

# Advisory Process for Infertility Services Key Recommendations Report

June 23, 2015

## Letter from the Chair:

On behalf of the members of the Advisory Process for Infertility Services (“Advisory Process”), I am pleased to submit this report of key recommendations to the Minister of Health and Long-Term Care. The information contained in this report is intended to advise the Government of Ontario on details for the proposed fertility services program. The advice focuses on clinical eligibility and the establishment of a quality framework to promote safe and high quality fertility services.

The Ministry of Health and Long-Term Care (MOHLTC) deemed the following as out of scope for the Advisory Process work:

- *Number of funded IVF cycles:* the Government has already determined the number of funded IVF cycles.
- *Access:* The Government has determined that access will be expanded to include both medical and non-medical infertility (single people, LGBTQ people, people with disabilities) under this new funding policy, however individual patient eligibility criteria is still to be determined and will be informed by evidence and advice received through the advisory process.
- *Funding Mechanism:* The method by which fertility services will be funded will be determined by the Government.
- *Prescription Drugs:* The Government will not contribute to the cost of drugs to support the IVF procedure. Families or health plans will continue to pay the cost of the associated drug treatments.

The recommendations are based on the best available evidence and the expertise of the committee. As the fertility services sector evolves, it will be important to evaluate and monitor the program on an ongoing basis. The committee recommends that the program is initially assessed after 18-24 months and necessary adjustments to the program be made.

Thank you for the opportunity to provide advice on this important initiative to help more people expand their family by increasing access to fertility treatments.

Sincerely,

Dr. Ellen Greenblatt  
Chair, Advisory Process for Infertility Services

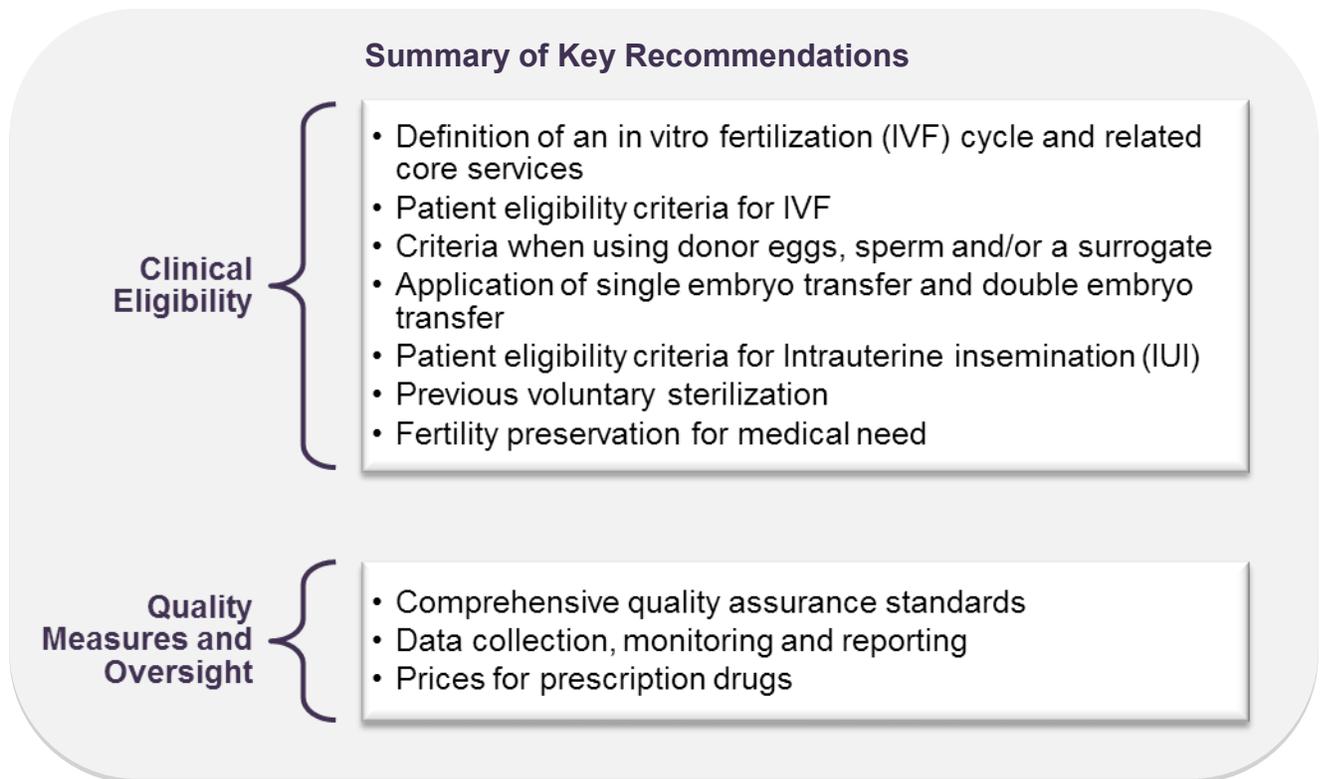
## Table of Contents

Executive Summary .....	3
Structure of the Advisory Process for Infertility Services .....	5
Background Information: Current State .....	6
Key Recommendations for Fertility Services in Ontario .....	8
Recommendation #1: Definition of an IVF Cycle and Related Core Services .....	8
Recommendation #2: Patient Eligibility Criteria for IVF .....	10
Recommendation #3: Criteria When Using a Donor .....	11
Recommendation #4: Single Embryo Transfer (SET) and Double Embryo Transfer (DET) .....	11
Recommendation #5: Intrauterine Insemination (IUI) Criteria .....	12
Recommendation #6: Voluntary Sterilization .....	13
Recommendation #7: Fertility Preservation for Medical Need .....	13
Quality Measures and Oversight for the Fertility Services Sector .....	13
Recommendation #8: Comprehensive Quality Assurance Standards .....	14
Recommendation #9: Expanded Data and Performance Reporting .....	16
Recommendation #10: Negotiate Prices for Prescription Drugs .....	17
Conclusion .....	18
Sources: .....	19

## Executive Summary

In 2014, the Ontario government committed to helping people who cannot conceive children by proposing to expand access to fertility treatments for all forms of eligible infertility.

To assist the Government in developing this program, an advisory process with medical experts and patient representatives was formed. The members of this group used clinical expertise, lived experience and evidence to develop recommendations based on two categories: clinical eligibility and quality measures and oversight. The purpose of this report is to summarize the ten recommendations made by the members of the Advisory Process.



The first draft of this report was prepared by MOHLTC staff, based on the final approved records of decisions for meetings held on December 4, 2014, January 17-18, 2015 and February 28, 2015. Subsequent revisions to the draft report were made by the Chair of the Advisory Process and by Advisory Process members, upon review and approval by the Chair.

## Context

Infertility is defined as the failure to conceive following twelve months of unprotected intercourse.<sup>i</sup> It is estimated that one in six couples in Ontario has experienced infertility at some point in their lives.<sup>ii</sup> In vitro fertilization (IVF) and intrauterine insemination (IUI) are two types of medical procedures that individuals and couples can use to conceive children. In fact, babies born through fertility treatments now represent about one to two percent of live births in Ontario.<sup>iii</sup>

In addition single people and LGBTQ people, though not necessarily infertile by definition, require access to fertility centres in order to have children.

On July 24, 2014, the Ontario Legislature passed *The Building Opportunity and Securing Our Future Act* (Budget Measures) 2014. The 2014 Budget stated the government's commitment to provide additional support for people in the province who want to become parents by expanding coverage of fertility services for one cycle of IVF per patient per lifetime for all causes of eligible infertility. In addition, the government committed to establishing an advisory process to review program implementation details and to provide advice on the establishment of a quality framework.

Comprehensive research, published evidence, and the review of such evidence supported the Advisory Process and key recommendations were developed based on the expert advice and cumulative experience of the members. This report outlines recommendations on the key themes of clinical eligibility as well as quality oversight and monitoring in the fertility services sector.

## Structure of the Advisory Process for Infertility Services

In 2014/15, the MOHLTC established a time limited advisory process with medical experts in the field of fertility and patient representatives to help inform the government on program implementation details and to provide advice on the establishment of a quality framework to promote safe, high quality fertility services.

Seven physicians with expertise in fertility medicine, one physician with obstetrics/obstetrical outcomes expertise, 2 embryology lab directors and three patients with experience of infertility or need for reproductive technologies were invited to participate in the Advisory Process. Participants were selected based on their medical and industry expertise including: obstetrics, reproductive endocrinology and infertility (REI), urology/andrology, quality assurance, clinical practice guidelines, in vitro fertilization program delivery (i.e., Quebec and Israel).

The mandate of the Advisory Process was to provide expertise and advice related to clinical services and eligibility criteria as well as quality measures, mechanisms, and oversight.

The Advisory Process, chaired by Dr. Ellen Greenblatt, Medical Director at Mount Sinai Hospital Centre for Fertility and Reproductive Health, includes the following members,

Dr. Arthur Leader	Dr. G. Scot Hamilton
Dr. Carl A. Laskin	Dr. Edward Hughes
Dr. Keith Jarvi	Dr. Hananel Holzer
Dr. Mathias Gysler	Dr. Rachel Epstein
Dr. Marie-Claude Léveillé	Dr. Amir Attaran
Dr. Mark Walker	Ms. Sandra Alsaffawi-David

To support the work of the Advisory Process the MOHLTC provided members with data and literature including a literature review on fertility services and published guidelines. The MOHLTC also engaged Health Quality Ontario (HQP) to enable knowledge translation of clinical evidence. HQO assisted with framing research questions and performed evidence synthesis reviews. Consultation questions were developed by the MOHLTC and were validated by a medical advisor, internal MOHLTC staff and HQO. These consultation questions were provided to the Advisory Process members to help frame their discussions and deliberations. To supplement research, additional experts in fields such as data oversight and collection as well as experts in law were consulted on an as needed basis.

The members of the Advisory Process met three times from December 2014 to February 2015 to develop recommendations on how to implement an expanded fertility services program. Two of the Advisory Process meetings were in-person deliberations focused on eligibility criteria for both IVF and IUI and on components for a proposed quality

framework. Thorough discussions at the meetings led to the recommendations discussed in detail in this report.

To supplement the advice from the Advisory Process, two legal experts were consulted regarding key legal considerations of expanding funding for infertility services in the province. The advice received from these experts complemented the recommendations of the Advisory Process.

## **Background Information: Current State**

### *Fertility Sector*

Use of fertility services is on the rise, representing 1% to 2% of live births. Currently, there are eighteen fertility clinics in Ontario providing IVF services; sixteen of these are privately owned and two are hospital clinics. There are approximately seven hundred Obstetrics & Gynaecology specialists, although only a small portion are REI subspecialty trained and offer IVF treatment. There are an unknown number of licensed physicians providing donor and partner insemination services.

There is currently, no overarching provincial legislation specifically governing the practice of/ or the quality and safety of the services provided by the fertility sector. Physicians and nurses and other regulated health professionals involved in the provision of fertility services are governed by their respective separate regulatory colleges and guided by National and International clinical practice guidelines. There is currently no regulatory college in place to govern the practice of laboratory fertility technologists/embryologists.

For hospital fertility clinics, hospitals operate under the *Public Hospitals Act*, and are accredited by Accreditation Canada. Private clinics may also be voluntarily accredited and are subject to very limited College of Physicians and Surgeons of Ontario (CPSO) assessments under the Out of Hospital Premises Inspection Program (OHPIP) where sedation is used for the egg retrieval procedure. Inspections are undertaken once every five years.

### *Current Funding*

Currently in Ontario the Ontario Health Insurance Plan (OHIP) insures all professional and diagnostic costs for the evaluation of infertility. OHIP also covers 3 IVF treatment cycles for those with the diagnosis of complete bilateral anatomical fallopian tube blockage, not resulting from voluntary sterilization. However, OHIP only pertains to medical doctor professional fees and blood and ultrasound cycle monitoring but not other costs related to an IVF treatment cycle (such as embryology lab equipment, laboratory supplies, disposables and labour (i.e. human resources)). In hospital IVF programs these non-professional cycle costs must be absorbed under the hospital global budget. An agreement to cover these non-OHIP billable costs has also been negotiated directly with the MOHLTC in one private clinic. The non OHIP (physician fee and cycle monitoring) costs of funded or unfunded IVF cycles are not currently covered in private fertility centres.

For patients without a diagnosis of bilateral tubal obstruction both the professional and non professional cost of IVF is uninsured. OHIP insures all physician and laboratory services for cycle monitoring related to IUI (with the exception of sperm processing costs) for all causes of infertility with no lifetime limits on the number of services (unlimited cycles). Costs for IVF range from \$0 - \$7,500 for insured IVF and \$7,000 - \$11,000 for uninsured IVF. In addition, there may be costs of up to \$5,000 for drugs, and ancillary services such as Intracytoplasmic sperm injections (ICSI), and cryopreservation. There is an average 25.3% clinical pregnancy rate per IVF cycle started<sup>iv</sup>, however, this can vary from under 5% to over 50% depending on patient age and other clinical factors.

For insured IUI treatment, cost ranges from \$500 - \$2,000 with additional medication costs of up to \$1,500 when controlled ovarian hyper-stimulation (COH) is used concurrently. There is a 5% - 22% success rate also linked to age among other factors.<sup>v</sup>

The multiple birth rate (MBR) for natural pregnancy is roughly 2%.<sup>vi</sup> Ontario's MBR for babies born through IVF is approximately 30%,<sup>vii</sup> due to the practice of transferring multiple embryos. Improvements of health outcomes for individual patients and babies would be achieved with a single embryo transfer (SET) policy, which would lower the current MBR for babies born through IVF. Similarly, Ontario's MBR for babies born through IUI is estimated to be between 21-29%,<sup>viii</sup> due to the concurrent use of ovarian stimulating drugs. Increased monitoring of how ovarian stimulating drugs are prescribed would help lower the current MBR for babies born through IUI.

### *Quality Oversight*

There is a need to develop a broad framework to address quality assurance, quality improvement and patient safety (QA, QI/PS) in the fertility sector. In 2004, the Government of Canada passed the *Assisted Human Reproduction Act* (AHRA), which set out federal prohibitions, regulatory controls, approval and licensing requirements for the use of assisted reproductive technologies in research and treatment. In December 2010, the Supreme Court of Canada found that certain aspects of the AHRA (e.g. the provisions regulating research and clinical practice) were outside the federal government's jurisdiction; providing an opportunity for the provinces to regulate in those areas should they choose to do so. Ontario currently has no comprehensive provincial legislation regulating fertility services in Ontario.

### *Data Reporting*

The Canadian Assisted Reproductive Technologies Registry (CARTR) is a voluntary registry where IVF clinics in Canada send their yearly results for compilation into a national average. In January 2013, CARTR merged with the Better Outcomes Registry & Network (BORN) Ontario, the Ontario perinatal registry. Although participation in this registry is voluntary, BORN-CARTR Plus has data sharing agreements with fertility clinics across Ontario.

BORN-CARTR Plus does not currently collect data on IUI, COH-IUI or other fertility treatment cycles and procedures.

In Ontario, BORN-CARTR Plus currently collects the following fertility data for IVF cycles:

- Patient demographics, reasons for treatment (infertility, need for donated gametes, gestational carrier);
- Past obstetrical/fertility treatment history;
- Ovarian stimulation (protocols, medications);
- Oocyte retrieval (# of oocytes);
- Embryology (insemination method, fertilization rate, embryo development, freezing of embryos/oocytes), prenatal genetic screening (PGS)/prenatal genetic diagnosis (PGD);
- Embryo transfer (embryo development stage, fresh embryo or thawed);
- Pregnancy and birth outcome; and
- Multiple Pregnancies

It should be noted that the clinic-level data submitted to BORN-CARTR Plus is owned by the clinic medical directors.

## Key Recommendations for Fertility Services in Ontario

To inform the details of the government’s expanded infertility services program, the Advisory Process summarized their key findings into the two categories with a total of ten recommendations. These recommendations will support the government in the development and implementation of the proposed program in Ontario.



### Clinical Eligibility for Expanded Fertility Services

For the purposes of this report, all recommendations below pertaining to clinical eligibility criteria are made in reference to funded IVF and IUI cycles only.

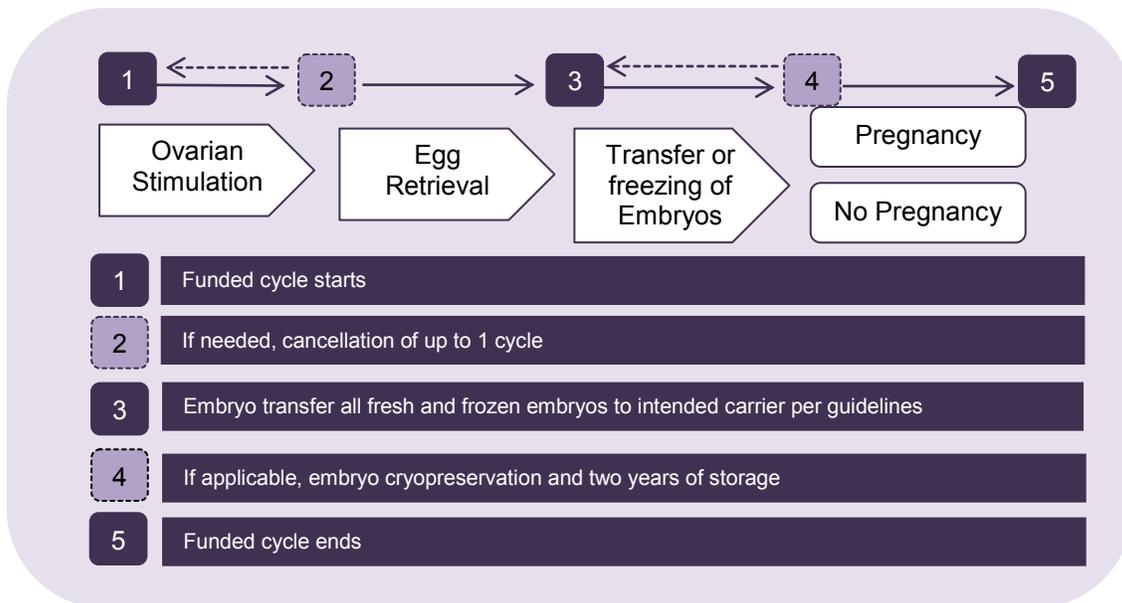
► *Recommendation #1: Definition of an IVF Cycle and Related Core Services*

IVF is a medical technique whereby eggs are collected from a person (egg retrieval) and fertilized with sperm outside the body. If fertilization is successful, the resulting embryo or

embryos is/are transferred into the uterus of the person who will carry the child, or frozen for future use.

The members of the Advisory Process suggest that an in vitro fertilization cycle starts with ovarian stimulation, followed by egg retrieval and through to the transfer of all viable fresh or frozen embryos to the patient who will carry the child or to the designated recipient. This would include stimulation and egg retrieval from an intended altruistic egg donor.

The graphic on the following page depicts the proposed definition of a funded cycle of IVF.



For the purposes of a government funded program, an IVF cycle should be considered complete even in the event of attempted oocyte retrieval with no oocytes retrieved or embryos resulting for transfer and/or freezing. It is recommended that patients should be able to still qualify for the funded IVF program if up to one IVF stimulation cycle has been cancelled for medical cause prior to oocyte retrieval. The second cycle should begin with the future oocyte retrieval. Those patients who cancel one cycle should still be covered for testing and monitoring should they begin their cycle again. If no viable eggs or embryos result from the cycle that proceeds to egg retrieval, there would be no further funded IVF care.

For patients who decide to interrupt treatment, it is recommended that the cost of embryo preservation be covered. This would include embryo freezing and two years of storage fees. At the third year, patients should be given the option to cover the cost of the embryo storage fees themselves.

Other jurisdictions have put a cap on the number of funded cycles a patient may receive once a live birth has been achieved. However, for the purposes of the Ontario program, it is recommended that if a live birth is achieved and cryopreserved embryos remain, the

patient should be able to re-enter the program until all viable embryos have been transferred.

The following is a list of the core services that should be included in a funded IVF cycle,

- Cycle monitoring
  - Cycle monitoring of ovarian stimulation to include: Estradiol (E2), Luteinizing Hormone (LH) and possibly progesterone monitoring and ultrasound.
  - Recommend that frequency of monitoring should be based on patient medical need.
- Use of donor egg and donor sperm
- Surgical sperm retrieval and processing and cryopreservation as needed
- Oocyte retrieval
- Embryo transfer with/without ultrasound guidance
- Intracytoplasmic sperm injections (ICSI)
- Assisted hatching
- Preimplantation genetic diagnosis (PGD) / Comprehensive Chromosomal Screening (CCS) for patients with known genetic risk
- Embryo Cryopreservation for up to two years
- Diagnostic evaluation for all patients including altruistic surrogates and gamete donors.

### ► *Recommendation #2: Patient Eligibility Criteria for IVF*

Recognizing that age and body mass index may have an impact on both fertility and IVF success rates, it is recommended that eligibility restrictions be implemented for the purposes of the funded program.

- Age
  - It is recommended that patients are no younger than 18 years of age and any age group that has a cumulative success rate (live birth) of less than 10% should not be funded<sup>ix</sup>. It is recommended that based on this 10% cumulative success rate, the age threshold for funded IVF be 42 years and 364 days of age, with cycle stimulation start prior to 43rd birthday. This age limit is based on current data and evidence.<sup>x</sup>
  - While we understand that the government has committed to contribute to the costs of one IVF cycle, the MOHLTC may wish to reduce the upper age limit to 42 years of age to potentially enable the provision of more than one funded cycle for women within a reduced age range.
  - Treatment at the upper age limit should be contingent on the absence of medical issues that would require resource intensive medical treatment prior the start of IVF that would likely delay treatment to beyond the 43rd birthday.

- Body Mass Index
  - Based on the American Society of Anesthesiologists guidelines, egg retrievals should not be undertaken on patients who score above ASA 2 for safety reasons.

► *Recommendation #3: Criteria When Using a Donor*

The AHRA prohibits the for profit sale of gametes, embryos or other reproductive services in Canada. Aligned with what is prohibited in the AHRA and based on clinical expertise, the following criteria are recommended when using donor material and gestational carriers:

- The egg donor is between 18 and 37 years of age while a sperm donor can be up to 40 years of age.
- The carrier has no medical contraindication to pregnancy and is greater than 21 years of age.
- No medical contraindications to pregnancy or controlled ovarian hyperstimulation (COH), (if required) and intrauterine insemination (COH IUI) if donor sperm is used in IUI.

► *Recommendation #4: Single Embryo Transfer (SET) and Double Embryo Transfer (DET)*

Globally, countries have adopted varying policies to guide the number of embryos to be transferred in an IVF cycle. For example, in Australia, SET is not a mandatory practice but is strongly encouraged.<sup>xi</sup> Guidelines have been developed that take age and embryo quality into consideration. On the other hand, in Sweden, SET is a mandatory policy except in exceptional circumstances.<sup>xii</sup> In countries such as Israel, there is no mandatory SET policy.<sup>xiii</sup>

In Ontario, a SET policy that encourages the physician to take embryo development stage, embryo quality, and history of previously failed transfers and age into consideration is recommended. The following table outlines the key considerations for a fresh or frozen SET policy.

SET vs. DET	
Age	# of Embryos
Up to age 35	One embryo, regardless of the development stage.
36 and 37	One embryo at blastocyst stage or a maximum of two embryos on day three of embryo development.
38 and older	Maximum of two embryos regardless of the development stage.
All ages	Proceed to DET after three failed SETs.

In order to help reduce the multiple pregnancy rates in Ontario it is recommended that monitoring of IVF clinics for their multiple pregnancy rates are implemented. Multiple

pregnancy rates (gestation) should be no greater than 10% prior to selective reduction. It is recommended that treatment (stimulation) must begin before a patients' 43<sup>rd</sup> birthday.

#### ► *Recommendation #5: Intrauterine Insemination (IUI) Criteria*

IUI is a service that includes the placement of processed sperm transcervically into the uterus via a catheter. IUI is a service used by heterosexual couples, single persons of any gender, lesbian, gay, bisexual, transgender or queer (LGBTQ) individuals and couples, people living with HIV, people with disabilities or others unable to achieve pregnancy via intercourse.

For the IUI Cycle Monitoring Process, 'routine' monitoring in which a schedule of blood and US monitoring is predetermined is not appropriate; Monitoring should go hand-in-hand with physician assessment of results and a decision for future monitoring be based on this assessment. There is no clinical value in daily Follicle Stimulating Hormone (FSH), Thyroid Stimulating Hormone (TSH), Prolactin monitoring during IUI treatment. It is recommended that serum Luteinizing Hormone (LH), Estradiol (E2), and transvaginal ultrasound for follicular tracking be funded up to a maximum of six episodes per IUI cycle and serum Progesterone (P4) once per IUI cycle. However, for patients with Polycystic Ovarian Syndrome (PCOS) on gonadotropin injections who need more intense monitoring, the six episodes would not apply and different metrics could be used based on physician assessment. To increase patient safety, patients should be monitored only as indicated by current clinical guidelines, for example, during stimulated cycles with IUI. The number of days of monitoring should be limited.

The Advisory Process recommends that the core services for IUI should include:

- Sperm wash and preparation.
- Third party reproductive counseling, for those using donor sperm.

The clinical recommendation for IUI depends on the particular reason a patient is accessing it. For sub-fertile patients or in individuals or couples in which the sperm provider has mild sperm or sperm function abnormalities it is recommended that a single insemination be conducted per IUI cycle. This includes patients who have at least one open fallopian tube, are younger than 35 and who have been trying to get pregnant through unprotected intercourse or home insemination for at least one year; or are over 35 years of age and have been trying via unprotected intercourse or home insemination for at least six months. For patients requiring donor-insemination IUI or patients with sexual dysfunction that precludes conception via intercourse, unstimulated IUI may be the recommended procedure that should be funded for up to twelve cycles. Depending on the patient's age and clinical recommendation of the physician, the patient may proceed to IVF treatment after only six cycles of IUI.

Pathway for COH-IUI and IVF		
Age	# of funded IUI Cycles	When to Move to IVF
Up to age 37	Up to six	May proceed to IVF after three failed cycles
38 to 40	Up to four	May proceed to IVF after two failed cycles
41 to 42	Up to two	May proceed directly to IVF or after two failed cycles

► *Recommendation #6: Voluntary Sterilization*

For various reasons, a patient seeking fertility services may have undergone a previous voluntary sterilization surgery (e.g., vasectomy or tubal ligation). Although patients may experience success in achieving a pregnancy after having the surgery reversed or undergoing IVF, it is not recommended that these patients have access to the government's expanded fertility services program.

► *Recommendation #7: Fertility Preservation for Medical Need*

Some medical situations (e.g., cancer, lupus, kidney disease, gender transition and others) require treatments may include chemotherapy or other gonadotoxic mediations that may negatively impact a patient's fertility. A fertility preservation program should inform, educate and support patients who are facing a medical treatment that may impact their fertility. While educating patients is important, it is necessary to also provide information to providers. This should be done through various organizations such as Cancer Care Ontario, the Ontario Oncofertility Working Group and Fertile Future and Cancer Knowledge Network, the Canadian Professional Association for Transgender Health, Rainbow Health Ontario, LGBTQ Parenting Network, and Sherbourne Health Centre. Partnerships with these kinds of organizations can result in the production of relevant patient educational materials.

In addition, it is recommended that patient educators be available at the point of care (e.g., oncology centres, immunology, renal, and medical practitioners providing transgender health care) so that patients are made aware of fertility preservation options prior to undergoing any medical treatment. In addition, patients should receive accelerated access to fertility consultation in urban and remote centres using satellite offices and the Ontario Telemedicine Network or its successors. Financial support for the collection, freezing and long term storage of gametes and embryos for those pursuing fertility preservation for medical need should also be included in this new programme.

## Quality Measures and Oversight for the Fertility Services Sector

Existing Quality/Regulatory processes for fertility services are limited and there is no comprehensive, quality framework in place. In 2010, the Supreme Court of Canada struck

down provisions in the federal Assisted Human Reproduction Act (AHRA) that dealt with the regulation of aspects of medical practices related to assisted human reproduction, providing the opportunity for provinces to regulate these aspects themselves. As a result of the Supreme Court decision, most provinces, including Ontario, have no provincial legislation in place regulating fertility services.

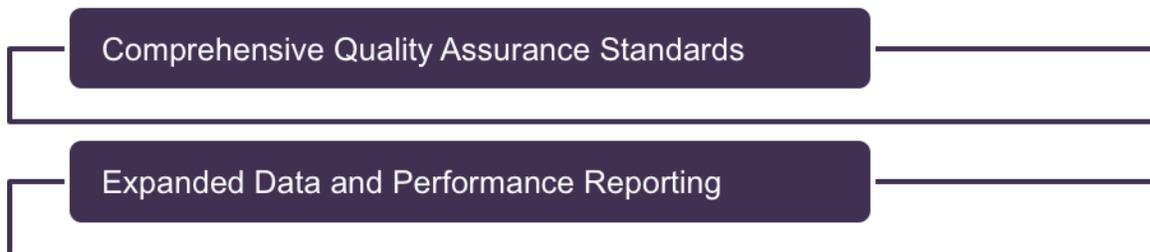
Quality measures and oversight in this sector is important to safeguard the health and safety of patients, donors and those children born as a result of fertility services. Regardless of who is paying for the service, the patient's safety is a priority. Therefore, the quality framework should aim to protect patients, donors and resulting children regardless of the funding model.

Currently, a voluntary accreditation program through Accreditation Canada is used by some fertility clinics in Ontario. In addition, Canadian fertility clinics can, on a voluntary basis, report data to a database called, "Canadian Assisted Reproductive Technologies Register Plus (CARTR Plus).

Beyond the voluntary quality mechanisms currently in place, the following recommendations support the establishment of a formal quality framework for fertility services in Ontario. All of the quality recommendations below are made in reference to both IVF and IUI cycles regardless of whether they are funded or not.

Above all, it is recommended that an ongoing quality committee, led by the MOHLTC, be developed to identify details and evolving concerns related to quality in this sector.

High-level key components of a proposed quality framework should include:



► *Recommendation #8: Comprehensive Quality Assurance Standards*

A quality framework must encompass mechanisms that will ultimately protect the patient and resulting offspring but also encourage continuous improvement within this sector. Accreditation, inspection, identified professional qualifications, laboratory quality assurance, quality assurance for new technologies and health equity awareness are all recommended components of a comprehensive quality framework.

*Program Standards:*

Accreditation Canada is a not-for-profit organization, which through standards and

programs, works with health care organizations to help them improve quality, safety, and efficiency so that they can offer the best possible care and service.<sup>xiv</sup> All hospital based fertility clinics and many of the privately operated fertility clinics in Ontario participate, on a voluntary basis, in this accreditation program.

It is recommended that participation in an accreditation program be a minimum requirement for all funded clinics and practitioners performing IVF and COH IUI in Ontario. In addition, the requirement for accreditation should be tied to a regulatory or licensing process.

A blended quality assurance model of accreditation and a quality assessment/inspection program recognizing the unique environmental requirements of fertility clinics by the College of Physicians and Surgeons of Ontario could also be considered.

#### *Professional Qualifications:*

A method must be developed to designate license and identify clinics that have been approved to deliver fertility services. The scope of practice for IVF and IUI services going forward should define minimum qualifications for practitioners.

IVF is a medical procedure that should be conducted within a fertility clinic by a qualified obstetrician/gynecologist further trained and certified in the subspecialty of gynecologic reproductive endocrinology and infertility (GREI). Currently, IUI procedures can be conducted in a variety of locations including but not limited to, fertility clinic, a primary care physician's office or other location by either an REI or non-REI physician.

It is recommended that gonadotropin stimulation for ovulation induction or IUI only be performed under the supervision of a physician holding Royal College of Physicians and Surgeons of Canada (RCPSC) subspecialty training in GREI or having been 'grandfathered' as a GREI subspecialist or holding American Board of Obstetrics and Gynecology (ABOG) subspecialty certification in REI. Alternatively, it could be conducted by a general OB/GYN who has been trained by a fellowship/grandfathered GREI and who also is affiliated with and supervised by a funded fertility clinic/practitioner.

Practitioners who perform IUI independently, or provide diagnostic/ cycle monitoring procedures in support of core services (IUI and IVF) should have an affiliation with a fertility clinic and thus be subject to the inspection and accreditation requirements of that fertility clinic. The fertility clinic shall be responsible to provide oversight in cases of any complications such as ovarian hyperstimulation. As such, Medical Directors will have increased accountability for the care both within their facility and within any independently run facility with which they are affiliated.

Sperm retrieval procedures for therapeutic reasons (IVF-ICSI, fertility preservation) should be limited to physicians who have Urologic Fertility subspecialty training and qualifications, or those who have at least the urology equivalent work experience to that obtained in fellowship training (grandfathering clause). The equivalent experience should be at a minimum 50 cases of sperm retrievals for IVF from individuals with obstructive

azoospermia, and 20 cases of sperm retrieval (using a micro-TESE approach) from men with non-obstructive azoospermia as well as a proven capacity to:

- appropriately investigate men with azoospermia
- counsel about treatment options (outcomes and risks and alternative options) for men with azoospermia
- manage complications of treatments

*Laboratory Quality Assurance:*

The Canadian Fertility and Andrology Society (CFAS) developed guidelines and standards for assisted reproductive technology laboratories. It is recommended that as a minimum, a quality framework would include the CFAS laboratory standards as they exist and may be changed from time to time as a requirement.

*Quality Assurance for New Technologies:*

Technology and processes for conducting fertility services is constantly evolving. It is important that a quality framework is flexible enough to address any quality concerns that may arise from the introduction of a new technology. It is recommended that a funding mechanism be developed to allow for the assessment and evaluation of new technologies and that the funding mechanism be reevaluated to allow for the incorporation of validated new technologies. It is recommended that the length of time of an accreditation visit be extended to all for discussion on this topic.

*Health Equity Awareness:*

Patients at fertility clinics who are accessing fertility services are likely from a diverse range of cultural, ethnic, language, religion, gender identity, sexual orientation and socio-economic backgrounds. In order to provide quality care to all patients, health inequities must be identified and addressed. It is strongly recommended that all clinical staff be encouraged to participate in equity training and ensure clinic processes and materials (i.e., forms) use inclusive language. In particular, this committee is concerned that LGBTQ people be assured that they will encounter services that are skilled and responsive to their needs.

► *Recommendation #9: Expanded Data and Performance Reporting*

Collecting and sharing information resulting from fertility treatments and services is a means to both measure and improve quality. When determining additional data requirements, it is recommended that the needs of the patients, the MOHLTC and clinics be taken into consideration. A mandatory requirement for all clinics should be to submit clinic specific data to the BORN-CARTR Plus database. In addition, to promote transparency, this data should be audited by a Quality Assurance and Improvement Committee (QA/IC) (to be established) and shared with the MOHLTC and any applicable accreditation/inspection body. Membership of this QA/IC should be similar to that of the Quality Control Committee of the CFAS who serve as an advisory group providing

assistance to clinics with lower than expected outcomes.

Databases should be kept as simple as possible with a minimum set of indicators to allow for adjustments as technology and outcomes change over time. Currently BORN-CARTR Plus does not capture data for IUI procedures. BORN-CARTR Plus captures IVF data such as implantation rates, cancellation rates and single/multiple birth rates. In addition, IUI outcomes and potentially demographic data should also be captured in BORN-CARTR Plus in order to gather the full scope of fertility related data.

► *Recommendation #10: Negotiate Prices for Prescription Drugs*

While we understand that the government has not committed to finance infertility medicines, members felt strongly that drugs cannot be ignored from the patient perspective because they comprise about 40% of the out-of-pocket spending on IVF. Therefore, Advisory Process members recommend that the MOHLTC negotiate with the manufacturers or distributors of infertility medicines to try to obtain a lower price for individuals and insurers. Currently the Ministry negotiates prices for hundreds of drugs, and doing likewise for a small number of infertility medicines is feasible. These MOHLTC negotiations could be done cooperatively with the other provinces and territories through the Pan-Canadian Pharmaceutical Alliance (PCPA), so as to pool their buying power and leverage deeper discounts.

## Conclusion

The Government of Ontario announced its intention to expand coverage of fertility services in support of one cycle of IVF per patient per lifetime for all causes of eligible fertility. The recommendations provided through the Advisory Process concentrated on the clinical eligibility criteria and the quality framework for fertility services in Ontario. As a result of the Advisory Process, ten recommendations are put forward for consideration by the MOHLTC as it develops and implements the expanded fertility services program.

### *Summary of Key Recommendations:*

1. Definition of an IVF cycle and related core services
2. Patient eligibility criteria for IVF
3. Criteria when using a donor
4. Single embryo transfer and double embryo transfer
5. IUI criteria
6. Voluntary sterilization
7. Fertility preservation for medical need
8. Comprehensive quality assurance standards
9. Expanded data and performance reporting
10. Negotiate prices for prescription drugs

The Ontario Government intends to help more people expand their family by increasing access to fertility treatments. It is expected that the recommendations made by the Advisory Process will support the government in developing and implementing an evidence-based expanded fertility services program.

## Sources:

---

- <sup>i</sup> De Melo-Martin, I. (2002). On Cloning Human Beings. *Bioethics*, 16:3, 246-265.
- <sup>ii</sup> Improving Access to Safe Fertility Treatments. News Release. (April 10, 2014). <http://news.ontario.ca/mohltc/en/2014/04/improving-access-to-safe-fertility-treatments.html>
- <sup>iii</sup> Improving Access to Safe Fertility Treatments. News Release. (April 10, 2014). <http://news.ontario.ca/mohltc/en/2014/04/improving-access-to-safe-fertility-treatments.html>
- <sup>iv</sup> CARTR Plus data for 2013, Presentation at the Canadian Fertility and Andrology Society 60<sup>th</sup> Annual Meeting September 11–14, 2014, available online at [https://www.cfas.ca/images/stories/pdf/BORN\\_CFAS\\_CARTR\\_Plus\\_presentation.pdf](https://www.cfas.ca/images/stories/pdf/BORN_CFAS_CARTR_Plus_presentation.pdf) at slide 19.
- <sup>v</sup> Taimur Bhatti and Akerke Baibergenova. *A Comparison of the Cost-Effectiveness of In Vitro Fertilization Strategies and Stimulated Intrauterine Insemination in a Canadian Health Economic Model*. Journal of Obstetrics and Gynaecology Canada. (May 2008).
- <sup>vi</sup> Expert Panel on Infertility and Adoption. (August 2009). Page 102. <http://www.children.gov.on.ca/htdocs/English/infertility/index.aspx>
- <sup>vii</sup> <sup>vii</sup> Expert Panel on Infertility and Adoption. (August 2009). Page 102. <http://www.children.gov.on.ca/htdocs/English/infertility/index.aspx>
- <sup>viii</sup> <sup>viii</sup> Expert Panel on Infertility and Adoption. (August 2009). Page 102. <http://www.children.gov.on.ca/htdocs/English/infertility/index.aspx>
- <sup>ix</sup> ART National Summary Report. National Center for Chronic Disease Prevention and Health Promotion. (November 2012). Figure 15. [http://www.cdc.gov/art/pdf/2012-report/national-summary/art\\_2012\\_national\\_summary\\_report.pdf](http://www.cdc.gov/art/pdf/2012-report/national-summary/art_2012_national_summary_report.pdf)
- <sup>x</sup> United States National Center for Chronic Disease Prevention and Health Promotion, Division of Reproductive Health, *2012 Assisted Reproductive Technology: Fertility Clinics Success Rates Report*, available online at <http://www.cdc.gov/art/pdf/2012-report/art-2012-fertility-clinic-report.pdf>.
- <sup>xi</sup> Australian Medical Association (2011). The multiple benefits of single embryo transfers. Retrieved Jan 2014 from <https://ama.com.au/media/multiple-benefits-single-embryo-transfers>
- <sup>xii</sup> Karlstrom, P.O. and Bergh, C. Reducing the number of embryos transferred in Sweden-impact on delivery and multiple birth rates (2007). *Human Reproduction*, v.22 no. 8. Retrieved March 2015 from: <http://humrep.oxfordjournals.org/content/22/8/2202.full.pdf+html>
- <sup>xiii</sup> Dr. H. Holzer. Personal communication.
- <sup>xiv</sup> Accreditation Canada. About Us. (2013). <http://www.accreditation.ca/about-us>