Ontario Fetal RhD Genotyping Task Force

TERMS OF REFERENCE
FEBRUARY 8, 2021

BACKGROUND

Prenatal Screening Ontario (PSO) is housed within BORN Ontario, and is funded by the Ministry of Health (MOH). Its mandate is to coordinate and oversee the operations of prenatal screening services in Ontario, in order to maintain an integrated program that operates as a "system of care".

PSO depends on input from experts and advisors from relevant fields to ensure that all elements of a robust screening program are best carried out. It relies on advice from committees of experts, including the Prenatal Screening Ontario Advisory Committee (PSO-AC), our condition-specific Working Group(s), and the various groups working to support quality assurance in prenatal screening.

The PSO-AC provides support to PSO in an advisory role, consults with the MOH on specific tasks as needed and makes recommendations to PSO and the MOH on conditions amenable to systematic population screening. As needed, task specific working groups are formed to work on items recommended by the Advisory Committee.

Screening pregnant individuals for Rhesus factor D (RhD) is routinely done in pregnancy to detect those at risk for RhD incompatibility. Pregnant persons that are RhD-negative are given RhD immune globulin proactively, in an effort to prevent alloimmunization. Determining the fetal RhD status is now possible by analyzing cell free DNA in maternal plasma. It is estimated that ~40% of RhD negative pregnancies are carrying an RhD negative fetus, thus negating the need for RhD immune globulin.

Ontario Health Quality recently conducted a health technology assessment (HTA) on noninvasive fetal RhD blood group genotyping and made a recommendation to publicly fund this testing for alloimmunized RhD negative pregnancies and, nonalloimmunized RhD negative pregnancies conditional on attaining reasonable cost-effectiveness in the future[1]. In respect of this recommendation, the MOH is seeking advice on the implementation considerations should this testing be made available in Ontario.

MANDATE AND SCOPE

The PSO-AC is seeking evidence-based and clinical/scientific leadership advice on the implementation considerations for noninvasive fetal RhD blood group genotyping in Ontario.

Task force members will leverage the HTA on Noninvasive Fetal RhD Blood Group Genotyping to inform a set of recommendations around the possible implementation of Fetal RhD Noninvasive Prenatal Testing (NIPT).

The Task Force is asked to consider a variety of implementation options for fetal RhD NIPT:

1. Alloimmunized population screening performed at a lab in Ontario
2. Non-alloimmunized screening performed at a lab in Ontario
3. Non-alloimmunized screening performed at a lab outside of Ontario.

Given each option, the Task Force will consider:

a) System components / patient care pathways including, but not limited to: sample logistics, patient tracking, potential need for additional phlebotomy, etc.
b) Data management and reporting
c) System cost analysis related to all aspects of implementation

While the expertise, advice and recommendations of the Task Force are essential to the process, the final decision on funding decisions or the implementation approach remain that of the Ministry.

MEMBERSHIP

The membership will be interdisciplinary and the following areas of expertise may be represented. Members will be chosen to meet the required content expertise and, where possible, to also provide geographic/regional/subspecialty representation. Ideally, membership will be from within Ontario however it is recognized that there may be value in pulling membership nationally. The committee will be comprised of a maximum of 8-10 members (2 of which could be from outside Ontario), including a chairperson. Representation will be from the following subject areas:

- Primary Care (Family Medicine, Midwifery)
- Specialty Care (Maternal Fetal Medicine, Hematology)
- Care for Indigenous Populations and/or Remote Care
- Health Economics and Health Policy
- Laboratory medicine (community, hematology, NIPT expertise)

MOH will participate as a non-voting member to observe and provide insight on MOH context and guidance on matters of policy and program needs. Non-voting guests may be invited as required for their subject matter expertise.

ACCOUNTABILITY AND REPORTING

The Ontario Fetal RhD Genotyping Task Force will report to the Prenatal Screening Ontario Advisory Committee, who will report on this work through PSO to the MOH. The Task Force may interact with other internal and external bodies as required to accomplish its tasks.

This is a time-limited Task Force, with deliverables expected to be submitted by mid-June, 2021. Additional documents, including potential publications, may result from this Task Force.

PROCEDURES

The advice and recommendations developed by the Task Force should reflect the consensus of the whole group.

The Chair will facilitate a consensus decision-making process that is inclusive and provides enough time for evaluation, discussion, proposed options, identification of concerns, and acceptable resolution of the items and/or issues under consideration.

The Members will agree to support a consensus decision or course of action and be willing to carry it out. Where Members are unable to reach consensus, the Task Force will seek to develop a clear and balanced statement or summary detailing the item or issue of disagreement to outline the differing positions tabled and options considered.

MEETINGS

The Ontario Fetal RhD Genotyping Task Force will meet by web conference at least once a month through deliverable completion. Additional meetings will be scheduled as required at the call of the Chair.

At the first meeting, the Task Force will develop its work plan.

CONFLICT OF INTEREST

Members will not include any person who's personal or professional activities constitute a conflict of interest (COI). Any potential COI must be disclosed to the Chair. Such activities include, but are not limited to, direct ties to private industry and personal interests in developing related technologies, including patents and patents pending. Incumbent and existing members will disclose to the Chair, without delay, any actual or potential situations that arise which might be reasonably interpreted as either a conflict of interest or a potential conflict of interest. The Chair has the right to excuse any member with a COI that is perceived to interfere with the deliverable.

CONFIDENTIALITY

Every member will respect the confidentiality of matters brought before the committee, subcommittee or any of its working groups. Meeting materials, including slides, are all to be considered confidential and may not be used outside committee work and may not be disclosed or shared with non-committee members. If such material is no longer confidential and may be circulated externally, the committee will be notified by the Chair.

COMPENSATION

Serving as a committee member is voluntary. Meetings will be held by web conference, in respect of travel and gathering restrictions currently in place.

ADMINISTRATIVE SUPPORT

PSO administrative staff will provide administrative support for the committee.

REFERENCES

1. Ontario Health. Noninvasive Fetal RhD Blood Group Genotyping: A Health Technology assessment. Ontario Health Technol Assess Ser [Internet]. 2020 Nov;20(15):1-160. Available from: https://www.hqontario.ca/evidence-to-improve-care/health-technology-assessment/reviews-and-recommendations/noninvasive-fetal-rhd-blood-group-genotyping