Guide to Applying the Out-of-Hospital Standards in Intervenotional Pain Premises

College of Physicians and Surgeons of Ontario

Approved by the Premises Inspection Committee
July 7, 2011
College of Physicians and Surgeons of Ontario Mandate

Build and maintain an effective system of self-governance.

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 new vision is the framework by which we organize ourselves. It guides our thinking and actions into the future. It defines not only who we are, but what we stand for, the role we see for ourselves, our critical relationships, in what system we work, and the outcomes we seek. Each component of our vision is defined below:

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. We are committed to developing and maintaining professional competencies, taking a leadership position on critical issues that impact the performance of the system, and actively partner to provide tools, resources, measurement, to ensure the optimal performance at all levels of the system.

Healthy System – the trust and confidence of the public and our effectiveness as professionals is influenced by the system within which we operate. Therefore, we as caring professionals are actively involved in the design and function of an effective system including:

- accessibility
- the interdependence of all involved
- measurements and outcomes
- continued sustainability.

Public Trust – as individual doctors garner the trust of their patients, as a profession we must aim to have the trust of the public by:

- building positive relationships with individuals
- acting in the interests of patients and communities
- advocating for our patients and a quality system.
Our Guiding Principles – Integrity, accountability, leadership and cooperation

The public, through legislation, has empowered the profession to regulate itself through the College. Central to the practice of medicine is the physician-patient relationship and the support of healthy communities. As the physician has responsibility to the patient, the profession has the responsibility to serve the public through the health-care system. To fulfill our vision of quality professionals, healthy system, public trust we will work to enhance the health of the public guided by professional competence and the following principles:

Integrity – in what we do and how we go about fulfilling our core mandate:

• Coherent alignment of goals, behaviours and outcomes
• Steadfast adherence to a high ethical standard.

Accountability to the public and profession – we will achieve this through:

• An attitude of service
• Accepting responsibility
• Transparency of process
• Dedicated to improvement.

Leadership – leading by proactively regulating our profession, managing risk and serving the public.

Cooperation – seeking out and working with our partners – other health-care institutions, associations and medical schools, etc. – to ensure collaborative commitment, focus and shared 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.

Members of the Out-of-Hospital Premises Standards Pilot Task Force

<table>
<thead>
<tr>
<th>Dr. Jacques Abourbih</th>
<th>Dr. Hugh Kendall</th>
<th>Ms. Sandra Robinson</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. Scott Barr</td>
<td>Ms. Judy Knighton</td>
<td>Dr. Frank Lista</td>
</tr>
<tr>
<td>Dr. Michael Gould</td>
<td>Dr. Matt Kurrek</td>
<td>Dr. Patricia Teal</td>
</tr>
</tbody>
</table>

Contact Information

Published and distributed by the College of Physicians and Surgeons of Ontario. For more information about the Out-of-Hospital Premises Inspection Program, contact:

Wade Hillier
Associate Director, Practice Assessment and Enhancement
College of Physicians and Surgeons of Ontario
80 College Street, Toronto, ON M5G 2E2

Toll free: 800-268-7096 ext. 636
416-967-2636
whillier@cpso.on.ca
Background:

The **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 9th, 2010.

The Regulation is appended in the OHP Standards and can also be found on the College website [www.cpso.on.ca](http://www.cpso.on.ca). For interventional pain OHPs specifically, the Regulation states the following definition of ‘procedure’:

\[(b)\text{ any act that, when performed in accordance with the accepted standard of practice on a patient, is performed with the administration of a local anaesthetic agent, including, but without being limited to, (iv) a nerve block solely for the treatment or management of chronic pain.}\]

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. An external review of the core OHP Standards identified opportunities to provide more practice specific information about the Standards and how they will be applied for the purpose of an inspection-assessment. To meet this opportunity, in 2010 the College engaged a working group consisting of a cross-section of interventional pain practitioners (including academic and community-based physicians) to provide guidance about the application of the core OHP Standards in this specialty setting.

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.
The Purpose of this Document:

This document was developed to help interventional pain practitioners plan for and participate in their inspection-assessments. It in no way replaces the core OHP 2010 Standards; rather, it helps the practitioner understand how the OHP Standards will be applied in their interventional pain practice. This Guide should be considered a required companion document to the OHP Standards for interventional pain practitioners as only those Standards requiring guidance are included. The core OHP Standards are available at www.cpso.on.ca>cpso members>out of hospital premises inspection program.

Please note, the use of sedation as defined in the OHP Standards for interventional pain procedures in OHPs is not considered the standard of practice by the Interventional Pain Working Group. Therefore the guidance in applying the OHP Standards in these premises is based on this safer patient practice. Any interventional pain procedure using/requiring sedation regardless of the procedure will fall under a Level 2 OHP and all of the associated, relevant OHP Standards must be applied.

Acknowledgements:

The College thanks the members of the Interventional Pain Working Group for their contributions:

Dr. Steve Bodley  Dr. Norm Buckley  Dr. Chris Giorshev
Dr. Howard Jacobs  Dr. Dwight Moulin  Dr. Kevin Rod
Dr. Eddie Wasser

Acronyms:

Note: Procedure/OR = Procedure room and/or operating room

ACLS  -Advanced Cardiac Life Support
AED  -automated external defibrillator
ASA  -American Society of Anesthesiologists
BLS  -Basic Life Support
CFPC  -College of Family Physicians of Canada
CNS  -central nervous system
CPSO  -College of Physicians and Surgeons of Ontario
CSA  -Canadian Standards Association
ECG  -electrocardiogram
MHAUS  -Malignant Hyperthermia Association of the United States
MRP  -most responsible physician
OHP  -Out-of-Hospital Premises
OHPIP  -Out-of-Hospital Premises Inspection Program
OR  - Operating Room
PALS  -Paediatric Advanced Life Support
QA  -Quality Assurance
RCPS  -Royal College of Physicians and Surgeons of Canada
RHP  -Regulated Health Professional
RHPA  -Regulated Health Professions Act
RN  -Registered Nurse
RPN  -Registered Practical Nurse
SVT  -supraventricular tachycardia

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3.1 OHP Levels, Page 8

Guidance to the Standard

The following procedures are suitable to be safely performed in a level 1 OHP include:

- Auriculotemporal nerve block
- Ilioinguinal/iliohypogastric/genitofemoral nerve blocks
- Infraorbital nerve block
- Median nerve blocks
- Mental nerve blocks
- Occipital nerve blocks
- Sacroiliac joint injection
- Spinal accessory nerve block
- Supraorbital nerve block
- Suprascapular nerve blocks
- Transcapular nerve block
- Zygomatic temporal nerve block

The following procedures are suitable to be safely performed in a level 2 OHP include:

- Brachial plexus blocks
- Caudal blocks
- Epidural blocks
- Femoral nerve block
- Intercostal nerve blocks
- Ketamine infusions
- Lidocaine infusions
- Lumbar sympathetic block
- Maxillary and Mandibular nerve blocks
- Paravertebral nerve blocks
- Pudendal blocks
- Sciatic nerve block
- Stellate ganglion block

Table 01: OHP Levels

<table>
<thead>
<tr>
<th>OHP Level</th>
<th>Anesthesia</th>
<th>Procedure</th>
</tr>
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<tbody>
<tr>
<td>OHP Level 1</td>
<td>Local – Infiltration</td>
<td>Minimal Invasive: No surgical wound is created (e.g., endoscopic procedures [with and without biopsy], polypectomy), and Procedure does not interfere with target organ function or general physiological function.</td>
</tr>
<tr>
<td>OHP Level 2</td>
<td>Sedation</td>
<td>Limited Invasive: Surgical wound is created, but not for the purpose of penetration of a body cavity or viscera (e.g., rhinoplasty, facelift), and Procedure has minimal impact on target organ or general physiological response.</td>
</tr>
<tr>
<td>OHP Level 3</td>
<td>General anesthesia</td>
<td>Significant Invasive: Surgical wound allows access to a body cavity or viscera (e.g., laparoscopic bleeding surgery, arthroscopy), OR; A significant amount of aspirate (e.g., 1000-4000 cc/gm) is removed (e.g., liposuction), OR; A prosthesis is inserted (e.g., augmentation mammoplasty).</td>
</tr>
</tbody>
</table>

Note: It is expected that any one procedure incorporating multiple blocks on any one patient will be performed within the accepted standard of practice.
4.2 Procedure Room/Operating Room Physical Standards, Pages 15-16

Guidance to the Standard

Physical Requirements, Standards 4.2.1.3 and 4.2.1.4 – are applicable to those interventional pain procedures where the standard of care requires they are performed in a sterile field.

Guidance to the Standard

Ventilation, Standard 4.4.2. – Standard 4.2.3 does not apply to interventional pain OHPs unless it is used.

Guidance to the Standard

Equipment, Standards 4.2.3 – items d), f), g) are not applicable.

e) If packs are used they must be sterile.

h) Suction equipment must be available on the premises.
Guidance to the Standard

Anesthetic and Ancillary equipment, Standard 4.2.4.1 and 4.2.4.2 – Medical gases used in interventional pain OHPs can be made available in tank form, in which case a back-up tank must be available. Tanks must be appropriately maintained, and maintenance documented as per the OHP Standards.

4.3 Recovery-Area Physical Standards, Page 16

Guidance to the Standard

Recovery-Area Physical Standards, Size and Layout: Standard 4.3.2 – does not apply. A specific room for patient recovery is not required for interventional pain OHPs.
4.4.3.1 Equipment for Monitoring and Resuscitation, Page 18

Guidance to the Standard

Equipment for Monitoring and Resuscitation, Standard 4.4.3.1 – Laryngeal mask airways or other types of back-up airway devices are required. A torso backboard is required.

4.4.3.2 Drugs for Resuscitation, Page 18

Guidance to the Standard

Drugs for Resuscitation, Standard 4.4.3.2 – Though some premises may indicate a need for the following drugs, they are not required in interventional pain premises:

- Antihypertensive IV
- BETA Blocker IV
- Calcium IV
- Flumazenil IV
- IV agent for SVT
- Morphine IV
- Naloxone IV
- Neuromuscular blocking agents
- Sodium bicarbonate IV

Note: If Morphine IV is stocked then Naloxone IV must be as well.
6.1.2 Pre-Procedure Requirements, Page 23

Guidance to the Standard

In a level 1 or 2 interventional pain OHP where sedation is not performed, the following Pre-Procedure Standards are applied:

- **6.1.2.1**

- **6.1.2.4** – documentation should be pertinent to the patient and the procedure as per the standard care.

- **6.1.2.6** and **6.1.2.8** – a rolling patient consent is suitable for the same procedure performed consecutively and should be documented as per the Standards in the patient chart.
6.1.3 Verification Process, Pages 24-26

Guidance to the Standard

Verification Process, Standard 6.1.3 – Minimal verification is required in interventional pain OHPs and should include verifying the patient, the procedure, and ensuring the patient chart corresponds to the patient.

<table>
<thead>
<tr>
<th>6.1.3 Verification Process</th>
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<tbody>
<tr>
<td>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.</td>
</tr>
<tr>
<td>NOTE: If the patient is unable to verify the information himself/herself (e.g., minor, incompetent), the legal guardian/alternate decision maker provides and verifies the appropriate information.</td>
</tr>
</tbody>
</table>

1. Procedures Included

All procedures that expose patients to more than minimal risk require verification of the correct patient, correct procedure, and correct site at two different times and locations, as follows:

<table>
<thead>
<tr>
<th>First verification</th>
<th>Where</th>
</tr>
</thead>
<tbody>
<tr>
<td>before entering the procedure room/</td>
<td>the pre-procedure area</td>
</tr>
<tr>
<td>OR</td>
<td></td>
</tr>
</tbody>
</table>

2. Procedures Excluded

2.1 Some procedures are outside the scope of this verification process, e.g., peripheral IV line placement, venipuncture, insertion of NG tube, or Foley catheter insertion.

2.2 Any procedures prior to the site marking (e.g., shaving) require confirmation of the patient identity, procedure, site and/or side with the patient/alternate decision maker.

Note: Procedures exempted from site marking still require a verification process.
6.2 Intra-Procedure Patient Care for Sedation, Regional Anesthesia or General Anesthesia, Page 27

Guidance to the Standard

Standard 6.2.1 – Interventional pain OHPs require physicians administering the anesthetic to have a current ACLS certificate. A second person is required on the premises that is a Regulated Health Professional (as per the Standard) who has a current BLS certificate. It is not necessary for the second person to be involved in the procedure but should be available for patient safety and emergency response.

Standard 6.2.2 – The patient should be appropriately attended by the physician, or second individual that is a Regulated Health Professional as defined above, from the beginning until the time they leave the premises.

Standard 6.2.3 – If clinically indicated, patient monitoring should include (i) O₂ saturation, (ii) blood pressure and (iii) pulse.

Standard 6.2.4 – This Standard does not apply to interventional pain OHPs.

Note: IV access should be established where clinically indicated, e.g., central neuraxial procedures, sympathetic blocks such as lumbar or stellate, and major plexus blockades.
6.3 Post-Procedure Patient Care for Sedation, Regional Anesthesia or General Anesthetic, Page 27

Guidance to the Standard:

This section does not apply to interventional pain OHPs.

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6.3 Post-Procedure Patient Care

1. Recovery area focus and staff requirements are as shown in Table 09. Depending on the invasiveness of the procedure and the level of anesthesia, the staffing requirements may be modified at the discretion of the most responsible physician as appropriate. This must ensure the safe recovery and discharge of the patients.

<table>
<thead>
<tr>
<th>Recovery Phase</th>
<th>OHP Level 1</th>
<th>OHP Level 2</th>
<th>OHP Level 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>NA</td>
<td>Staff required:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>* One RN in the same room at all times with the patient</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>* A second RN or RN available on site</td>
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</tbody>
</table>

2. Following sedation/regional anesthesia/general anesthesia, the anesthesiologist/physician must accompany the patient to the recovery area and communicate the appropriate information to the appropriate recovery area staff. This verbal report includes, but is not limited to:
   a) name and age of patient
   b) procedure performed
   c) pertinent history including allergies, medical/physical limitations
   d) type of anesthesia/sedation used
   e) other medications given
   f) any unusual or adverse events pertaining to patient
   g) estimated fluid or blood loss
   h) anesthetic course

3. The anesthesiologist/physician should stay with the patient until the appropriate recovery area staff accept responsibility for the patient.
6.4 Patient Discharge, Page 29

Guidance to the Standard:

Standards 6.4.1 and 2 – do not apply in interventional pain OHPs.

Standard 6.4.3 – for interventional pain procedures where it is the standard of practice, appropriate verbal and written discharge instructions are given to the patient where clinically indicated.

Note: Level 2 interventional pain OHPs always require discharge instructions as per Standard 3.

8. Quality Assurance (QA), Page 32

Guidance to the Standard:

A quality assurance program should be developed and monitored regardless of whether the OHP is a solo or group practice.