BORN Ontario Better Outcomes Registry & Network Registre et Réseau des Bons Résultats dès la naissance

PRENATAL SCREENING DÉPISTAGE PRÉNATAL ONTARIO

Approved By	Date
Genetics Working Group	28 May 2020
Revision Date(s):	

Terms of Reference

Genetics Working Group

Background

Screening is the systematic population-based application of a test or inquiry to individuals who do not have symptoms of a specific disease or condition in order to identify those who warrant further investigation and/or intervention to achieve better outcomes. The pillars of systematic screening include education, (offer of) enrolment, test administration, retrieval, treatment or intervention, evaluation and quality assurance/improvement.

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 the elements of a robust screening program are best carried out. The program will depend on advice from committees of experts, including the PSO Advisory Committee, our condition-specific Working Group(s), and our quality assurance Working Groups.

As of December 2017, the formal conditions screened for as part of the PSO include Trisomy 21 and Trisomy 18. MOH-funded prenatal screening occurs via a contingent serum screening approach for the average risk pregnant individual, followed by the option of NIPT via cell-free DNA (cfDNA) or diagnostic testing in pregnancies that are identified to be at increased risk. Pregnant individuals who are at a higher a-priori risk and who meet eligibility criteria are eligible for NIPT directly. Ontario's prenatal screening options are available through different laboratories across the province.

The goals of this Working Group are to recommend standards for prenatal screening algorithms and related clinical guidelines, and to review key performance indicators and request other data analyses related to screening for genetic conditions. The work of this task force should be based on principles of clinical utility, sound evidence, and the efficient use of resources, keeping in mind the best interests of pregnant individuals and their families.

Mandate and Scope

The PSO Genetics Working Group will provide advice as appropriate regarding clinical issues related to prenatal screening for genetic conditions. This will include:

- Identify optimal quality and performance metrics, feedback mechanisms, and reporting strategies for prenatal screening
- Review key metrics to identify gaps in screening performance

- Recommend solutions to address gaps in screening care or performance.
- Assess current screening algorithms and make recommendations to improve consistency
- Request the development of and/or review clinical guidelines specific to prenatal screening in Ontario
- Advise on implementation strategies for clinical changes in prenatal screening.
- Review and recommend clinical indicators for MOH-funded testing
- Review and provide feedback to the PSO on recommendations from other advisory bodies
- Review and make recommendations on the collection, use and dissemination of data to improve prenatal screening.
- Other issues as required.

The PSO Genetics Working Group will invite expert guests as needed to provide relevant perspectives on standards development, for example: relevant software specialists, other prenatal screening programs, experts in biotechnology development, quality-based procedure specialists, etc.

As needed, task-specific and time-limited *ad hoc* working groups may be formed to work on an item recommended by the Advisory Committee.

Accountability and Reporting

The Genetics Working Group will report formally to Prenatal Screening Ontario. PSO will report on this work through BORN Ontario to the Ministry of Health (MOH). The committee will interact with other internal and external bodies as required to accomplish its tasks.

Membership

The membership will be comprised of core members selected as individuals based on specific expertise and experience to best enable the work of this committee to be done in a positive and effective way. The committee will be comprised of up to 15 members, including the Chair and Vice-chair. Members of the working group will include:

- Maternal multiple marker screening (MMS) laboratory representative including Biochemist and/or Laboratory technologist
- Genetic Counsellor or Medical Geneticist associated with a provincial MMS laboratory
- Genetic counsellor
- Molecular Geneticist familiar with NIPT technology
- Medical Geneticist
- Maternal-Fetal Medicine specialist
- Primary care physician
- Midwife
- Expert in obstetrical ultrasound
- Patient representative
- Indigenous representative
- Expert in health technology/clinical utility assessments

Membership includes voting and non-voting members. The non-voting members may include ex-officio representatives from the MOH, PSO staff and any representatives who may be invited as subject experts.

All other members, including the Chair and Vice-chair, are voting members. Membership should be reviewed on a yearly basis and periodic rotation of members should occur. Membership should include a balanced geographical representation. PSO will provide a supportive secretariat function.

Administrative and resource support persons will be provided by PSO.

Nominations and Expression of Interest

PSO will issue a general call for Expressions of Interest for membership on the Genetics Working Group. A nominations committee established by PSO will review all submissions and will nominate individuals based on the aforementioned membership criteria, excluding any individuals with conflicts of interest (as detailed below).

Term

The inaugural Chair and Vice-chair will have a term of three years. At the end of the initial three years, the Chair structure of the Genetics Working Group will evolve and the Terms of Reference will be amended at that time. Each of the inaugural Chair and Vice-chair may remain as a committee member after the term is completed, and may return as Chair for another term after a cycle of a different Chair. If the Chair or Vice-chair can no longer fulfill their role, a member of the committee will be nominated by PSO to replace the Chair or Vice-chair until their term is completed.

Members of the committee will generally have terms of three years, renewable once. Renewed appointments will normally be for another 3 years, however, after the inaugural three years of the committee, some renewals will be for 1 or 2 years, to ensure continuity among the membership. Additional renewal may be possible to allow a member to assume the chair or vice-chair role, if requested.

Members are expected to attend a minimum of 50% of meetings per year to maintain membership.

Members are requested to withdraw membership if unable to attend meetings on a regular basis.

Meetings and Procedures

Face-to-face meetings will be held at the call of the chair no more than two times a year. Other business will be conducted by teleconference and email, with no interval between meetings of more than 4 months.

The advice and recommendations developed by the Genetics Working Group should reflect the consensus of the whole group. Decisions will be based on evidence whenever possible, and will always be made with the best interests of the pregnant individuals and families served by the PSO screening system in mind. The Chair and Vice-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, then a majority-based decision will be made. Decisions are binding and all members will support the decisions and work of the Genetics Working Group after decisions have been made.

Quorum

Quorum shall be 50 percent of voting members, either present in-person or via telephone-conference.

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 and Vice-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 and Vice-chair have 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 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 and Vice-chair.

Compensation

Serving as a committee member is voluntary. Meetings will typically be held by teleconference, but should travel expenses be incurred to attend meetings, members will be reimbursed for those expenses as per the BORN Travel Reimbursement Policy and Procedure.

Administrative Support

PSO administrative staff will provide administrative support for the committee.