcohol before the damage is done.

"It's a huge problem," said Rajesh Miranda, PhD, Professor in the Texas A&M College of Medicine and co-senior author of the article, "but we might not realize the full scope because infants born with normal-looking physical features may be missed, making many cases difficult to diagnose early." Consequently, there is a need for early biomarkers that can assist with predicting infant disability.

Utilizing a grant from the National Institutes of Health (NIH) - National Institute of Alcohol Abuse and Alcoholism (NIAAA) as part of a consortium known as the Collaborative Initiative on Fetal Alcohol Spectrum Disorders (CIFASD), the researchers looked at birth outcomes for 68 pregnant women enrolled in the study at two perinatal care clinics in Western Ukraine. The team obtained detailed health and alcohol consumption histories and second and third trimester blood samples from each woman. The results indicated that moderate to high levels of alcohol exposure during early pregnancy resulted in significant differences in some circulating small RNA molecules, termed microRNAs (miRNAs), in maternal blood. These differences were particularly notable in those mothers whose infants showed some physical or neurobehavioral signs of alcohol effects in the first 12 months of life.

"Collectively, our data indicate that maternal plasma miRNAs may help predict infant outcomes and may be useful to classify difficult-to-diagnose FASD subpopulations," Miranda added.

Part of the reason FASD may be difficult to diagnose is infants exposed to the same amount of prenatal alcohol may have vastly different outcomes.

"Although it is generally true that binge-drinking during pregnancy presents the greatest risk, not all women who consume substantial amounts of alcohol in pregnancy will have a child who is clearly affected," said Christina Chambers, PhD, Professor of Pediatrics at UC San Diego School of Medicine, principal investigator on the Ukraine project and co-senior author on the study. "That's why we examined specific biomarkers in the mother's blood in the second and third trimester of her pregnancy to determine if they are useful in identifying children who could benefit from early interventions."

Although FASD cannot be cured, early diagnosis is vital. "Early diagnosis is important because it permits early intervention to minimize the harm due to prenatal alcohol exposure," added

Wladimir Wertenleki, MD, the research team leader for the study investigators in the Ukraine. "Good nutrition, better perinatal health care, lowering stress levels and infant care interventions can all improve the outcome of alcohol-affected pregnancies."

The team's next steps include repeating this work in other and larger samples of mothers and infants, and determining if these early markers are predictive of longer term developmental outcomes for children exposed to alcohol.

"If we can reset developmental trajectories earlier in life, it is a lot easier than trying to treat disabilities later in life," Miranda said. "We hope this work will lead to a test that can allow health care providers to identify the mothers and infants most at risk and provide them with extra care for the best outcome possible."

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University of California San Diego Health Sciences comprises clinical and academic entities – UC San Diego Health system, the region's only academic health system; UC San Diego School of Medicine, one of the nation's top research-intensive schools of medicine; and the Skaggs School of Pharmacy and Pharmaceutical Sciences.

## Drug Shows Promise For Preventing Preterm Birth

Newswise — Researchers from the University of Adelaide have successfully tested a drug that is showing some early promise in efforts to prevent preterm birth.

The findings, published today in the Nature journal *Scientific Reports*, are a step forward in understanding the inflammatory mechanisms that lead to



The National Perinatal Association (NPA) is an interdisciplinary organization that gives voice to the needs of parents, babies and families and all those interested in their health and wellbeing. Within NPA, parents and professionals work together to create positive change in perinatal care through education, parent programs, professional guidelines and events.

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preterm birth and how they can be suppressed.

Researchers in the University's Robinson Research Institute tested a drug known for its abilities to switch off pro-inflammatory pathways. Using the drug in pregnant mice, the researchers found that preterm birth was entirely prevented, infant fatalities were significantly reduced, and the low birth weight normally associated with preterm birth was also reversed.

Preterm birth (being born at less than 37 weeks' gestation) is the major cause of death in children under five years of age, accounting for 1.1 million deaths annually. Preterm births represent 12% of all births worldwide.

"New interventions are urgently needed to tackle the underlying causes of preterm birth, prevent infant deaths and reduce the impact of a wide range of developmental impairments which can have lifelong health consequences," says lead author and Director of the Robinson Research Institute Professor Sarah Robertson.

The main causes of preterm birth are: bacterial infection (in around 50% of cases), physical injury or stress causing placental damage, carrying twins or triplets, or from environmental toxins such as air pollution. Each of these is associated with what researchers describe as an "inflammatory cascade," which can activate the mother's immune response and ultimately lead to spontaneous preterm birth.

This inflammatory cascade is triggered by an immune receptor known as Toll-Like receptor 4 (TLR4), responding to infection, physical injury or stress. TLR4 is critical to the body's immune response, but it also produces a number of pro-inflammatory effects that are harmful to pregnancy.

"TLR4 is a trigger of spontaneous pre-term birth," Professor Robertson says. "For this reason, we wanted to test a drug known for its ability to

block the actions of TLR4, to see if that would also prevent preterm birth."

The drug tested in this study is known as (+)-naloxone (pronounced: PLUS nal-OX-own).

"We found that by treating pregnant mice with (+)-naloxone, it provided complete protection against preterm birth triggered by bacteria. It also protected against stillbirth and infant death shortly after birth, and led to a correction in birth weight among infants that would otherwise be born at very low birth weight," Professor Robertson says.

"The babies born to mothers treated with (+)-naloxone developed normally, and were mostly indistinguishable from those born to the control group."

Professor Robertson says that while other drugs are currently in use to help prevent preterm birth, they are used at much later stages of the process leading to birth.

"By the time the conditions for preterm birth have already arisen, it's often too late for current treatments to do anything about it. What we really need is to stop the train at the station, as it were, before it can head down that track. Once it's left the station it's usually too late to stop it."

"Our studies give us some encouragement that it may be possible to prevent many preterm births, by using drugs that target the body's inflammatory mechanisms, probably in combination with antibiotics as well," she says.

Professor Robertson says more research will be needed to determine if (+)-naloxone or similar drugs could be used in human clinical trials.

This research has been supported by the National Health and Medical Research Council (NHMRC) in Australia, the Australian Research Council (ARC), the Canadian Institutes of Health Research, and the National Institutes of Health in the USA.

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## Antibody Protects Developing Fetus from Zika Virus

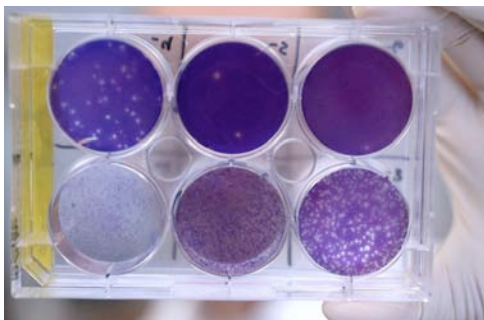
The most devastating consequence of Zika Virus Infection is the development of microcephaly, or an abnormally small head, in babies who were infected in utero. Now, researchers at Washington University School of Medicine in St. Louis and Vanderbilt University School of Medicine have identified a human antibody that prevents, in pregnant mice, the fetus from becoming infected with Zika and damage of the placenta. The antibody also protects adult mice from Zika disease.

"This is the first antiviral that has been shown to work in pregnancy to protect developing fetuses from Zika virus," said Michael Diamond, MD, PhD, the Herbert S. Gasser Professor of Medicine and the study's co-senior author. "This is proof of principle that Zika virus during pregnancy is treatable, and we already have a human antibody that treats it, at least in mice."

The study was published Nov. 7<sup>th</sup> in *Nature*, as a fast-track advance online publication.

Diamond, co-senior author James Crowe Jr., MD, of Vanderbilt, and colleagues screened 29 anti-Zika antibodies from people who had recovered from Zika infection. They found one, called ZIKV-117, that efficiently neutralized in the lab five Zika strains - representing the worldwide diversity of the virus.

To test whether the antibody also protects living animals, the researchers gave the antibody to pregnant mice either one day before or one day after they were infected



A researcher holds a tray of Zika Virus growing in Animal cells at Washington University School of Medicine in St. Louis. There is no treatment to block the Zika Virus. Credit: Huy Mach



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## Neonatologist and Neonatal ARNP Opportunities in Miami, Florida

Nicklaus Children's Hospital (formerly Miami Children's Hospital), a 289-bed freestanding children's hospital and Level III trauma center, and Pediatric Specialists of America (PSA), the physician-led multispecialty group practice of Miami Children's Health System, have two exceptional opportunities for a board-certified or board-eligible (BC/BE) fellowship-trained neonatologist, and a neonatal ARNP with at least three years of experience.

Both positions will be part of a comprehensive high-risk fetal and newborn medicine program to care for healthy mothers who are expecting a baby with complex medical issues. The labor and delivery unit, consisting of 16 private rooms, is located at The Miami Medical Center (TMMC). Opened as a joint venture between Miami Children's Health System and other collaborators, TMMC is a hospital with 67 luxury suites located near West Miami that offers world-class healthcare services, personalized hospitality and premium amenities. The unit is currently supported by three physicians and five ARNPs, with a projected volume of more than 500 deliveries for 2017.

The BC/BE neonatologist will be responsible for attending deliveries, resuscitating and stabilizing newborns in the delivery room, as well as provide leadership, oversight and supervision in the Level I nursery. The neonatologist would also be operationally involved in the 10-bed, high-risk delivery unit at Nicklaus Children's Hospital. The neonatal ARNP candidate should possess at least three years of experience and be proficient in newborn resuscitation, including neonatal intubation, umbilical line placement and peripheral cannulation, lumbar punctures and circumcision. Both roles are based in Miami and offer salaries that are competitive and commensurate with experience.

Nicklaus Children's neonatology program is consecutively ranked among the best in the nation by U.S. News & World Report. The 40-bed Level III and Level II neonatal intensive care unit (NICU) was the first of its kind in South Florida and receives referrals of the most critically ill neonates from hospitals throughout Florida, Latin America and the Caribbean.

Founded in 1950, the rebranded Nicklaus Children's Hospital is renowned for excellence in all aspects of pediatric medicine and has numerous subspecialty programs that are routinely ranked among the best in the nation. It is also home to the largest pediatric teaching program in the southeastern U.S. Many of our physicians have trained or worked at other leading medical institutions. Join a phenomenal team that brings lifelong health and hope to children and their families through innovative and compassionate care.

Nicklaus Children's Hospital is located in Miami, Florida, and offers all of the advantages of a tropical, diverse, metropolitan community. Enjoy abundant sunshine and warm weather year-round with easy access to beaches, golf courses, two international airports and sporting events such as the Miami Dolphins, Heat, Marlins and Panthers.

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with the virus. In both cases, antibody treatment markedly reduced the levels of virus in pregnant females and their fetuses, as well as in the placentas, compared with pregnant mice that did not get the antibody.

"These naturally occurring antibodies isolated from humans represent the first medical intervention that prevents Zika infection and damage to fetuses," Crowe said.

The placentas from the treated females appeared normal and healthy, unlike those from the untreated females, which showed destruction of the placental structure. Damage to the placenta can cause slow fetal growth, and even can cause fetal death, both of which are associated with Zika infection in humans.

"We did not see any damage to the fetal blood vessels, thinning of the placenta or any growth restriction in the fetuses of the antibody-treated mice," said co-author Indira Mysorekar, PhD, an Associate Professor of Obstetrics and Gynecology, and of Pathology and Immunology at Washington University, and Co-Director of the University's Center for Reproductive Sciences. "The anti-Zika antibodies are able to keep the fetus safe from harm by blocking the virus from crossing the placenta."

The antibody also protected adult male mice against a lethal dose of Zika virus, even when given five days after initial infection. Zika is rarely lethal in humans, so using a lethal dose allowed the scientists to see how well the antibody works under the most stringent conditions.

"We stacked the deck against ourselves by using a highly pathogenic strain of Zika, and even in that case, the antibody protected the mice," said Diamond, who is also a Professor of Pathology and Immunology, and of Molecular Microbiology.

These findings provide evidence that antibodies alone can protect adults and fetuses from Zika. Further, they suggest that a vaccine that elicits protective antibodies in women also may protect their fetuses in current and future pregnancies. A vaccine is already in human trials, but it was never tested in pregnant animals, so this new study represents strong evidence that a vaccine that elicits protective antibodies in adults is likely to protect fetuses as well.

A Zika vaccine is likely to be the cheapest and simplest method of preventing Zika-related birth defects. However, there is an outside possibility that a Zika vaccine could worsen symptoms in people who encounter the virus later. This is known to occur with dengue virus, a close relative of Zika. People who have antibodies against one strain of dengue virus get sicker when infected with a second strain than those who do not have such antibodies. The phenomenon, known as antibody-dependent enhancement, has been observed with Zika in a petri dish, but never in living animals or in epidemiologic surveys of people in Zika-endemic regions.

Nonetheless, the researchers tested whether they could eliminate the possibility of antibody-dependent enhancement of Zika infection by modifying the antibody so it could not participate in the process. The modified antibody, they showed, was just as effective as the original at protecting the placenta and fetus.

Until a human vaccine is available, it may be possible to protect fetuses by administering antibodies to pregnant women in an attempt to prevent transmission from mother to fetus. Under this scenario, a woman living in a Zika-endemic area would receive the antibodies throughout her pregnancy, starting when she first learns she is pregnant, regardless of whether she is diagnosed with Zika. Alternatively, pregnant women or their partners with acute infection could be treated with antibodies.

Crowe is continuing the process of developing the antibody as a potential therapeutic, ramping up production and laying the groundwork for human studies. Meanwhile, Diamond is focusing on determining whether antibodies could be used to clear persistent Zika infection. Together, they are working with others to gain a higher-resolution understanding of how ZIKV-117 binds the virus and inhibits infection.

"We know that Zika can persist in certain parts of the body, such as the eyes and the testes, where it can cause long-term damage, at least in mice," Diamond said. "We showed that the antibody can prevent disease, and now we want to know whether it can clear persistent infection from those parts of the body."

## NEONATOLOGY TODAY

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ISSN: 1932-7137 (digital).  
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**Company offices:**  
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News and Information for BC/BE Neonatologists and Perinatologists

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<p><b>NEONATOLOGY TODAY</b> News and Information for BC/BE Neonatologists and Perinatologists</p> <p>Volume 11 / Issue 8 August 2016</p> <p><b>IN THIS ISSUE</b></p> <p><b>Who Takes Care of Us?: Understanding and Managing</b></p>	<p><b>NEONATOLOGY TODAY</b> News and Information for BC/BE Neonatologists and Perinatologists</p> <p>Volume 11 / Issue 4 April 2016</p> <p><b>IN THIS ISSUE</b></p> <p><b>Role of Cross Sectional Imaging in Repair of Neonatal Hypoplastic Aortic Arch</b></p>	<p><b>NEONATOLOGY TODAY</b> News and Information for BC/BE Neonatologists and Perinatologists</p> <p>Volume 11 / Issue 3 March 2016</p> <p><b>IN THIS ISSUE</b></p> <p><b>Prenatal Diagnosis of Absent Sternum and Thoracic Ectopia Cordis</b></p>
<p><b>NEONATOLOGY TODAY</b> News and Information for BC/BE Neonatologists and Perinatologists</p> <p>Volume 11 / Issue 10 October 2016</p> <p><b>Table of Contents</b></p> <p><b>Respiratory Syncytial Virus (RSV) Update</b> By Leonard R. Kojouhar, MD</p>	<p><b>NEONATOLOGY TODAY</b> News and Information for BC/BE Neonatologists and Perinatologists</p> <p>Volume 11 / Issue 11 November 2016</p> <p><b>Table of Contents</b></p> <p><b>The Neonatal Nurse Practitioner as Surgeon</b> By Denise J. Costello, MD, Elyse R. Carlson, MD, PhD, Steven D. Dunlop, MD, PhD, Thomas J. Hagan, MD, PhD, James S. Madhokar, MD, PhD, Jennifer D. Richards, MD, PhD, Jennifer M. Stauder, MD, PhD</p>	<p><b>NEONATOLOGY TODAY</b> News and Information for BC/BE Neonatologists and Perinatologists</p> <p>Volume 11 / Issue 6 June 2016</p> <p><b>IN THIS ISSUE</b></p> <p><b>Pericardial Effusion with a Properly-Placed Umbilical Venous Catheter</b> By Ahmad A. Abouk, MD, Darshan Shah, MD, Jennifer Gibson, MD, PhD, Thomas J. Hagan, MD, PhD</p>
<p><b>NEONATOLOGY TODAY</b> News and Information for BC/BE Neonatologists and Perinatologists</p> <p>Volume 11 / Issue 9 September 2016</p> <p><b>Table of Contents</b></p> <p><b>Respiratory Syncytial Virus (RSV) Update</b> By Leonard R. Kojouhar, MD</p> <p><b>Who Takes Care of Us?: Understanding and Managing</b></p> <p><b>Respiratory Syncytial Virus (RSV) Update</b> By Leonard R. Kojouhar, MD</p>	<p><b>NEONATOLOGY TODAY</b> News and Information for BC/BE Neonatologists and Perinatologists</p> <p>Volume 11 / Issue 11 November 2016</p> <p><b>Table of Contents</b></p> <p><b>The Neonatal Nurse Practitioner as Surgeon</b> By Denise J. Costello, MD, Elyse R. Carlson, MD, PhD, Steven D. Dunlop, MD, PhD, Thomas J. Hagan, MD, PhD, James S. Madhokar, MD, PhD, Jennifer D. Richards, MD, PhD, Jennifer M. Stauder, MD, PhD</p>	<p><b>NEONATOLOGY TODAY</b> News and Information for BC/BE Neonatologists and Perinatologists</p> <p>Volume 11 / Issue 6 June 2016</p> <p><b>IN THIS ISSUE</b></p> <p><b>Pericardial Effusion with a Properly-Placed Umbilical Venous Catheter</b> By Ahmad A. Abouk, MD, Darshan Shah, MD, Jennifer Gibson, MD, PhD, Thomas J. Hagan, MD, PhD</p>