Applying the Out-of-Hospital Premises Inspection Program (OHPIP) Standards in Fertility Services Premises

DRAFT: September 27, 2016
College of Physicians and Surgeons of Ontario

Mandate
The profession, through and with the College, has a duty to serve and protect the public interest by regulating the practice of the profession and governing in accordance with the *Regulated Health Professions Act*.

Our Vision – Quality Professionals, Healthy System, Public Trust
Our vision guides our thinking and actions. It defines who we are, what we stand for, the role we see for ourselves, our critical relationships, in what system we work, and the outcomes we seek.

**Quality Professionals** - as a profession and as professionals, we recognize and acknowledge our role and responsibility in attaining at a personal, professional, and at a system-level, the best possible patient outcomes.

**Healthy System** - the trust of the public and our effectiveness as professionals is influenced by the system within which we operate. We demonstrate leadership by active involvement in the design and function of an effective system, one which is accessible, integrated, informed by evidence and sustainable.

**Public Trust** – we earn trust of the public by ensuring quality professionals and safe care, working collaboratively with partners towards a healthy system, acting in the interests of patients and communities and being accountable and transparent.

Our Guiding Principles – Integrity, Accountability, Leadership and Collaboration
To fulfill our vision of **Quality Professionals, Healthy System, Public Trust** we are guided by the following principles:

**Integrity** in fulfillment of our mandate and pursuit of our vision, achieved by aligning our goals, behaviours and outcomes and adhering to a high ethical standard.

**Accountability to the public and profession** achieved through an attitude of service, accepting responsibility, transparency of process and dedication to improvement.

**Leadership** demonstrated by proactive regulation of our profession, management of risk and service to the public.

**Collaboration** with health system partners to ensure shared commitment, focus and resources for the common good of the profession and public.
Guiding Policies

It is expected that physicians will manage medical and surgical conditions within the scope of their certification and experience. For all CPSO members this means practicing with the appropriate qualifications or equivalency subject to requirements set out by the RCPSC, or CPSO “Recognition of Non-Family Medicine Specialists” and “Changing Scope of Practice” policies.

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Background

In 2015, the Ontario Ministry of Health and Long-Term Care directed the College of Physicians and Surgeons of Ontario to develop and implement a quality and inspections framework for the delivery of fertility services in out-of-hospital premises (OHPs) and hospital-based settings across the province. In particular, the Ministry asked the CPSO to undertake the following:

- develop comprehensive quality assurance standards, professional qualifications and embryology quality assurance standards;
- develop clinical guidance for fertility services;
- enhance performance and quality data reporting requirements for fertility clinics; and,
- develop and implement a comprehensive inspections regime for the fertility services sector.

The College, through its Out-of-Hospital Premises Inspection Program (OHPIP) supports continuous quality improvement through developing and maintaining standards for the provision of medical care/procedures in Ontario out-of-hospital premises (OHPs), and inspecting and assessing for safety and quality of care. This is mandated by the amendment to Regulation 114/94 under the Medicine Act adding Part XI, Inspection of Premises where Certain Procedures are Performed, which was enacted on April 9, 2010.

In November 2009, Council adopted the core Out-of-Hospital Premises Standards which are the basis of inspection-assessments for the variety of procedures performed in OHPs.

It is expected that physicians will manage medical and surgical conditions within the scope of their certification and experience. For members of the College of Physicians and Surgeons of Ontario (CPSO), this means practicing with the appropriate qualifications or equivalency subject to requirements set by the Royal College of Physicians and Surgeons of Canada (RCPSC), or CPSO “Recognition of Non-Family Medicine Specialists” and “Changing Scope of Practice” policies.

Regulation Amendment for Fertility Services

In order to enable the College to fulfill its oversight responsibilities for fertility services, an amendment to Ontario Regulation 114/94, Part XI (Inspections of premises where certain procedures are performed) is currently out for consultation, as follows (underlined portion represents change to regulation):

44. (1) In this Part,

“inspector” means a person designated by the College to carry out an inspection under this Part on behalf of the College;

“premises” means any place where a member performs or may perform a procedure on a patient but does not include a health care facility governed by or funded under any of the following Acts:

1. The Long-Term Care Homes Act, 2007;
2. The Developmental Services Act;
3. The Homes for Special Care Act;
4. Revoked: O. Reg. 134/10, s. 1 (2);
5. Revoked: O. Reg. 192/14, s. 1;
6. The Ministry of Community and Social Services Act;
7. The Ministry of Correctional Services Act;
8. The Ministry of Health and Long-Term Care Act;
9. Revoked: O. Reg. 134/10, s. 1 (2);
10. The Private Hospitals Act;
11. The Public Hospitals Act;

“procedure” means,
(a) any act that, when performed in accordance with the accepted standard of practice on a patient, is performed under the administration of,

(i) general anaesthesia,
(ii) parenteral sedation, or
(iii) regional anaesthesia, except for a digital nerve block, and

(b) any act that, when performed in accordance with the accepted standard of practice on a patient, is performed with the administration of a local anaesthetic agent, including, but without being limited to,

(i) any tumescent procedure involving the administration of dilute, local anaesthetic,
(ii) surgical alteration or excision of any lesions or tissue performed for cosmetic purposes,
(iii) injection or insertion of any permanent filler, autologous tissue, synthetic device, materials or substances for cosmetic purposes,
(iv) a nerve block solely for the treatment or management of chronic pain, or
(v) any act that, in the opinion of the College, is similar in nature to those set out in sub-clauses (i) to (iii) and that is performed for a cosmetic purpose,

(b.1) any act that is performed in connection with,

(i) in vitro fertilization,
(ii) intra-uterine insemination,
(iii) fertility preservation for medical purposes,

but does not include,

(c) surgical alteration or excision of lesions or tissue for a clinical purpose, including for the purpose of examination, treatment or diagnosis of disease, or

(d) minor dermatological procedures including without being limited to, the removal of skin tags, benign moles and cysts, nevi, seborrheic keratosis, fibroepithelial polyps, hemangioma and neurofibromata.

O. Reg. 134/10, s. 1 (1, 2); O. Reg. 192/14, s. 1.

(e) the sole act of counseling or referral for the procedures set out in subsection (b.1).
Purpose of this Document

This document was developed to help fertility services practitioners plan for and participate in their inspection-assessments. It does not replace the core OHPIP 2013 Standards; rather, it helps the practitioner understand how the OHPIP Standards will be applied in their fertility services practice. This Guide should be considered a required companion document to the OHPIP Standards for practitioners.

An important distinction needs to be made with respect to the use of terminology in the OHPIP Standards. Wherever there is a reference to “operating” room, this would be considered a “procedure room” for the purpose of fertility services.

The core OHP Standards are available at http://www.cpso.on.ca/uploadedFiles/policies/guidelines/office/ohp_standards.pdf

All decisions made by the Premises Inspection Committee will be based on the information within these Standards as well as any additional relevant guidelines, protocols, standards and Acts that are current (i.e. CNO standards, national guidelines). This includes requirements set out by other regulatory bodies and provincial guidelines.

How this Document is Organized

For ease of reference, this document has been organized into two parts to coincide with the types of services offered by fertility services premises:

Part I: In Vitro Fertilization (IVF) Units

Part II: Ovulation Induction/Intracervical Insemination/Intrauterine Insemination (OI/ICI/IUI) Units

Within each Part of the document, specific sections of core OHPIP Standards have been clarified with regard to how they uniquely apply to fertility services premises. Premises are also required to comply with the additional requirements outlined in each section.

Note: This Guide should be considered a required companion document to the OHPIP Standards for practitioners. Premises must also comply where appropriate with all other requirements listed in the core OHPIP Standards.
PART I: In Vitro Fertilization (IVF) UNITS

NOTE: Within each Part of this document, the content is further organized as follows:

a) specific sections of the core OHPIP Standards have been clarified in how they uniquely apply to fertility services premises – as such, the numbered sub-sections mirror the numbering in the core OHPIP Standards.

b) additional requirements with which premises must comply.

This Guide should be considered a required companion document to the core OHPIP Standards for practitioners. Premises must also comply where appropriate with all other requirements listed in the core OHPIP Standards.
2.2.6 – OHP Policies and Procedures

2.2.6.1.1 Administrative

Guidance to the Standard

d) Does not apply.

2.2.6.1.5 Procedures

Guidance to the Standard

In addition to the procedures listed, the following clarification applies:

h) Medical and Laboratory Directives

In addition to the procedures listed, the following additions apply:

g) Handling of human gametes (sperm, eggs, embryos) and reproductive tissues

r) Urgent transfer of cryopreserved human cells and tissues for assisted human reproduction

2.2.6 OHP Policies and Procedures

1. The Medical Director is responsible for the regular review, update, and implementation of OHP policies and procedures, which must address the following areas:

2.2.6.1.1 Administrative:

a) responsibility for developing and maintaining the policy and procedure manual

b) organizational chart

c) scope and limitations of OHP services provided

d) overnight stays, if applicable.

e) ensuring that records are kept for each RHP working in the OHP are current and include qualifications, relevant experience, and relevant hospital privileges as appropriate to the RHP.

f) ensuring all physicians performing OHP procedures at the premises have provided online notification to satisfy the regulation requirements (see section 2.2.1), and documentation verifying approval (emails from College staff) is on file.

2.2.6.1.5 Procedures:

a) Adverse events: monitoring, reporting, and reviewing

b) Adverse events: response to an adverse event

c) Combustible and Volatile Materials

d) Delegating controlled acts

e) Emergency evacuation

f) Equipment: routine maintenance and calibration

g) Medications handling and inventory

h) Medical Directives

i) Patient booking system

j) Detailed and clear patient selection/admission/exclusion criteria for services provided at the OHP

k) Patient consent (written or verbal) based on the scope of the OHP practice

l) Patient Preparation for OHP procedures

m) Response to Latex Allergies

n) Safety precautions regarding electrical, mechanical, fire, and internal disaster.

o) Urgent transfer of patients (see Section 2.2.6.1.3)

p) Waste and garbage disposal
**Additional Requirements – Policies and Procedures**

The Medical Director shall ensure that there are separate policies and procedures documented for each of the clinic subsections (as applicable):

**Subsection Policy and Procedure (P&P) Manuals**
1. Physician (Including for OI, IUI and IVF Procedures)
2. Nursing – should include the policies and procedures governing safe nursing practice in an IVF clinic. The following CFAS nursing documents (in their most current form) are recommended and should be used as a reference and be included as an appendix to the nursing manual—
   b. Position Statement: Ovarian Hyperstimulation Syndrome (OHSS)
   c. Position Statement: Performing Intra-Uterine Insemination (IUI)
3. Ultrasound Services (If Independent Health Facilities (IHF) Ultrasound licence is within the premises— then, manual related to ultrasound licence of an IHF is acceptable)
4. Biochemistry Laboratory
5. Andrology Laboratory (Including IUI procedures and diagnostic testing)
6. IVF Laboratory
7. Storage and dispensing of medications
8. Information Technology (IT) (to include, but not limited to, EMR services, Data Protection and Privacy, Equipment Maintenance)
9. Housekeeping and Reprocessing
10. Administrative
11. Accounting and Financial Services
12. Human Resources
13. Research (basic and/or clinical)
14. Counselling (if offered at the premises)
15. Ethics (including ethics committee if applicable)
16. Leadership and Partnership Committee
17. Quality Assurance
4.1 General Physical Standards

Guidance to the Standard

Electrical, Standard 4.1.2.2 is clarified as follows:

Emergency power supply can:

- Provide for safe completion of egg retrieval or other related procedures and the safe recovery of the patient;
- Protect the integrity of gametes and embryos within the premises;

Layout, Standard 4.1.5.2 g) and h) are replaced by:

- IVF laboratory
- staff change room (where applicable)

Layout, Standard 4.1.5.2 - The following additional items also apply:

- i) diagnostic imaging (where applicable)
- j) diagnostic laboratories (phlebotomy, biochemistry, andrology) (where applicable)

<table>
<thead>
<tr>
<th>4.1 General Physical Standards</th>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Building Codes</strong></td>
<td>OHP site complies with all applicable building codes including fire safety requirements.</td>
<td></td>
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</tr>
</tbody>
</table>
| **Electrical** | 1. All electrical devices are certified by CSA or licensed for use in Canada.  
2. Emergency power supply can provide for safely completing the procedure and recovering the patient. | |
| **Access** | 1. Access for persons with disabilities complies with provincial legislation and municipal bylaws.  
2. Doors and corridors can safely accommodate stretchers and wheelchairs. | |
| **Size** | OHP size is adequate for all procedures to be performed. | |
| **Layout** | 1. Layout facilitates safe patient care and patient flow.  
2. These areas are functionally separate:  
a) administration and patient-waiting area  
b) procedure room and/or operating room  
c) recovery area  
d) clean utility area  
e) dirty utility room  
f) reprocessing room  
g) endoscope cabinet  
h) staff change room and staff room. | |
| **Emergency Measures** | Provisions are in place to ensure  
1. The safe evacuation of patients and staff in case of an emergency, i.e., stretchers, wheelchairs, or other adequate methods of transport are available, and  
2. There is appropriate access to the patient for an ambulance to transfer the patient to a hospital. | |
4.2 Procedure Room/Operating Room Physical Standards

Guidance to the Standard

Physical Requirements, Standard 4.2.1.1 is clarified as follows:

c) immediate access to hand-washing or hand hygiene facilities and proper towel disposal

Physical Requirements, Standard 4.2.1.3 is clarified as follows:

Space allows the physician and assisting staff, to move around the procedure table with access to all sides of the patient, and:

- be connected to the embryology lab through a “pass through” window or door for communication
- have a sink conveniently placed for hand washing if ABHR 70% or higher is unavailable or not used

<table>
<thead>
<tr>
<th>1 Physical Requirements</th>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. All OHP levels provide:</td>
<td>a) lighting as required for the specific procedure</td>
<td>b) floors, walls and ceilings that can be cleaned to meet infection control requirements</td>
<td>c) immediate access to hand-washing facilities and proper towel disposal</td>
</tr>
<tr>
<td>2. Space can accommodate equipment and staff required for the procedure.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Space allows the physician and assisting staff, when sterile, to move around the OR/procedure table with access to both sides of the patient, without contamination.</td>
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</tbody>
</table>
4.3 Recovery-Area Physical Standards

Guidance to the Standard

Size and Layout, Standard 4.3.2.1 is clarified as follows:

1. The size of the recovery area depends on planned use: it must accommodate the volume of patients expected for a minimum of 90 minutes post procedure time, i.e.,
   - 1 hour procedure = 2 patients
   - 0.5 hour procedure = 4 patients
   - 20 minute procedure = 6 patients

<table>
<thead>
<tr>
<th>1 Physical Requirements</th>
<th>1. A sink for hand washing is accessible.</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 Size and Layout</td>
<td>Level 1 NA</td>
</tr>
<tr>
<td>1. The size of the recovery area depends on planned use: it must accommodate the volume of patients expected for a minimum of two hours operating room time, i.e.,</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• 1 hour procedure = 2 patients</td>
</tr>
<tr>
<td></td>
<td>• 0.5 hour procedure = 4 patients</td>
</tr>
<tr>
<td></td>
<td>2. The recovery area allows for transfer of patients to/from a stretcher and performance of emergency procedures.</td>
</tr>
<tr>
<td>3 Equipment</td>
<td>Level 1 NA</td>
</tr>
<tr>
<td></td>
<td>Monitoring, suction, oxygen, and bag-valve mask devices, intravenous and other medical supplies are immediately available.</td>
</tr>
</tbody>
</table>
4.4 General Medication Standards

Guidance to the Standard

Standard 4.4.1 - The following addition applies:

j) if dispensed under the authority of a physician, medication(s) used in ovulation induction or controlled ovarian hyperstimulation prior to IUI or IVF and after discharge from the procedure must be stored, dispensed and discarded in keeping with the manufacturer’s requirements, good medical practice and accounted for on a daily basis.

Standard 4.4.2 – does not apply.

4.4 General Medication Standards

1. OHPs should:
   a) maintain a general medication inventory record
   b) periodically inspect all medications for viability
   c) date multidose vials of medication on opening and dispose according to manufacturer’s guidelines
   d) label medications in accordance with the Food and Drug Act (FDA) and the Controlled Drugs and Substances Act (CDSA) and its regulations
   e) store medications:
      i) according to the manufacturer’s recommendations (e.g., refrigeration if required)
      ii) in a manner suitable for security and restocking
   f) store emergency drugs in a common location. In facilities where procedures are done in multiple procedure rooms, a crash cart is advisable
   g) document administration of medications in the patient record
   h) dispense medications at discharge accompanied by verbal and written instructions that are given to the patient and/or accompanying adult
   i) make available resources to determine appropriate drug dosages and usage.

2. If services are provided to infants and children, the required drugs must be available and appropriate for that population.
Additional Requirements – OHP Physical Standards - Embryology

1 Power Supply and Critical Alarm System

Alternate Power Supply (e.g. generator, batteries, UPS) should/must be connected to critical equipment
Alarm system for critical equipment must have a backup power supply

2 Temperature and Air Quality

- Highest level of positive pressure that does not compromise gametes
- Air quality systems should be monitored on a regular basis, and the equipment be maintained to meet manufacturer’s standards
- Temperature and humidity regulated by thermostats should be tested and adjusted regularly.
- Oxygen sensors should be present and in proper working order in all areas where liquid nitrogen is being used.
5.6 – Nurse Qualifications

Guidance to the Standard:

Standard 5.6.1 - The following clarification applies:

b) additional training and appropriate experience as required for procedures performed including assisting with IVF procedures, counselling and supporting patients receiving treatments, performing delegated medical acts (if appropriate, e.g., donor or partner sperm insemination and/or IUI), caring for patients receiving anaesthetic and/or sedation, patient teaching, recognition and treatment of complications e.g., OHSS, and documentation of all interactions with patients. Written policies for all procedures should be available in each clinic.

Standard 5.6.2 - Does not apply.

5.6 Nurse Qualifications

1. Registered nurses (RNs) and registered practical nurses (RPNs) working within their scope of practice in OHPs must hold:
   a) current registration with the College of Nurses of Ontario
   b) additional training and appropriate experience as required for procedures performed
   c) current BLS certification
   d) must have current ACLS if administering sedation to, monitoring or recovering patients (RNs only).

2. Registered Nurses (RNs) working with a pediatric population (14 years and younger), who are involved in monitoring, administering sedation or recovering patients must maintain a current PALS certification.
Additional Requirements – OHP Staff Qualifications - Laboratory Staff Qualifications

1. **LABORATORY DIRECTOR**
   This position has responsibility for the day-to-day operation, management, organization and supervision of the laboratory staff. In addition to being responsible for the laboratory services, the Laboratory Director will also perform laboratory procedures on a regular basis and be directly involved in training of new employees.

2. **LABORATORY SUPERVISOR**
   The Laboratory Supervisor assumes a lead role in the Assisted Reproductive Technology (ART) Laboratory and is the responsible person in the absence of the Laboratory Director. This role has also previously been referred to as “coordinator” or “lead”.

3. **EMBRYOLOGIST**
   The Embryologist performs complex laboratory procedures in an ART Laboratory, which include:
   - Performing technical procedures in the ART Laboratory
   - Adhering to the standard operational procedures for the ART Laboratory, and
   - Demonstrating competency in obtaining and processing of gametes and embryos

4. **ANDROLOGIST**
   Some larger ART programmes, or specialized IUI/donor sperm programmes, have dedicated ART Andrology Laboratory staff members who do not have embryology responsibilities. A person who provides specialized andrology services in the ART Laboratory is designated as an Andrologist.
   Responsibilities may include, but are not limited to:
   - Performing diagnostic assays on human sperm specimens
   - Preparing human sperm specimens for ART procedures, including intrauterine insemination, and
   - Cryopreservation of human semen or sperm specimens
6 – Procedure Standards for all OHPs

Guidance to the Standard:

Standard 6.1 - The following clarification applies:

1) State of patient health, including co-morbidities (BMI, ASA physical status)

6.1 Pre-Procedure Patient-Care Standards

Guidance to the Standard:

Standard 6.1.2 – The following clarification applies:

Documentation:

All actions taken for pre-procedure patient care are entered in the patient record; informed consent, separate forms, e.g., consent for embryo freezing, consent for PGS, gamete shipping, legal forms, counseling forms, disposition of surplus gametes, tissues, and embryos if applicable, are placed in the patient record.

6 Procedure Standards for all OHPs

The ultimate judgment regarding the care of a particular patient and selection of procedure must be made by the physician considering all the circumstances presented in an individual case. Risk factors that should be considered as having the potential to jeopardize patient safety in an OHP include but should not be limited to:

1) State of patient health, including co-morbidities (ASA physical status)
2) Potential complication from a specific procedure
3) Complications in surgical management if more than one procedure is performed during a single operation
4) Anesthetic factors that place patient at higher risk
5) Necessity for prolonged recovery period
6) Duration of procedure
7) Availability of anti-hyperthermia measures
8) Anticipated blood loss
9) Hypothermia

6.1 Pre-Procedure Patient-Care Standards

1. The physician must:
   i. assess the risks inherent in each procedure or combination of procedures to determine if the OHP setting is safe; and
   ii. appraise each patient’s medical risk factors and capacity to undergo anesthesia

2. Documentation:

All actions taken for pre-procedure patient care are entered in the patient record; separate forms, e.g., consent form, are placed in the patient record.
6.2 Pre-Procedure Requirements: OHP Level 1

Guidance to the Standard

“BEFORE day of procedure” - a Nurse or Physician may be responsible for the requirements listed in table 06.

“BEFORE or ON day of procedure” - The following clarification applies:

3. a) focused history and physical examination that includes findings indicating the rationale for the proposed procedure and risk factors

<table>
<thead>
<tr>
<th>Table 06: Pre-Procedure Requirements: OHP Level 1</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BEFORE day of procedure:</strong></td>
<td></td>
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<tr>
<td>1. Provide fasting instructions as required.</td>
<td>Physician</td>
</tr>
<tr>
<td>2. Advise patient that a responsible adult should be accessible during the duration of the OHP stay.</td>
<td>performing procedure</td>
</tr>
<tr>
<td><strong>BEFORE or ON day of procedure:</strong></td>
<td></td>
</tr>
<tr>
<td>3. Conduct pre-procedure assessment, which includes, but is not limited to:</td>
<td>Physician performing procedure</td>
</tr>
<tr>
<td>a) focused history and physical examination that includes findings indicating the rationale for the proposed procedure</td>
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<tr>
<td>b) blood pressure and pulse</td>
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<tr>
<td>c) allergies.</td>
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<tr>
<td>4. The physician is responsible for obtaining informed consent and a procedure consent form signed by the patient or substitute decision maker and witnessed.</td>
<td></td>
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<tr>
<td><strong>ON day of procedure:</strong></td>
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<tr>
<td>5. Complete admission assessment: Confirm baseline history and physical as in point 3 above.</td>
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</tbody>
</table>

6.3 Pre-Procedure Requirements: OHP Levels 2 and 3

Guidance to the Standard

Standard 6.3.1 - The following clarification applies:

**BMI/ASA classification**

6.3 Pre-Procedure Requirements: OHP Levels 2 and 3

The physician providing anesthesia assigns an ASA classification for all prospective patients requiring anesthesia for OHP procedures; Class ASA4 and above are not generally acceptable for OHPs.

The pre-procedure anesthetic/sedation assessment includes but is not limited to the following:

1) ASA classification
2) a review of the patient’s clinical record (including pre-procedure assessment)
3) an interview with the patient
4) a physical examination relative to anesthetic aspects of care
5) a review and ordering of tests as indicated
6) a review or request for medical consultations as necessary for patient assessment and planning of care
7) orders for pre-procedure preparation such as fasting, medication, or other instructions as indicated.
Guidance to the Standard

Table 08: Pre-Procedure Requirements

Were appropriate, the responsibility for the actions listed in the chart below may be performed by appropriately qualified providers under the direction of the Most Responsible Physician (MRP).

Pre-Procedure Requirements: OHP Levels 2 and 3

<table>
<thead>
<tr>
<th>BEFORE day of procedure:</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Provide fasting instructions as required for the procedure, specific conditions, (e.g., diabetes), and for medications the patient routinely takes (e.g., diabetic medications, anti-hypertensives, anti-platelets).</td>
<td>Physician performing procedure</td>
</tr>
<tr>
<td>2. Advise patients if they will require adult accompaniment on leaving OHP after the procedure.</td>
<td></td>
</tr>
<tr>
<td>3. Advise patient that a responsible adult must be accessible during the duration of the OHP stay.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>BEFORE or ON day of procedure:</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>4. Conduct pre-procedure assessment that includes, but is not limited to: a) history and physical examination that includes findings indicating the rationale for the proposed procedure b) all current medications (prescribed and non-traditional, e.g., herbal remedies) c) weight, height, body mass index (BMI), blood pressure, and pulse d) allergies e) ECG, laboratory tests, x-rays, pre-procedure consultation, and investigations (all as indicated).</td>
<td>Physician performing procedure</td>
</tr>
<tr>
<td>5. For patients with significant co-morbidities (including sleep apnea), arrange a consultation with an anesthesiologist, and other medical specialists as required, prior to procedure acceptance. 5.1 If classified as ASA3, patients may be accepted only if the disease entity could not reasonably be expected to be affected adversely by the anesthetic or procedure. 5.2 The physician and anesthesiologist should discuss all Class ASA3 cases well in advance of the scheduled procedure, with regard to the: a) pre-procedure assessment and care required, b) intra-procedure and post-procedure requirements, and c) appropriateness of OHP setting for the safe performance of the procedure.</td>
<td>Physician performing procedure or Physician providing anesthesia</td>
</tr>
<tr>
<td>6. Obtain informed consent and a procedural consent form signed by the patient. A rolling patient consent (which requires specific information to be documented) is suitable for the same procedure performed consecutively and should be documented in the patient’s chart.</td>
<td>Physician performing procedure</td>
</tr>
<tr>
<td>7. Provide adequate explanation to the patient about the proposed anesthesia including anticipated outcome, significant risks, and alternatives available. This may be included in the procedure consent form.</td>
<td>Physician performing procedure or Physician providing anesthesia</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ON day of procedure:</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>8. Complete admission assessment: Confirm pre-procedure anesthetic/sedation assessment (may be unnecessary if anesthesiologist conducts pre-procedure anesthetic/sedation assessment on same day as procedure).</td>
<td>Physician providing anesthesia</td>
</tr>
<tr>
<td>9. Complete admission assessment: Confirm baseline history and physical as in point 4 above; update if &gt;14 days. Take vital signs (BP, pulse, respiration, oxygen saturation, temperature), and glucometer reading for diabetic patients where appropriate.</td>
<td>Health care provider</td>
</tr>
</tbody>
</table>
6.4 Verification Process

Guidance to the Standard

Standard 6.4.1 – The following clarification applies:

**Procedures Included**

Egg retrievals, sperm preparation, gamete culture, and embryo transfers all require verification process. This requires verification of the correct patient, partner and/or sperm sample, which includes, partner’s demographics and/or donor ID/number at two different times and locations, as follows:

<table>
<thead>
<tr>
<th>When</th>
<th>Where</th>
</tr>
</thead>
<tbody>
<tr>
<td>First verification</td>
<td>before entering the procedure room/ the pre-procedure area</td>
</tr>
<tr>
<td>Second verification</td>
<td>during the time-out in the procedure room/ operating room</td>
</tr>
</tbody>
</table>

**Note:** Procedures exempted from site marking still require a verification process.

6.5 First Verification

Guidance to the Standard

Standard 6.5.3 - The following clarification applies:

The nurse or physician preparing the patient for the procedure confirms the patient identity, and procedure.

1. The first verification takes place in the pre-procedure area.
2. The patient is awake and aware.
3. The nurse preparing the patient for the procedure:
   a) confirms the patient identity, procedure, site and/or side with the patient/substitute decision-maker/legal guardian
   b) documents the first verification on the Surgical Safety Checklist.
6.6 Second Verification

Guidance to the Standard

Standard 6.6.2 - The following clarification applies:
   The patient and her partner (if applicable) are required to be awake.

Standard 6.6.3 – The following clarification applies:
   The entire procedure team confirms the patient identity, procedure, consent and specimens according to their standard operating procedures.

The following additional requirements apply:

4. The physician performing an embryo transfer must verify the patient prior to the transfer.

   There should be a standard operating procedure for identity verification of the sperm sample for all procedures.

6.7 Site Marking

Guidance to the Standard

Standard 6.7 - Does not apply.

6.7 Site Marking

1. Marking must take place with the patient awake and aware, if possible.

2. The physician performing the procedure marks at or near the incision/insertion site. Site-sensitve areas must be marked above or lateral to the procedure site (e.g., scrotal surgery sites are marked on the groin area on the appropriate side of the body; breast sites are marked on the breast or above the breast on the upper chest area).

3. Procedures involving right/left distinction or multiple structures (fingers, toes) must be marked.

4. The mark must be:
   a) placed using a permanent marker
   b) visible at the time of patient preparation and visible at time of incision
   c) explicit (e.g., initials) to indicate the intended site of incision or insertion or actual incision line.

5. Site marking is exempted in the following situations:
   a) The procedure requires a surgical measurement to the operative part when applied on an awake and oriented patient.
   b) Patient refuses to allow site marking. In this situation, a risk report is completed and placed in the patient’s record.
6.8 Intra-Procedure Care for Sedation, Regional Anesthesia, or General Anesthesia

Guidance to the Standard

Standard 6.8 - In addition to the listed requirements, the following additional requirement applies:

5. Other required documentation for IVF:
   - Ovulation induction monitoring (stimulation sheet)
   - Consent forms
   - Procedure note with clear identification of physician performing the procedure

Requirements for managing patients undergoing sedation, regional anesthesia, or general anesthesia, are as follows. Note: See physician qualification as well.

1. If the physician administering the sedation or regional anesthesia is also performing the procedure, the patient must be attended by a second individual (physician, respiratory therapist, RN or anesthesia assistant) 1) who is NOT assisting in the procedure and 2) who is trained to monitor patients undergoing sedation or regional anesthesia.

   1.1 The second physician, respiratory therapist, RN or anesthesia assistant shall hold ACLS (and PALS if pediatric patients are being treated) certification and the following skills:
   1) assessing and maintaining patient airway
   2) monitoring vital signs
   3) venipuncture
   4) administering medications as required
   5) assisting in emergency procedures including the use of a bag-valve-mask device
   6) documenting in the Anesthesia/Sedation Record

2. Note: If assistance is required during the procedure, a third HCP must be available. The person monitoring the anesthetic shall remain with the patient at all times throughout the duration of anesthetic care until the patient is transferred to the care of a recovery-area staff in the recovery area.

3. Patients shall be attended for the duration of the anesthetic care as follows:

   3.1 O2 saturation must be continuously monitored and documented at frequent intervals. In addition, if the trachea is intubated or an LMA is used, end-tidal carbon dioxide concentration must be continuously monitored and documented at frequent intervals. Capnography must be available at the premises for use, where appropriate, on patients receiving deep sedation. Capnography is always required for patients receiving general anesthesia as defined in section 3.2.

   3.2 Pulse, blood pressure and electrocardiography must be in continuous use during the duration of anesthetic care. Heart rate and blood pressure shall be documented at least every 5 minutes. During sedation (see section 3.2) in healthy patients without cardiac disease and for whom no cardiovascular disturbance is anticipated, it may be acceptable to waive ECG monitoring as long as pulse oximetry is in continuous use and ECG monitoring is immediately available.

   3.3 Audible and visual alarms must not be indefinitely disabled. The variable pitch pulse tone and the low-threshold alarm of the pulse oximeter and the capnograph alarm must give an audible and visual alarm. Variable pitch tone pulse oximeter must be clearly audible at all times.

4. The Anesthesia/Sedation Record is completed; it includes the following:
   1) pre-procedure anesthetic/sedation assessment
   2) all drugs administered including dose, time, and route of administration
   3) type and volume of fluids administered, and time of administration
   4) fluids lost (e.g., blood, urine) where it can be measured or estimated
   5) measurements made by the required monitors:
      - O2 saturation must be continuously monitored and documented at frequent intervals. In addition, if the trachea is intubated or an LMA is used, end-tidal carbon dioxide concentration must be continuously monitored and documented at frequent intervals
      - Pulse, blood pressure documented at least every 5 minutes until patient is recovered from sedation
   6) complications and incidents (if applicable)
   7) name of the physician responsible (and the name of the person monitoring the patient, if applicable)
   8) start and stop time for anesthesia/sedation care
6.10 Patient Discharge

Guidance to the Standard

Standard 6.10.1 - The following clarification applies:

For IVF Procedures:

An anesthesiologist or another physician is responsible for writing the discharge order. However, the actual decision for discharge from the recovery area must be based on discharge criteria using an objective scoring system; the decision can be delegated to recovery-area staff (such as RNs).

6.10 Patient Discharge

For OHP levels 2 and 3:

1. An anesthesiologist or physician is responsible for writing the discharge order. However, the actual decision for discharge from the recovery area must be based on discharge criteria using an objective scoring system; the decision can be delegated to recovery-area staff.

2. All patients should be accompanied by an adult when leaving the OHP. Patients having received sedation or general anesthesia must be accompanied by a responsible adult.

3. Appropriate verbal and written post-discharge instructions are given to the patient and the accompanying adult.

4. The patient and accompanying adult are instructed to notify the OHP of any unexpected admission to a hospital within 10 days of the procedure.
Additional Requirements – Procedure Standards for Embryology

Verification

- Strict measures need to be taken to ensure safety and security of embryos/gametes, as well as the confidentiality of patient records.
- There should be at least 2 identification methods to assure all information pertaining to the patient material (e.g. sperm, oocytes, embryos, testicular or ovarian biopsy) is correct.
- The use of all biological material should be verified by two witnesses prior to their use.
- All information should be backed up to a secure secondary source.
7 – Infection Control

Guidance to the Standard

Standard 7 - In addition to the Standard, the following clarification applies:

Facilities offering Assisted Reproductive Technology (ART) laboratory services may use soap and water as an alternative for hand hygiene.

7 Infection Control

The CPSO, in partnership with Public Health Ontario (PHO), have developed accepted standards of practice for OHPs and physician offices for infection control. The document can be found at the following link: www.publichealthontario.ca/ClinicalPractice

Medical Directors should consult the specific section of the PHO website for the following information, which form part of the OHP standards expectations. Medical Directors are responsible to ensure periodic reviews of the CPSO and PHO website documents to stay current with standards for infection prevention and control, and ensure compliance with these recommendations.

OHPs shall adhere to the following:

1) Accepted standard(s) of infection control practices that are pertinent to the specific procedures performed at the OHP.

2) The Routine Practice approach to infection control. According to the concept of Routine Practices, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV and other blood borne pathogens.

3) Actions that minimize risk of infection in the operating room:
   a) adherence to proper use of disinfectants
   b) proper maintenance of medical equipment that uses water (e.g., automated endoscope reprocessors)
   c) proper ventilation standards for specialized care environments (i.e., airborne infection isolation, protective environment, and operating rooms)
   d) prompt management of water intrusion into OHP structural elements.

4) Accepted standards of handling regulated waste. “Regulated Waste” means:
   a) liquid or semi-liquid or other potential infectious material
   b) contaminated items that would release blood or other potential infectious materials in a liquid or semi-liquid state are compressed
   c) items that contain dried blood or other potential infectious materials and are capable of releasing these materials during handling
   d) contaminated sharps
   e) pathological and microbiological wastes containing blood or other potentially infectious materials.
8.1 – Monitoring Quality of Care

Clarification to the Standard

Standard 8.1 – In addition to this Standard, the following clarification applies:

The most recent BORN dashboard data submitted by the premises must be made available to the assessor for review (as requested).

If a center has chosen not to submit all patient data to BORN, it is expected the center provides complete data on all patients at a similar standard and detail as BORN for review by the CPSO assessor.

8.1 Monitoring Quality of Care

The purpose of monitoring activity is to identify problems and frequency, assess severity, and develop remedial action as required to prevent or mitigate harm from adverse events.

Monitoring OHP Activity

The OHP must have a documented process in place to regularly monitor the quality of care provided to patients. These activities include, but are not limited to, the following:

1) Review of non-medical staff performance

2) Review of individual physician care to assess
   a) patient and procedure selection are appropriate
   b) patient outcomes are appropriate
   c) adverse events (see 8.2)

The suggested protocol is, annually, random selection of 5-10 patient records to review:

i) record completion and documentation of informed consent

ii) percentage and type of procedures

iii) appropriate patient selection

iv) appropriate patient procedure

v) where required, reporting results in a timely fashion

vi) evaluation of complications (see 8.2)

vii) assessment of transfer to hospital, where required

viii) follow up of abnormal pathology and laboratory results

3) Review a selection of individual patient records to assess completeness and accuracy of entries by all staff

4) Review of activity related to cleaning, sterilization, maintenance, and storage of equipment

5) Documentation of the numbers of procedures performed: any significant increase/decrease (>50% of the last reported assessment).
Additional Requirements – Quality Assurance (QA)

1. Monitoring OHP Laboratory Activity
   1) Embryology Laboratory quality monitoring
   2) Andrology Laboratory quality monitoring
      a) IVF andrology services
      b) IUI andrology services
   3) Biochemistry Laboratory quality monitoring (if applicable)
   4) Documentation of lab errors and near misses
   5) Documentation of the numbers and types of laboratory procedures performed: including any significant increase/decrease

2. Quality Advisor Laboratory Activities
   Premises shall appoint a Quality Advisor for laboratory activities. The Laboratory Quality Advisor shall report to the Medical Director on a regular basis of no less than every 3 months and provide an annual report in writing. The annual report on quality review should include a summary of standard outcome measures tracked as per the BORN database, and all Tier 1 and 2 adverse events as defined by the CPSO.

3. Outcomes

   The recording, analysis and reporting of essential outcome measures is a reflection of the center’s commitment to providing quality patient care. The process provides road signs and future direction for improvement within the center.

   A) Monitoring Clinic Referral Pre-Screening (Barriers to Access/Gatekeeping)
      The Medical Director shall review and document:
      • Patient criteria for acceptance for consultation
      • Wait times/waiting lists for first appointments at the premises as well as for first cycles for each of OI, IUI, IVF treatments
      • Any referral for treatment rejections and the reasons for rejection

   B) Patient Population Monitoring
      The following shall be documented on an annual basis for all patients seen in the clinic:
      • Age
      • LHIN of residence
      • Primary diagnoses/reason(s) for treatment

   C) Intrauterine Insemination (IUI)
      • The most recent Better Outcomes Registry and Network (BORN) dashboard data submitted by the premises must be made available to the assessor for review (as requested). Premises should visit the BORN website for further information: https://www.bornontario.ca/

   D) Fertility Preservation
      • The most recent Better Outcomes Registry and Network (BORN) dashboard data submitted by the premises must be made available to the assessor for review (as requested). Premises should visit the BORN website for further information: https://www.bornontario.ca/
E) In Vitro Fertilization (IVF)

- The most recent Better Outcomes Registry and Network (BORN) dashboard data submitted by the premises must be made available to the assessor for review (as requested). Premises should visit the BORN website for further information: https://www.bornontario.ca/
PART II: OVULATION INDUCTION/INTRACERVICIAL INSEMINATION/INTRAUTERINE INSEMINATION (OI/ICI/IUI) UNITS

NOTE: Within each Part of this document, the content is further organized as follows:

a) specific sections of the core OHPIP Standards have been clarified in how they uniquely apply to fertility services premises – as such, the numbered sub-sections mirror the numbering in the core OHPIP Standards.

b) additional requirements with which premises must comply.

This Guide should be considered a required companion document to the core OHPIP Standards for practitioners. Premises must also comply where appropriate with all other requirements listed in the core OHPIP Standards.
2.2.6 – Policies and Procedures

2.2.6.1.1 Administrative

Guidance to the Standard

d) overnight stays - does not apply.

2.2.6 OHP Policies and Procedures

1. The Medical Director is responsible for the regular review, update, and implementation of OHP policies and procedures, which must address the following areas:

2.2.6.1 Administrative:

a) responsibility for developing and maintaining the policy and procedure manual
b) organizational chart
c) scope and limitations of OHP services provided
d) overnight stays, if applicable.

e) ensuring that records are kept for each RHP working in the OHP are current and include qualifications, relevant experience, and relevant hospital privileges as appropriate to the RHP.

f) ensuring all physicians performing OHP procedures at the premises have provided online notification to satisfy the regulation requirements (see section 2.2.1), and documentation verifying approval (emails from College staff) is on file.
Additional Requirements – OHP Policies and Procedures

Policies and Procedures (P&P) Manuals for Clinical Subsections

The Medical Director shall ensure that there are separate policies and procedures documented for each of the clinic subsections (as applicable):

1) Physician
2) Nursing
3) Ultrasound Services (If IHF Ultrasound licence in the premises– Manual related to ultrasound IHF is acceptable)
4) Biochemistry Laboratory
5) Andrology Laboratory (Including IUI procedures and diagnostic testing)
6) Information Technology (IT) (to include, but not limited to, EMR services, Data Protection and Privacy, Equipment Maintenance)
7) Housekeeping and Reprocessing
8) Administrative
9) Accounting and Financial Services
10) Human Resources
11) Research (basic and/or clinical)
12) Counselling
13) Ethics (including ethics committee if applicable)
14) Quality Assurance
### 4.1 – General Physical Standards

**Guidance to the Standard**

Layout, Standard 4.1.5.2 - The following clarifications apply:

- b) procedure room
- c) Does not apply
- d) Does not apply
- e) Does not apply
- f) dirty or clean processing room
- g) Does not apply
- h) staff room

<table>
<thead>
<tr>
<th>4.1 General Physical Standards</th>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1 Building Codes</strong></td>
<td>OHP site complies with all applicable building codes including fire safety requirements.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| **2 Electrical**              | 1. All electrical devices are certified by CSA or licensed for use in Canada.  
                                | 2. Emergency power supply can provide for safely completing the procedure and recovering the patient. |
| **3 Access**                  | 1. Access for persons with disabilities complies with provincial legislation and municipal bylaws.  
                                | 2. Doors and corridors can safely accommodate stretchers and wheelchairs. |
| **4 Size**                    | OHP size is adequate for all procedures to be performed. |
| **5 Layout**                  | 1. Layout facilitates safe patient care and patient flow.  
                                | 2. These areas are functionally separate:  
                                | a) administration and patient-waiting area  
                                | b) procedure room and/or operating room  
                                | c) recovery area  
                                | d) clean utility area  
                                | e) dirty utility room  
                                | f) reprocessing room  
                                | g) endoscope cabinet  
                                | h) staff change room and staff room. |
| **6 Emergency Measures**      | Provisions are in place to ensure  
                                | 1. The safe evacuation of patients and staff in case of an emergency, i.e., stretchers, wheelchairs, or other adequate methods of transport are available, and  
                                | 2. There is appropriate access to the patient for an ambulance to transfer the patient to a hospital. |
4.2 Procedure Room/Operating Room Physical Standards

Clarification of the Standard

Physical Requirements, Standard 4.2.1.1 is clarified as follows:

c) immediate access to hand-washing or hand hygiene facilities and proper towel disposal

Ventilation, Standard 4.2.2 – The following clarification applies:

2 and 3 – do not apply.

Equipment, Standard 4.2.3 - The following clarifications apply:

2 d) - does not apply
3 b) and c) – do not apply
3 e) table/chair that permits gynecological access
3 f) table/chair/stretcher that accommodates procedures performed and provides for adequate range of movement for procedures
3 g) – does not apply

<table>
<thead>
<tr>
<th>1 Physical Requirements</th>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. All OHP levels provide:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a) lighting as required for the specific procedure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) floors, walls and ceilings that can be cleaned to meet infection control requirements</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c) immediate access to hand-washing facilities and proper towel disposal</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d) openings to the outside effectively protected against the entrance of insects or animals by self-closing doors, closed windows, screening, controlled air current or other effective means</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

2. Space can accommodate equipment and staff required for the procedure.
3. Space allows the physician and assisting staff, when sterile, to move around the OR/procedure table with access to both sides of the patient, without contamination.

<table>
<thead>
<tr>
<th>2 Ventilation</th>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Ventilation must ensure patient and staff comfort; and fulfill occupational health and safety requirements.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Where applicable, ventilation and air circulation should be augmented to meet manufacturer’s standards and address procedure-related air-quality issues; e.g., cautery smoke, endoscopy, disinfecting agents (e.g., Glutacide venting is separate from the other internal ventilation).</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Where gas sterilization is used, a positive pressure outbound system is used, vented directly to the outside.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3 Equipment</th>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Medical equipment must be maintained and inspected yearly by a qualified biomedical technician.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Related documentation for all equipment is available:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a) equipment operating manuals</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) equipment maintenance contracts with an independent and certified biomedical technician</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c) log for maintenance of all medical devices</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d) Equipment necessary for emergency situations (i.e. Defibrillators, oxygen supply, suction) should be inspected on a weekly basis and documented.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. The following equipment is provided:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a) cleaning equipment as required for the specific procedure</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>b) accessible anesthetic material and equipment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c) blood pressure and oxygen saturation monitoring equipment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d) sterile supplies and instruments</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>e) table/chair that permits patient restraints and Trendelenberg positioning (level 2 &amp; 3)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>f) table/chair/stretcher that accommodates procedures performed and provides for adequate range of movement for anesthetic procedures</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>g) suction equipment and backup suction, for anesthesia provider’s exclusive use.</td>
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<td></td>
</tr>
</tbody>
</table>
4.2 Procedure Room/Operating Room Physical Standards (continued)

4.2.4 – Does not apply.

4.3 Recovery-Area Physical Standards

Guidance to the Standard

This Standard does not apply.

<table>
<thead>
<tr>
<th>4 Anesthetic and Ancillary Equipment</th>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Both a) anesthetic and ancillary equipment (selection, installation, maintenance) and b) medical compressed gases and pipelines must comply with:</td>
<td>NA</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>• Canadian Standards Association (CSA) or licensed for use in Canada, and</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Specific applicable recommendations arising from provincial legislation or as identified in other CPSO requirements</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. A second supply of (full cylinder) oxygen capable of delivering a regulated flow must be present.</td>
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<td></td>
</tr>
<tr>
<td>3. Level 3 OHP provides:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• a) anesthetic machine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• b) anesthetic equipment/drug cart.</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

4.3 Recovery-Area Physical Standards

Table 05: Recovery-Area Physical Standards

<table>
<thead>
<tr>
<th>1 Physical Requirements</th>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. A sink for hand washing is accessible.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2 Size and Layout</th>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The size of the recovery area depends on planned use: it must accommodate the volume of patients expected for a minimum of two hours operating room time, i.e.,</td>
<td>NA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 1 hour procedure = 2 patients</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 0.5 hour procedure = 4 patients.</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>2. The recovery area allows for transfer of patients to/from a stretcher and performance of emergency procedures.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3 Equipment</th>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monitoring, suction, oxygen, and bag-valve mask devices, intravenous and other medical supplies are immediately available.</td>
<td>NA</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
4.4 General Medication Standards

Guidance to the Standard

Standard 4.4.2 - Does not apply.

4.5 Controlled Substances Standards

Guidance to the Standard

This Standard (not shown) does not apply.

4.6 Drugs for Resuscitation

Guidance to the Standard:

This Standard (not shown) does not apply.

4.7 Monitoring and Resuscitation Requirements

Guidance to the Standard:

This Standard (not shown) does not apply.

1. OHPs should:
   a) maintain a general medication inventory record
   b) periodically inspect all medications for viability
   c) date multidose vials of medication on opening and dispose according to manufacturer’s guidelines
   d) label medications in accordance with the Food and Drug Act (FDA) and the Controlled Drugs and Substances Act (CDSA) and its regulations
   e) store medications:
      i) according to the manufacturer’s recommendations (e.g., refrigeration if required)
      ii) in a manner suitable for security and restocking
   f) store emergency drugs in a common location. In facilities where procedures are done in multiple procedure rooms, a crash cart is advisable
   g) document administration of medications in the patient record
   h) dispense medications at discharge accompanied by verbal and written instructions that are given to the patient and/or accompanying adult
   i) make available resources to determine appropriate drug dosages and usage.

2. If services are provided to infants and children, the required drugs must be available and appropriate for that population.
5.6 – Nurse Qualifications

Guidance to the Standard

Standard 5.6.1 - The following clarifications apply:

b) additional training and appropriate experience as required for procedures performed including assisting with IUI procedures, counselling and supporting patients receiving treatments, performing delegated medical acts (if appropriate, e.g., IUI), caring for patients receiving sedation, patient teaching, recognition and treatment of complications e.g., OHSS and documentation of all interactions with patients. Written policies for all procedures should be available in each clinic.

d) Does not apply

Standard 5.6.2 – Does not apply.

5.6 Nurse Qualifications

1. Registered nurses (RNs) and registered practical nurses (RPNs) working within their scope of practice in OHPs must hold:
   a) current registration with the College of Nurses of Ontario
   b) additional training and appropriate experience as required for procedures performed
   c) current BLS certification
   d) must have current ACLS if administering sedation to, monitoring or recovering patients (RNs only).

2. Registered Nurses (RNs) working with a pediatric population (14 years and younger), who are involved in monitoring, administering sedation or recovering patients must maintain a current PALS certification.

Additional Requirements – OHP Staff Qualifications for Lab Personnel

Some larger Assisted Reproductive Technology (ART) programmes, or specialized IUI/donor sperm programmes, have dedicated ART Andrology Laboratory staff members who do not have embryology responsibilities.

- additional training and appropriate experience as required for sperm sample assessment and preparation for IUI consistent with the clinic’s standard operating procedures.
6.1 Pre-Procedural Patient Care Standards

Guidance to the Standard:
Standard 6.1.1 - The following clarification applies:
   I. appraise each patient’s medical risk factors and capacity to undergo anticipated procedure.

6.3 Pre-Procedural Requirements

Guidance to the Standard:
Standard 6.3 – “The physician providing anesthesia assigns an ASA classification...” (first paragraph) does not apply.

Standard 6.3.1 – “ASA classification” is replaced by “consent for procedure”.

Also, the following clarifications apply:

4) Does not apply
5) a review and ordering of tests as indicated (such as infectious diseases)
6.4 Verification Process

Guidance to the Standard

Standard 6.4.1 - The following clarification applies:

Procedures Included

Sperm preparation require verification process.

This requires verification of the correct patient, partner and/or sperm sample, which includes, partner’s demographics and/or donor ID/number at two different times and locations, as follows:

<table>
<thead>
<tr>
<th>When</th>
<th>Where</th>
</tr>
</thead>
<tbody>
<tr>
<td>First verification</td>
<td>before entering the procedure room</td>
</tr>
<tr>
<td></td>
<td>the pre-procedure area</td>
</tr>
<tr>
<td>Second verification</td>
<td>during the time-out</td>
</tr>
<tr>
<td></td>
<td>in the procedure room</td>
</tr>
</tbody>
</table>

First verification takes place in the pre-procedure area.

Second verification during the time-out in the procedure room.

Note: Procedures exempted from site marking still require a verification process.

6.5 First Verification

Guidance to the Standard

Standard 6.5.3 - The following clarifications apply:

The nurse or physician preparing the patient for the procedure confirms the patient identity, and procedure.

b) Does not apply.

6.4 Verification Process

The verification process (prevention of wrong site, wrong procedure, or wrong patient) ensures that the correct patient has the correct procedure performed on the correct site.

NOTE: If the patient is unable to verify the information him/herself (e.g., minor, incompetent), the legal guardian/substitute decision maker provides and verifies the appropriate information.

1. Procedures Included

Procedures with any of the following components require a verification process; a) intravenous sedation; b) surgical incision (of any size); c) removal of tissue; d) primary procedure is itself an injection of any kind. This requires verification of the correct patient, procedure, and correct site at two different times and locations, as follows:

<table>
<thead>
<tr>
<th>When</th>
<th>Where</th>
</tr>
</thead>
<tbody>
<tr>
<td>First verification</td>
<td>before entering the procedure room/</td>
</tr>
<tr>
<td></td>
<td>operating room</td>
</tr>
<tr>
<td></td>
<td>the pre-procedure area</td>
</tr>
<tr>
<td>Second verification</td>
<td>during the time-out</td>
</tr>
<tr>
<td></td>
<td>in the procedure room</td>
</tr>
</tbody>
</table>

Note: Procedures exempted from site marking still require a verification process.
6.6 Second Verification

Guidance to the Standard

The following clarifications apply:

2. Does not apply.

3. The entire procedure team confirms the patient identity, procedure, consent and specimens according to their standard operating procedures.

The following additions apply:

4. The physician performing an insemination must verify the patient prior to the transfer.

There should be a standard operating procedure for identity verification of the sperm sample for all procedures.

6.7 Site Marking

This Standard does not apply.

6.8 Intra-Procedure Care for Sedation, Regional Anesthesia, or General Anesthesia

This Standard (not shown) does not apply.

6.9 Post-Procedure Patient Care

This Standard (not shown) does not apply.
6.10 Patient Discharge/Post Procedure Care

Guidance to the Standard

In place of items 1 to 4, the following applies:

Appropriate post-procedure instructions are given to the patient. Such as any side effects of the procedure or medication.

6.10 Patient Discharge
For OHP levels 2 and 3:

1. An anesthesiologist or physician is responsible for writing the discharge order. However, the actual decision for discharge from the recovery area must be based on discharge criteria using an objective scoring system; the decision can be delegated to recovery-area staff.

2. All patients should be accompanied by an adult when leaving the OHP. Patients having received sedation or general anesthesia must be accompanied by a responsible adult.

3. Appropriate verbal and written post-discharge instructions are given to the patient and the accompanying adult.

4. The patient and accompanying adult are instructed to notify the OHP of any unexpected admission to a hospital within 10 days of the procedure.

Additional Requirements – Procedure Standards for Gonadotrophin Stimulation for Ovulation Induction

The physician prescribing gonadotrophins should have the appropriate training and/or experience, including a plan to deal with potential complications inherent to the use of gonadotrophins, including an established relationship with an IVF centre (see Physician Qualifications section in core OHPIP Standards).
7 – Infection Control

Guidance to the Standard

In addition to the Standard, the following clarification applies:

Facilities offering Assisted Reproductive Technology (ART) laboratory services may use soap and water as an alternative for hand hygiene.

7 Infection Control

The CPSO, in partnership with Public Health Ontario (PHO), have developed accepted standards of practice for OHPs and physician offices for infection control. The document can be found at the following link: www.publichealthontario.ca/ClinicalPractice

Medical Directors should consult the specific section of the PHO website for the following information, which form part of the OHP standards expectations. Medical Directors are responsible to ensure periodic reviews of the CPSO and PHO website documents to stay current with standards for infection prevention and control, and ensure compliance with these recommendations.

OHPs shall adhere to the following:

1) Accepted standard(s) of infection control practices that are pertinent to the specific procedures performed at the OHP.

2) The Routine Practice approach to infection control. According to the concept of Routine Practices, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV and other blood borne pathogens.

3) Actions that minimize risk of infection in the operating room:
   a) adherence to proper use of disinfectants
   b) proper maintenance of medical equipment that uses water (e.g., automated endoscope reprocessors)
   c) proper ventilation standards for specialized care environments (i.e., airborne infection isolation, protective environment, and operating rooms)
   d) prompt management of water intrusion into OHP structural elements.

4) Accepted standards of handling regulated waste. “Regulated Waste” means:
   a) liquid or semi-liquid or other potential infectious material
   b) contaminated items that would release blood or other potential infectious materials in a liquid or semi-liquid state are compressed
   c) items that contain dried blood or other potential infectious materials and are capable of releasing these materials during handling
   d) contaminated sharps
   e) pathological and microbiological wastes containing blood or other potentially infectious materials.
8.1 – Monitoring Quality of Care

Guidance to the Standard

Standard 8.1.2 - The following clarification applies:

Review of individual physician care

Standard 8.1.2 - The following addition applies:

d) Review a selection of individual patient records (OI/ICI/IUI) to assess completeness and accuracy of entries by all staff

Standard 8.1.5 - The following clarification applies:

Documentation of the numbers of procedures performed: any significant increase/decrease

8.1 Monitoring Quality of Care

The purpose of monitoring activity is to identify problems and frequency, assess severity, and develop remedial action as required to prevent or mitigate harm from adverse events.

Monitoring OHP Activity

The OHP must have a documented process in place to regularly monitor the quality of care provided to patients. These activities include, but are not limited to, the following:

1) Review of non-medical staff performance
2) Review of individual physician care to assess
   a) patient and procedure selection are appropriate
   b) patient outcomes are appropriate
   c) adverse events (see 8.2)
3) Review a selection of individual patient records to assess completeness and accuracy of entries by all staff
4) Review of activity related to cleaning, sterilization, maintenance, and storage of equipment
5) Documentation of the numbers of procedures performed: any significant increase/decrease (>50% of the last reported assessment).
Additional Requirements – Quality Assurance

In situations where an OI/ICI/IUI center provides its own laboratory services as part of the OI/ICI/IUI treatment, the center is expected to provide evidence of quality monitoring as follows:

1. Monitoring OHP Laboratory Activity (if applicable)

   1) Andrology Laboratory quality monitoring
   3) Biochemistry Laboratory quality monitoring
   4) Documentation of lab errors and near misses
   5) Documentation of the numbers and types of laboratory procedures performed: including any significant increase/decrease

2. Quality Control

   The most recent BORN dashboard data submitted by the premises must be made available to the assessor for review (as requested).

   If a center has chosen not to submit all patient data to BORN, it is expected the center provides complete data on all patients at a similar standard and detail as BORN for review by the CPSO assessor.