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## Are IVF Doctors Exempt from the Hippocratic Oath?

By Janet Farrell Leontiou, PhD

Recently, *The New York Times* ran two informative articles on the topic of in vitro fertilization. According to the physicians cited in the text, "Consumers can easily be overwhelmed by the available data and be unable to distinguish between good medical practices and a sales pitch."<sup>1</sup>

That statement was a lot to take in for reasons I will go on to explain, but then came the next statement that hit like a punch to the stomach. The doctor continued, "We all consider twin pregnancy to be an undesirable outcome that can be completely avoided if doctors and patients agree that a single embryo transfer is the right thing to choose."<sup>2</sup>

What do these, and statements like these, do to vulnerable couples seeking help for issues with fertility? The first statement implies that there are some physicians who are nothing more than snake oil sales persons. I had assumed because I went to the major teaching hospitals in New York City that I would not be met with charlatans. I was wrong! The statement also places the onus of responsibility on the patient or the couple seeking medical advice and evidence-based medicine. Notice that the physician did not say that doctors who give the patient a sales pitch are unethical? Instead it is the consumer who chooses unwisely to have twins when their fertility doctor encourages double or triple embryo transfers. I am now faced with the truth that even with a PhD, I fell for the sales pitch. I did not fall for one, but for several sales pitches. In total, we had four IVF cycles and each time, we transferred more than one fertilized egg upon the recommendations of the doctors. Not a single physician warned about the risks associated with twins or higher order multiples. That is a total of three fertility specialists and my ob/gyn doctor who did not tell, and we did not ask any question about the increased risks involved both for me or for my infants. The sales pitches that I responded to were as follows, "Hopefully two eggs will implant; hopefully they will be a boy and girl. Instant family." The question as to the number of eggs to transfer was asked as I lay on the table prepared for the transfer procedure. When I did conceive twins, the doctor said, "Three is considered the gold standard. Can we transfer three?" We said, "Yes." We were easily sold given that we had already been through three cycles involving a multitude of

eggs, and none of them resulted in a pregnancy. The doctor asked, "Is it ok with you if we say God Bless as we perform the transfer?" "Yes," we answered. Was evoking the name of God part of the sales pitch?

The last embryos transfer was successful. Our twin boys arrived in 2002. One boy is typically developing and the other boy has cerebral palsy. He is both nonverbal and non-ambulatory. There is no other explanation for his disability other than he is the result of a multiple birth. It is very difficult to live with the fact that doctors have known of the high incidence of disability associated with multiples for at least twenty years. It is difficult to wrap my head around the fact that doctors, because of financial greed, have knowingly contributed to creating a disabled population. I once heard a doctor on National Public Radio state that everyone knows about the disability rates associated with multiples...except the parents.

We were duped by an industry that I thought was looking out for our welfare. I will never again follow blindly the directives of a physician.

---

***"It is very difficult to live with the fact that doctors have known of the high incidence of disability associated with multiples for at least twenty years. It is difficult to wrap my head around the fact that doctors, because of financial greed, have knowingly contributed to creating a disabled population. I once heard a doctor on National Public Radio state that everyone knows about the disability rates associated with multiples...except the parents."***

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## EVIDENCE-BASED WEBINAR

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

See us at Neo 2017 in Orlando, FL at **booth #201/203** to learn more, or view the webinar on-demand at [INOMAX.com/earlieruse](http://INOMAX.com/earlieruse)

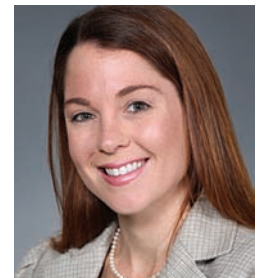
### Created by practitioners, for practitioners.

Review various elements of HRF treatment, including:

- Acute HRF in newborns
- The pathophysiology of HRF
- 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.

INOMAX<sup>®</sup> is a registered trademark of INO Therapeutics LLC, a Mallinckrodt Pharmaceuticals company.

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My entire family has paid dearly for this knowledge. I also take responsibility for creating our son's disability.

We agreed to these transfers without questioning, and without adequate or then current information. We, therefore, share the responsibility for the choices made. We will bear half of the responsibility. What I cannot tolerate is the fertility industry's avoidance of their mutual responsibility. The doctor's quote above about twins not perceived as a desired outcome makes it seem that this has always been their position. I do not even know if it is consensually true for the industry as a whole. His one statement is to erase history and negates experience such as ours. We were offered not a single word of caution, and in fact, we were encouraged to transfer seven eggs during one cycle. The doctor's statement, while economically prudent, is morally reprehensible.

Since the birth of our boys, technology has changed the access to information. A quick Google search reveals that multiples are 50% likely to have the presence of some form of disability. When I speak about how I could have potentially made different choices if we were given the information, I am told that there is no guarantee that we would have made a different choice. Fair enough. The point is that choice was taken from us because we were not informed. During the NPR program mentioned above, I heard a doctor say that the human womb was made for one baby at a time. I wish someone had offered that statement to us at the time when we going through the IVF experience. At least, then, I would have had some language to counter the "instant family" rhetoric.

Another rhetorical strategy I have seen by the medical community since the birth of our twins is to blame the patient. I have heard doctors state that they try to discourage parents against having twins but the parents are set on the idea. I have experienced this tactic used by doctors when my baby started having seizures on the second day of life. He was given a very aggressive course of prophylactic antibiotics without my knowledge or approval when his brother medically required the medicine. When I learned of it after the fact, the doctors said the other baby was given the drugs because they shared the same womb. The logic is still a mystery to me. The neonatal doctors asked our ob/gyn two times if I took drugs while pregnant? The irony here is outstanding. I was sick for nine months and would not take anything (against doctors orders) because I was fearful of what the drugs may do to the developing fetuses.

The doctors gave the babies several types of antibiotics, and when one started to have a seizure, the doctors looked to blame me.

The rhetorical stance of the doctors blaming the patients for the conception of twins is illogical. Since when do doctors throw up their collective hands and give up to conform to the wishes of the patient wanting medically unsound procedures? Do we see doctors conforming to the wishes of parents who question the efficacy of vaccinations? I cannot think of another single medical example where this kind of argument is used.

Our family has now joined rank with the families who have a child with disabilities. There is no underlying reason for our son's disabilities other than the fact that he is a multiple. We do not fit the preconditions for most who end up with a child with cerebral palsy. I went almost to term. At 38 weeks, we had an elective C-section upon doctor's orders. The boys were large at birth; 7 lbs. 11 ozs. for our



# NeoHeart: Cardiovascular Management of the Neonate

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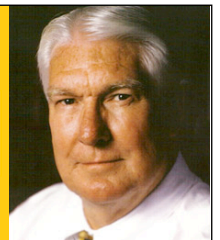
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Featured Keynote Speaker





typical son and 6 lbs. 2 ozs. for our child with disabilities. They both had high Apgar scores at birth; there were no indications that anything was wrong until one of the twins started to seize on the second day of life. Our decision to transfer more than one egg at a time has set our son on the path of most likely requiring the help of others for daily living for the rest of his life. My husband and I feel that it is an honor to care for him, and we give him all that we can. We have had to make peace with the decision we made. I see no such responsibility taken on the part of doctors. I asked my ob/gyn doctor, whom I had known since we were teenagers, what her response was to my book I wrote about our medical experiences. She said that she found the book to be angry. She sees no culpability on her part; her conscious is clear. She seems not to have engaged with the content of the book at all. She has moved on from us. This strategy of bifurcation, I guess, is how doctors continue to move on and recreate other families like ours.

Since the birth of my twins, there have been articles written by physicians who are sounding the warning alarm to prospective parents who are embarking on entering the world of Assisted Reproductive Technologies.

***“The rhetorical stance here of the doctors blaming the patients for the state of twins is illogical. Since when do doctors throw up their collective hands and give up to conform to the wishes of the patient wanting medically unsound procedures? Do we see doctors conforming to the wishes of parents who question the efficacy of vaccinations? I cannot think of another single medical example where this kind of argument is used.”***

One such article is the Position statement by the National Perinatal Association ([www.nationalperinatal.org](http://www.nationalperinatal.org)) that the Assisted Reproductive Technology industry is largely unregulated.<sup>4</sup>

If the physician does not adhere to the oath of *primum non nocere* (first do no harm), then it is up to the patient to adhere to *caveat emptor* (let the buyer beware).

#### References

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## Upcoming Medical Meetings

**Progress in Perinatal Cardiology 2017**  
Feb. 11-12, 2017; Tampa, FL USA  
[www.PeriCardConference.com](http://www.PeriCardConference.com)

**Specialty Review in Neonatology**  
Feb. 21-26, 2017; Orlando, FL USA  
[www.specialtyreview.com](http://www.specialtyreview.com)

**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)

**Annual Convention of the American Institute of Ultrasound in Medicine**  
Mar. 25 - 29, 2017; Orlando, FL USA  
[www.aium.org/annualConvention](http://www.aium.org/annualConvention)

**2017 Workshop on Perinatal Practice Strategies**  
Mar. 31 - April 2, 2017; Scottsdale, AZ USA  
<https://shop.aap.org/2017-workshop-on-perinatal-practice-strategies/>

**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**  
Apr. 23 - 26, 2017; London, UK  
[www.worldmfnm.eu](http://www.worldmfnm.eu)

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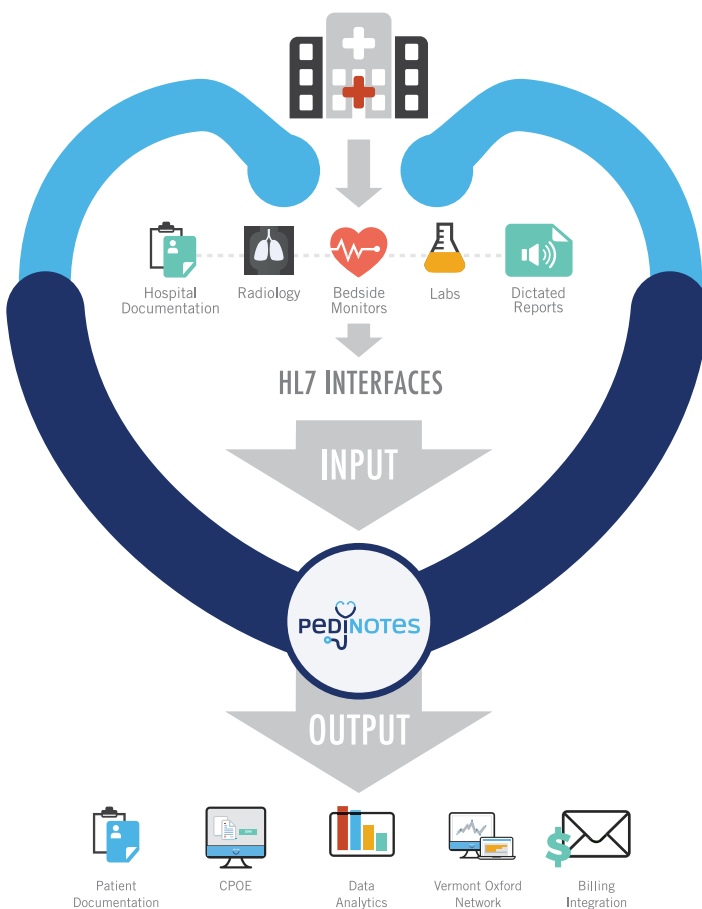
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# 3 BIG THINGS



**HATHAWAY**  
HEALTHCARE EXECUTIVES

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

# Clinical Trials (from clinicaltrials.gov)

## Impact of Deprivation on Hospital Care Efficiency in Paediatrics (PRECAPED)

This study is currently recruiting participants.

**Sponsor and provider of information:**  
**Assistance Publique - Hôpitaux de Paris**  
**ClinicalTrials.gov Identifier: NCT02617251**  
**Health Authority:** France: Ethics Committee  
First received: November 19, 2015  
Last updated and verified: August 12, 2016  
Plans to Share Data

### Purpose

Many studies have shown that deprived patients 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 summarize both hospital and patient characteristics. Uni- and bivariate analyses will be carried out by focusing on 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.

**Study Type:** Observational

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

| Condition   | Intervention           |
|-------------|------------------------|
| Deprivation | Other: No intervention |

**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 2015

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

**OXYGEN IS A DRUG**      **HOW MUCH O<sub>2</sub> IS TOO MUCH?**      **HYPEROXIA: KNOW THE RISK**

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## Eligibility

- Ages Eligible for Study: Child, Adult, Senior
- Both Genders Eligible for Study
- Does Not Accepts Healthy Volunteers
- Non-Probability Sampling Method

## Study Population

Hospitalization in neonatology and pediatrics

## Criteria

| Group / Cohorts                              | Assigned Interventions |
|--|------------------------|
| neonatology patients<br>neonatology patients | Other: No intervention |
| paediatric patients<br>paediatric patients   | Other: No intervention |

## 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.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02617251

## Contacts

- Jean-Claude Carel, MD, PhD; Phone: +33140034105; email: [jean-claude.carel@aphp.fr](mailto:jean-claude.carel@aphp.fr)
- Karine Chevreul, MD, PhD; Phone: +33140274148; email: [karine.chevreul@urc-eco.fr](mailto:karine.chevreul@urc-eco.fr)

**Locations:** Robert Debre Hospital, Paris, France, 75019

**NT**

38th annual conference

March 9-11, 2017 | Atlanta, Georgia

# Perinatal Mental Health:

Advocating for the Health  
and Wellbeing of Families

early identification



of 1 in 7 moms

layered supports



in our community

Complex problems require  
interdisciplinary solutions.

specialized help



for at-risk dads

expert care for



the full spectrum  
of disorders

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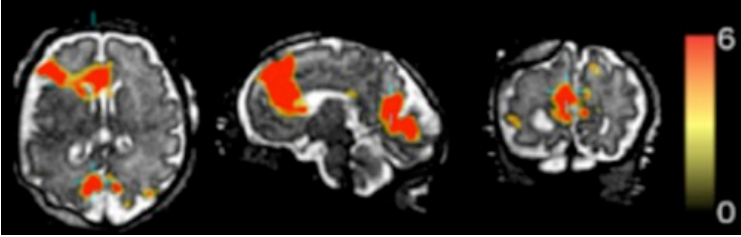
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# Medical News, Products & Information

Compiled and Reviewed by Tony Carlson, Senior Editor

## New Technology Reveals Fetal Brain Activity - Method Makes Imaging of Moving Subjects Possible



Credit: S. Seshamani, et al.  
Functional MRI of a fetal brain, showing activated regions (red) of the default mode network—a collection of areas that are active when the brain is at rest.

Newswise — NIBIB-funded researchers at the University of Washington have pioneered an approach to image functional activity in the brains of individual fetuses, allowing a better look at how functional networks within the brain develop. The work addresses a common problem of functional MRI; if the subject moves during the scanning, the images get distorted.

By creating a way to correct for motion, the team was able to make a four-dimensional reconstruction of brain activity in moving subjects, opening the door for studies on subjects that don't stay still for long, like fetuses and small children. The new strategy enables investigations into both normal brain development and the effects of a mother's diet or environment on the functional development of the fetal brain.

The new work focused on the default mode network—a collection of regions that are active when the brain is at rest, when someone is daydreaming or letting their mind wander, not concentrating on a specific task. Fetal brains are in default mode for much of the time, but it is not very well known how this network develops.

"This is one of the first papers to take individual fetuses and look at the naturally-developing default mode network in the human fetal brain," says Vinay Pai, PhD, Director of the Division of Health Informatics Technologies at NIBIB. Since movement of the baby or the mother is no longer an issue, "It allows you to look at more natural developmental stages."

In the new study, published online in August 2016 in the journal *Human Brain Mapping*, researchers aimed to create a four-dimensional movie of fetal default mode network activity. To do this, they used functional MRI—a technique that detects brain activity based on blood flow; active regions have higher levels of blood flowing to them. Besides blurring the image, the problem with movement—either from the fetus moving or the mother's breathing—is that it shifts the focus, making it hard to locate where any signals of activity are coming from. While typically just one measurement is collected for each position at each time point, the team collected multiple measurements, each providing slightly different perspectives. Using the multiple measurements, they were able to reposition the images to create an estimate of what the activation over a period of a few minutes would look like.

The team first tested their method on adults by telling them to purposely move their head in the scanner. After showing they could successfully quantify brain activity in moving subjects, they then scanned eight fetuses between 32 and 37 weeks of pregnancy, as infants born prematurely at that age have been shown to have active default mode networks. The resulting images were compiled to create a four-dimensional view of each of the brains over a five-minute time window.

"It really hasn't been explored when these activity networks—these collections of brain areas that start to work together in the brain—emerge and what types of cells and tissues they emerge in," says Colin Studholme, PhD, a professor with joint appointments in Pediatrics and Bioengineering at the University of Washington and senior author of the paper. "What this is leading to is not just collecting data from individual babies, but also understanding and building a four-dimensional map of brain activity and how it should emerge in a normal baby."

The technique can also be used to compare differences in brain development in premature and full-term babies; the effects of alcohol, drug use, or stress during pregnancy; or if there are any prenatal differences in babies that go on to develop neurodevelopmental disorders like autism. And it is not restricted to imaging the brain; Studholme also plans to study the placenta and how its development influences the brain.

But the immediate application—for squirmy babies—is promising in itself. "Techniques that minimize the effect of motion resolve a lot of problems," says Pai. "In fetal imaging, you don't have too many options."

The team received support for this study from NIBIB (EB017133), the National Institute of Neurological Disorders and Stroke (NS055064), and the National Center for Advancing Translational Sciences (UL1TR000423).—Teal Burrell, special to NIBIB

## AAP Announces New Safe Sleep Recommendations to Protect Against SIDS

Infants should sleep in the same bedroom as their parents - but on a separate surface, such as a crib or bassinet, and never on a couch, armchair or soft surface -- to decrease the risks of sleep-related deaths, according to a new policy statement released by the American Academy of Pediatrics.

"SIDS and Other Sleep-Related Infant Deaths: Updated 2016 Recommendations for a Safe Infant Sleeping Environment," draws on new research and serves as the first update to Academy policy since 2011.

Recommendations call for infants to share their parents' bedroom for at least the first six months and, optimally, for the first year of life, based on the latest evidence.

The policy statement and an accompanying technical report was released Oct. 24<sup>th</sup>, at the *AAP National Conference & Exhibition* in San Francisco. The report, published in the November 2016 issue of *Pediatrics* (online Oct. 24), includes new evidence that supports skin-to-skin care for newborn infants; addresses the use of bedside and in-bed sleepers; and adds to recommendations on how to create a safe sleep environment.

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"We know that parents may be overwhelmed with a new baby in the home, and we want to provide them with clear and simple guidance on how and where to put their infant to sleep," said Rachel Moon, MD, FAAP, lead author of the report. "Parents should never place the baby on a sofa, couch, or cushioned chair, either alone or sleeping with another person. We know that these surfaces are extremely hazardous."

Approximately 3,500 infants die annually in the United States from sleep-related deaths, including Sudden Infant Death Syndrome (SIDS); ill-defined deaths; and accidental suffocation and strangulation. The number of infant deaths initially decreased in the 1990s after a national safe sleep campaign, but has plateaued in recent years.

AAP recommendations on creating a safe sleep environment include:

- Place the baby on his or her back on a firm sleep surface such as a crib or bassinet with a tight-fitting sheet.
- Avoid use of soft bedding, including crib bumpers, blankets, pillows and soft toys. The crib should be bare.
- Share a bedroom with parents, but not the same sleeping surface, preferably until the baby turns one, but at least for the first six months. Room-sharing decreases the risk of SIDS by as much as 50%.
- Avoid baby's exposure to smoke, alcohol and illicit drugs.

Skin-to-skin care is recommended, regardless of feeding or delivery method, immediately following birth for at least an hour as soon as the mother is medically stable and awake, according to the report.

Breastfeeding is also recommended as adding protection against SIDS. After feeding, the AAP encourages parents to move the baby to his or her separate sleeping space, preferably a crib or bassinet in the parents' bedroom.

"If you are feeding your baby and think that there's even the slightest possibility that you may fall asleep, feed your baby on your bed, rather than a sofa or cushioned chair," said Lori Feldman-Winter, MD, FAAP, member of the Task Force on SIDS and co-author of the report.

"As soon as you wake up, be sure to move the baby to his or her own bed," she said. "There should be no pillows, sheets, blankets or other items that could obstruct the infant's breathing or cause overheating."

While infants are at heightened risk for SIDS between the ages 1 and 4 months, new evidence shows that soft bedding continues to pose hazards to babies who are 4 months and older.



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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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Other recommendations include:

- Offer a pacifier at nap time and bedtime.
- Do not use home monitors or commercial devices, including wedges or positioners, marketed to reduce the risk of SIDS.
- Infants should receive all recommended vaccinations.
- Supervised, awake tummy time is recommended daily to facilitate development.



The AAP recommends that doctors have open and nonjudgmental conversations with families about their sleep practices. Media outlets and advertisers may also play a role in educating parents by following safe sleep recommendations when presenting images and messages to the public.

"We want to share this information in a way that doesn't scare parents, but helps to explain the real risks posed by an unsafe sleep environment," Dr. Moon said. "We know that we can keep a baby safer without spending a lot of money on home monitoring gadgets, but through simple precautionary measures."

For more information, visit <http://www.aap.org>.

### **Nutritional Supplement Could Prevent Thousands of Early Preterm Births**

Newswise — Sophisticated analyses of two clinical trials, one in the U.S. and the other in Australia, suggest that thousands of early preterm births, those at or before 34 weeks gestation, could be prevented if pregnant women took daily docosahexaenoic acid (DHA) supplements.

The randomized controlled trials in which pregnant women took daily DHA supplements independently found statistically significant reductions in early preterm birth. The statistical model examined low-, moderate- and high-risk births from mothers supplemented with DHA during pregnancy as compared to placebo controls. The researchers estimated that more than 106,000 high-risk early preterm births could be avoided in the U.S. and about 1,100 could be prevented in Australia each year, if pregnant women took daily supplements of the omega fatty acid.

Infants born very preterm often require lifesaving treatments and longer hospitalizations at birth and are at increased risk for additional hospitalizations in the first year of life — and that is in the developed world. Further, these infants are at risk for serious disability or death the earlier they are born, said Susan Carlson, A.J. Rice Professor of Nutrition at the University of Kansas Medical Center, who co-directed the U.S. study with John Colombo, KU Professor of Psychology and Director of the Life Span Institute.

"At present there is no effective method to prevent spontaneous early preterm birth," Carlson said. "Our recent studies suggest that DHA could be a promising agent for reducing this critical public health problem."

Both the KUDOS (Kansas DHA Outcome Study), directed by Carlson and Colombo, and the DOMInO (DHA to Optimize Mother Infant Outcome) study directed by Maria Makrides, Professor of Human Nutrition and Healthy Mothers, Babies and Children theme leader for the South Australian Health & Medical Research Institute, and Robert Gibson, Professor of Functional Food Science at the University of Adelaide, saw a small overall increase in gestation length, but this increase was found to be related to a decrease in deliveries at higher risk for early preterm birth.

DHA (docosahexaenoic acid) occurs naturally in cell membranes with the highest levels in brain cells, but levels can be increased by diet or supplements. An infant obtains DHA from his or her mother in utero and postnatally from human milk, but the amount received depends upon the mother's DHA status, Carlson said.

"U.S. women typically consume less DHA than women in most of the developed world," Carlson said. "The intake of DHA is both the U.S. and Australia is well below that reported by Japanese women."

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By using the results of DOMInO and KUDOS, the researchers in both studies found that early preterm births could be reduced to only 1.3% in Australia or 1.5% of births in the U.S. in demographically similar populations.

“These percentages are remarkably similar and may reflect the lowest rate of spontaneous early preterm birth that can be achieved in any population,” Carlson said.

The study, Predicting the effect of maternal docosahexaenoic acid (DHA) supplementation to reduce early preterm birth in Australia and the United States using results of within country randomized controlled trials, was published in *Prostaglandins, Leukotrienes and Essential Fatty Acids*, 112 (2016) 44-69.

KUDOS was supported by a grant from the Eunice Shriver National Institute of Child Health and Human Development. The DOMInO trial was supported by the Australian National Health and Medical Research Council.

### Hospital Rooms and Patients Equally Likely to Transmit Pathogens

Newswise — Hospital rooms, not just the patients in them, can spread germs through contact with health care personnel, a Duke Health study reports.

“This study is a good wake-up call that health care personnel need to concentrate on the idea that the health care environment can be contaminated,” said Deverick Anderson, MD, the study’s lead author and Associate Professor of Medicine at Duke University School of Medicine. “Any type of patient care, or even just entry into a room where care is provided, truly should be considered a chance for interacting with organisms that can cause disease.”

Anderson presented the study’s findings on Oct. 27<sup>th</sup> at *IDWeek*, the annual meeting of the Infectious Diseases Society of America (IDSA), the Society for Healthcare Epidemiology of America (SHEA), the HIV Medicine Association (HIVMA), and the Pediatric Infectious Diseases Society (PIDS).

The Duke-led research team set out to understand how pathogens travel between the “transmission triangle” in a health care setting: patients, the environment where care is administered, and the health care provider.

During the study, the researchers took cultures from the sleeves, pockets, and midribs of the surgical scrubs of 40 intensive care unit nurses at Duke University Hospital. Each set of scrubs was new and the samples were collected at the start (before any patient interaction) and end of each shift. Cultures were also collected from the bodies of all patients the nurse cared for during each shift and the patients’ room contents (bed, bedrail, and supply cart).

In total, 167 patients received care over 120, 12-hour shifts. The study collected 2,185 cultures from the nurses’ clothing, 455 from patients, and 2,919 from patients’ rooms.

Molecular analysis identified organisms on the nurses’ clothing that were not present at the beginning of a shift, but were present at the end. The researchers then looked for those same organisms in the samples collected from patients and their rooms.

Specifically, they searched for five pathogens known to cause difficult-to-treat infections, including MRSA, a staphylococcus strain that is resistant to antibiotics. If such pathogens are present on nurses’ scrubs, they could be transferred between patients or lead to infection of the nurses themselves.

During the shifts considered, the researchers confirmed 12 instances when at least one of the five pathogens was transmitted from the patient or the room to the scrubs. Six incidents each involved transmission from patient to nurse and room to nurse. An additional ten transmissions were from the patient to the room.



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The researchers did not document any nurse-to-patient or nurse-to-room transmission.

The analysis found that pockets and sleeves of the scrubs were most likely to be contaminated, as were the bed rails in the rooms.

"I think sometimes there's the misconception that if, for instance, a nurse is just talking to patients and not actually touching them, that it might be okay to skip protocols that help reduce pathogen transmission, like washing hands or wearing gloves," Anderson said. "The study's results demonstrate the need for caution whenever health care providers enter a patient room, regardless of the task they're completing."

Anderson said the results were also significant because previous studies on pathogen transmission focused mainly on the patient-to-nurse interaction, while this study demonstrated that the room itself should be approached with equal consideration and caution.

"Oftentimes, especially when dealing with very sick patients, health care personnel may feel a conflict between providing care and following protocol that helps prevent pathogen transmission," Anderson added. "Our study shows following prevention strategies has to be a top priority, and that health care providers should be looking for ways to improve the likelihood that they are."

In addition to Anderson, study authors include: Bobby Warren, Rachel Addison, Batu Sharma Kuinkel, Yuliya Lokhnygina, Laura Rojas Coy, Susan D. Rudin, Robert A. Bonomo, David J. Weber, William A. Rutala, Vance G. Fowler, Jr. and the CDC Prevention Epicenters Program.

The authors report no conflicts of interest. The study was funded by the Centers for Disease Control and Prevention (U54CK000164).

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### Getting Doctors and Nurses to Work Together at Patient Bedsides

Newswise — The structure of health care systems helps determine how doctors and nurses collaborate during hospital rounds, according to Penn State College of Medicine researchers. A greater understanding of such team-based treatment in hospitals could help improve patient care.

Collaboration among different types of health care professionals, like doctors and nurses, is good for patients because it provides greater communication, coordination of care and patient-centered decision making.

One way to promote this type of team-based care is by having a mix of providers visit hospital patients together, called rounding. Although significant research has been conducted on bedside rounds, little has been done on interprofessional collaboration during these patient visits, said Dr. Jed D. Gonzalo, Assistant Professor of Medicine and Public Health Sciences.

The limited existing research on the topic finds that the amount of interprofessional bedside care that goes on in hospital settings — such as Internal Medicine, Pediatrics or Intensive Care — can vary widely, ranging from 1% to 80%. To date, no study has looked at how frequent this practice is across a variety of units in a single hospital. Also, little data exists on what promotes bedside interprofessional rounds in hospital units.

Based on the benefits of collaborative care, Penn State Health Milton S. Hershey Medical Center conducted a hospital-wide initiative starting in 2012 to increase bedside interprofessional rounds. The goal was for at least 80% of patients at the hospital to receive collaborative care at their bedside.

To determine how common bedside interprofessional rounds became following this effort, researchers from the College of Medicine analyzed data from nurses working in 18 of the hospital's units.

Of 29,173 patients treated in those units during the study period, 21,493 — 74% — received bedside interprofessional rounds.

The researchers also examined the factors associated with the shift toward collaborative care. They considered unit characteristics such as number of beds and square feet per bed; staffing characteristics, such as nurse-to-patient ratios; patient-level characteristics, such as length of stay; and nurses' perceptions of team collegiality and the use of scripts to guide bedside rounding.

Gonzalo and his team found several factors associated with greater incidence of bedside interprofessional rounds. Patients who were in the Intensive Care or Intermediate Care Unit, or who were hospitalized for five or more days were more likely to be seen by a nurse and a doctor together. These units generally have more nurses for every patient, Gonzalo said, increasing the likelihood of a nurse being available for bedside rounds when an attending physician sees patients. A longer hospital stay may also provide more opportunities for doctors and nurses to sync up when visiting patients, he added. It is also possible that patients with shorter stays may present cases that do not require as much collaborative care.

The use of rounding scripts and nurses' perception of staff support for this type of team-based care was also linked to higher use.

Gonzalo, who is also Associate Dean for Health Systems Education at the College of Medicine, said the study suggests that institutional and relationship factors drive collaborations between doctors and nurses.

These "structural factors increase the odds of this process actually occurring," Gonzalo said. "When it comes to interprofessional collaborative care, structure drives behavior."

Rather than simply telling doctors to integrate nurses into their bedside rounds more frequently, hospital administrators must understand the underlying challenges and work to overcome them.

"My hope would be that we increasingly think about the structure of our systems rather than 100% of the time saying it's just about the people," Gonzalo said. "People are the operators, but they're operating in a system, and how we design things matters. Better structural and process designs that are more conducive to collaboration and bringing providers together and patients together matter."

The study, recently published in the *journal BMC Health Services Research*, was itself an example of interprofessional collaboration, Gonzalo added, involving the internal medicine, nursing, quality and public health sciences departments.

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### Controlling Risk of C. Diff Saves Lives, Prevents Infection and Reduces Health Care Costs

Newswise — The constant fear of having an embarrassing bathroom accident paralyzed Judy Post. Mental, physical and emotional stress consumed her. She wondered if her life would ever return to normal.

"It was very difficult on me. I kept thinking nothing was going to help me," Post said. "I was really scared."

She was diagnosed with a *Clostridium difficile* infection and was treated for it with vancomycin and got better. However, a few days after she stopped the vancomycin, the diarrhea would come back as the infection relapsed. After talking with several doctors she was directed to Matthew Sims, MD, PhD, Director of Infectious Disease Research at Beaumont Hospital, Royal Oak, who enrolled her in a research study and broke the cycle of relapses.

"I had no idea what *C. difficile* was. My family members hadn't heard of it, either," she said.

*C. difficile* is an infection that causes life-threatening diarrhea. According to an article published in the *New England Journal of Medicine*, nearly 30,000 people die from *C. difficile* every year in the United States. Doctors say more than 450,000 are battling the infection. Twelve percent of all hospital-acquired infections are *C. difficile*.



The Agency for Healthcare Research and Quality recently awarded Dr. Sims with a \$2.4 million grant to study a theory that could prevent thousands of *C. difficile* infections and deaths all over the world. This is one of the largest grants Beaumont Health has ever received.

Some people carry *C. diff* spores in their colon, but don't get sick because their good bacteria keeps it in check. However, when *C. diff* carriers take antibiotics to treat an infection elsewhere in the body, those antibiotics can also kill off the good bacteria.

When good bacteria dies, this removes the restraints on the *C. diff* and allows it to grow out of control, which causes the person to become sick.

Dr. Sims believes oral vancomycin can keep the *C. diff* in check when the good bacteria is killed by other antibiotics and should prevent the patient from becoming sick. Participants in the study will be given vancomycin or a placebo along with the antibiotics treating the original infection.

"Treatment with oral vancomycin will not kill the spores. It will not cure people. Patients will still carry the spores in their body. However, the drug should prevent those spores from turning into a full blown *C. difficile* infection, holding them at bay like the good bacteria would have, and thus prevent the patient from becoming sick," Dr. Sims said.

The StOP CDI study will test this idea in a randomized, double-blinded, placebo-controlled trial. If successful in demonstrating that vancomycin can prevent the disease, the research could save thousands of lives, stop tens of thousands of infections, and save millions of health care dollars.

Post is not part of the StOP CDI study, but she says the research study she participated in with Dr. Sims was like a miracle that changed her life and she's eager to see what the new study will find.

"Every day, I become more positive about my life. I still carry a bottle of vancomycin with me, just in case I might need it," Post said.

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- Neonatal Endocrinology and Metabolism
- Neonatal Gastroenterology and Nutrition

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