

NEONATOLOGY TODAY

News and Information for BC/BE Neonatologists and Perinatologists

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Upcoming Meetings

2015 PAS Annual Meeting

Apr. 25-28, 2015; San Diego, CA USA
www.pas-meeting.org

The 26th Annual Meeting of the European Society of Paediatric and Neonatal Intensive Care (ESPNIC 2015)

Jun. 10-13, 2015; Vilnius, Lithuania
espnice.kenes.com

UCLA Fetal Echocardiography Symposium Saturday

Oct. 24, 2015; Los Angeles, CA USA
www.cme.ucla.edu/courses/event-description?registration%5fid=96321

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Pericardial Effusion with a Properly Placed Umbilical Venous Catheter

By Ahmad A. Aboaziza, MD; Darshan Shah, MD; Jennifer Gibson, MD; Otto H. Teixeira, MD

thrombus formation and myocardial necrosis.

Case Presentation

A preterm, 27-week, appropriate for gestational age female was immediately transferred to NICU after delivery due to prematurity and Respiratory Distress Syndrome. Her Apgar scores were 6 and 8 at 1 and 5 minutes, respectively.

Introduction

Pericardial effusion caused by Umbilical Venous Catheter (UVC) is described with intracardiac location of the tip of the UVC. Mechanisms of injury range from direct myocardial perforation to

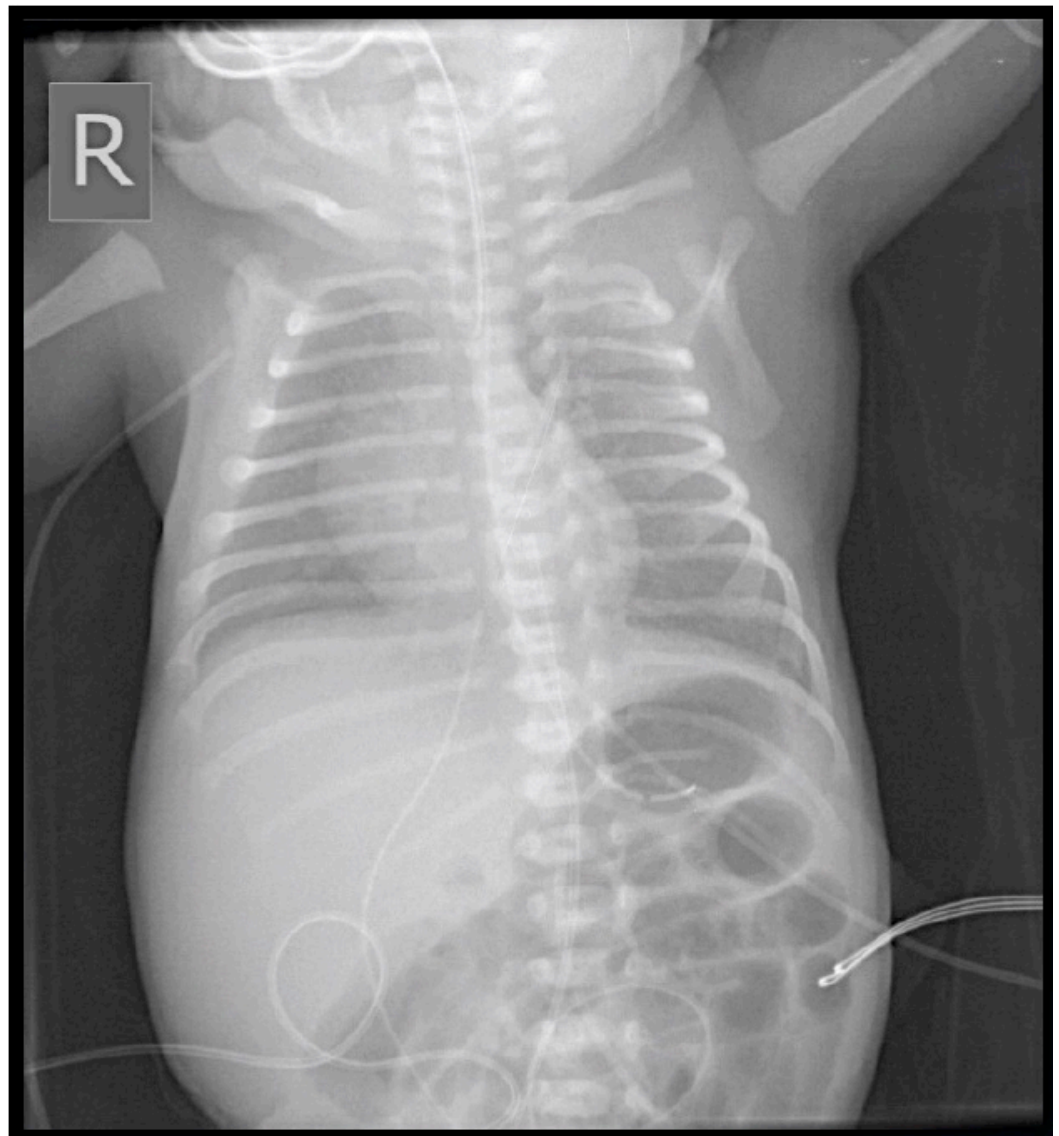


Figure 1. Chest- X-ray (PA view) showing UVC and UAC line placements.

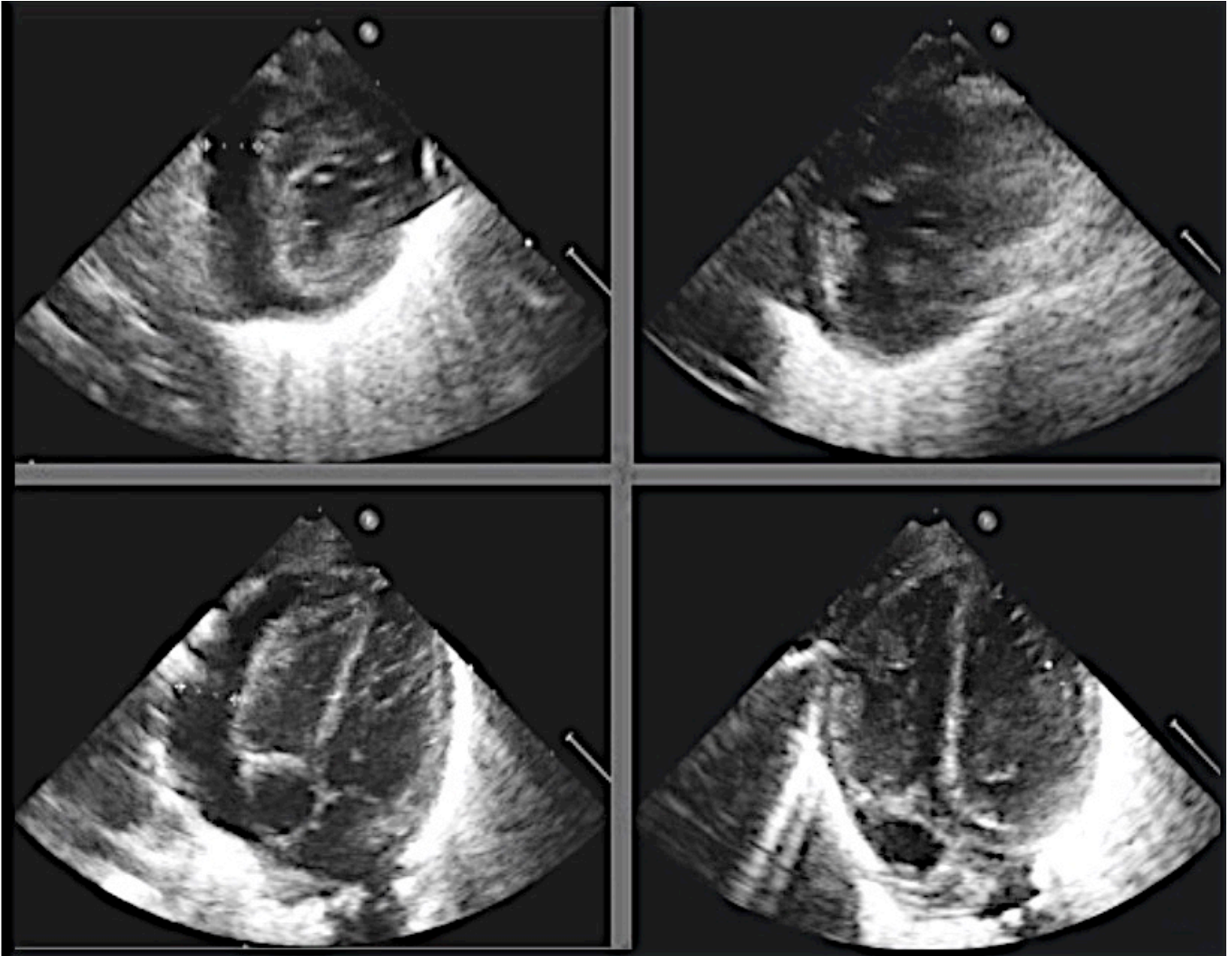


Figure 2. Echocardiograms (apical 4-chamber and short axis view) before and after UVC removal.

Physical exam revealed an active preterm female in moderate respiratory distress with subcostal retractions. Vital signs included a temp of 100.9° F, a pulse 189bpm, respiratory rate 61bpm, blood pressure 57/27mmhg, and weight 1335g. On lung auscultation there were diffuse rhonchi over both lung fields. Mild hypotonia was present. The remainder of the exam was unremarkable.

Umbilical artery and venous lines were placed upon arrival to the NICU. As demonstrated in Figure 1, the umbilical arterial catheter tip was located at the level of the T6, and

the umbilical venous catheter tip projected at the caoatrial junction.

On Day of Life (DOL) 1, an echocardiogram did not show any pericardial effusion.

Repeat imaging showed the arterial line with its tip at the T7 level and the venous line with its tip at the T6 level.

On DOL 3, an echo showed a small circumferential pericardial effusion. The X-ray showed 'optimal position' of

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UVC. Echocardiograms failed to show the catheter tip in the heart on Day 1 or on Day 3. Ejection fraction was 91.7%. Clinically, the infant deteriorated and required intubation for worsening blood gas.

On DOL 4, repeat echo showed a moderate circumferential pericardial effusion with no evidence of cardiac tamponade. The effusion was mainly located posteriorly and was slightly larger compared to the previous day. Ejection fraction remained unchanged. In view of these findings, the umbilical lines were then removed, and a PICC line was placed.

On DOL 5, the pericardial effusion had decreased as the infant remained stable on vent support.

By DOL 7, there was no pericardial effusion seen on echocardiogram.

Discussion

It is possible for a properly placed UVC to cause pericardial effusion as happened with our patient. Even if the UVC is not in the heart, it is always important to take it out ASAP in event of pericardial effusion. Pericardial effusion associated with UVC may be treated conservatively if signs of cardiac tamponade are absent.

Possible causes of pericardial effusion in this setting include direct trauma to the endothelial wall during UVC placement or irritation to the endothelial lining caused by hyperosmolar infusates.

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“It is possible for a properly placed UVC to cause pericardial effusion as happened with our patient. Even if the UVC is not in the heart, it is always important to take it out ASAP in event of pericardial effusion. Pericardial effusion associated with UVC may be treated conservatively if signs of cardiac tamponade are absent.”



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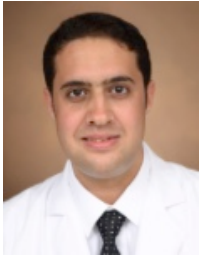
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www.barthsyndrome.org

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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 correct English. The final manuscript may be between 400-4,000 words, and contain pictures, graphs, charts and tables. Accepted manuscripts will be 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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Neonatology Today (NT) is the leading monthly publication that is available free to qualified Board Certified (BC) neonatologists and perinatologists. Neonatology Today provides timely news and information to BC neonatologists and perinatologists regarding the care of newborns, and the diagnosis and treatment of premature and/or sick infants. In addition, NT publishes special issues, directories, meeting agendas and meeting dailies around key meetings.

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Incidence, Risk Factors and Neonatal Outcome of Intraventricular Haemorrhage (IVH) Among Very Low Birth Weight Infants (VLBW) in Singapore General Hospital

By Varsha Atul Shah, MBBS, MD (Paed), MRCP (UK), FAMS (Sing); Mary Grace S. Tan, MD, DN (Sing)

Objective

This article is a retrospective analysis of 573 Very Low Birth Weight Infants (VLBW) with birth weight of 1500 gm or less, and who were screened for Intraventricular Haemorrhage (IVH) using cranial ultrasound. The incidence, risk factors and outcome of IVH in the neonatal period for these neonates were analysed.

Methods

Retrospective analysis of 12 years of data of all VLBW screened for IVH, managed by Singapore General Hospital, for maternal, neonatal risk factors.

Maternal factors were:

- Age
- Preeclampsia
- Pyrexia
- Prolonged Rupture of Membrane (PROM)
- Antepartum Haemorrhage (APH)
- Multiple births
- Tocolysis
- and antenatal steroids

Neonatal factors were:

- Gender
- Gestational Age (GA)
- Birth Weight (BWT)
- 1 and 5 minutes Apgar Scores
- Hypothermia
- Hypotension
- Hyaline Membrane Disease (HMD)
- Surfactant Usage
- Patent Ductus Arteriosus (PDA)
- Air Leak
- Pulmonary Haemorrhage
- Hypoglycaemia
- Necrotizing Enterocolitis (NEC)
- Hydrocephalus requiring shunt
- and death

Results

The incidence of IVH amongst VLBW was 15.5% (89/573). The majority, 34.8%, were Grade I, 22.4% were Grade II, 30.3% were Grade III, and 12.3% were Grade IV.

Eighty-four percent of IVH occurred in the first week of life. By univariate analysis, maternal risk factors for IVH were:

- PROM
- Pyrexia
- Fetal distress
- Male gender with low 1 and 5 minutes Apgar scores
- HMD requiring surfactant
- Hypothermia
- Sepsis
- Hypotension
- PDA
- Air-leak
- Pulmonary haemorrhage
- Hypoglycaemia
- and NEC were significant risk factors for IVH ($p < 0.0005$).

Periventricular cyst (PVL) was seen in 16.8% (15/89), bilateral dilated ventricles in 31.5% (28/89), and unilateral ventricular dilatation in 10% (9/89) VLBW. Ventriculoperitoneal shunt (VP) was needed in 4.5% (4/89) infants due to hydrocephalus. Mortality rate with IVH was 27% (24/89).

Conclusion

Prevention of prenatal labour by preventing maternal infection and PROM, and treatment of the mother with antenatal steroids are useful. In neonates, prevention and treatment of hypoxia, HMD, hypothermia, hypotension, optimal respiratory, ventilator therapy with treatment of PDA, pulmonary haemorrhage, air leak, and NEC are important factors in decreasing the incidence of IVH in VLBW.

NT

“Prevention of preterm labour by preventing maternal infection and PROM, and antenatal steroids is useful.”

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Clinical Trials - Selected & Edited from ClinicalTrials.gov

Compiled and Reviewed by Tony Carlson, Senior Editor

High Frequency Oscillatory Ventilation Combined With Intermittent Sigh Breaths: Effects on Lung Volume Monitored by Electric Tomography Impedance

This study is currently recruiting participants

Verified November 2014 by Rigshospitalet, Denmark

Sponsor: Rigshospitalet, Denmark

Information provided by (Responsible Party):

Christian Heiring, Rigshospitalet, Denmark

Purpose: Background: Ventilator-induced Lung Injury (VILI) remains a problem in neonatology. High Frequency Oscillatory Ventilation (HFOV) provides effective gas exchange with minimal pressure fluctuation around a continuous distending pressure and, therefore, small tidal volume. Animal studies showed that recruitment and maintenance of functional residual capacity (FRC) during HFOV ("open lung concept") could reduce lung injury.

"Open-Lung HFOV" is achieved by delivering a moderate high mean airway pressure (MAP) using oxygenation as a guide for lung recruitment. Some neonatologists suggest combining HFOV with recurrent sigh-breaths (HFOV-sigh) delivered as modified conventional ventilator-breaths at a rate of 3/min. The clinical observation is that HFOV-sigh leads to more stable oxygenation, quicker weaning and shorter ventilation. This may be related to improved lung recruitment.

Electric Impedance Tomography (EIT) enables measurement and mapping of regional ventilation distribution and end-expiratory lung volume (EELV). EIT generates cross-sectional images of the subject based on measurement of surface electrical potentials resulting from an excitation with small electrical currents and has been shown to be a valid and safe tool in neonates.

Purpose, aims:

- To compare HFOV-sigh with HFOV-only and determine if there is a difference in global and regional EELV (primary endpoints) and spatial distribution of ventilation measured by EIT
- To provide information on feasibility and treatment effect of HFOV-sigh to assist planning larger studies. We hypothesize that EELV during HFOV-sigh is higher, and that regional ventilation distribution is more homogenous.

Methods:

Infants at 24-36 weeks corrected gestational age already on HFOV are eligible. Patients will be randomly assigned to HFOV-sigh (3 breaths/min) followed by HFOV-only or vice versa for 4 alternating 1-hour periods (2-treatment, double crossover design, each patient being its own control). During HFOV-sigh set-pressure will be reduced to keep MAP constant, otherwise HFOV will remain at pretrial settings.

Sixteen ECG-electrodes for EIT recording will be placed around the chest at study start. Each recording will last 180s, and will be done at baseline and at 30 and 50 minutes after each change in ventilator modus.

Feasibility: No information of EIT-measured EELV in babies on HFOV-sigh exists. This study is a pilot-trial.

In a similar study-protocol of lung recruitment during HFOV-sigh using "a/A-ratio" as outcome, 16 patients were estimated to be sufficient to show an improvement by 25%. This assumption was based on clinical experience in a unit using HFOV-sigh routinely. As the present study examines the same intervention, we assume that N=16 patients will be a sufficient sample size. We estimate including this number in 6 months.

Condition:

- Respiratory Distress Syndrome in Premature Infants
- Bronchopulmonary Dysplasia
- Ventilator-Induced Lung Injury
- Functional Residual Capacity

Intervention - Other: HFOV combined with sigh breaths

Study Type: Interventional

Study Design:

- Allocation: Randomized
- Endpoint Classification: Efficacy Study
- Intervention Model: Crossover Assignment
- Masking: Open Label
- Primary Purpose: Treatment

Ages Eligible for Study: 24 Weeks - 44 Weeks

Genders Eligible for Study: Both

Accepts Healthy Volunteers: No

Inclusion Criteria:

- Infants at 24-36 weeks corrected gestational age
- Already ventilated with high frequency ventilation
- Requiring FiO₂=21%-70% to maintain adequate oxygen saturation
- Clinically stable, i.e. ventilated on current settings for more than just a few hours with stable, but not necessarily normalized blood gases, transcutaneous values and oxygen requirement
- Parent(s) or guardian able and willing to provide informed consent)

Exclusion Criteria:

- Major congenital cardiovascular or respiratory abnormalities (excluding Patent Ductus Arteriosus).
- Poor skin integrity precluding use of adhesive ECG electrodes used for EIT monitoring

- The physician responsible for the baby considers one of the ventilation modes unsuitable for the infant or the patient unsuitable for EIT monitoring
- Lack of parental signed written informed consent or if both parents are under 18 years of age (due to complexities of obtaining consent)

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Judith Hough, PhD; +61 3163 8250; judith.hough@mater.org.au

Locations: Australia, Queensland, Department of Neonatology, Mater Mothers Hospital

Recruiting:

- Brisbane, Queensland, Australia
- Principal Investigator: Christian Heiring, neonatologist
- Principal Investigator: Luke Jardine, Neonatologist
- Sub-Investigator: Andreas Schibler, PhD
- Sub-Investigator: Judith Hough, PhD
- Sub-Investigator: Andrew Shearman, Scientist
- Sub-Investigator: Deborah Caldararo, RN
- Sub-Investigator: Gorm Greisen, Professor

Principal Investigator:

Christian Heiring, Neonatologist
 Department of Neonatology, Rigshospitalet, Copenhagen

Luke Jardine, Neonatologist
 Department of Neonatology, Mater Mothers Hospital,
 Brisbane, Australia

ClinicalTrials.gov Identifier:

NCT0196281
 Other Study ID Numbers: 1936M
 Study First Received: October 9, 2013
 Last Updated: November 4, 2014

Effects of Delayed Cord Clamp and/or Indomethacin on Preterm Infant Brain Injury

*This study is currently recruiting participants.
 Verified August 2014 by University of Kentucky*

Sponsor: John Bauer, University of Kentucky

Purpose: Intraventricular Hemorrhage (IVH) and Periventricular Leukomalacia (PVL) are brain lesions that commonly occur in preterm infants, and are well-recognized major contributors to long-term brain injury and related disabilities later in life. Despite its prevalence, long term consequences, and enormous medical and social costs, mechanisms of IVH and optimal strategies to prevent or treat its occurrence are poorly defined, especially for extremely premature infants. Only one medical therapy, prophylactic indomethacin during the first 3 days of life, has been shown to prevent or decrease the severity of IVH in preterm infants, but its use is limited by toxic side effects and debatable effects on long-term outcomes. Several small studies and case reports suggest that delayed umbilical cord-clamping (DCC) may also decrease the incidence of IVH

in premature infants, but thus far these trials have indomethacin treatment mixed within their cord clamping protocols. The investigators are conducting a randomized, blinded investigation of 4 treatment groups:

- 1) Control (no intervention)
- 2) DCC alone
- 3) Prophylactic indomethacin alone
- 4) Combination of DCC/indomethacin, with respect to survival, IVH or PVL incidence and severity, neurodevelopmental outcomes, and relevant mechanistic effects.

With the steady rise in extreme premature births and clear links of IVH to long-term disabilities there is a need to improve care for these patients.

This multi-disciplinary project addresses an important medical problem for an understudied patient population, where the current practice has clear limitations.

Condition:

- Intraventricular Hemorrhage
- Periventricular Leukomalacia
- Brain Injury
- Renal Injury

Intervention:

- Drug: Indomethacin
- Procedure: delay in umbilical cord clamp at birth

Phase 1 and 2

Study Type: Interventional

Study Design:

- Allocation: Randomized
- Endpoint Classification: Safety/Efficacy Study
- Intervention Model: Parallel Assignment
- Masking: Double-Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
- Primary Purpose: Prevention

Estimated Enrollment: 400

Study Start Date: August 2014

Estimated Primary Completion Date: December 2019 (Final data collection date for primary outcome measure)

Ages Eligible for Study: 24 Weeks to 30 Weeks

Genders Eligible for Study: Both

Accepts Healthy Volunteers: No

Inclusion Criteria:

- Pregnant women admitted >24weeks and <30weeks gestational age
- In-hospital birth (allowing for cord clamp randomization)

Exclusion Criteria:

- Preterm infant <24weeks or >30weeks at birth
- Maternal risks identified by obstetrician

- fetal risks identified by obstetrician
- Any congenital abnormality of newborn infant
- Placental abruption/placental previa
- Delivery less than 2hrs from consenting to study participation

Contacts:

Peter J Giannone, MD; peter.giannone@uky.edu

Locations and Recruiting:

Kentucky Childrens Hospital
University of Kentucky (UK)
Neonatal Intensive Care Unit
Kentucky, USA

Study Director: Vicki Whitehead, RN

University of Kentucky, Section of Neonatology, Kentucky, USA

Principal Investigator:

John Bauer, PhD
University of Kentucky, Department of Pediatrics, Kentucky, USA

Study Director:

Hong Huang, MD, PhD
University of Kentucky, Section of Neonatology, Kentucky, USA

ClinicalTrials.gov Identifier:

NCT02221219

Other Study ID Numbers: HD070792

Study First Received: August 18, 2014;

Last Updated: August 19, 2014

Vermont Oxford Network Very Low Birth Weight Database (VON VLBW)

*This study is currently recruiting participants
Verified April 2013 by Vermont Oxford Network*

Sponsor: Vermont Oxford Network

Information provided by: Vermont Oxford Network

Study Type: Observational [Patient Registry]

Study Design: Observational Model: Cohort

Time Perspective: Prospective

Target Follow-Up Duration: 1 Year

Primary Outcome Measures: Registry of baseline and outcome data for VLBW infants with data collected in a uniform manner [Time Frame: up to 1 year]

[Designated as safety issue: No] Data items include infant and maternal characteristics, delivery room interventions, respiratory care and outcomes, surgeries, infections, comorbid conditions, and length of stay. Time frames for data collection include: characteristics of birth; at day 28; and at discharge. Tracking ends at discharge home (including for infants transferred out) or at one year.

Estimated Enrollment: 60000

Study Start Date: January 1990

Estimated Study Completion Date: December 2040

Estimated Primary Completion Date: December 2040
(Final data collection date for primary outcome measure)

Ages Eligible for Study: up to 28 Days

Genders Eligible for Study: Both

Accepts Healthy Volunteers: No

Sampling Method: Non-Probability Sample

Study Population: Infants who are 401 to 1500 grams birth weight or 22 to 29 weeks gestational age and who are admitted to Vermont Oxford Network member centers within 28 days of birth without first going home

Inclusion Criteria: Any infant who is born alive and whose birth weight is 401 to 1500 grams or 22 weeks 0 days and 29 weeks 6 days gestational age (inclusive) who is born at or admitted to a Vermont Oxford Network member center within 28 days of life without having first gone home, regardless of the where the infant receives care.

Exclusion Criteria:

- Stillborn infants
- Infants discharged home prior to admission to a member center
- Infants admitted after 28 days

Contact: Beth Anderson; 802-865-4814;
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Locations:

United States, Vermont
Vermont Oxford Network

Recruiting:

Burlington, Vermont, USA
Contact: Jeffrey D Horbar, MD; 802-865-4814;
mail@vtxford.org

Study Chair:

Jeffrey D Horbar, MD
Vermont Oxford Network

ClinicalTrials.gov Identifier:

NCT01825499

Other Study ID Numbers: VON001

Study First Received: March 27, 2013

Last Updated: December 8, 2014

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Medical News, Products & Information

Compiled and Reviewed by Tony Carlson, Senior Editor

Using Tablets to Screen Moms for Perinatal Depression

Pregnant women and new mothers at one central Illinois public health clinic will soon receive depression screenings using mobile health - also called mHealth - technology.

Researchers from the School of Social Work at the University of Illinois are collaborating with staff members at Champaign-Urbana Public Health District on a project that will provide perinatal depression screenings using tablet computers.

"We've talked to clinicians at other sites, and the mHealth technology is a no-brainer - it's easy, people are comfortable with it, it's faster and it's paperless - there are so many great things about it," said principal investigator Karen M. Tabb Dina, a professor of social work. "But clinics across the country are struggling with how to implement universal screening, and from what we've learned, they're implementing it without getting staff feedback first."

Early in the project, focus groups were held with Public Health staff members to gain their perspectives about the clinic's paper-based screening system and the possibility of using technology to overcome language barriers and other obstacles.

Tabb Dina is the lead author on a paper about the project that is forthcoming in the journal *General Hospital Psychiatry*. She also is the principal investigator for Identifying Depression through Early Assessment, a multidisciplinary project that is exploring the prevalence of perinatal depression among women in Brazil and the U.S.

Perinatal depression - which begins during pregnancy or up to a year after childbirth - may affect up to 20% of women worldwide. Some recent studies suggested that the disease might be twice as prevalent among low-income women.

Under a 2008 Illinois law, clinics and hospitals that provide prenatal care, labor and delivery services are required to screen women for perinatal depression.

Champaign-Urbana Public Health District serves about 3,100 pregnant women and postpartum women each month, administering a depression questionnaire at least once during each client's pregnancy and again after delivery.

"The paper-based screenings are great if you complete them and score them immediately, but sometimes there's a little bit of delay, which can be a barrier if you have to find the client later," said

Brandon Meline, Director of Maternal and Child Health Management at Public Health. "We have a pretty transient population, so we try to get everything done - education, interventions and referrals - while the client is here."

The tablets are equipped with electronic versions of the Edinburgh Postnatal Depression Scale, a 10-item questionnaire commonly used by clinics.

Because the software provides the questionnaire in numerous languages, clients can complete the screening in the language they are most comfortable using. And audio technology enables even women with poor literacy skills to complete the screening independently, Tabb Dina said.

"Most of our moms come in with smartphones, so they're savvy to the use of mobile technology and touch-screen functionality," said Meline, adding that data will not be stored on the tablets but in the clinic's electronic medical records system.

Tabb Dina purchased three tablets for the project with funding from a Monkman Endowment Award for Faculty Research from the School of Social Work.

Tabb Dina's co-authors were social work professor Hellen G. McDonald, graduate student Shinwoo Choi and Pineros-Leano, all at Illinois; Rachel Kester and Hsiang Huang, both of Cambridge Health Alliance at Harvard Medical School; and Meline. Huang, Meline, Tabb Dina and graduate student Heather Sears were Pineros-Leano's co-authors on the paper published by *Family Practice*.

The U. of I. Campus Research Board, the Fulbright Scientific Mobility Program, and the U.S. Dept. of Agriculture's Agriculture and Food Research Initiative provided additional funding for the project.

Preemies May Have Psychiatric Problems as Adults, But Study Finds Less Alcohol and Substance Abuse

Newswise — The good news is that people born as Extremely Low Birth Weight babies are less likely than others to have alcohol or substance use disorders as adults. The less encouraging news is that they may have a higher risk of other types of psychiatric problems.

A study by McMaster University researchers, published in the journal *Pediatrics*, also found that extremely low birth weight (ELBW) babies whose mothers received a full



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course of steroids prior to giving birth are at even greater risk for psychiatric disorders.

“Importantly, we have identified psychiatric risks that may develop for extremely low birth weight survivors as they become adults, and this understanding will help us better predict, detect and treat mental disorders in this population,” said Dr. Ryan Van Lieshout, lead author of the study and a professor of psychiatry and behavioural neurosciences for the Michael G. DeGroot School of Medicine at McMaster.

The study involved 84 adults who were born weighing less than 1,000 grams (two pounds, 2 ounce), and 90 normal birth weight babies. All were born in Ontario between 1977 and 1982.

The research found that in their early 30s, those low birth weight babies are nearly three times less likely to develop an alcohol or substance use disorder. But, they were two and a half times more likely than adults born normal birth weight to develop a psychiatric problem such as depression, an anxiety disorder or attentive-deficit/hyperactivity disorder (ADHD).

However, those extremely low birth weight babies who received a full course of life-saving steroids before birth as part of their treatment had even higher odds (nearly four and a half times) of developing those same psychiatric issues, and they were not protected against alcohol or substance use disorders.

The study was funded by a research team grant from the Canadian Institutes for Health Research.

Do Clothes Make the Doctor? U-M Researchers Report on Patient Perceptions of Physicians Based on Attire, Age, Culture & Type of Care Matter – New Survey Will Look at Impact

Newswise — What should doctors wear? And how does something as simple as their choice of a suit, scrubs or slacks influence how patients view them?

A new analysis takes a comprehensive look – and finds that the answer isn’t as simple as you might think.

It also finds that doctors don’t seem to be getting a lot of guidance on how to dress – despite the influence their attire can have on patients’ perceptions.

In general, the study finds, people prefer their physicians dress on the formal side – and definitely not in casual

wear. Doctors of either gender in suits, or a white coat, are more likely to inspire trust and confidence.

But fashion takes a back seat when it comes to emergency, surgical or critical care, where data show clothes don’t matter as much—and patients may even prefer to see doctors in scrubs.

How you feel about your doctor’s attire can depend greatly on your age and culture, the researchers find. In general, Europeans and Asians of any age, and Americans over age 50, trusted a formally dressed doctor more, while Americans in Generation X and Y tended to accept less-dressy physicians more willingly.

The findings were compiled by a University of Michigan Health System team, from a comprehensive international review of studies on physician attire, and other sources. In all, the data they reviewed came from 30 studies involving 11,533 adult patients in 14 countries. Their review has been published in *British Medical Journal Open*.

Currently, the team is preparing to launch their own international study of the impact of physician clothing choices, under the name “Targeting Attire to Improve Likelihood of Rapport” or TAILOR. They’ll work to quantify how patients’ views of physicians change based on what they’re wearing, and where they’re providing care. The team will also evaluate how attire might affect patients’ trust in what that doctor says or recommends.

Lead author Christopher Petrilli, MD, an Internal Medicine Resident at the U-M Health System who worked in the sharp-dressed world of investment banking before switching to medicine, says the study grew out of his conversations with senior physicians, including senior author Vineet Chopra, MD, MSc, and co-author Sanjay Saint, MD, MPH.

“As physicians, we want to make sure that we’re dressing in a way that reflects a level of professionalism and also mindful of patients’ preferences.”

Petrilli explains. “Many studies have looked at various aspects of physician attire, so we wanted to look across this body of literature to find common threads. But at the same time, we found a lack of detailed guidance from top hospitals to their physicians about how to dress.”

One size does not fit all

In all, 21 of the 30 studies found that patients expressed clear preferences about what they felt doctors should wear, or said that physician attire affected their percep-

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tions of a physician. In 18 of those studies, formal attire or a white coat was the preferred attire.

When the researchers drilled down further, they found that four of the seven studies that involved surgery patients reported that attire choice didn't matter or that scrubs were preferred. The same was true of four of five studies that involved patients receiving emergency care or intensive care.

Chopra, a hospitalist and U-M Medical School assistant professor of general medicine, adds that patient satisfaction now influences how doctors, and hospitals are paid – making the impact of patient perceptions of their doctors' knowledge, caring, professionalism and trustworthiness all the more important.

And, he says, the findings of the new study suggest that a "one size fits all" approach to policies and guidance for doctors won't work.

"In order to better tailor physician attire to patient preferences and improve available evidence, we would recommend that healthcare systems capture the 'voice of the customer' in individual care locations, such as intensive care units and emergency departments," he says.

The subject of what to wear isn't covered directly in medical school. Even for physicians in practice at hospitals on the *U.S. News & World Report* Best Hospitals ranking, specific guidelines are few and far between. Only 5 of those surveyed by the U-M team had official guidance for physicians about attire at all, and most just recommended it be "professional." The others offered no formal guidance.

Gathering more data

The new TAILOR study will survey patients in outpatient general medicine and specialty clinic waiting rooms and inpatient medical units. Hospitals in three countries have signed on to participate, making it the largest such study of its kind. While pediatric patients and their parents will not be included, the researchers note that this is another area ripe for research.

"Everything is supposed to be evidence-based in medicine," says Petrilli. "With this review and our new study, we can provide compelling evidence to influence the way physicians dress."

In addition to Petrilli, Chopra and Saint, the research team included: Megan Mack, MD; Jennifer Janowitz Petrilli, and Andy Hickner. Saint, Chopra and Mack all hold positions at the VA Ann Arbor Healthcare Center. Saint and Chopra are members of the U-M Institute for Healthcare Policy and Innovation, and the VA Center for Clinical Management Research.

Funding for the research came in part from the Agency for Healthcare Research and Quality.

Reference: *BMJ Open* 2015; 5:e006578. doi:10.1136/bmjopen-2014-006578

Being Born 4-6 Weeks Premature Can Affect Brain Structure, Function

The brains of children who were born just a few weeks early differ from those born on time, and these differences may affect learning and behavior, according to a study presented at the *2014 Pediatric Academic Societies (PAS)* annual meeting in Vancouver, British Columbia, Canada.

Studies have shown that children who were born between 34 and 36 weeks' gestation (late preterm) have more social, behavioral and academic problems than children born at full term (37-41 weeks). However, few studies have looked at the brain structure of late preterm children.

Researchers from the University of Iowa conducted magnetic resonance imaging (MRI) scans on 32 children ages 7-13 years old who were born at 34-36 weeks' gestation. In addition, they administered cognitive tests to the children, including the Wechsler Intelligence Scale for Children, Benton Judgment of Line Orientation (which assesses visual perception), Grooved Pegboard (which assesses fine motor skills and coordination) and Children's Memory Scale. Parents also completed a behavioral assessment.

Results were compared to 64 children born at full-term who were recruited for another study in which they completed the same cognitive and behavioral assessments, neurological exam, and MRI sequences as the late preterm group.

Preliminary analysis showed differences in both cognitive function and brain structure in the late preterm children compared to full term children. Functionally, late preterm children had more difficulties with visuospatial reasoning and visual memory. They also had slower processing speed. Processing speed refers to the ability to perform automatically a simple task in an efficient manner. Children with slower processing speed may require more time in the classroom setting to accomplish a task.

Structurally, the brains of late preterm children had less total cerebral white matter, which is critical to communication between nerve cells, and smaller thalami, a brain region involved in sensory and motor signaling.

"Late preterm birth accounts for 8% of all births each year in the United States, making it a public health issue," said presenting author Jane E. Brumbaugh, MD, FAAP, University of Iowa Stead Family Department of Pediatrics. "The effects of late preterm birth on the brain have not yet been fully characterized, and it has been assumed that there are no significant consequences to being born a few weeks early. Our preliminary findings show that children born late preterm have differences in brain structure and deficits in specific cognitive skills compared to children born full term."

Parents of late preterm children also reported more problems with hyperactivity, inattention, opposition and aggression than parents of full-term children.

"The developing brain is vulnerable to what most might consider a minor 'insult' in being born late preterm. Moreover, these effects are enduring," said senior author Peggy C. Nopoulos, MD, Professor of Psychiatry, Neurology and Pediatrics with University of Iowa Health Care.

Typical Pregnancy is Now Only 39 Weeks: Late Preterm Births Increase

March of Dimes Foundation - The most common length of pregnancy in the United States is now 39 weeks, a week shorter than the traditional definition of a full-term pregnancy. This shift occurred between 1992 and 2002, according to a new analysis by the March of Dimes published in a special supplement of the *Journal Seminars in Perinatology*.

In 2002, one-quarter of all singleton babies were born full term at 39 weeks. Births at or after 40 weeks decreased by nearly 21%. During the decade studied, there was also a 12% increase in births occurring between 34 and 36 weeks, referred to as "late preterm births" (sometimes called "near-term births").

"Late preterm infants are a growing concern," said Nancy Green, MD, Medical Director of the March of Dimes. "Some babies born just a few weeks early need medical and nursing attention beyond that given to full term newborns. They have a greater likelihood of breathing problems like Respiratory Distress Syndrome (RDS), feeding difficulties, temperature instability (hypothermia), jaundice and reduced brain development than full-term babies."

The March of Dimes analysis suggests that increasing rates of Cesarean-section deliveries and induced labor have probably contributed to, but do not completely explain, these shifts in deliveries, said Michael Davidoff, Manager of Informatics, Research and Development at the March of Dimes and the paper's lead author.

Clinicians weigh the risk for the mother and the fetus of continuing a medically complicated pregnancy, versus the risks associated with earlier delivery. For some high-risk pregnancies, early delivery may promote better outcomes for both the mother and the baby. The availability of more data on the outcomes of late preterm births will better inform providers and the public about potentially preventable risks. Pregnancies should continue to term if medically and obstetrically advisable, thereby avoiding unnecessary preterm inductions and c-sections.

The March of Dimes study, "Changes in Gestational Age Distribution Among U.S. Singleton Births: Impact on Rates of Late Preterm Birth, 1992 to 2002," was one of the research papers presented at a symposium addressing late preterm birth in July 2005, hosted by the National Institute of Child Health and Human Development of the National Institutes of Health. The scientific meeting focused on definitions, trends and complications faced by late preterm babies. These studies are published in a

Seminars in Perinatology special supplement on late preterm birth.

For more information, visit marchofdimes.com. To access PeriStats, and online source for perinatal statistics, go to www.marchofdimes.com/peristats.

Certain Factors Influence Survival and Prognosis for Premature Infants

Several factors influence how well a severely premature infant (23 weeks gestation) will do after birth and over the long term, according to researchers at Loyola University Medical Center. These findings were published in the December 2014 issue of the *American Journal of Perinatology*.

Researchers found that males, multiples and premature infants born in a hospital without a Neonatal Intensive Care Unit had a significantly higher death rate. Lack of exposure to steroids before birth and lower birth weights also significantly increased the risk for disability. Some studies suggested that babies born via Cesarean-section had survival advantages. African-American infants also had higher survival rates in certain studies, but conflicting evidence remains on the role of race and prognosis for these infants.

"The survival of extremely premature infants has improved considerably over the past three decades," said Jonathan Muraskas, MD, lead author, Co-Medical Director, Neonatal Intensive Care Unit, Loyola University Health System, and Professor, Loyola University Chicago Stritch School of Medicine. "Despite these survival rates, the number of infants born with severe or profound developmental disabilities remains high. This study sheds light on factors that may protect these infants."

These data come from a retrospective review over a 25-year period (1987-2011) of 87 successfully resuscitated infants at 23 weeks of pregnancy. Researchers studied the effects of poor prenatal care, race, gender, inflammation of fetal membranes, steroid use during pregnancy, delivery route and location, Apgar score, birth weight and multiple births on short- and long-term outcomes.

Forty-three percent of the infants in the study did not survive, and 88% of the survivors were evaluated at 2 years of age with 66% diagnosed with moderate to severe neurological impairment.

"There is no consensus on early treatment strategies that can accurately predict survival and profound developmental impairments based on observations in the first 48 hours of life," study authors noted. "Infants born 16 to 17 weeks early can survive, but may have cerebral palsy, blindness and deafness and may require significant resources for the rest of their life. This study will help to identify those infants at risk and help us guide how we care for them."

Standardized SIMPLE Feeding Program® Reduces Length of Stay, Costs in NICU

A new standardized approach for feeding infants in the Neonatal Intensive Care Unit (NICU) helps babies attain full oral feeds sooner, improves their growth and sends them home sooner. The guidelines, developed by clinician-scientists at Nationwide Children's Hospital and published in the *Journal of Parenteral and Enteral Nutrition*, also reduces the cost of care for these babies by shortening their stays in the NICU by as much as two weeks.

Feeding is a complex process that involves the integration of functional connectivity between the brain, airway and foregut. For babies in the NICU, achieving full oral feeds -- milk by mouth without tubes or limitations -- is a critical step for growth and the journey to discharge. Because many infants have complicated feeding difficulties and changes in clinical caregivers throughout their hospital stay, Sudarshan R. Jadcherla, MD, Director of the Neonatal and Infant Feeding Disorders Program and principal investigator in the Innovative Feeding Disorders Research Program at Nationwide Children's, hypothesized that a standardized approach to feeding could eliminate variability and simplify the transitions from enteral feeding to full oral feeding.

The team collected baseline data from 92 infants before initiating their quality improvement study with another 92 infants they enrolled in their SIMPLE (simplified, individualized, milestone-targeted, pragmatic, longitudinal and educational) program.

"Our SIMPLE feeding approach resulted in improved growth, eventually leading to more time at home with parents," Dr. Jadcherla says. "The emphasis of our program was on implementation of guidelines that can still be tailored to the infant's and parent's individual needs."

This specific program involved analyzing critical aspects of institutional processes, building consensus, developing educational workshops, monitoring compliance and accountability and providing constant feed-forward information.

"Simply removing the variability from feeding practices, cutting wastage of resources and optimizing staff training with regards to feeding and nutrition has helped us attain feeding success," Dr. Jadcherla says. "It also has helped us give babies more time at home and reduced costs."

Babies on the SIMPLE feeding program spent significantly less time on trophic feeds, which stimulate the gut but do not provide sufficient nutrients for growth, and less time being tube-fed. They were also able to tolerate the introduction of oral feeds and exclusive oral feeding earlier than babies prior to the guideline implementation. The team credits this improved feeding trajectory with the greater daily weight gains achieved by babies on the SIMPLE plan, which in turn led to stays of about 15 days shorter duration.

"The standardization and development of pragmatic feeding guidelines has resulted in acceleration of feeding milestones. These infants also had fewer days on mechanical breathing machines," says Dr. Jadcherla, who also is a principal investigator in the Center for Perinatal Research in The Research Institute and a Professor of Pediatrics at The Ohio State University College of Medicine. "Importantly, the length of stay was reduced while balancing measures and co-morbidities such as necrotizing enterocolitis, chronic lung disease, mortality and re-admission rates remained similar or trended downward."

There are no accepted benchmarks for feeding babies in an all-referral NICU, where admission requirements and sickness levels can be heterogeneous. Dr. Jadcherla founded the concept of the SIMPLE feeding program, developed the core group, trained feeding providers and led a multi-disciplinary team of NICU caregivers in this quality improvement endeavor. They gradually refined their approaches until all providers were educated and familiar with the guidelines and the recommendations reflected a wide range of clinical circumstances.

"We saw an opportunity to create a standardized approach to our feeding management strategies that would be monitored through multi-disciplinary feeding rounds," Dr. Jadcherla says.

The researchers hope the program's success at Nationwide Children's will be obtainable by other hospitals, as well.

"The guidelines were designed with an understanding of infant development, aerodigestive reflexes and individual clinical needs that will be adaptable to any NICU population," Dr. Jadcherla explains. "The SIMPLE feeding program also provides a forum for regular collaboration in regards to feeding management, which will help other institutions easily incorporate it into their care efforts."

Dr. Jadcherla and his collaborators at Nationwide Children's are now working to develop methods to optimize the diagnosis and management of gastroesophageal reflux disease, dysphagia and feeding intolerance in order to improve overall growth and development in premature infants while also lowering the economic burden of care.

Partners for Kids at Nationwide Children's Demonstrate Cost Savings, Quality as Pediatric ACO

A new study published in *Pediatrics* demonstrates the cost-saving and health care quality outcomes of the pediatric Accountable Care Organization (ACO) Partners for Kids. Results of this study indicate that Partners for Kids successfully improved the value of pediatric healthcare over time through cost containment, while maintaining quality of care.

Partners for Kids (PFK) is a pediatric ACO serving approximately 300,000 Medicaid-eligible children in Ohio, designed to address rising costs and concerns about the

quality of care delivered to low-income patients. In 1994, Nationwide Children's Hospital partnered with community pediatricians to create PFK, a physician-hospital organization with governance shared equally between Nationwide Children's and physician primary and specialty practice groups. ACOs are responsible for healthcare costs and quality across a defined population. To succeed, the ACO must improve value by reducing costs while either maintaining or improving the quality and outcomes of care.

"We believe this study is the first evaluation of a pediatric ACO. Our data demonstrate the potential for an ACO to minimize the growth in cost of care for a pediatric population, all while maintaining or improving quality of care," says lead author Kelly Kelleher, MD, MPH, VP of Community Health Services at Nationwide Children's and a member of the faculty at The Ohio State University College of Medicine.

The study assessed the value of care provided by PFK from January 2008 through December 2013. Costs of care were compared to overall reported costs of Medicaid within Ohio. Quality measures were derived from the Agency for Healthcare Research and Quality (AHRQ) Pediatric Quality Indicators, which focus on potentially preventable complications and hospitalizations and provide targets for interventions at both the provider and patient level. Four additional measures targeted specifically by PFK included neonatal intensive care days; emergency department visits due to asthma; diabetes care management; and 3- to 6-year-old well-child checks.

Results of cost comparisons indicated that PFK had lower cost growth than Medicaid fee-for-service programs and Medicaid managed care plans. From 2008 to 2013, costs per member per month for PFK grew at a rate of \$2.40 per year. Managed care plans grew at a rate of \$6.47 per year and Medicaid fee-for-service costs grew at a rate of \$16.15 per year.

Quality metrics based on AHRQ indicators stayed consistent on most other measures, showed improvement for three measures (including two measures of overall quality of care), and declined on two measures. PFK-specific quality measures showed improvements including fewer NICU days, fewer visits to the ED for asthma and a significant increase in the number of well-child visits. A slight deterioration was seen in diabetes care management.

Overall, the results indicate the PFK model substantially reduced growth in the cost of care compared to other Ohio Medicaid plans. In addition, quality-of-care measures held steady, with some small changes in both directions.

"PFK delivered on the promise of the ACO to reduce the rate of health care cost growth while maintaining or improving the quality of care," Dr. Kelleher states.

Pediatric ACOs may prove to be efficient models of reforming healthcare, Dr. Kelleher says. The National Committee on Quality Assurance, a non-profit organization dedicated to improving health care quality, is developing

an accreditation and measurement proposal for ACOs. PFK will participate in its analysis.

"While an additional 30 million Americans will have access to health coverage under the Patient Protection and Affordable Care Act, the difficult work of creating a system of better care, better health and lower cost will occur gradually, through pilot projects designed to encourage innovation, improve effectiveness and reduce costs," explains study co-author Richard Brill, MD, Chief Medical Officer at Nationwide Children's and a member of the faculty at The Ohio State University College of Medicine. "One of the primary vehicles through which the new law encourages such innovation is through provisions that establish Accountable Care Organizations in Medicare and for pediatrics, in Medicaid or CHIP."

Kelleher K, Cooper J, Deans K, Carr P, Brill RJ, Allen S, Gardner W. "Cost Saving and Quality of Care in a Pediatric Accountable Care Organization." *Pediatrics*. Feb 9, 2015.

This study was supported in part by Funding Opportunity Number CMS-1c1-12-0001 from the Centers for Medicare and Medicaid Services, Center for Medicare and Medicaid Innovation.

More information is available at NationwideChildrens.org.

Use of Sedation Protocol Does Not Reduce Time on Ventilator for Children

Among children undergoing mechanical ventilation for acute respiratory failure, the use of a nurse-implemented, goal-directed sedation protocol compared with usual care did not reduce the duration of mechanical ventilation, according to a study in *JAMA*. The study was being released to coincide with its presentation at the *Society of Critical Care Medicine's 44th Critical Care Congress*.

Although sedation therapy benefits critically ill infants and children, it is also associated with adverse effects. Numerous studies in adult critical care support a minimal yet effective approach to sedation management. In contrast, few data inform sedation practices in pediatric critical care. Knowledge generated in adult critical care may not translate to the care of critically ill children, according to background information in the article.

Martha A.Q. Curley, RN, PhD, of the University of Pennsylvania, Philadelphia, and colleagues studied 2,449 children (average age, 4.7 years) mechanically ventilated for acute respiratory failure in pediatric intensive care units (PICUs) to a sedation intervention (17 sites; n = 1,225 patients) or sedation with usual care (14 sites; n = 1,224 patients). The intervention PICUs used a protocol that included targeted sedation, arousal assessments, extubation (removal of breathing tube) readiness testing, sedation adjustment every 8 hours, and sedation weaning. Patients were followed up until 72 hours after opioids were discontinued, 28 days, or hospital discharge. The study (RESTORE) was conducted from 2009-2013.

The duration of mechanical ventilation, the primary outcome for the study, was not different between the 2 groups (intervention: median, 6.5 days vs control: median, 6.5 days). There were no group differences in the time to recovery from acute respiratory failure, duration of weaning from mechanical ventilation, PICU and hospital lengths of stay or 28- or 90-day in-hospital mortality. There were no significant differences in sedation-related adverse events including inadequate pain management, inadequate sedation management, extubation failure, ventilator-associated pneumonia, catheter-associated bloodstream infection, or new tracheostomy. Intervention patients experienced more postextubation stridor (an abnormal sound made when the breathing passages are narrowed; 7 percent vs 4 percent) and fewer stage 2 or worse immobility-related pressure ulcers (<1% vs 2%).

"Exploratory analyses of several secondary outcomes indicated that the sedation protocol was associated with a difference in patients' sedation experience; patients in the intervention group were able to be safely managed in a more awake and calm state while intubated, receiving fewer days of opioid exposure and fewer sedative classes without an increase in inadequate pain or sedation management or clinically significant iatrogenic [consequence of treatment] withdrawal compared with patients receiving usual care, but they experienced more days with reported pain and agitation, suggesting a complex relationship among wakefulness, pain, and agitation," the authors write.

The researchers add that although this study focused on the process of how sedatives are administered, future studies should compare the best sedative agent for varied lengths of critical illness. "Outcomes of interest include efficacy as well as an evaluation of the immediate risk-benefit ratio and an evaluation of the long-term effect of sedatives on neurocognitive development and post-traumatic stress."

"Curley and colleagues answered the call for the conduct of a large clinical trial in children and have contributed valuable data to help advance approaches to sedation management in critically ill children," writes Sangeeta Mehta, MD, FRCPC, of Mount Sinai Hospital and the University of Toronto, in an accompanying editorial.

"While it is disappointing that this trial showed no advantage of a complex sedation management strategy, it is reassuring that the overall clinical outcomes related to 'usual care' in the 14 control PICUs were not significantly different than protocolized sedation in the intervention PICUs. It is imperative that high-quality research in this field continues, not only to learn more about the short-

and long-term effects of sedation strategies but, more importantly, to improve clinical care and outcomes for these vulnerable patients."

The study was supported by grants from the National Heart, Lung, and Blood Institute and the National Institute of Nursing Research, National Institutes of Health. Please see the article for additional information, including other authors, author contributions and affiliations, financial disclosures, etc.

Editorial: Protocolized Sedation in Critically Ill Children
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Premature Infants Exposed to Unsafe Levels of Chemical in Medical Products

Hospitalized premature infants are exposed to unsafe levels of a chemical found in numerous medical products used to treat them, raising questions about whether critically ill newborns may be adversely affected by equipment designed to help save their lives.

The chemical, di(2-ethylhexyl)phthalate (DEHP), is used to increase flexibility of many plastic devices. These products, made from polyvinyl chloride (PVC), include most intravenous tubing, catheters, endotracheal tubes, and fluid and blood product bags. DEHP doesn't bind chemically to PVC, and is able to leach into fluids and body tissues in contact with it. New Johns Hopkins Bloomberg School of Public Health research suggests that critically ill preterm infants may be exposed to DEHP at levels approximately 4,000 to 160,000 times higher than those believed to be safe. Infants can receive high exposures to DEHP during weeks to months of treatment in a hospital's neonatal intensive care unit (NICU).

The results were reported online Nov. 13th by the *Journal of Perinatology*.

"It's remarkable that the care of sick and developmentally vulnerable preterm infants depends on an environment composed almost entirely of plastic," says neonatologist Eric B. Mallow, MD, MPH, a Senior Research Program Coordinator at the Bloomberg School and the study's leader. "The role of these synthetic materials in the clinical course of our patients remains almost completely unexplored. PVC is the predominant flexible plastic in most NICUs, and this can result in considerable DEHP exposures during intensive care."

Mallow and co-investigator Mary A. Fox, PhD, MPH, an Assistant Professor in the Department of Health Policy



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and Management, reviewed and analyzed previously published studies of DEHP and its potential risks. Nearly all public attention to the health effects of phthalates, for both the general population and hospitalized patients, has focused on their role as endocrine disruptors - substances that can interfere with normal hormone function.

However, the researchers found abundant published evidence that DEHP has a wide range of non-endocrine toxic effects, and they propose that these could affect the short- and long-term health of NICU patients. DEHP has been shown repeatedly in animal studies to increase inflammation, cause liver injury, and interfere with development of lung, brain, and eye. Clinical studies confirm that some of these effects occur in NICU patients as well.

"We were floored by how high the exposures are when you look at all of the devices together," Fox says. "It's a population that we know is vulnerable to begin with. They're struggling to survive. And the concern now is whether this phthalate exposure is actually contributing to their problems when these medical products are supposed to be helping them get better."

Phthalates, including DEHP, are found in a wide range of consumer products, such as food packaging, clothing, upholstery, vinyl flooring, cosmetics, and fragrances. DEHP is the only phthalate approved for medical devices in the U.S., and its use is unregulated. In contrast, DEHP and several other phthalates are limited to trace amounts in children's toys and childcare products.

The new research finds that the total daily exposure for a two-kilogram (four-pound) critically ill infant can reach 16 mg/kg per day. The largest sources are blood products, and endotracheal tubes placed in the airway to deliver breathing support with a ventilator. In analyzing toxic thresholds, the researchers determined that daily DEHP intakes are approximately

4,000 times higher than desired to prevent a type of male reproductive toxicity, and 160,000 times higher than desired to prevent liver injury. They say that a lower DEHP exposure could be one reason why preemies who can be managed without a ventilator seem to have better lung outcomes.

The researchers say that replacing DEHP-containing products in the NICU with existing alternative products that don't contain DEHP would be the most effective initial step in reducing phthalate exposures during critical care. Further reductions could be attained by addressing other sources of phthalates in the NICU, including construction materials (such as vinyl flooring and paints); equipment such as ventilators and incubators; soaps, lotions and other cosmetics used by staff and visitors; and even the soaps, lotions and powders used for baby care.

"We do have to make tradeoffs and we want to save these babies," Fox says. "But can we save them by using alternative products that reduce their exposures to substances that may be harming them? It seems like we could."

"Phthalates and critically ill neonates: device-related exposures and non-endocrine toxic risks" was written by Eric B. Mallow and Mary A. Fox.

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