




BMJ Open Feasibility of establishing a Canadian Obstetric Survey System (CanOSS) for severe maternal morbidity: a study protocol

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ABSTRACT

Introduction Severe maternal morbidity (SMM)—an unexpected pregnancy-associated maternal outcome resulting in severe illness, prolonged hospitalisation or long-term disability—is recognised by many, as the preferred indicator of the quality of maternity care, especially in high-income countries. Obtaining comprehensive details on events and circumstances leading to SMM, obtained through maternity units, could complement data from large epidemiological studies and enable targeted interventions to improve maternal health. The aim of this study is to assess the feasibility of gathering such data from maternity units across Canadian provinces and territories, with the goal of establishing a national obstetric survey system for SMM in Canada.

Methods and analysis We propose a sequential explanatory mixed-methods study. We will first distribute a cross-sectional survey to leads of all maternity units across Canada to gather information on (1) Whether the unit has a system for reviewing SMM and the nature and format of this system, (2) Willingness to share anonymised data on SMM by direct entry using a web-based platform and (3) Respondents' perception on the definition and leading causes of SMM at a local level. This will be followed by semistructured interviews with respondent groups defined a priori, to identify barriers and facilitators for data sharing. We will perform an integrated analysis to determine feasibility outcomes, a narrative description of barriers and facilitators for data-sharing and resource implications for data acquisition on an annual basis, and variations in top-5 causes of SMM.

Ethics and dissemination The study has been approved by the Mount Sinai and Hamilton Integrated Research Ethics Boards. The study findings will be presented at annual scientific meetings of the Society of Obstetricians and Gynaecologists of Canada, North American Society of Obstetric Medicine, and International Network of Obstetric Survey Systems and published in an open-access peer-reviewed Obstetrics and Gynaecology or General Internal Medicine journal.

Strengths and limitations of this study

- This study which will be conducted simultaneously across all provinces and territories in Canada, will enable the identification of gaps in local review systems for severe maternal morbidity (SMM), and assess the feasibility of establishing a Canadian Obstetric Survey System.
- A sequential explanatory mixed-methods approach will identify variations in leading causes of SMM across and between Canadian provinces and territories as well as barriers and facilitators to sharing data on SMM.
- Although we have identified units providing maternity care across all Canadian provinces and territories as part of a prior study, this project is ambitious in scope, given the decentralisation of Canada's healthcare system, and disparities in the provision of pregnancy services across the country.

INTRODUCTION

Severe maternal morbidity (SMM) refers to a set of unexpected maternal outcomes related to pregnancy, labour, childbirth and the postpartum period resulting in severe illness, prolonged hospitalisation, long-term disability or high case fatality.^{1 2} Since maternal mortality in most high-income countries is low, SMM is now recognised by many, as the preferred indicator of the quality of maternity care.³ In Canada, the incidence of SMM rose from 13.9 per 1000 births in 2007 to 16.1 per 1000 births in 2016.^{4 5} Through epidemiological studies, the Canadian Perinatal Surveillance System (CPSS), the Public Health Agency of Canada (PHAC), the Canadian Neonatal Network (CNN) and

the Society of Obstetricians and Gynaecologists of Canada (SOGC) have identified national priorities, trends, and clinical risk factors for SMM. However, epidemiological studies using administrative or clinical datasets have a limited capacity to provide detailed information on the events leading to SMM, the interplay between clinical and social determinants of health resulting in SMM, whether SMM occur because of patient-related, provider-related or systems-related issues, and whether these adverse outcomes are potentially preventable through targeted interventions.

Engaging with maternity units within communities and conducting an in-depth appraisal of individual cases of SMM, based on a holistic assessment of the structural, clinical, and social determinants underlying SMM may improve our understanding of these adverse maternal outcomes. Detailed clinical data obtained through this approach would complement findings from large epidemiological studies by identifying preventable causes that may be amenable to targeted interventions and/or future research. Such an approach has been successfully adopted in countries such as the UK, through the development of obstetric networks conducting periodic targeted surveys focused on specific SMM types. The UK's Obstetric Surveillance System (UKOSS)—through a nationwide, anonymised, online, monthly, case-collection scheme—has been an effective surveillance tool for selected types of SMM and other rare disorders in pregnancy, since its inception in 2005,⁶ and published their first report on eclampsia. Here, nationwide data were gathered to identify important and under-appreciated facts about this preventable condition,⁷ followed by effective dissemination of their findings.^{8–10} Although UKOSS has not repeated a study on eclampsia, indirect evidence from the most recent Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK report indicates a reduction in pre-eclampsia and eclampsia related mortality, from 18 maternal deaths (0.85 per 100 000 maternities) in the 2003–2005 triennium to 6 (0.28 per 100 000 maternities) in the 2017–2019 triennium.¹¹ Since then, the publication of key findings on 61 rare pregnancy conditions has influenced clinical practice and health policy (online supplemental appendix A). Importantly, UKOSS was able to rapidly implement surveillance of impacts of pandemic illness in pregnant women, both during the 2009A/H1N1 pandemic^{12 13} and during SARS-CoV-2.¹⁴ The success of UKOSS has prompted other countries to develop obstetric survey systems (OSS), which are part of the International Network of OSS (INOSS).¹⁵ A recent publication has demonstrated that the implementation of mandatory training and modifications to treatment protocols for hypertension by the Netherlands Obstetrics Surveillance System resulted in a reduction in the incidence of eclampsia in the Netherlands from 6.2/10 000 births in 2004–2006 to 1.8/10 000 births (relative risk (RR) 0.28, 95% CI 0.22 to 0.36) and accompanying perinatal mortality, that corresponded with an increase in

the use of antihypertensive medications (RR 18.4, 59% CI 9.74 to 34.70) and magnesium sulfate for seizure prophylaxis (RR 1.08, 95% CI 10.4 to 1.12).¹⁶

Canada does not have a national OSS for gathering detailed event-centred data on SMM. Prior to developing a nationwide OSS, it is important to explore the preferred and most feasible methods for gathering SMM data on a national scale, and the challenges to collecting data posed by disparate systems of maternity care delivery across and within Canadian provinces and territories. In addition, obtaining local perspectives on leading causes of SMM will help to inform a list of priority conditions for targeted surveillance using the OSS as well as the type of data elements to be collected and harmonised across jurisdictions.

We hypothesise that most units providing maternity care in Canada have some formal or informal system in place for reviewing cases of SMM on a regular basis. Through this study, we will engage representatives of maternity units to identify local surveillance systems for reviewing cases of SMM in their units, assess barriers and facilitators to data collection and data sharing, and explore their perceptions on the leading causes of SMM. This in turn will enable estimation of resource implications to develop and sustain a Canadian OSS (CanOSS). This nationwide mixed-methods study will provide an opportunity to engage with local stakeholders across the diverse Canadian population and healthcare settings, and will be the first step in the development and future implementation of CaOSS.

METHODS AND ANALYSIS

This study which will be conducted between 1 October 2021 and 30 September 2024 has four specific objectives (1) To determine if and what type of local and regional systems exist for reviewing cases of SMM, (2) To assess barriers and facilitators of gathering granular data on SMM from maternity unit reviews across Canada, (3) To explore local perspectives on the definition and leading causes of SMM at a regional level and (4) To determine resource implications on gathering data on SMM regionally, provincially, or nationally on an ongoing basis.

We will address these objectives through a sequential explanatory mixed-methods design. We will first collect data using a cross-sectional survey, and use the results to inform qualitative interviews to further explore the survey results. This will be followed by an integrated analysis of all data, which will allow for a comprehensive evaluation of the feasibility, barriers, and facilitators, that would need to be considered in estimating resources required for SMM data acquisition on an ongoing basis. The study will be conducted simultaneously in all Canadian provinces and territories.

As required for mixed-methods research, we have identified separate research questions for the quantitative and qualitative components of this work, as well as an

overarching mixed-methods question.¹⁷ These research questions align with the study's objectives as follows:

Research question 1 (Survey—quantitative): What is the nature of the existing system/processes for reviewing SMM, and can we leverage and map-out existing systems for SMM review in local maternity units across Canada? [Objective 1].

Research question 2 (Interviews—qualitative): What are the general and unit-specific barriers and facilitators to gathering and sharing granular data on SMM? [Objective 2].

Research question 3 (Survey—quantitative): How do maternity unit leads define SMM, what do they perceive as the leading causes of SMM in each unit and how do they vary across regions, provinces, and territories? [Objective 3].

Research question 4 (Mixed-methods): How do the interview findings enhance the understanding of the survey results and help in estimating resources needed for ongoing data gathering on SMM? [Objective 4].

Population

We anticipate that every province and region in Canada has its own unique challenges in relation to SMM. Therefore, we will approach one representative (unit or risk-management lead) from every unit providing maternity care in Canada, defined for purposes of this study, as a unit providing care to women and people during pregnancy, childbirth and/or the postpartum period, irrespective of size/volume or care provider type. We will start with a list of Canadian maternity units identified through a prior study (<https://phsr.obgyn.ubc.ca/tiers-of-service/>). In addition, units offering maternity care will be identified through our collaborators' networks, including the SOGC, the Canadian Association of Midwives, and the College of Family Physicians of Canada. We will ensure to approach smaller units in both rural and remote areas and obtain high-quality data from the province of Quebec, which is often underrepresented in national statistics.

Approach

This study will involve two distinct components—a cross-sectional survey and qualitative interviews. As part of the mixed-methods approach, data obtained through the survey will be used to inform data collection through subsequent interviews.¹⁸ The project will, therefore, have four steps as described below and illustrated in figure 1.

STEP-1: Survey administration

We will conduct a cross-sectional online survey (online supplemental appendix B) using REDCap,¹⁹ a secured online data collection tool hosted by McMaster University, across all maternity units in Canada, and aim to obtain responses from a representative at each unit (henceforth referred to as 'respondents'), to three main questions related to the first three objectives of the study: (1) Whether the unit has a system in place for reviewing all cases of SMM on a regular basis and

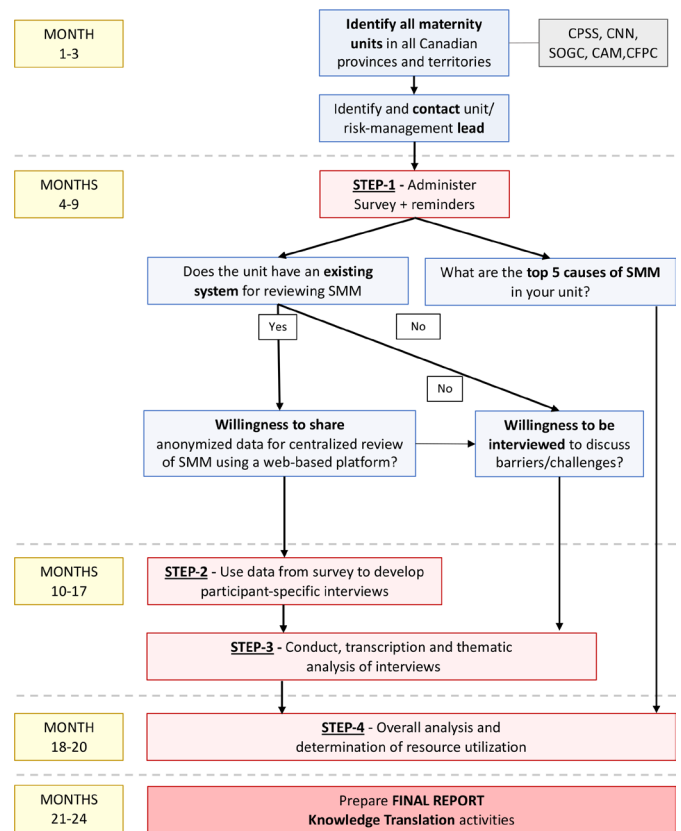


Figure 1 Study schematic – Canadian Obstetric Survey System Feasibility Study. CAM, Canadian Association of Midwives; CNN, Canadian Neonatal Network; CPSS, Canadian Perinatal Surveillance System; SOGC, Society of Obstetricians and Gynecologists of Canada; SMM, Severe maternal morbidity.

the nature of this system, (2) Barriers and facilitators to sharing data and willingness to share data on SMM with a provincial OSS by direct data entry into a web-based platform and (3) Local perspectives on the definition and top five causes of SMM, and whether this information has been obtained through internal statistics or personal judgement/experience. Additional open-ended questions will allow respondents to provide other details to inform the semi-structured qualitative portion of the study, and their contact information, should they be willing to be contacted.

STEP-2: Stratification of respondents and preparation for personalised interviews

Based on the survey results, respondents will be stratified into four groups as follows: group 1—Respondents with a local SMM review system in place and willing to share anonymised information by direct data entry into a web-based platform; group 2—Respondents with a local SMM review system in place but not willing/able to commit to data entry; group 3—Respondents from units without an SMM review system in place, willing to set up a review system for SMM, and willing to share data once a review system is put in place; and group 4—Respondents from units without an SMM review system

in place, unwilling to establish a review system for SMM and/or share data. Since the direction of questioning for respondents is likely to be very different for respondents between, and possibly within each of the four groups, the research team comprising knowledge-users and an expert in qualitative research methodology, will first analyse data from the survey and use the findings to develop and pilot-test respondent-specific, semistructured interview guides. In addition to these four groups, we will stratify maternity units based on care provider type, annual number of births, urban versus rural setting, tertiary versus community hospital, and health regions within provinces. As these strata are outlined, we will optimise representation within each stratum, so that the diverse nature of maternity healthcare delivery within each province is comprehensively captured.

STEP-3: Qualitative descriptive interviews

All representatives of maternity units that respond to the survey will be invited to participate in interviews, although those in groups 2 and 4 will be prioritised. The interview process will be grounded in qualitative description, a method of inquiry that explores individuals' perceptions and experiences of a phenomenon,²⁰ with the aim of generating rich and straightforward descriptions of an experience rooted in the language used by respondents.²¹ Through these interviews, we will aim to explore concerns, experiences, and perceptions as they relate to: (1) challenges and barriers to sharing anonymised data centrally; (2) resources and time commitment; (3) ethical and legal implications; and (4) any other thoughts or suggestions, explicitly linking questions to the survey results. Two researchers with expertise in qualitative research will conduct the interviews, transcribe the data, and perform thematic analysis. Each interview is expected to last 30 min and will be conducted in French or English, as needed. All interviews will be audiorecorded, transcribed verbatim and analysed using a method of reflective thematic analysis.²² Although the aim is to obtain an understanding of a phenomenon by identifying themes or patterns through a process of coding,²³ given the exploratory nature of this study, there will be no predetermined coding scheme. Instead, two appropriately trained qualitative researchers will use a 6-step approach to data analysis, which includes familiarisation with the data, generation of initial codes, a systematic search for themes, review of the themes, definition and naming of themes, and production of a final report.²⁴ Interviews will continue until data saturation is attained,²⁵ which in our case would refer to no new information obtained from two successive interviews within each of the predetermined groups.

STEP-4: Overall analysis

In this step, we will display the findings of the survey and interviews alongside each other, using a table called a 'joint display',²⁶ which allows for an integrated analysis,

while still ensuring that each data set remains analytically separate from the other.²⁷ If there are inconsistencies between survey vs interview responses, we will aim to explain these through interview data. For example, a survey response stating unwillingness/ uncertainty about sharing data may be modified on clarification of the study intent; a negative survey response to whether there is a system within the unit for reviewing SMM may change to a positive response on appreciating that the unit's informal review process qualifies. The identification of these contradictions between survey and interview findings will be important to structure outstanding interviews, and to generate new research questions.^{28 29} The results obtained through the overall analysis will enable us to estimate resource allocation for establishing and sustaining CanOSS.

Outcomes

This study will enable reporting on seven distinct outcomes related to feasibility, barriers and facilitators to data sharing and resource requirements, and variations in the leading causes of SMM across Canada. The alignment of these outcomes with the study objectives and research questions are presented in the [table 1](#).

Analysis

For [outcomes 1](#) (existence of an SMM review system) and [3](#) (willingness to share data), we will describe the results as proportions with percentages. For [outcome 2](#) (nature of the SMM review system), we will present a descriptive analysis of the types of systems across Canada, stratifying responses by units and regions. Analysis for [outcome 4](#) is described as part of step 4 above. For [outcome 5](#), we will descriptively present variations in the definitions of SMM and graphically present the perceived leading causes of SMM across the country. For [outcome 6](#), we will attempt to map out the outcomes of greatest concern, based on region/ province and setting (rural vs urban). For [outcome 7](#), based on analysis of data gathered through the survey and interviews, we will estimate resources required (personnel, information technology and other support) and their associated costs, by region and province. This will be a simple cost analysis and not a formal economic evaluation. For example, for units with no SMM review system in place, we will estimate the cost for establishing an SMM review system, and costs for data entry on prespecified SMM types using a web-based system on a monthly basis depending on unit volume. In addition, for units with an SMM review system in place and with an existing infrastructure to enter data directly into a web-based system, resources would be estimated for costs related to centralised data analysis. Estimates would similarly be made for time and resources needed for research ethics applications and data-sharing agreements. This will enable us to estimate initial costs and ongoing costs for the establishment and implementation of CanOSS on an ongoing basis.

Table 1 Canadian Obstetric Survey System (CanOSS) Feasibility Study—linking study objectives and research questions with study outcomes

Objective	Research question	Outcome
1. Feasibility outcomes	1. Quantitative	1. Existence of a system for reviewing SMM. 2. Nature of the system and the variation between regions. 3. Willingness to share data on SMM, regionally, provincially, or nationally, through direct data entry into a web-based platform.
2. Barriers to data sharing	2. Qualitative	4. Barriers, challenges, perspectives, concerns and suggestions, obtained through thematic analysis.
3. Leading causes of SMM	3. Quantitative	5. Top five causes of SMM. 6. Variations in perceived causes of SMM between and within regions, provinces and territories.
4. Resource utilisation	4. Mixed-Methods	7. Estimate of resources required for ongoing collection of granular data on SMM as part of the Canadian Obstetric Survey System (CanOSS).

SMM, Severe maternal morbidity.

Patient and public involvement in research

Patient partners and advocates (RA, JC and SH) have been involved in the design of this study from its inception and are co-authors on this study protocol. They have provided input in designing the survey questions, which is informed by their priorities, experience and preferences. Patient advocates will continue to be involved in the study, providing feedback on the analysis, interpretation and dissemination, as part of the study steering committee.

DISCUSSION

There is no standard definition of SMM,^{30 31} and a patient-centred definition is currently lacking. This study aims to understand variations in definitions of SMM held by leads of maternity units and the nature of SMM review systems across Canada, to determine barriers and challenges for gathering granular data on SMM in Canada, and to describe perceived definitions and leading causes of SMM. By using a sequential explanatory mixed-methods approach, this research will enable us to estimate resource implications and costs involved in gathering national data on SMM on an ongoing basis. We will use the successful UKOSS methodology for SMM surveillance, tailored to the Canadian context. This study may unravel unforeseen barriers which may need to be resolved through consultation with research ethics boards, legal teams, maternity unit administrators, provincial and federal organisations, and patient-advocacy groups. Notwithstanding these challenges, this study which engages stakeholders at the grassroots level will lay the foundations for a CanOSS to complement ongoing efforts aimed at improving health and outcomes for pregnant women and people in Canada.

Ethics and dissemination

The study has been approved by the Mount Sinai Hospital Research Ethics Board (#20-0344-E) and Hamilton Integrated Research Ethics Board (#2021-14002). Participants will provide informed consent for both, the survey and interviews. Our final report will be a summary of findings

of the survey, integrated analysis, estimate of costs and resources, and future directions. We will prepare a detailed report of our findings as well as power-point presentations, infographics, lay summaries and manuscripts for publication as part of our knowledge mobilisation plan. These findings will be featured on websites of CPSS, CNN, PHAC and SOGC; presented at the SOGC annual conference; and submitted to the Canadian Medical Association Journal. The broader research and clinical community representing members in midwifery, obstetrics, nursing, family medicine, anaesthesiology, neonatology, obstetric medicine and allied specialties will be reached through existing collaborations with national and international organisations, such as the INOSS. Importantly, broad dissemination of this protocol may facilitate assessing the feasibility of establishing a national OSS in other jurisdictions.

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Contributors IM and RD'S conceptualised the study and are principal investigators on this project, which is funded by the Canadian Institutes of Health Research. RD'S wrote the first draft of the manuscript. RD'S and IM revised all versions of the manuscript. RS, the post-doctoral fellow executing the project, helped with design of the participant survey. MK, TvdA, KKC and ST provided insight on study design based on their experience with INOSS, UKOSS, and NethOSS. KSJ led the regionalisation project that identified hospitals across Canada providing care to pregnant women and newborns. MO provided input regarding social determinants of health and health equity. KSJ, SD, JFRB, JCo, PSS and HS represent national organisations working in the area of perinatal mortality and morbidity and provided vital input with regard to adapting the study to the Canadian context. Input from specialty disciplines was sought from SL (critical care), ST (cardiology), LS (haematology), family practice (MF), BM-D (midwifery), RS (nursing), KKC (obstetric medicine). AM and DBF provided input from the perspective of perinatal epidemiologists with expertise in large database research. RA, JCh and SH provided input from the health service user perspective. All authors approved of the final version of the manuscript.

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