Beyond Networks & Registries for Clinical

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Declaration of Conflicts

- No conflicts to declare
Data Flow & Security

Data Flow and Security for CNN, CPN and CAPSNet

- Patient identifiable information will be removed before the data send to the data center.
- Communication between external users and secure web server by 128-bit SSL encryption.
- Data entry at participating institutions via customized window program across internet.
- Project management team monitors for accuracy and quality of data.
- Statistical Team download data sets for analysis.

EPIQ
Evidence-based Practice for Improving Quality
Variations in Canadian NICU

Crude rate (%)

Adjusted rate (%)

Site

EPIQ
Evidence-based Practice for Improving Quality
EPIQ Conceptual Model

(Adapted from Kitson et al., 2002) – Promoting Action on Research Implementation in Health Services (PARIHS) Model

- **Evidence**
  - (PROJECT 1, 3, 4)

- **Context**
  - (PROJECT 2)

- **Process Outcomes**

- **Clinical Outcomes**

- **Facilitation**
  - (PROJECT 3, 4, 5)
A Cluster RCT using EPIQ to reduce nosocomial infection and BPD in Canadian NICUs
Cluster RCT

EPIC 12 NICU

Group A
- NI
- Excluded 1 NICU

N = 250

NI 5 NICU

N = 2465

Group B
- BPD

BPD 6 NICU

N = 3070

Group C
- Non-EPIC 5 NICU
- Control 5 NICU

N = 984

N = 3070

N = 250

N = 2465

N = 984
Cluster RCT of EPIQ in 12 Canadian NICUs

<table>
<thead>
<tr>
<th>Incidence</th>
<th>NI Group</th>
<th>BPD Group</th>
<th>Control Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>NI</td>
<td>↓34%</td>
<td>↓44%</td>
<td>No change</td>
</tr>
<tr>
<td>BPD</td>
<td>No change</td>
<td>↓15%</td>
<td>No change</td>
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</table>

Cost Savings

- Estimated cost savings based on reduced length of NICU stay of 2 days per patient

$70 million annually
EPIQ-II Clinical Trial
- improving multiple
EPIQ-II Multi-Center Clinical

- $5 million 5 year CIHR funded study
- 29 tertiary level NICUs in Canada
- Target mortality and 5 major morbidities simultaneously: BPD, IVH, NEC, ROP, infection
- Combining best practice techniques from around the world – Canada, Europe, Japan
- Standardized neuro-developmental outcomes assessment at 18 months and 36 months
- Developing a Canadian NICU Best Practices Model
EPIQ-II Year 1 Interim Results

Percent Change

- Mortality: -12%
- NI: +19%
- NEC: -20%
- ROP: +19%
- IVH: -20%
<table>
<thead>
<tr>
<th>%Change In Incidence</th>
<th>-75%</th>
<th>-66%</th>
<th>-27%</th>
<th>-33%</th>
<th>-54%</th>
<th>-46%</th>
</tr>
</thead>
</table>

Sunnybrook Outcomes Incidence 2008–10

Evidence-based Practice for Improving Quality
Lessons from Europe &

Children’s Hospital, University of Cologne
Tallinn Children’s Hospital
Osaka Medical Center & Research Institute for Maternal & Child Health
Gentle Resuscitati
The Cologne Approach
Paradigm Changes

- Deliver infant early in presence of an inflammatory process
- Prenatal steroids
- Delayed cord clamping
- Avoid mechanical ventilation – allow 3 minutes for transition before intubation and aggressive resuscitation
- Avoid intubation for surfactant administration
- Avoid general anesthetics, narcotics and paralytics
- Minimize handling; maximize developmental care

Use NI-HFOV to treat apnoea of prematurity
Outcomes <27 weeks - Canada/

- Mortality: Canada - 17.5, Cologne - 35.0, 52.5, 70.0
- BPD: Canada - 0
- IVH Grade 1 or 2: Canada - 17.5, Cologne - 35.0, 52.5, 70.0
- NEC: Canada - 0
- ROP Grade 2 or more: Canada - 0

Legend: 
- Canada
- Cologne
EPIQ GentleR Pilot Trial

- Protocol and simulation training modules
- Funding by MOHLTC
- Pilot at Mt Sinai Hospital
- Started September 2010
- Objective = assess safety, streamline protocol
- Outcome = need for aggressive resuscitation
- Individual consent
- Eligible infants = 25+0 to 28+6 weeks GA
- Dedicated group of trained staff

- 11 babies recruited – 1 required intubation
Family Integrated

The Estonian Model
Mothers health and wellbeing is considered essential to the baby’s wellbeing

midwife
psychologist
physician

Atmosphere of team support; mother and baby are a unit, The nurse partners mother in the baby’s care
Estonia Care Model

- Parents are Primary Care-Givers, not nurses
- Parents responsible for all care except IV, medication
- Parents participate in rounds, reports, charting
- Encourage developmental & kangaroo care
- Nurses are teachers and consultants

Results =
- 30% reduction in NI
- 30% improvement in weight gain
- 20% reduction in LOS
- 50% reduction in nurse utilization
Current Family Centered Care

- Family
- Baby
- Nurse
- Doctor
- Therapist

EPIQ
Evidence-based Practice for Improving Quality
Family Integrated Care Model

- Mother (family)
- Infant
- Adult Physician
- Midwife
- Nurse
- Neonatologist
- Psychologist / therapist
- Parent Volunteer
Family Integrated Care

- Funded by AHFMR/MOHLTC
- Formative pilot at Mt Sinai started March 2011
- Eligible patients = CPAP or less support
- Parents and Providers as planning co-leads
- Tremendous support from parent volunteers
- Planning, protocols, training modules, ethics, legal completed
- 20 families enrolled to date
- Full clinical trial planned for 2012
## Preliminary Results

<table>
<thead>
<tr>
<th></th>
<th>FIC</th>
<th>Controls</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight gain</td>
<td>38% increase over Controls</td>
<td>baseline</td>
</tr>
<tr>
<td>Nosocomial Infection</td>
<td>0</td>
<td>11.5%</td>
</tr>
<tr>
<td>Critical Incident</td>
<td>0</td>
<td>2</td>
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</table>
Japan NEC Strategy

- Exclusive breast milk feeding for <28 weeks
- Aggressive feeding – full feeds in one week
- Avoid umbilical catheters
- Early use of PIC lines to reduce skin breaks
- Use antibiotics only if evidence of infection
- Transpyloric feeding catheters
- Probiotics
- Glycerin enema
- Minimal handling
- Encourage developmental & kangarooo care
Japan Hemodynamic Strategy

- Cardiovascular hemodynamics are key to development of IVH and NEC
- Use of functional echo-cardiography to guide fluid management and inotrope therapy
- All Japanese neonatologists are skilled in performing functional echo
- Aggressive monitoring and management of PDA
Morbidities <1500g BW – Canada/Japan

- BPD
- NI
- IVH 1/2
- PVL
- NEC
- ROP 3/4

Canada vs. Osaka
EPIQ Best Practices

EPIQ-II
Gentle Neonatal Care

GentleR
NI-HFOV

TLC by Parent

NEC & Hemodynamic

Enhanced Neonatal Follow-Up Program

EPIQ Lessons

Human Milk Bank

Evidence-based Practice for Improving Quality
## Targets for Potential % Reduction in

<table>
<thead>
<tr>
<th>Condition</th>
<th>Cologne (&lt;27 wks)</th>
<th>Japan (&lt;1500g)</th>
</tr>
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<tbody>
<tr>
<td>Mortality</td>
<td>10</td>
<td>?</td>
</tr>
<tr>
<td>BPD</td>
<td>92</td>
<td>71</td>
</tr>
<tr>
<td>NI</td>
<td>?</td>
<td>72</td>
</tr>
<tr>
<td>IVH 3/4</td>
<td>52</td>
<td>75</td>
</tr>
<tr>
<td>NEC</td>
<td>81</td>
<td>57</td>
</tr>
<tr>
<td>ROP 3/4</td>
<td>81</td>
<td>–20</td>
</tr>
</tbody>
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Paradigm Changes

**Current**

- Keep baby in-utero as long as possible
- Intervene rapidly – neonatal resuscitation
- Technology intensive – ventilation, TPN
- Care for patient
- Family centered care

**New**

- Deliver early if evidence of inflammation
- Facilitate transition – gentle resuscitation
- Minimal intervention – non-invasive ventilation, feed
- Care for whole family
- Family integrated care
Health System Implications

- Parents provide care
- Milk Bank
- Developmental care
  - Improved feeding
  - Enhanced Follow-Up
- Re-develop facilities
- Re-organize perinatal regionalization
- Appropriate use of technology
- Change in roles
  - Fewer staff
  - Re-train staff

- Improved outcomes
- Reduced costs

FAMILY INTEGRATED CARE

GentleR

EPIQ
Evidence-based Practice for Improving Quality
Questions to Ponder……

- Why do both the Cologne (less intensive) and Osaka (more intensive) approaches give good results?

- Is more better?

- Do we have the right model of care?

- Is the reductionist method the appropriate analytic approach?

- Why are these innovations coming from non-evidence based institutions?
With thanks to the Canadian Neonatal Network

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