Care Standardization and Clinical Guidelines: The future is now for CDH

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I have no financial disclosures
Optimal Health Care Delivery

• The optimal delivery of health care is guided by the following principles:
  • People are treated safely
  • The treating environment is suitable to a patient’s needs
  • There is shared decision-making
  • Care providers are suitably trained and supported
  • The **optimal quality of care** is being provided

Adapted from Royal College of Physicians of England Standards for Children’s Surgery – Children’s Surgical Forum
Standardization

• Process of developing, agreeing upon and implementing uniform technical specifications, criteria, methods, processes, designs or practices that can increase compatibility, interoperability, safety, repeatability and quality
Standardization

• Widely used for decades in non-health care industry
• **Assumes failure** from start to end of process
• Creates a system that proactively attempts to mitigate risk, provide surveillance while enacting barriers to potential hazards
the management of industries. Some of these are new adjustments of “function” (responsibilities and duties) clarified, charted, defined; regular instruction, such as drill in technic and manual dexterity and correct form; practice in team work; the printing on instruction cards of the best standard practice covering all ordinary acts and activities; constant inspection by one delegated to this duty; record of successes and errors like a ball-player’s fielding average or a government office tally of character of work done; promotion by rating, and finally, a series of studies, undertaken as in the other mechanical crafts, by measurement of motion, speed, fatigue and efficiency.
Why Standardize in Health Care?

- Knowledge transfer has occurred through mentorship for generations
- Exponential growth in medical evidence over the last 50 years
  - Hard for clinicians to keep abreast of rapidly evolving treatment paradigms
  - Increasing complexity of medical conditions
Why Standardize in Health Care?

• High level evidence supports routine clinical decision making only 20% of the time \(^1\)
• Even when evidence-based guidelines are available, only 2/3 of patients receive recommended care and 25% receive unnecessary or harmful care \(^2\)
• **Successful outcomes** are assumed as the baseline (contrary to non-healthcare industry)

• Development of “standard operating procedures”
  • Guidelines, clinical pathways, protocols

Clinical Practice Guidelines

• High quality, evidence-informed clinical practice guidelines (CPGs) can provide a way to bridge the gap between
  • Health policy
  • Best practices
  • Local clinical contexts
  • Patient choice
Clinical Standard Work Pathways in Pediatrics

Differences between Pre- and Postpathway Period:
Slopes $-5.55$ (95% CI $-2.45$ to $-1.64$); $P = .001$.
Intercepts $4256$ (95% CI $2382$ to $6131$); $P < .001$.

$R^2$ for model: 0.98

Prepathway Period:
Intercept $5951$ (95% CI $5857$ to $6145$).
Slope $+126$ (95% CI $+60$ to $+191$).

Postpathway Period:
Intercept $14.168$ (95% CI $12.851$ to $15.485$).
Slope $-29$ (95% CI $-92$ to $+34$).

$R^2$ for model: 0.97
Standardization in LMIC’s

**Surgical Safety Checklist**

Before induction of anaesthesia
(with at least nurse and anaesthetist)

- Has the patient confirmed his/her identity, site, procedure, and consent?
  - Yes
- Is the site marked?
  - Yes
  - Not applicable
- Is the anesthesia machine and medication check complete?
  - Yes

Before skin incision
(with nurse, anaesthetist and surgeon)

- Confirm all team members have introduced themselves by name and role.
- Confirm the patient's name, procedure, and where the incision will be made.
- Has antibiotic prophylaxis been given within the last 60 minutes?
  - Yes
  - Not applicable

Before patient leaves operating room
(with nurse, anaesthetist and surgeon)

- Nurse Verbally Confirms:
  - The name of the procedure
  - Completion of instrument, sponge and needle counts
  - Specimen labelling (read specimens labels aloud, including patient name)
  - Whether there are any equipment problems to be addressed

**Standardization in pat High 5s project**

**Agnès Leotsakos**, **Hao Zheng**, **Rick Crotty**, **Carolyn Hoffman**, **Louise Morganstein**, **D margaret Duguid**, **Christian Thomeczek**, **Bill Munier**

This checklist is not intended to be comprehensive. Additions and modifications to fit local practice are encouraged.
Definition of CPG

2011 – statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and the assessment of the benefits and harms of alternative care options.
What are the goals of guidelines and pathways?

• Provide consistent care
• Provide efficient care
• Remove *unwanted* variation in care
• Use evidence to guide clinical decision-making

• Many consider CPGs as an essential component of quality care delivery
Terminology

• Guidelines – generally relate to broader systems with a primary care focus (e.g. food security, water and air quality)
  • Developed and used by policy makers, service organizations, funders, regulatory authorities

• Care pathways – series of evidence-informed steps which can include a multidisciplinary team at various care levels
  • More details on the sequence, timing and provision of care

• Protocols – pertain to explicit rules or instructions on how to perform a process or task without error
Potential Benefits of Clinical Guidelines?

**Patients**
- Improved outcomes
- Reduced morbidity and mortality
- Consistency of care
- Empowerment
- Influence public policy

**Providers**
- Improved quality of clinical decision making
- Highlight knowledge gaps and influence research
- Medicolegal protection

**Health Systems**
- Improve efficiency
- Standardize care
- Guideline compliance is a testament to commitment to excellence
Potential Harms of Clinical Guidelines?

**Patients**
- Trust
- Patients vs Individuals?
- Threat to shared decision-making
- Reduction of access or coverage for services
- Misuse by advocacy groups

**Providers**
- Trust
- Poor recommendations are inefficient or wasteful
- Conflicting guidelines?
- Outdated guidelines?
- Discourage ongoing research or innovation?

**Health Systems**
- Adds cost
- Wastes limited resources
Why are the effects of standardization often less than desired?

CPG’s → Implementation

- Anticipated Outcome
- Unexpected outcomes
- Inefficient resource utilization
- Care deviation (knowledge vs Innovation)

This information is often not collected

Adapted from J. Sharma, ACS Safety and Quality Conference 2018
Why are the effects of standardization often less than desired?

CPG’s

Implementation

Anticipated Outcome

Unexpected outcomes

Inefficient resource utilization

Care deviation (knowledge vs Innovation)

Adapted from J. Sharma, ACS Safety and Quality Conference 2018
Canadian CDH Collaborative
The complex interplay of roles between specialists and the lack of evidence informing best practices across the various phases of care leads to:

- Practice and outcome variation within and between hospitals in Canada
- Inefficiencies in healthcare resource utilization

Baird et al., J Pediatr Surg, 2011
Understanding the Morbidity of CDH...

- Of 100 CDH infants born in Canada with CDH\(^1\)
  - 22 will die despite “state of the art” intensive neonatal care
  - 55 will have ongoing cardiorespiratory, feeding and/or developmental problems that require specialized follow-up
  - 30 will have detectable psychomotor or neurodevelopmental disability by 1 years of age
  - 48 will have some form of disability by 3 years of age

\(^1\)CAPSNet Annual Report, 2014 (www.capsnet.org)
CDH

- Improvement in survival has been offset by the substantial disability in survivors
  - Patients and families experience morbidity burdens similar to other chronic diseases

- Multi-system morbidity spans into adulthood
  - Pulmonary
  - Gastrointestinal (feeding, growth)
  - Cardiac
  - Musculoskeletal
  - Neurodevelopmental

Peetshold, Pediatr Surg Int, 2006
CDH

• Financial implications
  • Annual hospitalization costs exceed $10 million\(^1\)
  • Underestimates overall cost burden
    • Direct costs
      • Inpatient care
      • Outpatient care
    • Indirect societal costs
      • Lost caregiver productivity
      • Patient becomes an adult with economically limiting disability

\(^1\) Lam JC et al., J Pediatr Surg, 2006
Scope and Purpose

• Provide pragmatic guidance on the optimal health care and health surveillance for CDH patients
  • Prenatal diagnosis
  • During birth hospitalization
  • Through childhood/adolescence
Guideline Development Group

- Multi-disciplinary specialist group
  - Maternal-fetal medicine
  - Neonatology
  - Pediatric intensive care
  - Pediatric surgery
  - Pediatric anesthesia
  - Pediatric cardiology
  - Neonatal follow-up

- Views and preferences from
  - Rare Disease Foundation
  - Canadian Family Advisory Board
  - Allied Health Professionals
    - Nursing
    - Respiratory Therapy
Existing Guidelines

• Two groups previously published recommendations relevant to CDH care
  • CDH Euroconsortium (2010\textsuperscript{1}, 2016\textsuperscript{2}) [36 recommendations]
  • ATS/AHA guidelines on the management of pulmonary hypertension (2015\textsuperscript{3}) [7 recommendations]

• The CCC steering committee sent a survey to each collaborative member to “accept”, “modify”, or “reject” these recommendations

\textsuperscript{1}Reiss et al., Neonatology, 2010
\textsuperscript{2}Snoek et al., Neonatology, 2016
\textsuperscript{3}Abman et al., Circulation, 2015
• **Accept** – recommendation may be adopted without formal discussion
  - >80% agreement amongst participants [6 recommendations]
• **Modify** – worthy of consideration but not acceptable as written and in need of discussion
• **Reject** – recommendation is either wrong, out of date or so unimportant as to not require inclusion in the guideline
Discussions during the consensus meeting would focus on:

- "Modified" or "Rejected" recommendations from CDH EURO or ATA/AHA
- Areas of additional prioritization identified by CCC participants
1. What are the preferred methods of antenatal diagnosis, and with what prognostic criteria should antenatal counselling be conducted?
2. What is the current role for fetal intervention for antenatally diagnosed CDH?
3. At what gestation and by what route should CDH infants be delivered?
4. What precautions should be taken for women with CDH pregnancies at risk for premature delivery?
5. When should mechanical ventilation be instituted after an antenatally diagnosed CDH is delivered?
6. What is the role of pharmacologic sedation and paralysis after delivery?
7. What ventilation parameters and blood gas targets should be used to guide cardiopulmonary stabilization?
8. What ventilatory “rescue therapies” should be used when conventional ventilation fails to achieve desired targets?
9. What is the role of surfactant therapy in CDH?
10. What physiologic monitoring, fluid therapy and medications should be used for the optimization of hemodynamic status?
11. When should echocardiography be performed and what functional indices should be trended?
12. What pharmacologic therapies targeting pulmonary hypertension should be used in CDH?
13. What is the therapeutic role of extracorporeal life support (ECLS) in CDH?
14. If ECLS is required, when should surgery be performed?
15. What criteria should be used to determine readiness for surgery?
16. What is the optimal material for patching large diaphragmatic defects not amenable to primary repair?
17. What is the role of minimally invasive surgery (MIS) in CDH treatment?
18. What is recommended for treatment of gastroesophageal reflux (GER) associated with CDH?
19. What are the recommendations for long term follow-up?
• Participants were organized into theme-based work groups
  • Tasked with creating visual, summarized evidence reviews to be presented to the consensus group
Formulation of Recommendations

• CCC face-to-face meeting was held over 2 days with 17 participants in Banff, AB
  • Experienced guidelines facilitator
  • Record keeper
  • Non-voting observer (USA)
• Facilitator ensured work plan fidelity
Evidence Review Process and Taxonomy

<table>
<thead>
<tr>
<th>Level A</th>
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<tbody>
<tr>
<td></td>
<td>• High-quality evidence from more than 1 RCT</td>
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<td></td>
<td>• Meta-analyses of high-quality RCTs</td>
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<td></td>
<td>• One or more RCTs corroborated by high-quality registry studies</td>
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<tr>
<th>Level B-R (Randomized)</th>
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<tbody>
<tr>
<td></td>
<td>• Moderate-quality evidence from 1 or more RCTs</td>
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<tr>
<td></td>
<td>• Meta-analyses of moderate-quality RCTs</td>
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<tr>
<th>Level B-NR (Non-randomized)</th>
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<tbody>
<tr>
<td></td>
<td>• Moderate-quality evidence from 1 or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies</td>
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<td>• Meta-analyses of such studies</td>
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<tr>
<th>Level C-LD (Limited data)</th>
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<tbody>
<tr>
<td></td>
<td>• Randomized or nonrandomized observational or registry studies with limitations of design or execution</td>
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<tr>
<td></td>
<td>• Meta-analyses of such studies</td>
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<tr>
<td></td>
<td>• Physiological or mechanistic studies in human subjects</td>
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<thead>
<tr>
<th>Level C-EO (Expert Opinion)</th>
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<tbody>
<tr>
<td></td>
<td>• Consensus of expert opinion based on clinical experience</td>
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</table>
Evidence Appraisal and Modified Delphi Methods

- Evidence reviews were distributed prior to the face-to-face meeting.
- Consensus would be determined using the anonymized audience response tool “Poll Everywhere™”.

**Consensus Framework**

1. Strongly agree
2. Somewhat agree
3. Neither agree or disagree
4. Somewhat disagree
5. Strongly disagree

- **Strong agreement with recommendation:** >80% #1 or #5
- **Good agreement with recommendation:** >80% of #1 + #2 or #4 + #5 but >50% of the votes as #1 or #5
- **Weak agreement with recommendation:** >80% of #1 + #2 or #4 + #5 but <50% of the votes as #1 or #5
- **No consensus**
Preparation of Final Recommendations

- At completion of meeting
  - Compiled, edited and finalized recommendations
  - Work groups prepared evidence summaries, search strategies and PRISMA flow diagrams
  - Summaries and recommendations were prepared into manuscript form
  - “Hot Potato” editing process
  - Format according to AGREE-2 framework
Diagnosis and management of congenital diaphragmatic hernia: a clinical practice guideline

The Canadian Congenital Diaphragmatic Hernia Collaborative*


<p>| Table 1 (part 1 of 2): Abridged recommendations for diagnosing and managing congenital diaphragmatic hernia |</p>
<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Strength of recommendation</th>
<th>Level of evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prenatal diagnosis</td>
<td>Ultrasound measurement of O/E LHR should be used between 22 and 32 w of gestational age to predict the severity of pulmonary hypoplasia in isolated CDH. In left-sided CDH, an O/E LHR &lt; 25% predicts poor outcome. In right-sided CDH, an O/E LHR &lt; 45% may predict poor outcome. Fetal magnetic resonance imaging should be used (where available) for the assessment of lung volume and liver herniation in moderate and severe CDH.</td>
<td>B-NR</td>
</tr>
<tr>
<td>Ventilation</td>
<td>Newborns with CDH and immediate respiratory distress should be preferentially intubated at birth. Bag-valve-mask ventilation should be avoided. Sedation should be provided to all mechanically ventilated newborns with CDH. Deep sedation and neuromuscular blockade should be provided selectively to those with greater ventilation or oxygen requirements. A T-piece should be used with the ventilator to avoid a peak inspiratory pressure &gt; 25 cm H₂O. An arterial pCO₂ between 45 and 60 mm Hg and a pH between 7.25 and 7.40 should be targeted in all newborns with CDH. Supplemental oxygen should be titrated to achieve a partial pressure of oxygen at least 85%, but not &gt; 99%. Gentle, intermittent mandatory ventilation should be the initial ventilation mode for newborns with CDH who require respiratory support. High-frequency oscillatory ventilation or high-frequency jet ventilation should be used when the peak inspiratory pressure required to control hypoxemia using intermittent mandatory ventilation exceeds 25 cm H₂O.</td>
<td>C-EO</td>
</tr>
<tr>
<td>Hemodynamic support</td>
<td>Treatment of poor perfusion (capillary refill &gt; 3 s, lactate ≥ 3 mmol/L, urine output &lt; 1 ml/kg/h) and blood pressure below norms for age should include: judicious administration of crystalloids, generally not exceeding 20 ml/kg; isotonic agents such as dopamine or epinephrine; and hydrocortisone. If poor perfusion continues, assessment of cardiac function (i.e., echocardiogram, central venous saturation) should be performed</td>
<td>B-NR</td>
</tr>
<tr>
<td>Echocardiography</td>
<td>Two standardised echocardiograms, one within 48 h of birth and one at 2-3 w of life, are needed to assess pulmonary vascular resistance, as well as left ventricular and right ventricular function. Additional studies may be conducted as clinically indicated.</td>
<td>C-EO</td>
</tr>
<tr>
<td>Management of pulmonary hypertension</td>
<td>IHO is indicated for confirmed suprasystemic pulmonary arterial hypertension without left ventricular dysfunction, provided lung recruitment is adequate. In the absence of clinical or echocardiographic response, IHO should be stopped. Sildenafil should be considered in patients with refractory pulmonary hypertension (i.e., unresponsive to IHO) or as an adjunct when weaning IHO. Milrinone should be used to treat cardiac dysfunction, particularly if it is associated with pulmonary hypertension. Prostaglandin E₁ can be used to maintain ductus arteriosus patency and reduce right ventricular afterload in patients with pulmonary hypertension with right ventricular failure, or in the presence of a closing ductus. Extrapulmonary life support The possibility of extrapulmonary life support should be discussed during prenatal counselling for CDH, and should disclose that available evidence does not suggest a survival benefit to its use.</td>
<td>CDH</td>
</tr>
</tbody>
</table>

22 Recommendations covering the 3 phases of CDH care
Implementation
CPG Implementation Barriers

• Utilization of CPG’s may be hampered by:
  • Poor acceptance
  • Local implementation barriers
  • Institutional readiness to accept change

• “Organizational readiness to change” (ORCA) is a key overarching principle to assesses the capacity and the collective perception that its members can execute change in an efficacious or successful manner

• If an organization’s readiness for change is high
  • More likely to be successful in implementing change
  • More resilient when confronting obstacles
Standardizing congenital diaphragmatic hernia care in Canada: Implementing national clinical practice guidelines

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\textsuperscript{b} Division of Pediatric Surgery, British Columbia Children's Hospital, University of British Columbia, Vancouver, British Columbia, Canada
\textsuperscript{c} Division of Pediatric Surgery, Health Sciences Centre Children's Hospital, University of Manitoba, Winnipeg, Manitoba, Canada
Research Questions

1. Do clinicians across Canada know about CPG?
2. Are they using it?
2. What are the local barriers to using the CPG?
3. How can the CPG be better implemented at the local level?
Methods

• A validated readiness assessment was sent to all 16 CAPSNet site coordinators via SurveyMonkey™
  • 32 questions
  • Forwarded to multidisciplinary CDH stakeholders

• Organizational Readiness to Change Assessment*
  • Stakeholder assessment of evidence strength
  • Quality of the environment slated for change
  • Local facilitation

• Survey valid from 11/2018 - 02/2019
  • 2 email reminders

Results

15/16 CAPSNet Sites

- Neonatology (n=27)
- Pediatric Surgery (n=25)
- Respiratory Therapy (n=10)
- Responses from other specialties and health professionals

86 Responses

56 completed entire survey (65%)

79% aware of CPG

63% using CPG
70% of respondents felt that the CDH recommendations were informed by the best available evidence.

>75% felt that local clinical leaders would support recommendations.
Can they be implemented?

>80% felt they could implement more than three-quarters of the CPG recommendations
85-90% felt responsibility to improve CDH outcomes and would work collaboratively with clinical leadership and implementation team.
Which recommendations within the CPG would be most difficult to implement?

Fetal Intervention
ECMO
Surgery on ECMO
How can the CPGs be better implemented?

Common team goals
Provider Buy-in
Regular evaluation
Compliance testing
Survey Summary

- Majority aware of CPGs
  - Evidence is strong and broadly utilized in part or whole

- Fetal and ECLS are not necessary at all centers
  - Prenatal and long-term surveillance should be possible with additional resources and network support

- Provider buy-in
  - Multi-D intervention teams
  - Evaluation
Guideline Updates

New data consistent with current recommendations

• Original report remains unchanged
• Strength of recommendation may be modified

New data is inconsistent with current recommendations

• New evidence does not alter the initial conclusions
• Strength of new evidence will alter current conclusions in original document
Where are we now and how does this affect care delivery CDH?
Clinical Practice Guidelines in CDH?

Table 3 – Key components of CDH management with frequency of inclusion in 27 CDH CPGs.

<table>
<thead>
<tr>
<th>Management component</th>
<th>Number of CPGs (%)</th>
<th>Details</th>
</tr>
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<tbody>
<tr>
<td>Delivery plan</td>
<td>8 (30)</td>
<td>Two CPGs recommend intubation only with respiratory distress</td>
</tr>
<tr>
<td>Immediate intubation at birth for all CDH patients</td>
<td>19 (70)</td>
<td></td>
</tr>
<tr>
<td>Insert Replogle at delivery</td>
<td>24 (89)</td>
<td>One CPG recommended bagging pressures &lt;25 cm H2O</td>
</tr>
<tr>
<td>Avoid hand bagging</td>
<td>14 (52)</td>
<td></td>
</tr>
<tr>
<td>Umbilical or right radial arterial line</td>
<td>23 (85)</td>
<td>1. one CPG recommends femoral line</td>
</tr>
<tr>
<td>Umbilical venous access</td>
<td>20 (74)</td>
<td>2. Six recommend early PICC insertion after or concurrent with UVC</td>
</tr>
<tr>
<td>Sedation addressed</td>
<td>18 (67)</td>
<td>1. 10 use morphine first-line, 7 fentanyl</td>
</tr>
<tr>
<td>Neuromuscular blockade discouraged</td>
<td>19 (70)</td>
<td>2. 12 specify midazolam, 1 lorazepam</td>
</tr>
<tr>
<td>HFOV = high-frequency oscillatory ventilation; PICC = peripherally inserted central catheter; UVC = umbilical venous catheter.</td>
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So where do we go now?

• There is a significant opportunity for standardization of care in CDH
  • CDH Euro-Consortium, Canadian CDH Collaborative

• Process issues
  • Strength of evidence vs expert opinion
  • Pragmatism vs prescription
  • Support innovation
  • Include all stakeholders, including patients, families and advocacy groups

• Applying the best care and evidence to local context
Summary

✓ There is value in the standardization of care for CDH
  ✓ Removes unwanted variability without stifling innovation
  ✓ Cornerstone for CQI and patient safety
  ✓ Value of pragmatism vs prescription
  ✓ Local context

✓ Need to update guidelines based on new, emerging evidence
  ✓ Use app to “push” new evidence/recommendations

✓ Assessment of Implementation barriers is essential for guideline uptake

✓ Quantify the impact of the CPGs on CDH outcomes