

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

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

Standardization in Surgery

VOLUME LXIII
NUMBER 9

JAMA (1914)

STANDARDIZATION OF SURGERY

AN ATTACK ON THE PROBLEM *

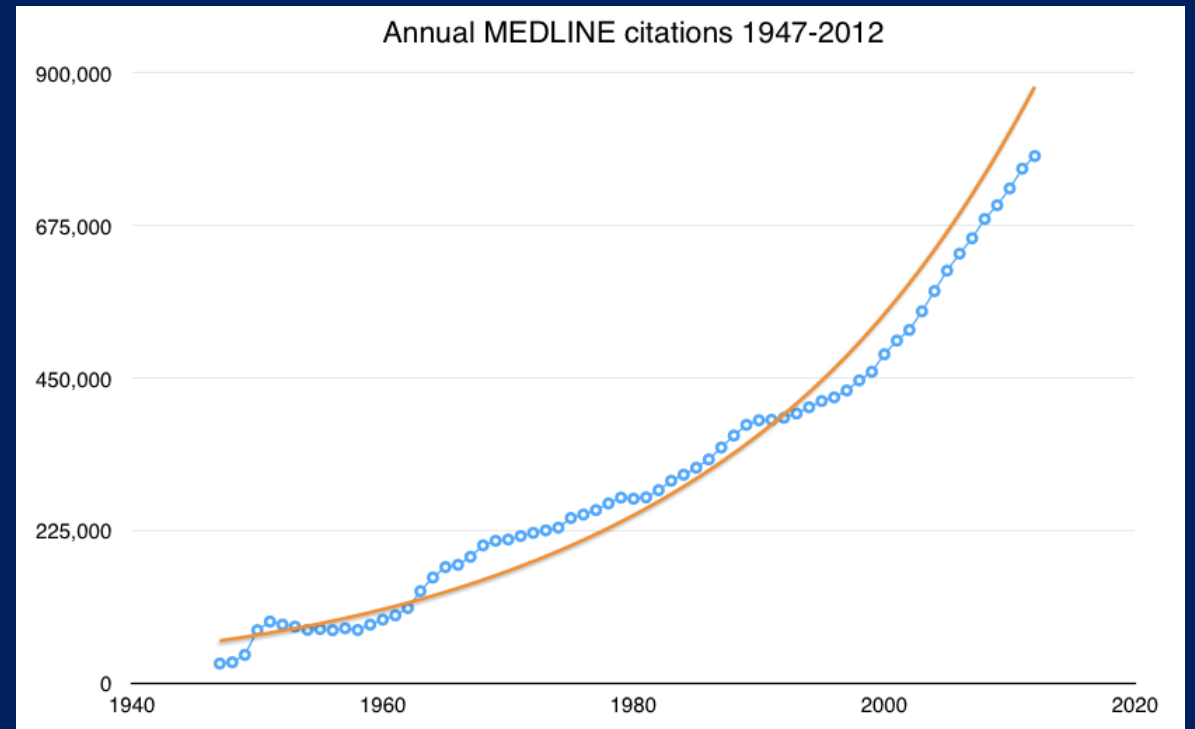
ROBERT L. DICKINSON, M.D.

BROOKLYN

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?

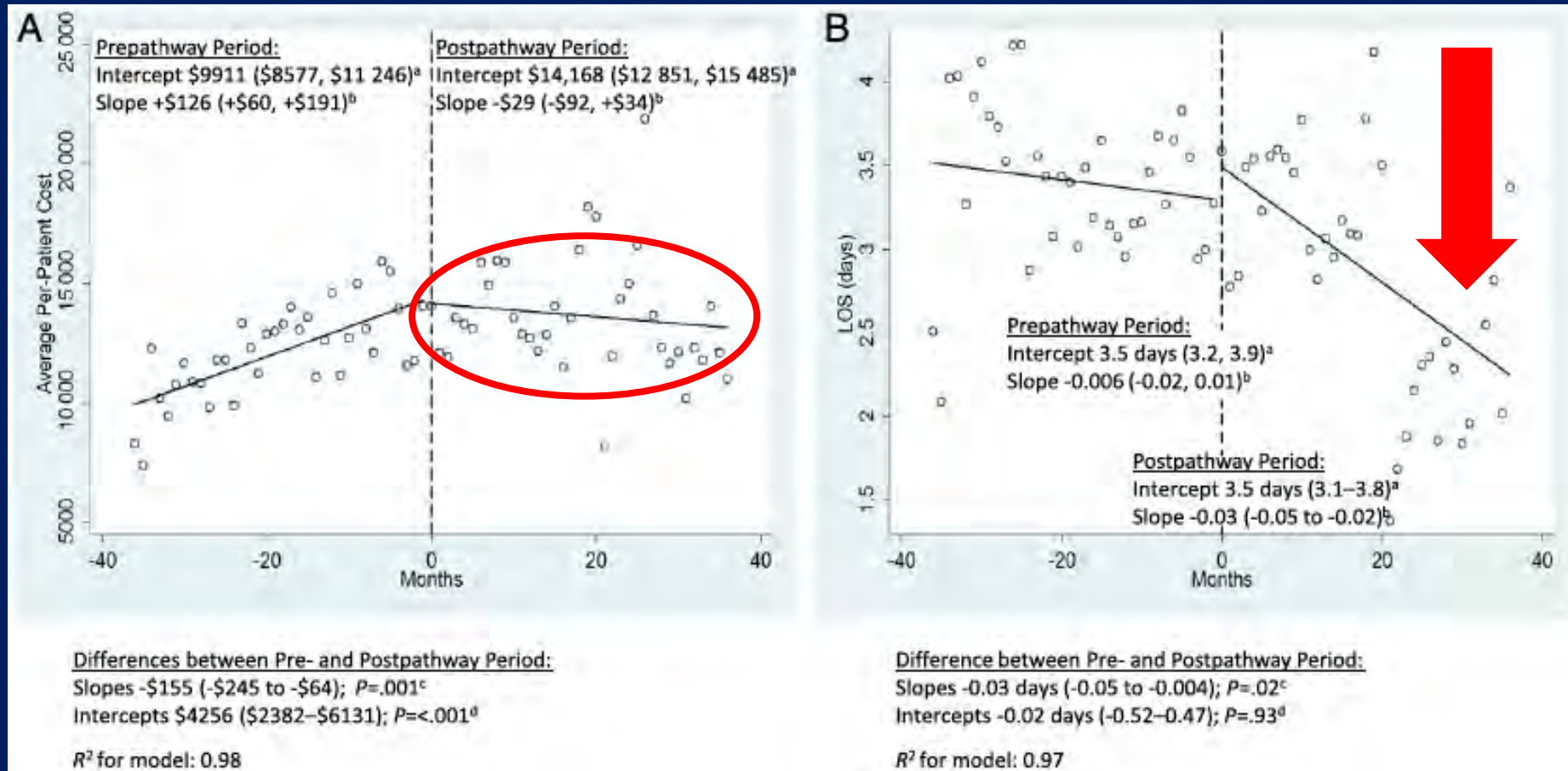
- High level evidence supports routine clinical decision making only 20% of the time ¹
- Even when evidence-based guidelines are available, only 2/3 of patients receive recommended care and 25% receive unnecessary or harmful care ²
- **Successful outcomes** are assumed as the baseline (contrary to non-healthcare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



Standardization in LMIC's

Surgical Safety Checklist



World Health Organization

Patient Safety
A World Alliance for Safer Health Care

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 anaesthesia machine and medication check complete?

Yes

Is the pulse oximeter on the patient and functioning?

Yes

Does the patient have a:

Known allergy?

No
 Yes

Difficult airway or aspiration risk?

No
 Yes, and equipment/assistance available

Risk of >500ml blood loss (7ml/kg in children)?

No
 Yes, and two IVs/central access and fluids planned

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

Anticipated Critical Events

To Surgeon:

What are the critical or non-routine steps?
 How long will the case take?
 What is the anticipated blood loss?

To Anaesthetist:

Are there any patient-specific concerns?

To Nursing Team:

Has sterility (including indicator results) been confirmed?
 Are there equipment issues or any concerns?

Is essential imaging displayed?

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 specimen labels aloud, including patient name)
 Whether there are any equipment problems to be addressed

To Surgeon, Anaesthetist and Nurse:

What are the key concerns for recovery and management of this patient?

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

Revised 1 / 2009

© WHO, 2009

Standardization in patient High 5s project

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BILL MUNIER¹¹

medicines (concentrations of care)
procedure at the correct
re handovers.
event health care-



Definition of CPG

2011 – statements that include
In current or guideline – a systematic way of
recommendations intended to optimize
developing statements to present a
patient care that are informed by a systematic
and patient decisions about a procedure
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

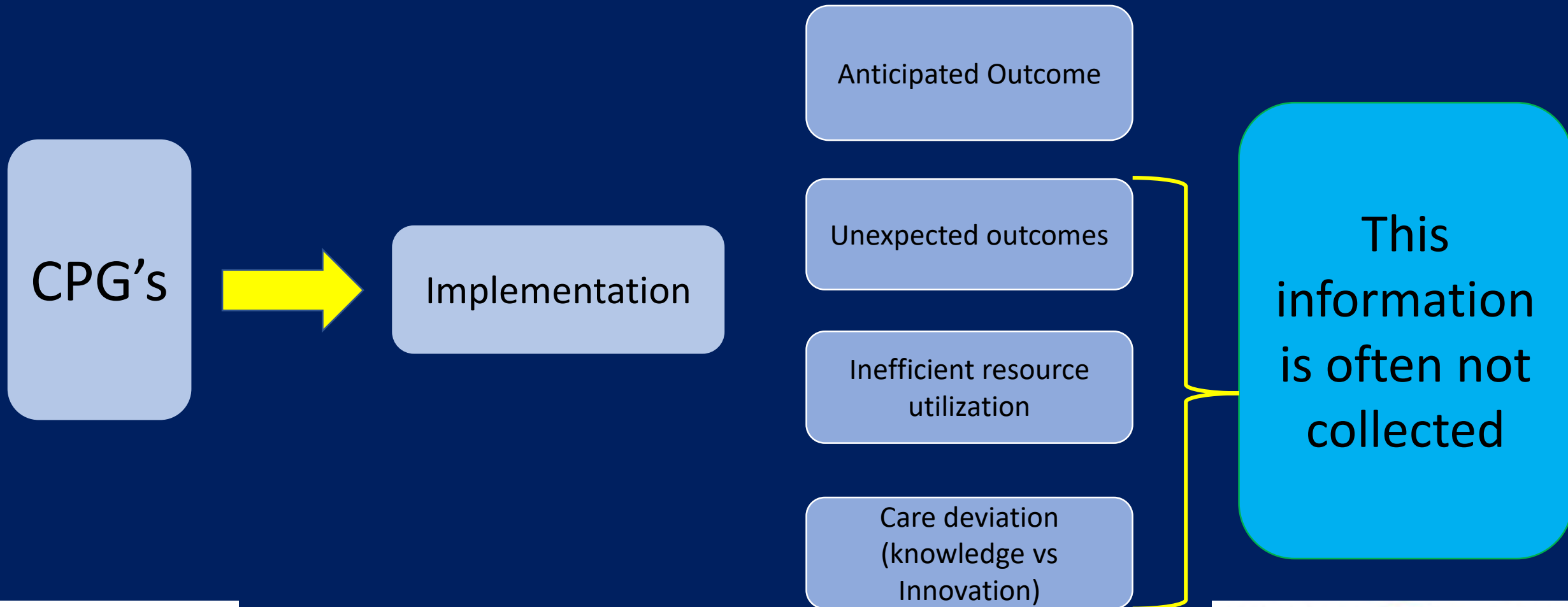
Providers

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

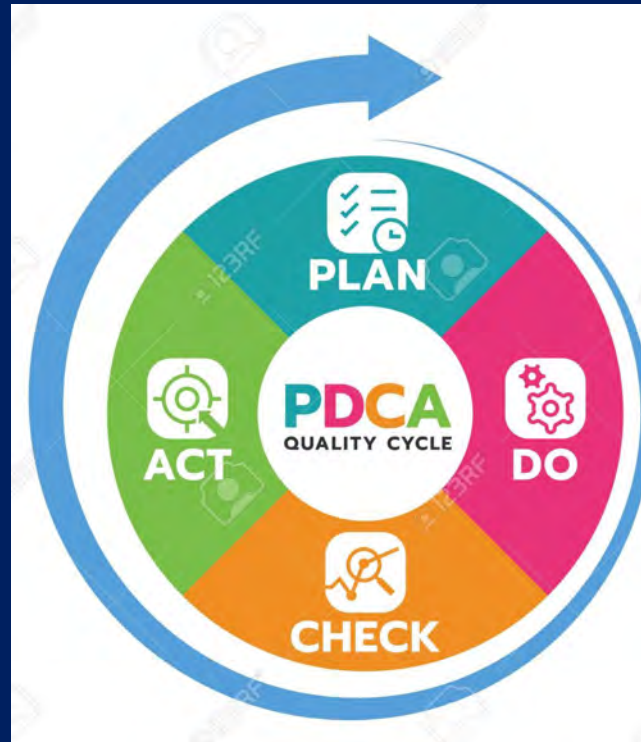
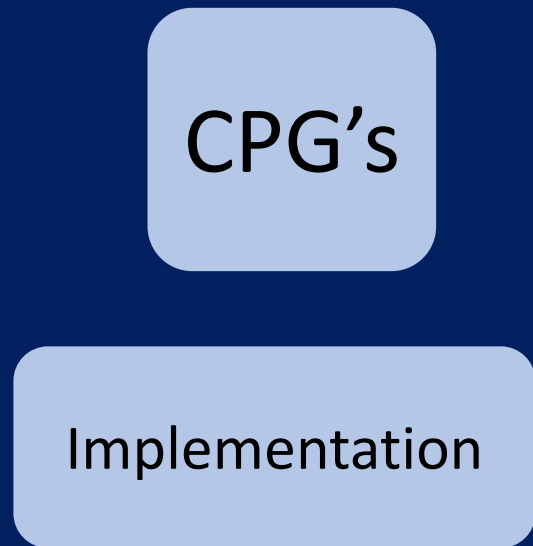
Health Systems

- Adds cost
- Wastes limited resources

Why are the effects of standardization often less than desired?



Why are the effects of standardization often less than desired?



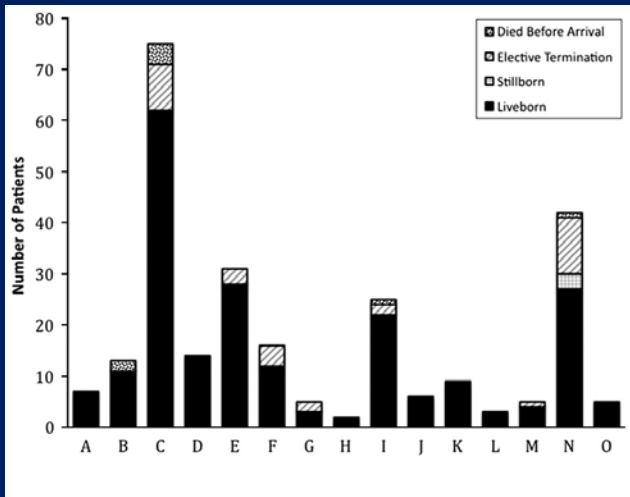
- Anticipated Outcome
- Unexpected outcomes
- Inefficient resource utilization
- Care deviation (knowledge vs Innovation)

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

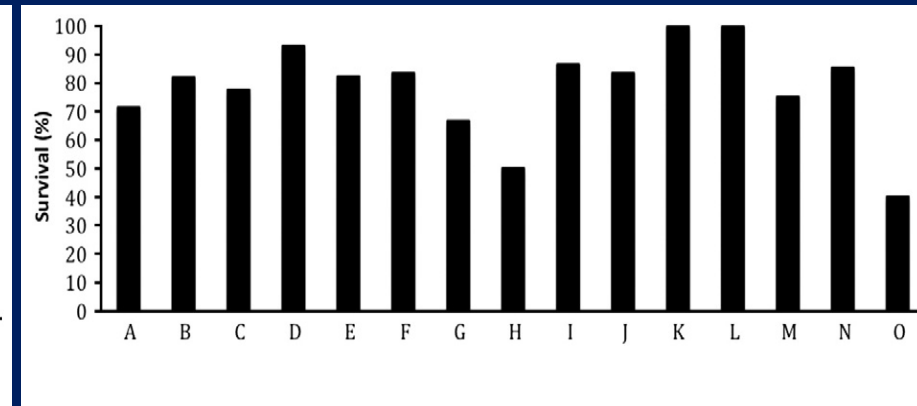
Prenatal



Surgery

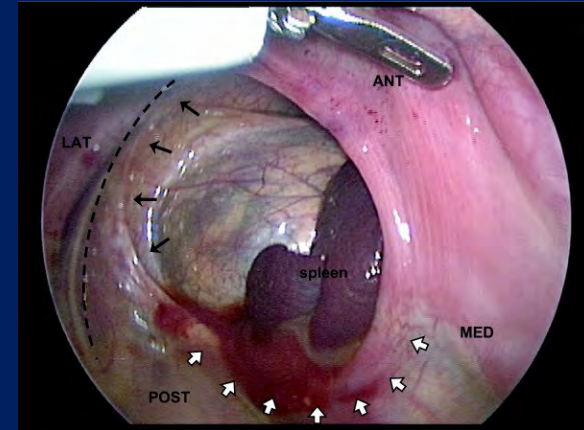


Survival



Understanding the Morbidity of CDH...

- Of 100 CDH infants born in Canada with CDH¹
- 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



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

CDH

- Financial implications

- Annual hospitalization costs exceed \$10 million¹

- **Underestimates** overall cost burden

- Direct costs

- Inpatient care

- Outpatient care

- Indirect societal costs

- Lost caregiver productivity

- Patient becomes an adult with economically limiting disability



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 (2010¹, 2016²) [36 recommendations]
 - ATS/AHA guidelines on the management of pulmonary hypertension (2015³) [7 recommendations]
- The CCC steering committee sent a survey to each collaborative member to “accept”, “modify”, or “reject” these recommendations

¹Reiss et al., Neonatology, 2010

²Snoek et al., Neonatology, 2016

³Abman 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?

Prenatal

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?

Intensive Neonatal Care

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?

Surgery

18. What is recommended for treatment of gastroesophageal reflux (GER) associated with CDH?
19. What are the recommendations for long term follow-up?

Surveillance

- Participants were organized into theme-based work groups
 - Tasked with creating visual, summarized evidence reviews to be presented to the consensus group

Prenatal Diagnosis, Risk Stratification, Optimal Delivery	
Dr. Greg Ryan	Dr. Titilayo Oluyomi-Obi
Ventilation Strategies in CDH	
Dr. Shyamala Dakshinamurti	Dr. Doug McMillan
Dr. Brian Kavanagh	Dr. Michael Traynor
Dr. Conor McDonnell	
Management of Pulmonary Hypertension (including ECMO)	
	Dr. Arthur Cogswell
Dr. Therese Perreault	Dr. Bruno Piedbeouf
Dr. Sandesh Shivananda	
Type, Timing and Indications for Surgical Repair in CDH	
Dr. Robert Baird	Dr. Mary Brindle
Dr. Pramod Puligandla	Dr. Erik Skarsgard
Pain Management, Sedation	
Dr. Richard Keijzer	Dr. Thomas Pennaforte
Treatment of GE Reflux	
Dr. Helene Flageole	
Surveillance Protocols for Disability in CDH	
Dr. Anne Synnes	Dr. Michelle Bailey
Dr. Patricia Riley	Dr. Priscilla Chiu

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

• N
f
S

Level A
<ul style="list-style-type: none">• High-quality evidence from more than 1 RCT• Meta-analyses of high-quality RCTs• One or more RCTs corroborated by high-quality registry studies
Level B-R (Randomized)
<ul style="list-style-type: none">• Moderate-quality evidence from 1 or more RCTs• Meta-analyses of moderate-quality RCTs
Level B-NR (Non-randomized)
<ul style="list-style-type: none">• Moderate-quality evidence from 1 or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies• Meta-analyses of such studies
Level C-LD (Limited data)
<ul style="list-style-type: none">• Randomized or nonrandomized observational or registry studies with limitations of design or execution• Meta-analyses of such studies• Physiological or mechanistic studies in human subjects
Level C-EO (Expert Opinion)
<ul style="list-style-type: none">• Consensus of expert opinion based on clinical experience

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





Editor's pick: Congenital diaphragmatic hernia guideline

GUIDELINE **CPD**

Diagnosis and management of congenital diaphragmatic hernia: a clinical practice guideline

The Canadian Congenital Diaphragmatic Hernia Collaborative*

*The complete list of authors appears at the end of the article.

■ Cite as: *CMAJ* 2018 January 29;190:E103-12. doi: 10.1503/cmaj.170206

CMAJ Podcasts: author interview at <https://soundcloud.com/cmajpodcasts/170206-guide>

Table 1 (part 1 of 2): Abridged recommendations for diagnosing and managing congenital diaphragmatic hernia

Recommendation	Strength of recommendation*	Level of evidence†
Prenatal diagnosis		
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.	●●●●	B-NR
In left-sided CDH, an O/E LHR < 25% predicts poor outcome. In right-sided CDH, an O/E LHR < 45% may predict poor outcome.	●●●○	B-NR
Fetal magnetic resonance imaging should be used (where available) for the assessment of lung volume and liver herniation in moderate and severe CDH.	●●●●	B-NR
Ventilation		
Newborns with CDH and immediate respiratory distress should be preferentially intubated at birth. Bag-valve-mask ventilation should be avoided.	●●●●	C-EO
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.	●●●●	B-NR
A T-piece should be used with the ventilator to avoid a peak inspiratory pressure > 25 cm H ₂ O.	●●●●	B-NR
An arterial pCO ₂ between 45 and 60 mm Hg and a pH between 7.25 and 7.40 should be targeted in all newborns with CDH.	●●●●	B-NR
Supplemental oxygen should be titrated to achieve a productal saturation of at least 85%, but not > 95%.	●●●●	B-EO
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 hypercapnia using intermittent mandatory ventilation exceeds 25 cm H ₂ O.	●●●●	B-NR
Hemodynamic support		
Treatment of poor perfusion (capillary refill > 3 s, lactate > 3 mmol/L, urine output < 1 mL/kg/h) and blood pressure below norms for age should include: • judicious administration of crystalloid, generally not exceeding 20 mL/kg; • inotropic 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	●●●●	B-NR
Echocardiography		
Two standardized 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.	●●●●	C-LD
Management of pulmonary hypertension		
iNO 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, iNO should be stopped.	●●●○	C-EO
Sildenafil should be considered in patients with refractory pulmonary hypertension (i.e., unresponsive to iNO) or as an adjunct when weaning iNO.	●●●○	B-R
Milrinone should be used to treat cardiac dysfunction, particularly if it is associated with pulmonary hypertension.	●●●●	B-NR
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.	●●●○	C-LD
Extracorporeal life support		
The possibility of extracorporeal 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.	●●●○	B-R

Table 1 (part 2 of 2): Abridged recommendations for diagnosing and managing congenital diaphragmatic hernia

Recommendation	Strength of recommendation*	Level of evidence†
Surgery		
The following physiologic criteria should be met before surgery: • urine output > 1 mL/kg/h • FiO ₂ < 0.5 • productal oxygen saturation between 85% and 95% • normal mean arterial pressure for gestational age • lactate < 3 mmol/L • estimated pulmonary artery pressures less than systemic pressure. Failure to meet these criteria within 2 w should prompt consideration of either attempted repair or a palliative approach.	●●○○	C-EO
Patch repair: For diaphragmatic defects that are not amenable to primary repair, oversized, tension-free polytetrafluoroethylene/GORE-TEX patches should be used.	●●●●	C-LD
Open repair v. minimally invasive surgery: A minimally invasive surgical approach or technique should not be used in the repair of neonatal CDH because of the high rates of recurrence.	●●●●	B-NR
For patients on extracorporeal life support: Surgery should be avoided until after decannulation. If the patient cannot be weaned off extracorporeal life support, consideration should be given for either surgery or palliation, as appropriate.	●●●●	C-LD
Long-term follow-up		
• We recommend standardized multidisciplinary follow-up for children with CDH to provide surveillance and screening, optimal and timely diagnosis and clinical care adjusted to the level of risk.	●●●●	B-NR
• We recommend identifying the subset of CDH survivors at high risk for long-term morbidity as comprising those infants and children who require extracorporeal life support, who have been repaired with a patch or who required respiratory support at 30 days of life.	●●●●	B-NR

Note: CDH = congenital diaphragmatic hernia, iNO = inhaled nitric oxide, O/E LHR = observed-to-expected lung-head ratio.
*Strength of recommendation: the number of circles represents the level of expert consensus during creation of recommendations (see Box 2).
†Level of evidence: evidence supporting the recommendation (see Box 1).

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



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Standardizing congenital diaphragmatic hernia care in Canada: Implementing national clinical practice guidelines[☆]

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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?

Assess Readiness



App Development



QI Initiatives

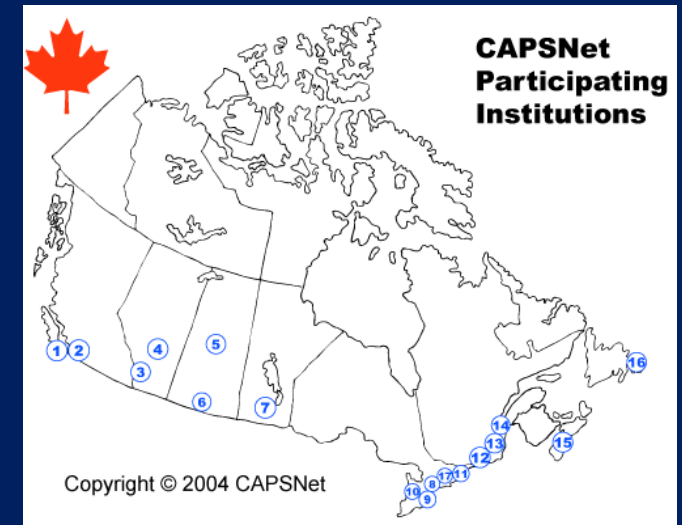


Outcome Evaluation



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%)



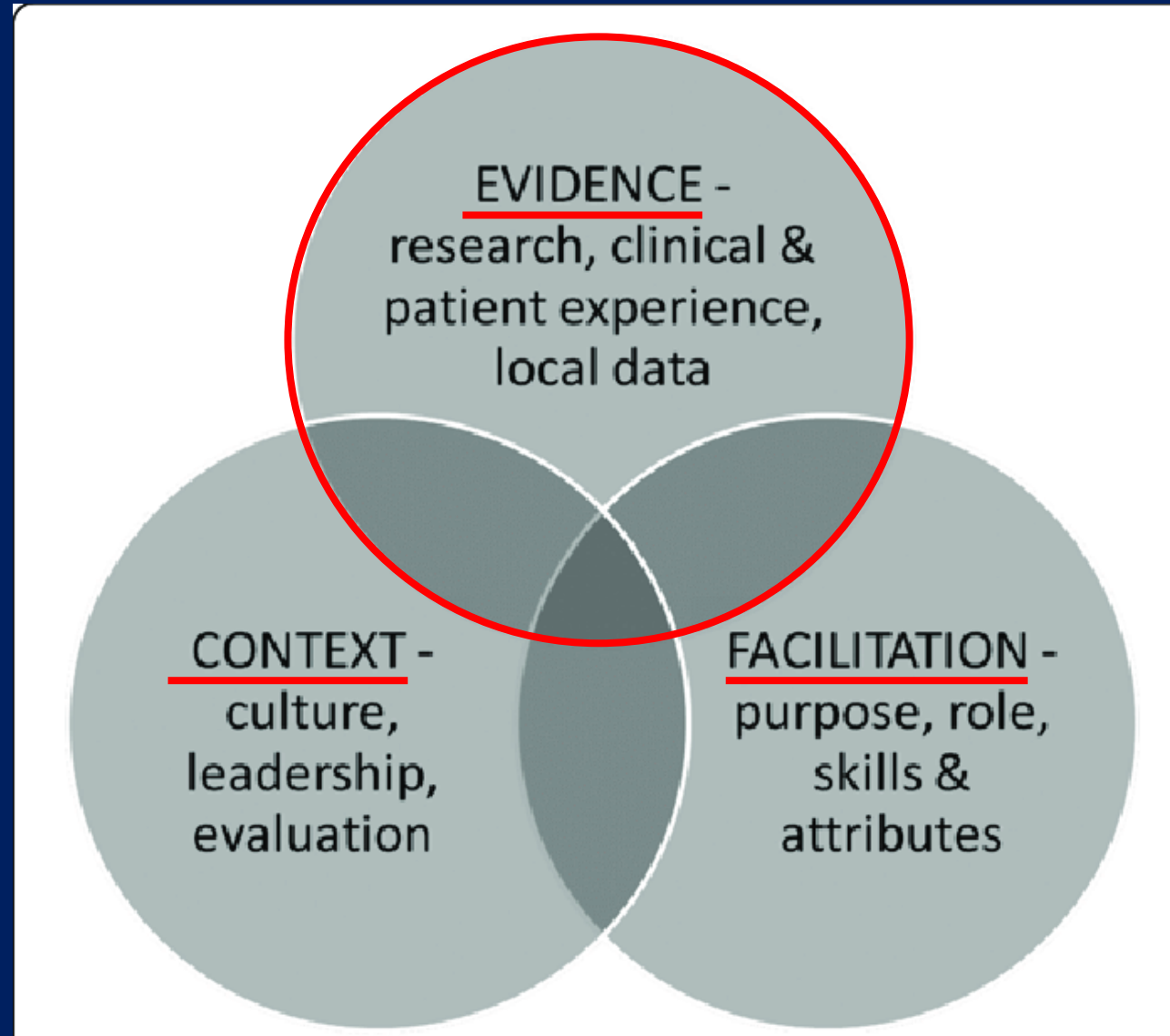
79% aware of CPG



63% using CPG

Promoting Action on Research Implementation in Health Services (PARiHS) Framework

- 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?



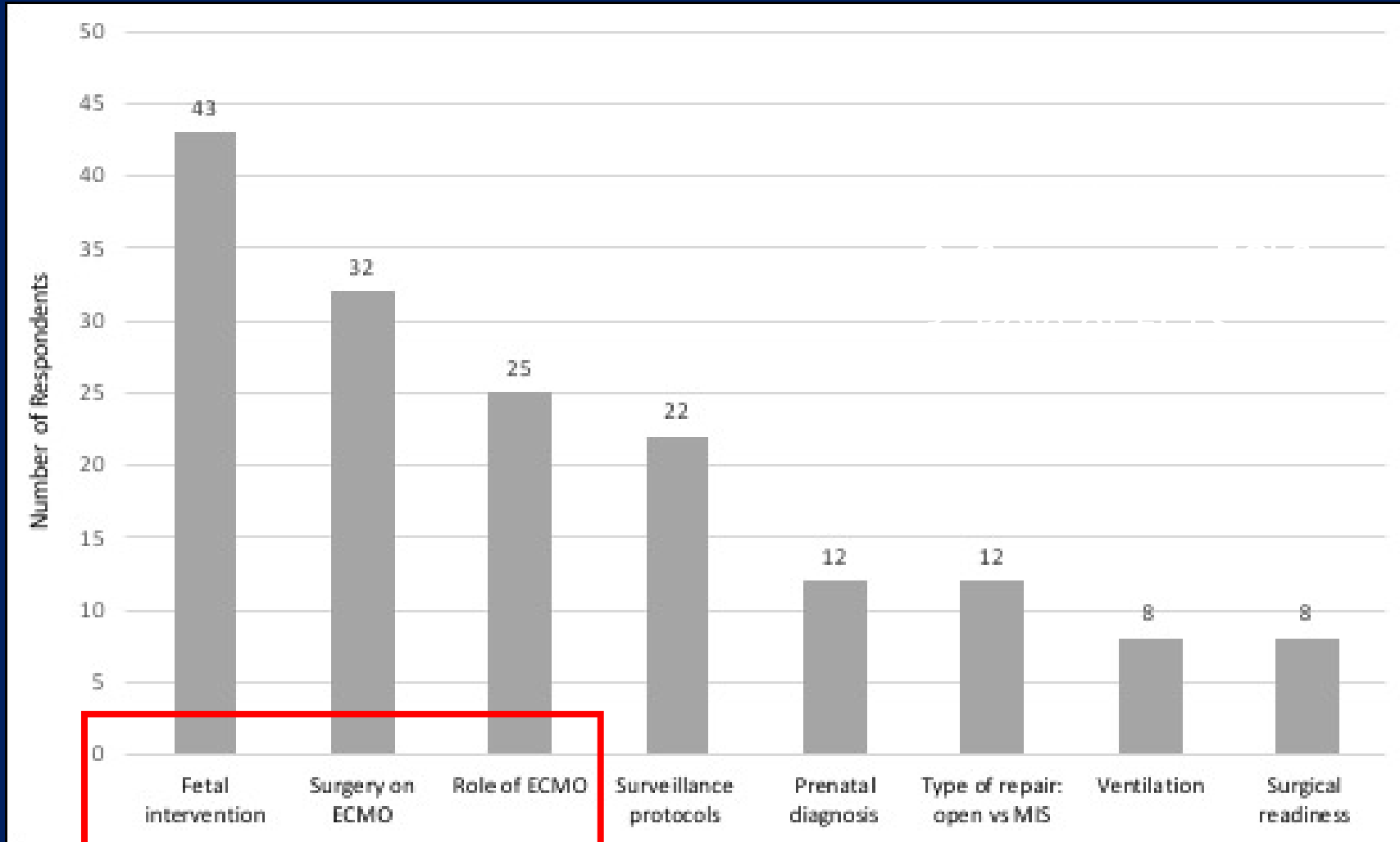
>80% felt they could implement more than three-quarters of the CPG recommendations

Promoting Action on Research Implementation in Health Services (PARiHS) Framework

- 85-90% felt responsibility to improve CDH outcomes and would work collaboratively with clinical leadership and implementation team

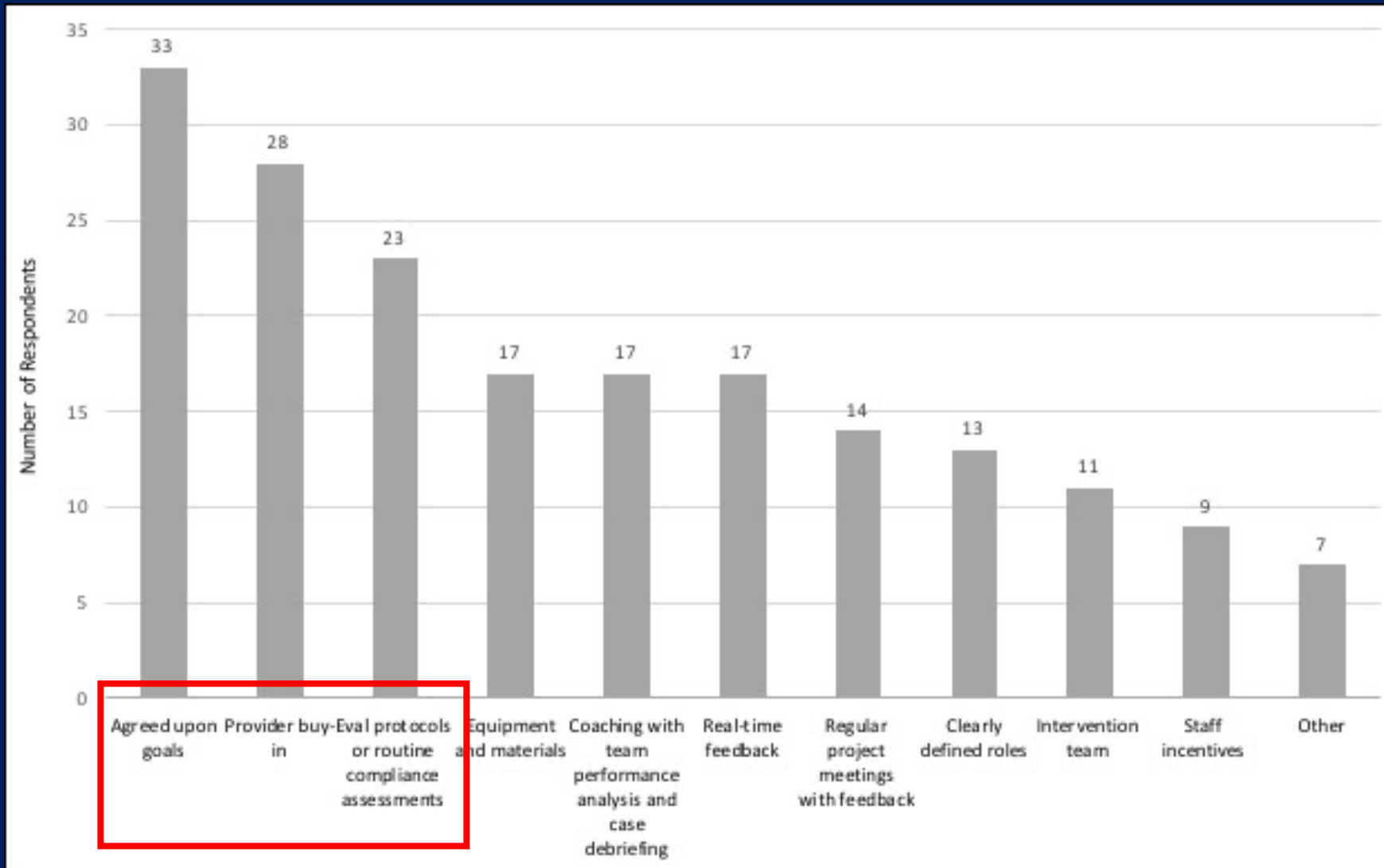


Which recommendations within the CPG would be most difficult to implement?



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



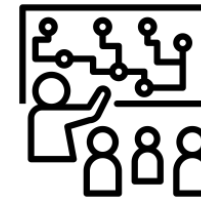
Majority aware of CPGs

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?

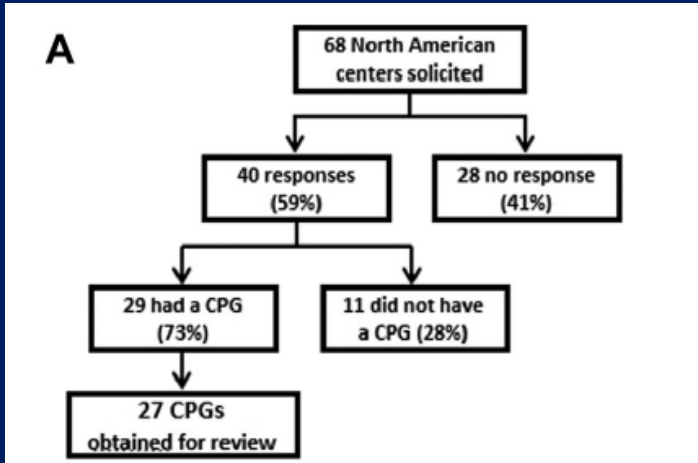


Table 3 – Key components of CDH management with frequency of inclusion in 27 CDH CPGs.

Management component	Number of CPGs (%)	Details
Delivery plan	8 (30)	
Immediate intubation at birth for all CDH patients	19 (70)	Two CPGs recommend intubation only with respiratory distress
Insert Replogle at delivery	24 (89)	
Avoid hand bagging	14 (52)	One CPG recommended bagging pressures <25 cm H ₂ O
Umbilical or right radial arterial line	23 (85)	
Umbilical venous access	20 (74)	1. one CPG recommends femoral line 2. Six recommend early PICC insertion after or concurrent with UVC
Sedation addressed	18 (67)	1. 10 use morphine first-line, 7 fentanyl 2. 12 specify midazolam, 1 lorazepam
Neuromuscular blockade discouraged	19 (70)	10 describe indications for blockade (extremis, procedure, poor ventilation, HFOV)

HFOV = high-frequency oscillatory ventilation; PICC = peripherally inserted central catheter; UVC = umbilical venous catheter.

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

Questions?



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