

Independent Health Facilities

Clinical Practice Parameters and Facility Standards

Endoscopy



THE
COLLEGE
OF
PHYSICIANS
AND
SURGEONS
OF
ONTARIO

The College of Physicians and Surgeons of Ontario

Vision Statement

The best quality care for the people of Ontario by the doctors of Ontario.

Mission Statement

The College of Physicians and Surgeons of Ontario merits the trust and respect of the public and the profession by:

1. Maintaining a rigorous and efficient regulatory process,
2. Focusing on the ongoing improvement of quality,
3. Being open and accountable,
4. Communicating clearly and effectively,
5. Promoting excellence in health care,
6. Working with others to achieve our vision.

We demand of ourselves the same exacting standards that we expect of the profession.

Goals

The vision of Council will be implemented by:

1. Advocating for quality health care in partnership with other stakeholders,
2. Integrating the roles of clinical education, evidence-based clinical practice and regulatory responsibilities to improve patient care at the individual and system level,
3. Evaluating and improving the effectiveness and efficiency of the current investigative and disciplinary processes and identifying potential alternatives,
4. Accelerating efforts to find creative ways to address physician resource needs without compromising registration standards,
5. Providing publicly accessible regulatory information about physicians
6. Engaging stakeholders in a public debate about the limits of medicine and focusing on what patients can expect from their physicians,
7. Establishing a comprehensive and effective communication plan to improve recognition of the CPSO by its stakeholders,
8. Establishing an effective and transparent governance model for the College.

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**It is with much sadness we report Dr. John Bradley died suddenly on March 6, 2006. Dr. Bradley contributed significantly and with great enthusiasm to the work of the Endoscopy Task Force in the creation and final development of this first edition of the Clinical Practice Parameters and Facility Standards for Endoscopy*

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Preface

The Independent Health Facilities Act (IHFA), proclaimed in April 1990, amended in 1996 and 1998, gives the College of Physicians and Surgeons of Ontario the primary responsibility for carrying out quality assessments in Independent Health Facilities. These out-of-hospital facilities may provide some of the following insured services:

- in diagnostic facilities: radiology, ultrasound, magnetic resonance imaging, computed tomography, nuclear medicine, pulmonary function, and sleep studies
- in treatment or surgical facilities: one or more of a variety of procedures in peripheral vascular disease, plastic surgery, obstetrics and gynaecology, dermatology, nephrology, ophthalmology, and their related anaesthetic services and perhaps other specialties.

The College of Physicians and Surgeons of Ontario has a legislative mandate under the Act to perform quality assessment and inspection functions. This responsibility, and others set out by agreement with the Ministry of Health and Long-Term Care, contribute to the College achieving its goals as stated in the College's Mission Statement. An important goal of the College is to promote activities which will improve the level of quality of care by the majority of physicians. The Independent Health Facilities program helps reach this goal by developing and implementing explicit clinical practice parameters and facility standards for the delivery of medical services in Ontario, assessing the quality of care provided to patients, and as a result, promotes continuous quality improvement.

Purpose of Clinical Practice Parameters

The Independent Health Facilities clinical practice parameters and facility standards are designed to assist physicians in their clinical decision-making by providing a framework for assessing and treating clinical conditions commonly cared for by a variety of specialties. The primary purpose of this document is to assist physicians in developing their own quality management program and act as a guide for assessing the quality of patient care provided in the facilities.

Note: The parameters and standards are not intended to either replace a physician's clinical judgement or to establish a protocol for all patients with a particular condition. It is understood that some patients will not fit the clinical conditions contemplated by certain parameters and that a particular parameter will rarely be the only appropriate approach to a patient's condition.

In developing these clinical practice parameters, the objective is to create a range of appropriate options for given clinical situations, based on the available research data and the best professional consensus. The product, therefore, should not be thought of as being “cast in stone”, but rather subject to individual, clinically significant patient differences.

Role of the College of Physicians and Surgeons

At the beginning of this process, the College adopted the role of a facilitator for the development of clinical practice parameters and facility standards. Representatives of national specialty societies and sections of the Ontario Medical Association, and individuals with acknowledged skill, experience and expertise formed specialty-specific Task Forces.

The Task Force members’ initial work, distributed in March 1991, was sent to the following organizations for their review and comments:

- all relevant specialty physicians in Ontario, national specialty societies and specialty sections of the Ontario Medical Association
- Ontario Chapter of the College of Family Physicians of Canada
- Canadian Medical Association
- American Medical Association
- Canadian Council on Health Facilities Accreditation (now the Canadian Council on Health Services Accreditation)
- College of Nurses of Ontario

The Task Forces continue to adhere to the following principles:

- clinical practice parameters must be based on the appropriate mix of current, scientifically-reliable information from research literature, clinical experience and professional consensus.
- any parameter-setting exercise must be done exclusively from the quality perspective. That may well mean that some of the conclusions reached could add to medical care costs.
- parameters have to be flexible enough to allow for a range of appropriate options and need to take into account the variations in practice realities from urban to rural areas.
- parameters need to be developed by consensus and consultation with the profession at large.
- parameters should provide support and assistance to physicians without boxing them in with “cookbook formulas.”
- parameters will need to be regularly updated based on appropriate research studies.

- parameters should reduce uncertainty for physicians and improve their clinical decision-making.
- information on practice parameters must be widely distributed to ensure that all physicians benefit from this knowledge.

Responsibilities of the College

Responsibilities of the College include:

- assessing the quality of care when requested by the Ministry. The College will maintain a roster of physicians, nurses, technologists and others to serve as inspectors and assessors as required.
- inspecting the illegal charging of facility fees by unlicensed facilities when requested by the Ministry.
- monitoring service results in facilities. The College's information system will monitor individual and facility outcome performance. This is a unique feature of the legislation, which for the first time in North America, requires facility operators to establish and maintain a system to ensure the monitoring of the results of the service or services provided in a facility.
- providing education and assisting facilities so that they may continually improve the services they provide to patients. The College will work with and assist physicians in these facilities so that they can develop their own quality management programs based on the parameters and standards, monitor facility performance by conducting quality assessments, work with facilities to continually improve patient services, assist in resolving issues and conducting reassessments as necessary.

Updating this Document

These parameters and standards are subject to periodic review, and amendments in the form of replacement pages may be issued from time to time. Such pages will be mailed automatically to all relevant independent health facilities. It is planned to issue new editions of the parameters and standards at intervals not greater than five years. The external review process will be repeated to validate the new parameters as they are developed.

Radiology Guiding Principles

Extracted from the first edition (February 1995) of Clinical Practice Parameters and Facility Standards for Diagnostic Imaging, *Appendix I: Goals and Objectives.*

A diagnostic imaging practice is a consultative physician service rendered by qualified specialists who have completed an accredited residency program in diagnostic radiology which includes using all modalities in the imaging portrayal of human morphology and physiological principles in medical diagnosis.

The elements of radiologic consultation include:

- pre-examination evaluation by a referring physician.
- a request for radiologic consultation. The requisition includes pertinent clinical findings, a working diagnosis, and signature of referring physician or other qualified professional.
- a safe patient environment in which the radiologist supervises a qualified staff whose efforts are directed at producing a radiologic examination yielding maximum diagnostic information and consistent with the least possible exposure to radiation.

Diagnostic imaging is a patient care specialty and it is an important function of the radiologist to advise referring physicians about the best sequence of examinations for resolving a clinical problem expeditiously and with the least risk and cost.

It is not possible to establish a “minimum” or “optimum” standard of care. Guiding principles and attributes for appropriate care in diagnostic imaging can be summarized as follows.

- Examinations and procedures are performed with the greatest benefit and least risk to the patient.
- Examinations and procedures are interpreted with the highest degree of competence using all available information including comparison with previous examinations and procedures.
- Examination/procedure findings and conclusions are communicated promptly and expeditiously to the referring physician.
- Referring physicians are consulted in order to select and perform only the most useful examinations/procedures.
- Flow of data including storage, retrieval, and general handling of films and reports are managed efficiently.
- Patient services provided are considerate of the human side of care as well as the purely technical component of care.

- Patient services are managed so that productivity is maintained and optimal use of available resources is assured.

These principles should constitute the basis for the evaluation of desirable and undesirable practice patterns.

**Independent Health Facilities:
Clinical Practice Parameters
and Facility Standards:
Endsocopy**

Volume 1

Facility Standards

Chapter 1 Staffing a Facility

Overview

Different personnel including the Endoscopist will be required in an Endoscopy Facility depending on the type of endoscopy being performed and the sedation/anaesthesia being administered. Physicians required will include the Endoscopist and if required an Anaesthesiologist. Registered nurses will both assist in the procedures and with patient preparation and monitoring. Endoscopy Reprocessing Technicians are required for cleaning and decontamination of the endoscopes and ancillary equipment. An adequately trained nurse may perform this job.

Each procedure will require a procedure specific number of personnel to complete the procedure safely.

A recovery area will also need to be staffed by Registered Nurses.

Physician Qualifications

It is clear that physicians need not only to be qualified and competent to perform individual procedures, but also need appropriate qualification and competence to provide conscious sedation, or delegate this task to an appropriately qualified and competent colleague.

There may be situations where the training and qualifications necessary to function in a non-hospital environment may exceed those normally required for a hospital setting, where immediate back up is available.

Physicians with appropriate endoscopic training performing endoscopy in an independent health facility:

- Have certification from the Royal College of Physicians and Surgeons of Canada (RCPSC)

or

- Are family physicians with acceptable certification

or

- Have an equivalent certification from another country

and

- Must be licensed by the College of Physicians and Surgeons of Ontario.

Credentials and qualifications necessary to perform specific endoscopic procedures by each individual physician in a facility should be met, with specific reference to:

- Upper gastrointestinal endoscopy
- Colonoscopy including polypectomy
- Bronchoscopy
- Cystoscopy including ureteroscopy with instrumentation.

Appropriate training and competence is defined by one of the following:

- Completion of a residency program incorporating structured experience with competency documented by the instructor or training program.
- Equivalent post-graduate training incorporating structured experience with competency documented by the instructor or preceptor or training program.
- Hold current privileges to perform the procedure in an accredited hospital in Ontario.

Physicians Using Conscious Sedation

If conscious sedation is used in the performance of an endoscopic procedure, the physician should have an appropriate level of training in this field, acquired either during the training period, or separately in a structured experience, with competency documented by the instructor or preceptor.

A physician certified and current in ACLS or trained in general anaesthesia should be on site or available within five minutes. At least one of the IHF personnel currently certified in BCLS must be present on-site during the endoscopic procedure.

Note: If a physician performing the endoscopic procedure is not trained in mild or moderate conscious sedation, another physician qualified to do this task must be present.

In all cases involving deep sedation, a physician qualified to administer general anaesthesia should be present.

Anaesthesiology assistance is recommended in the following situations:

- Increased risk for complication due to severe medical co-morbidity (ASA III)
- Anticipated intolerance to standard sedatives, particularly if Propofol is considered.
- Increased risk for airway obstruction due to variant anatomy.

If the physician does not have hospital admitting privileges, prearranged emergency transfer agreements with a nearby hospital must be in place.

Continuing Medical Education

Physicians are expected to participate in relevant continuing medical education activities equivalent to those of other hospital -based physicians.

Physicians performing endoscopy in a non-hospital environment are expected to participate in the same quality assurance as would be expected in a hospital setting.

Quality Advisor

As outlined in the IHF Regulations “Every licensee shall appoint a Quality Advisor to advise the licensee with respect to the quality and standards of services provided in the independent health facility”.

Every Quality Advisor shall:

- be FRCP or FRCS qualified (or equivalent) with similar privileges for endoscopy in a hospital or whose training enables him/her to advise the licensee on matters pertaining to standards or quality of care.
- be appointed by the licensee to advise on issues of quality and standards of endoscopic care in the IHF
- seek advice from other health professionals where necessary to ensure that all aspects of the services provided through the IHF are provided in accordance with generally accepted professional standards.
- chair the Quality Advisory Committee at least semi-annually if the IHF has more than six full-time staff equivalents including the Quality Advisor, otherwise at least annually, and to document the substance of the discussion, the actions agreed upon and the completion date for any actions agreed upon.

The Quality Advisor shall advise the facility licensee and document this advice concerning the following:

- qualifications, selection and ongoing education of the professional and technical staff working in the independent health facility.
- whether adequate and appropriate staffing, equipment and procedures are available to ensure patient and staff safety in the independent health facility.
- testing being performed on a periodic basis to ensure the accuracy and reliability of the independent health facility’s equipment

- proper design of consultation requests, performance protocols, documentation and reports used at the independent health facility.
- development and maintenance of a quality assurance program for the facility.

Every licensee shall have a written agreement with the Quality Advisor requiring and authorizing the Quality Advisor to fulfill the requirements as set out above.

Note: Whenever the Quality Advisor has reasonable grounds to believe the conduct of the endoscopy services might jeopardize the safety of patients or the proper performance of services and where, in the judgment of the Quality Advisor, he or she is constrained from correcting the perceived deficiencies by actions taken or not taken by the licensee, then the Quality Advisor reports those concerns in writing to the Director, Independent Health Facilities as required by the Regulations under the Independent Health Facilities Act.

It is understood that the sections above do not in any manner remove from the licensee or impose upon the Quality Advisor the obligation or responsibility for operating the facility; it being understood that the Quality Advisor's sole responsibility is to provide advice to the licensee on the matters specified.

Nurse Qualifications

Nurses assisting in endoscopy procedures in an IHF must have current registration with the College of Nurses of Ontario. In addition, it is recommended that nurses participate in the following:

- ECG interpretation course
- Health assessment course
- Training in electrocautery application
- X-ray Safety as regulated by the Healing Arts Radiation Protection Act (HARP)

Registered Nurses Using Conscious Sedation

Education and training of personnel in the pharmacology of agents commonly used during sedation/analgesia includes:

- knowledge of pharmacology of opioids and benzodiazepines administered
 - Manufacturer's recommendations regarding:
 - dosages

- titration
- possible side effects (allergies, anaphylaxis)
- use of reversal agents
- potentiation of sedative-induced respiratory depression by concomitantly administered opioids
- knowledge of time intervals between doses of sedatives or analgesics resulting in cumulative overdose
- familiarity of pharmacological antagonists for sedative or analgesics (opioids and benzodiazepines)
- knowledge of complications associated with opioids and benzodiazepines.
- ability to recognize associated complications and be trained to perform basic life support skills (CPR, bag-valve-mask ventilation)

Note: It is required that an individual with advanced life support skills be immediately available (within 5 minutes) when sedation is used.

Competency Requirements

To assure adequately trained staff, the facility should provide a basic level of training for all staff members involved in delivery of conscious sedation. This includes but is not limited to the following:

- training
- equipment/set-up
- pre-sedation
- sedation
- post-sedation

Training

All registered nurses administering sedation and analgesia are trained in the following:

- basic cardiopulmonary resuscitation
- airway management
- IV fluid administration

- patient monitoring of the following:
 - pulse oximetry
 - blood pressure
 - respiratory rate
 - heart rate and cardiac dysrhythmias
 - titration of medications and potential side effects
 - knowledge in the administration of reversal agents

Endoscopy Reprocessing Technicians Qualifications

The qualifications for endoscopy reprocessing technicians employed in an independent health facility include but are not limited to the following:

- sterile processing certificate from a recognized community college.
- hands-on training which includes:
 - written endoscope specific reprocessing instruction for every endoscope model and automated endoscope reprocessor (AER)
 - infection control standards and practices as recommended by appropriate governing body. (The Canadian Society of Gastroenterology Nurses and Associates (CSGNA), Infection Control: Recommended Guidelines in Endoscopy Setting).
 - safety practices to include:
 - knowledge of chemical hazards associated with the processing of endoscopes, including the relevant Workplace Hazardous Material Information System (WHMIS) guidelines.
 - knowledge of infection hazards associated with procedures and equipment processing
 - knowledge of proper protective apparel (gowns, masks, aprons and eye protection)
 - immunization for Hepatitis B
 - monitor for tuberculosis by occupational health and safety

The endoscopy technician's work should be monitored until competency is documented for each reprocessing task from cleaning through storage of endoscope.

Additional training and documented competency for new models of endoscopes or AERs as they are introduced in the facility is evident.

Chapter 2 Policies and Procedures

Overview

There are current written policies and procedures to provide staff with clear direction on the scope and limitations of their functions and responsibilities for patient care.

Policies and Procedures

The procedure manual is available for consultation by all personnel. The manual is reviewed annually, revised as necessary and dated to indicate the time of the last review and revision.

There is documentation to indicate whom makes the policies, sets the standards, and who supervises physicians, nurses and other staff.

Procedures in the manual include but are not limited to the following:

- instructions regarding routine preparation of patients
- delegated controlled act
- scope and limitations of services provided by the facility

Note: The facility should have a culture/gender sensitive policy in place, allowing for accompanying personnel during the procedure.

- patient booking systems
- patient consent – written or verbal, based on the scope of practice in the facility
- maintenance of proper infection control
- latex anaphylaxis
- specific first aid measures to be followed in the event of an adverse effect, including a description of the arrangements for transferring patients to an acute care facility when required.
- maintenance of requisitions, records and interpretive reports (See Appendix I Independent Health Facilities Act – Ontario Regulation 364/04 – Amended to O. Reg. 57/92)
- confidentiality

- safety precautions with regards to electrical, mechanical, fire and internal disaster
- material Safety Data Sheets (MSDS) for all chemicals maintained in the facility
- routine maintenance and calibration of equipment
- list of safety equipment and medications to be maintained.

Chapter 3 Facility Standards for Type I, II, III Endoscopy Facilities

Overview

In general, the Endoscopy Task Force has adopted much of the documentation from the Canadian Association for Accreditation of Ambulatory Surgery Facilities Inc. as representing appropriate facility standards for use by Endoscopy Independent Health Facilities.

Type I Endoscopy Facility – Topical/Local Anaesthesia Only.

All Type One endoscopy facilities using topical anaesthesia, local infiltration or peripheral nerve blocks have:

- adequate space and equipment to ensure safe and aseptic treatment of the patient.
- adequate space for endoscopy
 - proper lighting
 - smooth floors and walls that are easy to wash

Note: If individual floor tiles are used, they must be sealed with a polyurethane sealant.

- cove molding must extend from floor up to the wall for 4”-6”
- adequate hand-washing facilities and proper towel usage and disposal.
- all openings to the outer air effectively protected against the entrance of insects or animals by self-closing doors, closed windows, screening, controlled air current or other effective means.
- emergency airway equipment that is accessible and properly maintained.
- proper cleaning equipment present
- monitoring equipment including blood pressure apparatus
- suction equipment of acceptable standards is present in the endoscopy and recovery room areas at all times. Secondary suction is required.
- an adequate waiting area space for accompanying people

- a business office that is separate from the area used for endoscopy
- medications for anaphylactic reactions
- required emergency drugs – intravenous set-up
- a proper double locked narcotic cupboard and narcotic record book with fixed pages
- defibrillator and emergency resuscitation equipment.

The facility must be kept neat, clean and free of waste material. Dry dusting and sweeping cannot be utilized.

Type II Endoscopy Facility – Topical Anaesthesia with Sedation

All type II endoscopy facilities using local anaesthesia with sedation have:

- Adequate space and equipment to ensure safe and aseptic treatment of the patient
- Adequate space for endoscopy
 - Proper lighting
 - Smooth floors and walls that are easy to wash

Note: If individual floor tiles are used, they must be sealed with a polyurethane sealant.

- cove molding must extend from floor up to the wall for 4”-6”
- adequate hand-washing facilities and proper towel usage and disposal.
- all opening to the outer air effectively protected against the entrance of insects or animals by self-closing doors, closed windows, screening, controlled air current or other effective means.
- proper cleaning equipment present.
- patient monitoring equipment including blood pressure apparatus, ECG, and oximeter. This equipment must be tested on the day of and prior to endoscopy.
- an adequate waiting area space for accompanying people
- a business office that is separate from the area used for endoscopy.
- at least one endoscopy room that is used exclusively for endoscopy and at least one full recovery room or designated area. The size of the endoscopy room is adequate for flow of patients and equipment.

- a suitable endoscopy table or stretcher with full capability for the performance of all scheduled cases.
- all equipment for the administration of anaesthetics readily available, kept clean and properly maintained.
- suction equipment of acceptable standards present in the endoscopy and recovery room areas at all times. Secondary suction is required.
- resuscitation equipment present including:
 - defibrillator
 - endotracheal tubes
 - airways
 - laryngoscope
 - oxygen sources with positive pressure capabilities
 - emergency drugs
 - oxygen tanks
- means of performing a tracheotomy or cricothyroidotomy
- equipment required for an endoscopy procedure before the endoscopy commences
- appropriate equipment for the administration of intravenous fluids
- appropriate and readily available stretchers and wheelchairs for the transport of patients
- adequate space within the endoscopy room to ensure that patients can be transferred free of encumbrances
- an anaesthetic recovery room with adequate space that allows the transport of patients and movement of personnel. Continuous oxygen delivering system and suction is available. Oxygen tanks capable of eight hours @51/ min is present.
- office space, personnel areas, lounge areas and consultation dressing rooms of adequate space so as not to jeopardize the safe treatment of patients
- access to a hospital for the transfer of emergency cases
- physicians who have endoscopy privileges to endoscope in the facility. As well, the physician has admitting or endoscopy privileges in a nearby hospital or has access to appropriate referral by prior arrangement
- an emergency power source available which will provide adequate lighting, essential area lighting, and have the capacity to operate all essential equipment for a period of four hours. Emergency power source must be tested on a weekly basis.
- a proper locked narcotic and drug cupboard and narcotic records.
- cross and type blood tubes for emergency and vacutainers for all blood screening electrolytes, arterial gases, and blood sugar.
- a two-stage fire alarm system.

- an endoscopy log book
- packs and instruments sterilized. The bacillus stearothermophilus vial which monitors sterility is used.
- adequate access for transportation of patients on a stretcher in the event of an emergency evacuation.

The facility is kept clean, neat and free of waste material. Dry dusting and sweeping cannot be utilized.

Type III Endoscopy Facility – General or Regional Anaesthesia

All type III endoscopy facilities using general, major regional or IV blocks have:

- adequate space and equipment to ensure safe and aseptic treatment of the patient.
- adequate space for endoscopy
 - proper lighting
 - smooth floors and walls that are easy to wash

Note: If individual floor tiles are used, they must be sealed with a polyurethane sealant.

- cove molding must extend from floor up to the wall for 4”-6”
- hand-washing facilities and proper towel usage and disposal.
- all openings to the outer air effectively protected against the entrance of insects or animals by self-closing doors, closed windows, screening, controlled air current or other effective means.
- proper cleaning equipment available
- patient monitoring equipment including blood pressure apparatus, ECG, and oximeter. This equipment must be tested on the day of and prior to endoscopy.
- adequate waiting area space available for accompanying people.
- a business office available and separate from the area used for endoscopy.
- at least one endoscopy room that used exclusively for endoscopy and at least one full endoscopy recovery room or designated area. The size of the endoscopy room is adequate for flow of patients and equipment.
- a suitable endoscopy table or stretcher available with full capability for the performance of all scheduled cases.

- all equipment for the administration of anaesthetic readily available, kept clean and properly maintained.
- suction equipment of acceptable standards available in the endoscopy and recovery room at all times. Secondary suction is required.
- resuscitation equipment present including:
 - defibrillator
 - endotracheal tubes
 - airways
 - laryngoscope
 - oxygen sources with positive pressure capabilities
 - emergency drugs
 - oxygen tanks
- means of performing a tracheotomy or cricothyroidotomy
- equipment which is required for an endoscopy procedure present before endoscopy commences
- appropriate equipment for the administration of intravenous fluids
- appropriate and readily available stretchers and wheelchairs for the transport of patients.
- adequate space within the endoscopy room to ensure that patients can be transferred free of encumbrances
- office space, personnel areas, lounge areas and consultation dressing room areas of adequate space so as not to jeopardize the safe treatment of patients.
- access to a hospital for the transfer of emergency cases.
- physicians who have endoscopy privileges to endoscope in the facility. As well, the physician has admitting or endoscopy privileges in a nearby hospital or has access to appropriate referral by prior arrangement.
- an emergency power source available which will provide adequate lighting, essential area lighting, and have the capacity to operate all essential equipment for a period of four hours. The emergency power source is tested weekly.
- a separate patient isolated grounding system available
- an FRCP(C) anaesthesiologist present for all general and spinal anaesthesia

Note: Exceptions can be made on consideration of the Quality Advisor.

- the anaesthesiologist is present in the facility until such time that the last endoscopy patient of the day is deemed fully conscious.

- a certified anaesthetic machine present that only handles no explosive anaesthetics. A CO₂ analyzer must be attached to the equipment utilized for general anaesthesia.
- testing of nitrous oxide performed annually and documentation maintained.
- proper locked narcotic and drug cupboard and narcotic records.
- a thermometer probe for monitoring of patients' temperature
- an endoscopy room of such size that it can easily house the endoscopy room table, anaesthetic equipment, monitoring equipment, supply cupboard, and personnel and at the same time allow the turning of patient stretchers to transport the patient unimpeded.
- an endoscopy log book
- an endoscopy room that is proven pathogen free. This is performed with routine cultures taken twice a year.
- packs and instruments sterilized. The bacillus stearothermophilus vial which monitors sterility is used.
- dates of sterilization marked on supplies and checked at appropriate intervals.
- an anaesthetic recovery room with adequate space that allows the transport of patients and movement of personnel. Continuous oxygen delivering system and suction is available. Oxygen tanks capable of eight hour @5l/min is present.
- medication for the treatment of malignant hyperthermia (i.e. sodium dantrolene) and treatment of anaphylactic shock must be readily available.
- one recovery room for endoscopy requiring general anaesthesia which is not used for other purposes (i.e. as an examining room, treatment room)
- adequate access for transportation of patients on a stretcher in the event of emergency evacuation.
- two stage fire alarm system.

Emergency Drug List

An emergency kit is available consisting of a defibrillator and the following medications essential for CPR, or at the discretion of the anaesthetist:

- Atropine sulfate 0.6 mg/ml (pre-filled syringe)
- Amiodarone 300 mg
- Calcium chloride 10% (pre-filled syringe)
- Diazepam or versed 1 mg/ml

- Dopamine infusion
- Epinephrine
- Hydrocortisone sod succ 500 mg
- Isoproterenol 0.2 mg/ml (5ml ampoule)
- Labetalol hydrochloride
- Lidocaine infusion 0.4%
- Lidocaine 2% (pre-filled syringe)
- Morphine sulfate
- Narcan
- Anexate
- Oxygen
- Phenytoin
- Propranolol 1 mg/ml or metopndol 1 mg/ml
- Sodium bicarbonate
- Trimethaphan camsylate
- Verapamil 2.5 mg/ml
- Water for injection (30 ml)
- Dextrose 5% in water
- Dextrose 50% in water
- Alcohol skin prep
- Needle (20 gauge 1")
- Syringe 12 ml
- Syringe 3 ml with 22 gauge needle.

Health Standards

The Independent Health Facility must ensure that:

- all sanitary, safety, building code and fire regulations meet local standards.
- all waste and garbage are disposed of according to current regulations and legislation
- appropriate electrical hazards are controlled according to local jurisdiction

- emergency power supply is provided as outlined under each type:
 - Type 1 – emergency light source
 - Type 2 – emergency power supply which can be maintained for a period of four hours
 - Type 3 – emergency power supply source that can be maintained for a period of four hours.
- smoking is prohibited in all areas of endoscopy
- combustible materials are handled in the approved manner conforming to local regulations
- volatile supplies are stored similarly in a safe manner according to local jurisdiction
- approved fire extinguishers of types required by the local fire chief are in place and routinely inspected.
- necessary fire and emergency drills are held to update personnel
- endoscopy and recovery room personnel are trained in cardiopulmonary resuscitation and they remain current.
- acceptable procedures to minimize infections are employed
- appropriate sterilizers are used with necessary inspections. If gas sterilizers are used, proper venting is necessary. Unsterile supplies are not mixed with sterile supplies and items are appropriately labeled.
- dates of sterilization are marked on supplies and checked at appropriate times.
- all new equipment where required have a CSA or equivalent label. Inspection of equipment such as autoclaves, endoscopy tables, cautery equipment, electrical outlets, transformers is to be carried out annually and documentation maintained.

Chapter 4 Patient Records

Overview

The independent health facility must maintain patient records for the required length of time as outlined in the Independent Health Facilities Act. (*see Appendix I – Independent Health Facilities Act -Ontario Regulation 346/04 Amended O. Reg.57/92*).

Paper or electronic record that is accessible and readable is acceptable.

Patient Records

Each patient record should include, but is not limited to the following:

- appropriate history and record of the physical examination
- risk factor for latex allergies (*see Appendix II – Recommended Guidelines for Preventing Allergic Reactions to Natural Rubber Latex*)
- endoscopy notes or reports
- progress notes
- complete record of medications and allergies
- laboratory and pathology results
- appropriate consent forms

Pre-sedation Documentation

Prior to the administration of sedation, the nurse will document in the patient's chart the following:

- history and physical
- nursing assessment including baseline heart rate, respiratory rate, blood pressure, O₂ saturation, and medication allergies.
- assessment of NPO status
- informed consent
- patient IV access
- review of patient discharge instructions
- confirmation of person responsible for post-procedure transportation.

Sedation

- Medications administered by the nurse under the direction of the physician
- IV medications are to be given in small incremental doses and titrated to desired effect.
- Monitoring including O₂ saturation, heart rate, respiratory rate, blood pressure throughout the entire procedure
- Cardiac monitoring if history of cardiac disease or anomaly
- Continuous patient monitoring with documentation at least every 5 minutes during titration of medications until a stable level of sedation is established.
- At minimum monitoring should be documented at least every 15 minutes during the procedure
- Supplemental O₂ may be administered as needed.

Post Sedation

- Patient monitoring may be discontinued when the patient meets criteria established by the facility
- Adequate safety measures are provided.

Anaesthesiologists

When an Anesthesiologist participates in the procedure an aesthetic record for pre-operative, intra-operative and post-operative charting must meet the guidelines of the Canadian Anesthesiologists' Society.

Chapter 5 Providing Quality Care

Overview

A Quality Advisory Committee is established as per the IHF Act. The advisory committee shall consist of health professionals who provide health services in or in connection with the independent health facility. Regular meetings are held and minutes maintained (IHF Act Regulation 57/92).

Note: An exception to this is where the physician is the sole provider of the services, is owner/operator and Quality Advisor, and the services provided are part of his/her office practice.

To provide quality of care, there is evidence that patients' needs for endoscopic services are assessed. The services planned and provided are consistent with those needs and assure diagnostic and therapeutic reliability and patient safety.

Provision of Quality

Quality endoscopy care requires trained endoscopists, properly trained nursing and ancillary personnel, functioning well maintained equipment, adequately furnished preparation, endoscopy and recovery areas, adequate scope cleaning and reprocessing equipment, rooms and procedures and personnel trained in cardiopulmonary resuscitation.

Quality improvement processes do not simply identify problems but assess the frequency and severity of issues and develop processes to resolve issues and improve outcomes.

Facilities providing endoscopic services must ensure that:

- The facility is set-up and equipped to run primarily for endoscopy
- The Quality Advisor is involved in the day-to-day running of the facility
- At least one physician is on the premises during endoscopy procedures. Physician must be available until the patient has been discharged from recovery phase.
- Access to appropriate diagnostic radiologic and laboratory equipment is available

- Medical Records are appropriately maintained and stored.
- All pathology material is sent for examination
- Safety measures for endoscopic, electrosurgical, laser, radiologic equipment undergoes periodic scheduled inspections.
- Maintenance contracts are in place for all equipment used in the endoscopy room.
- Appropriate sterilization and cleaning is maintained
- Appropriate hand-washing procedures are maintained
- Drugs are stored appropriately
- Use of reusable and disposable instruments is monitored appropriately
- Disposal of soiled laundry, dressing and single use equipment is performed
- Continuing education for medical, nursing and ancillary staff is maintained
- A safe clean environment is available for bowel preparation, pre-procedure and post-procedure education.
- Communication with staff through the facility is well established and documented
- Agreements with surrounding hospitals for emergency transfer of patients are in place.

Monitoring Quality of Care

The facility must have a mechanism in place to monitor the quality of care provided to patients in this facility. These quality management activities include but are not limited to the following:

- Ongoing internal review of charts and records be conducted by the Quality Advisory Committee. The suggested protocol is:
 - Five charts to be reviewed from each physician performing endoscopic services. The review will look at the following components:
 - Chart completion
 - Evaluation of complications
 - Adverse events
 - Assessment of transfer to hospitals
 - Follow-up of abnormal pathology
 - Lab results.
- Nursing peer review

- Appropriate pre-procedure testing based on patient co-morbidities and type of procedure
- Periodic patient satisfaction surveys
- Periodic referring physician surveys
- Periodic review of standards for cleaning, sterilization, maintenance and storage of equipment
- Provision of pre-printed bowel preparation, other pre-preparation, post-procedure and other educational material
- Ensuring patient is accompanied and/or driven home at discharge
- Periodic assessment of medical necessity of procedures and appropriateness of care.

Chapter 6 Infection Control & Prevention for Endoscopy Procedures

Overview

The following comments have been taken from the “Guidelines for Infection Prevention and Control in Endoscopy”, Endoscopy Working Group Infection Control Subcommittee, Manitoba Advisory Committee on Infectious Disease (September 2000).

Infection Control & Prevention of Endoscopy Procedures

Gastrointestinal endoscopes come into contact with mucous membranes and are considered semi-critical items. High level disinfection between each patient use is the current minimum reprocessing standard of practice.

Accessories such as re-usable biopsy forceps that penetrate mucosal barriers are classified as critical items and must be sterilized between each patient use. If these accessory items are labeled “single-use”, “disposable” they should not be reprocessed.

Endoscopes that enter sterile body spaces (i.e. cystoscopes) should be sterilized before each use. There are some references that suggest when sterilization is not feasible, endoscopes should receive at least high-level disinfection.

Transmission of organisms from contaminated bronchoscopes have illustrated problems associated with automated reprocessing machines. Some bronchoscope models are not compatible with certain automated reprocessing systems. Appropriate connector systems, both device and model-specific are essential.

Endoscopes have been implicated in the transmission of disease when appropriate cleaning, disinfection or sterilization procedures were not employed. Of particular significance is the need to thoroughly manually clean equipment prior to any manual or automated disinfection or sterilization process.

Safety of Personnel

Consistent practice must be maintained to prevent the spread of disease and to protect staff from the dangers of chemicals used in the cleaning and high-level disinfection of endoscopes. Practices that should be followed include:

- all personnel performing or assisting with endoscopic procedures follow universal precautions and wear appropriate equipment to protect themselves from fluid and body substances including but not limited to gowns, gloves, goggles and masks.
- all personnel should be immunized for Hepatitis B
- bronchoscopy personnel should be monitored for exposure to tuberculosis as required
- yearly TB skin test
- health care workers who have respiratory problems (asthma, latex or chemical allergies) should be assessed prior to working in the area
- irritation can be minimized with covered containers and by using disinfectants in a well-ventilated area.
- eye protection and moisture resistant masks or face shields should be worn to prevent contact with splashes during the cleaning procedure and disinfection/sterilization process.
- moisture resistant gowns should be worn to prevent contamination of personnel due to splashes of blood or other body fluids or injury due to chemical disinfectant/sterilant contact. Gowns should be changed between patient procedures or when visibly soiled.
- protective apparel should not be worn outside the procedure room and cleaning room.
- non-sterile gloves must be worn for handling and cleaning dirty equipment, as well as for any potential contact with blood or body fluids. Gloves are recommended when handling disinfectant solutions in order to prevent caustic effects.
- all needles and sharps are to be appropriately disposed of in puncture-resistant containers at their point of use. Do not recap needles.
- fingernails should be kept short to prevent puncturing of gloves. Jewellery should not be worn on the hands because it harbors microorganisms, hinders handwashing and may puncture gloves.
- meticulous hand-washing with an appropriate anti-microbial solution must be done between patient contact, after glove removal, and when entering or leaving the endoscopy area. If hands or other skin surfaces are contaminated with blood or body fluids, wash immediately.

- health care workers who have exudative lesions or weeping dermatitis should refrain from all direct patient care and from handling patient care equipment until the condition resolves.
- health care workers who have significant percutaneous, non-intact skin or mucous membrane exposure to the blood and/or body fluids of any patient should be promptly report such contact to the Quality Advisor for evaluation and proper follow-up.
- all personnel performing or assisting with endoscopic procedures and personnel responsible for reprocessing the equipment must be knowledgeable about the infectious and chemical hazards associated with these procedures and equipment, including the relevant Workplace Hazardous Material Information System Guidelines.

Standards for Occupational Exposure to Bloodborne Pathogens

Preamble

Bloodborne Pathogens means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to: hepatitis B virus (HB) and human immunodeficiency virus (HIV).

Other Potential Infectious Materials means:

- The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids.
- Any unfixed tissue or organ (other than intact skin) from a human (living or dead).

Regulated Waste

Regulated Waste means liquid or semi-liquid or other potential infectious material; contaminated items that would release blood or other potential infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potential infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials.

Universal Precautions

Universal Precautions is an approach to infection control. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV and other bloodborne pathogens.

Work Practice Controls

Work Practice Controls means controls that reduce the likelihood of exposure of altering the manner in which a task is performed (e.g. prohibiting recapping of needles by a two handed technique).

Universal precautions must be observed in each facility in order to prevent contact with blood or other potentially infectious materials. All blood or other potentially infectious material will be considered infectious, regardless of the perceived status of the source individual.

It must be stressed that basic hygiene cleanliness is important. Proper handwashing is critical.

CAAASF BLOODBORNE PATHOGENS STANDARD EXPOSURE CONTROL CHECKLIST

Exposure Determination

The Physician in charge should explain to employees who might have occupational exposure.

Methods of Control

Universal Precautions of Body substance Isolation Procedures followed

- Hazardous wastes must be placed in the appropriate marked container and disposed of according to the directions of that Province and local Health Department.

Engineering Controls

- Contaminated sharp instruments placed in puncture resistant disposable containers.
- Specimens of blood/other potential infectious material placed in containers to prevent leakage.
- Mechanical devices or one-handed techniques used for recapping or removal of needles
- Mechanical pipetting devices used (if applicable).
- Biosafety cabinet/ventilation system used (if applicable).

Work Practice Controls

- Hand washing facilities available
- Skin washed immediately after contact with blood/other potential infectious material or removal of personal protective equipment
- Antiseptic hand cleaner used if hand washing facilities not feasible
- Shearing or breaking of contaminated needles or two handed recapping prohibited
- Reusable sharps placed in puncture resistant, leak proof containers immediately after use
- Procedures involving blood/other potential infectious material conducted to minimize splashing and spraying
- Eating, drinking, smoking, applying cosmetics, or other hand to mouth activities and handling contact lenses are prohibited in areas where blood/other potential infectious materials are present
- Food and/or drink storage prohibited in areas where blood/other potential infectious wastes are present
- Contaminated equipment is decontaminated prior to service or shipping

Personal Protective Equipment (PPE)

- PPE provided to employees in appropriate sizes at no cost and is readily accessible
- PPE used by employees when occupationally exposed to blood/other potentially infectious material
- PPE material does not permit blood/potentially infectious material to pass through under normal circumstances
- Contaminated PPE removed and replaced as soon as feasible following contamination

- All PPE removed prior to leaving work area
- PPE placed in designated area or storage container for storage, washing, decontamination or disposal
- PPE cleaned, laundered or disposed of by employer at no cost to the employees
- PPE repaired or replaced by employer at no cost to employees
- Gloves worn during hand contact with blood/other potentially infectious material, mucous membrane, non intact skin, when performing vascular access procedures, and when touching contaminated items.
- Hand washing after glove use is required
- Masks in combination with eye protection devices with solid side shields or chin length face shield worn when splashes, spray splatter or droplets of blood/other potentially infectious material reasonable anticipated.
- Surgical cap/hoods and shoe covers worn when gross contamination reasonably anticipated
- Resuscitation devices available (if applicable)

Housekeeping

General purpose household gloves should be used for housekeeping chores, but disposable gloves must be used for cleaning up spills.

Environmental surfaces such as walls, floors and other surfaces are not associated with transmission of infections to patients or health care workers. Attempts to disinfect or sterilize these environmental surfaces are not necessary. Cleaning and removal of soil should be done routinely.

- Written schedules for cleaning and methods of decontamination work areas and equipment
- Work surfaces decontaminated following procedures, contamination or end of shift
- Protective equipment or surface coverings removed and replaced following contamination
- Reusable containers inspected and decontaminated periodically and after contamination
- Employees not allowed to open, empty or manually clean reusable sharps containers
- Contaminated broken glassware picked up only by mechanical means, not by hand
- Contaminated sharps placed in closable, leak-proof, puncture resistant and labeled containers

- Containers are easily accessible, labeled, maintained upright and not overfilled
- Regulated wastes placed in closable, leak-proof, labeled containers
- Sharps and regulated waste containers closed prior to transport and placed in secondary closable, leak-proof and labeled container if leakage possible or outside contamination occurs
- Regulated wastes disposed of according to applicable federal, provincial or local regulations
- Contaminated laundry placed in leak proof and labeled/colour coded bags or containers
- Contaminated laundry bagged or containerized but not rinsed or sorted at location of use
- Protective gloves and other appropriate PPE used by employees handling contaminated laundry

Hepatitis B Vaccination

- Provided at no cost, after training and within 10 working days of initial assignment
- Not provided when employee has previously received vaccine series, immunity revealed through antibody testing, or vaccine is medically contraindicated
- Participation in prescreening not a prerequisite for receiving the Hepatitis B vaccine
- Employees who decline vaccine must sign a release to this effect
- Booster doses be made available

Post-Exposure Evaluation and Follow-Up

- The facility director must ensure that the employee is referred to the appropriate health physician
- Routes of exposure and circumstances of exposure is documented
- Source individual identified and referred to the proper health authority according to the dictates of the provincial law
- Results of source individual testing (if applicable) available to exposed employee and employee informed of privacy and disclosure laws related to the course individual testing
- Exposed employee's blood collected and tested after consent is obtained or the employee be referred to the appropriate medical officer of health
- Post-exposure prophylaxis provided when medically indicated by the proper health official

Communication of Hazards to Employees

- Warning labels are affixed to containers of regulated waste, refrigerators or freezers of blood/other potentially infectious material, other containers used to store, transport or ship blood/other potentially infectious material. Red bags or containers may be substituted for labels.
- Labels are orange/red coloured with the word “biohazard” or “hazardous waste”

Record keeping

- The facility director or head nurse must keep records of the dates of training sessions with regard to bloodborne pathogens, exposure and control. This must be carried out annually
- Medical records of employees must contain the employee name, social insurance number and hepatitis B vaccination status
- Records are confidential and not disclosed except to the employee or the facility director
- Medical records are kept for the duration of employment plus 30 years

Waste Disposal

Biomedical Waste

Includes all dressings, sponges, gloves, gauze pads, underpads, liners for suction containers, tubing, rectal tubes, catheter bags, catheters, blood and serum specimens or any disposable item which has been contaminated with blood or body fluids.

1. Packaging Requirements

- Green or black garbage bags
- Garbage can

2. Collection and Handling

- Any item that might leak must be placed in a plastic bag and secured tightly before placing in lined garbage container

3. Method of Disposal

- Transferred to a landfill site by a purchased hauler

Infectious Waste

Infectious waste is waste of any type which is contaminated or suspected to be contaminated with causative agents of infectious disease or their toxic products and capable of infecting or causing disease in susceptible individuals or animals exposed to them.

To be classified as infectious, waste should not merely contain pathogens, but should also be capable of transmitting infection. An understanding of the factors necessary for transmission of infection is useful in classifying waste as infectious.

Infectious waste may include:

- Human anatomical
- Animal anatomical
- Non-anatomical
- Microbiological
- Blood, blood products, body fluids suspected to contain microbial agents of disease
- Waste generated by patients in isolation
- Waste containing anti-neoplastic agent

1. Packaging Requirements

- Yellow bag and biohazard box
- Waste may be collected in any plastic bag and tied off before placing in a yellow bag

2. Collection and Handling

- Assemble biohazard box
- Line with yellow bag
- Wear gloves
- Tie off each bag individually
- Close and seal biohazard box
- Indicate department of original box

3. Method of Disposal

- Transported by licensed hauler to authorized incineration site

Guidelines for the Reprocessing of Endoscopes

Facilities should refer to the manufacturer's instructions for cleaning and disinfecting each specific model of endoscope. Only trained personnel should perform this procedure.

Inspection

At all stages of handling, the endoscope should be inspected for damage.

According to manufacturer's recommendations, leak testing of the endoscope should be performed each time prior to starting the cleaning process. A leak test involves applying air pressure to the inside of the endoscope insertion tube and watching for air bubbles, which identify leaks either in the covering or internally into one of the channels.

If damage is detected during the leak test (i.e. bubbling occurs) do not proceed with cleaning. Send to be repaired immediately. If the scope cannot be cleaned prior to transport, ensure it is clearly labeled as "contaminated" and is packaged and transported appropriately.

Cleaning

Reprocess immediately after use. Do not allow to dry prior to manual cleaning. If unable to initiate the manual cleaning process immediately, the endoscope may be flushed and left soaking in an enzymatic detergent solution. It is important to remove all detachable parts before reprocessing.

Wipe the outer surface of the endoscope with enzymatic detergent-soaked gauze immediately after removal from the patient. Using the air/water channel valve, flush the air/water channel with water from the water bottle. For endoscopes with an elevator wire, manual flushing of this channel with an enzymatic detergent and rinsing is required. Transport the scope to the cleaning area in a closed container.

After determining there are no leaks, fully immerse the scope in a solution of enzymatic detergent cleaner to prevent the drying of secretions. Brush all channels to remove organic material and decrease the number of organisms present. Ensure the air/water/CO₂ channels are also cleaned.

Ensure the outer surface of the scope is thoroughly cleaned. Use of a soft bristle toothbrush to clean the lens end is acceptable.

All channels must be irrigated and brushed to remove particulate matter. Channel irrigators should be used to facilitate cleaning of all channels.

Rinse all the channels and the endoscope thoroughly with copious amounts of tap water following the cleaning process to remove the residual of the enzymatic detergent.

Remove all excess water from the channels by injecting air via the all-channel irrigator to decrease the chances of diluting the disinfectant solution.

For endoscopes with an elevator wire, this channel must be manually flushed with an enzymatic detergent and rinsed.

Sterilization and Disinfectant

When deciding whether to sterilize or disinfect the endoscope, it is important to refer to the following classifications:

Critical items – enter sterile tissue, the vascular system or sterile body spaces. They require meticulous cleaning and sterilization between uses.

Semi-critical items – come in contact with mucous membranes or non-intact skin. They require meticulous cleaning and at minimum, high-level disinfection between uses.

Non-critical items – come in contact with intact skin. They require meticulous cleaning and low-level disinfection between uses.

Endoscopes that enter sterile body cavities (i.e. cystoscopes, biopsy forceps, polynares) are classified as critical items and require meticulous cleaning and sterilization between uses.

Endoscopes that come in contact with mucous membrane (i.e. laryngoscopes, flexible endoscopes including bronchoscopes, colonoscopes, duodenoscopes) require high-level disinfection between use.

Non-critical items (i.e. cameras, light source) require meticulous cleaning and low-level disinfection between use.

Sterilization or high-level disinfection of the endoscope internally and externally must be performed after scrupulous mechanical cleaning has been completed. All processes may be rendered ineffective if any organic material or moisture is retained on or in the endoscope.

Rinsing

To remove all traces of the disinfectant, adequate rinsing must follow the disinfection process. Any residual chemical can cause toxic effects in a patient if it is transmitted during the next endoscopic procedure.

The use of sterile water for rinsing is preferred, but tap water can be used.

Drying

If tap water is used for the final rinse, always follow rinse step with 70% alcohol flush and dry with compressed air.

Always use an alcohol flush and compressed air drying for scopes that will be stored before next use (i.e. not point-of-use reprocessing).

Channel valves and video caps should be kept separately from scopes during storage to facilitate drying.

Ensure the scope and channels are dried completely. Alcohol flush facilitates the drying.

When a scope is processed through an Automated Endoscope Reprocessor (AER), it still requires an alcohol rinse followed by manual forced air drying prior to storage.

Storage

Endoscopes should be stored hanging vertically in well-ventilated areas in a way that prevents recontamination or damage. They should not be coiled and stored in their cases.

Store valves separately from endoscopes. Failure to do this may result in microbial overgrowth in the channels.

Wipe down the storage cupboard weekly with an approved low-level disinfectant/cleaner.

Automated Endoscope Reprocessors (AER)

Endoscopy unit cleaning/disinfection processes may be standardized by the use of an automated endoscope reprocessor. This equipment may be useful in circulating germicides, containing vapors and decreasing

exposure of personnel to contaminated equipment and disinfectants. Operating of this equipment should be limited to those individuals trained in its proper use.

Note: The use of any automated system must be preceded by meticulous manual cleaning and leakage check as previously described.

The following capabilities must be present in any AER:

- enzymatic detergents and/or disinfectants should be circulated through all channels at equal pressure without trapping air.
- washing and disinfecting cycles should be followed by thorough rinsing cycles followed by forced air to remove the used solution.
- disinfectant should not be diluted with wash or rinse water.
- if an alcohol rinse is not part of the AER cycle, perform alcohol rinse manually.
- forced air drying cycle or air drying by hand should be contemplated after the final rinse
- routine disinfection of the AER according to the manufacturer's recommendations must be done.
- when used to disinfect duodenoscopes, ensure the channel for the elevator wire is cleaned and disinfected as part of the processing cycle or it may require manual processing.
- residual water remaining in the water hoses and reservoirs may cause microbial colonization of an AER. This could lead to contamination during subsequent instrument processing
- protocols for both the specific scope and the specific AER are necessary to ensure effective functioning of the AER.

Recommendations For Accessories

Non-disposable accessories require meticulous manual cleaning and disinfection or sterilization after each use according to manufacturer's guidelines. Ultrasonic cleaning is more effective for cleaning stainless steel compared to plastic devices.

Lubricate "O" rings on buttons, valves, and cleaning adaptors according to manufacturer's recommendations.

Biopsy Forceps

Meticulous manual cleaning with an enzymatic agent is required as soon as possible after the procedure.

Ultrasonic cleaning is recommended to remove debris that hand cleaning can not. Biopsy forceps break the mucosal barrier, therefore, they are classified as critical items and require sterilization.

The only method that will effectively penetrate the metal coils of the spring-like structure and any residual organic material is steam under pressure. Chemical sterilization does not completely penetrate the coils and therefore is not effective.

Water Bottle

For endoscopic irrigation fill the bottle with sterile water.

Sterilize or high-level disinfect the water bottle and its connecting tubing at least daily.

Other Accessories

Accessories that penetrate mucosal barriers (i.e. papillatomes, cytology brushes) should either be disposable or mechanically cleaned utilizing an ultrasonic cleaner and sterilized between patient use.

Medical Equipment

There must be routine cleaning of non-critical equipment (i.e. teaching heads, light sources, cameras) using an approved low-level disinfectant/cleaner.

Recommendations for Environment

General Cleaning

For general cleaning of equipment such as procedure carts, stretchers, sinks etc after each use, use an approved low-level disinfectant/cleaner.

Spills

In keeping with routine practices:

- Using gloves, blot spills of blood or body fluid with disposable towels.
- Wipe the area with clean, disposable towels soaked with an approved low-level disinfectant/cleaner.
- Disinfectant spills should be handled by consulting the solution MSDS (Material Safety Data Sheet) WHMIS guidelines.

Waste

Minimal handling of all medical waste should be encouraged.

The storage of disposal of waste should be handled according to the facility's policy and provincial and federal guidelines.

Facility Design

Patient care areas should be separate from cleaning/disinfection areas.

A designated area is required for hand-washing.

Clean and dirty areas should be separate with proper plumbing and drains. Ensure access to sinks to facilitate immersion of scopes during cleaning and rinsing.

Adequate space should be provided for drying and storing endoscopes and endoscopic accessories.

Air-exchange equipment (i.e. ventilation system, exhaust hoods, etc.) should be utilized to minimize the exposure to potentially toxic vapors.

If glutaraldehyde is used for high-level disinfection, then periodic air quality monitoring for glutaraldehyde fumes should be performed.

Chapter 7 Cystoscopy

Overview

Direct visualization of the anterior and posterior urethra, bladder neck, and bladder is accomplished by cystourethroscopy. The primary indication for cystourethroscopy is the diagnosis of lower urinary tract disease. Access to the upper urinary tract for diagnosis and treatment requires cystoscopy. Additionally, radiological and fluoroscopic devices are required for upper tract procedures. This section relates only to diagnostic cystourethrography.

Personnel

A trained endoscopist carries out the procedure. The endoscopist may be:

- Urologist
- Gynaecologist, or surgeon who has received training in an accredited program to perform cystoscopies and interpret the findings.

Note: The endoscopist should provide consultation to the patient and the referring physician as to the medical and surgical aspects of the diseases as they relate to cystoscopic findings and should not be an individual who provides technical service only. The endoscopist must also ensure continuing medical education through attendance at meetings dealing with Urology.

An RN or RPN to monitor the patient's condition, and assist the endoscopist with technical aspects of the procedure.

If conscious sedation will be used, additional personnel required for this procedure include a registered nurse (RN) or a respiratory therapist suitably trained to administer and monitor conscious sedation.

Cystourethrography

Cystourethroscopy can be performed with either rigid or flexible cystoscopes.

Rigid Cystourethrography

The size of cystourethroscopes is usually given using the French scale and refers to the outside circumference of the instrument in millimeters. Instruments of different sizes are available to accommodate paediatric patients (No. 8 to 12 Fr) and adults (No. 16 to 25 Fr).

Modern rigid cystourethroscopes consist of a sheath, an obturator, bridges and telescopes with varying degrees of angle of vision. The most common ones are the 30 degree lens and the 70 degree lens. With the advent of flexible cystoscopes, other lenses with various other angles of vision are less commonly used.

Flexible Cystourethrography

Flexible cystourethroscopes contain fiberoptic bundles within a flexible shaft for illumination and visualization. The shaft has an irrigating channel and a working channel for passage of accessory instruments. The tip of a flexible endoscope can be deflected 180 to 220 degrees by a thumb control located near the eyepiece.

Equipment

At minimum, the equipment needed to perform this procedure include but are not limited to the following:

- Patient examination table capable of accommodating cystoscopy in the supine and in the lithotomy position.
- Suitable system for disposal of irrigant fluid and body fluids generated during the procedure.
- Adequate supply of sterile normal saline irrigant fluid.
- Endoscopic light source, or video equipment
- Disposable irrigant fluid tubings and taps

Note: It is advisable to have latex free tubing and gloves.

- Sterile drapes and gloves
- Urine specimen bottles for urinalysis and culture; tuberculosis culture; and urine cytology specimens
- Tumey syringes/bulb syringes, hypodermic syringes: range of sizes and basins for manual irrigation through the cystoscope or Foley catheter

- Sterilization solutions, prepping trays and catheterization kits
- Dilatation sound sets: male and female; paediatric.
- Range of 2-way and 3-way Foley type catheters.

Patient Selection and Preparation

Prior to cystoscopy, the urine should be sterile. If not, precystoscopy antibiotics should be administered to minimize the possibility of postprocedure problems with systemic infection and septicemia. If the patient has a known valvular heart disease, he/she should be treated with antibiotics to prevent endocarditis, according to the guidelines established by the New York Heart Association.

Informed Consent

Written informed consent is obtained prior to sedation.

Anticoagulation

Anticoagulation needs to be assessed prior to cystoscopy. Because there is an unpredictable need for biopsy in patients undergoing cystoscopy arrangements for appropriate anticoagulation should be made well before the procedure takes place. In patients with low risk conditions (i.e. uncomplicated non-valvular atrial fibrillation, bioprosthetic valve, mechanical valve in aortic position) warfarin should be discontinued 3-5 days before the scheduled procedure.

Patients with high risk conditions (i.e. atrial fibrillation associated with valvular heart disease, mechanical valve in the mitral position, mechanical valve and prior thromboembolic event) may need anticoagulation with heparin when the warfarin is discontinued and the INR falls to below therapeutic levels.

Aspirin and NSAIDS may be held for elective procedures. However the endoscopist should weigh the relative indications for these medications against the potential for bleeding.

There is inadequate data about the safety of patients undergoing biopsy. Temporary discontinuation of antiplatelet agents is desirable but must be weighed against the patient's risk of an adverse cardiac event related to discontinuation of the medication.

Medication in Special Patients

Patients who normally take cardiac medications including anti-hypertensives should take their usual medications on the day of the procedure with sips of water.

Approach to diabetic patients should be individualized and documented in the patient's chart.

Before the Procedure

A full history and physical examination should take place before the procedure. The patient will be brought to the procedure room after changing and will be placed on the procedure table.

During the Procedure

The perineum and external genitalia are prepared with topical antiseptic solution and appropriate sterile draping applied to prepare a sterile field. Sedation or anaesthetics appropriate for the procedure and the facility may be given. Topical anaesthetic may be inserted into the urethra. The cystoscope is introduced into the urethra. Residual urine is collected and sent for urinalysis, culture or cytological studies if this is appropriate. The cystoscopic examination is then carried out. The bladder may need to remain filled for ancillary post cystoscopy procedures such as:

- uroflowmetry
- trial voiding
- residual urine measurements.

The bladder is emptied prior to the termination of the procedure.

After the Procedure

Following the procedure, the patient returns to the change room where bathroom facilities are available for the patient to urinate if necessary and to wash off the preparation solution before dressing and leaving the facility. Before discharge from the facility the patient **MUST** have the means of emptying the bladder spontaneously or mechanically or be aware of steps to follow in case of difficulty in voiding, haematuria or symptoms of UTI/Urosepsis. The patient's general condition is recorded before he/she is discharged.

The patient will be advised that there may be some discomfort on urination or some blood on urination and that this should pass within 24 hours. There is a clearly identified method for the patient to contact the physician performing the procedure or his qualified delegate should the patient be concerned about any untoward symptoms encountered after the cystoscopy. Post-operative antibiotics may or may not be used according to the nature of the procedure and risk factors for infection that the patient may have.

Chapter 8 Flexible Bronchoscopy

Overview

Flexible bronchoscopy is an invasive procedure that is utilized to visualize the nasal passages, pharynx, larynx, vocal cords, and tracheal bronchial tree. It is utilized for both the diagnosis and treatment of lung disorders.

Personnel

A dedicated operator performs the procedure. Personnel required for this procedure include a registered nurse (RN) or a respiratory therapist to administer and monitor conscious sedation. A second RN should be readily available to assist in the procedure room, as well as the dedicated RN or a respiratory therapist to assist the dedicated operator with the procedure. All supporting personnel should be familiar with the procedure being performed, as well as the appropriate handling of the specimens. This will maximize patient comfort, safety, and yield.

Flexible bronchoscopy may be performed under local anaesthesia with or without conscious sedation. An additional RN or RT should be immediately available if necessary.

Expertise in flexible bronchoscopy for the diagnosis of lung diseases is absolutely necessary. Trainees should perform procedures in a supervised setting to establish basic competency. In addition to the number of procedures, the competency of each trainee should be certified by the program director or the director of the bronchoscopy unit. Finally, it is important that training include competency in assisting a dedicated operator in the performance of the procedure.

The bronchoscopist must also ensure continuing medical education through attendance at meetings dealing with bronchoscopy.

Equipment

The equipment needed to perform this procedure may include but are not limited to the following:

- bronchoscope
- light source
- cytology brushes
- biopsy forceps
- needle aspiration catheters
- suction apparatus
- supplemental oxygen
- pulse oximetry
- sphygmomanometer
- EKG monitoring and equipment for resuscitation including an endotracheal tube
- video monitor is a useful accessory but not required
- fluoroscopy (C-arm) may be needed to facilitate certain transbronchial biopsy procedures.

Note: If fluoroscopy is used at an Independent Health Facility, then regulations will fall under the Clinical Practice Parameters and Facility Standards for Diagnostic Imaging.

Limitations

Flexible bronchoscopy can be used to visualize the respiratory tract up to and including the level of 2nd to 3rd generation bronchi. Samples from lower airways and the alveoli can only be obtained by employing the technique of bronchoalveolar lavage, the use of cytology and microbiologic brushes and the use of biopsy forceps. In some cases, there is a need for fluoroscopy localization of the areas to be sampled.

Patient Selection and Preparation

Note: *In cases where infectious etiologies are suspected (including but not limited to suspected tuberculosis, SARS) a negative pressure room is necessary for the preparation, recovery and the actual procedure.*

Informed Consent

Written informed consent is obtained prior to sedation.

Before the Procedure

A full history and physical examination should take place before the procedure as well as a clinical assessment of the patient's suitability for the bronchoscopy. The patient should be placed in either a semi-recumbent or supine position after IV access has been obtained. The patient should fast for at least 4 hours prior to the procedure. If the dedicated operator chooses to use the nose as the orifice of entry, the patient should have a topical anaesthetic applied to the pharynx and nasal passages. After the topical anaesthetic has taken effect, the bronchoscope is introduced either through the nose or mouth with a bite block in place.

The oropharynx is examined. After a thorough examination is performed and on reaching the vocal cords, the patient is usually again anaesthetized topically. The vocal cords are examined for abduction and adduction. The bronchoscope is passed through the vocal cords, and a complete airway inspection is performed.

Both therapeutic and diagnostic procedures can be performed during flexible bronchoscopy. Depending on the indication, the following diagnostic procedures can be performed:

- Bronchoalveolar lavage – (BAL)
- Endobronchial or transbronchial biopsies
- Cytologic wash or brush
- Transbronchial Needle Aspiration (TBNA)

Anticoagulation

Anticoagulation needs to be assessed prior to bronchoscopy. Because there is an unpredictable need for biopsy in patients undergoing bronchoscopy arrangements for appropriate anticoagulation should be made well before the procedure takes place. In patients with low risk conditions (i.e. uncomplicated non-valvular atrial fibrillation, bioprosthetic valve, mechanical valve in aortic position) warfarin should be discontinued 3-5 days before the scheduled procedure.

Patients with high risk conditions (i.e. atrial fibrillation associated with valvular heart disease, mechanical valves in the mitral position, mechanical valve and prior thromboembolic event) may need anticoagulation with heparin when the warfarin is discontinued and the INR falls to below therapeutic levels.

Aspirin and NSAIDS may be held for elective procedures. However the endoscopist should weigh the relative indications for these medications against the potential for bleeding.

There is inadequate data about the safety of patients undergoing biopsy. Temporary discontinuation of antiplatelet agents is desirable but must be weighed against the patient's risk of an adverse cardiac event related to discontinuation of the medication.

Medication in Special Patients

Patients who normally take cardiac medications including anti-hypertensives should take their usual medications on the day of the procedure with sips of water.

Approach to diabetic patients should be individualized and documented in the patient's chart.

Chapter 9 Capsule Endoscopy

Overview

This is a non-invasive means of examining the mucosal lining of the gastrointestinal tract and has particular value in evaluation of the small bowel.

Personnel

Upon arrival, nursing staff will input patient details into the computer workstation. To ingest the capsule a physician should be present if there may be any patient swallowing issues.

Nursing staff are provided with appropriate training concerning patient preparation and workstation operation.

Physicians must be trained in interpreting the images obtained. The physician must be well trained in gastroenterologic or general surgical interpretation of GI tract endoscopic pathology. CE training courses are offered and should be taken prior to performing this procedure.

Equipment

No endoscopes are used in this procedure. A computer workstation with specifically configured software and hardware is required. This is used for patient initialization, video image downloading, reviewing and interpreting the results of the procedure. A patient data recorder is also required. This equipment is mounted into a waist mounted holster and worn by the patient for the ambulatory procedure.

Patient Selection and Preparation

A full history and physical examination should take place before the procedure. Twenty-four hours prior to the capsule endoscopy procedure

the patient is instructed to consume only a clear liquid diet for lunch and supper. They will be asked to be NPO for 12 hours prior to the procedure and take either a light or full bowel prep at the discretion of the physician.

Anticoagulation

Since a biopsy cannot be performed with this technique no precautions are required related to anticoagulant medication.

Informed Consent

Written informed consent is obtained prior to ingestion of the capsule.

Medication in Special Patients

Patients who normally take cardiac medications including anti-hypertensives should take their usual medications on the day of the procedure with sips of water.

Approach to diabetic patients should be individualized and documented in the patient's chart.

Technique

Once the patient's data has been recorded into the computer and the data recorder is initialized the sensor array is affixed to the patient's abdomen and then connected to the data recorder in the holster.

The capsule is then ingested in the presence of a physician.

Note: Pro-motility medications may be necessary to hasten the capsule's exit from the stomach when gastroparesis may be a problem as in diabetic patients.

The capsule is taken with a glass or two of water and verification of proper capsule function is made by means of a flashing LED on the data recorder. The patient is then released for the approximately 7-8 hour procedure. Once they return to the facility, the equipment is removed and the patient images are downloaded from the recorder to the workstation. Patients need to verify with their doctor once the capsule has been excreted which is usually within 24-48 hours.

Once the study is downloaded the physician can review and interpret the images.

Chapter 10 Upper Gastrointestinal Endoscopy - Esophagogastroduodenoscopy

Overview

Endoscopic examination of the upper gastrointestinal tract is an accurate and informative method of evaluating a wide variety of digestive symptoms. It provides diagnostic and therapeutic options depending on the type and site of pathology.

Personnel

Endoscopy must be performed by individuals with training and expertise in both diagnostic procedures as well as therapeutic techniques such as biopsy, dilatation and haemostasis. This training should take place in an accredited program in either gastroenterology or general surgery.

In addition to technical competence, this individual should have a thorough knowledge of the interpretive and cognitive aspects of endoscopy. This includes the management of esophageal and gastric diseases for which the endoscopy is taking place. The endoscopist should provide consultation as to the medical or surgical aspects of the disease as they relate to endoscopy and should not be an individual who only provides technical service.

The endoscopist must also ensure continuing medical education through attendance at meetings dealing with endoscopy.

A nurse should be available at all times during the endoscopy to monitor the patient's vital signs, administer medications, and assist the endoscopist with certain technical aspects of the procedure.

Equipment

Forward viewing and oblique and side viewing video-endoscopes/fibre optic endoscopes are used for examination of the upper gastrointestinal tract. They vary in diameter depending on the purpose of the endoscopy and the pathology suspected. Light source and video monitor are

required plus ancillary equipment such as video capture units and equipment for suction, biopsy and any other therapeutic procedure may be required.

Patient Selection and Preparation

A full history and physical should take place before the procedure. The endoscopist is responsible to ensure the procedure is indicated. Following clinical assessment of a patient's suitability for elective endoscopy the patient should fast for 6 hours prior to the procedure. Pre-medication for analgesia and conscious sedation may be given if required. Topical pharyngeal anaesthesia may be administered by spray or gargle.

Prophylactic Antibiotics

Antibiotics may be indicated prior to the procedure in selected patients with certain cardiac conditions. (ASGE guidelines)

Anticoagulation

Anticoagulation needs to be assessed prior to endoscopy. Arrangements for appropriate management of anticoagulation should be made well before the procedure takes place and documented in the patient's chart. In patients with low risk conditions (i.e. uncomplicated, non-valvular atrial fibrillation, bioprosthetic valve, mechanical valve in the aortic position) Warfarin should be discontinued 3-5 days before the scheduled procedure.

Patients with high risk conditions (i.e. atrial fibrillation associated with valvular heart disease, mechanical valve in the mitral position, mechanical valve and prior thromboembolic event) may need anticoagulation with heparin when the Warfarin is discontinued and the INR falls to below therapeutic levels.

Aspirin and NSAIDS may be held for elective procedures. However, the endoscopist should weigh the relative indications for these medications against the potential risk for bleeding.

There is inadequate data on the safety of antiplatelet agents in patients undergoing biopsy. Temporary discontinuation of antiplatelet agents is desirable but must be weighed against the patient's risk of an adverse cardiac event related to discontinuation of the medication.

Laboratory Testing

There are no routine pre-procedure tests recommended for patients undergoing endoscopy. Pre-procedure testing should be performed selectively based on the medical history and physical exam. Measurement of coagulation parameters including platelet count is recommended when there is a history of a bleeding disorder, chronic liver disease or haematologic disorder that might interfere with clotting. An electrocardiogram should be considered for those with a history of heart disease.

Medication in Special Patients

Patients who normally take cardiac medications including anti-hypertensives should take their usual medications on the day of the procedure with sips of water.

Approach to diabetic patients should be individualized and documented in the patient's chart.

Informed Consent

Written informed consent is obtained prior to sedation.

Technique

During the procedure an assistant monitors the overall clinical status of the patient and provides technical assistance for the endoscopist. The patient is appropriately positioned and the flexible endoscope is guided through the mouth and either under direct vision through the upper esophageal sphincter or by asking the patient to swallow and with gentle pressure the endoscope is advanced through the sphincter. This procedure may also be performed transnasally with a thin endoscope in which case the scope is passed into a nostril and under direct vision passes through the upper sphincter of the esophagus.

The instrument is then passed under direct vision through the length of the esophagus and stomach and is usually passed through the pylorus into the cap and commonly the second portion of the duodenum. Insufflation of gas and suction of gastrointestinal secretions are usually required. Careful inspection of all mucosal surfaces to identify pathology is performed during both scope insertion and withdrawal. Photography and/or video recording may be performed.

Endoscope channels allow for procedures such as:

- Biopsy
- Cytology
- Therapeutic maneuvers such as positioning of
 - a flexible guide wire
 - a dilating device
 - a cautery device
 - a laser fibre
 - a basket for foreign body extraction
 - Injection needle.

Chapter 11 Colonoscopy

Overview

Endoscopic examination of the lower gastrointestinal tract is an accurate and informative method of evaluating a wide variety of digestive symptoms pertaining to colonic function. It provides diagnostic and therapeutic options depending on the type and site of pathology

Personnel

Colonoscopy must be performed by individuals with training and expertise in both diagnostic procedures as well as therapeutic techniques such as snare polypectomy and haemostasis. This training should take place in an accredited program in either gastroenterology or general surgery.

In addition, to technical competence this individual should have a thorough knowledge of the interpretive and cognitive aspects of endoscopy. This includes the management of colonic diseases for which the colonoscopy is taking place. The endoscopist should provide consultation as to the medical or surgical aspects of colorectal disease as they relate to colonoscopy and should not be an individual who only provides technical service.

The endoscopist must also ensure continuing medical education through attendance at meetings dealing with endoscopy.

A nurse should be available at all times during the endoscopy to monitor the patient's vital signs, administer medications and assist the endoscopist with certain technical aspects of the procedure.

Equipment

Forward viewing video-endoscopes are used for examination of the lower gastrointestinal tract. Light source and video monitor are required plus ancillary equipment such as video capture units and equipment for suction, biopsy and any other therapeutic procedure may be required.

Patient Selection and Preparation

A full history and physical examination should take place before the procedure. The endoscopist is responsible to ensure that the procedure is indicated and that the patient is in acceptable condition to undergo the procedure.

Bowel Preparation

Inherent in a colonoscopy procedure is the bowel preparation. The quality of colonic examination is dependent on the quality of bowel preparation. The endoscopist should have a thorough understanding of the options available, the benefits and risks of each.

The endoscopist should individualize the bowel regimen based on each patient's medical history and on the indications for the procedure.

Prophylactic antibiotics

Antibiotics may be indicated prior to the procedure in selected patients with certain cardiac conditions. (ASGE guidelines)

Anticoagulation

Anticoagulation needs to be assessed prior to colonoscopy. Arrangements for appropriate management of anticoagulation should be made well before the procedure takes place and documented in the patient's chart. In patients with low risk conditions (ie. uncomplicated, nonvalvular atrial fibrillation, bioprosthetic valve, mechanical valve in the aortic position) Warfarin should be discontinued 3-5 days before the scheduled procedure. Patients with high risk conditions (ie. Atrial fibrillation associated with valvular heart disease, mechanical valve in the mitral position, mechanical valve and prior thromboembolic event) may need anticoagulation with heparin when the warfarin is discontinued and the INR falls to below therapeutic levels.

Generally aspirin and NSAIDS are held for elective procedures. However, the endoscopist should weigh the relative indications for these medications against the potential risk for bleeding.

There is inadequate data on the safety of anti-platelet agents in patients undergoing biopsy or polypectomy. Temporary discontinuation of the agents is desirable but must be weighed against the patient's risk of an adverse cardiac event related to discontinuation of the medication.

Laboratory Testing

There are no routine pre-procedure tests recommended for patients undergoing colonoscopy. Pre-procedure testing should be performed selectively based on the medical history and physical exam. Measurement of coagulation parameters including platelet count is recommended when there is a history of a bleeding disorder, chronic liver disease or hematologic disorder that might interfere with clotting. An electrocardiogram should be considered for those with a history of heart disease.

Medication in Special Patients

Patients who normally take cardiac medications including anti-hypertensives should take their usual medications on the day of the procedure with sips of water.

Approach to diabetic patients should be individualized and documented in the patient's chart.

Informed Consent

Written informed consent is obtained prior to sedation.

Procedure

Colonoscopy is generally performed with conscious sedation administered intravenously. However, there are some patients who tolerate the procedure well without sedation. If intravenous sedation is used then the appropriate standard of care must be employed (see section on sedation). During the procedure an assistant monitors the overall clinical status of the patient and provides technical assistance for the endoscopist.

The patient is generally placed in the left lateral decubitus position and a perianal examination including a digital rectal examination is performed. The colonoscope is inserted into the rectum and maneuvered to the terminal ileum. The endoscopist must be skilled in techniques that improve patients comfort and that lead to a high percentage of complete procedures. These include:

- loop prevention and reduction
- transabdominal pressure
- changes in body position

For colon cancer screening and surveillance, cecal intubation rates approaches 95% of otherwise asymptomatic patients.

Careful examination of the colon on withdrawal of the scope is essential to minimize polyp miss rates. Retroflexion in the rectum is encouraged especially for evaluation of hematochezia.

Endoscopists should be skilled in the following techniques:

- Tattooing
- Biopsy
- Polypectomy (including submucosal injection)
- Polyp retrieval.

In addition, the endoscopist must have skills to deal with post polypectomy bleeding.

Some effective techniques may include: injection, cautery, and placement of endo-loops and clips.

Chapter 12 Sigmoidoscopy

Overview

Traditionally, sigmoidoscopy, initially as applied to rigid sigmoidoscopy has been performed in hospitals, clinics and physicians' offices. More recently, flexible sigmoidoscopy has been used, particularly in a clinic or office setting without the necessity of having an Independent Health Facility designation.

These recommendations therefore should apply only to the standards and practice parameters associated with flexible sigmoidoscopy within the setting of a designated IHF.

Personnel

The endoscopy procedure must be performed by individuals with training and expertise in both diagnostic procedures as well as therapeutic techniques used in sigmoidoscopy. In addition to technical competence this individual should have a thorough knowledge of the interpretive and cognitive aspects of endoscopy. The endoscopist must also ensure continuing medical education through attendance at meetings with dealing with endoscopy.

Handling, cleaning and processing of endoscopes and accessories must meet identical standards with colonoscopy and gastroscopy procedures.

A nurse may be available during the sigmoidoscopy to monitor the patient's vital signs, administer medications, and assist the endoscopist with certain technical aspects of the procedure.

Equipment

Forward viewing video-endoscopes/fibre optic endoscopes are used for examination of the rectum and sigmoid colon. Light source and video monitor are required plus ancillary equipment such as video capture units and equipment for suction, biopsy and any other therapeutic procedure may be required.

Patient Selection and Preparation

A full history and physical examination should take place before the procedure. The endoscopist is responsible to ensure that the procedure is indicated and that the patient is in acceptable condition to undergo the procedure.

Bowel Preparation

Inherent in a sigmoidoscopy procedure is the bowel preparation. The quality of colonic examination is dependent on the quality of bowel preparation. The endoscopist should have a thorough understanding of the options available, the benefits and risks of each.

The endoscopist should individualize the bowel regimen based on each patient's medical history and on the indications for the procedure.

Prophylactic antibiotics

Antibiotics may be indicated prior to the procedure in selected patients with certain cardiac conditions. (ASGE guidelines)

Anticoagulation

Anticoagulation needs to be assessed prior to sigmoidoscopy. Arrangements for appropriate management of anticoagulation should be made well before the procedure takes place and documented in the patient's chart. In patients with low risk conditions (ie. uncomplicated, nonvalvular atrial fibrillation, bioprosthetic valve, mechanical valve in the aortic position) Warfarin should be discontinued 3-5 days before the scheduled procedure. Patients with high risk conditions (ie. Atrial fibrillation associated with valvular heart disease, mechanical valve in the mitral position, mechanical valve and prior thromboembolic event) may need anticoagulation with heparin when the warfarin is discontinued and the INR falls to below therapeutic levels.

Generally aspirin and NSAIDS are held for elective procedures despite a small collection of data that suggests these agents in standard doses are safe in patients undergoing colonoscopy with biopsy or polypectomy. However, the endoscopist should weigh the relative indications for these medications against the potential risk for bleeding.

There is inadequate data on the safety of anti-platelet agents in patients undergoing biopsy or polypectomy. Temporary discontinuation of the agents is desirable but must be weighed against the patient's risk of an adverse cardiac event related to discontinuation of the medication.

Laboratory Testing

There are no routine pre-procedure tests recommended for patients undergoing sigmoidoscopy. Pre-procedure testing should be performed selectively based on the medical history and physical exam. Measurement of coagulation parameters including platelet count is recommended when there is a history of a bleeding disorder, chronic liver disease or haematologic disorder that might interfere with clotting. An electrocardiogram should be considered for those with a history of heart disease.

Medication in Special Patients

Patients who normally take cardiac medications including anti-hypertensives should take their usual medications on the day of the procedure with sips of water.

Approach to diabetic patients should be individualized and documented in the patient's chart.

Informed Consent

Written informed consent is obtained prior to sedation.

**Independent Health Facilities:
Clinical Practice Parameters
and Facility Standards:
Endoscopy**

Volume 2

Clinical Practice Parameters

Chapter 13 Cystoscopy

Overview

Direct visualization of the anterior and posterior urethra, bladder neck and bladder is accomplished by cystourethroscopy. The primary indication for cystourethroscopy is the diagnosis of lower urinary tract disease. However, access to the upper urinary tract for diagnosis and treatment can be accomplished cystoscopically.

With respect to the diagnosis of lower urinary tract disorders, signs and symptoms that may be related to the urinary tract are evaluated using cystourethroscopy to directly visualize lower urinary tract anatomy and macroscopic pathology, which may be responsible for the clinical picture under evaluation. In addition, material for both cytologic and histologic examination can be obtained using cystourethroscopic techniques. One of the most common indications for cystourethroscopy is in the evaluation of microscopic and gross haematuria. By combining radiographic and endoscopic techniques, one can usually determine the source of bleeding in the upper or lower urinary tract. Other indications for cystourethroscopy include evaluation of voiding symptoms (obstructive and irritative), which may be the result of neurologic, inflammatory, neoplastic or congenital abnormalities.

The section relates only to lower urinary tract visualization by cystourethrography.

Indications

Indications for cystoscopy include the investigation of:

- suspected genitourinary infection
- malignant and benign lesions of the lower genitourinary tract
- trauma
- urinary incontinence
- neurogenic bladder
- haematuria gross and microscopic
- pre-transplant evaluation
- suspected congenital/acquired abnormalities of the lower urinary tract.

Surveillance cystoscopy for:

- malignant lesions of the lower urinary tract
- urinary incontinence/neurogenic bladder
- congenital/acquired lesions of the lower genitourinary tract.

Contraindications

Absolute

There are no absolute contraindications to cystourethrography under local anaesthetic or conscious sedation in the adult male or female patient.

Relative

The relative contraindications for this procedure relate to the comorbidities of the patient. For most IHF facilities ASA classes I and II level cases are appropriate. For specific cases ASA class III can be performed when an Anaesthesiologist is on site.

Specific examples related to the urologic condition include:

- known severe stricture disease or Bladder Neck Contracture requiring vigorous dilatation
- history of difficult cystoscopy.

Risks

Risks include:

- urethral trauma
- bladder perforation – extraperitoneal, intraperitoneal
- severe bleeding with frequent clots, not responsive to manual irrigation
- urinary tract infection
- urosepsis
- urinary retention.

Documentation

Documentation in the patient's chart includes but is not limited to the following:

- type, amount and time of administration of anaesthesia, analgesia and sedation.
- type, amount and time of administration of other drugs
- vital signs including heart rate, blood pressure and O₂ saturation pre-operatively and at least every 5 minutes during the procedure.
- continuous ECG recording in select cases
- procedure technique
- procedure findings
- treatment advice
- pathology and lab results
- post-procedure vital signs
- discharge and follow-up instructions
- any adverse outcome resulting from the procedure.

Chapter 14 Flexible Bronchoscopy

Overview

Flexible bronchoscopy is an invasive procedure that is utilized to visualize the nasal passages, pharynx, larynx, vocal cords, and tracheal bronchial tree. It is utilized for both the diagnosis and treatment of lung disorders.

Indications

Indications include, but are not limited to:

- undiagnosed pulmonary infiltrates
- lung masses
- mediastinal lymphadenopathy
- haemoptysis
- airway disorders
- endobronchial lesions
- therapeutic suctioning.

Contraindications

Absolute

There are no absolute contraindications to flexible bronchoscopy under local anaesthetic or conscious sedation in the adult male or female patient.

Relative

The relative contraindications for this procedure relate to the comorbidities of the patient. For most IHF facilities ASA class I and II level cases are appropriate. For specific cases ASA class III can be performed when an Anaesthesiologist is on site.

Special attention must be paid to respiratory and bleeding status.

Risks

Diagnostic flexible bronchoscopy is usually an extraordinarily safe procedure. Major complications such as bleeding, respiratory depression, cardiorespiratory arrest, arrhythmia, and tension pneumothorax on site occur in ~ 1% of cases. Mortality is rare with a reported death rate of 0 to 0.04% in 68,000 procedures. Physicians must be able to deal with tension pneumothorax and able to deal with airway management.

Flexible Diagnostic Bronchoscopy

Flexible bronchoscopy is a procedure in which the upper and lower respiratory systems are accessed with the fiberoptic bronchoscope via the oral or nasal route. The indications include, but are not limited to:

- identification of endobronchial lesions
- identification of extrinsic or intrinsic compression of the airways
- identification of site of bleeding in cases of haemoptysis
- visualization of bronchial anastomose in lung transplant recipients
- visualization of bronchial stumps in patients with pneumonectomy/lobectomy
- visualization of the vocal cords and the anatomy of the pharynx
- toileting of pulmonary secretions.

Flexible Diagnostic Bronchoscopy with Bronchoalveolar Lavage

Bronchoalveolar lavage is performed with flexible diagnostic bronchoscopy by the instillation and subsequent suctioning of 60-200 cc of normal saline into the lobar segment of interest. These include, but are not limited to obtaining appropriate:

- culture material from the lower respiratory tract for the diagnosis of infection

- material for cytology from the lower respiratory tract in order to diagnose a malignancy
- material for cell count and differential in order to help in the diagnosis of interstitial lung disease
- material for the diagnosis of diffuse alveolar haemorrhage.

Flexible Diagnostic Bronchoscopy with Endobronchial or Transbronchial Biopsy

Endobronchial or transbronchial biopsy is performed by using alligator forceps in order to obtain material for pathologic examination, under direct visualization (endobronchial) and/or blindly or with fluoroscopic visualization (transbronchial). The indications for this procedure include, but are not limited to transbronchial:

- or endobronchial biopsy of abnormal masses for the diagnosis of malignancy
- biopsy in patients with diffuse lung disease for the diagnosis of interstitial lung disease
- or endobronchial biopsy of abnormal areas for the diagnosis of infection.

Note: Chest X-ray should be readily available if biopsy is performed.

Flexible Diagnostic Bronchoscopy with Cytology or Microbiology Brushing

Brushes can be used in order to obtain material from endobronchial lesions or from other abnormal areas of the lung blindly or with fluoroscopic guidance. The protected brush is used for microbiologic sampling, while the cytology brush is used for other specimens. The indications include, but are not limited to obtaining material:

- with a sterile brush (protected brush specimen) from a particular area of the lung for microbiologic analysis
- suitable for cytologic examination either with direct visualization, blindly or with fluoroscopic guidance.

Flexible Diagnostic Bronchoscopy with Transbronchial Needle Aspiration

Transbronchial needle aspiration (TBNA) is a minimally invasive procedure that provides a non-surgical means to diagnose and stage bronchogenic carcinoma by sampling the mediastinal lymph nodes. The needle can also be used to sample endobronchial lesions under direct or fluoroscopic visualization.

Note: Some of the procedures described above can be aided by the use of fluoroscopy. If an IHF has fluoroscopy available, then it also needs to follow the Clinical Practice Parameters and Facility Standards for Diagnostic Imaging.

Documentation

Documentation in the patient's chart includes but is not limited to the following:

- type, amount and time of administration of anaesthesia, analgesia and sedation
- type, amount and time of administration of other drugs
- vital signs including heart rate, blood pressure and O₂ saturation pre-operatively and at least every 5 minutes during the procedure
- continuous ECG recording in select cases
- procedure technique
- treatment advice
- pathology and lab results
- post-procedure vital signs
- discharge and follow-up instructions.

Chapter 15 Capsule Endoscopy

Overview

Capsule Endoscopy (CE) is undertaken to define causes of obscure Gastrointestinal Tract bleeding and to assess and diagnose specific conditions in the small bowel. It is a new technique that is ideally suited to being performed in an IHF.

Indications

Capsule Endoscopy is indicated for the evaluation of obscure causes of gastrointestinal bleeding. It is also useful for diagnosis and evaluation of disease severity in small bowel disease in the gastrointestinal tract.

Contraindications

Absolute

There are no absolute contraindications to capsule endoscopy in the adult male or female patient.

Relative

The relative contraindications for this procedure relate to the comorbidities of the patient. For most IHF facilities ASA class I and II level cases are appropriate. For specific cases ASA class III can be performed when an Anaesthesiologist is on site.

Special attention must be paid to:

- oropharyngeal dysphagia
- benign or malignant esophageal, gastric, small bowel or colonic stricture
- small or large bowel obstruction.

Documentation

Documentation in the patient's chart includes but is not limited to the following:

- type, amount and time of administration of other drugs
- procedure technique
- procedure findings
- treatment advice
- pathology and lab results
- discharge and follow-up instructions
- any adverse outcome resulting from the procedure.

Chapter 16 Upper Gastrointestinal Endoscopy Esophagogastroduodenoscopy

Overview

Endoscopic examination of the upper gastrointestinal tract is an accurate and informative method of evaluating a wide variety of digestive symptoms. It is an invasive technique, which may require sedation and analgesia to perform. Both diagnostic and therapeutic options exist depending on the pathology identified.

Indications

The conditions for which upper gastrointestinal endoscopy may provide diagnostic information include:

- upper abdominal distress, especially after a trial of therapy
- persistent esophageal reflux symptoms despite appropriate therapy
- swallowing difficulties
- persistent vomiting of unknown cause
- clinical or X-ray findings of a tumor in the upper GI tract
- x-ray findings of gastric or esophageal ulcer, stricture or mass
- gastrointestinal bleeding
- surveillance for specific conditions such as Barrett's esophagus, adenomatous gastric polyps and some ulcers of the stomach and esophagus to demonstrate healing.

Upper Abdominal Distress (Dyspepsia)

Most patients with dyspepsia as an isolated symptom may be treated empirically, however those patients with no response to therapy, or with symptoms recurrence or those who show signs of severe systemic illness and/or develop signs of complications of peptic ulcer disease such as bleeding, weight loss, obstruction or perforation will require endoscopy as the initial diagnostic evaluation.

If an x-ray is performed and the findings are normal or equivocal endoscopy can establish a precise diagnosis.

Persistent Esophageal Reflux Symptoms

Gastroesophageal reflux is characterized clinically by retrosternal burning relieved by antacids and associated symptoms of regurgitation, dysphagia and odynophagia.

Following an initial trial of therapy if symptoms persist endoscopy is recommended. If clues exist of severe reflux such as symptoms of dysphagia, bleeding, progression of symptoms while on therapy or a mass on x-ray endoscopy is always indicated for evaluation. Presence of a hiatus hernia or gastroesophageal reflux on x-ray alone is not an indication for endoscopy.

Follow-up endoscopy for gastroesophageal reflux disease is generally not necessary if symptoms respond to therapy and there is no evidence of an esophageal ulcer or requirement for repeat biopsy to clarify a diagnosis.

In a patient with severe esophagitis or in one who is unresponsive to therapy biopsy may be necessary. Biopsy and cytology may be needed to identify malignancy and metaplastic columnar mucosal changes of Barrett's esophagus.

Clinical or X-ray Findings of a Tumor of the Upper Gastrointestinal Tract

Patients with a prior upper gastrointestinal x-ray demonstrating a radiologically "malignant" lesion should always undergo endoscopy and biopsy.

X-ray Findings of Gastric or Esophageal Ulcer, Stricture or Mass

Patients with an upper gastrointestinal x-ray demonstrating a gastric ulcer should be followed by endoscopic evaluation to obtain tissue for diagnosis and ensure that the ulcer has healed.

Gastrointestinal Bleeding

In patients with active upper gastrointestinal bleeding endoscopy is the most useful initial diagnostic procedure. For the purposes of these guidelines bleeding can be considered in 3 categories:

1. Active haemorrhage, which is usually manifested by hematemesis and for which transfusion requirements and evidence of hypovolemia are frequently seen - this type of patient should not be dealt with in an IHF
2. Acute self-limited blood loss in which cessation of active bleeding is presumed because there is haemodynamic stability and no evidence of continuing fresh blood loss
3. Chronic bleeding occurring over weeks or months.

Category 1

Patients with active haemorrhage should not be endoscoped in an IHF since prolonged monitoring following the procedure is required and urgent endoscopy during active bleeding requires the participation of appropriate personnel and therapeutic techniques which may not be available in the IHF.

Category 2

Patients in this category who are haemodynamically stable without evidence of active ongoing haemorrhage may have benefit from urgent endoscopy especially in patients with known liver disease, and in patients with rebleeding after initial stabilization. If identification of the bleeding source seems appropriate endoscopy is most accurate when done within 24 hours of the bleeding episode.

Category 3

Patients in this category often require study of the entire gastrointestinal tract. The source of occult bleeding in asymptomatic patients is usually discovered in the colon, however endoscopic search for upper gastrointestinal sites may be indicated by history. Most of the therapeutic techniques for control of active upper gastrointestinal haemorrhage will not be required for management of category 2 and 3 bleeding.

Surveillance of premalignant conditions of the upper gastrointestinal tract

There is a well-recognized risk of developing adenocarcinoma in the esophagus of patients with Barrett's esophagus. Although the long-term benefits of endoscopic surveillance have not been determined patients with histologic confirmation of Barrett's esophagus may benefit from periodic endoscopic examination and biopsies of the columnar portion of the esophagus.

Gastric mucosal adenomatous polyps carry a risk for malignancy. All patients with polypoid defects on x-ray should be initially endoscoped and biopsied.

Contraindications

Absolute

There are no absolute contraindications to upper gastrointestinal endoscopy esophagogastroduodenoscopy under local anaesthetic or conscious sedation in the adult male or female patient.

Relative

The relative contraindications for this procedure relate to the comorbidities of the patient. For most IHF facilities ASA classes I and II level cases are appropriate. For specific cases ASA class III can be performed when an Anaesthesiologist is on site.

Special attention must be paid to:

- lack of patient cooperation
- known or suspected perforated viscus.

Complications

Upper gastrointestinal endoscopy is a relatively safe procedure. Major complications include bleeding, perforation, aspiration or cardiac events.

Serious complications during diagnostic endoscopy occur approximately 1 in 800 and the risk of death is approximately 1 in 5,000. Risks with therapeutic endoscopy are higher and depend on the type of therapy as well as the pathology being treated.

Documentation

Documentation in the patient's chart includes but is not limited to the following:

- type, amount and time of administration of anaesthesia, analgesia and sedation.
- type, amount and time of administration of other drugs
- vital signs including heart rate, blood pressure and O₂ saturation pre-operatively and at least every 5 minutes during the procedure
- continuous ECG recording in select cases
- procedure technique
- procedure findings
- treatment advice
- pathology and lab results
- post-procedure vital signs
- discharge and follow-up instructions.
- any adverse outcome resulting from the procedure.

Chapter 17 Colonoscopy

Overview

Endoscopic examination of the lower gastrointestinal tract is an accurate and informative method of evaluating a wide variety of digestive symptoms. It is an invasive technique which often requires sedation and analgesia to perform. Both diagnostic and therapeutic options exist with this procedure depending on the type and site of pathology identified.

Indications

Indications for colonoscopy include but are not limited to the following:

- Colon Cancer Screening/Surveillance:
 - asymptomatic individuals age >50
 - family history of polyps/cancer
 - personal history cancer/polyps
 - individuals with several years history of Ulcerative or Crohn's colitis
- Investigation of unexplained gastrointestinal bleeding
 - Overt and occult
- Investigation of unexplained iron deficiency anemia
- Chronic IBD –when determining extent or severity of disease and the information is likely to change clinical management
- Abnormal Barium enema such as a filling defect or stricture
- Chronic Diarrhea
- Treatment of bleeding from a lesion such as angiodysplasia, ulceration, neoplasia and polypectomy site
- Foreign body removal
- Excision of polyps
- Balloon dilation of stenotic lesions
- Palliative treatment of stenosing or bleeding lesions
- Marking a neoplasm for surgical removal
- Fecal Incontinence
- Decompression of sigmoid volvulus

Contraindications

Absolute

There are no absolute contraindications to colonoscopy under local anaesthetic or conscious sedation in the adult male or female patient.

Relative

The relative contraindications for this procedure relate to the comorbidities of the patient. For most IHF facilities ASA class I and II level cases are appropriate. For specific cases ASA class III can be performed when an Anaesthesiologist is on site.

Special attention must be paid to:

- acute diverticulitis
- recent MI
- peritonitis
- toxic megacolon

Complications

Post polypectomy bleeding

This is the most common post-polypectomy complication and may occur immediately or be delayed (usually within one week but can occur up to 2 weeks after the procedure). The risk of bleeding depends on the nature of the polyp with large, sessile polyps carrying the most risk. The overall rate of bleeding is 1-2%.

The risk of bleeding can be reduced by the sole use of coagulating current and slow transection. Bleeding that occurs immediately can usually be controlled by the endoscopist. Techniques include resnaring the stalk, retranssection, placement of endoloops or clips, Epinephrine injection, BICAP, heaterprobe and APC. When delayed bleeding occurs the patient may present after the facility is closed. Therefore, there must be arrangements with a local Hospital for after hours care and the patient must be given appropriate written instructions on where to seek medical care in such an event. Usually an emergency colonoscopy is indicated and the above techniques used.

Perforation

Perforation is an uncommon complication following colonoscopy with rates of 1 in 2500. The risk is higher after polypectomy (0.04 to 2%). The risk is also related to polyp size and location with large, right sided, sessile polyps having the highest risk. When frank perforation occurs immediate surgery is needed and the patient should be transported to the nearest hospital while being supported by intravenous fluids and antibiotics. When perforation is not frank but suspected because of pain, leukocytosis, or fever the patient should be admitted to hospital, given iv fluids, antibiotics and a surgical consultation obtained.

Post-polypectomy syndrome/serositis/transmural burn syndrome

This syndrome is a result of a transmural burn causing irritation of the serosal surface with a localized inflammatory response. It occurs in 1% of polypectomies. The patient may complain of localized pain, tenderness, guarding and rigidity. There may be fever, tachycardia and leucocytosis. Patients usually present 6 hours to 5 days post-polypectomy. Patients with severe symptoms require hospitalization, iv fluids and close observation, Symptoms usually resolve in 2-5 days. Appropriate imaging and surgical consultation may be needed as the differential diagnosis is perforation.

Documentation

Documentation in the patient's chart includes but is not limited to the following:

- type, amount and time of administration of anaesthesia, analgesia and sedation
- type, amount and time of administration of other drugs
- vital signs including heart rate, blood pressure and O₂ saturation pre-operatively and at least every 5 minutes during the procedure
- continuous ECG recording in select cases
- procedure technique
- procedure findings including adequacy of bowel preparation
- treatment advice
- extent of visualization (cecum confirmed by photography)
- pathology and lab results
- post-procedure vital signs

- discharge and follow-up instructions
- any adverse outcome resulting from the procedure.

Outcome Indicators

The facility should maintain a system to track the following outcome indicators:

- Appropriateness of procedure
- Complication rate
- Appropriate management of complications
- Patient satisfaction
- Technical success
- In Cases of screening/surveillance colonoscopy
 - Cecal intubation rates
 - Polypectomy rates

Chapter 18 Sigmoidoscopy

Overview

Traditionally, sigmoidoscopy, initially as applied to rigid sigmoidoscopy has been performed in hospitals, clinics and physicians' offices. More recently, flexible sigmoidoscopy has been used, particularly in a clinic or office setting without the necessity of having an Independent Health Facility designation.

These recommendations therefore should apply only to the standards and practice parameters associated with flexible sigmoidoscopy within the setting of a designated IHF.

Indications

Indications for sigmoidoscopy include but are not limited to the following:

- recent rectal bleeding
- persistent diarrhea, particularly with urgency
- diarrhea associated with rectal bleeding
- screening for colorectal cancer
- follow-up of positive fecal blood testing with DCBE when colonoscopy refused or unavailable in a timely fashion
- decompression of sigmoid volvulus
- follow-up of lesions of rectum and/or sigmoid
- follow-up of inflammatory bowel disease, particularly left sided
- surveillance for neoplasia after subtotal colectomy

Contraindications

Absolute

There are no absolute contraindications to sigmoidoscopy under local anaesthetic or conscious sedation in the adult male or female patient.

Relative

The relative contraindications for this procedure relate to the comorbidities of the patient. For most IHF facilities ASA classes I and II level cases are appropriate. For specific cases ASA class III can be performed when an Anaesthesiologist is on site.

Special attention must be paid to:

- severe acute diverticulitis
- peritonitis
- toxic megacolon

Documentation

Documentation in the patient's chart includes but is not limited to the following:

- type, amount and time of administration of anaesthesia, analgesia and sedation.
- type, amount and time of administration of other drugs
- vital signs including heart rate, blood pressure and O₂ saturation pre-operatively and at least every 5 minutes during the procedure
- continuous ECG recording in select cases
- procedure technique
- procedure findings
- treatment advice
- pathology and lab results
- post-procedure vital signs
- discharge and follow-up instructions
- any adverse outcome resulting from the procedure.

Appendix I

Independent Health Facilities Act - Ontario Regulation 346/04 Amended to O. Reg. 57/92

Note: Ontario Regulation 57/92 has previously been amended. Those amendments are listed in the Table of Regulations - Legislative History Overview which can be found at www.e-laws.gov.on.ca. Facilities are encouraged to check the Ontario Government Website for updates.

Quality Advisor and Advisory Committee

1 (1) Every licensee shall appoint a quality advisor to advise the licensee with respect to the quality and standards of services provided in the independent health facility.

(2) If the quality advisor dies or ceases to be the quality advisor, the licensee shall appoint a new quality advisor forthwith.

(3) The quality advisor must be a health professional who ordinarily provides insured services in or in connection with the independent health facility and whose training enables him or her to advise the licensee with respect to the quality and standards of services provided in the facility.

(4) It is a condition of a licence that the quality advisor be a physician if all the insured services provided in the independent health facility that support the facility fees that the licensee may charge are provided by physicians.

(5) In subsection (4), an insured service supports a facility fee if the facility fee is for or in respect of a service or operating cost that supports, assists or is a necessary adjunct to the insured service.

(6) A licensee who is qualified under subsection (3) may appoint himself or herself as the quality advisor only if there is no other health professional who is qualified to be the quality advisor who will consent to be the quality advisor. O Reg 57/92, s.1.

2 (1) Every licensee shall appoint an advisory committee to advise the quality advisor.

(2)The advisory committee shall consist of health professionals who provide health services in or in connection with the independent health facility.

(3)The quality advisor shall be the chair of the advisory committee.

(4)Every licensee shall use his or her best efforts to ensure that there is a representative on the advisory committee from the health profession and each specialty and sub-specialty of medicine, practitioners of which provide health services in or in connection with the independent health facility. O Reg. 57/92, s.2.

3 (1)Every licensee shall give the Director the name of the quality advisor in writing forthwith after the quality advisor is appointed.

(2)If the quality advisor dies or ceases to be the quality advisor, the licensee shall inform the Director in writing forthwith.

(3)Every licensee shall give the Director, on request, the names of the members of the advisory committee in writing. O. Reg. 57/92, s.3.

Standards

4 (1)Every licensee shall ensure that all aspects of the services provided in the independent health facility are provided in accordance with generally accepted professional standards.

(2)Every licensee shall ensure that the persons who provide services in the independent health facility are qualified, according to generally accepted professional standards, to provide those services.

(3)If the quality advisor has reasonable grounds to believe that this section is not being complied with, he or she shall inform the Director forthwith. O. Reg. 57/92, s.4.

5 Every licensee shall keep a system to monitor the results of the services provided in the independent health facility. O. Reg. 57/92, s.5.

6 (1)Every licensee shall ensure that all tissues removed from a patient during an operation or curettage performed in an independent health facility are sent to a laboratory for examination and report unless the physician performing the operation or curettage is of the opinion that it is not necessary according to generally accepted medical standards.

(2)The licensee shall ensure that a short history of the case and a statement of the findings of the operation or curettage are sent with the tissues. O. Reg. 57/92, s.6.

Records of Employees

7 (1) Every licensee of an independent health facility shall maintain, for each employee of the facility who is not a physician, an employment record setting out the employee's qualifications and employment history including a record of any registration with or licensing by the governing body of a health profession.

(2) Every licensee shall retain an employee's employment record for at least two years after the employee ceases to be an employee. O. Reg. 57/92, s.7.

8 (1) Every licensee of an independent health facility shall maintain a record of qualifications and work history for:

(a) each person the licensee contracts with to manage the facility; and

(b) each person who is not a physician who the licensee contracts with to provide patient-related services in the facility.

(2) The record shall include a record of any registration with or licensing by the governing body of a health profession.

(3) Every licensee shall retain the record for a person the licensee contracts with for at least two years after the licensee ceases to contract with the person. O. Reg. 57/92, s.8.

9 (1) Every licensee shall maintain a declaration of professional standing for each physician who provides professional services in the independent health facility.

(2) A declaration of professional standing must include the following information:

1. The physician's name
2. The physician's registration number with the College of Physicians and Surgeons of Ontario
3. The physician's number registered with the Health Insurance Division of the Ministry of Health.
4. The class of the physician's licence issued under Part III of the *Health Disciplines Act* and any terms and conditions attached to it.
5. The physician's specialty.

(3) Every licensee shall give the Director a copy of each declaration of professional standing, forthwith after the obligation to maintain it begins under subsection (1).

(4) Every licensee shall give the Director a written statement of any change in a declaration of professional standing forthwith after the change.

(5) Subsections (3) and (4) do not apply with respect to physicians providing services on a temporary basis for less than twelve weeks. O. Reg. 57/92, s.9.

Patient Records

10 (1) Every licensee of an independent health facility shall keep, for each person who is or was a patient, a health record relating to the health services provided in the facility.

(2) A patient's health record must include:

- (a) the patient's name and home address
- (b) the patient's date of birth
- (c) the patient's health number
- (d) the name of any attending physician or practitioner and his or her number as registered with the Health Insurance Division of the Ministry of Health
- (e) the name of any referring physician or practitioner and his or her number as registered with the Health Insurance Division of the Ministry of Health
- (f) a history of the patient
- (g) a written record of any orders for examinations, tests, consultations or treatments
- (h) particulars of any examination of the patient
- (i) any reports of examinations, tests or consultations including any imaging media from examinations and any physicians' interpretive or operative reports
- (j) any reports of treatment including any physicians' operative reports
- (k) any orders for and reports of any discharge of the patient from supervised care
- (l) any consents; and
- (m) any diagnoses of the patient.

(3) A patient's health record need not contain a history of the patient if the patient came to the independent health facility for diagnostic services only and received only such services.

(4) Every licensee shall ensure that every part of a patient's record has a reference on it identifying the patient or the record.

(5) If information in a patient's record is kept in the form of a chart, each entry in the chart must be dated and it must be initialled by the person authorizing the entry. O. Reg. 57/92, s.10.

11 (1) Every licensee shall retain a patient's health record or a copy of it for at least six years following:

(a) the patient's last visit; or

(b) if the patient was less than eighteen years old when he or she last visited the facility, the day the patient became or would have become eighteen years old.

(2) Despite subsection (1), a licensee is not required to retain imaging media from any examination other than a mammography for more than three years following:

(a) the patient's last visit; or

(b) if the patient was less than eighteen years old when he or she last visited the facility, the day the patient became or would have become eighteen years old.

(3) Every licensee shall retain the film from a mammography for at least ten years following the patient's last visit. O. Reg. 57/92, s.11.

(4) On the transfer of a licence under section 11 of the Act, the transferor of the licence shall transfer to the transferee of the licence in a manner that will protect the privacy of the records, the records maintained under section 10 of this Regulation, and the transferee of the licence shall retain those records in accordance with this section.

Section 12 of the Regulation is revoked and the following substituted:

12 (1) No licensee shall allow any person to have access to any information concerning a patient that is not subject to the *Personal Health Information Protection Act, 2004* except in accordance with subsection (3).

(2) The reference to "information concerning a patient" in subsection (1) includes information or copies from a health record, even if anything that could identify the patient is removed. :

(3)A licensee may provide information described in subsection (1) to the following persons if anything that could identify the patient is removed from the information:

- 1. Any person, if the information is to be used for health administration or planning or health research or epidemiological studies and the use is in the public interest as determined by the Minister.**
- 2. Cancer Care Ontario.**

Books and Accounts

12.1(1)This section applies to licensees of independent health facilities that are funded under section 24 of the Act, other than independent health facilities whose funding is based solely on the Ministry of Health publication titled “Schedule of Facility Fees”.

(2)Every licensee shall keep the following records in relation to the independent health facility:

- 1. Current financial records showing:**
 - i. the amounts paid by the Minister to the licensee under section 24 of the Act.**
 - ii. the revenue earned by the licensee from facility fees charged by the licensee for or in respect of services or operating costs that support, assist or are a necessary adjunct to the primary insured services set out in the licensee’s licence, and**
 - iii. the expenditures, assets and liabilities of the facility that relate to the costs paid by the Minister under section 24 of the Act.**
- 2. A reporting record listing each service provided in the facility that is a primary insured service set out in the licensee’s licence and each service provided in the facility that is a funded service under section 24 of the Act and showing how many of each of such services are provided.**
- 3. An annual income and expense statement showing the income received and the expenses incurred by the licensee in connection with the services mentioned in paragraph 2.**
- 4. An annual inventory of the assets of the facility that have an acquisition cost exceeding \$3,500 and that relate to the costs paid by the Minister under section 24 of the Act.**

(3)Every licensee shall ensure that the records required under section (2):

- (a) are kept in the independent health facility; and
- (b) are kept in a bound or looseleaf book or are recorded by a system of mechanical or electronic data processing or any other information storage device.

(4) Every licensee shall ensure that any part of a record required under subsection (2) that relates to a period of time is retained for at least six years following the end of the period.

(5) Every licensee shall ensure that the accounts of the independent health facility are audited by a person licensed under the *Public Accountancy Act*. O. Reg. 283/94, s.1, *part*.

12.2 Every licensee of an independent health facility shall furnish such information and accounts as the Director may require. O. Reg. 283/94, s.1, *part*.

Notices

13. Every licensee of an independent health facility,

(a) who decides to cease operating the facility at a future date shall give the Director, as soon as possible, written notice of the date; and

(b) who ceases operate the facility shall give the Director, within seven days after the date the licensee ceases to operate the facility, written notice of the date. O. Reg. 57/92, s.13.

14. Every licensee of an independent health facility shall give the Director:

(a) if the licensee is a corporation, written notice of any change in the location of the licensee's head office within ten days after the change; and

(b) written notice of any change in the name under which the licensee carries on business within ten days after the change. O. Reg. 57/92, s.14.

Miscellaneous

15. It is a condition of a licence that the licensee post the first page of the licence in a conspicuous place in the independent health facility. O. Reg. 57/92, s.15.

16 (1) The fee for a licence is \$100.

(2) The fee for the transfer of a licence is \$100.

(3)The fee for the renewal of a licence is \$100. O. Reg. 57/92, s.16.

17.The administrative charge for the purposes of section 36 of the Act is \$50. O. Reg. 57/92, s.17.

Appendix II **Recommended Guidelines for Preventing Allergic Reactions to Natural Rubber Latex**

Overview

The Canadian Society of Gastroenterology Nurses and Associates has set out recommended guidelines for preventing allergic reactions to natural rubber latex. These guidelines are listed below.

Definition

Natural latex is a milky fluid obtained from the *hevea braziliensis* (rubber) tree found in Africa and South-east Asia. Various chemical agents such as vulcanizers, accelerators, stabilizers and anti-oxidants are added to natural latex.

Background

The latex allergy is an enormous public health problem faced by health care workers and patients. Healthcare workers have become the fastest growing group to experience latex sensitivity and more often its adverse affects.

Latex is a common component in health care products and consumer products. In 1989 there were 400 reported anaphylactic reactions and 15 deaths due to latex contact.

The implementation of universal precautions in 1987, to prevent HIV and other blood borne pathogens infections resulted in an increased demand for gloves. Manufacturing processes may have temporarily changed to meet this dramatically increased demand for gloves, resulting in latex products with higher allergic and irritant properties being produced and used. Repeated exposure to latex products can cause hypersensitivity

reactions locally and systemically. Reducing exposure to latex products will definitely decrease sensitization and symptoms. There is no treatment for latex allergy except complete avoidance of latex.

Goals in Management:

The two major goals in the management of latex reactions are successful identifications and treatment of all dermatitis, to prevent future sensitization and identification of latex allergy to prevent serious life threatening sequelae whenever possible.

Types of Reactions to Latex

Irritant contact dermatitis

- Most common type of reaction
- Not an allergic reaction involving the immune system but rather a skin irritation caused by the chemicals added to the latex during the manufacturing of the glove powder itself, repeated irritation from sweating under the gloves or from gloves rubbing against the hands, characterized by dry, flaky skin and papules, redness, fissures and thickening of skin

Allergic contact dermatitis: Type IV

- Delayed type hypersensitivity
- A cell-mediated allergic reaction to the chemicals used during the processing of latex. The more common sensitizers/allergens are thiurams and carbamates (accelerators)
- Results from prolonged contact with these chemicals in gloves
- Symptoms usually appear 6-48 hours after exposure
- Characterized by localized redness, clustered vesicles, swelling, itching, cracking eczema and fingertip fissures

Immediate allergic reaction: Type I

- An immediate immunoglobulin E mediated allergic response to the latex protein themselves
- Reaction usually occurs 5-30 minutes after exposure
- The response is introduced by direct contact with latex on non-intact skin resulting in sensitization before manifesting as a generalized reaction
- Once sensitivity has been initiated, any contact with latex may cause a recurrence of the reaction

- The protein allergens have been found in water-soluble extracts from latex rubber film. It may also be absorbed by glove powder, which may become airborne
- The severity of the immediate reaction will depend in the route of exposure; cutaneous, mucosal, inhalation and parenteral, the amount of latex allergen and the degree of individual sensitivity
- Mild reactions involve skin redness-hives-itchiness
- More severe reactions may imply edema, itching, conjunctivitis around the eyes, rhinitis, nasal itching, sneezing, shortness of breath, asthma, airway obstruction due to bronchospasm, anaphylactic shock

Risk Factors for Latex Sensitivity and Allergy

- Persons with spina bifida
- Patients and congenital urogenital defects, history of indwelling urinary catheters of repeated catheterizations
- Patients who have undergone recurrent surgical procedures
- Workers with ongoing latex exposure – health care workers, housekeepers, food handlers, tire manufacture workers, workers in industry who use gloves regularly
- Atopic individuals – persons with multiple allergic conditions, eczema, asthma, rhinitis
- Individuals allergic to certain food, banana, avocado, chestnut, apricot, kiwi, papaya, passion fruit, pineapple, peach, nectarine, plum, cherry, melon, fig, grape, potato, tomato and celery may cause a cross reactivity with latex protein
- No treatments are available to cure latex allergy. The best treatment is to avoid exposure. The treatment for individual allergic to latex is to ensure a safe environment. Medications are available to alleviate the allergy symptoms.

Recommendations

Patients

- All patients are assessed for adverse reactions or contraindicated substance during their admission assessment. We should provide a latex safe environment for patients allergic and sensitive to latex.

- History for presence of allergies such as hay fever, childhood or adult eczema, asthma and food allergies
- Multiple surgeries
- Undiagnosed reactions or complications during surgery anesthesia or dental work – angioedema, shortness of breath, rash
- History of latex exposure: type of latex device, nature and duration of exposure
- History of latex allergy such as cutaneous symptoms (dermatitis-eczema-urticaria) respiratory symptoms, (rhinitis, wheezing, coughing, sneezing, shortness of breath)
- Any respiratory symptoms experienced when in contact with products containing rubber
- Other symptoms such as itchy hands, conjunctivitis, localized angioedema, possible systemic anaphylactic symptoms with the use of household latex cleaning gloves, balloons, condoms and diaphragms.

If a patient has any of the above categories the following measure should be taken:

- Patients with severe documented allergy to latex should be assessed for the need of a private room
- A cart containing all latex free supplies that are necessary for patient care from admission to discharge. This cart will follow patient to other departments.
- Wear non-latex examination and sterile gloves. Vinyl gloves should be changed every 15 minutes to protect the health care worker from blood borne pathogens
- Identify chart, patient, bed, medication profile, kardex, physicians order sheet with latex allergy stickers
- Post latex allergy sign on patient's door
- Wear a cover gown if the possibility that your uniform contains residues of powder from latex gloves
- Tape over IV tubing ports and do not use
- Do not inject via T-connectors, buritrol or IV bag, inject and administer medication only through plastic stopcock
- Remove rubber stoppers from vial then draw up medication. Needle puncturing a rubber stopper can shear off particles of latex, and cause a systemic reaction
- Glass syringe or latex free syringe must be used, if plastic syringe are used, the solution must be injected immediately after being drawn up

- If pulse oximetry is used, cover the patient's finger with tegaderm then apply probe. The inside surface of most pulse oximeters is covered with latex
- Avoid skin contact with the bulb and tubing of the blood pressure cuff by placing cloth under the rubber to shield the skin
- Stethoscope tubing can be covered with a stockinette
- If catheterization is necessary, use silastic foley catheter
- Utilize single dose ampules for parenteral medication
- Patients that are highly reactive, may require medications at the bedside. Epinephrine should be available if an anaphylactic shock occurs
- If the patient develops an allergic reaction, remove suspected allergen and provide immediate care
- All staff interacting with this patient must follow proper hand washing procedures before caring for these patients in order to minimize the exposure to and transfer of latex protein

Health Care Workers

Health care workers should protect themselves from latex exposure and allergy in the workplace:

- Use non-latex gloves for activities that do not involve contact with blood or body fluid
- For activities where contact with infectious materials is expected and latex gloves are used, choose a reduced protein, powder free glove
- Workers with hand dermatitis should never wear oil hand cream or lotion with latex gloves. Oil breaks down latex, damages the glove barrier and releases additional allergen. Detergents and other chemicals also degrade latex glove
- After removing gloves, wash hands with soap and dry thoroughly, never reuse glove
- If you experience any symptoms possibly related to latex allergy, report it to Health and Safety Department, avoid contact with latex gloves until you see your allergist
- Attend latex allergy education session

If allergic to latex:

- Avoid contact with latex gloves, latex containing products and objects such as computer keyboards, telephones, that have been contaminated with latex gloves or glove powder
- Avoid areas where you might inhale the powder from latex gloves worn by other workers
- Wear medical alert bracelet
- Attend latex allergy education session
- Carry an emergency epinephrine auto-injector
- Avoid cross-reacting food such as; kiwi, avocado, chestnut
- Follow your physician's instructions for dealing with allergic reaction to latex

Institution

To eliminate or reduce the risk for latex sensitization of asymptomatic staff and minimize the risk of latex exposure to staff already sensitized:

- Eliminate unnecessary use of latex gloves by providing workers with non-latex gloves when there is minimal potential for contact with blood or bodily fluid
- When selecting a latex glove for barrier protection from infectious materials, choose a reduced protein, powder free glove. Glove should be approved by the Canadian General Standard Board.
- Provide education to employees about latex allergies, hand care and the importance of early care for dermatitis or other allergy symptoms. Identify and instruct worker in work practices to prevent exposure
- Implement a latex allergy assessment protocol including a screening history questionnaire and protocol of evaluation and treatment of latex reaction symptoms
- Conduct a worksite evaluation, identify areas contaminated with latex dust and make sure cleaning is done more frequently. Ensure that filtration and ventilation systems provide adequately re-circulated air in area with high levels of latex aerosols
- Alternative latex free devices must be available
- Identification of medical product containing latex
- Incorporate latex allergy education as part of the annual safety and infection control program, orientation program and also conduct in services

Once a diagnosis of latex allergy is confirmed, the employee should accommodate the affected workers. Extremely sensitive individuals may have to be re-assigned to areas where no latex gloves are used.

Disclaimer

The Canadian Society of Gastroenterology Nurses and Associates does not assume responsibility for the practices or recommendations of any individual, or for the practices and policies of any Gastroenterology Unit or Endoscopy unit.

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Appendix III ASA Physical Status Classification

Overview

The following describes the ASA Physical Status Classification.

Category	Description
I	Healthy Patient - no underlying organic disease
II	Mild or moderate systemic disease that does not interfere with daily routines (e.g. well controlled asthma, essential hypertension, stable CAD)
III	Organic disease with definite functional impairment (e.g. severe steroid dependent asthma, insulin dependent diabetes, uncorrected congenital heart disease, class II angina and moderate COPD).
IV	Severe systemic disease that is a constant threat to life (e.g. unstable angina).
V	Moribund patient unlikely to survive 24 hours with or without endoscopy.

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