

First-Trimester Screening Program for the Risk of Pre-eclampsia Using a Multiple-Marker Algorithm: Recommendation

Final Recommendation

Ontario Health, based on guidance from the Ontario Health Technology Advisory Committee, recommends publicly funding a population-wide first-trimester screening program for the risk of pre-eclampsia using the screening algorithm developed by the Fetal Medicine Foundation.

Rationale for the Recommendation

The Ontario Health Technology Advisory Committee has reviewed the findings of the health technology assessment.¹

The Ontario Health Technology Advisory Committee made the above recommendation after considering the clinical and economic evidence, and patient preferences and values. The committee members noted that a population-wide first-trimester screening program for the risk of pre-eclampsia using the screening algorithm developed by the Fetal Medicine Foundation (“the FMF algorithm”) provides benefit for pregnant people at high risk for pre-eclampsia. This FMF-based screening program likely reduces the risk of pre-eclampsia with delivery at less than 37 weeks’ gestation compared with standard care. It may also reduce the risks of low birth weight and poor Apgar score (the latter assesses the status of a newborn infant immediately after birth). Committee members considered the lived experience of pregnant people, who described the potential positive clinical and social impacts of the population-wide FMF-based screening program. Moreover, the committee noted that although there are additional costs associated with this screening program, there are likely cost savings from pre-eclampsia cases prevented, and the overall budget impact is relatively small.

Ontario Health Technology Advisory Committee members discussed access issues associated with the mean uterine artery pulsatility index (UtA-PI), one of the components of the FMF algorithm, because it is not easily accessed in all parts of Ontario. The committee also noted that the prevalence of pre-eclampsia is higher in certain regions in Ontario (such as rural and remote areas), and in certain racial and ethnic groups. There was committee consensus that a recommendation in favour of publicly funding the population-wide FMF-based screening program would help to promote equitable outcomes through a structured approach to screening.

Decision Determinants for a First-Trimester Screening Program for the Risk of Pre-eclampsia Using a Multiple-Marker Algorithm

Overall Clinical Benefit

Effectiveness

How effective is the health technology/intervention likely to be (taking into account any variability)?

The FMF-based screening program can be more effective than standard care in reducing the risk of pre-eclampsia with delivery at less than 37 weeks' gestation (GRADE: Moderate) and may reduce the risk of low birth weight and low Apgar score after birth (GRADE: Low). The FMF algorithm can be more accurate than conventional algorithms in predicting pre-eclampsia with delivery at less than 37 weeks' gestation.

Safety

How safe is the health technology/intervention likely to be?

Testing for the components used in the FMF algorithm is generally safe. These components are mean arterial pressure, placental growth factor (PLGF), mean UtA-PI, and pregnancy-associated plasma protein A (PAPP-A). PLGF and PAPP-A require blood work, but the risk of harm is very low. Low-dose acetylsalicylic acid (ASA [Aspirin]) is recommended for people who have a screen-positive result on the FMF algorithm, but the risk of bleeding from taking low-dose ASA is low.

Burden of Illness

What is the likely size of the burden of illness pertaining to this health technology/intervention?

Pre-eclampsia affects up to 5% of pregnancies, most frequently after 20 weeks of gestation. According to the data from the Better Outcomes Registry and Network, Ontario, the prevalence of pre-eclampsia in Ontario is about 0.8%.

Need

How large is the need for this health technology/intervention?

No structured program currently exists in Ontario to screen for pre-eclampsia risk. Although we were unable to obtain the annual number of pregnancies, 136,625 babies were born in Ontario between July 1, 2020, and June 30, 2021.

Patient Preferences and Privacy

Patient Preferences and Values

Do patients have specific preferences, values, or needs related to the health condition, health technology/intervention, or life impact that are relevant to this assessment?

Participants strongly value the preventive nature of the screening program, including receiving information and education about pre-eclampsia.

Autonomy, Privacy, Confidentiality, and/or Other Relevant Ethical Principles as Applicable

Are there concerns regarding accepted ethical or legal standards related to patient autonomy, privacy, confidentiality, or other ethical principles that are relevant to this assessment?

The purpose of screening programs is to identify people in a healthy population who are at higher risk for a condition, so that early treatment or intervention can be offered. The FMF-based screening program demonstrates an acceptable level of accuracy, and the risk of harm associated with the screening program is minimal, whereas the risks of developing pre-eclampsia and not receiving adequate attention can be severe. For a first-trimester screening program to achieve improvements at the population-health level, it is important that pre-eclampsia screening be reasonably available across the province within an appropriate time frame. It will also be necessary to adhere to informed-consent requirements to respect a person's autonomy in the screening program.

Equity and Patient Care

Equity of Access or Outcomes

Are there disadvantaged populations or populations in need whose access to care or health outcomes might be improved or worsened that are relevant to this assessment?

There are equity considerations that are relevant to this health technology assessment. Specifically, the prevalence of pre-eclampsia is higher in certain racial and ethnic groups, and in certain regions in Ontario. In terms of equitable access to the intervention, UtA-PI (one component of the FMF algorithm) is not easily accessed in all parts of Ontario.

Patient Care

Are there challenges in the coordination of care for patients or other system-level aspects of patient care (e.g., timeliness of care, care setting) that might be improved or worsened that are relevant to this assessment?

Patient care coordination might be improved. A population-based screening program would allow for the identification of people at high risk of pre-eclampsia. Once identified, prophylactic treatment with ASA can be started in a timely manner.

Cost-Effectiveness

Economic Evaluation

How efficient is the health technology/intervention likely to be?

Compared with standard care (a case-finding approach), we estimate that the population-wide FMF-based screening program would prevent 371 cases of pre-eclampsia with delivery at less than 37 weeks' gestation and cost an additional \$1.28 million each year. This would result in an estimated incremental cost-effectiveness ratio of \$3,446 per prevented case of pre-eclampsia with delivery at less than 37 weeks' gestation.

Feasibility of Adoption Into Health System

Economic Feasibility

How economically feasible is the health technology/intervention?

We estimate that publicly funding the population-wide FMF-based screening program in Ontario would cost an additional \$1.23 million in year 1 to \$3.56 million in year 5, for a total of \$8.50 million over the next 5 years.

Organizational Feasibility

How organizationally feasible is it to implement the health technology/intervention?

Structures are in place in Ontario to support the implementation of the population-wide FMF-based screening program. The FMF biomarker tests are already part of aneuploidy screening in Ontario, and data for the screening program can be stored in the Better Outcomes Registry and Network, Ontario. Training may be required for sonographers to take UtA-PI measurements in the first trimester. Implementation of a population-wide FMF-based screening program should ensure that all providers of prenatal care can order the PlGF test.

Reference

- (1) Ontario Health. First-trimester screening program for the risk of pre-eclampsia using a multiple-marker algorithm: a health technology assessment. Ont Health Technol Assess Ser [Internet]. 2022 Dec;22(5):1–118. Available from: [hqontario.ca/evidence-to-improve-care/health-technology-assessment/reviews-and-recommendations/first-trimester-screening-program-for-the-risk-of-pre-eclampsia-using-a-multiple-marker-algorithm](https://www.hqontario.ca/evidence-to-improve-care/health-technology-assessment/reviews-and-recommendations/first-trimester-screening-program-for-the-risk-of-pre-eclampsia-using-a-multiple-marker-algorithm)

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Ontario Health
130 Bloor Street West, 10th Floor
Toronto, Ontario
M5S 1N5
Toll Free: 1-877-280-8538
TTY: 1-800-855-0511
Email: OH-HQO_HTA@OntarioHealth.ca
www.HQOntario.ca

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