Thursday October 26 – Jumpstarting Quality 3.0

- Change Ideas Exchange - What Are You Working On?  
  D. Dukhovny
- 2017 Crafting a SMART Aim  
  M. Gupta
- Introduction to SQUIRE 2.0  
  T. Ho
- What, Why and How To: Develop a Driver Diagram  
  R. Vartanian
- 2017 Measurement and Metrics - the Basics!  
  Heather Kaplan
- Plotting the Dots: Run Chart Interpretation and Intro to Control Charts  
  M. Gupta
- Time to Take Action: Planning and Executing Small "Tests of Change" / PDSA Cycles  
  R. Vartanian

Friday October 27 – Newborn Antibiotic Stewardship National Summit

- Implementation of the Sepsis Risk Calculator  
  D. Braun and A. Fischer
- Emerging Resistance and Fungal Prophylaxis  
  R. Soll
- Is Improvement Contagious? Clinicians Perspective  
  K. Puopolo
Saturday October 28 – Annual Quality Congress Day 1

Sunrise Sessions

- VON Serial Data
  
  E. Edwards

- AAP Verification of NICU Levels of Care Project
  
  A. Stark

Day 1 Plenary Sessions

- Intro: Framing the Evidence Challenges
  
  R. Soll

- Translating the Evidence Into Practice: Antenatal Steroids
  
  A. Jobe

- Improvement Brief / Variations in VLBW Infant Outcome and Practices Between Neonatal Units in Switzerland And the US
  
  M. Adams

Day 1 Breakout Sessions

- BPD: Why Are We Failing to Move the Big Dot?
  
  A. Jobe

- Safe Sleep in the Newborn Nursery, NICU and Beyond!
  
  R. Moon

- Confirming or Ruling Out Sepsis in Hours - Not Days!
  
  K.O. Sullivan

- Hot Topics in Combatting the Growing NAS Epidemic
  
  L. Marcellus
  S. Patrick

- Beyond Training! Using Simulation to Improve Quality & Safety
  
  K. Firestone
  L. Halamek

- Improving the Quality of Newborn Care in Low Resource Settings: Use of the AAP Improvement Guide
  
  C. Bose
  J. Patterson

- Why Follow-up is Not Enough and Follow-Through Can't Wait!
  
  J. Litt
• Engaging Paid NICU Families as DR Liaisons During the Golden Hour  
  N. Kuemin  
  S. Tilbury

• Team Examples of Mapping and Mining EMR Data for QI  
  J. Seigel  
  J. Perciaccante  
  L. D. Hatch III  
  Y. Arain

• The Art of the Audit: Best of VON Teams Share Audits That Drive Improvement  
  R. Soll

• Learning from Innovative Statewide Quality Improvement Projects - Part 1  
  S. Bonifacio

Sunday October 29 – Annual Quality Congress Day 2

Day 2 Plenary Sessions

• Vermont Oxford Network Data at the "Edges" of Viability  
  D. Ehret

• Controversies With Using "Calculators" or "Estimators"  
  M. Rysavy

• Improvement Podium Brief / Health disparities persist despite intervention  
  M. Bidegain

• Strategies for Shared Decision-Making  
  G. Moore

• Social Determinants of Health and the New World Disorder  
  P. O’Campo

• Neonatal Follow-up - Are We Asking the Right Questions?  
  M. McCormick

Day 2 Breakout Sessions

• The Evidence: Delayed Cord Clamping  
  R. Soll  
  W. Tarnow-Mordi

• Antibiotic Stewardship Podium Briefs  
  S. Banerjee  
  A. Daly  
  K. Patamia
• **World-Class Care for NAS Infants in a Small, Rural Community Hospital**  
  H. Pham  
  D. U-Ren

• **24/7 Situational Awareness: Benefit to Your NICU, L/D, and Hospital System**  
  S. Bache

• **Learning from Simulated Small Tests of Change to Improve Care in Our Micropremature Care Unit**  
  L. Halamek

• **Building and Empowering a Nurse-Led Neonatal Resuscitation Team in Ethiopia**  
  A. Atwater  
  S. Teman

• **A Call for Healthcare System Redesign to Support Pre-term Infants and Families After NICU Discharge**  
  L. Pollack  
  T. Eusterbrock  
  P. Platt  
  S. Hally  
  M. Tadesse

• **Lessons on Shared Decision-Making in the NICU**  
  D. Kuo  
  G. Moore
Change Ideas Exchange - What Are You Working On?

Dmitry Dukhovny MD, MPH  
Assistant Professor of Pediatrics  
Oregon Health and Science University  
Portland, OR

Dr. Dukhovny is a board-certified Pediatrician and Neonatologist and a Pediatric Health Services Researcher. His academic focus involves applying cost-effectiveness analysis and decision science to help optimize resource utilization and allocation in perinatal care, a critical issue given the current constraints on the health care system. Dr. Dukhovny also has a strong interest and focus in medical education and leadership. He is currently the associate program director of the Neonatal Perinatal Medicine Fellowship at OHSU. With his colleagues at Oregon Health & Science University (OHSU), he developed an improvement science curriculum for the Neonatology fellows at OHSU, as well as continuing to expand educational opportunities in improvement science for all Neonatology nationally in his role as the Fellow liaison for VON in partnership with the Section of Neonatal-Perinatal Medicine of the AAP. Currently, he is co-leading the regional effort to improve antibiotic stewardship in Oregon and Southwest Washington, involving all 11 NICUs in the region under the Northwest Improvement Priority: Antibiotic Stewardship (NW IPAs). He has presented and organized workshops at national conferences, including Pediatric Academic Societies, Vermont Oxford Network Annual Quality Congress, and Perinatal Workshop.

Jump Starting Quality 3.0, Thursday, October 26, 2017  
Change Ideas Exchange - What Are You Working On?

Objective: Identify 4 key strategies to structure your change ideas into viable quality improvement projects, using the Model for Improvement.
Change Ideas Exchange – What Are You Working On?

Dmitry Dukhovny MD, MPH

Disclosure

- Dr. Dukhovny serves as faculty and consultant for Vermont Oxford Network; and consultant for Gerson Lehrman Group.

Overview of the Afternoon

- Welcome – Jeffrey Horbar
- Crafting a SMART Aim – Munish Gupta
- Key Driver Diagrams – Rebecca Vartanian
- Measurements and Metrics – Heather Kaplan
- The Basics of Run Charts – Manish Gupta
- The PDSA Cycle – Rebecca Vartanian
- Publishing your QI work – Timmy Ho
- Moderators – D. Dukhovny, T. Ho
- With mini work sessions in between!

Learning Objectives for JSQ 3.0

- Identify 4 key strategies to structure your change ideas into viable quality improvement projects, using the Model for Improvement
- Apply the SQUIRE guidelines to design both a successful and publishable quality improvement project
- Write/refine a project SMART aim that is specific, measurable, attainable, relevant and time bound
- Develop a draft of a driver document relevant to a SMART aim
- Apply basic measurement tools to a quality improvement data set to create a basic run chart or statistical process control chart

What are you working on? (Why?)

Additional Considerations
Change Ideas Exchange – What Are You Working On?

Dmitry Dukhovny MD, MPH

<table>
<thead>
<tr>
<th>QI vs. Research</th>
<th>Two criteria to consider to help distinguish QI vs. Research</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Can be a blurry line, but differences exists</td>
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<tr>
<td>• Intent for publication is NO LONGER a criteria</td>
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<tr>
<td>• Why is it important to distinguish?</td>
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<td>– Human subjects protection (e.g. IRB and compliance implications)</td>
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<td>– Different approach</td>
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Two criteria to consider:

1. Direct benefit to the patients/families involved
2. Impositions of Additional Risks or Burdens to the patients/families

FILE WITH YOUR IRB

(Casarett et al., JAMA 2000)

<table>
<thead>
<tr>
<th>How to mobilize support?</th>
<th>Questions/ Comments?</th>
</tr>
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<tbody>
<tr>
<td>• New initiative vs. ongoing work?</td>
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<tr>
<td>• What resources do you need?</td>
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<tr>
<td>• How do you engage NICU leadership, senior leadership?</td>
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<td>• How do you engage front line participation in the entire NICU?</td>
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<tr>
<td>• How do you engage families? (both current and graduates)</td>
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Casarett et al., JAMA 2000

How to mobilize support?
Objective: Craft a SMART aim that is specific, measurable, attainable, relevant and time bound.
Crafting a SMART Aim: Laying the Foundation for Improvement
Munish Gupta MD, MMSc

**Objectives**
- Craft a SMART aim that is specific, measurable, attainable, relevant and time bound.

**A Typical Scenario**
- You’re a NICU fellow. You’re told you have to do a QI project as part of your fellowship. You happen to also think QI is important.
- At a meeting with your fellowship director, she asks you, “so... what do you want to work on for your QI project?”
- Where do you begin?

**Model for Improvement**
- Setting Aims
- Establishing Measures
- Selecting Changes
- Testing Changes

**Disclosures**
I have no relevant financial relationships to disclose.
Crafting a SMART Aim:
Laying the Foundation for Improvement
Munish Gupta MD, MMSc

Model for Improvement

<table>
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<tr>
<th>Setting Aims</th>
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<tr>
<td>Establishing Measures</td>
<td>Selecting Changes</td>
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<td>Testing Changes</td>
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Setting Aims

Overall objective: be as clear and specific as possible with regards to your improvement goals

Three steps:
1. Identify an improvement area
2. Narrow the focus
3. Create an Aim statement

Step 1: Identify an Improvement Area

Ideal health care:
- Safe
- Effective
- Patient-centered
- Timely
- Efficient
- Equitable

Step 1: Identify an Improvement Area

The IHI Triple Aim

Population Health

Experience of Care

Per Capita Cost

Step 1: Identify an Improvement Area

Look at your systems!
- What practices don’t seem ideal?
- What does the data show?
- What frustrates you?
Crafting a SMART Aim:  
Laying the Foundation for Improvement

Munish Gupta MD, MMSc

### A Typical Scenario

- You just participated in the admission of a newborn 26 week gestational age infant, and you were struck by how complex and ‘hectic’ the process seemed to be. Although the admission seems to have happened fairly smoothly, you wonder whether there are ways to make the process even better.
- Where do you go from here?

### Setting Aims

Three steps:
1. Identify an improvement area
2. Narrow the focus
3. Create an Aim statement

### Step 2: Narrow the Focus

“FINER”
- Feasible
- Interesting
- Novel
- Ethical
- Relevant

### A Typical Scenario

- You’re talking with some of the nurses and physicians in the NICU about the ‘golden hour’ for VLBW infants, and they rattle off a long list of things they think could be improved: communication, timed cord clamping, use of CPAP, earlier surfactant, thermoregulation, placement of umbilical lines, etc.
- How can you focus your project?

### Setting Aims

Three steps:
1. Identify an improvement area
2. Narrow the focus
3. Create an Aim statement

### A Typical Scenario

- You review the last six VLBW admissions to your NICU, and find 5 had admission temperature less than 36 °C. You discuss this with your team, and everyone agrees that improving temperature regulation to decrease admission hypothermia is an important and feasible goal for your first improvement effort.
- How do you take this improvement focus and make it into an AIM statement?
Crafting a SMART Aim: Laying the Foundation for Improvement

Munish Gupta MD, MMSc

Step 3: Create an Aim Statement

What is an ‘Aim Statement’?

“An aim statement is a clear, explicit summary of what your team hopes to achieve over a specific amount of time including the magnitude of change you will achieve. The aim statement guides your work by establishing what success looks like.”

-- NICHQ

Why is an ‘Aim Statement’ important?

- Provides direction, defines scope of project
- Helps keep a project on task, avoids waste
- Aligns multiple stakeholders
- Insures buy-in from key participants
- Aids in identifying appropriate measures
- Elevator pitch!

A Typical Scenario

- You’ve decided to work on reducing admission hypothermia for premature infants by improving delivery room practices.
- How would you write a SMART AIM for this effort?

Some is not a number; soon is not a time.

“Here is what I think we should do. I think we should save 100,000 lives. And I think we should do that by June 14, 2006 – 18 months from today.

Some is not a number; soon is not a time.

Here’s the number: 100,000.

Here’s the time: June 14, 2006 – 9 a.m.”

Don Berwick
December 14, 2004
Crafting a SMART Aim: Laying the Foundation for Improvement
Munish Gupta MD, MMSc

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<td><strong>Aim statement, first draft:</strong></td>
<td><strong>Aim statement, second draft:</strong></td>
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<tr>
<td>We will reduce admission hypothermia in preterm infants in our NICU.</td>
<td>We will reduce the percentage of very low birth weight infants (BW&lt;1500 gm) admitted to our NICU with admission temperature less than 36 °C.</td>
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<tr>
<td><strong>Aim statement, third draft:</strong></td>
<td><strong>Aim statement, fourth draft:</strong></td>
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<tr>
<td>By June 2018, we will reduce the percentage of very low birth weight infants (BW&lt;1500 gm) admitted to our NICU with admission temperature less than 36 °C from 50% to 20%.</td>
<td>By June 2018, by improving delivery room practices, we will reduce the percentage of very low birth weight infants (BW&lt;1500 gm) admitted to our NICU with admission temperature less than 36 °C from 50% to 20%.</td>
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OGirnc et al., Fundamentals of Health Care Improvement, Joint Commission and Institute for Healthcare Improvement, 2012
Crafting a SMART Aim: Laying the Foundation for Improvement
Munish Gupta MD, MMSc

Laying the Foundation: Project Charter

Laying the Foundation: Driver Diagram

One Final Point

All of this (and more) should be done BEFORE considering changes to test.

A common mistake in quality improvement: jumping to changes before specifying aims and measures.

References


Keep up the good work!
Introduction to SQUIRE 2.0

Timmy Ho MD, MPH
Neonatal Fellow
Harvard Neonatal and Perinatal Fellowship Program
Boston Children’s Hospital
Boston, MA

Timmy Ho is a neonatology attending at Beth Israel Deaconess Medical Center and Boston Children's Hospital. He is the first graduate of a joint research fellowship between the Harvard-wide Pediatric Health Services Research Fellowship and the Institute for Healthcare Improvement. He explores mechanisms of improving the efficiency, work flow, and patient experience of healthcare delivery by applying fundamental skills in improvement science. An innovator, he has both participated in and mentored hackathons sponsored by the groups at MIT and Harvard, developed a mobile application to improve resident workflow, and hopes to lead multidisciplinary teams to transform how health care workers care for patients.

Jump Starting Quality 3.0, Thursday, October 26, 2017
Introduction to SQUIRE 2.0

Objective: Apply the SQUIRE 2.0 guidelines to design both a successful and publishable quality improvement project.
Publishing Your QI Work

Timmy Ho MD, MPH

Publishing Your QI Work

Timmy Ho MD, MPH
October 27, 2017

Disclosures

I have no financial relationships to disclose or relevant conflicts of interest (COIs) to resolve.

Learning Objectives

1. Apply the SQUIRE 2.0 guidelines both to design and publish a successful project
2. Organize the critical steps needed to plan your improvement project
3. Identify the characteristics that make an improvement project publishable

Plan ahead

• Start with: “Let’s plan a QI project with the goal of publishing in Journal X”
• Look at SQUIRE 2.0
• Look at Author Guidelines for Journal X

SQUIRE 2.0

• Eighteen items
• Theory: What is the rationale? Why did you think this idea would work?
• Context: Generalizable? Replicable?
• Studying the interventions
Publishing Your QI Work

Timmy Ho MD, MPH

SQUIRE 2.0

Keep a lab notebook

Traits of publishable projects
1. Generalizability
2. Novel or different interventions
3. Replicability: context and change theory
4. Multiple measures, including outcome, process, and balancing measures
5. Account for secular trends, co-interventions

Practice makes... improvement

What are you reading?

The Elements of Style
Publishing Your QI Work

Timmy Ho MD, MPH

Kabongo et al., BMJ Open Qual 2017

Pronovost et al., NEJM 2006

Where to publish

- Quality improvement journals
  - BMJ Open Quality
  - Pediatric Quality and Safety
- Pediatric journals
  - Pediatrics
  - Journal of Perinatology

Write as you go

Online resources

- https://hip.wisc.edu/qi_Publish
- http://www.ihi.org/education/IHIOpenSchool/resources/Pages/Publications/default.aspx
Summary

• Plan ahead: start with SQUIRE 2.0 and Author Guidelines
• Consider traits of publishable projects
• Read and write early and often
• Don’t wait to write... write as you go!

Acknowledgments

• Madge Buus-Frank and Dmitry Dukhovny for the invitation to participate and present
• Vermont-Oxford Network and TECaN (Trainee and Early Career Neonatologists)

References

• https://www.ou.org/life/files/Plan‐Ahead.jpg
• http://blogs.bl.uk/science/2015/03/resistance‐is‐futile.html
• https://en.wikipedia.org/wiki/Gantt_chart
• http://www.amazon.com/Sleepeasy‐Solution‐Exhausted‐Parents/dp/0757305601
• https://www.amazon.com/Wise‐Mans‐Fear‐Kingkiller‐Chronicle/dp/0756407915/ref=sr_1_1?s=books&ie=UTF8&qid=1505157807&sr=1‐1&keywords=wise+man%27s+fear
• https://www.amazon.com/Elements‐Style‐Fourth/dp/0881030686

Questions?
What, Why and How To: Develop a Driver Diagram

Rebecca J. Vartanian MD
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Division of Neonatal-Perinatal Medicine
Department of Pediatrics and
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Rebecca Jane Vartanian MD is an Assistant Professor in the Division of Neonatal-Perinatal Medicine within the Department of Pediatrics and Communicable Diseases at the University of Michigan. She received her medical degree from Wayne State University School of Medicine and completed her Pediatrics and Neonatology training at the University of Michigan. Dr. Vartanian joined the faculty in 2010. Dr. Vartanian oversees and facilitates the quality improvement initiatives in the Newborn Intensive Care Unit, including multi-center collaborations within Vermont Oxford Network. Her clinical interests include oxygen management in premature infants, optimization of neonatal nutrition, and the care of extremely low birth weight infants.

Jump Starting Quality 3.0, Thursday, October 26, 2017
What, Why and How To: Develop a Driver Diagram

Objective: Draft or refine a driver document relevant to your SMART aim.
What, Why and “How To” for Developing Driver Diagrams

Rebecca Vartanian MD

Disclosures

I do not have any financial arrangement or affiliations with a commercial entity.
I will not be discussing the unlabeled use of a commercial product in my presentation.

Learning Objectives

Draft or refine a driver document relevant to your SMART aim.
• To describe the role of a driver diagram as a quality improvement tool.
• To understand the anatomy of a driver diagram.
• To develop a driver diagram for a given clinical scenario.

What is a Driver Diagram?

• Background
  – System of Profound Knowledge
    • Developed from the teachings of W. Edwards Deming
    • 4 interdependent principles necessary for transformation and improvement of a system
    • Allows us to understand and manage the systems we work in and how to make them better

What is Theory of Knowledge?

• Knowledge is built on theory
  – Theory allows questioning
  – Theory allows revision
  – Theory allows prediction
• Plan-Do-Study-Act
  – Continual testing of the theory for continued improvement

I thought we were talking about driver diagrams???

• A driver diagram is the visual representation of this shared theory of knowledge
  – It is a “broad prediction of the changes required to accomplish the given aim” (Bennett 2015)
  – It is built by a team of stakeholders
  – Each theory can be tested in a systematic way → PDSA
What, Why and “How To” for Developing Driver Diagrams
Rebecca Vartanian MD

Why Use a Driver Diagram

• Simple
• Visual
• Keeps you and your team on track
• Provides administration/management with a one page synopsis of your plan
• Aligns your change ideas to the bigger goal

Driver Diagram Example

Driver Diagram Example

How to Make a Driver Diagram

Tips

• There is no “right” diagram... just good enough
  – Change the diagram as your work progresses
• You won’t always have secondary drivers
• If your diagram is getting too complicated, may need to make multiple diagrams (keep it simple)
• Drivers may be co-dependent
  – More than one secondary driver may link to a primary driver
What, Why and “How To” for Developing Driver Diagrams

Rebecca Vartanian MD

Small Group Exercise

- As a group, develop a driver diagram for the following SMART AIM
- Spend 5-10 minutes
  - Brainstorm
  - Cluster
  - Link
- Build your driver diagram

How to Make a Driver Diagram

References

- Institute for Healthcare Improvement: www.ihi.org
- NHS Institute for Improvement and Innovation 2006-2013: http://www.institute.nhs.uk/

Questions?
Measurement and Metrics - the Basics!

Heather Kaplan MD, MSCE
Assistant Professor of Pediatrics,
Perinatal Institute and The James M. Anderson Center for Health Systems Excellence,
Cincinnati Children’s Hospital Medical Center
Cincinnati, OH

Heather Kaplan MD, MSCE is an Assistant Professor of Pediatrics in the Perinatal Institute and the James M. Anderson Center for Health Systems Excellence at Cincinnati Children’s Hospital Medical Center (CCHMC). Heather is a neonatologist and health services researcher interested in enhancing care delivery and studying how systems of care can be improved using innovative approaches. She completed her neonatal-perinatal fellowship training, including earning a Master's degree of science in clinical epidemiology, at The Children’s Hospital of Philadelphia/University of Pennsylvania. She joined the faculty at CCHMC in August 2007. Heather’s early research focused on understanding variation in adoption of evidence-based practices in neonatal care and quality improvement as a strategy for implementing evidence in practice. With funding from the Robert Wood Johnson Foundation, she studied the role of context in the success of quality improvement initiatives and developed a model, the Model for Understanding Success in Quality (MUSIQ). MUSIQ is a tool for developing theories about which aspects of context help or hinder a specific project, and designing and implementing tests of changes to modify those aspects of context. Her current work examines the way research and improvement networks ("learning networks") can be used to improve care delivery and outcomes. She is specifically interested in scaling improvement to reach entire populations of patients and the ways technology, quality improvement methods, and N-of-1 trial methods can be combined to create a personalized learning healthcare system for the individual. Heather also has extensive experience with front-line quality improvement in perinatal care. Dr. Kaplan serves as the Improvement Advisor for the Ohio Perinatal Quality Collaborative (OPQC) neonatal improvement work. She also serves as a faculty expert for Vermont Oxford Network quality collaboratives and has been working with teams to improve their system of improvement by using MUSIQ to identify and modify key aspects of context that are affecting the success of the quality improvement projects and to help them engage with senior leadership around their improvement work.

Objective: Compare and contrast different types of measures used for quality improvement and develop an operational definition for a measure relevant to your QI project.
Measurement and Metrics - The Basics!

Heather Kaplan MD, MSCE

Assistant Professor of Pediatrics
Perinatal Institute and The James M. Anderson Center
for Health Systems Excellence
Cincinnati Children's Hospital Medical Center

Disclosures
I have no financial disclosures related to the content of this workshop.

Learning Objectives:

• Compare and contrast different types of measures used for quality improvement and develop an operational definition for a measure relevant to your QI project.
• Identify key strategies to structure your change ideas into viable quality improvement projects, using the Model for Improvement.
• Apply the SQUIRE guidelines to design both a successful and publishable quality improvement project.
• Write/refine a project SMART aim that is specific, measurable, attainable, relevant, and time bound.
• Develop a draft of a driver document relevant to a SMART aim.

Take Home Points

Measurement should speed improvement, not slow it down
The goal is improvement, not measurement
Measurement is meant to help you tell if the change is making an improvement
You need just enough information to help you know if changes are resulting in improvement

Types of measures

Ways to categorize measures

• What the measure is about:
  – Outcome measures
  – Process measures
• Role the measures play in a project:
  – Balancing measures
  – All-or-none measures
Measurement and Metrics - The Basics!

Heather Kaplan MD, MSCE

Types of Measures: Process

- **What we do.**
  - Represents the workings of the system
  - Usually "proximal" in terms of cause and effect
  - Easier to control, more sensitive
  - Examples:
    - % of Alarm Limits Set in Target Range
    - Average Time Spent Out of Target Saturation Range
    - % of infants <1000 grams receiving Vitamin A
    - % infants >26 wks receiving early CPAP in the DR
    - % of deliveries <34 weeks with O2 blender set at 40%
    - Number of Ventilator Days per Month

Types of Measures: Outcomes

- **What the patients experience.**
  - Traditionally described as most important to patients
  - Less easy to control
  - Examples:
    - % of infants discharged with CLD
    - % of infants discharged with severe ROP
    - % of infants discharged home on oxygen
    - Number cases of VAP per 1000 ventilator days

Types of Measures: Balancing

- **Balancing Measures**
  - Are we improving parts of our system at the expense of others?
  - Example: To increase the use of CPAP in the delivery room (and reduce the amount of surfactant used)
  - Balancing Measure=Pneumothorax: % of infants with a pneumothorax
  - Example: To increase compliance with new target oxygen saturation range of 90-95%
  - Balancing Measure=Severe ROP: % of infants with >Stage 2 ROP

Types of Measures: All or None

- **Measure performance on multiple discrete measures for the same condition**
- **Best suited for process measures**
- **When project requires several measures all hitting certain goal**
- **Apply at the patient level**, no partial credit given
- **Advantages**
  - Reflects the interests and desires of patients
  - Important when process components interact with each other synergistically or partial execution is insufficient
  - Quality may be an "all or none" property
  - Encourages system perspective (sequence of care)

A project may need several measures to tell the full story, including balancing measures

### Hypothermia Key Driver Diagram

**AIM**

- "Outcome" & Balancing Measures
- Process Measures

**DRIVERS**

- DRIVERS
  - Maintaining Hand Dry
  - Staff Awareness & Education
- Process Measures

**CHANGES**

- CHANGES
  - Maintaining Hand Dry
  - Staff Awareness & Education
- Process Measures
Hypothermia Measures

- **Outcome**
  - Percent of infants with BW<1500 gm or GA<30 weeks admitted with a temperature <36°C
- **Process**
  - Percent of admissions with delivery room check list completed
  - Percent of admissions with all components of the heat loss bundle completed
- **Balancing**
  - Percent of infants with BW<1500 gm or GA<30 weeks with admission temperature > 38°C

Operationalizing measures

“Data” vs. “Measure”

- **Data**
  - A piece of information that has no independent meaning until it is part of a measure.
  - Examples:
    - ROP exam date/time
    - Infant PMA at time of ROP exam
- **Measure**
  - Designed to tell you what you want to know
  - “Measures” require “data”
  - Example:
    - Measure: % of infants receiving ROP exam at suggested PMA
    - Data: ROP exam date/time, PMA at time of ROP exam

Properties of useful measures

- **Meaningful**
  - Provide us with information and ultimately, knowledge
  - Say something useful about the system
  - Important to all stakeholders
  - Related to the project
- **Can be operationalized**
  - It is feasible to go from concept to detail
    - Data can be obtained with existing resources
    - Can be calculated easily

Operational Definitions

- A “concept” is not the same as a “measure”
  - Example 1:
    - Concept: “# Times Late to Work”
    - Measure: “XXX”
      - What is late? Within 5 minutes?
      - Where do you arrive? At parking garage? At desk?
  - Example 2:
    - Concept: “% Infants Discharged on Human Milk”
    - Measure: “XXX”
      - Which infants? All? VLBW?
      - How much milk? Any? >50% of feeds?

“Being free from grease is not rigorously definite; to some people it means clean enough to eat on; to the experimental physicist it may in some instances mean baked out at a high temperature under a vacuum”

—Walter Shewhart
Measurement and Metrics - The Basics!

Heather Kaplan MD, MSCE

Operationalizing Measures

• Clearly Define:
  – What you are measuring?
  – Why you are measuring it?
  – How much data is needed (sample size)?
  – How will it be measured (numerator, denominator, definition, sampling)?
  – How long will it be measured (project duration)?
  – Where will the data come from?
  – Who will collect the data?

A Word on Sampling...

• Why Sample?
  – Looking at All the data may not be possible or desirable
  – Data may be difficult to obtain
  – Cost and/or time to gather data may be too great
• Rules for Sampling
  – Sample must be representative of the entire population
  – Samples must be large enough to contain defects
• Types of Sampling
  – Random sampling
  – Systematic random sampling (at fixed interval)
  – Stratified random sampling (selecting from a predefined group)

Hypothermia Measures

• “Outcome”
  – Percent of infants with BW<1500 gm or GA<30 weeks admitted with a temperature <36°C
• Process
  – Percent of admissions with delivery room check list completed
  – Percent of admissions with all components of the heat loss bundle completed
  – Percent of deliveries where room temperature was measured at >77°F at the time of the delivery
• Balancing
  – Percent of infants with BW<1500 gm or GA<30 weeks with admission temperature > 38°C

Hypothermia Checklist

All-or-One Heat loss Bundle Compliance

Operational Definition

<table>
<thead>
<tr>
<th>OPERATIONAL DEFINITION</th>
<th>N</th>
<th>D</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measure Name</td>
<td>Percent of admissions with all components of the heat loss bundle completed</td>
<td></td>
</tr>
<tr>
<td>Type of Measure</td>
<td>Process</td>
<td></td>
</tr>
<tr>
<td>Included Population</td>
<td>Infants ≤ 1500 grams at birth</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt;30 weeks gestation at birth</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Inborn</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Checklist completed at birth</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Admitted directly from LDR/OR to NICU</td>
<td></td>
</tr>
<tr>
<td>Excluded</td>
<td>Comfort care only</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NICU team not present at delivery</td>
<td></td>
</tr>
</tbody>
</table>

All-or-One Heat loss Bundle Compliance

Operational Definition

<table>
<thead>
<tr>
<th>OPERATIONAL DEFINITION</th>
<th>N</th>
<th>D</th>
</tr>
</thead>
<tbody>
<tr>
<td>Numerator</td>
<td>Number of admissions with compliance on all of the following elements of the DR checklist:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Radiant warmer pre-heated on arrival of NICU team</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Radiant warmer side rails up on arrival of NICU team</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Room Temp set at ≥77°F on arrival of NICU team</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Unknown, Black, or Temp ≤77°F is non-compliant</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Infant placed immediately in plastic bag</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Temp probe attached and infant placed on sensor within 2 min</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hat placed on infant after transfering head</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Radiant warmer side rails remain up until infant in transporter</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Skin temp checked at 5 min and documented on checklist</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Transport incubator pre-warmed to 37-37.5°C</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Warm blankets in transporter prior to leaving OR/LDR</td>
<td></td>
</tr>
<tr>
<td>Denominator</td>
<td>Number of admissions with completed checklist</td>
<td></td>
</tr>
</tbody>
</table>
All-or-None Heat Loss Bundle Compliance

**Operational Definition**

<table>
<thead>
<tr>
<th>Operational Definition (Cont’d)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Data Collection Approach</strong></td>
</tr>
<tr>
<td>Admit RN takes checklist from cabinet with PPE supplies</td>
</tr>
<tr>
<td>Admit RN completes checklist and returns to charge RN</td>
</tr>
<tr>
<td><strong>Data Source</strong></td>
</tr>
<tr>
<td>DIR Checklist (manual data collection)</td>
</tr>
<tr>
<td><strong>Sampling</strong></td>
</tr>
<tr>
<td>None (data collected on all admits)</td>
</tr>
<tr>
<td>Estimated 10-30 infants per month</td>
</tr>
<tr>
<td><strong>Data Reported As</strong></td>
</tr>
<tr>
<td>Monthly percent compliance with heat loss bundle</td>
</tr>
<tr>
<td><strong>Improvement Noted As</strong></td>
</tr>
<tr>
<td>Increase in the percent</td>
</tr>
</tbody>
</table>

**Exercise**

• Identify a group of measures (no more than 6 measures) for your QI Project including:
  – Process Measures
  – Outcome Measure(s)
  – Balancing Measure(s)

• Pick one measure and operationalize it including:
  – Population included/excluded
  – Numerator, Denominator
  – Data Source
  – Sampling plan/frequency (estimated sample size)
  – Define unit and degree of precision for all data elements (e.g., is LOS in days, hours, minutes; is pain scale whole numbers?)
  – If judgement is required (e.g., late or inappropriate), list the criteria used to make the judgement

**Take Home Points**

• Measurement should speed improvement, not slow it down

• The goal is improvement, not measurement

• Measurement is meant to help you tell if the change is making an improvement

• You need just enough information to help you know if changes are resulting in improvement
Plotting the Dots: Run Chart Interpretation and Intro to Control Charts

Munish Gupta MD, MMSc
Neonatologist
Beth Israel Deaconess Medical Center
Boston, MA

Munish Gupta MD, MMSc, is a staff neonatologist and the Director of Quality and Safety for the Department of Neonatology at Beth Israel Deaconess Medical Center in Boston MA. He is also chair of the Neonatal Quality Improvement Collaborative of Massachusetts.

Jump Starting Quality 3.0, Thursday, October 26, 2017
Plotting the Dots: Run Chart Interpretation and Intro to Control Charts

Objectives:
1. Compare and contrast the difference between run charts and statistical process control charts.
2. Apply the standard rules for creating and interpreting run charts and SPCC.
Plotting the Dots: Introduction to Run Charts and Control Charts

Munish Gupta MD, MMSc

October 26, 2017
Jump Starting Quality 3.0

Objectives

• Compare and contrast the difference between run charts and statistical process control charts.
• Apply the standard rules for creating and interpreting run charts and control charts.

Where we are in our ‘journey’

Aims

Measures

Changes

Testing Changes

Some basics about data for QI...

VON Data

Admission Temperature 32.0 to 35.9, VLBW Infants

Center 388 and Network Values

Infant Characteristics - All VLBW Infants

<table>
<thead>
<tr>
<th>Birth Year</th>
<th>Center</th>
<th>Network</th>
<th>Cases</th>
<th>%</th>
<th>N</th>
<th>%</th>
<th>Q1</th>
<th>Q3</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
<td>581</td>
<td>117</td>
<td>44,542</td>
<td>17.7</td>
<td>45.5%</td>
<td>44.9%</td>
<td>50.5%</td>
<td></td>
</tr>
<tr>
<td>2007</td>
<td>96</td>
<td>134</td>
<td>39,382</td>
<td>14.6</td>
<td>45.0%</td>
<td>44.5%</td>
<td>50.0%</td>
<td></td>
</tr>
<tr>
<td>2008</td>
<td>48</td>
<td>128</td>
<td>34,819</td>
<td>13.0</td>
<td>45.0%</td>
<td>44.5%</td>
<td>50.0%</td>
<td></td>
</tr>
<tr>
<td>2009</td>
<td>70</td>
<td>132</td>
<td>33,257</td>
<td>11.5</td>
<td>45.0%</td>
<td>44.5%</td>
<td>50.0%</td>
<td></td>
</tr>
<tr>
<td>2010</td>
<td>40</td>
<td>123</td>
<td>35,800</td>
<td>10.6</td>
<td>45.0%</td>
<td>44.5%</td>
<td>50.0%</td>
<td></td>
</tr>
<tr>
<td>2011</td>
<td>35</td>
<td>168</td>
<td>33,851</td>
<td>12.2</td>
<td>45.0%</td>
<td>44.5%</td>
<td>50.0%</td>
<td></td>
</tr>
<tr>
<td>2012</td>
<td>27</td>
<td>119</td>
<td>34,052</td>
<td>10.7</td>
<td>45.0%</td>
<td>44.5%</td>
<td>50.0%</td>
<td></td>
</tr>
</tbody>
</table>

What is helpful about this presentation of your data? What could be more helpful?
What is helpful about this presentation of your data? What could be more helpful?

Data for QI
- Measurement is critical for improvement
- Graphs are better than tables
- Yearly data has value, but not great for **improvement**

Data Over Time
- Measurement is critical for improvement
- Graphs are better than tables
- Yearly data has value, but not great for **improvement**
- Data over time much better than before-after

Understanding Variation
- In improvement, we are looking for changes in key data.
- But all things vary naturally (fact of life).
- We need tools to understand variation in data, to identify **true changes** versus **natural variation**.
- And, we would like to detect true change fast.
Plotting the Dots: 
Introduction to Run Charts and Control Charts
Munish Gupta MD, MMSc

Signal vs. Noise

<table>
<thead>
<tr>
<th>SIGNAL</th>
<th>NOISE</th>
</tr>
</thead>
<tbody>
<tr>
<td>• means something</td>
<td>• statistically indistinguishable from other data points</td>
</tr>
<tr>
<td>• contains information</td>
<td>• contains no new information</td>
</tr>
<tr>
<td>• difference with a distinction</td>
<td>• difference without a distinction</td>
</tr>
<tr>
<td>• special cause variation — specific causes not part of usual process (good or bad)</td>
<td>• common cause variation — causes inherent as part of usual process (good or bad).</td>
</tr>
</tbody>
</table>

Why this is important

Type of variation → type improvement action

- Type of variation
  - Special cause
    - Reduce unnatural variation
    - Establish stable work process
  - Common cause
    - Improve basic process, reduce natural variation
    - Improve overall outcomes

Statistical Process Control Tools

1. Run charts – minimal standard
2. Control charts

Keys:
- Plot and evaluate over time
- Interpret visually and statistically
What is a Run Chart

- Visual display of data over time, annotated
- Center line: Median or mean value

Interpreting Run Charts: Signal

- Run Charts

Using Run Charts

- Simple but effective tool for analyzing QI data
- Should be used for monitoring and feedback
- Needs to be interpreted with knowledge of system
- Ideally is annotated with changes -- can be ‘summary’ of QI project that can be shared widely

Example

Admission Hypothermia, VLBW Infants, BIDMC
Run Charts

- Minimum standard for QI project data
- Can start with first few data points!
- Need at least 10 data points to use signal rules
- Simple to create (no software needed)
- Can be used with all types of data

But... not as powerful as a control chart

Data for QI

- Measurement is critical for improvement
- Graphs are better than tables
- Yearly data has value, but not great for improvement
- Data over time much better than before-after
- Annotated run chart is minimum standard

Run Charts and Control Charts

Running record of the process over time

Run chart: Center line is the median.
Control chart: Center line is often the mean.
Control limits that reflect inherent variability in data or the extent of common cause variation
Plotting the Dots:
Introduction to Run Charts and Control Charts
Munish Gupta MD, MMSc

**Continuous Data**
1. Numerical value for each unit in a group

**Discrete (Integer) Data**
2. Classification: Presence or not of an attribute
3. Count: How many attributes occur in sample

**Constructing Control Charts**
- Type of data
- Sample size
- Type of chart
- Math (software)

**Which Control Chart To Use**
- Type of data
- Distribution
- Control chart

**Types of Data & Control Charts**

<table>
<thead>
<tr>
<th>Type of Data</th>
<th>Example</th>
<th>Distribution</th>
<th>Control Chart</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discrete</td>
<td>Any late infection</td>
<td>Binomial</td>
<td>P-chart</td>
</tr>
<tr>
<td>Continuous</td>
<td>Number of times skin-to-skin</td>
<td>Poisson</td>
<td>U-chart or C-chart</td>
</tr>
</tbody>
</table>

**Control Charts: Special Cause Variation**

- TEST 1: 1 point outside outer control limit
- TEST 2: 2 out of 3 points more than 2 SD from center line
- TEST 3: Run of 8 points in a row on one side of center line
- TEST 4: Trend of 6 points in a row increasing or decreasing

**Control Charts vs. Run Charts**

- More sensitive and more powerful for detecting special cause variation
- Can estimate capability of a stable process and predict future performance

But...
- More difficult to generate
- Need 15-20 points to start interpreting control limits
Data for QI

- Measurement is critical for improvement
- Graphs are better than tables
- Yearly data has value, but not great for improvement
- Data over time much better than before-after
- Annotated run chart is minimum standard
- Control charts ideal (not easy, but not hard)

Interpreting a Run Chart or Control Chart

1. Is this the right chart?
   - Are the measures appropriate (y-axis)?
   - Is the time analysis appropriate (x-axis)?
   - Is the sample size for each data point adequate?
   - Is the control chart right for the type of data/measure?
2. Are there enough data points for meaningful conclusions?
3. Is there evidence of signal or special cause variation?
4. Does the chart match your knowledge of your system and its context?

References


Time to Take Action: Planning and Executing Small "Tests of Change" / PDSA Cycles

Rebecca J. Vartanian MD
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Department of Pediatrics and
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University of Michigan
Ann Arbor, MI

Rebecca Jane Vartanian MD is an Assistant Professor in the Division of Neonatal-Perinatal Medicine within the Department of Pediatrics and Communicable Diseases at the University of Michigan. She received her medical degree from Wayne State University School of Medicine and completed her Pediatrics and Neonatology training at the University of Michigan. Dr. Vartanian joined the faculty in 2010. Dr. Vartanian oversees and facilitates the quality improvement initiatives in the Newborn Intensive Care Unit, including multi-center collaborations within Vermont Oxford Network. Her clinical interests include oxygen management in premature infants, optimization of neonatal nutrition, and the care of extremely low birth weight infants.

Objectives:
1. To understand why tests of change are essential in quality improvement efforts
2. To describe the steps of the P-D-S-A cycle
3. To determine the appropriate scope of the PDSA cycle necessary based on culture, cost and risk
4. To develop 1-2 PDSA cycles to improve admission temperatures
Time to Take Action: Planning and Executing Small “Tests of Change”

Rebecca Vartanian MD

Objectives

- To understand why tests of change are essential in quality improvement efforts
- To describe the steps of the P-D-S-A cycle
- To determine the appropriate scope of the PDSA cycle necessary based on culture, cost and risk
- To develop 1-2 PDSA cycles to improve admission temperatures

Testing our theory

Why test?

- To increase belief that the change will result in improvement.
- To decide which of several proposed changes will lead to the desired improvement.
- To evaluate how much improvement can be expected from the change.
- To decide whether the proposed change will work in the actual environment of interest.
- To decide which combinations of changes will have the desired effects on the important measures of quality.
- To evaluate costs, social impact, and side effects from a proposed change.
- To minimize resistance upon implementation.

How to test: PDSA Methodology

Disclosures

I do not have any financial arrangement or affiliations with a commercial entity.

I will not be discussing the unlabeled use of a commercial product in my presentation.
Time to Take Action: Planning and Executing Small “Tests of Change”

Rebecca Vartanian MD

**Step 1: Plan**
- What is the objective of the cycle?
- What questions are being answered by this cycle? What is our prediction with the test?
- Plan out the test of change?
  - Who will be involved?
  - Where and when will it be done?
  - What data will be collected? How much data will we need?
- Tips:
  - Scale down (THINK SMALL)
  - Not trying to achieve buy-in or consensus yet

**Step 2: Do**
- Carry out the plan!
- Take note:
  - What worked (or did not)?
  - Was there anything unexpected?
  - What barriers did you encounter?
- Begin to analyze the data

**Step 3: Study**
- How do our results compare to our predictions?
  - If predictions match, our degree of belief about our knowledge increases
  - If our predictions do not match the data, we have the opportunity to investigate/learn why
- Take time to summarize what was learned

**Step 4: Act**
- Your team now needs to make decisions:
  - What additional testing (if any) is necessary to increase our degree of belief about the change?
  - What changes need to be made to the test?
  - How do we incorporate additional lessons learned from the change (unexpected results, costs, etc)?
  - Are we ready to scale-up the change?
  - Should the change be dropped?

**Scope of a PDSA cycle**

<table>
<thead>
<tr>
<th>Current Situation</th>
<th>Resistant</th>
<th>Indifferent</th>
<th>Ready</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost of failure</td>
<td>Very small-scale test</td>
<td>Very small-scale test</td>
<td>Very small-scale test</td>
</tr>
<tr>
<td>Cost of failure</td>
<td>Large-scale test</td>
<td>Small-scale test</td>
<td>Large-scale test</td>
</tr>
<tr>
<td>Cost of failure</td>
<td>Large-scale test</td>
<td>Large-scale test</td>
<td>Implement</td>
</tr>
</tbody>
</table>

Adapted from The Health Care Data Guide p.48
Remember....

• To increase belief that the change will result in improvement.
• To decide which of several proposed changes will lead to the desired improvement.
• To evaluate how much improvement can be expected from the change.
• To decide whether the proposed change will work in the actual environment of interest.
• To decide which combinations of changes will have the desired effects on the important measures of quality.
• To evaluate costs, social impact, and side effects from a proposed change.
• To minimize resistance upon implementation.

Pitfall: Thinking too large-scale

• How to think/do small:
  • Simulation
  • Have experts review the test of change and provide comments
  • One patient/one procedure
  • Short period (one hour/one day…)

• Remember, the goals of these early tests of change (among many) are:
  • To compare the theory to the data
  • To increase the belief in the change
  • To avoid wasted time, effort and energy

Pitfall: “Research” vs QI

• Implementing Multiple Tests of Change
  • Teams often test multiple changes at one time
  • Not trying to prove that one single change idea will result in the desired outcome
  • All change are linked to common aim
  • Involves linking several PDSA cycles together

Example - Improving Admission Temperatures

• The following example is realistic but data and are completely factitious

Tool 1

• Helpful to track the plan and outcome of multiple PDSA cycles (i.e. report card)
• Alternatively, one sheet could be used for each small cycle

Tool 2 - PDSA Tracker

• Worksheet to track very small tests of change
• Results can be added to Tool 1
• Documentation can be short hand and brief
Time to Take Action: Planning and Executing Small “Tests of Change”

Rebecca Vartanian MD

Improving Admission Temperatures

• After assembling your driver diagram, your team discusses which actionable item/change idea to address first
• Your team decides that you are behind the times (and NRP recommendations) to use an occlusive wrap to reduce evaporative heat loss
• After much debate, it is less clear which product will be easiest and most effective in your setting

Do!

<table>
<thead>
<tr>
<th>Plan</th>
<th>Do</th>
<th>Study</th>
<th>Act</th>
</tr>
</thead>
<tbody>
<tr>
<td>What are you trying to prove?</td>
<td>What are you trying to prove?</td>
<td>What are you trying to prove?</td>
<td>What are you trying to prove?</td>
</tr>
<tr>
<td>Help</td>
<td>Help</td>
<td>Help</td>
<td>Help</td>
</tr>
<tr>
<td>Planning</td>
<td>Planning</td>
<td>Planning</td>
<td>Planning</td>
</tr>
<tr>
<td>Convincing</td>
<td>Convincing</td>
<td>Convincing</td>
<td>Convincing</td>
</tr>
<tr>
<td>Results</td>
<td>Results</td>
<td>Results</td>
<td>Results</td>
</tr>
<tr>
<td>Results</td>
<td>Results</td>
<td>Results</td>
<td>Results</td>
</tr>
</tbody>
</table>

Study!

- Easier, more efficient
- Faster, more reliable
- Better, more effective

Act!

• Team now needs to decide whether to adopt, adapt or abandon the tested change idea?
  • What additional testing (if any) is necessary to increase our degree of belief about the change?
  • What changes need to be made to the test?
  • How do we incorporate additional lessons learned from the change (unexpected results, costs, etc.)?
  • Are we ready to scale-up the change?
  • Should the change be dropped?

References

• Institute for Healthcare Improvement: www.ihi.org
Time to Take Action: Planning and Executing Small “Tests of Change”

Rebecca Vartanian MD

Small Group Exercise

• Gather in groups of 3-5
• Each team will need
  • 1 quarter, 1 dime, 1 nickle, and 1 penny
  • 1 stopwatch and timer
  • 1 worksheet
• Instructions
• Debrief

Questions?
Implementation of the Sepsis Risk Calculator

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Regional Physician Coordinator
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NICU Director, Woodland Hills
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Neonatology
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Allen Fischer MD is the Regional Director of Neonatology for Kaiser Permanente in Northern California. Dr. Fischer is a graduate of the University of Pennsylvania (BA) and Stanford University Medical School. He trained in Pediatrics at Stanford University Medical Center. He then completed a fellowship in Neonatal-Perinatal Medicine at Stanford. Dr. Fischer oversees utilization and quality improvement activities related to neonatal care for the 15 hospital Kaiser Permanente network throughout Northern California. His current areas of focus are improving the care of newborns with neonatal abstinence syndrome and implementation of guidelines and information technology tools to reduce the use of antibiotics in term and late preterm infants. He also consults for Kaiser Permanente in the Mid Atlantic States addressing issues pertaining to quality and utilization of neonatal and perinatal care. He is a member of the California Children’s Services technical advisory committee. When Allen is away from work, he enjoys riding his road bicycle throughout the Bay Area. He is also an active wine collector.

Newborn Antibiotic Stewardship National Summit, Friday, October 27, 2017
Implementation of the Sepsis Risk Calculator

Objective: Identify key challenges and opportunities to consider when implementing the sepsis risk calculator in your local setting.
Implementation of the Early Onset Sepsis Calculator: Science, Statistics, and Emotion

David Braun MD
Allen F. Fischer MD

Vermont Oxford Quality Congress
Chicago, IL
October 27, 2017

Learning Objectives

- Identify key challenges and opportunities to consider when implementing the sepsis risk calculator in your local setting.
- Understand the use of Bayesian thinking in clinical decision making.
- Understand the connection between the objective risk calculation and subjective risk thresholds for intervention.
- Distinguish System 1 from System 2 thinking, strengths, and limitations.
- Identify clinical decision-making scenarios where each is preferable.

Prelude to Implementation of the EOS Calculator: Developing a Structure that Promotes Quality Improvement

- Promote group learning and expectation of change
- Forums for consensus building
- Agreement to Take Action

Imbalance between Infections and Sepsis Evaluations / Antibiotic Treatment

EOS incidence
0.3/1000 Live Births

Blood Cultures 14.4%
Antibiotics 5%

Data from KPNC 2010-2012
2014: Possible Tool for Improved Decision Making

- In 2014 the EOS calculator including both maternal factors and newborn exam became available.
- It is the most powerful tool to date for assessing neonatal risk of EOS.

Calculating a Newborn’s Risk of Sepsis
A Bayesian Approach

**FIRST STEP**
- Review maternal risk factors and calculate risk at the time of birth.

**DON’T STOP THERE**
- Examine the infant
- Monitor vital signs during the hospitalization
- If we are worried – may obtain laboratory work or a blood cx
- Re-examine infant as needed
- Update the infant’s risk of sepsis as new info becomes available

The Calculator Has a Conservative Bias

<table>
<thead>
<tr>
<th>Clinical Presentation</th>
<th>LR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Well Appearing</td>
<td>0.36</td>
<td>0.31 - 0.41</td>
</tr>
<tr>
<td>Equivocal</td>
<td>3.75</td>
<td>2.83 - 5.00</td>
</tr>
<tr>
<td>Clinical Illness</td>
<td>14.5</td>
<td>10.2 - 21.2</td>
</tr>
</tbody>
</table>

Stratification of risk of early-onset sepsis in newborns ≥34 weeks’ gestation.

Escobar GJ and Puopolo KM et al.

What risk can we live with?

- The calculator determines objective risk.
- Risk thresholds that trigger clinical action are subjective. Neonatal chiefs came to consensus around an EOS risk of:
  - <1/1000 for observation only,
  - 1-3/1000 for enhanced observation,

Readmissions for Positive Blood or CSF Culture in 1st week of life

<table>
<thead>
<tr>
<th>Time Period</th>
<th>Births</th>
<th>Cases</th>
<th>Rate per 10,000 births</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDC Guidelines</td>
<td>98,457</td>
<td>5</td>
<td>0.51</td>
</tr>
<tr>
<td>EOS Calculator #1</td>
<td>54,644</td>
<td>1</td>
<td>0.18</td>
</tr>
<tr>
<td>EOS Calculator #2</td>
<td>115,092</td>
<td>6</td>
<td>0.52</td>
</tr>
</tbody>
</table>
Implementation of the Early Onset Sepsis Calculator: Science, Statistics, and Emotion

David Braun MD / Allen F. Fischer MD

A Concern That Was Hardest To Address:
Personal Experience vs Statistical Models in Decision-making

You treat babies with the same risk differently! Be consistent!
I had a baby with a positive blood culture that the EOS calculator missed!
A patient isn’t just a statistic. Medicine is more than guidelines! Don’t take the doctor out of medicine!
You only think about the rare patients with infection. You underestimate all the other issues!

Human Evolution Selected for Intuitive Thinking, Not Statistics
System 1 Thinking
- We have evolved to optimize “system 1 thinking”
  - To value recent experiences more strongly
  - To value painful experiences even more strongly
  - To understand relationships as cause-effect
  - To react intuitively (quickly, by gestalt)
- Inputs/Outputs
  - Personal experience/emotion-linked drivers
- Works well in
  - High risk, high frequency events
  - Value-driven decisions
- Works poorly in
  - Low frequency events
  - Multifactorial events

Humans Also Have Created Analytical Tools
System 2 Thinking
- Increasing progress in recent millennia
- Inputs/Outputs
  - Measurable questions
  - Measurable answers
- Works better in
  - Low frequency events
  - Multifactorial events
- Works worse in
  - High risk, high frequency events
  - Incorporating personal values

Remember We All Have a Bit of Both
Use them Optimally
- Is it a system 1 or 2 question?
- Don’t overthink system 1’s
- Don’t underthink system 2’s
Remember that Clinical Problems Have A Bit of Both
Identify the Types of Questions and Apply the Right System of Thinking

- Overtreatment Must Be Minimized (System 1)
- Estimate predictive value of Test (System 2)
- Over-treatment Must Be Minimized (System 1)
- Measure performance of Test in Practice (System 2)
- Choose a target EOS miss rate (System 1)
- Delay in Treatment Must Be Minimized (System 1)

References

Emerging Resistance and Fungal Prophylaxis

Roger F. Soll MD
President, Vermont Oxford Network
H. Wallace Professor of Neonatology
University of Vermont
Burlington, VT

Dr. Soll is the H. Wallace Professor of Neonatology at the University of Vermont College of Medicine, the President of Vermont Oxford Network, and Director of Network Clinical Trials. Dr. Soll is an authority on evidence-based medicine and randomized clinical trials. He is the coordinating editor of the Cochrane Neonatal Review Group of the Cochrane Collaboration and author or co-author of the Cochrane Reviews of surfactant therapy. He is the author of numerous peer reviewed articles and book chapters on the subject of surfactant replacement therapy and evidence-based medicine. A native of New York City, Dr. Soll graduated from Cornell University with a degree in Genetics and History of Science in 1975. He received his MD degree from the University of Health Sciences/Chicago Medical School in 1978. He returned to New York City to complete his residency training in Pediatrics at Bellevue Hospital/New York University Medical Center in 1981. After 2 years with the Public Health Service, Dr. Soll returned to academic training. He completed the post graduate fellowship in Neonatal Perinatal Medicine at the University of Vermont in 1983 and has remained in Vermont ever since.

Newborn Antibiotic Stewardship National Summit, Friday, October 27, 2017
Emerging Resistance and Fungal Prophylaxis

Objective: Discuss the possible benefits and harms of prophylactic antifungal therapy in at risk preterm infants.
Emerging Resistance and Fungal Prophylaxis

Roger F. Soll MD

Objectives

Discuss the possible benefits and harms of prophylactic antifungal therapy in at-risk preterm infants.

Discrimination

Roger F. Soll is President of Vermont Oxford Network and the Coordinating Editor of Cochrane Neonatal.

Emerging Resistance and Fungal Prophylaxis

Newborn Antibiotic Stewardship Summit

Roger F. Soll MD

H. Wallace Professor of Neonatology
University of Vermont College of Medicine
President, Vermont Oxford Network
Coordinating Editor, Cochrane Neonatal

October 27th, 2017

"Just like antibiotics cure bacterial infections, antifungal medications save lives by curing dangerous fungal infections. And just like some bacterial infections are resistant to antibiotics, some fungi no longer respond to the antifungal medications that are designed to cure them.

This emerging phenomenon is known as antifungal resistance, and it's primarily a concern for invasive infections with the fungus Candida."

https://www.cdc.gov/fungal/antifungal-resistance.html


Prophylactic systemic antifungal agents to prevent mortality and morbidity in very low birth weight infants.


Identified 15 eligible trials enrolling a total of 1690 infants.

Ten trials (1371 infants) compared systemic antifungal prophylaxis versus placebo or no drug.

These trials were generally of good methodological quality.
Prophylactic systemic antifungal agents to prevent mortality and morbidity in very low birth weight infants.

**Invasive Fungal Infection (relative risk)**

Typical relative risk 0.43, 95% CI 0.31 to 0.59

**Invasive Fungal Infection (risk difference)**

Typical risk difference -0.09, 95% CI -0.12 to -0.06

Prophylactic systemic antifungal agents to prevent mortality and morbidity in very low birth weight infants.

**Death Prior to Hospital Discharge (relative risk)**

Typical relative risk 0.79, 95% CI 0.61 to 1.02

**Death Prior to Hospital Discharge (risk difference)**

Typical risk difference -0.04, 95% CI -0.07 to 0.00

Fungal Sepsis

Vermont Oxford Network Annual Reports 2000-2016

Rates of Fungal Sepsis by Gestational Age Category

Vermont Oxford Network 2016

<table>
<thead>
<tr>
<th>GA Category</th>
<th>N</th>
<th>%</th>
<th>Q1</th>
<th>Q3</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 24 Weeks</td>
<td>2,249</td>
<td>3.9%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>24 to 26 Weeks</td>
<td>13,212</td>
<td>1.9%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>27 to 29 Weeks</td>
<td>22,625</td>
<td>0.6%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>30 to 32 Weeks</td>
<td>16,240</td>
<td>0.3%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>&gt; 32 Weeks</td>
<td>4,820</td>
<td>0.1%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>All</td>
<td>59,146</td>
<td>0.9%</td>
<td>0.0%</td>
<td>0.7%</td>
</tr>
</tbody>
</table>

“It’s hard to improve on zero!”
Prophylactic antifungal therapy

Authors’ conclusions

Prophylactic systemic antifungal therapy reduces the incidence of invasive fungal infection in very preterm or very low birth weight infants.

This finding should be interpreted and applied cautiously since the incidence of invasive fungal infection was very high in the control groups of many of the included trials.

Meta-analysis does not demonstrate a statistically significant effect on mortality. There are currently only limited data on the long-term neurodevelopmental consequences for infants exposed to this intervention. In addition, there is a need for further data on the effect of the intervention on the emergence of organisms with antifungal resistance.

So what can we do to prevent fungal infection?

Risk factors for fungal infection in preterm infants

<table>
<thead>
<tr>
<th>Risk factor</th>
<th>Odds Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gestational age &lt; 25 weeks</td>
<td>4.15 (3.12 to 6.12)</td>
</tr>
<tr>
<td>Male</td>
<td>1.28 (1.01 to 1.62)</td>
</tr>
<tr>
<td>Central catheter</td>
<td>3.94 (1.48 to 12.3)</td>
</tr>
<tr>
<td>Broad-spectrum antibiotics in week before culture</td>
<td>1.77 (1.33 to 2.29)</td>
</tr>
<tr>
<td>Cephalosporin use by day of life 3</td>
<td>1.77 (1.31 to 2.38)</td>
</tr>
<tr>
<td>H2 blockers</td>
<td>2.44 (1.11 to 5.29)</td>
</tr>
</tbody>
</table>

Is Improvement Contagious?
The Clinician’s Perspective

Karen Puopolo MD, PhD
Chief, Section on Newborn Pediatrics
Pennsylvania Hospital
Associate Professor,
Clinical Pediatrics University of Pennsylvania Perelman School of Medicine
Philadelphia, PA

Karen M. Puopolo MD, PhD is a neonatologist who specializes in neonatal infectious diseases. She received her undergraduate degree in physics from Yale University in New Haven, Connecticut, and went on to obtain her MD as well as a PhD in molecular physiology from the Tufts University School of Medicine in Boston, Massachusetts. She completed Pediatric residency and Neonatal-Perinatal fellowship training at Boston Children’s Hospital. Upon completing her fellowship, Dr. Puopolo was appointed to the faculty of Harvard Medical School and joined the staff of the Brigham and Women’s Hospital and the Channing Laboratory, where she was an attending neonatologist and researcher from 2000-2014. Dr. Puopolo began her neonatal research career as a laboratory-based scientist investigating mechanisms of virulence in Group B Streptococcus (GBS). More recently her research has focused on the epidemiology of neonatal infection, with an emphasis on molecular epidemiology and risk assessment. Recent publications focus on the results of NIH-funded research describing the largest case-control study of risk factors for neonatal early-onset sepsis done in the era of GBS prophylaxis. Dr. Puopolo is an elected member of the Society for Pediatric Research and the American Pediatric Society. She serves on the editorial board for NeoReviews. In addition, she serves on the American Academy of Pediatrics Committee on the Fetus and Newborn, whose members study issues and current advances in fetal and neonatal care and make recommendations regarding national neonatal practice. Dr. Puopolo is currently on the faculty of the University of Pennsylvania Perelman School of Medicine. She is a member of the Division of Neonatology at Children’s Hospital of Philadelphia, and Section Chief for Newborn Pediatrics at Pennsylvania Hospital.

Newborn Antibiotic Stewardship National Summit, Friday, October 27, 2017
Is Improvement Contagious? The Clinician’s Perspective

Objective: Identify 4 key lessons learned by teams participating in antibiotic stewardship collaboratives and reflect on the power of collaborative learning communities to influence rapid-cycle implementation of new evidence and guidelines.
Is Improvement Contagious?  
The Clinician's Perspective  
Karen M. Puopolo MD, PhD

Objectives

Identify 4 key lessons learned by teams participating in antibiotic stewardship collaboratives and reflect on the power of collaborative learning communities to influence rapid-cycle implementation of new evidence and guidelines.

Antibiotic Stewardship Should be Contagious Because of These

Biologic imperative
- Increasing antibiotic resistance
- We are just beginning to understand our relationship to our microbiome

Demonstration of successful improvement
- VON individual teams and state collaboratives are both showing us the way

Leadership on national, state and local levels
- CDC, VON, ACOG, AAP and state quality collaboratives

Improvement Can Be Exhausting!

To Be REALLY Contagious, We Need These, too

Systematic requirements for stewardship
- Local hospital leadership should expect and fund the work needed for stewardship efforts
- National and state agencies should require antibiotic data just as they require infection data

Evolved Data systems
- EMR's should automatically generate data on infection and antibiotic use

Separate consideration of term and preterm
- Most meaningful data and outcomes
Is Improvement Contagious?
The Clinician’s Perspective
Karen M. Puopolo MD, PhD

Systems Change Requires that We Confront Our Individual Fears
• As David and Allen showed us, we must resolve the conflict between our System I and System II thinking...
  - System 2
  - Garter snakes are common in the Northeast U.S.
  - Garter snakes are not dangerous to humans

  • System 1
  - I scream
  - I run away
  - My husband thinks I’m nuts

Why Do We Scream and Run?
• Fear for the baby
  – No one wants the baby to die of sepsis
  – No one wants to set the well baby on a path to allergy or obesity, or set up the preterm baby for NEC or BPD
• Fear of the parents
  – No one wants to take a well baby from parents
  – No one wants to tell them their well baby got sick
• Fear of being wrong
  – Never underestimate the power of shame, or the fear of litigation

To Help Us Move Forward, Remember...
• There is value in standardization
  – We don’t always do what we say we do
  – NOT following a clear standard gets us in trouble
• We manage what we measure
  – We can constantly improve on the standard if we reliably measure our actions and outcomes

To End with the Now Immortal Words of Roger Soll
No antibiotics ≠ No care
• Our goal should not be to develop local, state and national collaboratives just to reduce the use of antibiotics
• Our goal should be to respect the powerful gift of antibiotics, and work together to use it responsibly
VON Serial Data – In Service of Quality Improvement

Erika M. Edwards PhD, MPH
Director of Data Systems and Analytics
Vermont Oxford Network
Research Assistant Professor Mathematics and Statistics
University of Vermont

As Director of Data Systems and Analytics at Vermont Oxford Network, Erika Edwards has developed content for and presented training programs on data and reporting resources for quality improvement. She oversees all member reporting and database research, and participates in development of data collection tools. In addition, she is a Research Assistant Professor of Mathematics and Statistics at the University of Vermont. Prior to joining Vermont Oxford Network she was a statistical analyst at the Vermont Department of Health, Boston University School of Public Health, and the Robert Wood Johnson Foundation. Erika has a M.P.H. and a Ph.D., both in Epidemiology, from Boston University.

Annual Quality Congress Sunrise Session, Saturday, October 28, 2017
VON Serial Data – In Service of Quality Improvement

Objective: Demonstrate how your team could use serial data to monitor the impact of practice changes on your outcomes of interest.
Learning Objective:
Demonstrate how your team could use serial data to monitor the impact of practice changes on your outcomes of interest.

Life Cycle of VON Data
- Eligible Birth Year
  - January 1 – December 31, 2017
- Finalization Period
  - April 1, 2018: Each eligible infant submitted
  - May 1, 2018: Data Contact Confirmation
  - June 1, 2018: Report Contact Finalization

Members Submit on Different Schedules

<table>
<thead>
<tr>
<th></th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>January</td>
<td>✔</td>
<td>✔</td>
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<tr>
<td>February</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>March</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>April</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>May</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>June</td>
<td>✔</td>
<td>✔</td>
</tr>
</tbody>
</table>

Finalization period starts January 1, and ends June 1

<table>
<thead>
<tr>
<th></th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>January</td>
<td>✔</td>
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<tr>
<td>February</td>
<td>✔</td>
</tr>
<tr>
<td>March</td>
<td>✔</td>
</tr>
<tr>
<td>April</td>
<td>✔</td>
</tr>
<tr>
<td>May</td>
<td>✔</td>
</tr>
<tr>
<td>June 1</td>
<td>✔</td>
</tr>
</tbody>
</table>
VON Serial Data - in Service of Quality Improvement
Erika Edwards PhD, MPH

Remember
• Your center’s data for the Most Recent Birth Year are done when your center finalizes.
• Your center’s data for the Current Birth Year are up-to-date 30 minutes from your last submission.

Serial Data and QI
• Outcomes occur infrequently and can vary with small samples.
• Benchmarks change little from year to year.
• Annually may be best way to measure outcomes.
  – Use Nightingale or Annual Report instead of Time Series.
• Process measures may be more amenable to more frequent time periods.

Sparkline

View Data By Year on Nightingale
• Unadjusted
  – Choose a Category
  – Choose a Measure
  – On Group By: drop-down, choose Birth Year.
• Adjusted
  – Choose a Risk Adjusted Category
  – Click on a Measure.
Can I view data by month or quarter?

Protected Health Information (PHI)
- Quarterly or monthly reports require dates
- Dates are Protected Health Information (PHI)
- Paper forms and eNICQ 5 record dates
- Dates not sent to VON until recently

“Quarterly” Report = Produced Quarterly Data are YTD

VON Now Accepts Dates*
- Business Associate Agreement
- Amendment to Membership Agreement stating that center will send VON PHI

*Except from centers in the European Union

Time Series Charts
- Cases, N, and % for infants discharged in time period (month, quarter, semi-annual time period)
- Median
- Goal line
- Trend over time
- Infant lists

Successful Use of Time Series
- Data submissions to Vermont Oxford Network should include all infants discharged in the time period
- Develop a system to ensure that data on every discharged infant gets tracked and submitted promptly
VON Serial Data - in Service of Quality Improvement
Erika Edwards PhD, MPH

Serial Data for QI
Rocco J. Perla, Lloyd P. Provost, Sandy K. Murray
The run chart: a simple analytical tool for learning from variation in healthcare processes. BMJ Quality and Safety. 2011; 20: 46-51

Shift
• Six or more consecutive points either all above or all below the median
• Skip points that fall on the median

Trend
• Five or more consecutive points all going up or all going down

Runs
• Too few (or too many) median line crossings
• Specific critical values; see Table 1 of Perla et al.

Astronomical Data Point
• Unusually large or small values

Serial Data for QI
Munish Gupta and Heather C. Kaplan
Using statistical process control to drive improvement in neonatal care: A practical introduction to control charts Clinics in Perinatology 2017; 44: 627-644
Serial Data and QI

- Process measures may be more amenable to Time Series
- VON tracks some process measures
- Others may need to be tracked at local level

Visit the Poster Session!

Thank you!
Erika Edwards
eedwards@vtoxford.org

SUPPLEMENTAL SLIDES
SMR Interpretation

- Standardized Morbidity/Mortality Ratios are model-based estimates
- VON reports estimates and confidence bounds
- SMR centered around 1
  - 1.6 (1.2, 2.1)
  - 0.7 (0.5, 0.9)
  - 1.1 (0.9, 1.1)
VON Serial Data - in Service of Quality Improvement
Erika Edwards PhD, MPH

**SMR Interpretation**
- Worse than Expected
- Better than Expected
- As Expected

**O-E Interpretation**
- Observed minus Expected
- Centered around 0
  - 6 (1, 10)
  - -3 (-5, -1)
  - 0 (-1, 1)

**O-E Interpretation**
- 1.6 (1.2, 2.1)
  - Worse than Expected
- 0.7 (0.5, 0.9)
  - Better than Expected
- 1.1 (0.9, 1.1)
  - As Expected

**O-E Interpretation**
- 6 (1, 10)
- -3 (-5, -1)
- 0 (-1, 1)

**O-E Interpretation**
- 6 (1, 10)
  - Worse than Expected
- -3 (-5, -1)
  - Better than Expected
- 0 (-1, 1)
  - As Expected
Q1, Median, and Q3

- Hospital rates ranked from highest to lowest
- Q1 = hospital rate at 25th percentile
- Median = hospital rate at 50th percentile (Q2)
- Q3 = hospital rate at 75th percentile

<table>
<thead>
<tr>
<th>Antenatal Steroids 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q3</td>
</tr>
<tr>
<td>Median (Q2)</td>
</tr>
<tr>
<td>Q1</td>
</tr>
</tbody>
</table>
AAP Verification of NICU Levels of Care Project

Dr. Ann Stark MD
Professor of Pediatrics
Fellowship Program Director
Division of Neonatology
Vanderbilt University School of Medicine
Nashville, TN

Dr. Ann Stark is Professor of Pediatrics at Vanderbilt University School of Medicine, where she is Director of the Neonatal-Perinatal Medicine Fellowship Program and Director of Fellowship Programs in the Department of Pediatrics. She received her MD at Harvard Medical School, trained in pediatrics at St. Louis Children’s Hospital and Children’s Hospital of Philadelphia, and completed her neonatology training at the Harvard Medical School Joint Program in Neonatology. As a member of the Harvard faculty until 2004, her positions included Medical Director of the NICU at Boston Children’s Hospital. Before joining the Vanderbilt faculty, she was Professor of Pediatrics at Baylor College of Medicine, where she was Head of the Section of Neonatology and Chief of Neonatology at Texas Children’s Hospital.

Dr. Stark is an experienced clinical investigator and is an author or co-author of numerous peer reviewed publications, as well as editorials and book chapters. She is Associate Editor of the Archives of Disease in Childhood; founding Co-Editor of the Manual of Neonatal Care, published by Wolters Kluwer and now in its eighth edition; and editor of the 7th edition of Guidelines for Perinatal Care.

Dr. Stark is Medical Director of the American Academy of Pediatrics (AAP) NICU Verification Program and Chair of the AAP Section Forum Management Committee. She previously served as Chair of the Section on Neonatal-Perinatal Medicine and of the AAP Committee on Fetus and Newborn. She is a member of the American Pediatric Society and the Society for Pediatric Research.

Annual Quality Congress Sunrise Session, Saturday, October 28, 2017
AAP Verification of NICU Levels of Care Project

Objectives:
1. Know the benefits of risk-appropriate newborn care.
2. Identify a concern of self-designated level of care.
Development of a Verification Program for NICU Levels of Care
Ann R Stark MD

VON Annual Quality Congress
October 28, 2017

Development of a Verification Program for NICU Levels of Care
Ann R Stark MD
Medical Director, AAP NICU Verification Program
Professor of Pediatrics, Vanderbilt

CONFLICT OF INTEREST
Ann R Stark MD has no conflicts of interest to disclose.

LEARNING OBJECTIVES
• Know the benefits of risk-appropriate newborn care.
• Identify a concern of self-designated level of care.

LEADERSHIP TEAM
• Neonatologists
  – Charles Hankins, MD
  – LuAnn Papile, MD
  – DeWayne Pursley, MD
• Nurses
  – Pattie Bondurant, DNP, RN
  – Rosanne Buck, RN, MS, NNP-BC
  – Tami Wallace, DNP, APRN, NNP-BC

Mortality risk increased for preterm infants not born in hospital with level III NICU*
Systematic review of 41 studies 1976-2010

<table>
<thead>
<tr>
<th></th>
<th>Non-III vs III</th>
<th>Adj Odds ratio (CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>VLBW &lt; 1500g</td>
<td>36% vs 21%</td>
<td>1.60 (1.33-1.92)</td>
</tr>
<tr>
<td>ELBW &lt; 1000g</td>
<td>59% vs 32%</td>
<td>1.80 (1.31-2.46)</td>
</tr>
<tr>
<td>VPT &lt; 32 wks</td>
<td>12% vs 7%</td>
<td>1.42 (1.06-1.88)</td>
</tr>
</tbody>
</table>

No change over 30 year period
*Analysis of adequate and high quality studies
Lasswell SM et al. JAMA 2010;304:992

BPD or death in VLBW infants lower in higher level NICUs

<table>
<thead>
<tr>
<th>Level</th>
<th>BPD or Death(%) (Risk-adjusted)</th>
<th>OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>II</td>
<td>50.9</td>
<td>1.23 (1.02-1.49)</td>
</tr>
<tr>
<td>III</td>
<td>46.4</td>
<td>1.04 (0.95-1.14)</td>
</tr>
<tr>
<td>IV</td>
<td>47.8</td>
<td>Ref</td>
</tr>
</tbody>
</table>

Lapcharoensap W et al. JAMA Pediatr 2015;169(2):e143676
Development of a Verification Program for NICU Levels of Care

Ann R Stark MD

NICU VOLUME AND OUTCOME
Annual volume of deliveries of VLBW infants

Jenson EA, Lorch SA. JAMA Pediatr 2015;169(8):3151906

NURSES CRITICAL TO VLBW OUTCOMES
• Outcomes are better when
  – Nurses are well educated
  – Nursing is valued and supported
  – Staffing is optimal

BETTER VLBW OUTCOMES IN HOSPITALS RECOGNIZED FOR NURSING EXCELLENCE

<table>
<thead>
<tr>
<th></th>
<th>*Adjusted OR (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mortality</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 7 days</td>
<td>0.83 (0.72-0.96)</td>
<td>.01</td>
</tr>
<tr>
<td>&lt; 28 days</td>
<td>0.87 (0.77-0.99)</td>
<td>.03</td>
</tr>
<tr>
<td>Before d/c</td>
<td>0.87 (0.78-0.96)</td>
<td>.02</td>
</tr>
<tr>
<td><strong>Morbidity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nosocomial infection</td>
<td>0.86 (0.74-0.99)</td>
<td>.03</td>
</tr>
<tr>
<td>Severe IVH</td>
<td>0.88 (0.77-1.00)</td>
<td>.05</td>
</tr>
</tbody>
</table>

Lake ET et al. JAMA 2012; 307:1709-16

AAP 2012 POLICY STATEMENT: 4 LEVELS
• Level I – Well newborn nursery
• Level II – Special care nursery
  – ≥32 week, ≥1500 g;
  – Short term ventilation or CPAP
• Level III – NICU
  – All infants, sustained life support, access full range of pediatric medical & surgical subspecialists, full range of respiratory support, advanced imaging
• Level IV - Regional NICU
  – III + complex surgery, specialists on site, facilitate transport, outreach education

REGIONALIZATION IS CRITICAL TO IMPROVED PERINATAL OUTCOMES
• Organizes a coordinated continuum of perinatal services in a geographic area
• Increases survival of high risk newborns
• Concentrates relatively rare cases at a few locations
• Centralizes expensive technologies
• Provides opportunities for clinical teams to develop expertise

DEFINITIONS, CRITERIA, AND REGULATION OF NEONATAL SERVICES VARY AMONG STATES
• All states regulate health care facilities but neonatal levels of service vary widely
  – In 2008, 33 states defined 2 to 6 levels of services with variable definitions located in multiple types of documents
• Compliance mechanisms very widely
  – License renewal; mandated reporting; on site inspections; self designation


TIOP III, 2010
Development of a Verification Program for NICU Levels of Care
Ann R Stark MD

**WHY DESIGNATE NICUS IN TEXAS?**
- A legislator’s personal experience raised concerns about quality and cost of neonatal care
  - 2011: NICU Council formed to develop standards
  - 2013: Rules for Neonatal Levels of Care passed - based on AAP Levels of Care (details added)
  - 2015: Neonatal designation required by August 31, 2018 (Maternal designation by August 31, 2020)
- Level of NICU must be designated to receive Medicaid funds for neonatal care

**WHY NOT SELF-DESIGNATE?**
- Texas Level of Care Survey 2012
  - Surveyed hospitals providing newborn care
  - Chief nursing officer, nurse manager, medical director asked to complete survey
  - Self-designation was compared to levels in initial AAP statement: I, IIA, IIB, IIIA, IIIIB, IIC

**TEXAS LEVEL OF CARE SURVEY 2012**
- Responses from 116 of 243 (68%) hospitals with newborn services or children’s hospital
- Responses from same hospital often not concordant
- Self-reported I and IIIC usually correct
- Self-reported IIIA and IIIB never matched
- Comparison 30-40% inaccurate
- Suggests verification of responses is important

**TEXAS ADMINISTRATIVE CODE**
[Image link]

**TIMELINE OF AAP EFFORT**
- Texas DSHS announced plan to solicit survey agencies to verify NICU levels of care (2013)
- AAP task force (2013-14)
- CDC grant for initial development (2014)
- Consult with ACS for surgery component
- Texas selects AAP as 1 of 2 survey agencies (2016)
- AAP board approved 1-year pilot program 5/2016
- Initial surveys started in November 2016

**VERIFICATION PROCESS**
- Pre-review questionnaire (PRQ)
  - NICU profile, code requirements, program plan
  - Credentialing information - spreadsheets
  - Site visit: interviews; review documents, records
    - Team: neonatologist, neonatal nurse, +/- surgeon
    - Verifies that state standards are met and identifies potential deficiencies
  - Report to facility for submission to Texas Department of State Health Services
  - State designates level of NICU care
AAP SITE VISIT GOALS

- Evaluate compliance with Texas Rules
- Provide documentation to submit to state
- Recognize excellent NICU practices, programs
- Help local team identify improvement opportunities
- Message to senior leadership for resources to support needed programs
- Consultative and collegial process

ALL NICUS REQUIRE PROGRAM PLAN

- Written plan that describes population, scope of available services; approved by facility’s governing body
- Plan includes
  - Practice standards
  - Necessary equipment and services
  - Minimal credentials for neonatal staff
  - Review & revision schedule for policies & procedures
  - Guidelines for triage, stabilization, and transfer

PROGRAM PLAN – cont.

- Description of
  - Neonatal follow-up
  - Disaster response, including evacuation to appropriate levels of care
  - Quality improvement specific to NICU data
  - Staff competency and skills assessment
  - Breastfeeding support
  - Outreach education for level III and IV

SITE VISIT AGENDA

- Intro: Survey team & facility key personnel
- Meet with key personnel
  - Neonatal Medical Director
  - Neonatal Program Manager (nurse director)
  - Advanced Practice Nursing Leadership
  - Neonatal Transport Director
  - Subspecialty Medical and Surgical Leadership
  - Hospital Department Leadership
  - Pharmacy/Lab/Radiology/Pathology
  - OT/PT/Speech/Social Work

SITE VISIT AGENDA - CONTINUED

- Review
  - Quality Program
  - Policies and Procedures
  - Credentialing files
  - Facility tour
  - Record review – 10 per surveyor
### Medical Records

Medical patients – reviewed by neo and nurse
- ELBW
- PPHN
- HIE receiving therapeutic hypothermia
- Received full CPR in DR or NICU
- Deaths at more than 7 days of age
- Any serious event; include subsequent review

### Medical Records

Surgical patients – reviewed by surgeon, sample by nurse
- Congenital diaphragmatic hernia
- Esophageal atresia
- Abdominal wall defects
- Malrotation with volvulus
- Abdominal compartment syndrome (including perforation)
- Any serious event with review

### Progress to Date

### What Have We Learned So Far?

- Too soon to assess impact on outcomes
- Much variation (no surprise)
  - Clinical practice
  - NICU leadership models
  - Investment in quality initiatives
  - Mechanisms for follow-up
  - Approach to practice review
  - Program resources

### What Have We Learned So Far? - 2

- Preparation for the survey is an improvement opportunity
- Program Plan was helpful
  - Enables facility to articulate all components of their NICU program, identify gaps and needed resources
  - Recognition by their Board of Directors improves understanding of the NICU and its value and needs

### What Have We Learned So Far? - 3

- Collaborative multidisciplinary care is essential to high functioning unit
- High performing centers are eager to share outcomes; less high performers are more circumspect
- Review processes for poor or unexpected outcomes need to be encouraged
- NICU staff are typically proud of the care they provide
Development of a Verification Program for NICU Levels of Care

Ann R Stark MD

CONCLUSION

• We have developed a program to verify compliance with standards for NICU levels of care
• The process of verification has the potential to improve care locally through introspection and external review
• We anticipate that this process will facilitate risk-appropriate care for vulnerable infants

REFERENCES

• Jensen SA, Lorch SA. Effects of a birth hospital’s neonatal intensive care unit level and annual volume of very low‐birth‐weight infant deliveries on morbidity and mortality. JAMA Pediatr 2015 Aug;169(8):e151906
• Lowell SM, Berfield WD, Rochat RK, Blackmon L. Perinatal regionalization for very low‐birth‐weight and very preterm infants: a meta‐analysis. JAMA 2010 Sep 1;304(9):992‐1000
Intro: Framing the Evidence Challenges

Roger F. Soll MD
President, Vermont Oxford Network
H. Wallace Professor of Neonatology
University of Vermont
Burlington, VT

Dr. Soll is the H. Wallace Professor of Neonatology at the University of Vermont College of Medicine, the President of Vermont Oxford Network, and Director of Network Clinical Trials. Dr. Soll is an authority on evidence-based medicine and randomized clinical trials. He is the coordinating editor of the Cochrane Neonatal Review Group of the Cochrane Collaboration and author or co-author of the Cochrane Reviews of surfactant therapy. He is the author of numerous peer reviewed articles and book chapters on the subject of surfactant replacement therapy and evidence-based medicine. A native of New York City, Dr. Soll graduated from Cornell University with a degree in Genetics and History of Science in 1975. He received his MD degree from the University of Health Sciences/Chicago Medical School in 1978. He returned to New York City to complete his residency training in Pediatrics at Bellevue Hospital/New York University Medical Center in 1981. After 2 years with the Public Health Service, Dr. Soll returned to academic training. He completed the post graduate fellowship in Neonatal Perinatal Medicine at the University of Vermont in 1983 and has remained in Vermont ever since.

Annual Quality Congress Plenary Session, Saturday, October 28, 2017
Intro: Framing the Evidence Challenges

Objective: Identify the importance of evaluating the evidence and the challenges with translating good quality evidence into action.
Translating Evidence Into Practice
Framing the Evidence Challenges

Roger F. Soll MD

Disclosure
Roger F. Soll is President of Vermont Oxford Network and the Coordinating Editor of Cochrane Neonatal

Objective
Identify the importance of evaluating the evidence and the challenges with translating good quality evidence into action.

Corticosteroids for Preterm Birth
Since 1972,
- there are multiple randomized controlled trials (N=18)
- involving a large number of infants (3735 infants)

but...

antenatal corticosteroids were not utilized in the vast majority of patients until...
Corticosteroids for Preterm Birth

“Antenatal corticosteroid therapy is indicated for women at risk of premature delivery with few exceptions and will result in a substantial decrease in neonatal morbidity and mortality, as well as substantial savings in health care costs”

Antenatal Corticosteroids

VERMONT OXFORD NETWORK ANNUAL REPORTS 1991-2015

% VLBW INFANTS

Antenatal Corticosteroids

NIH Conference

Inborn: 85%
Outborn: 58%

Postnatal Corticosteroids for the Prevention and Treatment of Bronchopulmonary Dysplasia

Postnatal Corticosteroid Therapy: Systematic Reviews

Early Steroid Treatment:
- before or at 7 Days
- studies 32
- enrolled infants 4395

Late Steroid Treatment:
- after 7 Days
- studies 21
- enrolled infants 1424

Early (≤ 7 days) and Later (> 8 days) Postnatal Corticosteroid Therapy

Doyle L, Cheong JL, Ehrenkranz RA and Halliday HL, Cochrane Library 2017

Typical Relative Risk and 95% CI
POSTNATAL CORTICOSTEROIDS TO TREAT OR PREVENT CHRONIC LUNG DISEASE IN PRETERM INFANTS

RECOMMENDATIONS FROM THE COMMITTEE ON THE FETUS AND NEWBORN 2002

On the basis of limited short-term benefits, the absence of long-term benefits, and the number of serious short-term and long-term complications, the routine use of systemic dexamethasone for the prevention or treatment of chronic lung disease in infants with very low birth weight is not recommended.

POSTNATAL CORTICOSTEROIDS TO TREAT OR PREVENT CHRONIC LUNG DISEASE IN PRETERM INFANTS

RECOMMENDATIONS FROM THE COMMITTEE ON THE FETUS AND NEWBORN 2002

Outside the context of a randomized controlled trial, the use of corticosteroids should be limited to exceptional clinical circumstances (e.g., an infant on maximal ventilatory and oxygen support). In those circumstances, parents should be fully informed about the known short- and long-term risks and agree to treat.

Postnatal Corticosteroid Use in VLBW Infants

VERMONT OXFORD NETWORK ANNUAL REPORTS 1991-2014

Risk Difference (%) for Death or CP among all participants vs. rate of CLD (%) in the control group


ELECTIVE HIGH FREQUENCY OSCILLATORY VENTILATION

META-ANALYSIS OF 19 RANDOMIZED CONTROLLED TRIALS

<table>
<thead>
<tr>
<th>OUTCOME (STUDY ES)</th>
<th>Risk Difference (95% CI)</th>
<th>Decreased Risk</th>
<th>Increased Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>PULMONARY AIRLEAK (13)</td>
<td>0.04 (0.03, 0.07)</td>
<td>0.2</td>
<td>0.5</td>
</tr>
<tr>
<td>IVH (12)</td>
<td>0.02 (-0.01, 0.05)</td>
<td>0.5</td>
<td>1.0</td>
</tr>
<tr>
<td>SEVERE IVH (18)</td>
<td>0.01 (-0.01, 0.04)</td>
<td>1.0</td>
<td>2.0</td>
</tr>
<tr>
<td>PVL (17)</td>
<td>0.00 (-0.01, 0.02)</td>
<td>2.0</td>
<td>4.0</td>
</tr>
<tr>
<td>SEVERE RENAL PATH (12)</td>
<td>-0.04 (-0.07, -0.01)</td>
<td>4.0</td>
<td>6.0</td>
</tr>
<tr>
<td>CHRONIC LUNG DISEASE (17)</td>
<td>-0.05 (-0.08, -0.02)</td>
<td>6.0</td>
<td>8.0</td>
</tr>
<tr>
<td>DEATH (17)</td>
<td>-0.01 (-0.03, 0.02)</td>
<td>8.0</td>
<td>10.0</td>
</tr>
<tr>
<td>CLD/DEATH @ 36 WKS PMA (17)</td>
<td>-0.05 (-0.08, -0.01)</td>
<td>10.0</td>
<td>12.0</td>
</tr>
</tbody>
</table>

Cools 2015

Relative Risk and 95% CI
Translating Evidence Into Practice
Framing the Evidence Challenges

Roger F. Soll MD

**High Frequency Ventilation**

VERMONT OXFORD NETWORK ANNUAL REPORTS 1991-2014

<table>
<thead>
<tr>
<th>Year</th>
<th>% VLBW INFANTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1993</td>
<td>6.05 (5.14, 6.94)</td>
</tr>
<tr>
<td>1995</td>
<td>9.09 (8.24, 9.95)</td>
</tr>
<tr>
<td>1997</td>
<td>12.00 (11.21, 12.79)</td>
</tr>
<tr>
<td>1999</td>
<td>15.00 (14.21, 15.79)</td>
</tr>
<tr>
<td>2001</td>
<td>18.00 (17.21, 18.79)</td>
</tr>
<tr>
<td>2003</td>
<td>21.00 (20.21, 21.79)</td>
</tr>
<tr>
<td>2005</td>
<td>24.00 (23.21, 24.79)</td>
</tr>
<tr>
<td>2007</td>
<td>27.00 (26.21, 27.79)</td>
</tr>
<tr>
<td>2009</td>
<td>30.00 (29.21, 30.79)</td>
</tr>
</tbody>
</table>

**Hypothermia for Hypoxic Ischemic Encephalopathy**

**Whole Body Cooling and Selective Head Cooling**

<table>
<thead>
<tr>
<th>Study</th>
<th>Risk Difference (95% CI)</th>
<th>Decreased Risk</th>
<th>Increased Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selective Head Cooling</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>-0.05 (-0.14, 0.04)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Major Disability</td>
<td>-0.09 (-0.24, 0.05)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death or Major Disability</td>
<td>-0.09 (-0.21, 0.03)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Whole Body Cooling</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>-0.10 (-0.16, -0.04)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Major Disability</td>
<td>-0.18 (-0.29, -0.09)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death or Major Disability</td>
<td>-0.16 (-0.23, -0.09)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Updated by Berg 2012

**Hypothermia for the Treatment of Hypoxic Ischemic Encephalopathy**

ILCOR recommendations

“Intensive care nurseries should now consider adopting one of the validated protocols for the selection of term infants with HIE, be appropriately equipped and train staff to offer hypothermia according to the protocol of the currently published large hypothermia trials.”

“Because HIE is a relatively uncommon condition, it would be highly desirable where possible to centralize this treatment to larger intensive care units.”

“With the data presently available, there is no longer any reasonable justification to deny this apparently efficacious treatment for those who most urgently need it.”

Hoehn and coworkers. Resuscitation 2008

**Cooling in Hypoxic Ischemic Encephalopathy**

What are we supposed to do?

**Difficulty of Translating Evidence to Practice**

**Efficacy:**

Mild hypothermia is a promising therapy in a highly selected population of infants with moderate to severe hypoxic ischemic encephalopathy when treated before 6 hours of age.
DIFFICULTY OF TRANSLATING EVIDENCE TO PRACTICE

Effectiveness and Efficiency:

• Does it work in the most affected infants? Does it provide a benefit to less severely affected infants?

• Does it work outside the restricted time window predicted by animal models and tested in clinical trials?

• Does selective or whole body hypothermia work better?

• What is the relationship of hypothermia to other therapeutic interventions?

ENCEPHALOPATHY REGISTRY:
Hypothermic Therapy 2006 to 2011

• 99 participating centers
• 2457 infants treated with hypothermia
• 726 (30%) did not meet criteria from RCTs
  - 40% with mild encephalopathy
  - 60% treated after 6 hours
  - 17% of all infants < 36 weeks gestation

Whole Body 74%
Selective Head 17%
Both 9%

Translating Evidence Into Practice
Framing the Evidence Challenges

Antenatal Steroids Alan H. Jobe, MD, PhD
Hypothermia for HIE Sonia Bonifacio, MD
Dr. Jobe graduated Phi Beta Kappa from Stanford University with a degree in Biology in 1967. He then completed MD and PhD degrees in 1973 at the University of California, San Diego. His PhD research was on regulation of the Lac operon with Drs. Melvin and Suzanne Cohn at the Salk Institute. Dr. Jobe completed his pediatric residency in 1975 and fellowship in Neonatology in 1977 at the University of California, San Diego. He joined the Department of Pediatrics at Harbor-UCLA in 1977 where he became a Professor of Pediatrics at UCLA in 1983. He became Director of the Perinatal Research Laboratories at the Walter P. Martin Research Center at Harbor-UCLA in 1995, and he was named the first Joseph W. St. Geme, Jr. Professor of Pediatrics at UCLA in 1995. He moved to Cincinnati Children’s Hospital, University of Cincinnati in 1997, where he presently is Professor of Pediatrics in the divisions of Neonatology and Pulmonary Biology.

Dr. Jobe performed many of the metabolic and physiologic studies that resulted in FDA approval of surfactant for the treatment of Respiratory Distress Syndrome. His research interests are in surfactant homeostasis, lung injury and Bronchopulmonary Dysplasia, fetal inflammation, and lung development. He has had continuous R01 funding since fellowship. He was the Director of a P-50 Program Project Grant from NHLBI to study surfactant homeostasis in transgenic animal models at Cincinnati Children’s Hospital Medical Center. He has worked for 27 years with NIH and Australian NHMRC funding in Perth, Western Australia and Cincinnati on translational research to understand fetal lung maturation, fetal inflammation, and the risks of Bronchopulmonary Dysplasia. He also directed two clinical studies funded by NHLBI to evaluate chorioamnionitis and lung outcomes in late-preterm infants (RO1) and to identify biomarkers for Bronchopulmonary Dysplasia (U10). He was Chair of the Steering Committee for the NICHD Neonatal Research Network from 1996 to 2006. He was a member of the National Advisory Child Health and Human Development Council for NIH from 2003 to 2007. He also was the Chair of the Steering Committee for the NICHD Global Research Network. He presently is a consultant for Bill and Melinda Gates for maternal and infant mortality. His CV lists over 380 peer reviewed publications and over 220 editorials, chapters, and other publications.
Translating the Evidence into Practice: Antenatal Steroids

Alan H. Jobe MD, PhD

Translating the Evidence into Practice: Antenatal Steroids

Alan H. Jobe MD, PhD
Cincinnati Children’s Hospital
University of Cincinnati
Cincinnati, Ohio

Conflicts of Interest Declaration

<table>
<thead>
<tr>
<th>Source</th>
<th>Purpose:</th>
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<tbody>
<tr>
<td>Grants</td>
<td>B&amp;M Gates Foundation</td>
</tr>
<tr>
<td></td>
<td>GSK (Matt Kemp)</td>
</tr>
<tr>
<td>Gifts for Research</td>
<td>Chiesi</td>
</tr>
<tr>
<td>Consulting</td>
<td>B&amp;M Gates Foundation</td>
</tr>
<tr>
<td>Consulting</td>
<td>Chiesi</td>
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<tr>
<td></td>
<td>Merck Fisher &amp; Paykel</td>
</tr>
<tr>
<td></td>
<td>Merck</td>
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</table>

Learning Objective:

Compare and contrast the evidence for the use of ANS and identify the impact of outcomes, key controversies, and clinical quandaries.

Current Status of ANS in Advanced Care Environments

<table>
<thead>
<tr>
<th>Who Receives ANS?</th>
<th>% of Delivery Population</th>
</tr>
</thead>
<tbody>
<tr>
<td>80-95% of women at risk of PTD at 24-34 weeks</td>
<td>4%</td>
</tr>
<tr>
<td>Repeated ANS used selectively (no data on % treated)</td>
<td>---</td>
</tr>
<tr>
<td>ALPS Trial (2016) ANS for 34-36 week deliveries</td>
<td>7%</td>
</tr>
<tr>
<td>ANS for previable deliveries (&lt;24 weeks)</td>
<td>1%</td>
</tr>
<tr>
<td>Elective C-section</td>
<td>10-60%</td>
</tr>
<tr>
<td>Total potential of pregnant women exposed</td>
<td>22-70%</td>
</tr>
</tbody>
</table>

More and more pregnancies are being treated, which changes the benefit to risk ratio.

Levels of Evidence Pyramid

- Meta-analysis
- Randomized Controlled Trials
- Cohort Studies
- Case-Control Studies
- Case Series, Case Reports
- Editorials, Expert Opinion
Translating the Evidence into Practice: Antenatal Steroids

Alan H. Jobe MD, PhD

Levels of Evidence Pyramid

Age of Data

Levels of Evidence Pyramid

Age of Data

Levels of Evidence Pyramid

Relevance of Populations Studied To current patients

Levels of Evidence Pyramid

Age of Data

Levels of Evidence Pyramid

Relevance of Populations Studied To current patients

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Age of Data

Levels of Evidence Pyramid

Relevance of Populations Studied To current patients

Levels of Evidence Pyramid

Age of Data

Levels of Evidence Pyramid

Relevance of Populations Studied To current patients

Overall survival time free of signals for updating for systematic reviews in adult Cardiology, Neurology, and GI (100 analyses of an average of 13 studies containing 2,600 patients).

Median Survival ± 2 SD


Eras and Numbers for RCTs for Single Course ANS

<table>
<thead>
<tr>
<th>Era of Trial</th>
<th>Trial Number</th>
<th>Women Recruited</th>
</tr>
</thead>
<tbody>
<tr>
<td>1970's</td>
<td>4</td>
<td>1470</td>
</tr>
<tr>
<td>1980's</td>
<td>9</td>
<td>1553</td>
</tr>
<tr>
<td>1990's</td>
<td>8</td>
<td>853</td>
</tr>
<tr>
<td>2000's</td>
<td>2</td>
<td>257</td>
</tr>
<tr>
<td>2010 +</td>
<td>7</td>
<td>3757</td>
</tr>
</tbody>
</table>

Early trials before 1990 – RDS and Death Outcomes
After 1990 – primarily for >34 weeks GA

Roberts – Cochrane Library, 2017
Translating the Evidence into Practice: Antenatal Steroids

Alan H. Jobe MD, PhD

Do ANS Work at Early GA?

RCT Data for Infants Born at <28 Weeks

<table>
<thead>
<tr>
<th>RDS</th>
<th>Trials</th>
<th>Treated</th>
<th>Control</th>
<th>Relative Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>4</td>
<td>48</td>
<td>54</td>
<td>0.79 (0.53-1.18)</td>
</tr>
<tr>
<td>IVH</td>
<td>1</td>
<td>34</td>
<td>28</td>
<td>0.34 (0.14-0.86)</td>
</tr>
<tr>
<td>Death</td>
<td>2</td>
<td>45</td>
<td>44</td>
<td>0.79 (0.56-1.12)</td>
</tr>
</tbody>
</table>

Inadequate RCT data that ANS are effective at early GA.

Some Epidemiology Studies Comparing ANS in ELBW Infants

<table>
<thead>
<tr>
<th>1st Author</th>
<th>Data Origin</th>
<th>Number</th>
<th>% No ANS</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carlo (2011)</td>
<td>NICHD-NIN</td>
<td>10,541</td>
<td>26%</td>
<td>ANS decreases death, improves ND outcome</td>
</tr>
<tr>
<td>Wong (2014)</td>
<td>Australia</td>
<td>2,549</td>
<td>12.5%</td>
<td>ANS decreases death, IVH, NEC</td>
</tr>
<tr>
<td>Wei (2016)</td>
<td>California</td>
<td>25,979</td>
<td>12.8%</td>
<td>ANS decreases IVH</td>
</tr>
<tr>
<td>Norman (2017)</td>
<td>EPICE-Europe</td>
<td>4,594</td>
<td>14.4%</td>
<td>ANS decreased death and IVH</td>
</tr>
<tr>
<td>Travers (2017)</td>
<td>Pediatrics</td>
<td>117,041</td>
<td>30%</td>
<td>ANS decreased death</td>
</tr>
</tbody>
</table>

Antenatal Corticosteroid Effects on Death and IVH

By Gestational Age

<table>
<thead>
<tr>
<th>GA</th>
<th>Patient #</th>
<th>% given ANS</th>
<th>NN to T</th>
</tr>
</thead>
<tbody>
<tr>
<td>24</td>
<td>2,133</td>
<td>84%</td>
<td>6</td>
</tr>
<tr>
<td>26</td>
<td>3,046</td>
<td>83%</td>
<td>17</td>
</tr>
<tr>
<td>28</td>
<td>4,922</td>
<td>86%</td>
<td>30</td>
</tr>
<tr>
<td>30</td>
<td>7,636</td>
<td>85%</td>
<td>130</td>
</tr>
<tr>
<td>32</td>
<td>10,273</td>
<td>81%</td>
<td>395</td>
</tr>
<tr>
<td>34</td>
<td>37,660</td>
<td>49%</td>
<td>795</td>
</tr>
</tbody>
</table>

No data on RDS

ANS Clinical Experience for Death Outcomes for Inborn Infants Pediatrix – 2009 to 2013

<table>
<thead>
<tr>
<th>GA</th>
<th>Patient #</th>
<th>% given ANS</th>
<th>NN to T</th>
</tr>
</thead>
<tbody>
<tr>
<td>24</td>
<td>2,133</td>
<td>84%</td>
<td>6</td>
</tr>
<tr>
<td>26</td>
<td>3,046</td>
<td>83%</td>
<td>17</td>
</tr>
<tr>
<td>28</td>
<td>4,922</td>
<td>86%</td>
<td>30</td>
</tr>
<tr>
<td>30</td>
<td>7,636</td>
<td>85%</td>
<td>130</td>
</tr>
<tr>
<td>32</td>
<td>10,273</td>
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<td>395</td>
</tr>
<tr>
<td>34</td>
<td>37,660</td>
<td>49%</td>
<td>795</td>
</tr>
</tbody>
</table>

Number needed to treat is very high at 34 weeks

Comparison of antenatal factors for population exposed and not exposed to ANS – EPICE cohort of 4,594 infants 24-31 weeks gestation – 14.4% Not

<table>
<thead>
<tr>
<th>Maternal Variables</th>
<th>ANS (84.6%)</th>
<th>No ANS (14.4%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preeclampsia</td>
<td>26%</td>
<td>11%</td>
</tr>
<tr>
<td>PPROM</td>
<td>32%</td>
<td>9%</td>
</tr>
<tr>
<td>C-section</td>
<td>68%</td>
<td>52%</td>
</tr>
<tr>
<td>Delivery at Level 3 assist</td>
<td>83%</td>
<td>57%</td>
</tr>
<tr>
<td>Delivery – day of admission</td>
<td>5%</td>
<td>67%</td>
</tr>
</tbody>
</table>

These populations are not similar.
Translating the Evidence into Practice: Antenatal Steroids

Alan H. Jobe MD, PhD

Mortality from RDS – US Population Data

Infant Mortality World-Wide - 2015

- Infant mortality is 45% of under 5 mortality.
  - 2.7 million
- Prematurity is a major associated cause
  - 1.1 million
- Many prematurity related deaths have a respiratory cause.

Can ANS in low-resource environment save lives?

ACT Trial in Africa, India, Pakistan, and Guatemala

WHO Recommendations on Interventions to Improve Preterm Birth Outcomes

ANS are #1 of 10 Recommendations

- ANS indicated for women at risk of PT delivery at 24-34 wks when:
  - GA is known
  - Birth is imminent (within 7d)
  - No clinical evidence of maternal infection (Chorio)
  - Care available for preterm infant
  - Beta-P - 4 doses of 6 mg every 12 hr

Levels of Evidence Pyramid

Reference:

Improvement Brief / Variations in VLBW Infant Outcome and Practices Between Neonatal Units in Switzerland And the US

Mark Adams, MSc, PhD(cand)
Network Coordinator
Swiss Neonatal Network
University Hospital Zurich, Switzerland

Fifteen years ago, Mark Adams and Prof. Dr. Hans Ulrich Bucher built the Swiss Neonatal Network (SNN) using VON as model and inspiration. Today, it collects continuous routine data for all Swiss very preterm born children at birth, at two and at five years of age and sometimes beyond. Since 2011, SNN is part of the VON Worldwide Community of Practice. Mark Adams provides the annual Swiss NICU quality reports and has actively participated in quality improvement collaboratives. Currently he is finishing his PhD in epidemiological research at the Epidemiology, Biostatistics and Prevention Institute at the University of Zurich.

Annual Quality Congress Plenary Session, Saturday, October 28, 2017
Improvement Brief / Variations in VLBW Infant Outcome and Practices Between Neonatal Units in Switzerland And the US

Objective: Identify 3 critical improvement methods or strategies employed by this improvement team to effect measurable improvement in the quality, safety and value of care for newborns.
Variations in VLBW Infant Outcome and Practices Between Neonatal Units in Switzerland and the US

Mark Adams MSc, PhD(c)

Department of Neonatology, University Hospital Zurich, Switzerland
mark.adams@usz.ch

Disclosure Statement

• I am the Network Coordinator of the Swiss Neonatal Network
• I declare no personal conflict of interest

Setting

• Swiss Neonatal Network (SNN = 13 units), US units of Vermont Oxford Network (US-VON = 696 units).
• VLBW infants (501 – 1500g birth weight) between 2012 – 2014, N >125'000.
• All live births (including delivery room deaths).
• Both networks robust and representative:
  • SNN 95% of all Swiss births (Federal Statistical Office)
  • US-VON 84% of all US births (CDC vital statistics report)

Aim

• Analyze difference of clinical care practices:
  • Obstetric / delivery room / neonatal
• Explore possible association with outcome variability:
  • Death or major morbidity: mortality, late onset sepsis, NEC, IVH 3-4, CLD, ROP 3-4
  • Morbidity: early deaths (birth – 12 hours of life)
  • Any major morbidity (survivors only)

Outcome variability - crude

<table>
<thead>
<tr>
<th>Units</th>
<th>Death or any major morbidity</th>
<th>Delivery room deaths</th>
<th>Any major morbidity (survivors)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SNN</td>
<td>33.7%</td>
<td>6.0%</td>
<td>22.8%</td>
</tr>
<tr>
<td>US-VON</td>
<td>46.9%</td>
<td>9.6%</td>
<td>38.1%</td>
</tr>
</tbody>
</table>

Outcome variability - adjusted

<table>
<thead>
<tr>
<th>Units</th>
<th>Death or any major morbidity</th>
<th>Delivery room deaths</th>
<th>Any major morbidity (survivors)</th>
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<td>38.1%</td>
</tr>
</tbody>
</table>

Adjusted* relative risk (95% CI)

<table>
<thead>
<tr>
<th>Units</th>
<th>Death or any major morbidity</th>
<th>Delivery room deaths</th>
<th>Any major morbidity (survivors)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SNN</td>
<td>0.56 (0.51 to 0.62)</td>
<td>2.0 (1.55 to 2.56)</td>
<td>0.49 (0.44 to 0.55)</td>
</tr>
<tr>
<td>US-VON</td>
<td>0.56 (0.51 to 0.62)</td>
<td>2.0 (1.55 to 2.56)</td>
<td>0.49 (0.44 to 0.55)</td>
</tr>
</tbody>
</table>

Sensitivity Analysis:
- Propensity score matching
- Competing risk: same results 25–29 weeks GA
Variations in VLBW Infant Outcome and Practices Between Neonatal Units in Switzerland and the US

Mark Adams MSc, PhD(c)

Summary & Conclusion

- Mortality ↑ in SNN units:
  - Possibly due to strategy for infants < 25w GA
- Death or major morbidity: ↓ in SNN units
  - Possibly driven by variations in evidence based practice

Next Steps

- Effect of evidence based practices on outcome?
  - EPICE-model* (Effective Perinatal Intensive Care in Europe for very preterm births)
  - Applied to SNN vs. US-VON
  - Posters # xyz

Acknowledgements

- We thank the Vermont Oxford Network and Swiss Neonatal Network member hospitals that contributed data used in this study.

BPD: Why Are We Failing to Move the Big Dot?

Alan H. Jobe MD, MPH
Director, Division of Perinatal Biology,
Cincinnati Children’s Hospital Medical Center
Professor, UC Department of Pediatrics
Cincinnati, OH

Dr. Jobe graduated Phi Beta Kappa from Stanford University with a degree in Biology in 1967. He then completed MD and PhD degrees in 1973 at the University of California, San Diego. His PhD research was on regulation of the Lac operon with Drs. Melvin and Suzanne Cohn at the Salk Institute. Dr. Jobe completed his pediatric residency in 1975 and fellowship in Neonatology in 1977 at the University of California, San Diego. He joined the Department of Pediatrics at Harbor-UCLA in 1977 where he became a Professor of Pediatrics at UCLA in 1983. He became Director of the Perinatal Research Laboratories at the Walter P. Martin Research Center at Harbor-UCLA in 1995, and he was named the first Joseph W. St. Geme, Jr. Professor of Pediatrics at UCLA in 1995. He moved to Cincinnati Children’s Hospital, University of Cincinnati in 1997, where he presently is Professor of Pediatrics in the divisions of Neonatology and Pulmonary Biology.

Dr. Jobe performed many of the metabolic and physiologic studies that resulted in FDA approval of surfactant for the treatment of Respiratory Distress Syndrome. His research interests are in surfactant homeostasis, lung injury and Bronchopulmonary Dysplasia, fetal inflammation, and lung development. He has had continuous R01 funding since fellowship. He was the Director of a P-50 Program Project Grant from NHLBI to study surfactant homeostasis in transgenic animal models at Cincinnati Children’s Hospital Medical Center. He has worked for 27 years with NIH and Australian NHMRC funding in Perth, Western Australia and Cincinnati on translational research to understand fetal lung maturation, fetal inflammation, and the risks of Bronchopulmonary Dysplasia. He also directed two clinical studies funded by NHLBI to evaluate chorioamnionitis and lung outcomes in late-preterm infants (RO1) and to identify biomarkers for Bronchopulmonary Dysplasia (U10). He was Chair of the Steering Committee for the NICHD Neonatal Research Network from 1996 to 2006. He was a member of the National Advisory Child Health and Human Development Council for NIH from 2003 to 2007. He also was the Chair of the Steering Committee for the NICHD Global Research Network. He presently is a consultant for Bill and Melinda Gates for maternal and infant mortality. His CV lists over 380 peer reviewed publications and over 220 editorials, chapters, and other publications.

Annual Quality Congress Breakout Session, Saturday, October 28, 2017
BPD: Why Are We Failing to Move the Big Dot

Objective: Link the evidence and mechanisms of BPD to clinical care strategies that QI teams might explore to reduce BPD.
BPD: Why are we failing to move the Big Dot?

Alan H. Jobe MD, PhD

Learning Objective:
Link the evidence and mechanisms of BPD to clinical care strategies that QI teams might explore to reduce BPD.

What is the Big Dot for you?
- Incidence of BPD in ELBW infants
- Severe BPD in preterm infants
- Early lethal BPD

Answer will depend on pathophysiology, epidemiology, definition of BPD, and Your perception of the disease.
By the end of this workshop we may have an answer.

Epidemiology: Essential to an understanding of the Big Dot
BPD: Why are we failing to move the Big Dot?

Alan H. Jobe MD, PhD

Data from Stoll, et al., Pediatr, 2010

NIH Workshop Definition

Bronchopulmonary Dysplasia in NICHD-NRN for infants 22-28 wks. GA

Rates of death and BPD in Vermont – Oxford Network for infants 501 to 1500g

What crucial information do you need to interpret the epidemiology?

- The definition of BPD used.
- Your thoughts about its adequacy
- Does the definition capture the population that you care about?

Definitions of BPD - Clinical

- Supplemental O₂ at 28d or for 28d
- Supplemental O₂ at 36 wks (Shennan)
- Mild – 28d O₂
- Moderate – O₂ use at 36 wks
- Severe - >30% O₂ + Positive Pressure
- Challenge of O₂ need or Flow at 36 weeks
Limitations to Definitions – “Facts” often Overlooked

- Preterm infants are abnormal.
- The lungs of VLBW infants develop abnormally.
- The lungs of VLBW infants are abnormal at 36 weeks / term.
- Comparison populations for incidence of BPD are abnormal – no “control” group.

Problems with Definitions

- 36 wks is an arbitrary time on a continuum of disease.
- Defined by O2 or positive pressure – not pathophysiology, lab, radiology.
- Diagnosis occurs months after opportunities to prevent or treat.
- Patients are unclassifiable with newer therapies.
  - High flow nasal cannula – No O2
  - Very low flow - 100% O2
- Diagnosis poorly predicts long term outcomes.

3 Populations to Consider Relative to a BPD Diagnosis

1. Infants that die of RDS + BPD before 36 wks.
2. Infants with “severe” BPD.
3. Infants that die with BPD after 36 wks.

  - Target populations for innovative therapies
  - Who are these infants and how many are there?

Cause of Death by Gestational Age – Survival >12h

3620 Total Deaths

<table>
<thead>
<tr>
<th>GA in Weeks</th>
<th>22w</th>
<th>23w</th>
<th>24w</th>
<th>25w</th>
<th>26w</th>
<th>27w</th>
<th>28w</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Deaths</td>
<td>871</td>
<td>1681</td>
<td>1506</td>
<td>487</td>
<td>491</td>
<td>483</td>
<td>367</td>
</tr>
<tr>
<td>RDS Deaths</td>
<td>46%</td>
<td>42%</td>
<td>33%</td>
<td>31%</td>
<td>28%</td>
<td>25%</td>
<td>22%</td>
</tr>
<tr>
<td>BPD Deaths</td>
<td>7%</td>
<td>8%</td>
<td>8%</td>
<td>10%</td>
<td>10%</td>
<td>11%</td>
<td>11%</td>
</tr>
<tr>
<td>RDS + BPD</td>
<td>53%</td>
<td>49%</td>
<td>40%</td>
<td>43%</td>
<td>48%</td>
<td>44%</td>
<td>44%</td>
</tr>
</tbody>
</table>

Patel, et al., NEJM, 2015

Proportionate Mortality at Postnatal Ages for 22-28 Week GA Infants

Patel, et al., NEJM, 2015
BPD: Why are we failing to move the Big Dot?
Alan H. Jobe MD, PhD

Estimates of Infants that Die that Could be Targets for New Treatments for BPD – U.S. Deaths

<table>
<thead>
<tr>
<th>Category</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Live births/year</td>
<td>4,000,000</td>
</tr>
<tr>
<td>Births &lt;29 wks = 1%</td>
<td>40,000</td>
</tr>
<tr>
<td>Deaths of infants &lt;29 wks = 27%</td>
<td>10,800</td>
</tr>
<tr>
<td>Deaths 12h to 28d = 42%</td>
<td>4,563</td>
</tr>
<tr>
<td>Deaths &gt;28d = 17%</td>
<td>1,857</td>
</tr>
<tr>
<td>Sum Treatable deaths</td>
<td>6,393</td>
</tr>
<tr>
<td>Deaths from RDS + BPD = 29%</td>
<td>1,853</td>
</tr>
</tbody>
</table>

*Of the infant population that does not die, what are the characteristics of infants who are diagnosed with BPD?

- Problem with definition/diagnosis
- BPD is a spectrum of disease from mild to severe
- New therapies should be targeted at SEVERE disease

A Brief Summary of the Clinical Landscape for Infants with GA <29 wks*

- Most infants survive 72%
- Many infants have BPD 68%
  - Mild (28d oxygen requirement) 27%
  - Moderate – oxygen requirement at 36 wks 23%
  - Severe – oxygen + respiratory support at 36 wks 18%

*Stoll, et al., Pediatr., 2010

Prediction of BPD by Postnatal Age

- Postnatal risk factors
  - Gestational age
  - Birth weight
  - Sex
  - Race and ethnicity
  - Respiratory support
  - FiO2 at 6 ages after birth

- Prediction improved with postnatal age
  Web based model: https://neonatal.rti.org
  Laughon, et al., AJRCCM, 2011

Confounding Lung Abnormalities in Infants at Risk for Severe BPD

- Fetal growth restriction lung
- Pulmonary hypoplasia
- Inflammation/pneumonia
- Maternal smoking

Rough Estimate of Infants to Target for Innovative Therapies – US Total

<table>
<thead>
<tr>
<th>Category</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deaths 12h to &gt;28d</td>
<td>1,853</td>
</tr>
<tr>
<td>Infants with severe BPD – 18% of population &lt;29 wks</td>
<td>7,200</td>
</tr>
<tr>
<td></td>
<td><strong>9,000 Infants</strong></td>
</tr>
</tbody>
</table>

The “orphan population” for a new BPD therapies
BPD: Why are we failing to move the Big Dot?

Alan H. Jobe MD, PhD

Challenges for Existing Definitions of BPD

- Recent changes in practice/management:
  - Room-air flow
  - High flow NC (positive airway pressure?)
  - Extremely low flow with 100% oxygen
  - Changes in O2 saturation targets
- Relevance of 36 week outcome (still preterm with problems with control of breathing).
- Not designed to predict longer-term respiratory outcomes.

NHLBI Prematurity and Respiratory Outcomes Program

- Prospective daily clinical and medication data on a cohort of 750 infants <29 wks GA
- 1 year pulmonary outcomes including iPFTs
- Determine if respiratory assessments prior to NICU discharge will predict respiratory disease in the 1st year of life
- Identify mechanisms and molecular biomarkers of respiratory disease risk in premature infants (<29 wks GA)
- Create a biospecimen repository

Subject Characteristics

<table>
<thead>
<tr>
<th>Infant Characteristics at Birth</th>
<th>n = 765</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gestational age, mean (SD), wk</td>
<td>26.7 (1.4)</td>
</tr>
<tr>
<td>GA, completed weeks, n (%)</td>
<td></td>
</tr>
<tr>
<td>23</td>
<td>25 (3.3%)</td>
</tr>
<tr>
<td>24</td>
<td>82 (10.7%)</td>
</tr>
<tr>
<td>25</td>
<td>117 (15.3%)</td>
</tr>
<tr>
<td>26</td>
<td>160 (20.9%)</td>
</tr>
<tr>
<td>27</td>
<td>193 (25.2%)</td>
</tr>
<tr>
<td>28</td>
<td>188 (24.6%)</td>
</tr>
<tr>
<td>Birth weight, mean (SD), g</td>
<td>916 (232)</td>
</tr>
<tr>
<td>&lt; 10th %tile for GA, n (%)</td>
<td>40 (5.2%)</td>
</tr>
<tr>
<td>Antenatal Corticosteroids</td>
<td>85.6%</td>
</tr>
<tr>
<td>Surfactant in DR</td>
<td>60.4%</td>
</tr>
</tbody>
</table>

Clinical Predictors, BPD and 1 Year outcomes

- Severe BPD
  - 210 of 765 (27.5%) had severe BPD
  - 34 infants were on 100% oxygen with flow > 0.1 LPM
  - 9 infants were on PPV or CPAP on 21% oxygen
- Death
  - >2 wks attributable to respiratory failure/BPD
  - 25 of 35 deaths at 2 wks to 36 wks
  - 2 of 3 deaths between 30 and 40 wks
- Perinatal indicators or BPD were equivalent as predictors of 1 Year outcomes
  - 36 week lung function and oxygenation measurements were poor predictors of 1 Year outcomes

Nasal Cannula Flow and Oxygen Use at 36 weeks for PROP Cohort

<table>
<thead>
<tr>
<th>Nasal Cannula Flow in l/m</th>
<th>0.1</th>
<th>0.1-1.0</th>
<th>1.1-1.99</th>
<th>2.0-5.99</th>
<th>&gt;6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>96</td>
<td>22</td>
<td>31</td>
<td>31</td>
<td>3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>FiO2</th>
<th>0.21</th>
<th>0.234</th>
<th>0.35</th>
<th>1.2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>58</td>
<td>26</td>
<td>38</td>
<td>74</td>
</tr>
</tbody>
</table>

Poindexter, Annals ATS, 2015
BPD: Why are we failing to move the Big Dot?
Alan H. Jobe MD, PhD

Follow-Up of Preterm Infants With and Without BPD

- Variable results suggesting airway disease, increased "asthma", decreased exercise tolerance.
- Interpretation is a "perspective problem"
  - What is "normal enough"?
  - What is trajectory of abnormalities?
- The lung continues to grow and remodel?
- Worst cases of BPD vs. the general population of infants with BPD.

Prediction of BPD based on cumulative supplemental oxygen (CSO) (511 infants ventilated at 7-14 d of age, ≤28 weeks)

- CSO use was a better predictor of BPD at 14d than 1, 3, 7d
- CSO at 14d was as good a predictor of BPD as at 28d

This approximation of area under the curve may be useful for identifying infants for intervention.

Wai et al J Peds 2016

Associations of 6 Traditional Bronchopulmonary Dysplasia (BPD) Definitions With Adverse Outcomes at 18 to 21 Months of Age

Serious respiratory morbidity

Serious neurosensory impairment

Association of Oxygen Use or Respiratory Support at 34 to 40 Weeks' Postmenstrual Age With Adverse Outcomes at 18 to 21 Months of Age

Serious respiratory morbidity

Serious neurosensory impairment

New Definitions of BPD

- International Neonatal Consortium – INC
- NICHD Workshop
- PROP Cohort – Judy Aschner
- Others

Variables that Contribute to a BPD Diagnosis

Clinical variables that contribute to BPD:
- Antenatal variables – IUGR, Intrauterine growth restriction
- Birth weight / gestational age / sex
- Early respiratory status
- Support modes – oxygen, positive pressure, drags
- Time course of support modes

Research variables that contribute to BPD:
- Genetic contributions
- Biomarkers
- Definitions of clinical / molecular phenotypes

Elements in definition:
- Time of assessment – 2M, 6M, 60m, at follow up
- Severity of BPD:
  - At a single time
  - Staging system
  - Continuous / Area under the curve
- Respiratory deaths prior to 26-41 weeks
BPD: Why are we failing to move the Big Dot?

Alan H. Jobe MD, PhD

Variables that Contribute to a BPD Diagnosis

- Clinicians – management of patients / outcomes
- Epidemiologists – disease incidence
- Researchers of BPD – pathophysiology
- Drug developers – consistent definitions that predict outcomes
- Parents – survival and long-term outcomes

Predictability for outcomes:
- Respiratory
- Neurodevelopmental
- Growth
- Others: 1+ to school age and older

Conclusion: No BPD definition will meet all needs

- Define a population of interest
- Define the endpoints of interest
- Define a 36 or 40 week outcome – Primary outcome
- Define a 1 year respiratory outcome – Secondary outcome

The Big Dot based on epidemiology is based almost exclusively on BPD = oxygen use at 36 weeks, with adjudication for discharge before 36 weeks.

- Is this a relevant definition?

Pathophysiology of BPD – Will that help us better understand the Big Dot?

- Associations with BPD
- Animal models

The Big Picture – Developmental Exposures that Degrade Lung Function in Later life

Preconceptional Exposures → Fetal Exposures → Early Childhood Exposures → Outcome

Compounding Effects: Pre-conceptional + Fetal + Early Childhood – Single Exposure – Different Exposures

Pathophysiology of BPD

- Based on infants who have died – autopsy
- Animal models of BPD
- A circular argument – infant anatomy mimics animal models and vice versa
- But – minimal anatomy for infants that survive
- Pathology probably much more variable than we appreciate
BPD: Why are we failing to move the Big Dot?

Alan H. Jobe MD, PhD

**BPD is a Collision of 3 Programs**

- Genetics
- Developmental Programming – epigenetics
- Stem cell populations
- Preconditioning to modulate response to a stimulus
- Systemic immune modulation
- Postnatal drug effects
- Nutrition
- Microbiology at Birth

**Prediction of BPD by Postnatal Age**

- Postnatal risk factors
  - Gestational age
  - Birth weight
  - Sex
  - Race and ethnicity
  - Respiratory support
    - \( \text{FiO}_2 \)
  - at 6 ages after birth

*Prediction improved with postnatal age
Web based model: [https://neonatal.ni.org](https://neonatal.ni.org)

Laughon, et al., AJRCCM, 2011

Two “Inducers” of Early Lung Maturation of Clinical Relevance to BPD:

- Antenatal maternal corticosteroids
  - 80-90% of VLBW infants exposed
- Antenatal infection/chorioamnionitis
  - 50-70% of VLBW infants exposed
- Both induce lung maturation, but cause alveolar simplification in animal models

**Meta-analysis of Antenatal Corticosteroids**

[21 Studies including 4269 infants]

Increased risk of BPD

Jobe, et al., AJRCCM, 2000

**Effect of Interval from 20 mg IA Endotoxin to Delivery**

Cohn, et al, JAMA, 2011

**Lung Volume**
- 45 mL (mL/kg)

**Interval to Preterm Delivery**
- 0-12 days

Jobe, et al, AJRCCM, 2000
BPD: Why are we failing to move the Big Dot?

Alan H. Jobe MD, PhD

Effect of IA Endotoxin and Maternal Betamethasone on Lung Structure

<table>
<thead>
<tr>
<th>Control</th>
<th>Betamethasone</th>
<th>Endotoxin</th>
</tr>
</thead>
</table>

Risk of BPD or Death Relative to Gestational Age Adjusted Birth Weight Percentiles for 4025 Infants Born at 24-31 Weeks Gestation

Antenatal Inflammation and Developmental Disruptors

- SGA
- Antenatal Steroids
- Chorioamnionitis
- Tobacco

The characteristics of postnatal lung injury are modulated by antenatal exposures.

The characteristics of postnatal lung injury are modulated by antenatal exposures.

Animal Models of BPD

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Weakness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Term rats and mice</td>
<td>O2 or bleomycin causes inflammation, septation inhibition, and vascular injury or pulmonary hypertension can test mechanistic pathways inexpensive and available</td>
</tr>
<tr>
<td>Preterm sheep</td>
<td>Can ventilate and expose to oxygen – mimic clinical care can use fetal exposures</td>
</tr>
<tr>
<td>Preterm monkeys/baboons</td>
<td>Can ventilate and expose to oxygen – mimic clinical care</td>
</tr>
</tbody>
</table>

Drug Therapies that Reverse Most of the Abnormalities of BPD in Animal Models

<table>
<thead>
<tr>
<th>Agent/Intervention</th>
<th>Clinical Testing/Effectiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-inflammatory</td>
<td></td>
</tr>
<tr>
<td>Glucocorticoids</td>
<td>Decrease BPD</td>
</tr>
<tr>
<td>Granulocyte inhibitors – CINC-1, Anti-CD-18, IL-1ra</td>
<td>NT</td>
</tr>
<tr>
<td>Block Macrophages</td>
<td>NT</td>
</tr>
</tbody>
</table>

*NT = Not Tested in Humans
BPD: Why are we failing to move the Big Dot?
Alan H. Jobe MD, PhD

Drug Therapies that Reverse Most of the Abnormalities of BPD in Animal Models

<table>
<thead>
<tr>
<th>Agent/Intervention</th>
<th>Clinical Testing/Effectiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antioxidants -</td>
<td></td>
</tr>
<tr>
<td>Vitamin A</td>
<td>Modest decrease in BPD</td>
</tr>
<tr>
<td>N-acetyl Cysteine</td>
<td>No benefit</td>
</tr>
<tr>
<td>Small MW antioxidants - baboons</td>
<td>NT</td>
</tr>
<tr>
<td>Peroxynitrite decomp. catalytes</td>
<td>Possible Benefit</td>
</tr>
<tr>
<td>Superoxide Dismutase</td>
<td>No benefit</td>
</tr>
<tr>
<td>Inhaled NO- rodents, sheep, baboons</td>
<td>No benefit</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Drug Therapies that Reverse Most of the Abnormalities of BPD in Animal Models</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Agent/Intervention</th>
<th>Clinical Testing/Effectiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Growth factors – VEGF, KGF</td>
<td>NT</td>
</tr>
<tr>
<td>Hepatocyte growth factor, anti-bombesin</td>
<td>No effect – not directly tested</td>
</tr>
<tr>
<td>Cox-2 inhibitors</td>
<td>NT</td>
</tr>
<tr>
<td>Anti-TNF-        antibodies</td>
<td>NT</td>
</tr>
<tr>
<td>Elafin – elastase inhibitors</td>
<td>NT</td>
</tr>
<tr>
<td>β-catenin inhibitor</td>
<td>Possibly effective</td>
</tr>
</tbody>
</table>

Thoughts About Targeted Treatments for BPD Based on Animal Models

- Multiple pathways can be manipulated in animal models to decrease the BPD phenotype:
  - Block inflammatory cell recruitment to lung/inflammation
  - Antioxidants, iNO, Growth factors, Others
  - Positive clinical results: Vit A and corticosteroids
  - Targeting specific pathways may be ineffective (complex pathophysiology)
  - Corticosteroid effects are proof of principal that inhibition of inflammations can decrease BPD.

Oxygen is harmful, but injury is decreased in:
- Newborns relative to adults
- Animals exposed to inflammation
- Animals pre-exposed to oxygen
- Corticosteroid treatment

Injury is increased by:
- Calorie deprivation
Sensitivity to oxygen is probably quite variable in preterm infants

[All associations in animal models]

Tolerance/Pre-exposure to Decrease Injury
Prior Low Exposure to an Insult Attenuates Injury to a Higher Exposure to the Same or Another Insult

<table>
<thead>
<tr>
<th>Preconditioning Low-Grade Insult</th>
<th>Time Interval</th>
<th>Large Insult</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypoxia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hyperoxia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LPS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Specific Cytokine</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Adapted from Mallard & Hagberg, Sem. Fetal & Neonatal Med., 2007

Lung Cytokine Responses to Intra-amniotic LPS in Preterm Sheep

Time after Intra-amniotic LPS Exposures

BPD: Why are we failing to move the Big Dot?

Alan H. Jobe MD, PhD

BPD is a complex disease caused primarily by oxygen and ventilation injury to a very preterm lung with antenatal and postnatal modulations.

- How successful have our interventions been?
- Why has the Big Dot not moved with effective therapies that have demonstrated mortality?

Some examples of therapies that should target the pathophysiology of BPD

<table>
<thead>
<tr>
<th>Abnormality</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antenatal</td>
<td>Prematurity ?</td>
</tr>
<tr>
<td>Inflammation/Corio ?</td>
<td></td>
</tr>
<tr>
<td>SGA/IUGR</td>
<td></td>
</tr>
<tr>
<td>Lung Immaturity</td>
<td>Antenatal Steroids</td>
</tr>
<tr>
<td>Resuscitation / Early support</td>
<td>Respiratory transition CPAP / Surfactant</td>
</tr>
<tr>
<td>RDS</td>
<td>Surfactant</td>
</tr>
<tr>
<td>Ventilation injury</td>
<td>Improved vent care / HFOV</td>
</tr>
<tr>
<td>Oxygen</td>
<td>Targeted use</td>
</tr>
</tbody>
</table>

Meta-Analysis of 13 Trials of Natural Surfactants to Treat RDS

Risk Ratio (95% CI)
- Death
- Pneumothorax
- INH
- BPD
- PDA
- Patentary ductus
- MEH
- No Benefit

Seger & Soll, Cochrane Data Base, 2009
BPD: Why are we failing to move the Big Dot?
Alan H. Jobe MD, PhD

Meta-analysis of 4 Trials Including 2,700 Infants Randomized to CPAP or Intubation and Surfactant Treatments at Birth

Schmolzer, et al., BMJ, 2013

BPD
Death
Death or BPD
Severe IVH
Surfactant Treatment
Any Mechanical Ventilation

Favors CPAP
Favors Intubation/Surfactant

Schunker, et al., MMJ, 2013

HFOV is not Superior to CV for Prevention of BPD – Meta-analysis of Individual Patient Data

Cools, et al., The Lancet, 375:2082, 2010

Interim Meta-Analyses for Major Outcomes Including 4,911 Randomized Infants

<table>
<thead>
<tr>
<th>Outcome</th>
<th>85-89% Sat</th>
<th>91-95% Sat</th>
<th>Risk Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BPD-Physiologic</td>
<td>34.6%</td>
<td>39.7%</td>
<td>0.85 (0.85-1.04)</td>
</tr>
<tr>
<td>Severe ROP</td>
<td>10.7%</td>
<td>14.5%</td>
<td>0.74 (0.59-0.92)</td>
</tr>
<tr>
<td>NEC</td>
<td>11.2%</td>
<td>9.0%</td>
<td>1.25 (1.05-1.49)</td>
</tr>
<tr>
<td>IVH - GR22</td>
<td>14.2%</td>
<td>14.1%</td>
<td>1.02 (0.88-1.19)</td>
</tr>
<tr>
<td>Death</td>
<td>19.3%</td>
<td>16.2%</td>
<td>1.18 (1.04-1.34)</td>
</tr>
</tbody>
</table>

Saugstad & Aune, Neonatol, 2014

Antenatal and Postnatal Intervention to Decrease BPD

<table>
<thead>
<tr>
<th>Intervention</th>
<th>BPD</th>
<th>Death</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antenatal Steroids</td>
<td>-↑</td>
<td>↓</td>
</tr>
<tr>
<td>DR CPAP</td>
<td>+/−</td>
<td>−</td>
</tr>
<tr>
<td>Surfactant</td>
<td>−</td>
<td>↓</td>
</tr>
<tr>
<td>Vent modes</td>
<td>+/−</td>
<td>−</td>
</tr>
<tr>
<td>Oxygen-high target</td>
<td>−</td>
<td>+/−</td>
</tr>
</tbody>
</table>

What Currently Available Treatments Work and can be Improved?

• Treatment for infants progressing to BPD are mostly unvalidated.
• Long-term use of drugs are untested
• Striking variabilities of use across units.

Major Drugs Used for VLBW Infants

• Antibiotics
• Diuretics
• Bronchodilators
• Oxygen
• Postnatal steroids
BPD: Why are we failing to move the Big Dot?
Alan H. Jobe MD, PhD

Variation in use of Diuretics for BPD by Hospital

Bronchodilator use in the NICU

Distribution of Sats for COT Trial

Survival of SGA vs. AGA Infants – Support Trial

Infants Targeted to Low Sats had More Hypoxic Events at Older Ages

Can we Decrease BPD by More Careful use of Oxygen?

- Very difficult to keep sick infants “in range”.
- “In range” may vary for different infants at different ages after birth
- Auto control systems – achieve somewhat better targeting with less nursing time.
- But – our VLBW infants on RA often have sats >95% and lowest risk of BPD.

Exposure to low sats has programmed physiological responses.
BPD: Why are we failing to move the Big Dot?
Alan H. Jobe MD, PhD

Postnatal Steroids for BPD Prevention and Treatment

- Multiple trials since 1970's
- Toxicity concerns
- AAP and CPA condemnation of use – 2002
- Four new trials of PNS – all showing benefit

DART Trial – Low Dose Dex for Extubation
- 0.15 mg/kg x 3d and Taper for 7d
- Median age = 23d

Meta-regression Analysis of Trials of 20 Trials of Postnatal Steroids for BPD

Summary of Recent Early Steroid Trials:

<table>
<thead>
<tr>
<th>Steroid Exposure</th>
<th>Inhaled Steroid Bassler - 2015</th>
<th>10-day Hydrocortisone Booth - 2011</th>
<th>Steroid + Surfact Yeh - 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steroid Exposure</td>
<td>Relatively targeted to lung, but higher dose</td>
<td>Very low dose, but systemic</td>
<td>Targeted to lung</td>
</tr>
<tr>
<td>Duration of Treatment</td>
<td>Off support or 32 weeks</td>
<td>10 days</td>
<td>Surfactant Treatments</td>
</tr>
<tr>
<td>Death</td>
<td>Increased 3.3%</td>
<td>Decreased 5%</td>
<td>Decreased 3%</td>
</tr>
<tr>
<td>BPD</td>
<td>Decreased 10.2%</td>
<td>Decreased 4%</td>
<td>Decreased 21%</td>
</tr>
</tbody>
</table>

These results are a convincing proof of principle that early steroid treatments are effective.

Which treatment strategy do you prefer?

A Concern – Repeated Exposures of ELBW Infants to Steroids.

- > 80% of ELBW infants exposed to 1 or more ANS treatments.
- Early use of steroids for hypotension.
- Steroid use to treat BPD (Dart or Hydrocortisone).
- More steroids for extubation.
- Post discharge steroid for wheezing.
BPD: Why are we failing to move the Big Dot?
Alan H. Jobe MD, PhD

What New Prevention or Treatments are in the Future?

<table>
<thead>
<tr>
<th>Time Period</th>
<th>Abnormality</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antenatal</td>
<td>Lung immaturity</td>
<td>Tests of global fetal maturation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>New dosing strategies for AVS</td>
</tr>
<tr>
<td></td>
<td>Fetal inflammation</td>
<td>Blockers of FRS</td>
</tr>
<tr>
<td>Early Postnatal</td>
<td>DR resuscitation</td>
<td>Cord management</td>
</tr>
<tr>
<td>Respiratory failure</td>
<td>Progression toward BPD</td>
<td>Respiratory management</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Stem cells</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Postnatal steroids</td>
</tr>
<tr>
<td></td>
<td></td>
<td>New anti-inflammatories</td>
</tr>
</tbody>
</table>

Follow-Up of Preterm Infants With and Without BPD

- Variable results suggesting airway disease, increased “asthma”, decreased exercise tolerance.
- Interpretation is a “perspective problem”
  - What is “normal enough”?
  - What is trajectory of abnormalities?
- The lung continues to grow and remodel
- Worst cases of BPD vs. the general population of infants with BPD.

Lung Function at 11 Years for Children Born at <26 Weeks GA in UK - 1995

Alveolarization in Children at 10-14 Years Using 3HNMR

Infant Lung Function Tracks to Adulthood
Can we move the Big Dot with QI?

- Attractive QI target because
  - Frequency of BPD is high
  - Multiple potential “best practices”

**QI for BPD Examples of “futility”?**

<table>
<thead>
<tr>
<th>Author</th>
<th>Years</th>
<th>Study Description</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walsh</td>
<td>2006</td>
<td>Multicenter NICHD – Cluster randomized trial to decrease BPD – using best practices.</td>
<td>Increased best practices – No change in BPD.</td>
</tr>
<tr>
<td>Payne</td>
<td>2010</td>
<td>Multicenter VO.QIC – improve respiratory care practices to decrease BPD</td>
<td>Care practices improved, survival increased, but BPD increased.</td>
</tr>
<tr>
<td>Vendettuoli</td>
<td>2014</td>
<td>Multicenter Italian NN – Decrease mechanical ventilation to decrease BPD</td>
<td>Decreased mechanical ventilation and death but no change in BPD.</td>
</tr>
<tr>
<td>Mola</td>
<td>2015</td>
<td>VO.QIC Respiratory care bundle to decrease BPD</td>
<td>Less invasive ventilation and less O2 but no change in BPD.</td>
</tr>
</tbody>
</table>

Rates of death and BPD in Vermont – Oxford Network for infants 501 to 1500g

Hsiaoar et al, JAMA Peds - 2017

Why are we failing to move the Big Dot?

- We are not failing – BPD is the collateral damage from care of smaller and sicker infants.
- But there are large unexplained differences in BPD rates between NUCUs.

References

Safe Sleep in the Newborn Nursery, NICU and Beyond!

Rachel Y. Moon  MD
Division Head
General Pediatrics
Professor of Pediatrics
University of Virginia School of Medicine

Rachel Moon is the Division Head of General Pediatrics and SIDS researcher at the University of Virginia. She received her medical degree from Emory University and completed her pediatric residency at the Children's Hospital of Philadelphia. She is Division Head of General Pediatrics and Professor of Pediatrics at the University Of Virginia School Of Medicine. Her research centers on SIDS and SIDS risk factors, particularly in high risk populations, such as African-Americans and infants attending child care. She is Chair of the American Academy of Pediatrics' Task Force on SIDS and associate editor for the journal Pediatrics.

Annual Quality Congress Breakout Session, Saturday, October 28 and Sunday, October 29, 2017
Safe Sleep in the Newborn Nursery, NICU and Beyond!

Objective: Participate in a workshop linking evidence and action to improve the care of infants and families.
Safe Sleep – in the Newborn Nursery, the NICU, and Beyond!
Rachel Y. Moon MD

Disclosure
• I have no relevant financial relationships with the manufacturers of any commercial products and/or providers of commercial services discussed in this CME activity.
• I do not intend to discuss an unapproved/investigative use of a commercial product/device in my presentation.

Workshop Objective
• Participate in a workshop linking evidence and action to improve the care of infants and families.

Overview
• Definition of SIDS and Sleep-Related Deaths
• Statistics
• Scenarios – how would you respond?

Definitions
• SUID = Sudden and unexpected infant death
  – Aka Sudden and unexpected death in infancy (SUDI)

SUID
EXPLAINED
Trauma
Drowning
Known Diagnosis
Accidental Suffocation

UNEXPLAINED
Known Diagnosis
Accidental Suffocation

SID
Unexplained
Undetermined
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Rachel Y. Moon MD

Sleep-Related Deaths
- Most SUIDs occur during sleep or in sleep environment
  - Sleep-related deaths
    - SIDS
    - Suffocation, strangulation, entrapment
    - Undetermined/ill-defined/unknown

SIDS
- Any SUID (i.e. sudden and unexpected death) that remains unexplained after:
  - A complete review of the history
  - An autopsy
  - A death scene investigation
- Typically, a seemingly healthy infant is found dead after a sleep period
  - A diagnosis of exclusion
  - SIDS is not predictable

Suffocation
- Asphyxia = any situation in which there is a decrease in oxygen (O₂) and an increase in carbon dioxide (CO₂) in the body.
  - If you stop breathing
  - If your mouth, nose, or airway becomes obstructed.
  - If you “rebreath” (imagine an infant face down in soft bedding).
- Suffocation = form of asphyxia
- Entrapment = infant is “trapped” in a situation that produces asphyxia.
- Strangulation = bed clothes or other material is wrapped around the neck, blocking the airway, causing asphyxia.

It does not take a lot of pressure to completely obstruct an infant’s airway

SIDS and Asphyxia
- Asphyxia has always been part of SIDS
- Many risk factors are associated with potentially asphyxiating environments
  - Prone sleeping
  - Soft bedding, pillows, bumper pads, etc.
  - Bedsharing
- Some asphyxial situations would cause death in any baby
  - In some, not all babies die
- Why do these babies die?

Triple Risk Model
- Brainstem dysfunction, Arousal defect, Gene polymorphisms
- Prone sleep position, smoke exposure, soft bedding
- Highest risk at 2-4 months
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Behavioral, Sociocultural, and Environmental Factors

Genetic Factors

Phenotype

SIDS

SIDS

Our current hypothesis is that SIDS results when a vulnerable infant cannot adequately defend against an asphyxiating environment — a level of asphyxia where most infants would not die.

Kinney et al have found abnormalities in autonomic control in the brainstem
- Decreased neurotransmitter (serotonin, acetylcholine, glutamate, GABAA) binding
- Network dysfunction
- Infants may not be able to sense and respond to hypercarbia or hypoxia

Weese-Mayer and others have found polymorphisms in serotonin transporter protein gene

Up to 70% of SIDS have neurotransmitter abnormalities
These abnormalities are not present in infants dying of other causes, including chronic hypoxia

Brain Dysfunction

Infant vulnerability and positional asphyxia

A safe sleep environment can reduce the incidence of both SIDS and Accidental Suffocation

Shading indicates the probability of death. Darker shaded = increased probability of death

SIDS? SIDS? Undetermined? Cause of death?

Increasing rates of other sleep-related deaths
- Accidental suffocation
- Entrapment
- Undetermined
- Most (80–90%) of these occur in unsafe sleep environments
  - Bedding
  - Bed sharing with others

SIDS Rate and Infant Sleep Position, 1988-2010
(Deaths per 100,000 live births)

However...

Chronic hypoxia

Brainstem dysfunction

Maternal smoking and alcohol

Prematurity

Severe vulnerability

Critical period of development

Non-asphyxiating

Sleep environment

Strangulation

Entrapment

Overlaying

CLEAR EVIDENCE FOR ACCIDENTAL SUFICATION


The position of the threshold between a diagnosis of SIDS or Accidental Suffocation is determined by the medical examiner based on history and death scene investigation.

Shading indicates the probability of death. Darker shaded = increased probability of death.

Interactions can occur anywhere along the continuum.

COMBINATIONS OF SIDS RISK FACTORS

- Prone sleep, soft bedding, over-bundling, head covered, bed sharing
- Chronic hypoxia
- Strangulation
- Entrapment
- Overlaying

A safe sleep environment can reduce the incidence of both SIDS and Accidental Suffocation.

Increasing rates of other sleep-related deaths
- Accidental suffocation
- Entrapment
- Undetermined
- Most (80–90%) of these occur in unsafe sleep environments
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  - Bed sharing with others

SIDS Rate and Infant Sleep Position, 1988-2010
(Deaths per 100,000 live births)
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Rates of SIDS and SUID

Why is SUID increasing?
- Diagnostic shift
  - Improved death scene investigation
  - Deaths previously called SIDS now called something else
- Increases in prone sleeping
- Increases in soft bedding use
- Increases in bed sharing (particularly with multiple people, bedding, etc.)

The New York Times
A Quiet Revolt Against the Rules on SIDS

By BRIAN BRAIKER
Published: October 18, 2005

In homes across the country, parents like Mrs. Stanciu are mounting a minor mutiny against the medical establishment. For more than a decade, doctors have advocated putting babies to bed on their backs as a precaution against sudden infant death syndrome, or SIDS. Increasingly, however, some new parents are finding that the benefits of having babies sleep soundly - more likely when they sleep on their stomachs - outweigh the comparatively tiny risk of SIDS.

The New York Times
Shhh...My Child Is Sleeping (in My Bed, Um, With Me)

By TARA PARKER-PPOSE
Published: October 23, 2007

"Ask parents if they sleep with their kids, and most will say no. But there is evidence that the prevalence of bed sharing is far greater than reported. Many parents are "closet co-sleepers," fearful of disapproval if anyone finds out, notes James J. McKenna, professor of anthropology and director of the Mother-Baby Behavioral Sleep Laboratory at the University of Notre Dame."

The New York Times
SLEEP RELATED INFANT DEATH ON THE RISE IN ILLINOIS

November 10, 2016

"DCFS said Illinois lost 145 infants to sleep-related death from 2009 to 2014, the most current reporting year. Herm-Pavelski said a majority of those deaths was a result of babies sharing the same sleep surface as parents. The Illinois Child Death Review Team recorded an annual average of 55 infant suffocation deaths from 2006 to 2014."

ASSB rates per 100000 live births, U.S., 1984-2014

Between 1984 and 2014, rates have increased sevenfold!
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Co-Sleeping, Cluttered Crib
Blamed for Sharp Rise in Infant Deaths
May 8, 2013

"Since 2009, 278 healthy babies in Los Angeles County have died from suffocation while sleeping, according to Deanne Tilton Durfee, executive director of the Inter-Agency Council on Child Abuse and Neglect.

In fact, more babies died from suffocation due to unsafe sleep than all accidental deaths for children under age 14 combined between 2008 and 2011."

Co-sleeping Deaths Persist in Milwaukee
Dec 4, 2013

"Police in Milwaukee are investigating yet another possible co-sleeping death, possibly the city’s 16th this year."

Wayne County, Detroit have particularly high numbers of sleep-related infant deaths
Sept 18, 2015

"Between 2010 and 2012, there were 121 sleep-related deaths in Wayne County...about 72% of the deaths involved an infant sleeping on the same surface as another person at time of death, 50% involved unsafe sleep locations, and two-thirds of infants were found in a position other than on their backs..."

Why are you telling me this?

- Parental report (Smith, 2010):
  - 54% receive no advice about infant sleep location/bedsharing
  - 73% receive no advice about pacifier use
  - 28% receive no advice about safe sleep position
  - More likely to use safe sleep practices if counselled by physician
- More than 90% of parents follow sleep recommendations from MD/RN
- 93% of parents who see infant placed prone by hospital personnel use prone (Brenner, 1998)

What’s the problem?

- Everybody thinks that his/her baby is the exception to the rule
  - Gastroesophageal reflux
  - Premature
  - “Bad” sleeper
- OR the rules don’t apply to their particular situation
  - “This only happens to other people”
  - “I pay close attention to my baby”
- Parents frequently think that experts do not understand their unique circumstances and their baby’s unique needs
- And so it’s okay to dismiss risk messaging

Risk of SIDS & SUID for the Ex-Premie

Source: CDC, NCHS
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**SIDIS Risk Increases as Gestational age Decreases**

*Source: CDC, NCHS*

**It takes a conversation…**

**It also takes…information**

- You need to know
  - Parents’ motivation; what do they perceive as barriers?
  - What are potential solutions?
- Remember that not all solutions will be what you would choose
  - Risk-benefit
  - Risk reduction

**Parents often believe that…**

- If they don’t do anything, it will fix itself
  - 5 year old who is still in your bed
  - 6 year old who still uses a pacifier
- You need to make active choices, or the choice will be made for you
- Think about what you want your life to be in 6 months, and start making those changes now

**Scenario #1**

- You work in a Baby-Friendly hospital, and the NICU has been working on increasing skin-to-skin time for babies who are stable. You go in to check on Baby Alex, and he is asleep, skin-to-skin with his mother Jennifer, who has fallen asleep on a recliner.
- What do you do?

**Skin-to-Skin**

- Skin-to-skin care is recommended for all mothers and newborns, regardless of feeding or delivery method, immediately following birth
  - Mom should be medically stable, awake, and able to respond to baby
  - When mother needs to sleep or take care of other needs, infants should be placed supine in a bassinet.
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Rachel Y. Moon MD

**However, you have to remember that…**

- If one falls asleep while skin-to-skin, it becomes bedsharing
- Why do we worry about bedsharing?
  - Overheating
  - Soft bedding
  - No safety standards for adult mattresses
  - Risk of entrapment, accidental suffocation and strangulation

**Factors increasing risk of SIDS with bedsharing**

- One or both parents are smokers (OR 2.3-17.7)
- When infant is <2-3 months old, regardless of parental smoking status (OR 4.7-10.4)
- Premature and low-birth weight infants (OR 5.1-8.0)
- Soft surfaces (couches, sofas, waterbeds) (OR 5.1-66.9)
- Soft bedding accessories (OR 2.8-4.1)
- Multiple bed sharers (OR 5.4)
- Bed sharing with people other than parents, incl. other children (OR 5.4)
- Parent consumed alcohol, drugs, or is overtired (OR 1.66)

**Factors increasing risk of SIDS with bedsharing**

- Returning the infant to his/her own crib is not associated with increased risk
- No studies have ever shown a protective effect of bed sharing on SIDS

**Breastfeeding, bedsharing, & SIDS**

- Breastfeeding is common reason for bedsharing (Hauck 2008)
- Bedsharing associated with longer duration of breastfeeding
  - Causal?
- Bedsharing is not essential for successful breastfeeding (Hauck 2009)
- Benefits of breastfeeding do not outweigh increased risk associated with bedsharing (Ruys 2007)
- NJ study: 25% of bedsharing deaths were breastfed infants (Ostfeld 2006)

**Roomsharing without bedsharing decreases SIDS risk by 50%**

- Safety-approved crib, bassinet, or cradle
- Placing crib next to parents’ bed will allow for more convenient breastfeeding and contact.
- Can bring baby to bed for nursing or comforting, but return to own crib when parent ready to go to sleep

**Parents often do not extrapolate the risk to a different situation**

- Many parents are aware of and follow safety rules for cribs
  - Firm surface
  - No pillows, blankets, or other bedding
- These same parents often ignore same rules when
  - Bringing baby into their bed
  - Falling asleep with them on chair or couch
Example: Parent who falls asleep with baby while feeding

- Acknowledge that this happens
- Discuss with the parent how to prepare for this proactively!
- It is safer to feed baby in adult bed than on a sofa or armchair

Breastfeeding in armchair

- Mom is breastfeeding with twins supine on recliner arms. She does this every night. She breastfeeds and wants to be ready whenever the babies awaken.
- Twins are 2 months old.
- Since Mom has done this every night, she thinks that it’s safe.

Entrapment in chair

- One twin was found dead when the mother awakened.
- The other twin remains alive.
- There were 2 cribs in the home. They had never been used.

Acknowledge that

- Use a firm, flat mattress without mattress topper or memory foam.
  - No waterbeds, air mattresses, couches, or armchairs
- No pillows, sheets, blankets, comforters and other soft bedding that could obstruct infant breathing or cause overheating
- It is safer to feed on an adult bed than an armchair or sofa if you might fall asleep
- Follow other safe sleep recommendations
  - Place the infant on the back for sleep

Be proactive!

Scenario #2

- You graduated several months ago from nursing school (where you learned all about safe sleep!) and have obtained your dream job at a local NICU. You are taking report from one of your colleagues about Emma, a 6 week old ex 26-week premie. The baby has no oxygen requirement, is transitioning to full oral feeds (occasionally needs to be gavage fed if she doesn’t take all of her calorie requirements), and is doing great. Your colleague reports that, during rounds, the attending mentioned that Emma should be transitioned to supine position for sleep.
  - You place Emma on the side (that’s halfway to the back) and continue with patient care. Her parents come in and say, “We thought that we were going to put Emma on the back now.” You tell them that being on the side is a transition position (safer than stomach), but that it doesn’t matter anyway, since she is still on a monitor.
  - Is this a reasonable approach? What are the pros/cons of this approach?
**Safe Sleep – in the Newborn Nursery, the NICU, and Beyond!**

Rachel Y. Moon MD

**Sleep Position: Side vs. Supine?**

- 1992: AAP recommended side or back to reduce the risk of SIDS
- 2000: Back preferred, but side better than prone
- Many people (including physicians and nurses) continue to use the side position

**Side vs. Supine**

- Risk of side position
  - Multiple studies have demonstrated that side position places infant at higher risk for SIDS than the back position
  - Recent studies show that risk with side (aOR 2.0) and prone (aOR 2.6) are similar (Li, 2003; Hauck, 2002)
  - Side position is unstable-unaccustomed prone

**Risk of Unaccustomed Prone**

- Recent studies show that risk with side (aOR 2.0) and prone (aOR 2.6) are similar (Li, 2003; Hauck, 2002)

**Recommendations**

- Infants should be placed for sleep in a supine position for every sleep.
- Avoid use of commercial devices marketed to reduce the risk of SIDS (wedges, etc.).
  - 2010 FDA/CPSC warning re: infant positioners

**Positioners**

- Infants should be placed for sleep in a supine position for every sleep.
- Avoid use of commercial devices marketed to reduce the risk of SIDS (wedges, etc.).
  - 2010 FDA/CPSC warning re: infant positioners
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Feeding tubes
- Nasogastric, orogastric, and gastrostomy tubes
  - no evidence that infants are at increased risk of aspiration if placed supine
- Nissen fundoplication
  - eliminates (or greatly reduces) risk for GE reflux
- Doesn’t matter if the feeds are bolus or continuous feeds

But the baby sleeps better…
- Prone babies have higher arousal thresholds, sleep longer and deeper

But is it really BETTER?
- This increased arousal threshold may be dangerous, as arousal may be the issue surrounding SIDS...
- Need to change definition of a “good” sleeper

Positioning in NICUs
- Increased risk of SIDS among premature and LBW infants.
- Premature infants more likely to be placed prone after hospital discharge. Possible explanations:
  - Frequently placed prone in NICU
  - Babies and caretakers used to prone

Positioning in Newborn Nurseries
- Infants in newborn nurseries often placed on side
  - Impression that they have to clear amniotic fluid from airways, less likely to aspirate
  - No evidence that fluid will be cleared more easily in side position
- Parents tend to copy practices that they observe in hospital, thus may be more likely to use side position at home

Recommendations
- Infants in NICUs should be placed supine for sleep as soon as they are stable
  - AAP Fetus and Newborn statement: by 32 weeks post-menstrual age
- Healthy term infants should be placed on their backs when they go into the bassinet
Scenario #3

- You are taking care of Elijah, who is a feeder and grower. It has been noted that he is spitting up after feeds.
- One of the medical students suggested that you place the baby prone and elevate the head of the bed to help with the spitting up.
- How do you respond?

Fear of choking/aspiration

- How do you know when a baby is choking?
  - Coughing or gagging (normal protective gag reflex) often misconstrued for choking or aspiration.
- Increased concern for aspiration with GE reflux
  - What percentage of babies reflux?

Aspiration/choking and sleep position

- No increased incidence of aspiration since the change to supine sleeping (Byard 2000, Malloy 2002, Tablizo 2007)

Sleep position and Reflux

- Supine does not increase the risk of choking and aspiration in infants, even those with GE reflux
  - Protective airway mechanisms
- Infants with GE reflux should be placed supine
  - RARE exception: infants for whom the risk of death from complications of GE reflux is greater than the risk of SIDS (i.e., those with upper airway disorders, for whom airway protective mechanisms are impaired).
  - Examples: infants with anatomic abnormalities (e.g., type 3 or 4 laryngeal clefts, who have not undergone antireflux surgery).
- Elevating the head of the infant’s crib while the infant is supine is not recommended.
  - Ineffective in reducing GE reflux
  - Infant may slide to the foot of the crib - may compromise respiration.

Reasons for soft bedding use

- Comfort – parent perceives baby is more comfortable
  - Baby sleeps better
  - Parent would be more comfortable
- Safety – soft surfaces cushion bumps
- Temperature – parent worries about baby being cold
- Aesthetics/tradition – looks nice; supposed to buy it; everybody does it

Scenario #4

- You are working on a QI project in your NICU to improve safe sleep practices. In your first audit, your team identifies soft bedding as an area for improvement. What are strategies that you might use to decrease NICU staff and parent use of soft bedding?
Safe Sleep – in the Newborn Nursery, the NICU, and Beyond!
Rachel Y. Moon MD

Reasons for soft bedding use in NICU

- Comfort – parent perceives baby is more comfortable
- Bonding – parent wants baby to have something from home
  - Shirts, blankets
  - Parent’s scent
- Temperature – nursing staff and parents worry about baby being cold
- Aesthetics – the bassinet looks so hard and sterile

Scenario #5

- Maya and Aliya are 4 week old ex-30 week premie twins. They have been weaned to a bassinet, and their parents would like to have them share a bassinet. “They were together for 8 months, and I think that they miss each other,” the father tells you.

- Is that a good idea? How would you respond?

Co-bedding of multiples

- Possible psychological and physiological benefits (anecdotal, observational studies)
  - More stable vital signs, temperature
  - Enhanced growth and development
  - Less apnea/bradycardia
  - Less agitation
  - Better sleep/wake synchronicity
  - Easier transition to home
  - Decreased length of hospital stay
  - Fewer rehospitalizations

Reasons for co-bedding multiples

- Multiples are often born prematurely and LBW – increased risk for SIDS (Malloy 1995, Sowter 1999)
- Increased potential for overheating and rebreathing
- Size discordance may increase risk of accidental suffocation (Tomashek 2007)
- Most co-bedded twins are on side (Hutchison 2010)
- Co-bedding of twins in hospital may encourage parents to continue this practice at home (Tomashek 2007)

Review of 8 studies (Tomashek 2007)

- Clinical outcomes (length of stay, infections)
  - 1 of 4 studies: co-bedded twins to have fewer blood infections (but compared data from DOL 7 to discharge; most co-bedding didn’t start until DOL 3-65).
- Weight gain
  - 2 of 5 studies: slightly increased weight gain (statistically significant but not clinically significant)
- Physiologic stress
  - 1 or 4 studies found difference in high activity heart rate but no other changes in stress cues, baseline heart rate, resp rate, O2 sat
- Apnea/bradycardia
  - 1 or 3 studies found fewer apneas <10 sec but no difference in apneas <15 sec. No differences in bradycardia
- Parental attitudes
  - 4 studies show mixed results.
  - Some had increased parental satisfaction; lower parental anxiety; others showed opposite

Disadvantages of co-bedding

- Multiples are often born prematurely and LBW – increased risk for SIDS (Malloy 1995, Sowter 1999)
- Increased potential for overheating and rebreathing
- Size discordance may increase risk of accidental suffocation (Tomashek 2007)
- Most co-bedded twins are on side (Hutchison 2010)
- Co-bedding of twins in hospital may encourage parents to continue this practice at home (Tomashek 2007)
Safe Sleep – in the Newborn Nursery, the NICU, and Beyond!
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Co-bedding of multiples
• No consistent evidence that it is helpful
• It may place infants at higher risk
• Prudent to not do it

Conclusion
• We’ve made a lot of progress in reducing sleep-related deaths
• NICU infants are still at increased risk
  – Baseline increased risk for SIDS
  – Increased risk of having unsafe sleep practices modeled in hospital
  – Increased risk of unsafe sleep practices at home
• We need to make sure that we:
  – Talk about safe sleep consistently
  – Model safe sleep practices consistently as soon as we can

Letter from NICU nurse
• "I wanted to thank-you for coming to xxx and sharing your knowledge with us yesterday. The conference feedback was very positive. The message of your SIDS prevention was powerful and I pray everyone teaches by the AAP. A very sad and ironic situation occurred last night - one of our premises died while co-bedding with his mother. It was his first night home. He was in our NICU for several months and was doing great. It is so sad. My guess is the heavy blankets or pillows were too much for him. He was a tiny little guy. Please keep delivering your message! We need to work together to save babies."

THANK YOU

References
Confirming or Ruling Out Sepsis in Hours - Not Days!

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Kaede Ota Sullivan is a board-certified pediatrician, infectious diseases specialist, and clinical microbiologist. She received her medical degree and pediatric residency training at McMaster University; and her ID fellowship, microbiology training, and a master’s degree in epidemiology and health care research at the Hospital for Sick Children and the University of Toronto. She is currently the Associate Director of Clinical Microbiology, Virology, and Immunology with the Temple University Health System and Associate Professor of Pathology and Laboratory Medicine at the Lewis Katz School of Medicine at Temple University. She is a member of the Society for Healthcare Epidemiology’s Guidelines Committee and a Healthcare Infection Control Practices Advisory Committee (HICPAC) working group member. Her research focuses on how laboratories can optimize their test procedures to support infection control and antimicrobial stewardship programs, particularly in neonatal populations.

Annual Quality Congress Breakout Session, Saturday, October 28, 2017
Confirming or Ruling Out Sepsis in Hours - Not Days!

Objective: Identify new diagnostic testing techniques that may be used to more rapidly confirm or rule out infection.
New Laboratory Tools to Confirm or Rule Out Sepsis in Hours Not Days!

Kaede Ota Sullivan MD

New Laboratory Tools to Confirm or Rule Out Sepsis in Hours Not Days!

Disclosures

I have received research funding and support from Nanosphere, Cepheid, Quidel, bioMérieux, and BD Diagnostic Systems.

Learning Objective:

Identify new diagnostic testing techniques that may be used to more rapidly confirm or rule out infection.

Three Parts

1) What’s out there: existing and emerging rapid laboratory tools for rapid diagnosis of sepsis in neonates.
2) How to “Go Live”: evidenced-based pointers for implementing rapid blood culture tests to maximize impact on stewardship outcomes.
3) Remembering the simple stuff: how to optimize blood volume and transport time to speed up the blood culture “alarm”.

The amount of published NICU data pertaining to rapid sepsis testing is like this...

But valuable strides have been made in adults...maybe we can learn from them.

Existing and emerging rapid laboratory tools for diagnosis of sepsis
New Laboratory Tools to Confirm or Rule Out Sepsis in Hours Not Days!

Kaede Ota Sullivan MD

The laboratory process

Blood draw
Incubation of blood
Blood culture is positive!
Gram stain
Subculture to agar plates and incubate
Identification (ID)
Antibiotic susceptibility Testing (AST)

48-72 hours to results

Expediting Organism ID in Sepsis

Blood draw
Incubation of blood
Blood culture is positive!
Gram stain
Subculture to agar plates and incubate
Rapid blood culture ID
AST

48-72 hours to results

Rapid Blood Culture Identification Methods

Nucleic acid-based testing
- PCR (Xpert, FilmArray)
- PNA FISH
- Microarray (Virigen)
- Automated biochemical panels (ex. Phoenix, Vitek)
- MRSA agar
- MALDI-TOF MS
- Phage amplification

“Standard methods” used off-label

Other methods

It started simple...

Xpert MRSA/SA BC
- Real-time PCR technology
- Used on positive blood cultures
- Detects spa gene (for S. aureus), mecA (methicillin resistance), and SCCmec (MRSA)
- Reports if MSSA or MRSA present
- Fully automated (easy!)
- 1 hour test (fast!)

Quick Primer on Polymerase Chain Reaction

Extract DNA from cells
Detect amplicons

PCR: A technology that produces lots of copies of a piece of a gene of interest so you can detect it.
www.thermofisher.com
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PNA FISH

- Fluorescent in situ hybridization using peptide nucleic acid probes
- Used on positive blood cultures
- Tests detect:
  - *S. aureus*/CoNS; *mecA*
  - *E. faecalis*/OE
  - Gram-negatives
  - *Candida* spp.
- Fastest version: 20 minutes

Very fast! But, PNA FISH is limited by lack of AST beyond *mecA*.

Then we got more elaborate: Verigene

- Microarray technology
- Used on positive blood cultures
- Test panels detect:
  - Gram-positive organisms (BC-GP)
  - Gram-negative organisms (BC-GN)
- Fully automated
- 2 hours

![Image of verigene machine with sample processing information]

![Image of bacterial DNA detection with signal amplification by silver enhancement of gold nanoparticles]

![Image of verigene test panel results with light-scattering array scanning]
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And then, really elaborate: FilmArray BCID
- Real-time PCR technology
- Used on positive blood cultures
- One test panel detects
  - Gram-positive organisms
  - Gram-negative organisms
  - Candida species
- Fully automated
- 1 hour

Biofiredx.com

FilmArray Meningitis/Encephalitis Panel

www.biomerieux.com

How is ME doing?
- Academic NICU in Michigan
- 62 infants (0-3 months of age) with suspected meningitis included
- 12 had bacteremia (9 GBS, 3 E. coli)


The four that were culture-negative, PCR-positive

<table>
<thead>
<tr>
<th>Clinical</th>
<th>PCR</th>
<th>CSF cell counts</th>
<th>Blood culture</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 week old/yes CNS microabscesses</td>
<td>GBS</td>
<td>Abnormal</td>
<td>Negative</td>
</tr>
<tr>
<td>5 week old/yes</td>
<td>GBS</td>
<td>Abnormal</td>
<td>GBS</td>
</tr>
<tr>
<td>1 day old/yes  E. coli</td>
<td>Abnormal</td>
<td>GBS</td>
<td></td>
</tr>
<tr>
<td>2 day old/yes  E. coli</td>
<td>Abnormal</td>
<td>E. coli</td>
<td></td>
</tr>
</tbody>
</table>

MALDI-TOF MS for positive blood cultures?


Yes! ID is fast (1-2 hours) but no AST.
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Many hospitals have liked the following aspects of the “panel”-based tests:
A. Full automation makes the FilmArray BCID and Verigene assays very easy to use.
B. The organism present in a positive blood culture is identified 24-48 hours earlier.
C. They help to speed up decision making about antibiotics.
D. All of the above.

Some hospitals have not liked the following aspects of the “panel”-based tests:
A. They are expensive (much more than standard lab procedures).
B. They can fail to identify an organism in mixed cultures.
C. They do not detect all organisms (just the ones they are designed to look for).
D. All of the above.

Expediting the organism ID and AST

Accelerate Pheno

- Fully automated
- FDA-cleared in Feb. 2017
- ID in ≈1.5h
- AST in ≈6.5 h!

E. coli and piperacillin-tazobactam

- Serial images taken of organism growing with antibiotic.
- Image data is compared to data in a database.
- An MIC and interpretation (S/I/R) are assigned.

Within 6.5 h of a blood culture alarming positive, you get ID and AST

www.acceleratediagnostics.com
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Why not just bypass growing the organism?

Direct PCR on blood

Blood draw

Summary of what’s new

- Rapid tests that identify a broad range of organisms in positive blood cultures are now widely available.
- We now have an FDA-cleared blood culture assay that provides rapid AST as well.
- They are easy to use.
- The more organisms detected by a test, the more costly the test.

Pointers for implementing rapid blood culture tests

Who should be notified of rapid blood culture ID results?

- Banergee et al. (adult study)
- Randomized controlled trial (no blinding)
- 8 month analysis at Mayo Clinic
- New cases of bacteremia were randomized to 3 groups: (a) no intervention, (b) BCID, (c) BCID + audit and feedback

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![Time to report or action](image)

**Who should receive results?**

- **To whom should results be sent?**
  - Positive blood culture
  - Gram stain result goes in EMR
  - Gram stain result phoned to nurse

**Perform rapid test and report in EMR**

**Rapid test result phoned to physician**

**Text result to stewardship pager**

Would this need to be modified in your NICU? How might the stewardship team fit in here?


**How should results be reported in the EMR? Let’s Discuss a Case…**

- **Four year old oncology patient with acute lymphoblastic leukemia.**
- **Blood culture drawn as febrile and neutropenic.**
- **Blood culture system alarmed positive.**

**As usual:**

- Gram stain
  - Broth was sub-cultured to solid media.
  - Verigene BC-GP was run.

**2.5 hours: BC-GP**

- **Genus level targets**
  - Staphylococcus spp.
  - *Streptococcus* spp.
  - *Serratia* spp.

- **Species level targets**
  - *A. aerogenes*
  - *A. baumannii*
  - *A. k genom*
  - *A. saprofita*
  - *A. proteus*
  - *A. eneteroprise*
  - *A. ferment *
  - *A. desnut riae*

**Antibiotic resistance determinants**
- vanA, vanB

Report: “MRSA isolated” in LIS/HIS and texted the same to the antimicrobial stewardship pager.

**12 h: Subculture**

**36 h: MSSA (methicillin-susceptible) by Vitek 2.**

What is going on?
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Possibilities

- False positive mecA by BC-GP? (Verigene had a false positive)
- False negative methicillin susceptibility status by Vitek 2 AST card? (Vitek 2 produced a false negative)
- Contamination somewhere in the procedure?

Further work up

- Isolate
  - Alere PBP 2a (detects the protein) = negative
  - Disk diffusion = cefoxitin and oxacillin susceptible
  - Repeat Vitek 2 = cefoxitin and oxacillin susceptible
- Repeat subculture
  - MSSA (PBP2a negative, cefoxitin DD susceptible)

On multiple plates, we recovered colonies of S. hominis (oxacillin R) in small quantities.

What we learned from this case

① We need to be careful with the language on reports (“Report the targets” and use a template).
② Labs and clinical teams should review the reporting scheme before go-live and discuss the limitations of the test.

Points to consider if “going live”

- In adults, the impact of rapid blood culture ID in adult populations is best when results are communicated to the clinical team and an expert in antibiotics.
- The NICU is a unique environment. Before go-live, it is useful to decide whom the rapid results should be communicated to.
- Labs and clinical teams should work together on reporting language before go-live.

Basics that may help speed blood cultures up!

Neonatologist to microbiologist: “This is the size of my babies in the NICU. How much blood do we really need to draw to detect bacteria?”
New Laboratory Tools to Confirm or Rule Out Sepsis in Hours Not Days!

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Also, considering lab operations...

- Study from Modena, Italy
- Analyzed 50,955 blood cultures from >7000 adults processed with the BACTEC FX system
- Pre-analytical time (interval from collection to insertion in blood culture instrument) was 1h (lab open) vs 13 h (lab closed)


Impact of delayed bottle entry into blood culture instrument

<table>
<thead>
<tr>
<th>Organism type</th>
<th>Lab Open</th>
<th>Lab Closed</th>
<th>aOR*</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>13.0%</td>
<td>10.8%</td>
<td>0.84 (0.80-0.89)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Bacteria</td>
<td>12.0%</td>
<td>10.0%</td>
<td>0.84 (0.80-0.89)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Yeast</td>
<td>1.0%</td>
<td>0.8%</td>
<td>0.85 (0.70-1.03)</td>
<td>NS</td>
</tr>
<tr>
<td>Gram-positive</td>
<td>6.9%</td>
<td>5.4%</td>
<td>0.80 (0.74-0.86)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Gram-negative</td>
<td>5.7%</td>
<td>5.1%</td>
<td>0.90 (0.83-0.98)</td>
<td>0.01</td>
</tr>
</tbody>
</table>

*Adjusted for: Type of blood sample (peripheral vs central), clinical ward, sex, and age

For every hour of increased pre-analytic time (collection through bottle insertion), blood culture yield decreased 0.3%.

The hurdles involved in getting to the positive blood culture in NICU patients

- Sometimes getting a “good” blood volume carries risks for the patient
- Fastidious organisms (difficult to grow) matter – ex. GBS
- Lab hours may be limited for many reasons

Take away points

- More blood is better (do what you can): increased sensitivity and shorter time to positivity.
- One larger draw (before antibiotics) is better than multiple small ones (but try to avoid single blood draws?).
- Try to get inoculated bottles to the lab ASAP.
- If your lab is not 24/7, double check how blood culture bottles are being handled.
New Laboratory Tools to Confirm or Rule Out Sepsis in Hours Not Days!

Kaede Ota Sullivan MD

Thank you!

Questions?
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Lenora is an Associate Professor in the School of Nursing at the University of Victoria. She has been involved in the field of maternal-infant nursing for over 30 years as a staff nurse, clinical nurse specialist, administrator, educator and researcher. Lenora’s current focus on research is the impact of substance use during pregnancy, neonatal opioid withdrawal, and supporting infants in foster care.

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Stephen W. Patrick, MD, MPH, MS, is an Assistant Professor of Pediatrics and Health Policy at Vanderbilt University School of Medicine and an attending neonatologist at Monroe Carell Jr. Children’s Hospital at Vanderbilt. He is a graduate of the University of Florida, Florida State University College of Medicine and Harvard School of Public Health. Dr. Patrick completed his training in pediatrics, neonatology and health services research as a Robert Wood Johnson Foundation Clinical Scholar at the University of Michigan. Dr. Patrick joined the faculty of Vanderbilt University in 2013. His National Institute on Drug Abuse-funded research focuses on improving outcomes for opioid-exposed infants and women with substance-use disorder and evaluating state and federal drug control policies. He previously served as Senior Science Policy Advisor to the White House Office of National Drug Control Policy and has testified before Congress on the rising numbers of newborns being diagnosed with opioid withdrawal after birth. He served as an expert consultant for the Substance Abuse and Mental Health Services Administration’s development of a Guide to the Management of Opioid-Dependent Pregnant and Parenting Women and Their Children, as a member of the American Academy of Pediatrics Committee on Substance Use and Prevention and as a board member on the US Office of Personnel Management’s Multi-State Plan Program Advisory Board. Dr. Patrick’s awards include the American Medical Association Foundation Excellence in Medicine Leadership Award, the Academic Pediatric Association Fellow Research Award and Tennessee Chapter of the American Academy of Pediatrics Early Career Physician of the Year. His research has been published in leading scientific journals including the New England Journal of Medicine, JAMA, Pediatrics and Health Affairs.

Hot Topics in Combatting the Growing NAS Epidemic

Objective: Participate in a workshop linking evidence and action to improve the care of infants and families affected by substance use disorder.
Hot Topics in Combatting the Growing NAS Epidemic

Lenora Marcellus PhD, MN, BSN, RN / Stephen Patrick MD, MPH, MS

October 28, 2017
Lenora Marcellus PhD, MN, BSN, RN
Stephen Patrick MD, MPH, MS

Disclosure
We have no interest to disclose

Learning Objective
Participate in a workshop linking evidence and action to improve the care of infants and families affected by substance use disorder.

Outline for Today
- Lenora – Conceptual overview
  - Foundational concepts in public health and social determinants of health
  - Discussion of harm reduction
  - Rightsizing our approach
- Stephen – Specific “hot” issues in NAS
  - Opioid Agonist Therapies for mothers
  - Home based infant treatment
  - Hepatitis C

I. FOUNDATIONAL PUBLIC HEALTH CONCEPTS

Health Equity

Equality does not equal Equity
Hot Topics in Combatting the Growing NAS Epidemic

Lenora Marcellus PhD, MN, BSN, RN / Stephen Patrick MD, MPH, MS

Social Determinants of Health

https://www.cdc.gov/socialdeterminants/

Moving upstream from behaviors to population health change

Determinants of Population Health
Social Justice

• The equitable, or fair, distribution of society’s benefits, responsibilities and their consequences.

• It focuses on the relative position of the social advantage of one individual or social group in relation to others in society, as well as on the root causes of inequities and what can be done to eliminate them.


II. HARM REDUCTION

What is Harm Reduction?

Harm reduction is a pragmatic public health approach to reducing the negative consequences of risky behaviors.

• A “contentious issue” in drug policy

• Emotion/ethics laden

• Many misperceptions

In Canada...

• 1990s – needle exchanges emerged

• 2003 – InSite – Vancouver’s safe injection site – opened

• HIV/AIDS public health officials and policy makers engaged

• City of Vancouver – 4 pillar approach

• “Unlikely coalitions” of public health authorities and activists

• Currently – ++ safe injection sites, managed alcohol programs, legalization of marijuana
Hot Topics in Combatting the Growing NAS Epidemic

Lenora Marcellus PhD, MN, BSN, RN / Stephen Patrick MD, MPH, MS

III. OVERTREATMENT?

- Increased engagement and retention in prenatal services and addiction treatment
- Increase referrals to other health and social services and increase engagement in services following birth
- Reduce alcohol and drug use and improve nutrition
- Reduce health care costs
- Improve health outcomes for women and their babies, including lower preterm births and babies born with low birth weight
- Increase the number of babies discharged home with their mothers following birth
- Encourage breastfeeding, early attachment and improve outcomes

“An Avalanche of Unnecessary Medical Care” – Atul Gawande

- Waste accounts for 30% of health care spending (Institute of Medicine)
- Information asymmetry (Kenneth Arrow – Nobel winning economist) – health care providers know more about treatment than the patients – a powerful position
- Greater fear of not doing enough, rather than doing too much
- Hidden harm – unnecessary care can crowd out necessary care
Hot Topics in Combatting the Growing NAS Epidemic

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From Minimal to Sufficiently Important Difference
- Smallest amount of patient valued benefit that an intervention would require to justify associated costs, risks, and other harms (p. 254) – “somewhat better”
- Orientation and perspective – differences between providers, patients, others – move to PROM
- How much benefit is needed in order to justify the costs and harms of a given treatment?


Ecological/Systems Approach
- Macrosystem: Society
- Exosystem: Institution or organization
- Mesosystem: Unit and team
- Microsystem: Infant and family

Microsystem: Infant and Family
- Shift in substance exposure patterns over the years
- Widening social inequities experienced by families
- Not the population that health care providers are most interested in providing care to – low tech, high tension
- Are infants with NAS seen as “appropriate” patients for the NICU?
- Phenomenon of motivated reasoning – emotional state, support personal bias
- Confirmation bias – interpret in a way that confirms preexisting hypotheses

Mesosystem: Unit and Team
- Physical environment
- Human factors
- Care model, staffing model, workload, collaboration,
- Shared values and unit culture
- Consistency in and skill of caregivers
- Pragmatic clinical guideline framework for practice, including ongoing training with scoring tool use
- Approach to integrating parents

Exosystem: Institution or Organization
- Administrative/leadership support for model of care
- Culture/shared beliefs that emphasizes performance standards
- Approach to risk

Macrosystem: Society
- Societal positioning and valuing/devaluing of marginalized populations
- Usually placing rights of infant ahead of mother
- Widening social inequities
- Legal parameters

Hot Topics in Combatting the Growing NAS Epidemic

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Weighing Benefits and Harms of NAS Care Above the Threshold (Can Depend on Your Perspective)

- Benefits
  - Iatrogenic exposure
  - Impaired attachment
  - Reduce discomfort
  - Avoid seizures, other complications*
- Harms
  - Support positive longer term outcomes

“Right Sizing” our Practices

- Provide optimal care to ensure we are assessing withdrawal, not other things
  - Mother-baby dyad commitment
  - Non-pharmacologic interventions
  - Adequate human resources
  - Appropriate physical environment
- Skilled and consistent application of assessment tools
- Re-examine use of automatic/hard threshold or cut off practices
- (and keep reflecting, researching!)

Opioid Agonist Therapies (OAT)

- Buprenorphine and methadone
  - Recommended to treat opioid use disorder in pregnancy
  - Methadone - full mu-opioid receptor agonist, typically requires daily outpatient visits to an OTP to receive medication
  - Buprenorphine - partial mu-opioid receptor agonist and kappa-opioid receptor antagonist generally used in the outpatient setting, not requiring daily visits

Evidence for OAT

- Eliminates peaks and troughs of opioid use
  - Fetus – repeated intoxication, withdrawal
- Reduced relapse
  - Fetus exposed to fewer illicit substances
  - Reduce risk of high-risk behaviors – HCV, HIV
- Recent meta-analysis
  - 120k methadone, 15k buprenorphine
  - Consistently lower rates of all cause mortality

Evidence for OAT

- Infant benefits –
  - Fewer cycles of intoxication/withdrawal -> less stress -> more likely to go to term/have higher birth weight
  - Risk of NAS
Hot Topics in Combatting the Growing NAS Epidemic

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Pregnant Women in Treatment Getting OAT

Analysis of the Substance Abuse and Mental Health Administration's Treatment Episode Discharge Dataset. Sample: Pregnant women treated for opioid use disorder in FL, KY, MA, MI, MO, NC, TN, WA, WV; 2013.

Accessing Treatment

Medically Supervised Withdrawal

• “If we can prevent NAS, shouldn’t we?”
• Tapering OAT in pregnancy, can be done.
  – Relapse rates as high as 90%
  – Highest risk of death, weeks that follow taper
• Not recommended by ACOG or SAMHSA

Lower Doses of OAT

• Logically, lower doses of OAT should result in lower risk of NAS
• Meta-analysis of methadone, lower dose does not decrease NAS risk
• Large analysis of buprenorphine also suggest lower does does not decrease NAS risk.

Decreasing NAS Risk

• Primary prevention, starts before pregnancy
• What increases risk?
  – Sustained release opioids vs. immediate release
  – Smoking
  – SSRI
  – Atypical antipsychotics
  – Gabapentin
  – Benzodiazepines
Summary

• What’s good for mom is good for baby
• Relapse bad for the dyad
• Primary prevention
• Expanding treatment
• Reducing NAS risk through additional exposures

V. Variable and Excessive Care?

Hospital Variability

• There remain significant inter and intra-hospital variation in treatment and outcomes for NAS
• Recent study of US children’s hospitals:
  – Only 5/14 used the same pharmacotherapy >80% of the time
  – Two-fold differences in risk-adjusted length of stay
• Large international quality improvement collaborative of 199 hospitals
  – 44.8% had a policy to standardize scoring
  – 48.6% had a policy on breastfeeding a substance-exposed infant
  – 68.0% had a policy on pharmacologic treatment of NAS

Standardizing Care Works

• Ohio perinatal collaborative, multicenter cohort
  – Protocol driven weans vs. no protocol – with shorter LOT (17.7 vs. 32.1 days, p<0.001)
• Vermont Oxford Network NAS collaborative 2013-2015
  – Participating hospitals, care standardized by protocol/policy development
  – Shortened LOT (16 -> 15, p=0.02) and LOS (21 -> 19, p=0.002)
  – Hospitals with protocols/policies on infant scoring lowest LOS

Is There One Right Protocol?

• No
• Evidence is accumulating, methadone, morphine, buprenorphine
• There is no one right answer, but standardization works

Can’t I Just Send them Home

• Increasingly centers are discharging infants home on medications
  – VON Collaborative ~20% even at end
• Phenobarbital – associated with developmental delay
• Who monitors weans at home?
Hot Topics in Combatting the Growing NAS Epidemic

Lenora Marcellus PhD, MN, BSN, RN / Stephen Patrick MD, MPH, MS

Can’t I Just Send them Home?

- Recent focus on reducing LOS
  - Infants with NAS 2x as likely to be readmitted in 30 days than uncomplicated term infants
  - Short LOS increase risk or readmission
- Many hospitals discharging home on medications
  - Shorter LOS - 11 (IQR 7-18) vs. 23 (IQR 14-35)
  - Longer LOT - 59 days (IQR 38-90) vs. 19 days (IQR 10-31)
  - Use of ED > in first 6 months (aOR 1.46, 95% CI 1.02-2.09)


Maalouf FI, MD, Cooper WO, Slaughter C, Dudley J, Patrick SW. Outpatient Treatment of Neonatal Abstinence Syndrome Associated with Longer Treatment and Higher Rates of Healthcare Utilization.

VI. It’s not just about the opioid ...

Hepatitis C Prevalence Among Pregnant Women

![Graph showing Hepatitis C prevalence among pregnant women in Tennessee and the US from 2009 to 2014.](image)

Beyond Training! Using Simulation to Improve Quality & Safety

Kimberly S. Firestone MSc, RRT
Neonatal Respiratory Outreach Clinical Liaison
Akron Children’s Hospital
Akron, OH

Ms. Kimberly Firestone MSc, RRT is currently the Neonatal Respiratory Outreach Clinical Liaison for the Neonatal Intensive Care Unit at Akron Children’s Hospital. She has been involved with simulation since the inception of their center in 2009. She has designed and implemented simulation programs for a NICU move to single patient rooms, NICU transport, post resuscitation and Neonatal Resuscitation. Ms. Firestone has been involved with the NICU’s process and quality improvement programs for many years with her involvement and membership of the Vermont Oxford Network Collaborative as well as the Ohio Perinatal Quality Collaborative. Her passion for improving the lives of babies in the NICU is evidenced by her continued commitment to quality improvement and ventilation enhancements.

Louis P. Halamek MD, FAAP
Professor and Associate Chief, Education and Training
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Louis P. Halamek MD, is a Professor and Associate Chief for Training and Assessment in the Division of Neonatal and Developmental Medicine, Department of Pediatrics, and (by courtesy) in the Division of Maternal-Fetal Medicine, Department of Gynecology and Obstetrics at Stanford University. He is also a Senior Fellow in the Center for Aviation Safety Research and Adjunct Faculty in the Department of Aviation in the Parks College of Engineering, Aviation and Technology at St. Louis University. He is a graduate of the Creighton University School of Medicine and completed residency and chief residency in Pediatrics at the University of Nebraska Medical Center followed by fellowship in Neonatal-Perinatal Medicine at Stanford University. He is certified by the American Board of Pediatrics in both Pediatric Medicine and Neonatal-Perinatal Medicine and is a Fellow in the American Academy of Pediatrics. He has a clinical appointment at Lucile Packard Children’s Hospital at Stanford where he works in the level IV neonatal intensive care unit. Through ongoing collaboration with colleagues at Johnson Space Center in Houston, Texas, Ames Research Center in Mountain View, California, and the Federal Aviation Administration in Washington, D.C., Dr. Halamek has learned the benefits of a cross-industries approach to risk assessment, safety and effectiveness. His current work centers on the development of hospital
operations centers linked with sophisticated simulation capabilities, optimization of human performance during high risk activities such as resuscitation, analysis of human and system error, and human factors and ergonomics in healthcare. In 2002 Dr. Halamek founded the Center for Advanced Pediatric and Perinatal Education (CAPE, http://www.cape.lpch.org), the world's first such center dedicated to fetal, neonatal, pediatric and obstetric simulation, located at the Lucile Packard Children's Hospital on the campus of Stanford University. He is currently a Special Consultant in Simulation- and Virtual Reality-based Learning to the U.S. Neonatal Resuscitation Program.

Annual Quality Congress Breakout Session, Saturday, October 28, 2017
Beyond Training! Using Simulation to Improve Quality & Safety

Objective: Explore innovative methods to perform PDSA cycles and small tests of change using intra-disciplinary team-based simulation.
Beyond Training! Using Simulation to Improve Quality and Safety

Kimberly S. Firestone MSc, RRT / Louis Patrick Halamek MD, FAAP

Beyond Training! Using Simulation to Improve Quality and Safety

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Disclosure
Neither Ms. Firestone nor Dr. Halamek have any disclosures pertinent to this educational session.

Learning Objectives

- Simulation-based training can be used to acquire, refine and maintain multiple cognitive, technical and behavioral skills, including but not limited to the skills necessary for successful resuscitation.
- Simulation is a useful quality assurance tool.
- Simulation learning can promote the opportunity to develop and refine processes and skills using a multidisciplinary approach without putting patients at risk.

Simulation for Quality Improvement

- Health care professionals are part of systems of care and care processes that affect outcomes for patients and families.
- Using tools in skill assessment stations make processes of care clear.
- Continuous quality improvement is an essential part of the daily work of all health professionals.

Quality Improvement Efforts

- Simulation can identify process gaps prior to a major institutional change
- Transition from a 59 bed open bay unit to a 75 bed, single room unit
- Hypothesis: Numerous process gaps could still be revealed after intense unit design that would enhance patient safety and improve perceived staff satisfaction with the transition
NICU Move Committee
- Formed Move Subcommittee from larger NICU Move Steering Committee
- Previous three year planning project with architects/leadership/bedside personnel
- Met weekly for 8 weeks
- Multidisciplinary team
  - Nursing, Neonatologists, APPs, Respiratory Therapy, Transport, Social Work, Nutrition, Biomed, Security, Volunteers, Parents, Pharmacy, Chaplain, Lab, Radiology, Pharmacy, IT, COE-center of excellence

59 Bed Open Pod Unit

75 Bed Unit
Two Floors
Single patient rooms

NICU Move Planning
Beyond Training! Using Simulation to Improve Quality and Safety

Kimberly S. Firestone MSc, RRT / Louis Patrick Halamek MD, FAAP

Simulation Education for all Personnel
- Perceived Satisfaction and/or Anxiety
- Nursing Personnel
- Respiratory Care Personnel
- Advanced Practice Providers
- Physicians
- Nurse Practitioners
- **Families**

Method
- 2 eight hour sessions for multidisciplinary team
- Meeting the objectives of low and high acuity patient platforms
- Evaluation forms were provided to reflect and summarize:
  - staff’s engagement
  - professional satisfaction pre/post simulation
  - their recommendations for process improvements

Method for PDSA cycles
- Debriefing themes after each simulation were shared with leadership staff.
- Process enhancements (ACT) were changed quickly and re-evaluated (Study) for the next scheduled simulation.
- Daily frequently asked questions (FAQ’s) and answers were shared via staff huddle and email.

Orientation
- Day one of orientation: 8 hours
- Day in the unit tour/ including lunch
- Neo-Cashing
- Vendor Orientation
- Cardiac monitors
- Volte communication phones
- Tubing systems
- Patient Rooms
- General Safety Training

Simulation
- Day Two of orientation: 8 hours
- Simulations
- Goal: decrease anxiety, review task training, and evaluate daily processes
- Not focused on staff skills
- Give staff objectives before class so they were not surprised & they could review before they attended
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Simulation

- Focus on task training, procedures/process skills
- Self-extubations
- Reintubation
- Answer call lights with several patients, using SP’s
- Procedures: thoracentesis (find equipment)
- Adult code
- Admission from ED
- Discharge
- Parent needs
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Move Simulation
four days before the actual move

- Stable transport
- Change in patient condition upon arrival
- Deterioration of patient condition in the connector during transport
- Code Blue after arrival

Identification: areas of improvement and positive “finds”

- Voalte phones worked consistently
- Family Support – introduce team; nurse to accompany family with volunteer
- Use middle elevator car to decrease number of turns required
- Only use transport elevator in KJP due to size
- Need to practice using shuttle, difficulty with maneuverability
- Monitor placement need to be changed – slid off the incubator

Results

- 274 staff members attended
- They identified over 40 discrete latent safety threats
- Theme of communication, organization, accommodations, ergonomic and technical safety threats—were resolved by workflow modification or practice change
- Overall staff satisfaction improved with perceived comfort level for the anticipated transition after each session

ACH Neonatal and Pediatric Transport Team
Beyond Training! Using Simulation to Improve Quality and Safety

Kimberly S. Firestone MSc, RRT / Louis Patrick Halamek MD, FAAP

Competency & Quality Improvement
- Meeting specific objectives
- Organization requirement
- Annual review
- Regulatory requirements
- CAMTS
- Proficiency
  - surgical, respiratory, cardiac patients

Highly skilled teams
- Paramedics
- Nurses
- Physicians
- Respiratory therapists
- Advanced Practice Practitioners

Specific to your hospital or practice
- Gastroschisis management
- Myelomeningocele management
- Thermoregulation practice
- Ventilator management
- New medications
- Communication with referral hospital personnel

Family and patient communication

Family conversation scenario design tool for simulations.
Oregon Science and Health University: VON

Family communication debriefing tool

Family communication debriefing tool
Beyond Training! Using Simulation to Improve Quality and Safety

Kimberly S. Firestone MSc, RRT / Louis Patrick Halamek MD, FAAP

**Using Simulation to Select, Train and Maintain Your Neonatal Resuscitation Teams**

How are the members of the resuscitation teams at your hospital selected?

How do the members of the resuscitation teams at your hospital maintain proficiency?

**Selection Process**

- formal application
- will include an essay
- review of references, work record
- interview with selection committee
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Selection Process
- skill assessment
  - cognitive
    - content knowledge
    - decision-making
  - technical
  - behavioral
- via simulated clinical scenarios at CAPE

Objective Assessment of Technical Skills
- Yes
- No
- Can't Tell

Objective Assessment of Behavioral Skills
- 5-point Likert Scale

Selection Process
- blinded review of all applicant scores
- desired blend of expertise
- senior, mid-level and junior facilitate mentorship, transitions

Once Selected...
- proficiency must be maintained
  - rigorous team training and assessment every 6 months
  - cameras in operative delivery rooms
  - objective, constructive debriefings

How many of you train and expect your resuscitation teams to debrief real clinical events?
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How are your debriefings initiated?

When you debrief real events, do you follow any type of protocol?

3 Guiding Principles

20 Specific Strategies

20+ years of debriefing simulated and real clinical events

A Key Point

Technical performance debriefings and critical incident stress debriefings have distinctly different objectives and no attempt should be made to conduct them simultaneously.

A technical performance debriefing is NOT therapy...

Using Simulation to Train for Patient-specific Real-life Clinical Scenarios

Planned Delivery of Omphaloischiopagus Twins

- prenatal MRI
- fusion of liver, diaphragm, pelvis
- single bladder, umbilical cord
- 3 lower extremities
- A: neck extension, B: neck flexion
How would you prepare for this delivery?

Insights Provided Via Simulation
- standard techniques modified

Using Simulation to Improve System Performance, Enhance Patient Safety and Reduce Cost

Do you link your simulation programs with real-world outcome data?
Beyond Training! Using Simulation to Improve Quality and Safety

Kimberly S. Firestone MSc, RRT / Louis Patrick Halamek MD, FAAP

Optimal Use of Simulation-based Learning

- in hospital drills
- care of real patients
- dedicated time in a simulator
- patient safety, risk, quality

Human and System Performance

- target: difficult deliveries
- intervention: obstetric team training
- obstetricians, L&D nursing, obstetric anesthesiology, related support staff
- conducted in simulator and at hospital
- sims mimic real-world problems as identified by Risk Management

OB Sim

- investment
  - annual baseline cost (nursing skills fair): $239,056
  - additional investment (sim-based multidisciplinary training): $166,343
  - costs increased by 70%

OB Sim

- gain
  - annual legal costs decreased by $717,720
  - comparing costs prior to OB Sim (3 year avg) vs costs after initiation (8 year avg)
  - ROI = 331%
  - precipitous fall in near misses and adverse events

Thank you.
Improving the Quality of Newborn Care in Low Resource Settings: 
Use of the AAP Improvement Guide

Carl L. Bose MD
Professor of Pediatrics
University of North Carolina School of Medicine
Chapel Hill, MC

In 1970, Dr. Bose completed an undergraduate degree at Duke University, followed by completion of medical school in 1974 at Emory University. He completed a Pediatric residency at the Emory University Hospitals and Bowman Gray School of Medicine, and a Fellowship in Neonatal-Perinatal-Medicine at the University of North Carolina. He has been involved in global health research with the goal of discovering strategies to reduce this health burden. As a site PI in the NICHD Global Network for Women’s and Children’s Health Research (GN), Dr. Bose participated in the sentinel First Breath Study which demonstrated the effectiveness of perinatal mortality by training newborn care providers in resuscitation and other aspects of essential newborn care. To add precision to their understanding of the causes of perinatal deaths, along with a junior colleague at UNC and GN investigators, he helped develop and test a verbal autopsy tool. Recently, they investigated the antecedents of stunting of growth in infancy, and discovered that most stunting does not result from a protein or micro-nutrient deficiency. Dr. Bose has been involved in two programs sponsored by the APP whose aim is to increase competency of providers of newborn care. The first was Helping Babies Breathe (HBB). This was followed by Essential Care for Every Baby (ECEB) that teaches care during the first few days after birth, and the second was Essential Care for Small Babies (ECSB) that teaches care of the small and preterm infant. Dr. Bose serves on the Planning Board for HBB, is the editor for ECEB and a co-author of ECSB.

Jacquelyn Patterson MD, MPH
Assistant Professor of Pediatrics
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Jackie Patterson completed her medical training, pediatric residency and perinatal-neonatal medicine fellowship at the University of North Carolina in Chapel Hill, NC and joined the faculty in the neonatal division in July 2016. She also holds a master of public health from the UNC Gillings School of Global Public Health, and certificate in quality and safety from the Institute for Healthcare Improvement. Jackie has a particular interest in effective translation of training into practice. She was co-investigator for an Essential Care for Every Baby implementation project in rural health centers in Nicaragua that resulted in improved early initiation of breastfeeding and skin-to-skin care. She participated in the development of Improving Care of Mothers and Babies, a quality improvement guide for low-resource settings published by the American Academy of Pediatrics and University Research Co, LLC. Jackie presented this guide at a World Health Organization Southeast Asia Quality Improvement workshop, where she also served as a facilitator for quality improvement training of hospital administrators and clinicians. She is currently pilot-testing the QI guide in twenty hospitals in Ethiopia with support from the Laerdal Foundation.
Objective: List three key reasons why improving the quality of care in resource limited settings should include training providers in QI methods.
Improving the Quality of Newborn Care in Resource Limited Settings: Use of the AAP Improvement Guide

Carl Bose MD / Jackie Patterson MD, MPH

Disclosures
We have no conflicts of interest to disclose in relation to this presentation.

Learning Objective
List three key reasons why improving the quality of care in resource limited settings should include training providers in QI methods.

Evidence Based Practices Prevent Newborn Death
- Simple, low-cost evidence based practices prevent mortality
- Evidence based practices inconsistently available or delivered in low-resource settings

Quality Gaps Are Not Just Caused By Insufficient Resources
- Limited essential commodities and staffing shortages not the sole cause of quality gaps
- Lack of knowledge and skills commonly identified
- Poorly organized processes, misaligned incentives and cultural beliefs also contribute

Quality gaps may be modifiable using facility-based quality improvement.

The Value of QI is Spreading Internationally
- Value of QI increasingly recognized internationally & nationally
- Facility-level QI adopted more slowly
- Successful facility-level QI has included
  - QI coaching
  - Low-cost solutions
  - Front-line worker engagement
Improving the Quality of Newborn Care in Resource Limited Settings: Use of the AAP Improvement Guide

Carl Bose MD / Jackie Patterson MD, MPH

AAP QI Guide Simplifies QI Methodology

Steps 1 to 6:
• Create an improvement team
• Decide what to improve
• Choose barriers to overcome
• Plan and test change
• Determine if change resulted in improvement
• Make improvement the norm

AAP QI Guide for Facility-based CQI

Sections guide user through learning, practice and action
• Objectives
• Key knowledge
• Practice exercises (newborn, maternal)
• Group discussion
• Improvement team actions

AAP QI Guide Facilitates Learning About Improvement

Case Scenario: Step 1

After meeting with Seetha and hearing about the positive changes in her hospital, Nirmala returns to her own facility with new energy to improve care. Each year, approximately 1,000 babies are born in Nirmala’s hospital. Nurse midwives provide prenatal, basic obstetric and postpartum care. Registered nurses and ward assistants help with postpartum care. A senior nurse manager supervises operation of the facility, including ordering supplies. There is a pharmacist on site.

Case Scenario: Step 1, Continued

Nursing students are usually present in the facility. A physician manages the labor ward and is available for emergencies, but does not provide care for women without complications. Mothers and babies usually remain in the delivery area for one hour after a birth and are then moved to a postpartum room. They are typically discharged about 24 to 48 hours later.

Nirmala wants to become a champion for quality care and wants to create an improvement team.

Case Scenario: Step 2

During a meeting of the improvement team at Nirmala’s hospital, gaps in quality of newborn care are discussed. Team members are not aware of a serious gap in quality. The leader suggests reviewing recent Delivery Register data to determine if a gap in quality exists.
Improving the Quality of Newborn Care in Resource Limited Settings: Use of the AAP Improvement Guide

Carl Bose MD / Jackie Patterson MD, MPH

Step 3: Choose Barriers to Overcome

References

Why Follow-up is Not Enough and Follow-Through Can’t Wait!

Jonathan S Litt MD, MPH, ScD  
Neonatologist and Perinatal Epidemiologist  
Department of Neonatology, Beth Israel Deaconess Medical Center  
Department of Pediatrics, Harvard Medical School  
Boston, MA

Dr. Litt is a practicing Neonatologist and health services researcher at Beth Israel Deaconess Medical Center and Harvard Medical School. He holds an MD from Case Western Reserve University School of Medicine in Cleveland, Ohio. Dr. Litt completed residency training in Pediatrics at the University of California, San Francisco and subspecialty fellowship training in Newborn Medicine at Boston Children’s Hospital. He is also a graduate of the Harvard Pediatric Health Services Research Fellowship program, an intensive mentored training program through which he pursued an MPH and then a doctoral degree in social science research methods at the Harvard TH Chan School of Public Health. His fellowship and dissertation work centered on the impact on early intervention programs for low birth weight infants on functional outcomes at school age. As an early career investigator, Dr. Litt has published several studies relating to learning disabilities and academic achievement among low birth weight children and adolescents, care coordination for children with special health care needs, and the effect of early intervention programs on school-age functional outcomes. His body of research is focused on the long-term health and neurodevelopmental outcomes of high-risk infants and evaluating the utilization and effectiveness of community-based intervention services. He is currently working to develop novel risk-prediction strategies for adverse health and neurodevelopmental outcomes among high-risk infants with the goal of improved matching of health services to need. He is active in the health services research community and currently serves as the chair of the Child Health Services Research Interest Group at Academy Health and the Director of Operations for the New England Follow-up Network.

Annual Quality Congress Breakout Session, Saturday, October 28, 2017
Why Follow-up is Not Enough and Follow-Through Can't Wait!

Objective: Analyze the real-world challenges for care beyond the NICU walls and identify opportunities to improve both the quality and the content of follow-up and community follow-through for NICU graduates and their families.
Why Follow-up is Not Enough and Follow-Through Can’t Wait!
Jonathan S Litt MD, MPH, ScD

Challenges, Innovations, and Opportunities for Improved Outcomes in High-risk Infant Follow-up
Jonathan S Litt MD, MPH, ScD
2017 VON Annual Quality Congress
Chicago, Illinois
October 28, 2017

Disclosure

I, Jonathan S. Litt, have no conflicts of interest or financial relationships to disclose.
The content of this presentation is evidence-based and free of commercial bias.

At the end of this activity, participants will be able to:
- Analyze the real-world challenges for care beyond the NICU walls and identify opportunities to improve both the quality and the content of follow-up and community follow-through for NICU graduates and their families.
- Describe historical and current approaches to high-risk infant follow-up after NICU discharge.
- Name at least three challenges to providing high-quality follow-up for high-risk infants.
- Identify potential strategies for improving follow-up care in the community setting.

Objectives

Introduction
- What is follow-up?
  - Defining risk
  - Then versus now
  - For whom, by whom?
  - Timing & frequency
- Challenges
- Questions & Opportunities
- Small group break-out
- Large group report-back
- Concluding remarks

Roadmap

What makes an infant high-risk?
At risk for...
- Technology dependence
- Chronic health conditions
- Limitations in physical stamina
- Difficulties with ADLs
- Delays in development
- Behavior problems
- Poor academic achievement

Compared to whom?
- Siblings
- Peers
- Population averages
- Those without antecedent illness

Over what time?
- Days
- Weeks
- Months
- Years?
- Decades?

NICU Graduates

- Risk of mortality associated with GA at birth, improved survival for all infants over the past four decades
- Premature birth impacts functioning of all organ systems with life-threatening morbidities related to cardiovascular, respiratory, immune, and nervous systems
  Reardon and Martin, 2010
- Normal birth weight infants have higher rates of post-discharge health care utilization after NICU admission
Why Follow-up is Not Enough and Follow-Through Can’t Wait!
Jonathan S Litt MD, MPH, ScD

Evolution of Follow-up
- Modern NICU Care
- Novel interventions
- Improved outcomes

Research Follow-up
- Clinical trials
  - Surfactant, CPAP, caffeine, etc...
  - Safety, efficacy of specific treatments
- Longitudinal cohort studies
  - Hack, Saigal, Vohr, Doyle, Marlow, et al
  - Developmental course of high-risk infants over time

Improving clinical care in the NICU

How and when do we follow?
- NICHD, 2004
  - ≤32 weeks, ≤1500 grams
- Wang, et al 2006
  - Quality indicators for neurodevelopmental follow-up of VLBW children
    - General Care (1-19)
    - Physical Health (20-28)
    - Vision, Hearing, and Speech/Language (29-46)
    - Development and Behavior (47-65)
    - Psychosocial well-being (66-70)
- Kuppala, et al 2012

Wang, et al 2006

Kuppala, et al 2012
Why Follow-up is Not Enough and Follow-Through Can’t Wait!

Jonathan S Litt MD, MPH, ScD

Why do we do follow-up?

**Primary Purpose of Follow-up**

<table>
<thead>
<tr>
<th>Purpose of Follow-up</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assess high-risk infants for developmental and functional problems</td>
<td>12</td>
<td>55</td>
</tr>
<tr>
<td>Collect data on the long-term outcomes of high-risk infants</td>
<td>4</td>
<td>18</td>
</tr>
<tr>
<td>Coordinate care for complex, high-risk infants after NICU discharge</td>
<td>4</td>
<td>18</td>
</tr>
<tr>
<td>Provide therapeutic services for high-risk infants</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Serve as a resource for families of high-risk infants</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>All of the above</td>
<td>1</td>
<td>5</td>
</tr>
</tbody>
</table>

**Challenges to providing follow-up**

- Defining high-quality follow-up
  - What is the purpose?
  - Research
  - Service provision
  - Care coordination
  - Whom should we follow?
  - Gestational age, birth weight
  - Morbidity count, symptom severity
  - Specific diagnoses (e.g. HIE, NAS)
  - Social risk
  - How long should we follow? With what frequency?

- Mechanics
  - Personnel – MD, NP, Psychologist, PT, OT
  - Capacity, waiting lists
  - Funding
  - Insurance coverage for visits, testing
  - Costs to families
    - Travel, parking
    - Child care for other children
    - Opportunity costs – time, missed work

**Measures**

- Physical exam
- Growth parameters
- Labs and diagnostic tests (e.g. electrolytes, HCT, PFTs)
- Motor assessments
- Psychometric testing
- IQ, MDI, PDI the outcomes of greatest import?
  - Behavior, mood, function, and participation

Challenges to providing follow-up
Why Follow-up is Not Enough and Follow-Through Can’t Wait!
Jonathan S Litt MD, MPH, ScD

Challenges to providing follow-up

- Value
  - To hospitals, providers, families
  - Matching services to need

Outcomes

- Vision/Hearing Impairment
- Cerebral Palsy
- Chronic Lung Disease
- Cardiovascular Disease
- Cognitive Delays
- Behavior Problems
- Impaired Executive Function
- Learning Disabilities
- Failure to Thrive/Obesity
- Metabolic Syndrome
- Poor Academic Performance

Group size: 5-10 individuals
Total time: 30 minutes
Activity:
- Identify and rank the top 3 priority areas for providing high-quality follow-up to high-risk infants
- Choosing 1 priority area, please
  - Describe at least 1 challenge to achieving this goal
  - Suggest a solution to meet the challenge(s)
  - Delineate what success will look like
  - “SMART” (specific, measurable, achievable, realistic, and timely)
- Report back to the entire group

Small Group Activity

New England Follow-up Network (NEFUN)

- Connecticut
  - University of Connecticut School of Medicine
  - Yale New Haven Medical Center
  - Hartford Hospital

- Massachusetts
  - Bay State Medical Center
  - Boston Children’s Hospital (BIDMC, SAA)
  - Children’s Hospital Boston
  - Massachusetts General Hospital
  - Massachusetts Children’s Hospital (CLF)
  - University of Massachusetts Medical Center
  - New England Sinai Medical Center
  - Rhode Island Hospital
  - Women and Infants Hospital
  - Vermont: University of Vermont Medical Center

- Maine
  - Maine Medical Center

- New Hampshire
  - Dartmouth-Hitchcock Medical Center

- Rhode Island
  - Women and Infant’s Hospital

- Vermont
  - University of Vermont Medical Center

Follow-up Retreat
- Variation in practice, opportunities for improvement
- Mission
  - Quality improvement initiatives
  - Collaborative research projects
  - VON ELBW Follow-up Program
  - Expertise
  - Support
  - Shared objectives

NEFUN
Why Follow-up is Not Enough and Follow-Through Can’t Wait!
Jonathan S Litt MD, MPH, ScD

**NEFUN**

Project #1
- Aim 1 – Determine follow-up rates for ELBW infants
- Aim 2 – Describe outcomes of ELBW infants participating in follow-up
- Aim 3 – Develop process for working together as a team

**NEFUN**

**Future Directions**
- Create and collect process measures
  - Referral and follow-through rates
  - Adherence to recommended surveillance
  - Hearing, vision
- Benchmark centers to network
- Develop and implement center-based and network-wide improvement strategies
- Participate in network-wide research

**NEFUN**

**With Gratitude**
- VON
  - Roger Soll, Charles Mercier, Madge Buus-Frank
- NEFUN
  - Tyler Hartman, Betty Vohr, Larry Rhein
  - Marie McCormick, DeWayne Pursley
- Today’s participants!

**Bibliography**
Engaging Paid NICU Families as DR Liaisons During the Golden Hour

Nancy Kuemin JD
Parent Host
Michigan Medicine
Ann Arbor, MI

Nancy Kuemin received her Juris Doctor from Thomas M. Cooley Law School in 1999. She worked as an attorney until her son was born prematurely at 33 weeks gestation. Nancy developed a passion to better care for NICU families and to create a culture of empathy and understanding within the hospital. Starting in 2007, she began working to support families experiencing the trauma of premature birth by volunteering with the March of Dimes and eventually Michigan Medicine. In 2015, Nancy accepted a position as a paid peer support staff to serve families in the Brandon NICU at C.S. Mott Children’s Hospital, and became a leader for Family Centered Care initiatives. Nancy has been able to collaborate with staff and faculty to create positive, supportive services to parents in the NICU. She views the baby as inseparable from the parents and encourages those who work in the NICU to care for the family as a whole.

Stacey Tilbury MSN, NNP-BC
Lead Neonatal Nurse Practitioner
Brandon Neonatal Intensive Care Unit
University of Michigan Hospitals
Ann Arbor, MI

Stacey Tilbury has been a NNP for 15 yrs. She is currently the Lead Neonatal Nurse Practitioner at the University of Michigan, a 52 bed Level IV NICU, where she oversees a group of 21 NNPs. At the U of Michigan, she has been involved in the Vermont Oxford projects for 3 yrs. She leads the Golden Hour project within the micropreemie NICQ-NEXT work group at Michigan. Stacey is also employed as a NNP part time at Rady Children’s Hospital in San Diego. She previously worked at Beaumont Hospital in Dearborn, MI and Children’s Hospital and Clinics of Minnesota. Her professional interests include neonatal resuscitation, role of the NP in the NICU, global neonatal health, and family centered care. Outside of work, her number one interest is Michigan sports. GO BLUE!

Annual Quality Congress Breakout Session, Saturday, October 28, 2017
Engaging Paid NICU Families as DR Liaisons During the Golden Hour

Objective: Identify 3 opportunities to improve family communication and engagement during the golden hour and explore the role of a designated family liaison.
Engaging Paid NICU Families as DR Liaisons During the Golden Hour

Nancy Kuemin JD / Stacey Tilbury MSN, NNP-BC

Learning Objective

• Identify 3 opportunities to improve family communication and engagement during the golden hour and explore the role of a designated family liaison.

Brandon Newborn ICU

• Ann Arbor, Michigan
• 52 Beds, single family rooms
• Level IV academic unit
• Regional referral center (both babies and mothers)
• 800 admissions/year
• 64% inborn, 36% outborn
• ~4700 deliveries/year with large MFM service

Role of Parent Host

• Began 9 years ago with 2 paid parent hosts
• How it came to be: previous Nurse Manager
  – Understood parents needed peer support
  – Parenting in the NICU is unlike any other experience
  – Calmer, more engaged parents = heal
• Primary role is peer support

Parent Hosts

• Daytime shift, 2 hosts
• Evening shift, 1 host and hiring another

Disclosure

• We have nothing to disclose
Engaging Paid NICU Families as DR Liaisons During the Golden Hour
Nancy Kuemin JD / Stacey Tilbury MSN, NNP-BC

Golden Hour Project
- Started in 2014 as part of VON Micropreemie group (POD)
- Goal was to improve care of babies in the delivery room/resuscitation area (NEST)

Family Presence in the DR
- Long standing history of family centered care
- Father or support person welcomed at bedside during resuscitation
- Family liaison/support role needed improvement

Initial Parent Input
- March of 2014, VON team met with FAC
  - How were you prepared for the first time you would see your baby?
  - What did caregivers say that was helpful or not helpful?
  - What would have made the experience less stressful?

What Parents Said
"Mom would like to see her baby before the baby is taken away, even if just for a moment"

VON Chicago 2015
- Ah-ha moment
  - How can we better support families?
    - We prepare them for the NICU with neonatology consultation and some get a tour
    - Do we prepare them for the birth? Do they know what to do as far as baby is concerned?
  - What if we had a support person for families in the DR to liaison with NICU team?

Parent survey - Before
- 46% not see baby before taken away
- 43% not updated as often as they wanted to
- Photos made them feel better
- See baby “even for a quick millisecond” before taking away
- Where did they take my baby?
Engaging Paid NICU Families as DR Liaisons During the Golden Hour
Nancy Kuemin JD / Stacey Tilbury MSN, NNP-BC

Parent survey - Before

- “I struggled significantly with bonding in the first year. I spent a lot of time wondering if those first few days had impacted our relationship for life. I was very distressed by it for a really long time.”
- “I wish I would have been able to tour the birthing center/NEST/NICU before I was put in this frightening situation.”
- “I wish the parent hosts or staff would have told us more accurately what the experience would be like, and provided tips on how to participate in the experience and bond with our child.”

Starting the work: 2015

October

- Who should support person be?
- Plan to develop role description
- Plan to provide training

Who should the support person be?

- Parent Hosts
- Social Workers
- Chaplains
- Volunteer family advisors

Who do we need to collaborate with?

- NICU DR team
- OB nursing
- NNP on L&D unit

More in 2015

November

- Observe GH training of staff NNP and nurses

How do we train the PH to do this?

- Observe deliveries in NEST
- Shadow DR nurse
- Shadow neonatology consultation
- ID gaps
  - Develop a PH data checklist
  - Keep talking to families
  - How do we fill gaps?
Engaging Paid NICU Families as DR Liaisons During the Golden Hour
Nancy Kuemin JD / Stacey Tilbury MSN, NNP-BC

Working on logistics: 2016

January
- DR meeting – role of family liaison announced

February
- Envision PH at all GH deliveries, maybe expand to all NICU deliveries
- What hours are we available?
- How to notify us of birth
- Conflicting duties
- Comfort of staff

Planning to measure success: 2016

June
- How much do parents want to know right away?
- Begin observations in DR

July
- Ways to measure
- Develop role description

Driver Diagram

AIM
To improve family contact before, during, and after resuscitation through pre-delivery introductions and presence of a parent host at 75% of eligible deliveries by December 2017

Primary Drivers
- Facilitate parent baby bonding
- Collaboration with OB team
- Physical liaison between medical team and support person at delivery
- Pre-delivery preparation

Secondary Drivers
- Advocate for time with mom and dad
- Updates in OR to mom and OB
- Photo advocate
- Touch advocate
- Explaining generalized clinical situation/resuscitation
- Prenatal consultations and introductions

Change Ideas
- Identified areas for improvement
  - Baby in a bag?
  - Restraints?
  - Who are all these people?
  - What is all of this equipment?
  - Dad looks overwhelmed
  - Whose job is it to update Mom?

PH begins observation in DR

Develop Role Description

- Introduced plan to have PH attend deliveries
  - Focus would be, in part, improving time to update parents
- Outlined two areas we wanted to improve
  - Meet with and tour expectant mothers with babies we expect to be NICU admits
  - Updates to mom should come from staff, not dad
- Listed goal
  - Reduce stress for parents
  - Show parents they can trust our team

Develop Role Description

- Listed our duties in the NEST
  - Greet parents/support person
  - Liaison with OB team
  - Ensure mom is updated by a NICU team member
  - Advocate for touch and photos
  - Bring in support staff as required: spiritual care, child life, interpreter, social work
  - Bereavement support
  - Complete Parent Host NEST checklist
Engaging Paid NICU Families as DR Liaisons During the Golden Hour
Nancy Kuemin JD / Stacey Tilbury MSN, NNP-BC

Parent Host Checklist

Press Ganey 2015-2016

Continuing to Develop Role: 2016

October

• PH meet with OB nursing leadership
• Shadow neonatal consult
• FAC input
• Begin offering tour to inpatient moms with neo consult

Antenatal tours

Antenatal NICU Tours

• Able to give tour to 80% of inpatient moms expecting a NICU admission Oct 2016-Aug 2017
• Clinic appointments
We begin: 2016

November

• GO LIVE!
• 2 of 3 hosts begin support

What do we tell families in DR?

• What’s happening
• Breathing
• Fluids
• Putting on standard monitor leads
• Who is who
• Physicians
• Nursing
• RT
• Students
• Chatting, calming, normalizing

Congratulations!

Moving forward: 2017

January

• Added in 3rd host

February

• Attended OB UBC

April

• DR staff survey sent

DR Staff survey results

• “[W]ith a short ‘report’ to [the PH], she was able to keep Dad with baby AND in communication with a Mom that wound up having to go to SICU post delivery! None of us could have pulled that off and taken care of the baby.”
• “I was hesitant about this role in the beginning but think it has been a fantastic addition to the NEST.”
• “While I most definitely want the opportunity to meet, talk, explain things to the parents myself as well, that isn’t possible ‘in the moment’. Having someone generally knowledgeable to support the parent initially is so important.”

Further Collaboration: 2017

May

• Met with OB doc and nursing
• Toronto on-site

July

• Parent “after” survey sent
Engaging Paid NICU Families as DR Liaisons During the Golden Hour
Nancy Kuemin JD / Stacey Tilbury MSN, NNP-BC

**Ideas from Toronto On-site**
- Combined OB/NICU time out
- Include PH in antenatal neonatal consultation

**Parent survey - After**
- Did you see your baby before taken to NEST?
  - Yes said 64%
- Dads who followed baby in NEST- what did you think of what you saw?
  - Overwhelming
- What was it like to touch the first time?
  - Scary

**Parent survey - After**
- Updated as often as you wanted?
  - 50-50
- Did photos ease mom’s stress?
  - Yes
- What do you wish you’d known?
  - Baby whisked away
  - Felt prepared
- What might have lessened stress?
  - Seeing baby
  - Updates

**Parent Survey - After**
- We asked the Dads: was the Parent Host of assistance?
  - 100% strongly agreed they felt supported by PH
  - 75% strongly agree and 25% agree
  - PH able to answer general questions
  - PH asked medical team to answer questions
  - PH helped make sure mom updated
  - PH helped take photos

**Baby Jack**
“Having the parent host present was an improvement over my last experience in the NEST. My interactions with [the PH] probably kept me from mentally/emotionally detaching myself from the situation.”

**How many births do PH attend?**
Engaging Paid NICU Families as DR Liaisons During the Golden Hour
Nancy Kuemin JD / Stacey Tilbury MSN, NNP-BC

Time to Update Mom vs Dad

Improving Time to Update

- So how can we do this?
  - Coordinate with OB to have PH enter operating room?
  - Text mom/her team updates: “baby breathing”
  - Exploring use of Facetime
  - Can make a plan during combined NICU/OB timeout

Time to Touch Mom vs Dad

Questions

- What are you doing to support families at birth/resuscitation?
- What is possible?
Team Examples of Mapping and Mining EMR Data for QI

**Jonathan Seigel MD, MMCi**
Neonatologist, WakeMed Health and Hospitals  
Associate Chief Medical Information Officer  
Medical Director, WakeMed Mothers’ Milk Bank  
Raleigh, NC

Dr. Jonathan Seigel is a board-certified Neonatologist who serves as a neonatologist for WakeMed Health and Hospitals in Raleigh, North Carolina. He received his medical degree from the University of Missouri - Columbia School of Medicine, completed his pediatric internship and residency at the University of North Carolina Hospitals, and completed his neonatal-perinatal fellowship at Duke University. Dr. Seigel also holds a master's degree in clinical informatics from Duke University's Fuqua School of Business. He completed his undergraduate education at Denison University in Granville, Ohio earning a bachelor's degree in biology as well as a bachelor's degree in economics. Dr. Seigel is a member of the American Academy of Pediatrics, the North Carolina Medical Society and the International Society for Research in Human Milk and Lactation. His interests outside of clinical medicine include the use and benefits of human milk in the preterm population, medical informatics and health information technology, and quality improvement research.

**James Perciaccante MD**
Pediatric Department Chair  
Neonatologist  
WakeMed Health and Hospitals  
Raleigh, NC

Dr. James Perciaccante is a neonatologist at WakeMed Health & Hospitals in Raleigh, NC. He currently serves as the Chair of the Department of pediatrics at WakeMed. He received his medical degree at SUNY Upstate Medical University in Syracuse, NY. He completed his pediatric residency and fellowships in neonatal-perinatal medicine at Wake Forest in Winston-Salem, NC. He also was awarded an NIH fellowship in the pathobiology of vascular disease while at Wake Forest University. Dr. Perciaccante is a member of the American Academy of Pediatrics and the North Carolina Medical Society.
Objective: Examine 3 key strategies and tactics that quality improvement teams used to avoid the need to manually collect data for their QI projects.
Exploratory Study of the Alarm Burden from Conventional Ventilation in the Neonatal Intensive Care Unit

Dupree Hatch MD, MPH

Learning Objectives
Examine 3 key strategies and tactics that quality improvement teams used to avoid the need to manually collect data for their QI projects.

Background
- Mechanical ventilation (MV) is common in the NICU
  - Ventilator technology has improved markedly in the last 50 years
- Alarms are a significant part of care in the NICU
  - Neonatal nurses are exposed to ~16.7 cardiorespiratory alarms per hour
  - 0.5% of cardiorespiratory alarms in children are “actionable”
  - Increased exposure to “non-actionable” alarms is associated with increased alarm response times
- No studies have quantified the alarm burden from MV

Reason for project

Setting
- Vanderbilt University Medical Center NICU
  - 96-bed, Level IV (regional), academic NICU
    - 20-bed open-bay unit
    - 76-bed single patient room unit
    - Connected by a long hall
  - ~1500 yearly admissions
    - 250-300 infants ≤1500 grams
    - ~125 infants <1000 grams
    - Cardiac and surgical infants
Exploratory Study of the Alarm Burden from Conventional Ventilation in the Neonatal Intensive Care Unit

Dupree Hatch MD, MPH

Setting

• Vanderbilt University Medical Center NICU
  – Staffed by ~500 nurses, respiratory therapists, physicians, fellows, residents, nurse practitioners
  – Protocols for initial ventilator alarm settings exist
  – 9/1/16-12/31/16

Potential Scope of the Problem

• During the 2016-2017 academic year:
  – 3723 ventilator days
  – 71,088 total hours of MV
  – 409 infants received MV
  – Three primary types of ventilation used:
    • Conventional MV-74%
    • High frequency jet-20%
    • High frequency oscillator-6%

Data Collection and Processing

• Data were downloaded to a USB drive from the ventilator at specific intervals
  – Three different files at each collection
  – Files are de-identified (IRB QI approval)
• Data files were merged, cleaned and transformed
  – R program 3.4.1
• Data were analyzed using STATA 14.2

Alarm Data Collection

Example patient with 32 days of consecutive ventilation that were all captured with data collection

Sept. 25

3

Infant is intubated

Sept. 25

7

Weekly manual ventilator downloads (Tuesdays)

Infant extubated

Performed by member of project team

Oct. 26

7

Final download performed by Respiratory Therapist

Data Cleaning and Transformation

Results- Total Alarms

• Total Conventional MV Time
  – By medical records review: 18,378 hours
  – Available ventilator data: 7,628 hours (42%)
• Ventilator alarms
  – Total: 118,063 (1 alarm per 3.9 minutes)
  – By alarm priority:
    • Low: 80,055 (68%)
    • Moderate: 24,994 (21%)
    • High: 13,014 (11%)
Exploratory Study of the Alarm Burden from Conventional Ventilation in the Neonatal Intensive Care Unit

Dupree Hatch MD, MPH

Alarms by Mode of Ventilation

- Volume-targeted modes
  - VC-SIMV: 61% of conventional MV
    - 1 alarm every 4.1 minutes
  - PC-PSV with VG: 22% of conventional MV
    - 1 alarm every 2.4 minutes
- Pressure-limited mode
  - PC-SIMV: 17% of conventional MV
    - 1 alarm every 8.3 minutes

Implications

- Alarms from conventional ventilators are common
  - ~767,000 alarms in our NICU annually
- Majority of these alarms are “nuisance” alarms
- Analysis of “green” ventilator data is feasible
- Strategies to decrease ventilator alarms in the setting of new ventilator technology are needed

Resources Needed

How could I replicate this at my center?

- Ventilators
  - With ability to capture alarms
- Personnel for data collection
  - Or automated data dumps
- Experience with data processing and analytics
  - Programming ability
- Data storage

Limitations/Barriers

- Takes specialized skills to process these data
  - Computational power (equipment)
  - Data processing programming skills (people)
- Data need to be fully validated
  - “Green data”
- Unable to capture all ventilator alarms
  - No data available on high frequency modalities
  - Missing data

What can we do with these “Green” Data?

Potential Future Uses

- Build custom alarm interventions for neonates
  - Drive the most evidence-based ventilation
- Use alarm patterns for prediction
  - Adverse events
  - De-escalation of care (extubation, weaning)
- Use alarms to analyze unit-level workload
- Build simulation scenarios for providers
Exploratory Study of the Alarm Burden from Conventional Ventilation in the Neonatal Intensive Care Unit

Dupree Hatch MD, MPH

Thank You

Timothy Newman
Dan France, PhD, MPH
Jason Slagle, PhD

NICU Respiratory Therapists who collected much of these data.

Parents and patients who allowed us to collect data.

Appendix

Thank you for your attention

Questions/Comments?

Dupree Hatch, MD, MPH
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Data Processing Program Step 1

Data Processing Program Step 3
The Art of the Audit: Best of VON Teams Share Audits That Drive Improvement

Roger F. Soll MD
President, Vermont Oxford Network
H. Wallace Professor of Neonatology
University of Vermont
Burlington, VT

Dr. Soll is the H. Wallace Professor of Neonatology at the University of Vermont College of Medicine, the President of Vermont Oxford Network, and Director of Network Clinical Trials. Dr. Soll is an authority on evidence-based medicine and randomized clinical trials. He is the coordinating editor of the Cochrane Neonatal Review Group of the Cochrane Collaboration and author or co-author of the Cochrane Reviews of surfactant therapy. He is the author of numerous peer reviewed articles and book chapters on the subject of surfactant replacement therapy and evidence-based medicine. A native of New York City, Dr. Soll graduated from Cornell University with a degree in Genetics and History of Science in 1975. He received his MD degree from the University of Health Sciences/Chicago Medical School in 1978. He returned to New York City to complete his residency training in Pediatrics at Bellevue Hospital/New York University Medical Center in 1981. After 2 years with the Public Health Service, Dr. Soll returned to academic training. He completed the post graduate fellowship in Neonatal Perinatal Medicine at the University of Vermont in 1983 and has remained in Vermont ever since.

Annual Quality Congress Breakout Session, Saturday, October 28, 2017
The Art of the Audit: Best of VON Teams Share Audits That Drive Improvement

Objective: Identify 3 novel strategies used by leading VON QI teams to perform simple audits to drive their quality improvement efforts.
The Art of the Audit
Roger F. Soll MD

Objectives
This workshop will highlight the evidence for data-driven improvement with the systematic use of audit and feedback and give participants the opportunity to discuss and design their own quality audit.

Identify 3 novel strategies used by leading VON QI teams to perform simple audits to drive their quality improvement efforts.

What type of audit do I plan on conducting?

**System Audit:** the who, what, where, when and how of the quality system used to produce its product.
  * “an inch deep but a mile wide”*

**Process Audit:** evaluation of the manner in which people, material, machines, etc., mesh together to produce a product.
  * “an inch wide but a mile deep.”*

**Product Audit:** detailed inspection of a finished product performed prior to delivering the product to the customer

**Compliance Audit:** Examines the written procedures, work instructions, contractual obligations, etc., and attempts to match them to the actions taken by the auditee to produce the product.
  * “say what you do—do what you say”*

Disclosure
Roger F. Soll is President of Vermont Oxford Network and the Coordinating Editor of Cochrane Neonatal.

Growing Literature, Stagnant Science?
Systematic Review, Meta-Regression and Cumulative Analysis of Audit and Feedback Interventions in Health Care

Noah M. Ivers, Jeremy M. Grimshaw, Gro Jamtvedt, Signe Flottorp, Mary Ann O’Brien, Simon D. French, Jane Young, and JanOgaard-Jensen.

The Art of the Audit
Roger F. Soll MD

Audit and Feedback

Audit and feedback is widely used as a strategy to improve professional practice, either on its own or as a key component of multifaceted quality improvement (QI) interventions.

Providing data regarding clinical performance may overcome health professionals’ limited abilities to accurately self-assess their performance.

It is posited that well-designed feedback demonstrates suboptimal performance for important and actionable targets, recipients are more likely to respond with efforts to improve quality of care.


Examples of Audits in Pediatric or Neonatal Medicine

The effectiveness of Audit and Feedback (A&F) has been evaluated in the third update of a Cochrane review, which included 140 randomized trials of A&F conducted across many clinical conditions and settings around the world.

The review found that A&F leads to a median 4.3% absolute improvement (interquartile range 0.5% to 16%) in provider compliance with desired practice.

One-quarter of A&F interventions had a relatively large, positive effect on quality of care, while another quarter had a negative or null effect.

Get Smart: Know When Antibiotics Work

Audit and feedback is a system of quality improvement that promotes individualized adherence to evidence-based practices.

The most effective methods involving audit and feedback are programs that compare individual clinician prescribing rates to co-workers’ or expected prescribing rates based on clinical practice guidelines.

In combination with clinician education, audit and feedback has been shown to be an effective method to improve antibiotic prescribing for common infections among outpatients.

http://www.cdc.gov/getsmart/community/improving-prescribing/interventions/audit-feedback.html

Effect of an outpatient antimicrobial stewardship intervention on broad-spectrum antibiotic prescribing by primary care pediatricians: A randomized trial.

Gerber JS, Prasad PA, Fiks AG, Localio AR, Grundmeyer RW, Bell LM, Wasserman RC, Keren R, Zaoutis TE.


Real time patient safety audits: improving safety every day.


Real time patient safety audits: improving safety every day.

Objective: Pilot study to determine the feasibility and utility of real time safety auditing during routine clinical work in an intensive care unit (ICU).

Methods: A 36 item patient safety checklist was developed via a modified Delphi technique. The checklist focused on errors associated with delays in care, equipment failure, diagnostic studies, information transfer and non-compliance with hospital policy.

Safety audits were performed using the checklist during and after morning work rounds thrice weekly during the 5 week study period from January to March 2003.
The Art of the Audit
Roger F. Soll MD

Real time patient safety audits: improving safety every day.

Random process audits, an industrial methods that could potentially be applied directly by front line clinical staff in real time; methods that would permit monitoring of a broad range of errors without draining time and energy from the busy staff.

Intuitive and simple method used routinely in banking, the pharmaceutical industry, and high risk industries such as steel manufacturing, has many of these characteristics.

In contrast to system and product quality audits which are typically done for purposes of formal evaluation, process audits are mainly used to engage employees directly in continuous improvement efforts.

Rather than attempting to monitor all potential errors all the time, random process auditing systematically chooses a subset of error prone points to monitor at any given moment, thereby permitting meaningful coverage of complex systems over time.

Results: A total of 338 errors were detected; 27 (75%) of the 36 items on the checklist detected >1 error.

Diverse error types were found including unlabeled medication at the bedside (n = 31), IO band missing or in an inappropriate location (n = 70), inappropriate pulse oximeter alarm setting (n = 22), and delay in communication/Information transfer that led to a delay in appropriate care (n = 4).

Conclusions: Real time safety audits performed during routine work can detect a broad range of errors. Significant safety problems were detected promptly, leading to rapid changes in policy and practice.

Staff acceptance was facilitated by fostering a blame free “culture of patient safety” involving clinical personnel in detection of remediable gaps in performance, and limiting the burden of data collection.

Policy Changes and Educational Initiatives resulting from information obtained via Safety Audit

• Development of a pulse oximeter saturation guideline.

• Education of the clinical staff as to optimal oxygen saturation targets for various clinical conditions.

• Change in the patient identification system used in the NICU.

• Education of the nursing staff as to the hospital policy concerning identification bands.

• Nursing leadership participation in a follow up safety audit study: revision of safety audit questions, creation of new safety audit questions, staff emails concerning findings of the study.

• An intermediate care unit in the hospital learned of the audits and started their own unit based safety audit system.

Improving Care for Neonatal Abstinence Syndrome


Pediatrics. May 2016, 37 (S) e20153835; DOI: 10.1542/peds.2015-3835
VON Days Quality Audits / NAS
Immediate “Feedback” to Individual Center

NICU and Hospital Length of Stay
for centers in both audits 1 and 4!

VON Day Quality Audit:
Choosing Antibiotics Wisely
148 Centers (143 NICUs and 5 Mother/ Baby Units) reviewed 4164 patients and completed a detailed audit of antibiotic use in 726 infants!

Infants on antibiotics due to late onset sepsis
18% of all infants treated with antibiotics on day of audit were being treated for late onset sepsis

Cultures obtained prior to therapy
Cultures obtained prior to therapy
Blood 87.2% 97.0% 22.6% 40.6%
VAP
NICU LOS
Hospital LOS

Maternal risk factors
Early onset infection
Late onset infection
VAP
CVC infection
UTI
Surgical site infection
UTI prophylaxis
Surgical prophylaxis
Fungal prophylaxis
MRSA colonization

2016 Choosing Antibiotics Wisely
The Art of the Audit
Roger F. Soll MD

Practice Feedback Interventions:
15 Suggestions for Optimizing Effectiveness

Jamie C. Brehaut, PhD, Heather L. Colquhoun, PhD, Kevin W. Eva, PhD, Kelly Carroll, MA, Anne Sales, PhD, Susan Michie, PhD, Noah Ivers, MD, PhD, Jeremy M. Grimshaw, MD, PhD.


Nature of the Action Sought
1. Recommend actions consistent with established goals and priorities. Feedback that supports actions consistent with established goals and priorities is more likely to be effective.
2. Recommend actions that can improve and are under the control of the recipient. Feedback should recommend actions that have room for improvement, and over which the recipient has control.
3. Recommend specific actions. Feedback that recommends specific rather than general actions is more likely to be effective.
4. Provide feedback multiple times.

Nature of the Data Available for Feedback
5. Provide feedback as soon as possible, at a frequency informed by the number of new patient cases.
6. Provide individual rather than general data. Evidence from psychology shows that feedback data that are specific to the individual recipient are usually more effective than data that summarize a group.
7. Choose comparators to reinforce desired behavior change. While feedback without an explicit comparison is feasible, practice feedback most often is given in the context of some kind of comparator or benchmark.
The Art of the Audit
Roger F. Soll MD

Display of the Feedback
8. Closely link the visual display and summary message. Feedback should include a verbal summary message and can often be effectively supported by visual or graphical elements.
10. Minimize extraneous cognitive load for recipients of feedback. (Cognitive load generally refers to effort required of short-term, working memory to process information; simpler, more easily processed information is said to entail less cognitive load).

Delivering the Feedback Intervention
11. Address barriers to use of feedback. Practice feedback interventions are likely to fail if they do not reach the intended target.
12. Provide short, actionable messages followed by optional detail.
13. Address credibility of the information (In order to enable practice change, feedback needs to be perceived as credible).
14. Prevent defensive reactions to feedback. Providing feedback often involves pointing out performance limitations that may elicit a defensive reaction in the recipient.
15. Construct feedback through social interaction. Effective feedback requires the recipient to actively work with the material, constructing and facilitating their own learning based on the data provided, often through social interaction.

Potentially ‘best practices’ when designing Audit and Feedback Interventions

<table>
<thead>
<tr>
<th>Audit components</th>
<th>Feedback components</th>
<th>Nature of the behavior change required</th>
<th>Targets, goals, and action plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data are valid</td>
<td>Presentation is multi-modal including either text and talking or text and graphical materials</td>
<td>Targeted behavior is likely to be amenable to feedback</td>
<td>The target performance is provided</td>
</tr>
<tr>
<td>Data is based on recent performance</td>
<td>Delivery comes from a trusted source</td>
<td>Recipients are capable and responsible for improvement</td>
<td>Goals set for the target behavior are aligned with personal and organizational priorities</td>
</tr>
<tr>
<td>Data are about the individual/team's own behavior(s)</td>
<td>Feedback includes comparison data with relevant others</td>
<td>Goals for target behavior are specific, measurable, achievable, relevant, time-bound</td>
<td>Goals for target behavior are specific, measurable, achievable, relevant, time-bound</td>
</tr>
</tbody>
</table>

What shall we audit?
Audit components
Feedback components
Nature of the behavior change required
Targets, goals, and action plan

What shall we audit?
Transfusion practice?
Delivery room teamwork?
Antibiotic utilization?
Let’s choose and discuss!

<table>
<thead>
<tr>
<th>Predictor</th>
<th>Scenario</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incidence of Early-Onset Sepsis</td>
<td>0.5/1000 live births (CDC National Incidence)</td>
</tr>
<tr>
<td>Gestational age</td>
<td>[enter weeks] [enter days]</td>
</tr>
<tr>
<td>Highest maternal antepartum temperature</td>
<td>[enter temperature]</td>
</tr>
<tr>
<td>ROM (Hours)</td>
<td>[enter hours]</td>
</tr>
<tr>
<td>Maternal GBS status</td>
<td>Negative, Positive, Unknown</td>
</tr>
<tr>
<td>Type of intrapartum antibiotics</td>
<td>Broad spectrum antibiotics &gt; 4 hrs prior to birth, Broad spectrum antibiotics 2–3.9 hrs prior to birth, GBS specific antibiotics &gt; 2 hrs prior to birth, No antibiotics or any antibiotics &lt; 2 hrs prior to birth</td>
</tr>
</tbody>
</table>
### The Art of the Audit

Roger F. Soll MD

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**CLINICAL PRESENTATION**

<table>
<thead>
<tr>
<th>Clinical Feature</th>
<th>Initial Approach</th>
<th>Further Evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poor Health</td>
<td>OBSERVE AND EVALUATE</td>
<td>TREAT EMPIRICALLY</td>
</tr>
<tr>
<td>Acute Illness</td>
<td>CONTINUE OBSERVATION</td>
<td>OR TREAT EMPIRICALLY</td>
</tr>
</tbody>
</table>

---

**Table:**

- **Simple task in 6th estimated three mortal risk factors**

- **0-0.5%3000** Risk factor
- **0.5-39%-3000** Risk factor
- **>39%-3000** Risk factor

---

**Data drowns members**

Too much information to process and improve

Audits provide much needed tool
Dr. Sonia Lomeli Bonifacio joined the Stanford faculty in May of 2015 and is the Associate Medical Director of the NeuroNICU. Sonia is a native San Franciscan and completed all of her medical training, medical school through fellowship, at the University of California in San Francisco. She was on the faculty at UCSF from 2009 to 2015 and was the Director of the Neuro-Intensive Care Nursery. Dr. Bonifacio is currently an Associate Professor of Pediatrics at Stanford. Her primary research interests are the neurodevelopmental outcomes of preterm and sick term newborns. During her fellowship, she worked under the mentorship of Drs. Donna Ferriero, Jim Barkovich, and Steven Miller. She plans to continue her work regarding the use of Magnetic Resonance Imaging as a predictor of outcomes in these at risk patient populations. In particular, she is interested in the impact of focused neurological care and its effects on neurodevelopmental outcome. Recent work includes studying the effect of hypothermia therapy on magnetic resonance imaging findings.

Dr. Dmitry Dukhovny is a board-certified Pediatrician and Neonatologist and a Pediatric Health Services Researcher. His academic focus involves applying cost-effectiveness analysis and decision science to help optimize resource utilization and allocation in perinatal care, a critical issue given the current constraints on the health care system. Dr. Dukhovny also has a strong interest and focus in medical education and leadership. He is currently the associate program director of the Neonatal Perinatal Medicine Fellowship at OHSU. With his colleagues at Oregon Health & Science University (OHSU), he developed an improvement science curriculum for the Neonatology fellows at OHSU, as well as continuing to expand educational opportunities in improvement science for all Neonatology nationally in his role as the Fellow liaison for VON in partnership with the Section of Neonatal-Perinatal Medicine of the AAP. Currently, he is co-leading the regional effort to improve antibiotic stewardship in Oregon and Southwest Washington, involving all 11 NICUs in the region under the Northwest Improvement Priority: Antibiotic Stewardship (NW IPAs). He has presented and organized workshops at national conferences, including Pediatric Academic Societies, Vermont Oxford Network Annual Quality Congress, and Perinatal Workshop.
Bonnie DiPietro RN, MS
Director of Operations
Maryland Patient Safety Center
Elkridge, MD

Bonnie DiPietro is a Registered Nurse with over thirty five years of experience in clinical, educational and managerial positions. She has served as the Director of Operations at the Maryland Patient Safety Center for over four years. In that role she provides coordination and oversight to the organization’s many patient safety collaboratives, and has developed highly successful strategies for participant recruitment and successful outcomes and goal achievement. Bonnie has a reputation as a hard-working, supportive and approachable program leader.

Heather Kaplan MD, MSCE
Assistant Professor of Pediatrics,
Perinatal Institute and The James M. Anderson Center for Health Systems Excellence,
Cincinnati Children’s Hospital Medical Center
Cincinnati, OH

Heather Kaplan MD, MSCE is an Assistant Professor of Pediatrics in the Perinatal Institute and the James M. Anderson Center for Health Systems Excellence at Cincinnati Children’s Hospital Medical Center (CCHMC). Heather is a neonatologist and health services researcher interested in enhancing care delivery and studying how systems of care can be improved using innovative approaches. She completed her neonatal-perinatal fellowship training, including earning a Master's degree of science in clinical epidemiology, at The Children's Hospital of Philadelphia/University of Pennsylvania. She joined the faculty at CCHMC in August 2007. Heather's early research focused on understanding variation in adoption of evidence-based practices in neonatal care and quality improvement as a strategy for implementing evidence in practice. With funding from the Robert Wood Johnson Foundation, she studied the role of context in the success of quality improvement initiatives and developed a model, the Model for Understanding Success in Quality (MUSIQ). MUSIQ is a tool for developing theories about which aspects of context help or hinder a specific project, and designing and implementing tests of changes to modify those aspects of context. Her current work examines the way research and improvement networks ("learning networks") can be used to improve care delivery and outcomes. She is specifically interested in scaling improvement to reach entire populations of patients and the ways technology, quality improvement methods, and N-of-1 trial methods can be combined to create a personalized learning healthcare system for the individual. Heather also has extensive experience with front-line quality improvement in perinatal care. Dr. Kaplan serves as the Improvement Advisor for the Ohio Perinatal Quality Collaborative (OPQC) neonatal improvement work. She also serves as a faculty expert for Vermont Oxford Network quality collaboratives and has been working with teams to improve their system of improvement by using MUSIQ to identify and modify key aspects of context that are affecting the success of the quality improvement projects and to help them engage with senior leadership around their improvement work.
Annual Quality Congress Breakout Session, Saturday, October 28, 2017
Learning from Innovative Statewide Quality Improvement Projects - Part 1

Objective: Analyze key aspects of state and health system quality improvement projects that might be generalizable to your regional context.
Northwest Neonatal Improvement Priority Alliance (NW IPA)
Multi-center QI Regional Collaboration among
11 NICUs in the Pacific Northwest

Dmitry Dukhovny MD, MPH

Disclosure
Dr. Dukhovny serves as faculty and consultant for Vermont Oxford Network; and consultant for Gerson Lehrman Group.

Objective
Analyze key aspects of state and health system quality improvement projects that might be generalizable to your regional context.

Teamwork: NW IPAs
• Kaiser Sunnyside Portland, OR
• Legacy Randall Children’s Hospital Portland, OR
• Legacy Salmon Creek Salmon Creek, WA
• Oregon Health & Science University Portland, OR
• PeaceHealth SW Vancouver, WA
• PeaceHealth Sacred Heart Eugene, OR
• Providence Portland Portland, OR
• Providence St. Vincent Portland, OR
• Asante Rogue Regional Medical Center Medford, OR
• Salem Hospital Salem, OR
• St. Charles Bend, OR

Setting
• 11 NICUs - Oregon and Southwest Washington
• All VON members
  ➢ All other hospitals/birthing centers in the region provide care to well newborn, as well as triage and stabilize newborns with issues
  ➢ ~50,000 live births/ year regionally
• 2016 Prematurity rate of 7.5% OR; 8.1% WA
✓ All 11 NICUs formed a collaborative – NW IPAs – Northwest Improvement Priority Alliance
✓ Concurrently joined VON 2016 Quality Improvement Collaborative: Choosing Antibiotics Wisely as a Statewide Partner (and 2017)
✓ Launched January 2016

Overall Aims
• Build an ongoing regional collaboration among the 11 NICUs in the region in order to help reduce morbidity and mortality in our patient population
• Develop a partnership with the Oregon Health Authority (OHA), March of Dimes, Oregon Perinatal Collaborative (OPC), Oregon Pediatric Improvement Partnership (OPIP) and other local/regional organizations to help optimize neonatal care and outcomes
Northwest Neonatal Improvement Priority Alliance (NW IPA)  
Multi-center QI Regional Collaboration among  
11 NICUs in the Pacific Northwest  

Dmitry Dukhovny MD, MPH

SMART Aims

- At the start of the project in January 2016, our SMART aim was to decrease the number of antibiotic days per 1,000 patient for the collaborative from a baseline of 197 (Median for 2015) to 180 antibiotic days per 1,000 patient days by December 2016 (a goal that we exceeded)

- In January 2017, we extended that goal by an additional 10% from the 155 (Median for 2016) to 140 antibiotic days per 1,000 patient days by December 2017

Key Drivers

- SMART AIM: To decrease the median antibiotic utilization rate (antibiotics/newborn/participating hospital/month) by 10% (from baseline year of 2016) in 2017

- Partner with other state and regional organizations involved in perinatal health and antibiotic stewardship
  - Oregon Health Authority (OHA)
  - March of Dimes
  - Oregon Perinatal Collaborative (OPC)
  - Oregon Pediatric Improvement Partnership (OPIP)

- Begin working together and sharing ideas as 11 NICUs
- Set up a venue for communication
- Set up additional teleconferences focused on regional antibiotic stewardship work
- Enroll in iNICQ 2016, 2017 as a region

Plan-Do-Study-Act - 2016

- PDSA 1 – Engaged leaders from each of the 11 NICUs to collaborate
- PDSA 2 – Joined VON iNICQ Choosing Antibiotics Wisely Initiative as a collaborative (NW IPAs)
- PDSA 3 – Assigned coaches to each of the 11 centers in NW IPAs
- PDSA 4 – Formed a regional listserv for communication and idea sharing
- PDSA 5 – Engaged state agencies (OHA, March of Dimes, OPC) as partners
- PDSA 6 – The 2016 Inaugural NW IPAs Meeting!

Plan-Do-Study-Act - 2017

- PDSA 7 – Joined VON iNICQ Choosing Antibiotics Wisely 2017 (with funding from the OHA for all 11 NICUs to participate)
- PDSA 8 – Monthly VON Day Audits
- PDSA 9 – Initiated conversations with OPIP for NW IPAs to join the group
- PDSA 10 – 2017 2nd Annual NW IPAs Meeting! (September 2017)

Measures

<table>
<thead>
<tr>
<th>Measure Type</th>
<th>Description</th>
<th>Number of NICUs participating</th>
<th>Source of Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outcome</td>
<td>AUR (CDC definition) monthly measure of AUR (number of antibiotic days per 1,000 patient days)</td>
<td>All</td>
<td>NW IPA Leadership</td>
</tr>
<tr>
<td>Process Measure</td>
<td>% centers participating in intervention activities per NW IPA group activities</td>
<td>All</td>
<td>NW IPA Leadership</td>
</tr>
<tr>
<td>Balancing Measures</td>
<td>NIC VON Nightingale measure (50MB)</td>
<td>All</td>
<td>VON Nightingale</td>
</tr>
<tr>
<td>Any infection</td>
<td>VON Nightingale measure (expanded database)</td>
<td>All</td>
<td>VON Nightingale</td>
</tr>
<tr>
<td>Family-Centered Care</td>
<td>Not yet developed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Value Measure</td>
<td>Not yet developed</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Results
Northwest Neonatal Improvement Priority Alliance (NW IPA)
Multi-center QI Regional Collaboration among
11 NICUs in the Pacific Northwest

Dmitry Dukhovny MD, MPH

**Antibiotic Utilization Within NW IPAs - 2016**
Baseline VON Day Audit Feb 2016 (10 centers)

**Antibiotic Utilization Within NW IPAs - 2017**
NW IPAs By Center Comparison of Antibiotic Utilization Rate - CDC Definition January 2015 to July 2016 [n=7 centers]

NW IPAs AUR Jan 2015 – May 2017
- Y-axis (left) – AUR
- Y-axis (right) – total patient days for NW IPAs
- X-axis – month/year
- Thick dark blue line – total AUR for ALL 11 participating centers in NW IPAs
- Individual lines – NW IPAs individual centers monthly AUR

-25% reduction from baseline in antibiotic utilization

Which antibiotics are we using? Day Audits Jan-Sept 2017

Discussion
- NW IPAs have successfully engaged all 11 NICUs in the region, as well as other regional stakeholders (i.e. OHA, March of Dimes, OPC, OPIP) in collaboration and participation around antibiotic stewardship
- All 11 NICUs have been able to determine their AUR using the CDC definition
  - Labor intensive (lots of manual work)
  - Need to account for accuracy
  - Ampicillin and Gentamicin are still the dominant antibiotics (good news or bad news?)
  - Initial antibiotic stewardship has a lot of low hanging fruit to decrease the AUR, but…

Next Steps
- Need to understand the AUR with respect to:
  - Within and between center variation
  - Relationship to census
  - Adjusting for acuity (first look by type of NICU – A, B, C)
  - Setting reasonable benchmarks
- Organization of NW IPAs (e.g. bylaws, mission, vision, etc.)
- Determine plans for 2018
  - NW IPA Priority: Keep ALL the centers engaged and keep doing on the ground quality improvement work!!!
Northwest Neonatal Improvement Priority Alliance (NW IPA)  
Multi-center QI Regional Collaboration among  
11 NICUs in the Pacific Northwest

Dmitry Dukhovny MD, MPH

Thank you
• Just the team leaders are listed here, although there are over 90 participants between the 11 sites (including physicians, nurses, nurse practitioners, pharmacists, parents, fellows and medical students)
- Kaiser Sunnyside (Portland, OR)
  • Kevin Sweeney (Portland, OR)
- Legacy Emanuel (Portland, OR)
  • Dmitry Dukhovny, MD MPH, Robert Schelonka, MD
- Legacy Salmon Creek (Salmon Creek, WA)
  • Bret Freitag, MD
- Oregon Health & Science University (Portland, OR)
  • Dmitry Dukhovny, MD MPH, Robert Schelonka, MD
- PeaceHealth Southwest (Vancouver, WA)
  • John Evered, MD, Wannasiri Lapcharoensap, MD, Tiffany Wright, NNP
- PeaceHealth Sacred Heart (Eugene, OR)
  • Mike Colasurdo, MD
- Providence Portland (Portland, OR)
  • Fred Baker, MD, Michael Garcia, PharmD, Tiffany Transue, RN, AnneMarie West, RN
- Providence St. Vincent (Portland, OR)
  • Stefanie Rogers, MD
- Asante Rogue Regional Medical Center (Medford, OR)
  • Katie Townes, DO, Tiffany Price, RN, Barbera Herzog Taft, RN
- Salem Hospital (Salem, OR)
  • Howard Cohen, MD, Cindy Davis, NNP, Ryan Lam, MD
- St. Charles (Bend, OR)
  • Robert Pfister, MD

Thank you
• The work of the NW IPAs is on behalf of the Antibiotic Stewardship Teams in the 11 individual sites
• NW IPAs Leadership
  – Wannasiri “Awe” Lapcharoensap, MD (OHSU)
  – Howard Cohen, MD (Salem Hospital)
  – Stefanie Rogers, MD (Providence St. Vincent)
• Infectious Disease/Control Support
  – Judith Guzman-Cottrill, DO (OHSU)
  – Dawn Nolt, MD MPH (OHSU)
• Support
  – Oregon Health Authority with funding from the CDC Epidemiology and Laboratory Capacity Grant
  – March of Dimes (Joanne Rogovoy)
• Collaborators:
  – Vermont Oxford Network (Madge E. Buus-Frank, DNP, APRN-BC, FAAN)
  – Oregon Pediatric Improvement Partnership (Colleen Reuland)
  – Oregon Perinatal Collaborative (Aaron Caughey, MD PhD)
NAS: Improving Care to Improve Outcomes
A Maryland Statewide Collaborative
Bonnie DiPietro RN, MS

Disclosure
Bonnie DiPietro has no conflicts to disclose

Learning Objectives
1. Analyze key aspects of state and health system quality improvement projects that might be generalizable to your regional context.
2. Describe the activities utilized in Maryland that lead to and established the Neonatal Abstinence Syndrome Collaborative.
3. Discuss the benefits of Maryland’s partnership with VON and access to the State-wide Implementation Package.
4. Identify the Maryland Collaborative goals and early results.

This Collaborative is funded by the
Maryland Department of Health
Maternal and Child Health Bureau

How did Maryland get started?
Q2: Does your hospital employ a standard screening (interview) tool to identify the use of opioids and/or other substances in pregnant women when they present to Labor and Delivery?

- Answered: 32 Skipped: 0

Q16: Do you have a policy that details first-line pharmacologic treatment?

- Answered: 32 Skipped: 0
NAS: Improving Care to Improve Outcomes
A Maryland Statewide Collaborative

Bonnie DiPietro RN, MS

Collaborative Timeline

- Fall 2015 to early 2016: Shaping structure for collaborative delineation and action
- Contacted with VON: Fall 2015, contacted with Dr. Mark Hudak
- Spring 2016: VON met and trained through Dr. Hudak
- June 2016: Confirmed partnership with VON to use NAS statewide implementation package
- July-August 2016: Recruitment of collaborative participants: 33 of 52 with hospital agreement to participate
- October 7, 2016: MD Collaborative kick-off meeting
- October 17-21, 2016: VON day audit
- Nov. 2016 to Aug. 2018: Collaboration calls, webinar, facility consultations, attitude survey, process measures, formal Year 1 in Face-to-Face meetings
- November 12, 2017: Second annual face-to-face
- September, October 2018: Second VON day audit
- November, 2018: Final Year 1 in Face

Goals of the MPSC NAS Collaborative

1. Reduce LOS in infants with NAS
2. Reduce 30-day readmissions of infants with NAS
3. Decrease transfers from birthing hospital to higher or extended levels of care for infants with NAS

Why we partnered with VON

- VON offers data-driven, action-oriented learning for improving outcomes and increasing the quality, safety, and value of newborn care.
- Our partnership with VON allows our participants to access to interactive reporting tools, established curricula and educational modules for quality improvement.
- The partnership with VON accelerated the work of our NAS collaborative.
- We had the funding to provide access for all 32 hospitals

One year highlights of the MD Collaborative

- Have a baseline LOS from VON day audit and baseline LOS from discharge data from the Health Department
- Learned that our VON day audit LOS was 19 days, whereas our state data showed 12 days. This revealed that the state data does not include the days from transfers to higher or extended level of care, whereas the VON day audit does
- VON shared an attitude survey which we conducted at the onset and will repeat at end of collaborative
- Developed our own MPSC NAS bundle
- Developed quarterly process measures surveys based on the MD NAS Bundle
- All but one birthing hospital participating – leaving us the opportunity to include a pediatric specialty hospital
- Excellent engagement of participating facilities

Challenges we have faced

- Will not have another VON day audit for 2 years
- Determining readmission rates
- Obtaining transfer rate data – only four hospitals in Maryland transfer for medical management of NAS
- Tracking monthly the number of completed modules per hospital; some glitches, but being corrected
- IT policies of one hospital blocked staff receiving outside e-mails
- Dependence on VON to reset passwords, generate reports: our participants are used to contacting us for such things.

How is Maryland Doing?
VON Modules in Maryland

- 32 Hospitals with access
- 3355 registered users as of August 31, 2017
- Registered users per hospital range from 14 to 322
- Potential for completion of 60,390 modules (3355 X 18 modules)
- Total modules completed as of August 2017: 19602 (32.5% of possible)

Four hospitals with no participation at all - interesting to note that 3 of those four do not treat medically, and the other reports very few cases. Not a priority?
NAS: Improving Care to Improve Outcomes  
A Maryland Statewide Collaborative  
Bonnie DiPietro RN, MS

**Selected References**


**Questions**

**Contact Information:**
Bonnie DiPietro  
b dipietro@marylandpatientsafety.org
Danielle Ehret graduated with honors from Cornell University with a Bachelor of Science degree in Human Biology, Health and Society. She received her MD from the State University of New York Upstate Medical University, during which she was inducted into the Gold Humanism Honor Society. Following her medical training, she was recruited to the pediatrics residency at Yale New Haven Children’s Hospital. While at Yale, she completed the pediatric global health track. As a resident, Danielle became a Master Trainer in the Helping Babies Breathe program and helped to educate local birth attendants in Rwanda.

Danielle pursued her passion of global maternal child health by simultaneously completing her fellowship in neonatal-perinatal medicine while obtaining her Master’s degree in Public Health at Harvard. She worked with Dr. Patricia Hibberd, Chief of the Division of Global Health at MassGeneral Hospital for Children. They utilized NIH Global Network site-specific data from Nagpur, India to evaluate Essential Newborn Care practices, and their relationship to neonatal outcomes in the Maternal Newborn Health registry. Locally, Danielle led a quality improvement project at Beth Israel Deaconess Medical Center with Dr. Munish Gupta involving the implementation of a timed umbilical cord clamping policy for preterm infants. Danielle was chosen to serve as co-chief fellow for 2014-2015.

Her dedication to education was also recognized with the Excellence in Teaching Award from her fellowship, the House Officer Development Award and Von L. Meyer Award from Boston Children’s Hospital, and the Martha May Eliot Scholarship from the Harvard School of Public Health. Danielle joined the faculty at UVM Children’s Hospital Division of Neonatology in July 2015, as assistant professor. She was also named as the inaugural Director of Global Health for the Vermont Oxford Network. Under the mentorship of Drs. Jeffrey Horbar and Roger Soll, she seeks to devote her academic work with VON to the synergy of quality improvement and implementation of evidence-based neonatal care practices globally. Under her leadership, VON’s Black Lion NICU project in Ethiopia will continue to evolve to meet the goals of a 2015 post-Millennium Developmental goal era.

**Objectives:**
1. Describe current national guidelines for antenatal steroids (ANS)
2. Recall key controversies and clinical quandaries
3. Summarize care delivery and outcomes for extremely premature infants in VON
4. Identify opportunities for improvement at the patient, hospital, referral network and national levels
Vermont Oxford Network Data at the “Edges” of Viability
Danielle Ehret MD, MPH

Learning Objectives
- Describe current national guidelines for antenatal steroids (ANS)
- Recall key controversies and clinical quandaries
- Summarize care delivery and outcomes for extremely premature infants in Vermont Oxford Network
- Identify opportunities for improvement at the patient, hospital, referral network and national levels

Current ACOG Guidelines
- Resuscitation: Consider at 22 weeks, Consider at 23 weeks, YES at 24 weeks
- Antenatal Steroids: NO at 22 weeks, Consider at 23 weeks, YES at 24 weeks

Background
- Variability in postnatal life support
- Variability in survival
- Quandary at 22 weeks: limited data, discordant recommendations
- Challenge of “shared decision-making”

Translating Practice into Evidence
Vermont Oxford Network 2012 - 2016:
- Provision of ANS and postnatal life support at 22 to 25 weeks
  - Association of ANS with survival to hospital discharge
  - Association of ANS with survival without major morbidities

Conflict of Interest Disclosure
Danielle Ehret
I have no financial relationships with a commercial entity producing healthcare-related products and/or services.
Vermont Oxford Network Data at the “Edges” of Viability

Danielle Ehret MD, MPH

Vermont Oxford Network 2012-2016

- 431 hospitals
  - VON member hospitals in US
  - Level III and IV NICUs that perform surgery on neonates
  - Median 66 infants per hospital

- 29,933 infants received postnatal life support
  - 22 weeks: 1,058 infants
  - 23 weeks: 6,371 infants
  - 24 weeks: 10,508 infants
  - 25 weeks: 11,996 infants

Demographics

- Postnatal Life Support
  - N=29,933
- Palliative Care
  - N=3,540
- No ANS Exposure
  - N=3,842
- ANS Exposure
  - N=26,091

<table>
<thead>
<tr>
<th>Demographics</th>
<th>No Antenatal Steroids</th>
<th>Antenatal Steroids</th>
</tr>
</thead>
<tbody>
<tr>
<td>Received prenatal care (%)</td>
<td>88</td>
<td>97</td>
</tr>
<tr>
<td>Race and Ethnic Group **</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black non-Hispanic (%)</td>
<td>41</td>
<td>35</td>
</tr>
<tr>
<td>White non-Hispanic (%)</td>
<td>33</td>
<td>40</td>
</tr>
<tr>
<td>Hispanic (%)</td>
<td>21</td>
<td>19</td>
</tr>
<tr>
<td>C-section (%)</td>
<td>52</td>
<td>67</td>
</tr>
<tr>
<td>Small for Gestational Age (%)</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Mean birth weight (grams)</td>
<td>655</td>
<td>670</td>
</tr>
</tbody>
</table>

**Race and ethnic group were self-reported P < .05 for all variables

Gestational Age

<table>
<thead>
<tr>
<th>Gestational Age</th>
<th>Proportion of infants receiving postnatal life support with ANS exposure (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>22 weeks</td>
<td>52</td>
</tr>
<tr>
<td>23 weeks</td>
<td>83</td>
</tr>
<tr>
<td>24 weeks</td>
<td>89</td>
</tr>
<tr>
<td>25 weeks</td>
<td>91</td>
</tr>
</tbody>
</table>

Survival (%)

<table>
<thead>
<tr>
<th>Gestational Age</th>
<th>Postnatal Life Support Only</th>
<th>Postnatal Life Support with ANS Exposure</th>
<th>aRR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>22 weeks</td>
<td>17.1</td>
<td>38.5</td>
<td>2.13 (1.70-2.68)</td>
</tr>
<tr>
<td>23 weeks</td>
<td>35.6</td>
<td>55.4</td>
<td>1.56 (1.41-1.72)</td>
</tr>
<tr>
<td>24 weeks</td>
<td>59.6</td>
<td>71.3</td>
<td>1.20 (1.14-1.27)</td>
</tr>
<tr>
<td>25 weeks</td>
<td>75.7</td>
<td>83.0</td>
<td>1.11 (1.07-1.14)</td>
</tr>
<tr>
<td>22-25 weeks</td>
<td>51.9</td>
<td>72.3</td>
<td>1.38 (1.33-1.43)</td>
</tr>
</tbody>
</table>
Vermont Oxford Network Data at the “Edges” of Viability

Danielle Ehret MD, MPH

Survival without Major Morbidities

- Composite:
  - Chronic Lung Disease (CLD)
  - Severe Intraventricular Hemorrhage (sIVH)
  - Cystic Periventricular Leukomalacia (PVL)
  - Necrotizing Enterocolitis (NEC)
  - Culture-confirmed Infection
  - Severe Retinopathy of Prematurity (sROP)

Survival without Major Morbidity (%)

<table>
<thead>
<tr>
<th>Gestational Age</th>
<th>Postnatal Life Support Only</th>
<th>Postnatal Life Support with Antenatal Steroid Exposure</th>
<th>aRR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>22 weeks</td>
<td>1.0</td>
<td>4.4</td>
<td>4.21 (1.81-9.80)</td>
</tr>
<tr>
<td>23 weeks</td>
<td>2.8</td>
<td>5.9</td>
<td>2.32 (1.04-5.19)</td>
</tr>
<tr>
<td>24 weeks</td>
<td>9.5</td>
<td>11.4</td>
<td>1.23 (0.99-1.49)</td>
</tr>
<tr>
<td>25 weeks</td>
<td>18.8</td>
<td>22.2</td>
<td>1.24 (1.08-1.42)</td>
</tr>
<tr>
<td>22-25 weeks</td>
<td>9.1</td>
<td>14.6</td>
<td>1.24 (1.08-1.42)</td>
</tr>
</tbody>
</table>

Morbidities Among Survivors

<table>
<thead>
<tr>
<th>22-25 weeks</th>
<th>Postnatal Life Support Only</th>
<th>Postnatal Life Support with ANS Exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Survival without CLD</td>
<td>36.0</td>
<td>35.1</td>
</tr>
<tr>
<td>Survival without sIVH</td>
<td>74.3</td>
<td>86.3</td>
</tr>
<tr>
<td>Survival without PVL</td>
<td>92.3</td>
<td>95.3</td>
</tr>
<tr>
<td>Survival without NEC</td>
<td>91.8</td>
<td>92.2</td>
</tr>
<tr>
<td>Survival without infection</td>
<td>69.9</td>
<td>73.1</td>
</tr>
<tr>
<td>Survival without sROP</td>
<td>74.5</td>
<td>75.2</td>
</tr>
</tbody>
</table>

Summary

- Many infants born at 22 and 23 weeks’ gestation received postnatal life support but lacked exposure to ANS
- Receipt of ANS was associated with higher survival and survival without major morbidities

Potential Opportunities for Improvement

- Advocacy: Explore disparities, follow-up and follow-through, improved coordination
- Improved OB-NICU coordination
- Evidence-based counseling, shared decision-making

Implications- Improved Coordination

<table>
<thead>
<tr>
<th>22 Weeks</th>
<th>23 Weeks</th>
<th>24 Weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resuscitation</td>
<td>Consider</td>
<td>Consider</td>
</tr>
<tr>
<td>Antenatal Steroids</td>
<td>NO</td>
<td>Consider</td>
</tr>
</tbody>
</table>
Vermont Oxford Network Data at the “Edges” of Viability

Danielle Ehret MD, MPH

Implications - Improved Coordination

<table>
<thead>
<tr>
<th>22 Weeks</th>
<th>23 Weeks</th>
<th>24 Weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>CONSIDER</td>
<td>Consider</td>
<td>YES</td>
</tr>
</tbody>
</table>

Antenatal Steroids and Neonatal Assessment for Resuscitation

Thank you

Questions?

Dehret@vtoxford.org
Controversies With Using “Calculators” or “Estimators”

Matthew Rysavy MD, PhD
Resident Physician,
Department of Pediatrics
University of Wisconsin
Madison, WI

Dr. Rysavy received his MD and PhD in epidemiology at the University of Iowa, where his thesis work focused on perinatal prognosis. He has published widely on this topic in journals including Pediatrics, JAMA Pediatrics, the Journal of Pediatrics, and the New England Journal of Medicine. His work has been covered by news outlets including The New York Times, The Economist, and NPR. He is currently leading an update of the widely used NICHD Neonatal Research Network extremely preterm birth outcome estimator.

Objective: Compare and contrast the impact of calculating survival and survival without disability based upon NICHD data, VON data, or locally derived outcomes.
Controversies With Using “Calculators” or “Estimators”

Matthew Rysavy MD, PhD

Learning Objective

Compare and contrast the impact of calculating survival and survival without disability based upon NICHD data, VON data, or locally derived outcomes.

Disclosure

Matthew Rysavy MD, PhD has no financial relationships or conflicts of interest to disclose.

“Medicine is a science of uncertainty and an art of probability.”

--- William Osler

Prognosis = “what to expect”

- pro = before
- gnosis = knowing

Prognosis allows eliciting and incorporating patient values and preferences.

Excluding prognosis leads to “cookbook medicine.”
Controversies With Using “Calculators” or “Estimators”
Matthew Rysavy MD, PhD

Controversy #1:
The weatherman’s predicament

Controversy #2:
The “center effect” on outcomes

Prognosis research interpretation:
– For groups -> Rates
  “Rate of death after extremely preterm birth is 40 in 100”
– For individuals* -> Risks (Probabilities)
  “Risk of death for an extremely preterm infant is 40%”

*For an individual, the rate will be either 0 or 1.
Clinicians need to be able to quote up-to-date and relevant information to parents facing the prospect of extremely low gestational age birth, and much has been made about improved precision in risk. The [NICHD NRN] provides data on outcomes of infants born at low gestational ages, which vary with birth weight, fetal sex, and the use of corticosteroids. This network provides an online calculator to refine this risk. For a parent facing a decision on what action the clinical staff should take during labor and after birth, these variations are somewhat irrelevant in the context of their child's birthplace.

Marlow N. JAMA Pediatr. 2015

Relative contribution of predictors to the multivariable model

<table>
<thead>
<tr>
<th>Predictor</th>
<th>Survival</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birth weight</td>
<td>35.8%</td>
</tr>
<tr>
<td>Infant sex</td>
<td>14.5%</td>
</tr>
<tr>
<td>Antenatal corticosteroids</td>
<td>8.4%</td>
</tr>
<tr>
<td>Plurality</td>
<td>0.7%</td>
</tr>
<tr>
<td>Gestational age</td>
<td>20.9%</td>
</tr>
<tr>
<td>Center of birth</td>
<td><strong>19.6%</strong></td>
</tr>
</tbody>
</table>

Why not just use local statistics?

- Small sample sizes
- Lack precision with variables
- High variability
- “Self-fulfilling” prognosis

Controversy #3: The “self-fulfilling” prognosis
Controversies With Using “Calculators” or “Estimators”
Matthew Rysavy MD, PhD

Updated NICHD NRN five-factor model using data for infants born 2006-2012

Included:
- 22-25 wk GA
- 400-1000 g

Excluded:
- syndromes/malformations
- ≥97%ile birth weight for GA

Evaluated the new model in VON
Outcome = death before discharge

Key difference:
Accounted for “center effects” in estimate
Controversies With Using “Calculators” or “Estimators”
Matthew Rysavy MD, PhD

Updated model better reflects contemporary outcomes
Center-specific estimates are more accurate
Center specific estimates reliable over time

But what does this mean for practice?

It’s tough to make predictions, especially about the future.

-Yogi Berra

References
Health disparities persist despite intervention to increase use of antenatal corticosteroids in mothers with preeclampsia

Improvement Podium Brief

Margarita Bidegain MD
Professor of Pediatrics-Neonatology
Duke University School of Medicine
Durham, North Carolina

Dr. Margarita Bidegain is a neonatologist and palliative care physician at Duke University. Her career has focused on developing new approaches to improving the quality of life of infants with serious clinical conditions. Her leadership roles also include diversity and inclusion and reducing health inequities in infant health.

Annual Quality Congress Breakout Session, Sunday, October 29, 2017
Health disparities persist despite intervention to increase use of antenatal corticosteroids in mothers with preeclampsia

Objective: Identify 3 critical improvement methods or strategies employed by this improvement team to effect measurable improvement in the quality, safety and value of care for newborns.
Health disparities persist despite intervention to increase use of antenatal corticosteroids in mothers with preeclampsia

Margarita Bidegain MD

**Health disparities persist despite intervention to increase use of antenatal corticosteroids in mothers with preeclampsia**

Margarita Bidegain MD 1

Rachel Greenberg MD1,2,3, Noelle Young MD1, Michael Cotton MD1, Marty McCaffrey MD1, Amy Murtha, MD1, Susan Gutierrez, BSN, RNC-NC1, Arthur Ollendorff MD1,2

1. Department of Pediatrics, Division of Neonatology
2. Duke Clinical Research Institute
3. Department of OB/GYN, Maternal Fetal Medicine
4. Department of Pediatrics, Division of Neonatology, University of North Carolina, Chapel Hill, NC
5. Department of OB/GYN/ MANC, Mission Hospital, Asheville, NC
6. Perinatal Quality Collaborative of North Carolina

Disclosure: I have no relevant financial relationships with the manufacturer(s) of any commercial product(s) and/or provider(s) of commercial services discussed in this presentation

**Aims**

1) Increase the rate of administration of a full course of Antenatal Corticosteroids for mothers with preeclampsia who deliver at <34 weeks, from baseline of 79% to 85% between March 2015 and April 2017

2) Describe variations in the rate of administration of a full course of Antenatal Corticosteroids by center level, maternal race and payer in eligible mothers with preeclampsia who deliver at <34 weeks between March 2015 and April 2017

**Setting**

- The Comprehensive Management of Preeclampsia (CMOP) is a statewide quality improvement (QI) initiative of the Perinatal Quality Collaborative of North Carolina (PQNC).
- Global aim: develop a consistent continuum of care for preeclampsia and threatened preterm birth across the state from large tertiary centers to smaller referral centers.
- 25 centers: (11 with Newborn Nursery/Level II NICU and 14 with Level III/Level IV NICU)

<table>
<thead>
<tr>
<th>Phase</th>
<th>No. Mothers delivered at &lt;34 weeks/Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase 0 (Pilot)</td>
<td>505/4991</td>
</tr>
<tr>
<td>Jan 2014- Feb 2015</td>
<td></td>
</tr>
<tr>
<td>Phase 1 (Pre-intervention)</td>
<td>671/7659</td>
</tr>
<tr>
<td>March 2015-March 2016</td>
<td></td>
</tr>
<tr>
<td>Phase 2 (Post-intervention)</td>
<td>502/5309</td>
</tr>
<tr>
<td>April 2016-Feb 2017</td>
<td></td>
</tr>
</tbody>
</table>

**Drivers of Change**

**Primary AIM**

Increase the rate of administration of a full course of Antenatal Corticosteroids to eligible pregnancies <34 weeks

**Primary Drivers**

- Preeclampsia is a major cause of prematurity
- Recognize the benefits of Antenatal Corticosteroids to reduce neonatal mortality and morbidity

**Primary AIM**

Describe variations in the rate of administration of a full course of Antenatal Corticosteroids to eligible mothers by center level, race and payer

**Secondary Drivers**

- Standardization of care to facilitate access to Antenatal Corticosteroids
- Order sets, medication availability
- Develop, test, implement and evaluate interventions
- Disparities have been reported in the use of Antenatal Corticosteroids by center level, race and payer

**Interventions**

- Individual leadership consultations with each hospital’s team to assure availability and timely access to Antenatal Corticosteroids
- Policy and process improvements: order sets, practice alerts, EMR changes
- Education: 4 in-person learning sessions
- 9 training webinars on various topics (recorded and posted on website)
- Patient-provider communication: adopt passport tool (March of Dimes)
- Each participating team conducted multiple PDSA cycles
- Accountability: Monthly review with hospital’s team of cases of missed or partial course of Antenatal Corticosteroids

**Measurement**

- Frequency (% of patients/total) and percentage (%) of Antenatal Corticosteroids (full course) use in mothers with preeclampsia who delivered at <34 weeks’ gestation in relation to:
  - Time period: Overtime monthly during Phase 0, 1 and 2
  - Center level: Newborn Nursery/Level II NICU or Level III/IV NICU
  - Maternal Race: White, African American or Other
  - Maternal Payer: Blue Cross Blue Shield, Medicaid, Other or Uninsured
- Monthly data submission by hospitals
- Delphi database used for data collection
Health disparities persist despite intervention to increase use of antenatal corticosteroids in mothers with preeclampsia

Margarita Bidegain MD

**Discussion/ Next Steps**
- The prevalence of Antenatal Corticosteroids use:
- Did not significantly differ among phases 0, 1, and 2. Goal of 85% administration rate may have been unrealistic and ceiling may have been reached in this sick population.
- White mothers have the highest prevalence of use in Phase 1 and 2, when compared to African American and Other mothers, while no difference was found among different payors.
- It is significantly higher for mothers in centers with level III-IV NICUs when compared to those who delivered at centers with Newborn Nursery/Level II NICUs.
- **Next steps:**
  - Continued analysis of failure to improve, Ceiling reached? Time of first dose? New interventions?
  - Does the severity of hypertensive disorders of pregnancy vary across populations?
  - 3 months pause in data collection followed by resuming data collection, to determine sustainability
  - **Audit days:** visits to facilities to see how they are doing with certain indicators
  - Improving North Carolina Birth Certificates documentation on Antenatal Corticosteroids use

**Results**

**ANTENATAL CORticosteroids use by center level**

(phase 0, 1 and 2 combined)

<table>
<thead>
<tr>
<th>Phase</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase 0</td>
<td>0.14</td>
</tr>
<tr>
<td>Phase 1</td>
<td>0.05</td>
</tr>
<tr>
<td>Phase 2</td>
<td>0.003</td>
</tr>
</tbody>
</table>

**ANTENATAL CORticosteroids use by maternal race**

<table>
<thead>
<tr>
<th>ANS (RACE)</th>
<th>White</th>
<th>African American</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase 1</td>
<td>75%</td>
<td>85%</td>
<td>86%</td>
</tr>
<tr>
<td>Phase 2</td>
<td>79%</td>
<td>85%</td>
<td>86%</td>
</tr>
</tbody>
</table>

**Discussion/ Next Steps**

- Perinatal Quality Collaborative of North Carolina leadership and the 25 teams who participated
- To all the participant pregnant mothers and families.
- Dr. Ronald Goldberg
- Dr. David Tanaka
- Dr. Leslie Pineda
- Amanda French MSN, RNC-OB, ACNS-BC

**Acknowledgements**
Strategies for Shared Decision Making

Gregory Moore MD, FRCPC
Children’s Hospital of Eastern Ontario (CHEO)
Ottawa, ON

Dr. Gregory Moore is an academic neonatologist practicing at the two hospitals in Ottawa that have level 3 neonatal intensive care units – the Children’s Hospital of Eastern Ontario and The Ottawa Hospital. After obtaining his medical degree from the University of Western Ontario, he completed his Paediatrics residency and the first 2 years of his Neonatal-Perinatal Medicine fellowship at the University of Ottawa in Ontario, Canada. He went on to enjoy a final enriching fellowship year at the Royal Women’s Hospital in Melbourne, Australia. He returned to Ottawa in 2009 as an attending neonatologist and an assistant professor on the clinician-teacher track through the University of Ottawa. In 2016, he was promoted to the associate professor level. He is a Clinical Investigator with the CHEO Research Institute and Ottawa Hospital Research Institute. His areas of academic interest are bioethics with a focus on working with families when their baby may be born at an extremely low gestational age, and post-graduate medical education. Outside of ‘hospital life’, he enjoys time with his wife and four children and competing as a national level Masters cyclist.

Annual Quality Congress Plenary Session, Sunday, October 29, 2017
Strategies for Shared Decision Making

Objective: Reflect on the potential effect of healthcare providers’ knowledge about outcomes, their personal beliefs, and their attitudes about disability on the shared decision making process with families facing anticipated extremely preterm birth.
Strategies for Shared Decision Making: Involving Parents in an Incredibly Difficult and Complex Decision

Objectives

After this session, participants will be able to:

1. Reflect on the potential effect of healthcare providers’ knowledge about outcomes, their personal beliefs, and their attitudes about disability on the shared decision-making process with families facing anticipated extremely preterm birth.

The Present

• Extremely Premature Infants (EPI)
  – 22 weeks+ 0 days to 25 weeks+ 6 days GA

Management options

• Palliative care

• Early intensive care
  – Possibility of different levels of intervention

• “Trial of intensive care”

Shared Decision Making

• ≥ 2 parties participate in the decision-making process

• Information/value sharing is a prerequisite
  – Two experts

• Mutual agreement on final decision


Disclosure

• I have no conflicts of interest to disclose
**Strategies for Shared Decision Making: Involving Parents in an Incredibly Difficult and Complex Decision**

Gregory Moore MD, FRCPC

---

### A Difference in what parents were told

<table>
<thead>
<tr>
<th>Weeks</th>
<th>Melbourne, Australia</th>
<th>Ottawa, Canada</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Local Survival</td>
<td>Local NDD in survivors</td>
</tr>
<tr>
<td>22+0 - 22+6 wks</td>
<td>No data</td>
<td>No data</td>
</tr>
<tr>
<td>23+0 - 23+6 wks</td>
<td>50%</td>
<td>50%</td>
</tr>
<tr>
<td>24+0 - 24+6 wks</td>
<td>67%</td>
<td>33%</td>
</tr>
<tr>
<td>25+0 - 25+6 wks</td>
<td>80%</td>
<td>25%</td>
</tr>
</tbody>
</table>

---

### Ottawa: 2010-2016

<table>
<thead>
<tr>
<th>GA</th>
<th>Early intensive care attempted (n)</th>
<th>Survivors at the time of NICU discharge in those who received early intensive care (n, %)</th>
<th>CNN</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td>22+0 - 22+6 wks</td>
<td>5 (20%)</td>
<td>18%</td>
</tr>
<tr>
<td>16%</td>
<td>23+0 - 23+6 wks</td>
<td>22 (95% CI 16, 56%)</td>
<td>41%</td>
</tr>
<tr>
<td>50%</td>
<td>24+0 - 24+6 wks</td>
<td>61 (95% CI 48, 72%)</td>
<td>67%</td>
</tr>
<tr>
<td>68%</td>
<td>25+0 - 25+6 wks</td>
<td>85 (95% CI 65, 83%)</td>
<td>79%</td>
</tr>
</tbody>
</table>

Lemyre et al. Paediatr Child Health 2017

---

### Moderate to Severe NDD (%)

<table>
<thead>
<tr>
<th>Weeks</th>
<th>Melbourne, Australia</th>
<th>Ottawa, Canada</th>
</tr>
</thead>
<tbody>
<tr>
<td>22 w</td>
<td>CA 18% N, 41% K, 67% L, 79% M</td>
<td>CNN 18%</td>
</tr>
<tr>
<td>23 w</td>
<td>CA 18% N, 41% K, 67% L, 79% M</td>
<td>CNN 18%</td>
</tr>
<tr>
<td>24 w</td>
<td>CA 18% N, 41% K, 67% L, 79% M</td>
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<tr>
<td>25 w</td>
<td>CA 18% N, 41% K, 67% L, 79% M</td>
<td>CNN 18%</td>
</tr>
</tbody>
</table>

Moore et al. JAMA Peds 2013
Guidelines … can they help?

• “… it became painfully obvious that the medical community had no uniform standard of care to apply to withholding and withdrawing life-sustaining medical treatment regarding infants.” Dr. G. Messenger 1995

Socio-Familial Factors

- Family structure
  - Number of children
  - Number of parents, extended family
- Religion, faith
- Cultural, social background
- Values and perspectives
- Economic, geographic context
- Life experience

Decision Aid for SDM re: Extremely Premature Infants

Change in Decisional Conflict Scale

<table>
<thead>
<tr>
<th>Decisional Conflict Scale (n=18)</th>
<th>Baseline (mean ± SD)</th>
<th>Post-DC (mean ± SD)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total DCS score</td>
<td>52 ± 25</td>
<td>10 ± 16</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Informed</td>
<td>66 ± 35</td>
<td>6 ± 16</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Values clarity</td>
<td>53 ± 31</td>
<td>11 ± 30</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Support</td>
<td>26 ± 22</td>
<td>6 ± 13</td>
<td>0.001</td>
</tr>
<tr>
<td>Uncertainty</td>
<td>68 ± 34</td>
<td>21 ± 31</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

It takes a team …
Strategies for Shared Decision Making: Involving Parents in an Incredibly Difficult and Complex Decision

Gregory Moore MD, FRCPC

**Facilitators**

Skills

Parents are more prepared and confident

"We felt like the parents were being heard a little bit more versus being told of how it was going to be…parents feel much more comfortable in their decision-making as well, and supported, and heard." (RN BU-4)

**Facilitators**

Social/ Professional Role and Identity

Choice should be the family's to make

"I think that is an important idea that families are the ones who are going to live with these choices for forever and so it should be their choice…" (Neo-4)

**Barriers**

Skills

HCP difficulty knowing when to apply SDM

"I think that the most difficult part is to determine when you feel the options are equally valid. So it's the outside cases and where is the line and how firm you apply your line. I think that that's the struggle." (Neo-5)

**Barriers**

Emotion

Stress and difficulty of decision for parents

"I felt like that could very overwhelming for parents if they come in at we'll say 22, 23-weeks not even having a thought about having a pre-term baby because they assume everything's going to be normal with their pregnancy…" (RN BU-1)

**What do parents want?**

- Differing involvement in decision making
- Information – balanced and accurate
- Good communication – words matter
- Trust
- Positives of prematurity
- Realistic hope
- Acceptance of the ‘grey’


**Persisting concerns**
Strategies for Shared Decision Making: Involving Parents in an Incredibly Difficult and Complex Decision

Gregory Moore MD, FRCPC

Positive in a difficult situation

“Your information session with us was very helpful and helped us understand the situation and make an educated decision. I would be happy to recommend [such a consultation] to anyone with similar issues. Thank you.”

Thank you!

Acknowledgements:

S. Ding  M. Lawson  A. Shephard
T. Daboval  B. Lemyre  SDM for EPI working group
S. Dunn  S. Redpath  C. Barker

References

6. Peabody JL, Martin CH. From how small is too small to how much is too much. Ethical issues at the limits of neonatal viability. Cmnl Perinatol 1996;23(3):473-89.

Social Determinants of Health and the New World Disorder

Pat O’Campo PhD  
Chair in Intersectoral Solutions to Urban Health Problems  
Professor, Dalla Lana School of Public Health, University of Toronto  
Research Scientist, Centre for Urban Health Solutions  
Toronto, Ontario, Canada

Dr. O’Campo is a Scientist at the Centre for Urban Health Solutions of St. Michael’s Hospital and the Chair of Intersectoral Solutions to Urban Health Problems. She is also a Professor at the Dalla Lana School of Public Health Sciences at the University of Toronto, an adjunct professor at the Johns Hopkins Bloomberg School of Public Health, and Fellow of the Canadian Academy of Health Sciences. Dr. O’Campo is an internationally renowned public health scholar who has an active research program that focuses on understanding the health impacts of complex urban social problems experienced by low-income populations. Her exceptional career includes a decade as director of one of Canada's top research centres committed to reducing health inequities by generating strong evidence to support social change, the Centre for Research on Inner City Health. Through her scholarship over the past 25 years, dedicated partnerships with affected communities, and leadership at a large multi-disciplinary health research centre for over a decade, she has advanced methodologies and generated strong evidence to improve the lives of pregnant women, infants and families. She has been widely recognized for her contributions to the well-being of women and children through the receipt of early and mid-career awards given by national and international career excellence awards from organizations such as the US Centers for Disease Control, American Academy of Pediatrics, American Public Health Association, & the US Institute of Medicine. As a recognized leader in social epidemiology and expert in epidemiologic methods, she has been asked to serve on numerous prestigious international panels such as the US Institute of Medicine's Board on Children, Youth and Families, the Federal Advisory Committee for the multi-billion dollar NIH National Children’s Study, the 2006 NIH Panel on the State-of-the-Science Conference: Cesarean Delivery on Maternal Request, WHO Urban H.E.A.R.T, and has contributed to research and policy documents about health behaviours in pregnancy such as the US Surgeon General’s Reports on Involuntary Smoking.

Annual Quality Congress Plenary Session, Sunday, October 29, 2017  
Social Determinants of Health and the New World Disorder

Objective: Review the social determinants of health and analyze the impact of these factors on the outcomes of infants and children in the NICU and beyond.
What do the Social Determinants of Health Have to do With NICU Care?

Patricia O’Campo PhD

**OBJECTIVES**

- Review the social determinants of health and analyze the impact of these factors on the outcomes of infants and children in the NICU and beyond.
- The importance of the social determinants of health (SDOH).
- How the SDOH impacts care and outcomes in the NICU.
- How to address the SDOH within a NICU setting.

**Health Equity**

- What

Attainment of the highest level of health for all people by addressing avoidable inequalities for those experiencing socioeconomic disadvantage or historical injustice so that all people and communities can achieve the highest level of health.

- Why SDOH

Addressing social determinants of health is the primary approach to achieving health equity. ...

Social determinants of health -- poverty, poor education, underemployment, stigma, racism, colonialism & unequal health care access-- are underlying, contributing factors of health inequities.

**Disclosure**

- Financial: No relevant financial relationships exist.
- Non-financial: No relevant non-financial relationships exist.

Adapted from ASTHO @ HealthEquityJrnl

Canadian Medical Association
What do the Social Determinants of Health Have to do With NICU Care?

Patricia O’Campo PhD

By creating a list of the issues, the problems seem straightforward and possibly simple to understand & solve.

Precariously housed are this much more likely to die than the poorest 5th of the population.

Precariously housed are this much more likely to die than the richest 5th of the population.

Women, Families & Housing

More women live in Substandard & Crowded Housing

Women have lower wages and more likely to be un- or under-employed; More lone mothers live in poverty and social assistance does not fully cover household expenses.

More women live without psychological or physical security in the home.

Women have fewer choices about where to live; women/lone mothers experience discrimination by landlords; have greater need to be close to services and work.

In some jurisdictions, if mothers lose housing they also lose their children.

In some areas, if mothers lose their housing they also lose their children.

In some areas, if mothers lose their housing they also lose their children.

In some areas, if mothers lose their housing they also lose their children.
What do the Social Determinants of Health Have to do With NICU Care?

Patricia O’Campo PhD

DO THE SDOH IMPACT CARE AND OUTCOMES OF NICU POPULATIONS?

Differential treatment in NICUs by race

2017 study of NICU care found racial differences in dissatisfaction with care by nursing staff

2017 Systematic Review of >40 studies documents widespread implicit bias among health care professionals across specialties and settings

DO YOU HAVE ENOUGH MONEY TO MAKE ENDS MEET EACH MONTH?

DO YOU HAVE STABLE HOUSING?

IS YOUR HOUSING AFFORDABLE?

Does your job allow you to take time off with pay?

WHAT CAN BE DONE?

SDOH in families of NICU/preterm infants up to 2 years after discharge

Canadian Paediatric Society recommends screening for psychosocial and SDOH
What do the Social Determinants of Health Have to do With NICU Care?

Patricia O’Campo PhD

Can Health Care Be Cured of Racial Bias?

Address unconscious bias and racial micro aggressions at multiple levels: clinician, division & institution with emerging evidence based solutions

References

"What you do makes a difference, and you have to decide what kind of difference you want to make."

- Jane Goodall
Neonatal Follow-up – Are We Asking the Right Questions?

Marie Clare McCormick MD, ScD
Professor of Maternal and Child Health
Department of Social and Behavioral Sciences,
Harvard T.H. Chan School of Public Health,
Professor of Pediatrics,
Harvard Medical School,
Senior Associate Director
Infant Follow-up Program,
Boston Children’s Hospital

Dr. McCormick is a pediatrician with a second doctorate in health services research, with all of her post-graduate training at Johns Hopkins. In 1987, she joined the faculty of the Department of Pediatrics at Harvard Medical School and, in 1991, she became Professor and Chair of the Department of Maternal and Child Health at the Harvard School of Public Health, and Professor of Pediatrics. She is currently the Sumner & Esther Feldberg Professor of Maternal & Child Health in the Department of Society, Human Development, and Health at the Harvard School of Public Health, and Professor of Pediatrics at the Harvard Medical School, and Senior Associate for Academic Affairs in the Department of Neonatology at the Beth Israel Deaconess Medical Center.

Her research has focused on the effectiveness of perinatal and neonatal health services on the health of women and children with a particular concern in the outcomes of very premature infants. She has been a senior investigator on the evaluations of two national demonstration programs (the Robert Wood Johnson Foundation National Perinatal Regionalization Program, and currently the federal Healthy Start Program). In addition, she has provided significant scientific, input, in a variety of roles, to the design and conduct of Infant Health and Development Project, the largest, multisite randomized trials of early childhood educational intervention, in particular, serving as the principal investigator of the follow-up at eighteen years of age.

She is a member of the National Academy of Medicine (Institute of Medicine), among other organizations. Her work on several committees, most notably the Immunization Safety Review Committee has earned her the David Rall Medal for exceptional service.

Objective: Re-conceptualize the need to move from a narrow view of neonatal “follow-up” to “follow-through” developing a model that would incorporate longitudinal changes in function, maturation, the impact of family dynamics and important social determinants of health.
Neonatal Follow-up: Are We Asking the Right Questions?

Marie Clare McCormick MD, ScD

Learning Objectives

- Re-conceptualize the need to move from a narrow view of neonatal “follow-up” to “follow-through” developing a model that would incorporate longitudinal changes in function, maturation, the impact of family dynamics and important social determinants of health.
- To be critical of the current approach to follow up of premature infants.
- To consider the rationale for altering this approach.
- To be aware of potential ways to develop a more nuanced and comprehensive framework for follow-up.

Conflict of Interest

- I have nothing to disclose
  - Neither I or any member of my immediate family has a financial relationship of interest with any proprietary entity producing health care goods or services related to the content of this activity.
  - My content will not include discussion/reference of commercial products or services
  - I do not intend to discuss an unapproved/investigative use of commercial products/devices.

Conventional Paradigm

- Generally using some matching variables
Neonatal Follow-up: Are We Asking the Right Questions?

Marie Clare McCormick MD, ScD

The Problems with the Box
- Attribution

The Problems with the Box
- Attribution
- Interaction

Interaction

The Problems with the Box
- Attribution
- Interaction
- Trajectory

Trajectory-Short Term

The perennial problem of which comes first.

Trajectory-Long term
Neonatal Follow-up: Are We Asking the Right Questions?

Marie Clare McCormick MD, ScD

The Problems with the Box
- Attribution
- Interaction
- Trajectory
- Diagnosis vs. Function

Time for A Reset
- Fortunately, conceptual frameworks to address these issues are available.
- In particular, the Institute of Medicine/National Academy of Medicine has provided a comprehensive format.

Better Understanding and Prognosis
- Attribution
- Interaction
- Trajectory
- Diagnosis vs. Function

Moving Forward
- Continued physiologic research on the biology of prematurity.
- Continued attention to reducing unnecessary harmful variations in care.
- Development of a more comprehensive template for obtaining outcome information, perhaps in formats other than a clinic visit.
- Involvement of families in determining the desired outcome information they wish to have.
Reference

The Evidence: 
Delayed Cord Clamping

Roger F. Soll MD  
President, Vermont Oxford Network  
H. Wallace Professor of Neonatology  
University of Vermont  
Burlington, VT

Dr. Soll is the H. Wallace Professor of Neonatology at the University of Vermont College of Medicine, the President of Vermont Oxford Network, and Director of Network Clinical Trials. Dr. Soll is an authority on evidence-based medicine and randomized clinical trials. He is the coordinating editor of the Cochrane Neonatal Review Group of the Cochrane Collaboration and author or co-author of the Cochrane Reviews of surfactant therapy. He is the author of numerous peer reviewed articles and book chapters on the subject of surfactant replacement therapy and evidence-based medicine. A native of New York City, Dr. Soll graduated from Cornell University with a degree in Genetics and History of Science in 1975. He received his MD degree from the University of Health Sciences/Chicago Medical School in 1978. He returned to New York City to complete his residency training in Pediatrics at Bellevue Hospital/New York University Medical Center in 1981. After 2 years with the Public Health Service, Dr. Soll returned to academic training. He completed the post graduate fellowship in Neonatal Perinatal Medicine at the University of Vermont in 1983 and has remained in Vermont ever since.

William Tarnow-Mordi BA, MBChB, MRCP, DCH, FRCPCH  
Foundation Director,  
Westmead International Network for Neonatal Education and Research, WINNER Centre  
Professor of Medicine,  
Westmead Hospital NHMRC Clinical Trials Centre,  
University of Sydney  
Sydney, Australia

Professor William Tarnow-Mordi was born in London to Elsie Tarnow, a single English mother of possibly Jewish extraction (her surname is a Polish town that was 50% Jewish in 1939 - 0% in 1943) and a Nigerian father, Chukwuma Mordi. His father persuaded him to change his ambition from football to medicine. At 18, he combined his parents’ surnames. He attended Christ’s Hospital School, Horsham and graduated with First Class Honours in medicine at Queens’ College Cambridge and King’s College Hospital, London. (Note the steadily diminishing status of these institutions’ patrons). In 1981-6 he trained in neonatology at Oxford, where he met Iain Chalmers, cofounder of the Cochrane Library, Richard Peto, co-director of the Clinical Trial Service Unit and Roger Soll, co-founder of the Vermont Oxford Network. He married Donna, a New Zealander in 1987 and they have four sons, aged 16-25. After 13 years at Ninewells Hospital, University of Dundee as Senior Lecturer, then Reader, they moved to the University of Sydney in 1999 where he held the inaugural Chair of Neonatology at
Westmead Hospital and The Children’s Hospital at Westmead and was Director of the Department of Neonatology at Westmead Hospital and Director of Neonatal and Perinatal Trials at the WINNER Centre for Newborn Research, NHMRC Clinical Trials Centre. He coordinated the International Neonatal Network, which originated the CRIB Score and has a longstanding clinical epidemiological interest in outcome prediction and comparison of quality of care in premature infants. He is a consistently strong advocate of large multicenter studies, which answer questions of fundamental importance in neonatal medicine. Professor Tarnow-Mordi’s ORACLE trials (I and II), were designed and conducted with Professor Sir Richard Peto and Professors Sara Kenyon and David Taylor between July 1994 and May 2000. These involved obstetricians and paediatricians from 161 centers in UK, Australia and 12 other countries in recruiting over 11,000 women. He was chief investigator of the ECSURF Study, which undertook a detailed cost analysis of 57 UK neonatal intensive care units, and the UK Neonatal Staffing Study, which recruited a prospective cohort of over 13,000 infants from 54 centers. He has been the recipient of over £4 million from UK grant bodies, the largest single grant being from the Medical Research Council for the ORACLE trials for £2.4 million. Since his move to Australia he has received over $20 million in grants from NHMRC and has been CIA on the INIS, BOOST II, APTS LIFT and LEAP1 trials, and a CI on the NHMRC WOMBAT Collaboration Enabling Grant. He has over 150 publications in peer reviewed journals, e.g. the INIS trial of adjunctive IVIG therapy in 3,493 infants, (NEJM 2011;365:1201) the BOOST II Australia trial in 1,135 infants (NEJM 2013;368:2094; NEJM2016;374:749) and TORPIDO1 in 292 infants (Pediatrics 2017 DOI: 10.1542/peds.2016-1452). In 2017, APTS (the Australian Placental Transfusion Study) completed enrolment of 1566 infants, the largest ever trial of immediate vs delayed clamping of the cord. He would like his tombstone to read “He believed in God, loving-kindness and randomization.”

Annual Quality Congress Breakout Session, Sunday, October 29, 2017
The Evidence: Delayed Cord Clamping

Objective: Analyze the evidence for delayed cord clamping and discuss 3 key challenges for implementation in the delivery room.
The Evidence: Delayed Cord Clamping

Roger F. Soll MD

H. Wallace Professor of Neonatology, University of Vermont College of Medicine
President, Vermont Oxford Network
Coordinating Editor, Cochrane Neonatal

Annual Quality Congress 2017
October 29th, 2017

Objectives

This workshop will highlight the evidence for delayed cord clamping (“deferred” cord clamping) with particular reference to care of the preterm infant.
Analyze the evidence for delayed cord clamping and discuss 3 key challenges for implementation in the delivery room.

Special Guest

William Tarnow-Mordi, BA, MBChB, MRCP (UK), DCH, FRCPCH
Professor of Neonatal Medicine, Sydney Medical School
Director, Neonatal and Perinatal Trials, NHMRC Clinical Trials Centre

“It often happens that the child appears to have been born dead when it is merely weak, and when before the umbilical cord has been ligatured, the blood has run out into the cord and its surroundings.
But experienced midwives have been known to squeeze back the blood into the child’s body from the cord, and immediately the child that a moment before was bloodless came back to life again.”

Aristotle, 350 BC

“Another thing very injurious to the child, is the tying and cutting of the navel string too soon which should always be left not only until the child has repeatedly breathed, but till all pulsations in the cord cease.
As otherwise the child is much weaker than it ought to be, a portion of the blood being left in the placenta, which ought to have been in the child.”

Erasmus Darwin 1801

Disclosure

Roger F. Soll is President of Vermont Oxford Network and the Coordinating Editor of Cochrane Neonatal
So where does the concept of “early” (read “immediate”) cord clamping come from?

**Physiology of Cord Clamping**

Decrease PVR → Increase in cardiac output to the lungs from 8% to 45 to 55%

If feto-placental circulation is still intact, this increased blood volume comes from the placenta.

If cord clamping occurs before the first breaths, when PVR drops, the volume of distribution increases without an increase in blood volume.

Blood may be drawn from systemic circulation → Relative hypoperfusion/“steal”

**Placental Transfusion:** In term infants,
- 50% of the placental blood-volume is transfused within one minute.
- 20 to 35 ml/kg total is transfused by 3 minutes of life (Yao et al. 1969)

Before the mid 1950s, the term early clamping was defined as umbilical cord clamping within 1 minute of birth, and late clamping was defined as umbilical cord clamping more than 5 minutes after birth.

In a series of small studies of blood volume changes after birth, it was reported that 80 to 100 ml of blood transfers from the placenta to the newborn in the first 3 minutes after birth and up to 90% of that blood volume transfer was achieved within the first few breaths in healthy term infants (Yao 1969).

Because of these early observations and the lack of specific recommendations regarding optimal timing, the interval between birth and umbilical cord clamping began to be shortened, and it became common practice to clamp the umbilical cord shortly after birth, usually within 15 to 20 seconds.

ACOG COMMITTEE OPINIONS: Delayed Umbilical Cord Clamping After Birth. Number E84, January 2017

Modern Medicine at it’s best!
The Evidence: Delayed Cord Clamping
Roger F. Soll MD

Effect of timing of umbilical cord clamping of term infants on mother and baby outcomes.
McDonald SJ, Middleton P, Dowswell T, Morris PS.

Objectives: To determine the effects of early cord clamping compared with late cord clamping after birth on maternal and neonatal outcomes.

Selection criteria: Randomized controlled trials comparing early and late cord clamping.

Main results: Included 15 trials involving a total of 3911 women and infant pairs. Trials judged to have an overall moderate risk of bias.

Early vs. late cord clamping: Effect on hemoglobin at 24 to 48 hours

Early cord clamping compared to early cord clamping:

Improves: Mean birth weight (101 gram increase 95% CI 45 to 157, 12 trials, 3139 infants).
Hemoglobin concentration in infants at 24 to 48 hours was significantly lower in the early cord clamping group (MD -1.49 g/dL, 95% CI -1.78 to -1.21; 884 infants).
Although this difference in hemoglobin concentration was not seen at subsequent assessments, improvement in iron stores appeared to persist, with infants in the early cord clamping group twice as likely to be iron deficient at three to six months compared with infants whose cord clamping was delayed.
Worsens: Fewer infants in the early cord clamping group required phototherapy for jaundice than in the late cord clamping group (RR 0.62, 95% CI 0.41 to 0.96, 7 trials, 2324 infants).
Makes no difference: Neonatal mortality (RR 0.37, 95% CI 0.04 to 3.41, 2 trials, 381 infants) or other neonatal morbidity outcomes, such as Apgar score less than 7 at five minutes or admission to the special care nursery or neonatal intensive care unit.
Effect of timing of umbilical cord clamping of term infants on mother and baby outcomes.

Maternal Outcomes

Immediate umbilical cord clamping has traditionally been carried out along with other strategies of active management in the third stage of labor in an effort to reduce postpartum hemorrhage. Consequently, concern has arisen that delayed umbilical cord clamping may increase the risk of maternal hemorrhage.

However, in a review of five trials that included more than 2,200 women, delayed umbilical cord clamping was not associated with an increased risk of postpartum hemorrhage or increased blood loss at delivery, nor was it associated with a difference in postpartum hemoglobin level or need for blood transfusion.

Effect of timing of umbilical cord clamping of term infants on mother and baby outcomes.

Authors’ conclusions

A more liberal approach to delaying clamping of the umbilical cord in healthy term infants appears to be warranted, particularly in light of growing evidence that delayed cord clamping increases early hemoglobin concentrations and iron stores in infants.

Delayed cord clamping is likely to be beneficial as long as access to treatment for jaundice requiring phototherapy is available.

The American College of Obstetricians and Gynecologists’ Committee on Obstetric Practice recommendations regarding the timing of umbilical cord clamping after birth:

In term infants, delayed umbilical cord clamping increases hemoglobin levels at birth and improves iron stores in the first several months of life, which may have a favorable effect on developmental outcomes.

Delayed umbilical cord clamping is associated with significant neonatal benefits in preterm infants, including improved transitional circulation, better establishment of red blood cell volume, decreased need for blood transfusions, and lower incidence of necrotizing enterocolitis and intraventricular hemorrhage.

Given the benefits to most newborns and concordant with other professional organizations, the American College of Obstetricians and Gynecologists now recommends a delay in umbilical cord clamping in vigorous term and preterm infants for at least 30 to 60 seconds after birth.

There is a small increase in the incidence of jaundice that requires phototherapy in term infants undergoing delayed umbilical cord clamping. Consequently, obstetrician-gynecologists and other obstetric care providers adopting delayed umbilical cord clamping in term infants should ensure that mechanisms are in place to monitor and treat neonatal jaundice.

Delayed umbilical cord clamping does not increase the risk of postpartum hemorrhage.

ACOG COMMITTEE OPINION. Delayed Umbilical Cord Clamping After Birth. Number 684, January 2017

Clinical Situations in Which Immediate Umbilical Cord Clamping Should Be Considered or Care Should Be Individualized

<table>
<thead>
<tr>
<th>Maternal</th>
<th>Neonatal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemorrhage, hemodynamic instability, or both</td>
<td>Need for immediate resuscitation</td>
</tr>
<tr>
<td>Abnormal placentation (previa, abruptio)</td>
<td>Placental circulation not intact (abruption, previa, cord avulsion, IUlGR with abnormal cord doppler evaluation)</td>
</tr>
</tbody>
</table>

ACOG COMMITTEE OPINION. Delayed Umbilical Cord Clamping After Birth. Number 684, January 2017

Process and Technique of Delayed Umbilical Cord Clamping

Delayed umbilical cord clamping is a straightforward process that allows placental transfusion of warm, oxygenated blood to flow passively into the newborn.

The position of the newborn during delayed umbilical cord clamping generally has been at or below the level of the placenta, based on the assumption that gravity facilitates the placental transfusion. However, a recent trial of healthy term infants born vaginally found that those newborns placed on the maternal abdomen or chest did not have a lower volume of transfusion compared with infants held at the level of the introitus. This suggests that immediate skin-to-skin care is appropriate while awaiting umbilical cord clamping.

In the case of cesarean delivery, the newborn can be placed on the maternal abdomen or legs or held by the surgeon or assistant at close to the level of the placenta until the umbilical cord is clamped.
The Evidence: Delayed Cord Clamping
Roger F. Soll MD

**Process and Technique of Delayed Umbilical Cord Clamping**

During delayed umbilical cord clamping, early care of the newborn should be initiated, including drying and stimulating for first breath or cry, and maintaining normal temperature with skin-to-skin contact and covering the infant with dry linen.

Secretions should be cleared only if they are copious or appear to be obstructing the airway.

If meconium is present and the baby is vigorous at birth, plans for delayed umbilical cord clamping can continue.

The Apgar timer may be useful to monitor elapsed time and facilitate an interval of at least 30 to 60 seconds between birth and cord clamp.

**What about the preterm infant?**

**Effect of timing of umbilical cord clamping and other strategies to influence placental transfusion at preterm birth on maternal and infant outcomes.**

Rabe H, Diaz-Rossello J L, Duley L, Dowsell T.

[Image of THE COCHRANE COLLABORATION®]

**Effect of timing of umbilical cord clamping and other strategies to influence placental transfusion at preterm birth on maternal and infant outcomes.**

Aladangady et al. (2006)

Found that by delaying cord clamping by 30 to 40 seconds, euvoelema (70 to 100ml/kg) could be achieved in preterm infants

**Effect of timing of umbilical cord clamping and other strategies to influence placental transfusion at preterm birth on maternal and infant outcomes.**

**OBJECTIVES:**

To assess the short- and long-term effects of early rather than delaying clamping or milking of the umbilical cord for infants born at less than 37 completed weeks' gestation, and their mothers.

**SELECTION CRITERIA:**

Randomized controlled trials comparing early with delayed clamping of the umbilical cord and other strategies to influence placental transfusion for births before 37 completed weeks' gestation.

**MAIN RESULTS:**

Fifteen studies (738 infants) were eligible for inclusion.

Participants were between 24 and 36 weeks' gestation at birth. The maximum delay in cord clamping was 180 seconds.
The Evidence: Delayed Cord Clamping

Roger F. Soll MD

Effect of timing of umbilical cord clamping and other strategies to influence placental transfusion at preterm birth on maternal and infant outcomes

Transfused for anemia

Effect of timing of umbilical cord clamping and other strategies to influence placental transfusion at preterm birth on maternal and infant outcomes

Number of Transfusions

Serum Bilirubin Peak (mmol/litre)

Bilirubin measurement: 15 mmol/liter = 0.9 mg/dL

Inotropic support for low blood pressure

(typical RR 0.42, 95% CI 0.23 to 0.77)

Intraventricular Hemorrhage

I VH (all grades): 7.6% fewer in delayed clamping
(Delayed versus early clamping: 13.5% versus 20.1%)
The Evidence:
Delayed Cord Clamping
Roger F. Soll MD

**Effect of timing of umbilical cord clamping and other strategies to influence placental transfusion at preterm birth on maternal and infant outcomes**

### Necrotizing Enterocolitis

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Mean placental transfusion</th>
<th>Risk Ratio</th>
<th>95% CI Lower</th>
<th>95% CI Upper</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bigelow 2007</td>
<td>0.10</td>
<td>0.85</td>
<td>0.47</td>
<td>1.51</td>
</tr>
<tr>
<td>London 2005</td>
<td>0.05</td>
<td>0.85</td>
<td>0.47</td>
<td>1.51</td>
</tr>
<tr>
<td>ferr 2002</td>
<td>0.05</td>
<td>0.85</td>
<td>0.47</td>
<td>1.51</td>
</tr>
<tr>
<td>Nurse (2025)</td>
<td>0.05</td>
<td>0.85</td>
<td>0.47</td>
<td>1.51</td>
</tr>
<tr>
<td>Total (2xSE)</td>
<td>0.05</td>
<td>0.85</td>
<td>0.47</td>
<td>1.51</td>
</tr>
</tbody>
</table>

Reduced incidence of NEC in delayed cord clamping:
26/117 (20.5%) delayed versus 39/124 (31.5%) early

**Effect of timing of umbilical cord clamping and other strategies to influence placental transfusion at preterm birth on maternal and infant outcomes**

### Oxygen Supplementation at 36 weeks' postmenstrual age

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Mean placental transfusion</th>
<th>Risk Ratio</th>
<th>95% CI Lower</th>
<th>95% CI Upper</th>
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<td>1.51</td>
</tr>
</tbody>
</table>

Typical relative risk 0.69 95% CI 0.42 to 1.13

**Effect of timing of umbilical cord clamping and other strategies to influence placental transfusion at preterm birth on maternal and infant outcomes**

### Infant Death (up until hospital discharge)

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Mean placental transfusion</th>
<th>Risk Ratio</th>
<th>95% CI Lower</th>
<th>95% CI Upper</th>
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<td>0.05</td>
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<td>0.47</td>
<td>1.51</td>
</tr>
</tbody>
</table>

Typical relative risk 0.63 95% CI 0.31 to 1.28

**Effect of timing of umbilical cord clamping and other strategies to influence placental transfusion at preterm birth on maternal and infant outcomes**

### Potential benefits

Additionally, there may be benefits to the enhanced stem cell transfusion and plasma transfusion associated with DCC:
- Long and short term immunity
- Host defense
- Repair

This represents an important area for future research

**How does the APTS Study help further inform our decision?**

Australian Placental Transfusion Study

60 seconds
The Evidence:  
Delayed Cord Clamping

Roger F. Soll MD

A pragmatic, international RCT in ~1600 babies < 30 weeks’ gestation

Main Research Question:
Will placental transfusion, by deferring cord clamping for 60 seconds, reduce mortality or morbidity by 36 weeks postmenstrual age?

Umbilical Cord Milking

Umbilical cord milking or stripping has been considered as a method of achieving increased placental transfusion to the newborn in a rapid time frame, usually less than 10 to 15 seconds.

It has particular appeal for circumstances in which the 30 to 60-second delay in umbilical cord clamping may be too long, such as when immediate infant resuscitation is needed or maternal hemodynamic instability occurs.

However, umbilical cord milking has not been studied as rigorously as delayed umbilical cord clamping.

Umbilical Cord Milking

Rabe et al. (2011)

Outlined procedure and assumptions
- Studies have shown that the cord contains 15 to 20cc of blood
- ~1/2 of cord length is available upon delivery = 7 to 10 cc
- Milking available cord 4 times = 30 to 40cc of blood transferred
- Milking done at rate of 20 cm/2sec, with a 1 to 2 second pause in between → approx. duration of procedure = 10 to 12 seconds


Heidi Al-Wassia, MD; Prakesh S. Shah, MD, MSc.

A recent meta-analysis of seven studies that involved 501 preterm infants compared:
• umbilical cord milking with immediate cord clamping (six studies) or
• delayed umbilical cord clamping (one study).

The method of umbilical cord milking varied considerably in the trials in terms of the number of times the cord was milked, the length of milked cord, and whether the cord was clamped before or after milking.
The Evidence: Delayed Cord Clamping
Roger F. Soll MD

Mortality before discharge in preterm infants

Oxygen requirement at 36 weeks’ postmenstrual age in preterm infants

Any intraventricular hemorrhage in preterm infants

Umbilical Cord Milking
This is an area of active research and several ongoing studies are evaluating the possible benefits and risks of umbilical cord milking compared with delayed umbilical cord clamping, especially in extremely preterm infants.

Currently, there is insufficient evidence to either support or refute umbilical cord milking in term or preterm infants.

What are the Barriers to Delayed Cord Clamping?
- Need for resuscitation
- Culture on L&D
- Comfort with preterm infants
- C-section
- Meconium
- Hypothermia
- Maternal bleeding
- Nuchal cord
- Short cord

Additionally, Cord blood banking, Observe worse cord blood gases (not consistent with clinical picture), Desire of mother to have baby placed on chest immediately following delivery

What are the Barriers to Delayed Cord Clamping?
What have your Maternal-Fetal Specialists decided to do?
For term infants?
For preterm infants?
What are the exceptions?
Are there formal guidelines?
What is the role of the Pediatric team?
The Evidence: Delayed Cord Clamping

Roger F. Soll MD
Antibiotic Stewardship and Infection Prevention
Podium Briefs

**Sujoy Banerjee MBBS, DCH, MD, MA (Medical Education), MRCP(UK), MRCPCH(UK)**
Consultant Neonatologist and Lead Clinician  
Neonatal Services Honorary Associate Professor  
Swansea University Medical School  
ABMU Health Board  
Swansea, UK

Dr. Sujoy Banerjee qualified from the University of Calcutta, India in 1990 and completed his postgraduate training and qualification in paediatrics in 1996. He arrived in the UK in 1997 for higher specialist training in neonatal medicine and obtained his CCT in 2005. He joined ABMU Health Board as a consultant neonatologist in 2006 and has special interest in medical education; quality improvement and neurodevelopment follow up. His other research interest includes feto-maternal temperature relationship. He is currently an honorary Associate Professor and the Deputy Director of Clinical Placements at the Swansea University Medical School.

**Alreca Daly BSN, RN, CCRN**  
Patient Outcomes Facilitator  
Baptist Children’s Hospital  
Miami, Florida

**Kimberly Patamia MSN, BA, RNC-OB, C-EFM**  
Unit-Based Educator  
Family Birth Center  
St. Joseph Medical Center  
Tacoma, WA

Kimberly Patamia is the clinical educator in the Family Birth Center at St. Joseph Medical Center in Tacoma, WA. She has worked in the field of maternal/child health for more than 20 years in a variety of roles including as the marketing and public relations manager at the American College of Nurse-Midwives, a labor doula in North Carolina, and as a labor and delivery nurse in Washington state. She is certified in both inpatient obstetrics and electronic fetal monitoring and is working to establish a culture of continuous quality improvement by leading multiple perinatal QI initiatives.
Deborah U-Ren RN, CCRN
Registered Nurse
St. Mary’s Medical Center
Grand Junction, CO

Deborah U-Ren has been involved in the VON team for the past three years, working on the Alarm Safety and the Antibiotic Stewardship Collaborative. She has actively participated in multiple hospital based quality improvement projects as well. She has held a position at St Mary’s Medical Center as a RN for the past twenty-five years practicing in the critical care setting for twenty years and the NICU setting the last five of these years. She is a bedside nurse, charge nurse, and a clinical shift supervisor for the Women’s and Children’s Service Department at St. Mary’s Medical Center.

Annual Quality Congress Breakout Session, Sunday, October 29, 2017
Antibiotic Stewardship and Infection Prevention Podium Briefs

Objective: Identify 3 critical improvement methods or strategies employed by this improvement team to effect measurable improvement in the quality, safety and value of care for newborns.
Setting
The Neonatal Intensive Care Unit (NICU) at Baptist Children's Hospital (BCH) is part of Baptist Hospital in Miami
- Our unit has a total of 36 beds (22 Level II beds / 14 Level III beds)
- Approximately 4100 deliveries per year
- Majority of the admissions to the NICU are inborn
- We also receive admissions from the pediatric emergency room, pediatric inpatient unit and transfers from other hospitals.

Core von Team

Aim
We aim to decrease our Antibiotic Utilization Rate (AUR) by December 2017 from 20.3% to ≤18.2%, which is a 10% decrease from our AUR in 2016. The population includes all babies admitted, screened and/or treated in the NICU for suspected infection. In addition to monitoring any increases in sepsis, we will also track instances when antibiotics are resumed due to positive cultures within 72 hours after discontinuation.

Drivers of Change
- Decrease Antibiotics on Admissions
- Decrease Antibiotics on Admissions low risk pts
- Decrease Antibiotics >3days on pts with negative cultures

Interventions / Tests of Change
- Literature Review & Standards of Practice
- Guideline for Antibiotic Initiation
- Education and Transparency
- Sepsis Risk Calculator
- Sepsis Risk Calculation
- Screening on Babies ≤34 weeks
- Administration and Documentation
- Prompt result availability
- 48 hour Time-Out
- Antifungal Prophylaxis
- Documentation of Parent Discussion/Education Regarding Antibiotic Therapy in EMR
- Parent Antibiotic Education and Inclusion in Rounds
- New Staff Education and Ongoing Education for Current Staff
- Sepsis Risk Calculator Screen on Babies ≤34 weeks
- Daily Review of Antibiotics and Culture Results by Pharmacists
- Daily Review of Antibiotics and Culture Results by Pharmacists
- Daily Review of Antibiotics and Culture Results by Pharmacists
- Daily Review of Antibiotics and Culture Results by Pharmacists

Alreca Daly BSN, RN, CCRN

### Measurement

<table>
<thead>
<tr>
<th>OUTCOME MEASURES</th>
<th>NUMERATOR</th>
<th>DENOMINATOR</th>
<th>UNIT</th>
<th>FORM</th>
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</thead>
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<tr>
<td>Antibiotic Utilization Rate</td>
<td>Antibiotic days</td>
<td>Patient Days</td>
<td>%</td>
<td>EMR data extraction Biweekly Emails, quality board and staff meetings</td>
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</tbody>
</table>

### PROCESS MEASUREMENTS

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<th>FORM</th>
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<tr>
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<td>Total # of patient admissions</td>
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</table>

### BALANCING MEASURES

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<thead>
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<th>OUTCOME MEASURES</th>
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<th>DENOMINATOR</th>
<th>UNIT</th>
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</thead>
<tbody>
<tr>
<td>Antibiotics &gt;3 Days with negative cultures Total # of patients on antibiotic &gt;3 days with negative cultures</td>
<td>Total # of patients on antibiotics &gt;3 days with negative cultures</td>
<td></td>
<td></td>
<td>EMR data extraction Monthly Emails, quality board and staff meetings</td>
</tr>
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</table>

### Discussion/ Next Steps

We realize that we still have areas for improvement.

Low hanging fruits:
- Antifungal Prophylaxis protocol.
- Parent inclusion in our NICU antibiotic stewardship and additional education through NICU specific Antibiotic Educational brochure.

We’ve learned that although this was a physician driven initiative, our collaboration and cooperation amongst different disciplines have made great improvements towards our antibiotic stewardship.

### Acknowledgements

- Andrew Kairalla MD Medical Director NICU
- Lourdes Castaneda RN Nursing Director of Baptist Children’s Hospital
- Ernesto Valdes MD Neonatologist
- Rosie Rodriguez PI and Patient Safety Manager for Baptist Children’s Hospital
- Monica Echevarreta Nurse Manager NICU
- Alreca Daly Patient Outcomes Facilitator NICU
- Marie Rossique-Gonzalez PharmD Pediatric Pharmacy manager
- Andrea Prentiss Nurse Scientist Baptist Hospital
Using the Model for Improvement to Decrease Prolonged Initial Empiric Antibiotic Exposure among Newborns Receiving NICU Care

Huong Pham PharmD

Disclosure Statement

• We have nothing to disclose

Setting

- A single, academically-affiliated, level III special care nursery
- Part of a regional perinatal referral center
- 36 beds, 4,000+ births and approximately 600 NICU admissions per year
- 25 neonatal physicians, 7 neonatal fellows, 30 neonatal nurse practitioners (NNPs), 100+ neonatal nursing providers, and 4 pharmacists
- Participation in iNICQ 2017 Choosing Antibiotics Wisely and Georgia Perinatal Quality Collaborative (GaPQC)

SMART Aim

Decrease the percentage of infants receiving empiric antibiotic therapy for greater than 48 hours among all infants admitted to the special care nursery from a baseline of 41% to 30% or less by 12/31/17

Drivers of Change

<table>
<thead>
<tr>
<th>SMART Aim: Decrease the percentage of infants receiving empiric antibiotic therapy for greater than 48 hours in the Special Care Nursery</th>
<th>Global Aim: Decrease nonselecting antimicrobials in our Special Care Nursery</th>
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<td>Global Aim: Decrease nonselecting antimicrobials in our Special Care Nursery</td>
</tr>
</tbody>
</table>

Interventions

- Engage a multidisciplinary stewardship team
- Test, refine, and implement early-onset sepsis treatment guidelines
- Address criteria for initiation and discontinuation of antibiotics
- Include pharmacist on rounds
- Use audits and feedback of antibiotic use

Interventions

- Pharmacy prospective audits Feb 2017
- Provider feedback during rounds May 2017
- Changes tested included:
  - Use of the Kaiser sepsis calculator
  - Lumbar puncture for infants located beyond 48 hours

PSDA 1

PSDA 2

PSDA 3

Early-onset sepsis (EOS) guidelines May 2017

PSDA 3

Early-onset sepsis (EOS) guidelines May 2017
Using the Model for Improvement to Decrease Prolonged Initial Empiric Antibiotic Exposure among Newborns Receiving NICU Care

Huong Pham PharmD

Pareto Analysis

Reasons provided for antibiotics continuation >48 hours

Measurement

- **Process measure:** the percentage of infants receiving empiric antibiotic therapy for early-onset sepsis for greater than 48 hours
  - **Numerator:** the number of culture-negative infants who received empiric initial ampicillin
  - **Denominator:** the number of infants admitted to the special care nursery who received empiric initial ampicillin
  - **Measure reporting:** a percentage at monthly intervals
- **Outcome measure:** Incidence of necrotizing enterocolitis, assessed at quarterly intervals

Discussion

**Improvements**

- Raised awareness among clinicians to carefully review criteria for antibiotic initiation and discontinuation
- Decrease in % of infants receiving >48 hours of initial antibiotics from 41% to 33%
- EOS guidelines have shown promise in n-of-1 and n-of-2 tests

**Next Steps**

- Continue working with our multidisciplinary team of physicians, pharmacists, nurses, and hospital leaders
- Ramp up testing of EOS guidelines with goal to implement early next year
- Expand the project (spread) to include lower-risk well-appearing newborns
- Sustain improvements through 2018
Using the Model for Improvement to Decrease Prolonged Initial Empiric Antibiotic Exposure among Newborns Receiving NICU Care

Huong Pham PharmD

Acknowledgements

iNICQ Team Members
Huong Pham, PharmD – Pharmacy Lead
Ava Alfeit, PharmD – Pharmacy Co-lead
Tabitha Carney, PharmD, BCPS – Senior Pharmacy Leader
Steve Moll, PharmD, BCPS – Pharmacy Expert in Infectious Diseases
Jesse Jacobs, MD, MSC – Physician Expert in Infectious Disease/Epidemiology
Shawnte James, MD – Future Physician Co-lead
Craig Shapiro, MD – Physician Expert in Pediatrics Antimicrobial Stewardship
Patricia Denting, MD – Unit Medical Director
Jessica Roberts, MD – Physician Co-lead
Ravi Mangal Patel, MD, MS – Physician Lead

Key Senior Leaders
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David Carlton, MD, Professor of Pediatrics, Division of Neonatology, Emory University School of Medicine
Kim Cooley, MSN, APRN, NNP-BC, CCNE, Neonatal Clinical Nurse Specialist, Emory University Hospital Midtown
World-Class Care for NAS Infants in a Small, Rural Community Hospital

Sarah Bache BSN, RNC-OB, CLC
Clinical Manager of Women & Children's Services
Rutland Regional Medical Center
Rutland, VT

Sarah began her nursing career completing her Associates of Science Degree at Castleton State College in 1998. She has spent her 19 year nursing career dedicated to Women’s Health, Obstetrics, and Pediatrics. Sarah worked as a staff nurse in the areas of maternal/newborn nursing, pediatrics, and low and high risk obstetrics until 2005 when she assumed the role of Clinical Nurse Manager for Women’s and Children's Services at Rutland Regional Medical Center in Rutland, Vermont. In addition, Sarah has served as Interim Nursing Director as well. Sarah returned to school and completed her Bachelors of Science Degree in Nursing in 2014 at Western Governors University and is currently pursuing her Masters of Science Degree as a Women’s Health Nurse Practitioner through Regis College. She has been a Certified Lactation Counselor since 2005 and has held her certification in inpatient obstetrics since 2007.

Sarah has been a part of improving the care provided to Opioid exposed newborns and their mothers since 2007. She was part of the team that led Rutland Regional Medical Center to be the first community hospital in Vermont to provide care to and treat infants experiencing Neonatal Abstinence Syndrome. Part of this was developing B.A.M.B.I, Babies and Mothers Beginning In-sync, a multidisciplinary community response team designed to support and provide comprehensive care for pregnant women experiencing opiate addictions and their newborns. Sarah and the team from Rutland Regional Medical Center have been engaged with state and regional quality improvement collaboratives, iNICQ, Northern New England Quality Improvement Network, ICON (Improving Care for Opiate-Exposed Newborns), to continually improve the care they are providing for these families.

Annual Quality Congress Breakout Session, Sunday, October 29, 2017
World-Class Care for NAS Infants in a Small, Rural Community Hospital

Objective: Participate in a workshop linking evidence and action to improve the care of infants and families affected by substance use disorder.
World-Class Care For NAS Infants In A Small, Rural Community Hospital

Sarah Bache BSN, RNC-OB, CLC

Disclosure

I do not have any financial relationship with any commercial interest currently or within the last 12 months.

Learning Objectives

- Participate in a workshop linking evidence and action to improve the care of infants and families affected by substance use disorder.

Rutland Regional Medical Center

- Community hospital in central Vermont
- Serving more than 60,000
- Licensed for 133 beds
- 350-400 deliveries a year
- Level I nursery

The Opioid Epidemic: Vermont

- 2nd highest rate of admissions to state-funded substance abuse treatment programs
- Statistically significant increase in number of newborns exposed to opiates from 2008 to 2015
- 2012: Rate of Neonatal Abstinence Syndrome was 5 times higher than national average

(Vermont Department of Health, 2017)
World-Class Care For NAS Infants In A Small, Rural Community Hospital
Sarah Bache BSN, RNC-OB, CLC

The Opioid Epidemic: Rutland Regional Medical Center
- 2007: Began caring for newborns with prenatal exposure to opiates
- 2008: Creation of BAMBI
- 2009: We had our first “ah ha!” moment
- Until 2010: Newborns requiring pharmacological treatment for NAS required transfer
- 100% increase in the number of opiate exposed newborns from 2012 to 2013
- 4.7% of newborns exposed to opiates in 2009
- 16.6% of newborns exposed to opiates in 2013

Collaborations
- Quality Improvement Collaboratives
  - Improving Care of the Opioid-Exposed Newborns (ICON)
  - Northern New England Quality Improvement Network (NNEPQIN)
  - VON iniQ

Barriers
- Caring for these infants in the absence of family
- Building Trust
- Staffs’ perceived attitudes regarding substance abuse in pregnancy
- Prolonged lengths of stay for newborns

Table Top Exercise
Please take 5 minutes at your tables to discuss the barriers that have been identified at your organization

Engaging Families
- Daily Nurse Leader Rounding
- Cuddler Program
- Rooming In
- Promotion of Non-Pharmacological Care
- Breastfeeding Support & Education
- Parents able to stay with newborn throughout their stay.

Keeping Families Together
Percent of Opiate Exposed Newborns Transferred for NAS
World-Class Care For NAS Infants In A Small, Rural Community Hospital
Sarah Bache BSN, RNC-OB, CLC

Pharmacological Treatment

Percentage of Opiate Exposed Newborns Requiring Pharmacological Treatment

Breastfeeding Results

Opiate Exposed Newborns Receiving Mother's Breastmilk

Breastfeeding Results

Opiate Exposed Newborns Breastfeeding at Discharge

Table Top Exercise

Please take 5 minutes at your tables to share solutions you have tested or are interested in testing at your organization.

Drivers of Change

- Decrease the transfer rate of infants requiring pharmacological treatment for NAS from 100% in 2008 to less than 15% by 2013
- Ability for rooming-in
- Optimal environment & ability to maximize non-pharmacological treatment
- Parental involvement & engagement in infant plan of care
- Administration Support
- Engaged Community Providers
- Local Department of Health
- Substance Abuse Providers
- Outpatient Maternal Child Health Nurses
- Support of Obstetrical & Pediatric Providers
- Support of local Tertiary Care Centers and Quality Improvement Networks (e.g., Improving Care for Opioid-exposed Newborns (ICON), Northern New England Quality Improvement Network (NNEPQIN), Vermont Oxford Network (VON) iNICQ)
- Engaged Staff
- Registered Nurses
- Licensed Nurses Aides
- Social Work Providers

Engaging Community Partners

- VON iNICQ 2013-2016
  - Universal Training Program
  - Center of Excellence in NAS Care

Completion Rates for VON NAS Universal Training: Center of Excellence in NAS Care
Ensuring Ongoing Treatment

- Service Line Social Worker
- West Ridge Treatment Center
- Community Response Team
- Engaged Community Partners
- Pediatric Follow-up within 48 hours
- Referrals to Maternal/Child Health Nurses

Evolving Innovations & The Next Horizon

- Centering Pregnancy
- Development of Centering Parenting
- Post Discharge Call Backs
- Continued participation in ICON & NNEPQIN NAS Regional Collaborative

Lessons Learned

- Administrative support is critical
- Collaboration is essential
  - Community Partnerships
  - State-wide, Regional, and National Quality Improvement Networks

Lessons Learned

- Community Medical Centers can provide the optimal environment
  - Focus on Non-Pharmacologic Care
  - Promotes bonding of the family unit
  - Encouraging active family engagement in care

References

- The University of Vermont Medical Center. (n.d.). Vermont Child Health Improvement Program: Improving care for opioid-exposed newborns (ICON). Retrieved from https://www.med.uvm.edu/vchip/icon
24/7 Situational Awareness: Benefit to Your NICU, L/D, and Hospital System

Louis P. Halamek MD, FAAP
Professor and Associate Chief, Education and Training
Division of Neonatal and Developmental Medicine, Department of Pediatrics
Stanford University
Director, Center for Advanced Pediatric and Perinatal Education
Attending Neonatologist, Lucile Packard Children's Hospital
Palo Alto, CA

Louis P. Halamek MD, is a Professor and Associate Chief for Training and Assessment in the Division of Neonatal and Developmental Medicine, Department of Pediatrics, and (by courtesy) in the Division of Maternal-Fetal Medicine, Department of Gynecology and Obstetrics at Stanford University. He is also a Senior Fellow in the Center for Aviation Safety Research and Adjunct Faculty in the Department of Aviation in the Parks College of Engineering, Aviation and Technology at St. Louis University. He is a graduate of the Creighton University School of Medicine and completed residency and chief residency in Pediatrics at the University of Nebraska Medical Center followed by fellowship in Neonatal-Perinatal Medicine at Stanford University. He is certified by the American Board of Pediatrics in both Pediatric Medicine and Neonatal-Perinatal Medicine and is a Fellow in the American Academy of Pediatrics. He has a clinical appointment at Lucile Packard Children’s Hospital at Stanford where he works in the level IV neonatal intensive care unit. Through ongoing collaboration with colleagues at Johnson Space Center in Houston, Texas, Ames Research Center in Mountain View, California, and the Federal Aviation Administration in Washington, D.C., Dr. Halamek has learned the benefits of a cross-industries approach to risk assessment, safety and effectiveness. His current work centers on the development of hospital operations centers linked with sophisticated simulation capabilities, optimization of human performance during high risk activities such as resuscitation, analysis of human and system error, and human factors and ergonomics in healthcare. In 2002 Dr. Halamek founded the Center for Advanced Pediatric and Perinatal Education (CAPE, http://www.cape.lpch.org), the world’s first such center dedicated to fetal, neonatal, pediatric and obstetric simulation, located at the Lucile Packard Children's Hospital on the campus of Stanford University. He is currently a Special Consultant in Simulation- and Virtual Reality-based Learning to the U.S. Neonatal Resuscitation Program.
Situation Awareness

Lou Halamek MD, FAAP

Learning Objectives
- Analyze the impact of tools and techniques to foster 24/7 situation awareness on the management and triage of patients in your NICU and L&D unit as well as the hospital system at large.

What is situation awareness?
- The perception of environmental elements and events with respect to time or space, the comprehension of their meaning, and the projection of their status after some variable has changed.

Situation Awareness
- Perception
- Comprehension
- Projection

Situation Awareness
- Perception [Latin, percipere (v), seize, understand]: the ability to see, hear, or become aware of something through the senses.
Situation Awareness

Lou Halamek MD, FAAP

Situation Awareness

- comprehension [*Latin, comprehendere (v), seize, comprise*]: the action or capability of understanding something

Situation Awareness

- projection [*Latin, proicere (v), throw forth*]: an estimate or forecast of a future situation or trend based on a study of present ones

What is situation awareness?

- the ability to maintain an adequate internal representation of the status of the environment in complex and dynamic domains where there are sudden fluctuations in conditions

Situation Awareness Video: Driving in Shanghai

Situation Awareness Video: Flying the Space Shuttle

Situation Awareness Video: Neonatal Resuscitation
How is situation awareness attained?
- recognition and processing of key cues
  - visual
  - auditory
  - tactile
  - kinesthetic

How can cues be reliably recognized and processed?
- practice under realistic conditions
- followed by facilitated or self-critique

Situation Awareness
- also important when decision-making requires translating large amounts of data into useful information
- e.g., NICU bed management

Situation Awareness of the NICU Census: A Tale of Two Viewpoints

Situation awareness should not be situational...

Immanuel Barshi, Ph.D.
Human Systems Integration
NASA Ames Research Center

References
Thank you.

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halam@stanford.edu
Learning From Simulated Small Tests of Change to Improve Care in Our Micro-Premature Care Unit

Amy Atwater MPA BSN, RN
Senior Quality Improvement Specialist
Helen DeVos Children’s Hospital NICU
Grand Rapids, MI

Amy Atwater is a Senior Quality Improvement Specialist at Helen DeVos Children’s Hospital in Grand Rapids Michigan. She works closely with the Neonatal and Pediatric Intensive Care, Cardiology, and ECMO leading quality improvement projects with multidisciplinary teams. As an active participant in Vermont Oxford Quality Improvement Collaborative since 2002, she uses her skills as a facilitator to plan and promote the implementation of best practices to improve outcomes and standardize care. For the past 3 years she has been focused on promoting neurodevelopmental supportive care to the micro preemie and helped organize the opening of the Small Baby Unit which opened in 2015. Since then the unit has hosted 11 site visits using an innovative approach to adult learning which included simulation and video ethnology. Currently she is working with Grand Valley State University mentoring students on quality improvement tools and projects. Prior to becoming involved in quality improvement activities, Amy worked as a bedside clinician and eventually assumed a supervisory role for 12 years in Labor and Delivery and Neonatal Intensive Care.

Susan Teman BSN, RN, CPPS
Simulation Specialist
Helen DeVos Children’s Hospital
Grand Rapids, MI

Susan Teman BSN, RN, CPPS has 30 years of experience in healthcare leadership, quality, patient safety and risk management. She currently is Program Manager for Simulation for Helen DeVos Children’s Hospital in Grand Rapids, Michigan. In this position she is in charge of the management of the simulation program, simulation laboratory and associated technology, development and implementation of the business plan for simulation, coordination of training programs among users by working with department leadership to establish high level priorities and maximizes the use of human factors integration principles. She led the safety culture transformation at Helen DeVos Children’s hospital which went on to be recognized by the Lucien Leape Foundation, National Patient Safety Foundation, Michigan Hospital Association and outlined in numerous publications. She is a national speaker on patient safety for the Children’s Hospital Association and for Solutions for Patient Safety.

Annual Quality Congress Breakout Session, Sunday, October 29, 2017
Learning From Simulated Small Tests of Change to Improve Care in Our Micro-Premature Care Unit

Objective: Describe an innovative model of quality improvement that employs stimulation techniques and technology to test new care practices in the NICU using iterative PDSA cycles.
Learning From Simulated Small Tests of Change to Improve Care in Our Micro-Premature Care Unit

Amy Atwater MPA BSN, RN / Susan Teman BSN, RN, CPPS

Using Simulation to Improve Quality and Safety Outcomes in the Neonatal Unit:
Learning From Simulated Small Tests of Change to Improve Care in Our Micro-Premature Care Unit

Amy Atwater MPA BSN, RN
Susan Teman BSN, RN, CPPS
October, 2017

Disclosure and Overview:
We have no conflict of interest to disclose…

• Overview of simulation as a tool for improvement
• Using simulation to improve care of the micropremie
• Table top activity and demonstration

Presentation Objectives
Describe an innovative model of quality improvement that employs simulation techniques and technology to test new care practices in the NICU using iterative PDSA cycles.

➢ Build an understanding about how team-based simulation may be designed and implemented in any patient-centered area of healthcare.
➢ Describe how simulation supports a safe patient and employee culture.
➢ Using simulation and small test of change to improve neurodevelopmental support in the micropremie.

Why?

Research
➢ Use of Simulation in Patient Safety Efforts

The Top Patient Safety Strategies that can be Encouraged for Adoption Now
Shekelle, Pronovost, Wachter et al
Annals of Internal Medicine, 5 March 2013
Learning From Simulated Small Tests of Change to Improve Care in Our Micro-Premature Care Unit

Amy Atwater MPA BSN, RN / Susan Teman BSN, RN, CPPS

Human Factors

- How human beings process information:
  - Physical Environment
  - Ergonomics
  - Communication
  - Distractions
  - Lack of resources
  - Stress
  - Lack of awareness
  - Fatigue
  - Normalized Deviance
  - Lack of Knowledge

Human Factors Complexity

- Cognitive Fixation
  - 'This and nothing else……'
  - 'Everything is OK……'

- Social Redundancy: Engineered Systems vs. Social Systems
  - In engineered systems, multiple defective parts may overlap to be able to support expected outcomes
  - Social Systems include hierarchy, role confusion, groupthink, communication issues

Current Healthcare Competency Practices

- Policies/Procedures
- Guidelines
- Webinars
- Power Points
- Staff Meetings
- Emails

Start Simply

- Develop a small team of experts
- Talk to some friendly physicians and staff to get their input
- Run an in situ simulation on a unit with an interested manager
- Debrief about the simulation
- Use PDSA thinking to improve for the next simulation
- Run another simulation………..

Brief

- Building psychological safety:
  - Introductions and roles
  - Team feedback on simulation scenario
  - Emphasize goals for simulation: communication, teamwork, discovery of system issues
  - Encourage questions
  - Encourage to act as they would in a regular care scenario
  - Emphasize the importance of this work in improving the care of children
Debrief: Closing the Gap

1. Description of the simulation
   - “Can someone summarize the case?”
2. Analysis
   - What went well?
   - Where can we improve?
   - Barriers to meeting standards
3. Summary and Thank You’s
   - “Tell me about one thing that you will take away from today”
   - Thank you so much for participating. We know it can be uncomfortable but it will improve our patient outcomes

Patient/Parent Engagement

- Parents as partners
- Participate in mock code development in NICU
- Patient and Family Advisory Committee feedback on potential simulations
- Rounding simulations for multidisciplinary bedside rounds
- Child life participation in simulations
- Simulations for various procedures and equipment care prior to discharge

How can we utilize simulation?

- Competency and orientation/task training
- High risk, low volume procedures
- Team training
- Leadership Development
- Crisis management
- Patient Experience
- Learner (resident/nursing student training)
- New site training
- Transports/Handovers
- New procedures

So the better question may be, how can we NOT utilize simulation?

Real Life Examples

1. What procedures/policies/processes do you have on your floors that are difficult to embed?
2. What are your trends in incident reporting?
3. Actual events
4. Feedback from staff
5. High risk/low volume procedures
6. NICU Examples: Response to NEC symptoms, Documenting codes, Ventilator troubleshooting, Exchange transfusion

Eyes Wide Open

- Choose patient(s) who have the potential for deterioration or cause for increased concern
- Identify the following
  - Risks
  - Equipment needs
  - Human resources for response
- Discuss barriers to provision of care
- Assign accountability for immediate follow up for identified concerns or barriers
Learning From Simulated Small Tests of Change to Improve Care in Our Micro-Premature Care Unit

Amy Atwater MPA BSN, RN / Susan Teman BSN, RN, CPPS

Questions?

AIM Drivers Mechanisms

Timeline of Project

Simulation

- Skin-to-skin sitting and standing transfer.
- Transfer on the oscillator
- Providing care during skin-to-skin

Simulation

- Admission
- Two person Care
- Focus on “changing our language” with parents.
- Opportunities for crucial conversations.
Learning From Simulated Small Tests of Change to Improve Care in Our Micro-Premature Care Unit

Amy Atwater MPA BSN, RN / Susan Teman BSN, RN, CPPS

Video of Skin to Skin

Utilizing Simulation for Micropremie Care

Table exercise: Small Test of Change for Improving Micropremie Care

Identify resources on your unit that you can use for simulation
- People
- Equipment
- Technology
- Communication
- Culture*

References
- The Top Patient Safety Strategies that can be Encouraged for Adoption Now Shekelle, Pronovost, Wachter et al Annals of Internal Medicine, 5 March 2013
- Patient Safety, A Human Factors Approach Deckier, S; 2011; pg. 68-80
- Early Skin-to-Skin Care in Extremely Preterm Infants: Thermal balance and Care Environment Victoria Karlsson RN, Ann-Britt Heinemann, RN, etc. in The Journal of Pediatrics Vol. 161, No. 3 September 2012

Questions and wrap up?
Building and Empowering a Nurse-Led Neonatal Resuscitation Team in Ethiopia

Lou Pollack MD
Wax and Gold
Oakland, CA

Following completion of fellowship at the University of Michigan, Dr. Pollack practiced neonatology in metropolitan Seattle for thirty years, developing two community-based private practices and briefly as director of Regional Newborn Network at Seattle Childrens. He served for ten years in various positions within the Perinatal Section of the American Academy of Pediatrics, including inaugural chair of the Committee on Practice, and was principle author of the original national neonatology practice survey. Dr. Pollack currently serves as president of Wax & Gold.

Thomas Eusterbrock MD
Neonatologist
Department of Neonatology
UCSF Benioff Children’s Hospital
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Oakland, CA

Dr. Eusterbrock has practiced clinical neonatology in Germany and the East Bay in California for thirty years, in community hospitals as well as multi-specialty referral and teaching hospitals. He has been involved as a volunteer since 2012 in maternal-newborn quality improvement projects in Ethiopia.

Phillip Platt RNC, NNP-BC
Senior Newborn Nurse Practitioner Specialist
Pediatrix - Amarillo
Baptist St. Anthony Hospital
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Amarillo, TX

Phillip Platt is a Neonatal Nurse Practitioner in a private medical group in Texas, USA. He has twenty eight years of experience at the community and university level. He is responsible for leading and coordinating institutional Quality Improvement initiatives including 6 years as a volunteer in Ethiopia working with Maternal and Newborn Health.
Suzanne Hally RN  
Staff Nurse  
Massachusetts General Hospital for Children  
Boston MA  
Director of Nursing Education  
Wax and Gold  
Boston, MA

Neonatal nurse with over 17 years’ experience in Level II/IV neonatal intensive care unit. Expertise includes ground transport and management of critically ill newborns, delivery room management of critically ill newborns, management of newborn requiring extracorporeal membrane oxygenation ECMO, nursing education and mentorship, Pediatric Ethics Consultation, and Palliative and End-of-Life Care.

Misrak Tadesse MD  
Staff Neonatologist  
Frederick Memorial Hospital  
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Dr. Tadesse has been a practicing clinical neonatologist in Maryland for seventeen years. In addition, she is actively involved in institutional maternal-newborn health quality improvement initiatives both locally and globally. Dr. Tadesse currently serves as the secretary of Wax & Gold, Inc.

Annual Quality Congress Breakout Session, Sunday, October 29, 2017  
Building and Empowering a Nurse-Led Neonatal Resuscitation Team in Ethiopia

Objective: Explore innovative methods to perform PDSA cycles and small tests of change to test and implement a nurse-led resuscitation team in resource-limited settings.
Learning Objectives
Participants will be able to:
- Explore innovative methods to perform PDSA cycles and small tests of change to test and implement a nurse-led resuscitation team in resource-limited settings.
- Describe origins of ALS Program at SPHMMC.
- Identify essential elements in the didactic and clinical curriculum.
- Discuss local circumstantial challenges met and overcome.
- Identify next steps in quality improvement program at SPHMMC.

Observations
- 30% of infants born at SPHMMC admitted to the NICU
- 80 – 90% of infants admitted to the NICU are hypothermic
- Lack of sufficient equipment to support thermoregulation and resuscitation in delivery room.
- Hypothermia almost universally considered a sign of sepsis resulting in admission and minimum seven day treatment with antibiotics
- Nurses not involved in the care and resuscitation of the newborn in the delivery room.

Goal: Nursing Empowerment
To collaborate with nurses in partnership through education to provide them additional knowledge, skills and attitudes necessary in the resuscitation and care of all newborns.
The Education Plan

The Curriculum

- NANN sections relevant to maternal fetal physiology, newborn resuscitation, and normal maternal resuscitation
- Maternal conditions that affect the outcome
- TACAL
- MB
c- EDAC
- MDP
- Over 300 hours of lectures followed by 300 hours of hands on training in the delivery room.

The Wax and Gold Team

Hands on Training
Why use plastic wrap for all infants?

"In resource-limited settings, to maintain body temperature or prevent hypothermia during transition (birth until 1 to 2 hours of life) in well newborn infants, it may be reasonable to put them in a clean food-grade plastic bag up to the level of the neck and swaddle them after drying (Class IIb, LOE C-LD). Another option that may be reasonable is to nurse such newborns with skin-to-skin contact or kangaroo mother care (Class IIb, LOE C-LD)." 

Challenges to data collection
Saint Paul Hospital Millennium Medical College (SPHMMC)
Maternal-Newborn Quality Improvement Project
Thomas Eusterbrock, Suzanne Hally, Phillip Platt, Lou Pollack, Misrak Tadesse

“The ALS nurses are the most qualified to resuscitate a newborn”

Tiguaded Demelash

Alem Kidane

“Tigist Tilahun

“There is no reason for a baby to be hypothermic. There will not be any more hypothermic babies on my watch”

“Frehiwot Dinku

“I am in awe that this baby that would have otherwise been ‘written off’ was suckling and warm and interacting with his mother. I realize it only takes a little bit of care to make a big difference”

“Alem Adugna

*I realized I really wasn’t a nurse until participating in this program”

Data Management
Saint Paul Hospital Millennium Medical College (SPHMMC)

Maternal-Newborn Quality Improvement Project

Thomas Eusterbrock, Suzanne Hally, Phillip Platt, Lou Pollack, Misrak Tadesse

Preliminary Outcomes

Next Steps
A Call for Healthcare System Redesign to Support Pre-term Infants and Families After NICU Discharge

Dennis Z. Kuo MD, MHS
Division Chief of General Pediatrics
University at Buffalo
Medical Director
Primary Care Services
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Dr. Kuo MD, MHS is a general academic pediatrician, Division Chief of General Pediatrics at the University at Buffalo, and Medical Director of Primary Care Services at Women & Children’s Hospital of Buffalo. He began his career with five years in full-time general pediatrics practice before completing a three year general academics pediatrics fellowship at Johns Hopkins University. Following his fellowship, he was on the pediatrics faculty at the University of Arkansas for Medical Sciences for eight years, where he was also an attending physician at Arkansas Children’s Hospital.

Dr. Kuo is particularly interested in population health, practice transformation, health care delivery and outcomes for children with special health care needs and medical complexity. His research interests focus on health care systems and quality improvement for children with special health care needs, children with medical complexity, the patient/family-centered medical home, and family-centered care.

Annual Quality Congress Breakout Session, Sunday, October 29, 2017
A Call for Healthcare System Redesign to Support Pre-term Infants and Families After NICU Discharge

Objective: Analyze the real-world challenges for care beyond the NICU walls and identify opportunities to improve both the quality and the content of follow-up and community follow-through for NICU graduates and their families.
A Call for Healthcare System Redesign to Support Pre-term Infants and Families After Discharge

Dennis Z. Kuo MD, MHS

A CALL FOR HEALTH SYSTEM REDESIGN TO SUPPORT PRETERM INFANTS AFTER DISCHARGE

October 29, 2017

Disclosures

- Work in this presentation was supported by HRSA Grant R40MC23626.
- I have no financial conflicts of interest to disclose.
- No commercial support was received.
- The scientific views, statements, and recommendations expressed during this activity represent those of the author/speaker and do not necessarily represent the views of The Robert Larner College of Medicine at The University of Vermont.

Objective

- Analyze the real-world challenges for care beyond the NICU walls and identify opportunities to improve both the quality and the content of follow-up and community follow-through for NICU graduates and their families.

Subobjectives

- Understand what makes a system of care
- Learn needs of preterm infants after discharge from the NICU
  - Perform care mapping
- Learn about potential models of care
  - Care coordination
  - Comanagement
  - Roles of neonatal, primary care, and others
- Understand payment reform and the potential to support health system redesign

Case presentation

- 26 week gestation – discharged to home at 37 weeks post gestation
- 2400 grams, on 24 calorie Neosure
- Slow feeder, responds well to pacing
- Home oxygen
- Apnea monitor
- ROP
- Etc...........
  - what is this child/family at risk for and what can we try to mitigate through excellent care delivery?
  - What role can you play in ensuring the child/family achieve the best outcomes?

What is a system of care?

- A range of services and supports
- Guided by a philosophy
- Supported by an infrastructure

A Call for Healthcare System Redesign to Support Pre-term Infants and Families After Discharge

Dennis Z. Kuo MD, MHS

Requirements
- Defined population
- Defined components
- Defined roles of components
- Values and principles

Changing health care systems
- Activities of change must be grounded in system of care values and principles
- Activities should address structure, processes, and relationships
- Coordinate changes across administrative and funding jurisdictions


Principles of the care system for children with special health care needs
- Responsive to family challenges, priorities, and strengths
- Developed in partnership with constituents
- Reflective and respectful of cultural norms and practices of families
- Accessible to everyone
- Affordable to those who need assistance
- Organized and coordinated through collaboration


Questions
- What are the values of a health care system for preterm infants after discharge from the NICU?
- What are the structure, processes and relationships of a system of care for preterm infants?

Epidemiology of prematurity
- Eight percent of births result in stay to NICU
  - 6% born under 28 weeks
  - Prematurity costs over $26 billion
- Medical risk continues after discharge
  - Chronic lung disease
  - ROP
  - Poor growth and feeding difficulties
  - Behavior and neurodevelopmental disabilities
  - Increasing # children discharged home with GT, trachs and other technologies

What happens after they leave the NICU?
- Frequent outpatient visits and prescription medication use
  - In first year ~20 outpatient visits/year
  - Excess hospitalization, particularly in the first two years after discharge
  - Readmission rates of 15-23% in first year of life
  - ELBW infants have readmission rates approaching 50%
  - Some infants >50%
- Readmission causes
  - Respiratory is primary cause
  - Other: infectious, growth/nutrition
A Call for Healthcare System Redesign to Support Pre-term Infants and Families After Discharge

Dennis Z. Kuo MD, MHS

Additional risk factors
• ELBW infants, particularly with male gender, prolonged NICU stay for pulmonary reasons
• Late preterm infants (33-36 weeks) still hospitalized at a rate greater than that of term infants
• Other costs include EI, special education, lost employment

Long term issues
• Impaired neurodevelopmental outcomes: cognitive, motor deficits, CP, vision and heating
• Higher likelihood of psychological and behavioral issues (ADHD, autism, difficulty in peer interactions)
• Adult outcomes
  • Increased rate of insulin resistance, hypertension
  • Overall lower rates of educational achievement, independence
  • Many adults do report similar quality of life to adults born at term

Questions
• What are modifiable factors that can improve care for children born preterm, particularly AFTER they leave the NICU?
• What health outcomes might be modifiable?
• What roles can we play in ensuring that ALL children who leave the NICU have access to such care?

The current system for NICU graduates
• (Almost) all children have primary care
  • Somewhat population based
  • Bright Futures guidelines for preventive care
  • Largely tailored towards typically developing children
  • Few guidelines for children who are born premature
• NICU followup clinics
  • Strong emphasis on developmental surveillance
  • Medical follow-up is variable
  • Not all children have access – not population based
• Education system – IDEA, Early Intervention
  • Population based
  • Developmental screening and natural environment therapies

Broad issues to address
• Medical issues
  • Neonatologist is often the medical authority
  • Few neonatologists provide continuous outpatient care
  • Many primary care physicians are not comfortable with the care of the child with medical complexity
• Care coordination
  • Addresses fragmented system of care
  • Sometimes multiple care coordinators can make things even more difficult

Medical care is a relatively small part of determining health

[Diagram showing the relative importance of medical care, social determinants, and genetics in determining health]
A Call for Healthcare System Redesign to Support Pre-term Infants and Families After Discharge

Dennis Z. Kuo MD, MHS

Care mapping for a NICU graduate
- 25 week gestation – discharged to home at 37 weeks post gestation
- 2400 grams, on 24 calorie Neosure
- Slow feeder, responds well to pacing
- Home oxygen
- Apnea monitor
- ROP
- Etc...........

Care map example

Call to action
- System change is needed for preterm infants
- Consider principles of care, values, components, and the roles that the components play
- What do YOU want to see happen?

Definitions
- Care coordination: team-based activity addressing “interrelated medical, social, developmental, behavioral, educational and financial needs to achieve optimal health and wellness outcomes”
- Co-management: “Effective division of responsibility among team members”
- Team-based care: families and providers work across multiple settings to “identify, coordinate, and address shared goals that meet the needs of the whole child”

System framework: Chronic Care Model

Components of effective care delivery for preterm infants in the primary care setting
A Call for Healthcare System Redesign to Support Pre-term Infants and Families After Discharge

Dennis Z. Kuo MD, MHS

What might this look like?

- Clinical care protocol. Care may be standardized among providers to take advantage of decision-making support. The protocol should be evidence- or guideline-based when available, with outcomes utilized for QI data purposes.
- Designated care team. Each preterm infant should have a designated physician who provides continuity of care, and a practice staff member such as a nurse who acts as a key contact and/or provides care coordination.
- Decision-making support. Each care team should have appropriate access to a consulting neonatologist and/or neonatology service such as a high-risk follow-up program who may provide expertise and guidance as needed, particularly for aspects of clinical management such as oxygen support, feeding management, and developmental surveillance.
- Family-centered care. Practitioners should be versed in the principles of partnership and the culture of family-centered care, including shared-decision making, self-management, and utilizing families as partners in the QI team process.

Alignment with health care reform

- Payment reforms, clinical practice guidelines, and outcomes research have the potential to transform the care of the preterm infant after NICU discharge.
- Defined population, clinical guidelines, potential for health care savings.

The future way of paying for health

- Four basic methods of payment:
  - Capitation – per person
  - Bundled payment – fixed amount for a given condition or event
  - Incentives – for quality
  - Shared savings – for costing less than predicted
- Note that these payments are not always tied to an encounter. This enables practices and hospital to be more flexible in how these dollars are used.

Future directions/Discussion

- Population focus on preterm infants
  - Opportunity with improvement – how low can hospitalization rate go? How can we improve developmental outcomes?
  - Integrated care system
  - Payment reform supporting change
- What primary care practices likely should do
  - Practice transformation
  - Care coordination
  - System reform
- How neonatology might consider collaborating
  - Determine and set care standards
  - Participate in co-management and collaboration
  - Support and maintain data registries

Takeaways

- Preterm children are a population focus of interest
- System reform is needed to transform care, including practice transformation, care coordination, comanagement
- Payment systems can support system change
- There is tremendous opportunity!
A Call for Healthcare System Redesign to Support Pre-term Infants and Families After Discharge

Dennis Z. Kuo MD, MHS

References

- Kuo DZ, Lyle RE, Casey PH, Stille CJ. Care System Redesign for Preterm Children After Discharge From the NICU. Pediatrics 2017 Mar 1. pii:e20162969.
Lessons on Shared Decision-Making in the NICU

Gregory Moore MD, FRCPCH
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Ottawa, ON

Dr. Gregory Moore is an academic neonatologist practicing at the two hospitals in Ottawa that have level 3 neonatal intensive care units – the Children’s Hospital of Eastern Ontario and The Ottawa Hospital. After obtaining his medical degree from the University of Western Ontario, he completed his Paediatrics residency and the first 2 years of his Neonatal-Perinatal Medicine fellowship at the University of Ottawa in Ontario, Canada. He went on to enjoy a final enriching fellowship year at the Royal Women’s Hospital in Melbourne, Australia. He returned to Ottawa in 2009 as an attending neonatologist and an assistant professor on the clinician-teacher track through the University of Ottawa. In 2016, he was promoted to the associate professor level. He is a Clinical Investigator with the CHEO Research Institute and Ottawa Hospital Research Institute. His areas of academic interest are bioethics with a focus on working with families when their baby may be born at an extremely low gestational age, and post-graduate medical education. Outside of ‘hospital life’, he enjoys time with his wife and four children and competing as a national level Masters cyclist.

Annual Quality Congress Breakout Session, Sunday, October 29, 2017
Lessons on Shared Decision-Making in the NICU

Objective: Identify 3 ways to improve family communication and engagement during the antenatal consultation.
Lessons on the Shared Decision Making Process Regarding Extremely Preterm Delivery in the Birthing Unit

Gregory Moore MD, FRCPC

DISCLOSURES
• I have no conflicts of interest to disclose.

OBJECTIVES
At the end of this session, participants will be able to:
1. Identify three ways to improve family communication and engagement during the antenatal consultation

GUIDELINES - Management Options

GUIDELINES ... can they help?
• “If guidelines for increased parental decision making are encouraged by the outcome of the Messenger trial, the verdict will be a victory ... for every set of prospective parents in this country.”
  (emphasis added)
  Harrison J Perinatology 1996

BACKGROUND - The Ottawa Guideline
• From:
  – GA-based
  – “black and white”, “informed choice”, coaxing?
• To:
  – Prognosis-based
  – SDM
• Applicability of SDM
• Use of recommendations in SDM

Guillen et al. Pediatrics 2015
Lemyre, J Perinatol 2016
Lessons on the Shared Decision Making Process Regarding Extremely Preterm Delivery in the Birthing Unit

Gregory Moore MD, FRCPC

IMPLEMENTATION - Why

- Misinformation
- Gestational ageism (Wilkinson Arch Ped Adol Med 2012)
  - Analogous to ‘ageism’
  - Form of prejudice
  - Negative stereotypes and attitudes
  - Age-based rationing of treatment
    - Strict form = ‘cut offs’
    - Moderate form = ‘influencing factor’

METHODOLOGY – Working Group

- Assembled to create a local guideline; use AGREE-II
- 16 members:
  - 3 parents of children born extremely premature
  - 3 neonatologists, 1 MFM specialist
  - 2 NICU RNs, 2 BU RNs, 1 MFM RN
  - 1 ethicist
  - 1 expert in shared decision making (ex-NICU RN)
  - 1 NICU fellow
  - 1 social worker

CPS GUIDELINE - Consultation Process

CPS GUIDELINE - Framework

** In the clear majority of cases, the risk estimation for NDD does not reach the ‘extremely high likelihood’ category. Most cases where palliative care is recommended usually relate to an ‘extremely high likelihood’ of mortality, even when providing intensive care.

** Given the lack of moral authority on the suggested level of care, parents may choose a non-recommended option. HCPs should engage with them to determine their infant’s management plan.

*** Additional risk factors include: small for gestational age (GA), absence of antenatal corticosteroids (ANCS), multiple gestation, GA early within week of gestation, birth outside of a tertiary centre, acute chorioamnionitis, major congenital anomalies present on ultrasound.

BRAINSTORMING and DISCUSSION
Lessons on the Shared Decision Making Process Regarding Extremely Preterm Delivery in the Birthing Unit

Gregory Moore MD, FRCPC

BACKGROUND – Patient Decision Aids
- Evidence-based tool
- Guide patients through decision-making process
- Shown to:
  - Increase patient involvement
  - Improve patient knowledge and risk perception
  - Improve values-choice agreement

Existing Decision Aid #1
- Independently created by authors (?)
- Tested on women at >28 weeks GA:
  - Improved knowledge about outcomes at 23 wks GA

Existing Decision Aid #2
- Decision aid systematically developed and pre-tested on simulated patients
  - 6 cards
  - “At Birth”
  - Local survival rates
  - Long-term neurodevelopmental impairment (NDI) rates
  - 3 postnatal complications
  - Corresponding user guide/script

METHODOLOGY – IPDAS Checklist

RESULTS – IPDAS Checklist

RESULTS – IPDAS Checklist
Lessons on the Shared Decision Making Process Regarding Extremely Preterm Delivery in the Birthing Unit
Gregory Moore MD, FRCPC

RESULTS – IPDAS Shortcomings

- Pre-modification IPDAS Checklist scoring showed need for:
  - Palliative care card
  - Updated, specific data
  - More information

RESULTS – I P D A S

Shortcomings

- Pre-modification IPDAS Checklist scoring showed need for:
  - Palliative care card
  - Updated, specific data
  - More information

Satisfaction questions

<table>
<thead>
<tr>
<th>Post-decision coaching (N=18)</th>
<th>Agree strongly n (%)</th>
<th>Agree somewhat n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The decision coach seemed to understand the stresses I am facing **</td>
<td>14 (78)</td>
<td>3 (17)</td>
</tr>
<tr>
<td>2. The decision coach helped us identify what I needed to know to make decisions about what would happen to my baby</td>
<td>16 (89)</td>
<td>2 (11)</td>
</tr>
<tr>
<td>3. I felt better about my ability to make a good decision after meeting with the decision coach **</td>
<td>14 (77)</td>
<td>2 (11)</td>
</tr>
<tr>
<td>4. The decision coaching session was about the right length of time</td>
<td>17 (94)</td>
<td>1 (6)</td>
</tr>
<tr>
<td>5. The decision coach was truly concerned about our baby's well being **</td>
<td>14 (78)</td>
<td>2 (11)</td>
</tr>
<tr>
<td>6. The decision coaching session was valuable to me</td>
<td>16 (89)</td>
<td>2 (11)</td>
</tr>
</tbody>
</table>

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BRAINSTORMING and DISCUSSION
Lessons on the Shared Decision Making Process Regarding Extremely Preterm Delivery in the Birthing Unit

Gregory Moore MD, FRCPC

COMMUNICATION - How

- Table 3 in the CPS statement
  - Provides tips
  - In line with what most parents desire
- Experience
- Practice/Training

COMMUNICATION – What do parents want?

- Differing involvement in decision making
- Information – balanced and accurate
- Good communication – words matter
- Trust


COMMUNICATION – What do parents want?

- Positives of prematurity
- Realistic hope
- Acceptance of the ‘grey’
- Support
- Focus beyond gestation
- Importance of experience

Moore et al. Paed Child Health 2017

COMM’N – Value laden questions

SOBPIE:
- What is the Situation?
- Consider Opinions around and Options for the situation
- Ensure Basic human interactions
- Truly get the Parents’ story/concerns/needs/goals
- Provide truthful and desired Information
- Manage the Emotions and relational aspects of decision making

Janvier et al. Semin Perinatol/ 2014

COMM’N – Value laden questions

ANSWER:
- Actively listen after you ask open-ended questions
- Perform a Needs assessment to determine the exact reason
- Be Self-aware of one’s own values and their influence on you
- Clarify Whose values are being used when looking at the sit’n
- Elicit/explore values through deeper discussion and communication
- Formulate a Recommendation or Response to the question

Tucker-Edmonds et al. Pediatrics 2015
Lessons on the Shared Decision Making Process Regarding Extremely Preterm Delivery in the Birthing Unit

Gregory Moore MD, FRCPC

IMPLEMENTATION – Pitfalls

• Ottawa versus Canada survival data
• Attitude/Culture
  – Experience based
  – Lack of reading
  – Desire for ‘black/white’ instead of the ‘grey’ reality

IMPLEMENTATION – Pitfalls

• Inadequate education sessions
  – Night-shift RNs
  – RTs
  – Method to voice dissent – lacking?
• Preparedness
• Existence of moral distress

BRAINSTORMING and DISCUSSION

It is a process ...

“[The NICU team’s] efforts and compassion will always be appreciated and [the NICU team] will always be in our hearts.”

QUESTIONS? COMMENTS?

THANK YOU!
Lessons on the Shared Decision Making Process Regarding Extremely Preterm Delivery in the Birthing Unit

Gregory Moore MD, FRCPC