PRENATAL SCREENING PROGRAM
PROGRAMME DE DÉSPITAGE PRÉNATAL

STANDARDS TASK FORCE

Terms of Reference

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.

Ontario's Prenatal Screening Program (PSP) is housed within BORN Ontario, and is funded by the Ministry of Health and Long Term Care (MOHLTC). 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".

PSP 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 3 task forces: (1) Education Task Force, (2) Standards Task Force and (3) Data Monitoring and Quality Assurance Task Force.

As of December 2017, the *formal* conditions screened for as part of the PSP include Trisomy 21 and Trisomy 18. MOHLTC-funded prenatal screening occurs via a contingent serum screening approach for the average risk woman, followed by the option of NIPT via cell-free fetal DNA (cffDNA) or diagnostic testing in pregnancies that are identified to be at increased risk. Women 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 task force are to recommend standards for prenatal screening algorithms and related clinical guidelines. 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 women and their families.

SCOPE

The PSP Standards Task Force will provide advice as appropriate regarding clinical issues related to prenatal screening. This will include:

- 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 MOHLTC-funded testing
- Review and provide feedback to the PSP on recommendations from other advisory bodies
- Other issues as required.

The PSP Standards Task Force 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 task force.

ACCOUNTABILITY

The Standards Task Force will report formally to the Prenatal Screening Program. There will be interaction with the PSP-AC and other community partners as needed to accomplish its tasks.

MEMBERSHIP

The PSP Standards Task Force will be comprised of 8 to 10 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.

- Biochemist involved in maternal multiple marker screening
- Genetic counsellor
- Molecular Geneticist familiar with NIPT technology
- Medical Geneticist
- Maternal-Fetal Medicine specialist
- Primary care physician
- Midwife
- Expert in obstetrical ultrasound
- Patient representative advisory member
- Expert in health technology/clinical utility assessments

Task force members will have been selected as individuals to represent a specific expertise, or will be specific delegates nominated by their organization or region. Alternate delegates will not normally be invited to meetings, except where specific expertise is indicated.

Membership includes voting and non-voting members. The non-voting members may include ex-officio representatives from the MOHLTC, PSP staff and any representatives who may be invited as subject experts. All other members, including the Chair, are voting members.

Membership should be reviewed on a yearly basis and periodic rotation of members should occur. PSP will provide a supportive secretariat function.

Nominations/Expressions of Interest Process
The PSP will issue a general call (across all Task Forces) for Nominations from partner laboratory and clinical sites, to ensure representation and input into the operations of the PSP.

The PSP will also issue a call for Expression of Interest for membership on this task force to ensure broader community participation. A nominations committee established by BORN will review all submissions and will nominate individuals based on the aforementioned membership criteria, excluding any individuals with conflicts of interest (as detailed below).

Responsibilities
Chair: The task force Chair will have a leadership role in providing effective governance and administration of the task force and is responsible for:

- Working with the PSP staff to schedule meetings and notify committee members
- Inviting guests to attend meetings when required
- Guiding the meeting in accordance with the agenda, including ensuring decision items result in a decision or action
- Reviewing and approving meeting minutes and ensuring circulation to all members of the committee (with the assistance of BORN staff)

Task force members**:** Members will review agenda items, make recommendations, collaborate as part of working groups on educational material.

A PSP Resource Person will assist the Chair with meeting planning and agenda development as well as documentation and communications as requested. The PSP leadership will be present to support meeting discussions and facilitate action items agreed to at task force meetings.

Term
The chair will have a term of three years, but may remain as a committee member after the term is completed. The position is not renewable, but a person may return as chair for another term after a cycle of a different chair.

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

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 6 months. Meetings will be conducted according to Robert's Rules of Order; however, every effort will be made to reach decisions by consensus.

Quorum

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

DECISION-MAKING PROCESS

Members share accountability for decisions. There should be open and direct communication based on honesty, respect and transparency, to ensure that all perspectives are heard. Decisions should be evidence or most-promising practice based. Decisions will be made by consensus whenever possible.

CONFLICT OF INTEREST

Members will not include any person whose personal or professional activities constitute a conflict of interest. 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.

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. Members will be reimbursed for expenses incurred to attend meetings as per the BORN Travel Reimbursement Policy and Procedure.

ADMINISTRATIVE SUPPORT

PSP Administrative staff will provide administrative support for the committee.

FORMAL REVIEW

The Terms of Reference shall be reviewed annually.