

A multicentre confidential enquiry of severe pregnancy-related cardiovascular morbidity and mortality

Isabelle Malhamé MD MSc FRCPC

INOSS Meeting, Rome 2026

Conflicts of interest

No conflicts of interest to declare

Funding for this project is provided by the Canadian Institutes for Health Research and the Heart & Stroke Foundation



Objectives

Following this lecture, participants will be able to:

- Design a mixed-methods confidential enquiry study, focusing on rare, severe morbidity outcomes
- Share methodological insights to strengthen confidential enquiry study methodology

CanOSS-Cv: Feedback



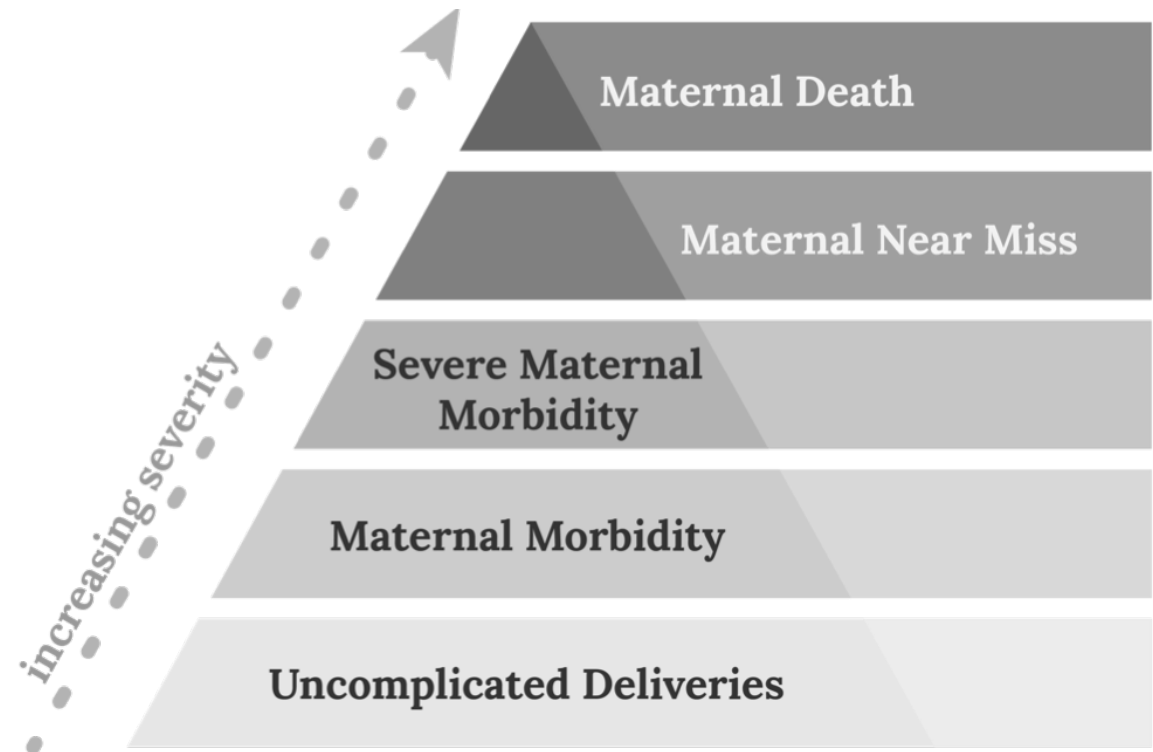
Background

The facts

For every death during or after pregnancy approximately **85-100 experience severe maternal morbidity**¹

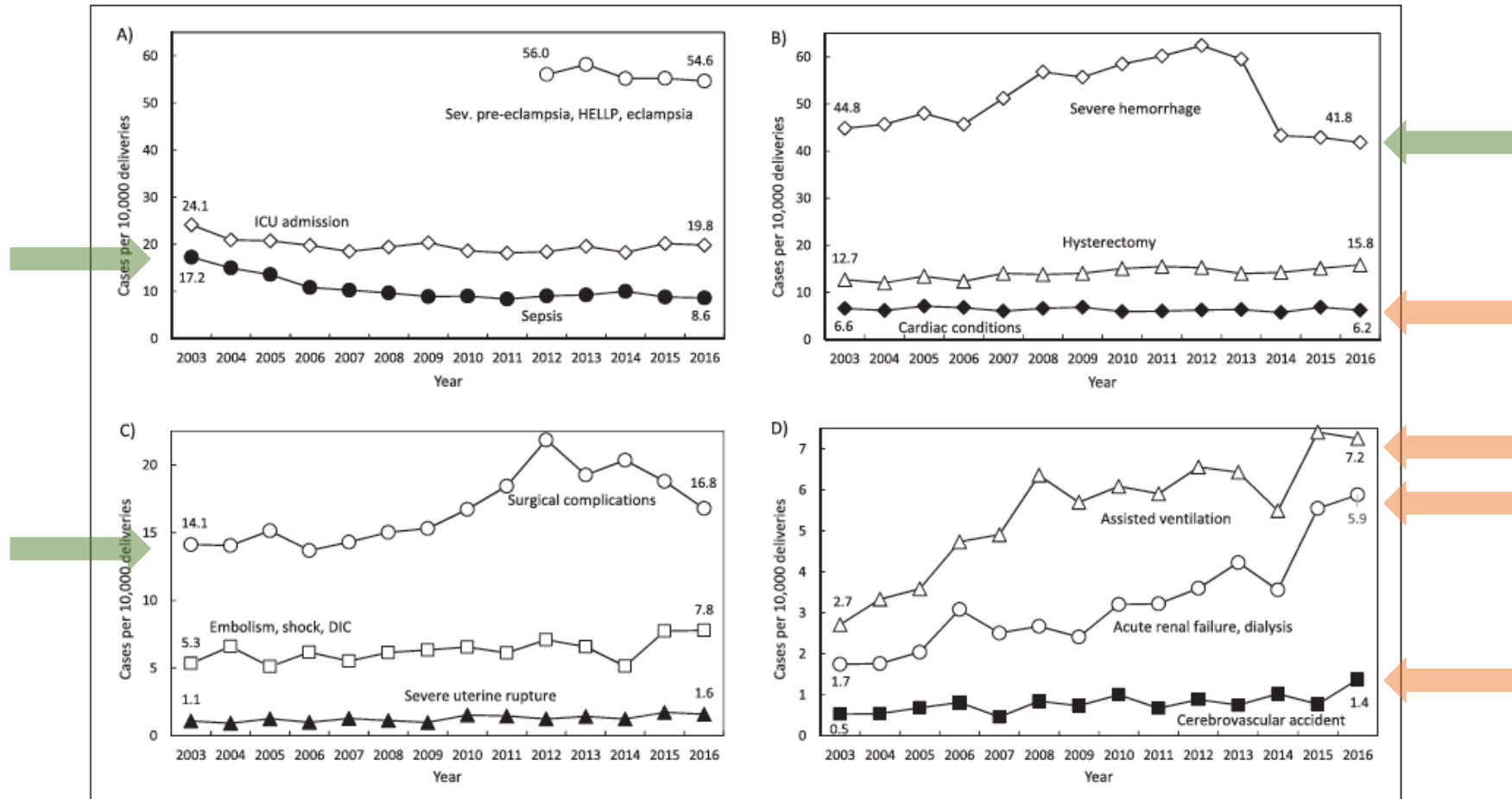
The World Health Organization has **recommended a focus** on severe maternal morbidity²

In Canada, the incidence of severe maternal morbidity is **on the rise**³

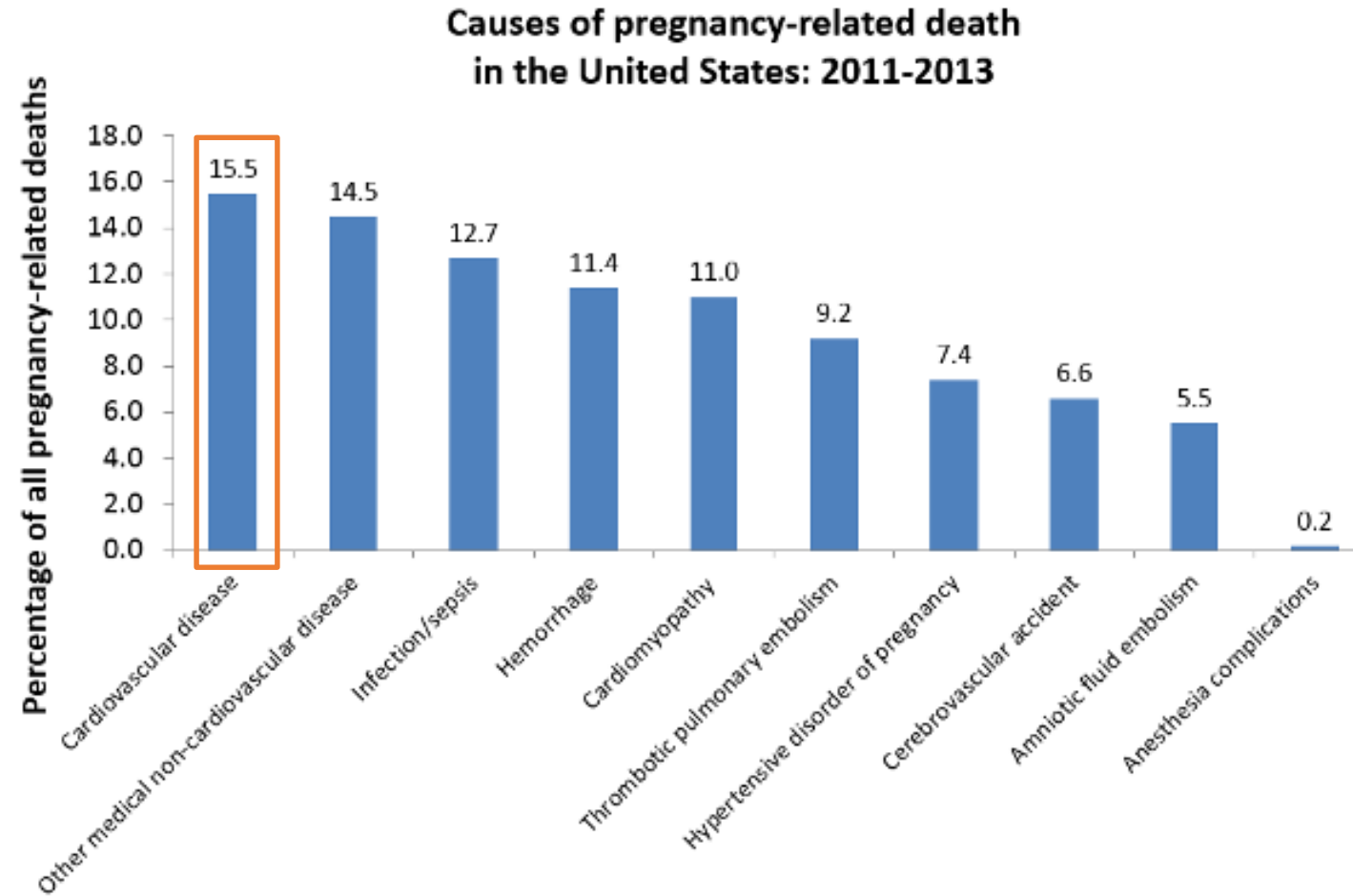


Background

Evolving causes of severe maternal morbidity

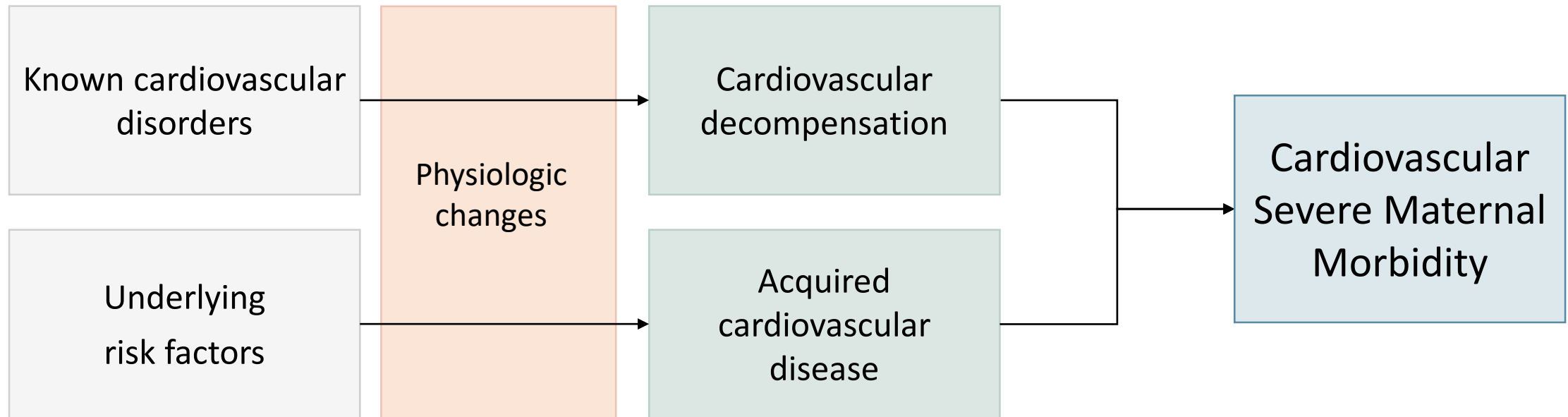


Maternal mortality



Background

Cardiovascular severe maternal morbidity



Identifying cardiovascular severe maternal morbidity

We regrouped cardiovascular indicators of severe maternal morbidity

Acute myocardial infarction
Pulmonary edema/Acute heart failure
Cardiac arrest/Ventricular fibrillation
Conversion of cardiac rhythm
Heart failure/Arrest during surgery or procedure
Cardiogenic shock
Aneurysm
Puerperal cerebrovascular disorders



**Cardiovascular
Severe Maternal
Morbidity**

Landmark Guidance 2004

Guidance calling for reviews of maternal deaths and complications using an approach going “beyond the numbers” to develop an understanding of *why* events happened and *how* they could be averted

Beyond the Numbers

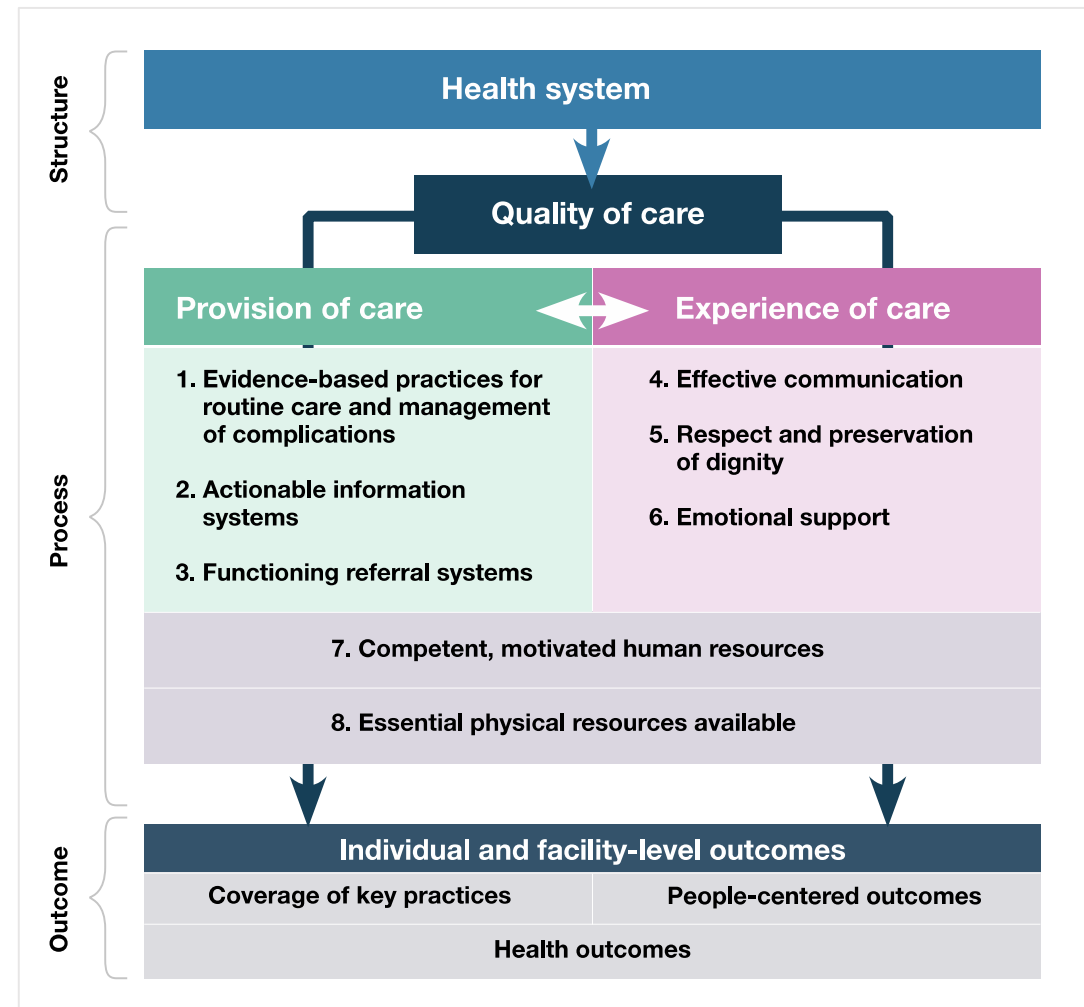
Reviewing maternal deaths and complications to make pregnancy safer



World Health Organization, Geneva, 2004

WHO Quality of Care Framework

Encompassing the provision of care as well as the experience of care



Objectives

A structured national confidential enquiry

Identify **contributing clinical and structural factors** contributing to events

Develop **equity-informed recommendations** for the local, provincial and national levels

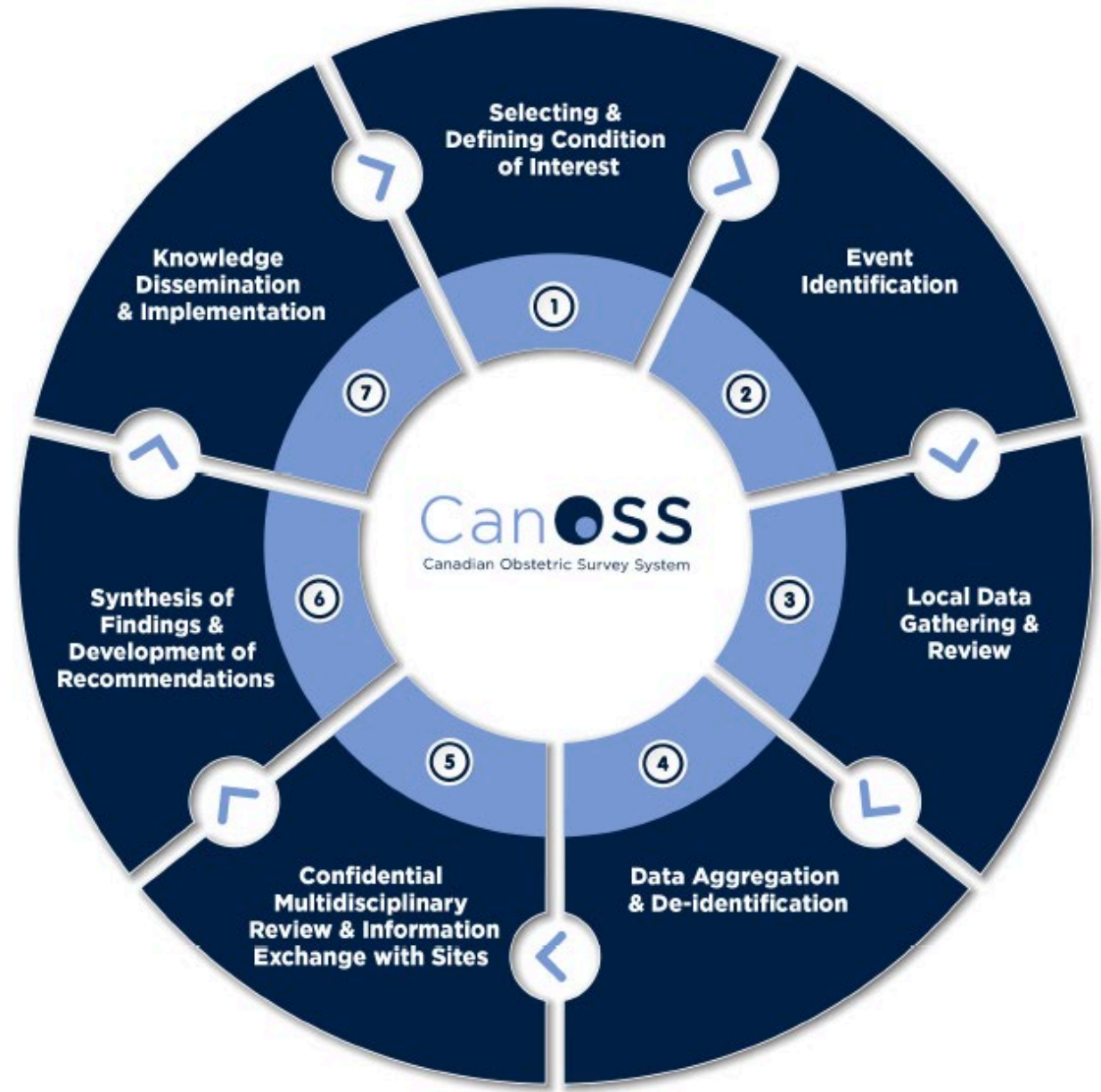
Characterize **disparities in contributing factors** across regions, care settings and demographic groups

Support a **learning health system** by translating findings into practice and policy

Multistep process

Canadian Obstetric Survey System (CanOSS) approach, adapted to the cardiovascular context

Prospective, multicentre
confidential enquiry
mixed methods study

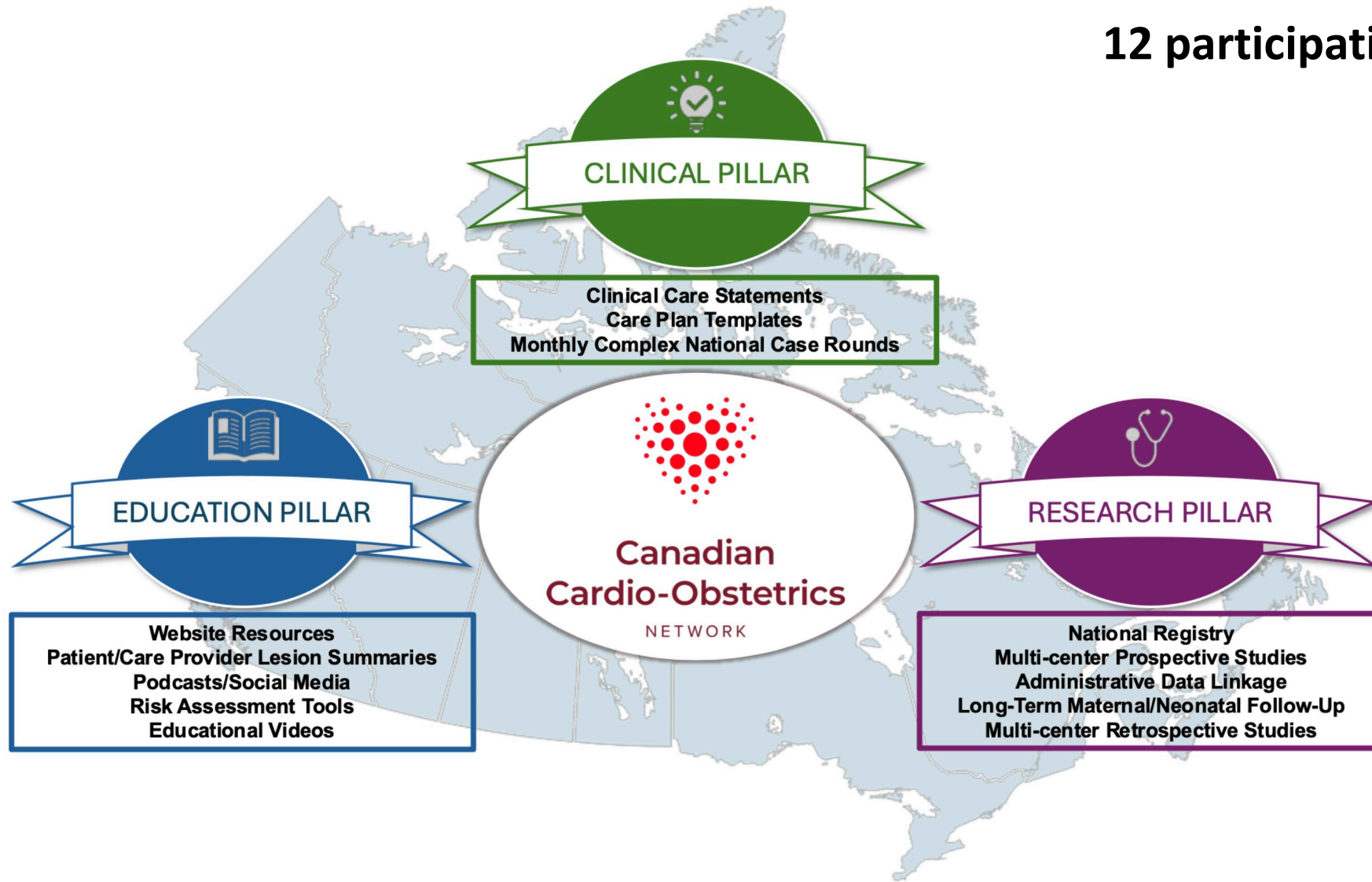


Methods

Event identification

- Pregnant or recently pregnant women at a **participating site**
- A **cardiovascular event** serious enough to result in:
 - Significant maternal harm
 - Urgent intervention beyond usual care, and/or
 - Unplanned critical admission
- Event occurs **from conception through one year** after the end of pregnancy

12 participating sites



Methods

Event identification

- **Clinical team engagement:** rounds, M&M, QI meetings and established cardio-obstetrics clinical networks
- **Monthly survey:** Automated monthly request to site leads, with one reminder after two weeks
- **Administrative codes:** Administrative or medical records-based searches where feasible; site lead confirms eligibility
- **Inclusive reporting:** Clinically significant events may be reported even if a specific code is not listed

Methods

Data gathering

Standardized data collection forms

- Demographics + social determinants
- Clinical history + comorbidities
- Antenatal + peripartum care
- Cardiovascular condition + treatment
- Care trajectory + key decision points
- Outcomes

Narrative summary

- Chronological account
- Makes space for description of the whole trajectory of care
- Uses neutral factual language
- Removes patient, provider and institution identifiers
- Becomes the primary material for external assessment

Methods

Asynchronous reviews

National group of assessors; structured assessment domains for
potential contributing factors

Domain	Details
Care processes	clinical decision-making, protocols, and procedures
Equipment and supplies	availability, functionality, and design
Patient-related factors	relevant clinical and contextual factors
Work environment and team	staffing, communication, workload, and coordination
Organization and management	policies, resources, and organizational processes
External and structural factors	health-system, regulatory, geographic, and broader structural determinants

Methods

Centralized reviews

- Multidisciplinary representation, including persons with lived experience
- The coordinating team will compile the assessments and prepare materials summarizing the findings
- Central meeting with aim to:
 - Discuss and clarify the contributing factors identified during asynchronous assessments
 - Consider complementary or differing perspectives across disciplines
 - Review equity-related factors, uncertainties, and information gaps identified through the equity prompts
 - Identify recurring or system-level patterns across cases
- Finalize SMART (Specific Measurable Achievable Relevant Timebound) recommendations

Methods

Embedding equity considerations

Domain	Details
Data	Respectful collection of demographic of demographic and social determinants data with disaggregation where appropriate
Assessment	Health Equity Assessment Tool (HEAT)-informed prompts consider structural, geographic, communication, cultural and health-system barriers
Interpretation	EDI/SGBA+ expertise and persons with lived experience contribute to thematic interpretation
Recommendations	Ask who benefits, who may be disadvantaged, and what adaptations/resources are needed
Advisory	Throughout the process, be involved with an advisory structure with expertise in health equity

Methods

Data analysis

Quantitative

Descriptive statistics

- Characteristics
- Timing
- Care trajectory
- Contributing-factor domains
- Outcomes

Qualitative

Thematic analysis

Deductive and inductive approach

Based on the Canadian Framework for Incident Analysis

Integration

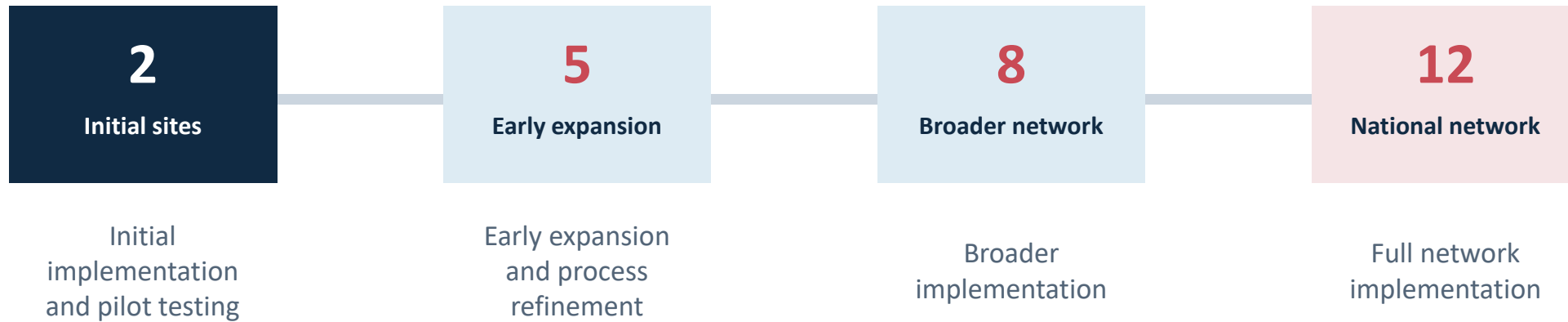
- Convergence matrix
- Complementarity
- Divergence

Methods

Knowledge dissemination

- **Site-level feedback**
 - Annual dashboards: reporting, event volumes, data quality
 - De-identified QI feedback as findings mature
- **National CanOSS-Cv report**
 - Plain language clinical, policy and patient-facing summaries
 - Shared via CanOSS-Cv website, SOGC, provincial perinatal programs and social media
- **Scientific dissemination**
 - Peer-reviewed publications (open access where feasible) and scientific meetings
 - Findings shared with professional organizations and guideline developers
- **Educational resources**
 - Free training materials on incident analysis and recommendations development

Planned roll out



Immediate next steps

- Confirm participating centres and designated site leads/data extractors
- Finalize REB approvals and data-sharing or data-transfer agreements
- Finalize DCFs, data dictionary, Manual of Procedures and training
- Begin implementation at the first two sites and refine processes before expansion

Questions

- What do you find important, valuable in the proposed methods?
- What gaps, challenges, considerations would you highlight?
- Any suggestions to strengthen the protocol?
- Anything you would like to share to help inform our methods?
- Please stay in touch 😊



Thank you!

Harika Dasari
Rohan D'Souza
Jasmine Grewal
Candice Silversides
Samuel Siu
Amy Metcalfe



Email:
isabelle.malhame@umontreal.ca

Twitter/X: @IsabelleMalhame

CanOSS-Cv: Feedback

