

Independent Health Facilities

Clinical Practice Parameters and Facility Standards

Ophthalmology 4th Edition



**THE COLLEGE OF
PHYSICIANS &
SURGEONS
OF ONTARIO**

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The College of Physicians and Surgeons of Ontario

Strategic Plan

The Council of the College of Physicians and Surgeons of Ontario developed a strategic plan to establish College priorities for the next several years. The priorities articulated in the strategic plan serve as a guide to action and focus our energies toward attaining our new vision – **Quality Professionals, Healthy System, Public Trust.**

Our Mandate

Build and maintain an effective system of self-governance. The profession, through and with the College, has a duty to serve and protect the public interest by regulating the practice of the profession and governing in accordance with the Regulated Health Professions Act.

Our Vision Defined

Quality Professionals, Healthy System, Public Trust.

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

Quality Professionals – as a profession and as professionals, we recognize and acknowledge our role and responsibility in attaining at a personal, professional, and at a system-level, the best possible patient outcomes. We are committed to developing and maintaining professional competencies, taking a leadership position on critical issues that impact the performance of the system, and actively partner to provide tools, resources, measurement, to ensure the optimal performance at all levels of the system.

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

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

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

- building positive relationships with individuals
- acting in the interests of patients and communities
- advocating for our patients and a quality system

Our Guiding Principles

Integrity, accountability, leadership and cooperation

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

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

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

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

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

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

Cooperation – seeking out and working with our partners – other health-care institutions, associations and medical schools, etc. – to ensure collaborative commitment, focus and shared resources for the common good of the profession and public.

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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. Regulation changes were introduced in 1999. 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, PET, pulmonary function, and sleep studies.
- in treatment of 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 anesthetic 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 detailed provider 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.

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".

Note: The parameters and standards are not intended to replace a physician's clinical judgment 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.

Role of the College of Physicians and Surgeons

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.

All Clinical Practice Parameters and Facility Standards undergo an external review process. External Reviews include: Registrars of other regulatory colleges, department heads at relevant academic institutions, relevant national and provincial organizations, independent health facilities, IHF assessors and other stakeholders as determined by the relevant Task Force.

Task Forces members ensure that:

- 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 from time to time. 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.

Independent Health Facilities: Clinical Practice Parameters and Facility Standards

Ophthalmology

Volume 1

Facility Standards

Chapter 1 Staffing a Facility

Overview

The Independent Health Facility is managed under the direction of one or more certified ophthalmologists who have privileges to perform the same surgery in a general hospital, have admitting privileges or have access to appropriate referral by prior arrangement to a nearby hospital for emergency patients if necessary.

It is expected that physicians will manage medical and surgical conditions within the scope of their specialty training, certification and experience.

All staff who administer sedation or regional anesthesia or who monitor and recover such patients must maintain a current BLS (basic life support) certificate.

Physician Qualifications

Physician Qualifications

The physician is a member licensed to practice in Ontario by the College of Physicians and Surgeons of Ontario and one of the following:

- RCPSC certification that confirms training and specialty designation pertinent to the procedures being performed
- CPSO recognition as a specialist that would include, by training and experience, the procedures performed (as confirmed by the CPSO “Recognition of Non-Family Medicine Specialists” policy)
- Satisfactory completion of all CPSO requirements for a physician requesting a change in their scope of practice (based on the CPSO policy, *Changing Scope of Practice*) **and** active privileges to support similar procedures at their local hospital.

Quality Advisor

The role of the Quality Advisor is an important one. Quality Advisors play a vital role in the overall operation of the Independent Health Facility to ensure that the services provided to patients are being conducted appropriately and safely.

Each IHF licensee is responsible for operating the facility and providing services in accordance with the requirements of the IHFA. Pursuant to O. Reg. 57/92 under the *Independent Health Facilities Act*, every licensee is required to appoint a Quality Advisor to advise the licensee with respect to the quality and standards of services provided in the independent health facility. The Quality Advisor must be a health professional who ordinarily provides insured services in or in connection with the 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.

The Quality Advisor is responsible for advising the licensee with respect to the quality and standards of services provided. In order to fulfill this duty:

- The Quality Advisor shall personally attend the facility at least twice each year, and may attend more frequently, where in the opinion of the Quality Advisor it is necessary based on the volume and types of services provided in the facility. The visits may be coordinated as part of the Quality Advisory Committee (QA Committee) meetings.
 - The Quality Advisor shall document all visits to the facility made in connection with the Quality Advisor's role.
 - The Quality Advisor shall ensure that a qualified physician be available for consultation during the facility's hours of operation.
 - The Quality Advisor shall seek advice from other health professionals where in the opinion of the Quality Advisor it is necessary to ensure that all aspects of the services provided in the facility are provided in accordance with generally accepted professional standards and provide such advice to the licensee.
 - The Quality Advisor shall chair the QA Committee. The QA Committee shall meet at least twice a year if the facility employs more than six full-time staff equivalents including the Quality Advisor; otherwise the QA Committee shall meet at least once a year. Regular agenda items should include: review of cases; policies and procedures; quality control matters on equipment; incidents, medical and technical staffing issues.
 - All QA Committee meetings shall be documented.
 - The Quality Advisor shall obtain copies of assessment reports from the licensee/owner/operator. If deficiencies were identified in the assessment, the Quality Advisor shall review same with the QA Committee and document such review. The Quality Advisor's signature is required on any written plan submitted by the licensee to the College.

- The Quality Advisor shall advise the licensee on the implementation of an ongoing quality management (QM) program, which should include, but not be limited to, the following:
 - Ensuring ongoing and preventive equipment maintenance
 - Follow-up of interesting cases
 - Follow-up of patient and/or medical and technical staff incidents
 - Continuing education for medical and technical staff
 - Ensuring certificates of registration, BCLS, etc. are current
 - Regular medical and technical staff performance appraisals
 - Patient and referring physician satisfaction surveys

- The Quality Advisor will advise the licensee, and document the provision of such advice, in connection with the following:
 - **Health professional staff hiring decisions**, in order to ensure that potential candidates have the appropriate knowledge, skills and competency required to provide the types of services provided in the facility.
 - **Continuing education** for all health professional staff members employed in the facility, as may be required by their respective regulatory Colleges or associations.
 - **Appropriate certification** for all health professional staff members employed in the facility with the respective regulatory Colleges or associations.

- **Leadership**, as may be required to address and resolve any care-related disputes that may arise between patients and health professional staff.
- **Appropriate resources** for health professional staff members employed in the facility.
- **Formal performance appraisals** for all health professional staff.
- **Technology** used in the facility, in order to ensure it meets the current standard(s) and is maintained through a service program to deliver optimal performance.
- **Establishment and/or updating of medical policies and procedures** for the facility, eg., consultation requests, performance protocols, infection control, and standardized reports, and other issues as may be appropriate.
- **Equipment and other purchases** as may be related to patient care.
- **Issues or concerns** identified by any staff member, if related to conditions within the facility that may affect the quality of any aspect of patient care.
- **Establishing and/or updating system(s)** for monitoring the results of the service(s) provided in the facility.

If the Quality Advisor has reasonable grounds to believe the licensee is not complying with the licensee’s obligation to ensure that services are being provided in accordance with the generally accepted standards and to ensure that the persons who provide services in the facility are qualified to provide those services, the Quality Advisor must inform the Director of Independent Health Facilities forthwith in accordance with the provisions and Regulations under the *Independent Health Facilities Act*.

The Quality Advisor should acknowledge, in writing, his/her role in connection with Quality Assurance.

To assume the duties and responsibilities of a Quality Advisor he/she may delegate these duties to a suitably qualified physician that meet the training requirements outlined in this Chapter.

Continuing Professional Development (CPD)

The Quality Advisor ensures all physicians in the IHF comply with the CPD requirements of the CPSO.

Other Health Care Staff

Nursing Qualifications

Registered nurses (RNs) and registered practical nurses (RPNs) working in the IHF must hold:

- Current registration with the College of Nurses
- Additional training and appropriate experience as required
- Current BLS certification.

Other Staff Qualifications

Staff from other regulated health professions must be adequately trained and registered with their regulatory body.

Chapter 2 Policies and Procedures

Overview

Policies and procedures are written, updated regularly, dated accordingly and are available for reference by all staff.

The IHF ensures that all staff:

- Read the policies and procedures manual on hire, and confirm action with signature and date.
- Review the policies and procedures manual annually, and confirm action with signature and date.
- Read their individual job descriptions of duties and responsibilities and sign and date indicating they have been read and understood.

Policies and Procedures

Policies and procedures include, but are not limited to, the following:

Administrative

- Quality Advisor roles and responsibilities
- Staff qualifications, roles, responsibilities
- Surgery scheduling/log book
- Required maintenance logs
- Responsibility for developing and maintaining the policy and procedure manual
- Organizational chart
- Scope and limitations of services provided within the IHF
- Confidentiality
- Medical Directives
- Controlled Acts that can be delegated
- Transfer agreement requirements

Emergency Care

- Malignant hyperthermia
- Latex sensitivity
- Cardiac arrest protocols
- Anaphylaxis shock
- Equipment/medication requirements for resuscitation

Surgical Services

- Requirements for conscious sedation/anesthesia
- Requirements for verification process
- Requirements for preoperative care: minimum testing requirements, consent

Materials Management

- Central supply stocking
- Equipment evaluation/purchase
- Outdates and rotation of stock
- End of the year inventory

Quality Assurance/Risk Management

- Quality assurance/ Quality Advisory Committee
- Risk management, including: patient-related risks, medical staff risks, employee-related risks, other risks; analysis of risk; risk evaluation; reporting forms
- Adverse events: monitoring, reporting, and reviewing; response to an adverse event

Education/Orientation

- New employee orientation
- Annual review of policies and procedures
- In-service/staff meetings
- Fire prevention
- Sterilization – Bowie Dick test
- Transport of the patient in the OR

Safety

- Electrical safety
- Fire safety
- Laser safety
- Emergency evacuation
- Electrosurgery
- Universal precautions
- Temperature and humidity monitoring (cataract IHF)

Infection Control

- Infection Control Committee
- Surgical attire
- Cleaning/processing anesthesia equipment
- Environmental cleaning in the ambulatory surgery setting
- Cleaning and caring for surgical instruments and power equipment

- Aseptic technique
- Biohazardous waste handling
- Hand washing and surgical hand scrub
- Post-operative infection monitoring/reporting
- Product recall
- Sterilization standards
- Sterilization – STERRAD
- Sterilization – “Flash” sterilization
- Sterilization – Event related

Medical Staff

- Medical staff requirements
- Involvement in staff committees (Quality Assurance, Infection Control)

Nursing Staff

- Nursing Staff positions
- Job description/qualifications and evaluation
 - Director of Nursing/Nurse Manager
 - Registered Nurse
 - Surgical Technologist
 - Materials Manager

Medical Records

- Patient chart contents, including intake form, discharge form, OR record, anesthesia/monitoring record
- Informed consent
- Retention and storage of medical records (see Appendix I, Independent Health Facilities Act – Ontario Regulation 57/92)
- Observers in OR

Pharmacy

- Ordering, Handling and Storage of Medications
- Administering Medication
- Reporting of Medication Errors

Chapter 3 Facilities, Equipment and Supplies

General Physical Standards

Each IHF site complies with all applicable building codes, including fire safety requirements.

Electrical

- Electrical hazards are managed according to applicable codes
- All electrical devices are certified
- Emergency power supply can provide for safely completing the procedure and recovering the patient
- Electrical renovations are approved by municipal inspector sign-off

Access

- Access for handicapped persons complies with provincial legislation and municipal laws
- Doors and corridors can safely accommodate stretchers and wheelchairs

Size

- IHF size is adequate for all procedures to be performed safely

Layout

- Layout facilitates safe patient care and patient flow
- These areas are physically separate, where appropriate
- Administration and patient-waiting area
- Procedure room and/or operating room
- Recovery area
- Clean utility area
- Dirty-utility room
- Non-sterile storage area
- Sterile area
- Staff change room and staff room

Emergency Measures

Provisions are in place to ensure:

- The safe evacuation of patients and staff in case of an emergency, i.e. stretchers, wheelchairs, or other adequate methods of transport are available and
- There is easy access for an ambulance to transfer patients to a hospital.

General Medication Standards

- Maintain a general medication inventory record

- Periodically inspect all medications for viability
- Label medications in accordance with the Food and Drug Act (FDA) and the Controlled and Substances Act (CDSA) and its regulations
- Store medications according to the manufacturer’s recommendations (e.g. refrigeration, if required) and in a manner suitable for security and restocking
- Document administration of medications in the patient record
- Dispense medications at discharge accompanied by verbal and written instructions that are given to the patient and/or accompanying adult
- Make available resources to determine appropriate drug dosages and usage

Controlled Substances Standards

- Controlled substances are handled and administered in accordance with Food and Drug Act (FDA) and the Controlled Drugs and Substances Act (CDSA) and its regulations.
- The IHF ensures that controlled substances are:
 - Assigned to one qualified staff (RN, RPN with medication skills, physician)
 - Stored in a designated locked cabinet
 - Accounted for in a “Log of Controlled Substances: that specifies
 - For each controlled substance: name, quantity, date received, expiry date; loss (damaged, expired, spilled) date and quantity and for patient administration:
 - Patient name
 - Drug name and amount removed from inventory
 - Date and time
 - Name of staff administering the medication.
- On each day that controlled substances are used, an end-of-day balance of the inventory of controlled substances must be calculated by physical count and verified by signatures of two qualified staff. In the event of a discrepancy, an investigation must be conducted and documented with the action taken.

Required Drugs for resuscitation for all IHFs

- Diphenhydramine
- Epinephrine for injection
- Oxygen
- Salbutamol

Required Drugs for resuscitation if using neuroleptics or general anesthesia

- Amiodarone IV
- Antihypertensive IV (at least one of Labetalol, Hydralazine)
- ASA 81 mg po
- Atropine IV
- Benzodiazepine IV (at least one of Midazolam, Diazepam, Lorazepam)
- BETA Blocker IV (at least one of metoprolol, propranolol, esmolol)
- Calcium IV (chloride or gluconate)
- Dextrose 50% IV

- Diphenhydramine (oral and IV)
- Epinephrine for injection
- Flumazenil IV
- Hydrocortisone IV 100 mg or 500 mg
- IV agent for SVT (at least one of Adenosine, Esmolol, Verapamil)
- MHAUS treatments if triggering agents present, following MHAUS guidelines
- Morphine IV
- Naloxone IV
- Neuromuscular blocking agents, if qualified staff available
- Nitroglycerine spray
- Pressor IV (at least two of: Epinephrine, Ephedrine, Vasopressin, Phenylephrine)
- Oxygen
- Pressor IV (at least two of Epinephrine, Ephedrine, Vasopressin, Phenylephrine)
- Sodium bicarbonate IV

Procedure Room/Operating Room Physical Standards

Note: Depending on the procedure performed, not all standards may apply

Physical Requirements

- Lighting as required for the specific procedure
- Floors and walls that can be cleaned to meet infection control requirements
- Adequate hand-washing facilities and proper towel disposal
- Openings to the outside effectively protected against the entrance of insects or animals by self-closing doors, closed windows, screening and controlled air current or other effective means
- Space can accommodate equipment and staff required for the procedure
- Space allows the physician and assisting staff, when sterile, to move around the OR table with access to both sides of the patient, without contamination.
- Ceiling is constructed of a smooth washable surface if a sterile field is required.

Ventilation

- Ventilation to ensure patient and staff comfort
- Where applicable, ventilation and air circulation should be augmented to address procedure related air-quality issues
- Where gas sterilization is used, a positive pressure outbound system is used, vented directly to the outside

Equipment

- Equipment must comply with the Canadian Standards Association (CSA) and be maintained and inspected regularly for functionality

- Related documentation for all equipment is available:
 - Equipment operating manuals
 - Equipment maintenance contracts
 - Log for maintenance of all medical devices
- The following equipment is provided:
 - Cleaning equipment as required for specific equipment
 - Accessible anesthetic material and equipment
 - Blood pressure and oxygen saturation monitoring equipment
 - Small equipment table
 - Sterilized packs and instruments
 - Table/chair/stretchers that accommodate procedures performed and provides for adequate range of movement for anesthetic procedures including an adjustable headrest to facilitate intubation
 - Suction equipment and backup suction for anesthesia provider's exclusive use

Anesthetic and Ancillary Equipment

Both anesthetic and ancillary equipment (selection, installation, maintenance) and medical compressed gases and pipelines must comply with:

- Canadian Standards Association (CSA) standards and
- Specific applicable recommendations arising from provincial legislation.

A second supply of oxygen (normally a spare cylinder) with pressure gauge, regulator and wrench shall be available.

Monitoring and Resuscitation Requirements

Equipment for Monitoring and Resuscitation for all IHFs

- Adequate equipment to manage local anesthetic toxicity
- Assortment of disposal syringes, needles, and alcohol wipes
- Means of giving manual positive pressure ventilation (e.g. manual self-inflating resuscitation device)
- Oxygen source

Additional Equipment for Monitoring and Resuscitation for IHFs using Neuroleptics or General Anesthesia

- IV Set up
- Cardiopulmonary resuscitation equipment with current ACLS compatible defibrillator
- ECG monitor
- Intubation tray with a variety of appropriately sized blades, endotracheal tubes, and oral airways
- Laryngeal mask airways
- Pulse oximeter
- Suction with rigid suction catheter
- Torso backboard

Implants

- All implants must be Health Canada approved.

Recovery Area Physical Standards

- A sink for hand washing is immediately accessible
- Electrical outlets that meet required code are available
- Minimum recovery-area size complies with current applicable building codes
- The recovery area allows for transfer of patients to/from a stretcher and performance of emergency procedures
- Appropriate monitoring, suction, oxygen and bag-valve-mask devices, adequate intravenous and other medical/surgical supplies are immediately available

Chapter 4 Procedure Standards

Pre-procedure Patient Care Standards

The physician must assess the risks inherent in each procedure or combination of procedures to determine if the IHF setting is safe and appraise each patient's medical risk factors and capacity to undergo anesthesia.

Documentation: All actions taken for pre-procedure patient care are entered in the patient record.

Pre-Procedure Requirements

The physician providing sedation/anesthesia assigns an ASA classification for all prospective patients requiring sedation/anesthesia for IHFs. Class P4 and above are not generally acceptable for IHFs.

| | |
|----|---|
| P1 | A normal healthy patient |
| P2 | A patient with mild systemic disease |
| P3 | A patient with severe systemic disease |
| P4 | A patient with severe systemic disease that is a constant threat to life |
| P5 | A moribund patient who is not expected to survive without the operation |
| P6 | A declared brain-dead patient whose organs are being removed for donor purposes |

Before day of procedure

- Advise patients they may require adult accompaniment when leaving the IHF after the procedure if indicated.

Before or on day of procedure

- Conduct pre-procedure assessment, which includes, but is not limited to:
 - Focused history and physical examination that includes findings indicating the rationale for the proposed procedure
 - All current medications (prescribed and non-traditional e.g. herbal remedies)
 - Blood pressure and pulse
 - Allergies
- Perform pre-procedure anesthetic/sedation assessment, including ASA Classification.

Note: If performed before day of procedure, must be within 14 days of procedure date.

- The pre-procedure anesthetic/sedation assessment includes but is not limited to the following:
 - ASA classification
 - A review of the patient's clinical record (including pre-procedure assessment)

- An interview with the patient
- A physical examination relative to anesthetic aspects of care
- A review and ordering of tests as indicated
- A review or request for medical consultations as necessary for patient assessment and planning of care
- Orders for pre-procedure preparation such as fasting, medication, or other instructions as indicated
- Obtain informed consent and a procedure consent form signed by the patient and witnessed

On day of procedure

- Complete admission assessment: confirm baseline history and physical as described above.

Verification Process

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

Note: *If the patient is unable to verify the information his/her legal guardian/substitute decision maker provides and verifies the appropriate information.*

Procedures Included

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

| | When | Where |
|---------------------|---------------------------------------|--------------------------|
| First Verification | Before entering the procedure room/OR | The pre-procedure area |
| Second Verification | During the time-out | In the procedure room/OR |

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

First Verification

- The first verification takes place in the pre-procedure area
- The patient is awake and aware
- The nurse preparing the patient for the procedure:
 - Confirms the patient identity, procedure, site and/or side with the patient/substitute decision-maker/legal guardian
 - Documents the first verification on the “Surgical Safety Checklist” (see Appendix II).

Second Verification

- The second verification must be conducted during the time-out in the location where the procedure takes place, immediately before starting the procedure.
- The patient is not required to be awake.

- The entire procedure team confirms the patient identity, procedure, site and/or side and acknowledges their agreement: nurse[s], attending physician, attending anesthesiologist (if applicable), and physician assistant (if applicable).

Pre-Procedure Staff Responsibilities

Nurse Preparing the Patient for the Procedure

The nurse preparing the patient for the procedure is responsible to verify that the:

- history and physical is document
- Informed consent is documented
- The required consent form(s) are signed and witnessed
- As applicable that the booking request form/referral form, informed consent, consent form, and elective surgical list are in agreement
- That all ordered diagnostic test(s) result(s) and laboratory result(s) are included in the patient's record
- Complete the first verification process

Nurse Assisting in the Procedure Room/OR

The nurse assisting in the procedure room/OR is responsible to:

- Ensure the physician's pre-procedure assessment, consent form and elective surgical list are in agreement
- Verify with the physician the correct patient position and availability of correct implants or special equipment required for the procedure prior to starting the procedure
- Initiate the time-out and document this on the "Surgical Safety Checklist" (see Appendix II)

Physician Performing the Procedure

The physician performing the procedure is responsible to:

- mark the site
- participate in the time-out and acknowledge verification process confirmation

Intra-procedure Patient Care

IHF's offering procedures under neuroleptic or general anesthesia must have an anesthesiologist administering and monitoring the patients.

Post Procedure Patient Care

Following neuroleptic/general anesthesia, the anesthesiologist/physician must accompany the patient to the recovery area and communicate the appropriate information to the appropriate recovery-area staff. This verbal report includes but is not limited to:

- Name and age of patient

- Procedure performed
- Pertinent history including allergies, medical/physical limitations
- Type of anesthesia used
- Other medications given
- Any unusual or adverse events pertaining to the patient
- Estimated fluid or blood loss
- Anesthetic course

The anesthesiologist/physician should stay with the patient until the appropriate recovery area staff accept responsibility for the patient.

Recovery area staff caring for patients provide care and document it in the patient record; it includes but is not limited to:

- Patient identification, date and time of transfer to recovery area, initial and routine monitoring of blood pressure, pulse, respirations, SpO₂, temperature, level of consciousness, pain score, procedure site and general status
- Continuous monitoring of vital signs until the patient has met requirements of discharge criteria using an objective scoring system from time of transfer to recovery area until discharge from Phase II recovery
- Medication administered: time, dose, route, reason and effect
- Treatments given and effects of such treatment

An anesthesiologist/physician must remain on site until the patient has met discharge criteria.

Recovery area staff may carry out action(s) according to a direct order or a medical directive.

An order is a prescription for a procedure, treatment, drug or intervention. It can apply to an individual patient by means of a direct order or to more than one patient by means of a directive.

- A **Direct Order** is for a specific patient upon assessment by the physician that the procedure is warranted; it should be a part of the permanent patient record. This also applies to the electronic patient record.
- A **Medical Directive** may be implemented for a number of patients when specific conditions are met and when specific circumstances exist. A medical directive is always written, signed by all most-responsible physicians (MRP), and included in the policy and procedure manual.

Patient Discharge

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

All patients should be accompanied by an adult when leaving the IHF.

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

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

Chapter 5 Quality Management

Overview

A Quality Advisory Committee (QA Committee) is established as per the IHF Act (*see Appendix I*). 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.

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.

The requirements for, and responsibilities of the Quality Advisor (QA) are detailed in Chapter 1 – Staffing a Facility.

Monitoring Quality of Care

The purpose of the quality assurance program is to ensure the delivery of the highest quality of care to its patients in the most efficient and effective manner using available resources. The program is designed to meet the following objectives:

- Ensure patients and their families are treated with respect and dignity and that all patient rights are observed.
- Provide a co-ordinated method of information flow to identify and assess problem patterns.
- Assess patient care problems in terms of performance criteria that reflect clinically sound, achievable patient care practices.
- Develop problem correction and monitoring methods to assure identified problems do not recur.
- Assure through credentialing, staff development and evaluation policies that all staff members are qualified professionals.
- Evaluate the quality assurance program annually and submit a written report to the Quality Advisory Committee to review and revise the program as needed.

Scope

The scope of the quality assurance program focuses on the processes of providing direct clinical care as well as the support services. These areas include but are not limited to:

- Patient care process (pre-admissions, admission, treatment, discharge planning, post discharge follow-up)
- Ancillary services quality of care (laboratory, pharmacy)
- Patient medical record
- Utilization review, infection control, safety, clinical privileges, patient satisfaction, personnel services and staff education

Quality Assurance Co-ordinator

The Director of Nursing (or her/his designee) has the following responsibilities:

- Co-ordination and implementation of all quality assurance activities
- Problem identification process and the education of the staff to use it
- Preparation of tissue review, anesthesia review, infection control and risk management summaries for presentation at QA meetings
- Enforcement of confidentiality policies

Quality Advisory Committee

The Quality Advisory Committee responsibilities include but are not limited to:

- Quarterly meetings with documentation
- Assurance that all information gathered will be reviewed and disseminated appropriately to the licensee and staff
- Providing recommendations regarding staff continuing education needs according to the findings from the quality assurance projects
- Setting priorities and criteria for problems that require assessment
- Implementing corrective actions and monitoring to assure problems to not recur
- Quarterly written evaluation of each quality assurance project including outcomes

Quality Advisory Committee Membership

The Quality Advisory Committee membership includes but is not limited to: Quality Advisor, Medical Director (if applicable), Director of Nursing, Anesthesiologist and any additional assigned staff within the facility.

Peer Review

A physician shall review the following cases in the absence of the operating physician:

- A realistic sampling of cases (5% up to a maximum of 25 cases) from procedures performed during the preceding 3 months to determine if prescribed criteria have been met.
- All cases involving major complications (see list) or death
- All cases in which there was a major discrepancy between pre- and post-operative diagnosis

Surgery or Anesthesia Related Complications

- See Appendix III

Risk Management

A risk management program is designed to work with the quality assurance program and is designed to identify, analyze, resolve and evaluate liability exposure within the facility. It is designed to protect the safety and welfare of patients and employees, and will include quality assessments, peer review, infection control procedures and an employee safety program.

Assignment of Responsibilities/Event Review

Overall responsibility for the risk management program will rest with the Quality Advisory Committee.

Selection of Risk Management Issues/Identification of Risk

The following areas of risk will serve as the basis of consideration and identification of risk at the IHF:

Patient-Related Risks

- Issues related to informed consent
- Patient confidentiality issues
- Questions/issues relating to surgical or anesthesia care
- Issues related to patient education or perioperative teaching
- Complications and unintended outcomes resulting in extended length of stay or hospital admission

Reporting of Unusual Occurrences/Variations

As a means of protecting patient and employee safety at the IHF, the following events will be reported immediately to the Quality Advisor:

- Operating on the wrong patient
- Performing an incorrect procedure
- Performing a procedure on an incorrect site
- Improperly signed or unsigned consents
- Injuries to patients, visitors or employees
- Breaks in sterile technique allowing for potential patient, employee or physician exposure
- Anesthesia or medical complications
- Cardiac or respiratory arrests
- Medication errors resulting in a change in patient condition or status
- Patient or family/visitor complaints which appear not to have been resolved to satisfaction
- Post-operative infections requiring medical treatment
- Unintended retained foreign body
- Hospital transfers
- Deaths
- Breach of security
- Breach of confidentiality

Adverse Event Reporting

Adverse events should be reported immediately to the Quality Advisor, and submitted in writing to the Quality Advisor within 24 hours of the event.

The written report should include the following:

- Name, age, and sex of the person(s) involved in the incident; includes staff and patients
- Name of witness(es) to the event (if applicable)
- Time, date, and location of event
- Description of the incident and treatment rendered
- Date and type of procedure (if applicable)
- Analysis of reasons for the incident
- Outcome

Review of Adverse Events and other QA Monitoring

The Quality Advisor should:

- Review all adverse events reports and QA monitoring findings occurring over a 12 month period.
- Document the review and any relevant corrective actions and quality improvement initiatives taken.
- Provide feedback to all staff.

Independent Health Facilities: Clinical Practice Parameters and Facility Standards

Ophthalmology

Volume 2

Clinical Practice Parameters

Clinical Practice Guidelines, Policy Statements and Standards

IHF's performing any ophthalmological services must be in compliance with the Canadian Ophthalmological Society Clinical Practice Guidelines, Policy Statements and Standards. IHFs should ensure that they routinely refer to these guidelines, policy statements and standards at the following website:

<http://www.eyesite.ca/english/program-and-services/policy-statements-guidelines/index.htm>

APPENDICES

Appendix I Independent Health Facilities Act – 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 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 on such service.

(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. O Reg. 346/04, s.2.

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 loose-leaf 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 to 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 Surgical Safety Checklist



SURGICAL SAFETY CHECKLIST

www.safesurgerysaveslives.ca

Your Organizational Logo

BRIEFING – Before induction of anesthesia

Hand-off from ER, Nursing Unit or ICU

- Anesthesia equipment safety check completed
- Patient information confirmed
 - Identity (2 identifiers)
 - Consent(s)
 - Site and procedure
 - Site, side and level marked
 - Clinical documentation
 - History, physical, labs, biopsy and x-rays
- Review final test results
- Confirm essential imaging displayed
- ASA Class
- Allergies
- Medications
 - Antibiotic prophylaxis: double dose?
 - Glycemic control
 - Beta blockers
 - Anticoagulant therapy (e.g., Warfarin)?
- VTE Prophylaxis
 - Anticoagulant
 - Mechanical
- Difficult Airway / Aspiration Risk
 - Confirm equipment and assistance available
- Monitoring
 - Pulse oximetry, ECG, BP, arterial line, CVP, temperature and urine catheter
- Blood loss
 - Anticipated to be more than 500 ml (adult) or more than 7 ml/kg (child)
 - Blood products required and available
 - Patient grouped, screened and cross matched

BRIEFING (continued)

- Surgeon(s) review(s)
 - Specific patient concerns, critical steps, and special instruments or implants
- Anesthesiologist(s) review(s)
 - Specific patient concerns and critical resuscitation plans
- Nurses(s) review(s)
 - Specific patient concerns, sterility indicator results and equipment / implant issues
- Patient positioning and support / Warming devices
- Special precautions
- Expected procedure time / Postoperative destination

TIME OUT – Before skin incision

- All team members introduce themselves by name and role
- Surgeon, Anesthesiologist, and Nurse verbally confirm
 - Patient
 - Site, side and level
 - Procedure
 - Antibiotic prophylaxis: repeat dose?
 - Final optimal positioning of patient
- "Does anyone have any other questions or concerns before proceeding?"

DEBRIEFING – Before patient leaves OR

- Surgeon reviews with entire team
 - Procedure
 - Important intra-operative events
 - Fluid balance / management
- Anesthesiologist reviews with entire team
 - Important intra-operative events
 - Recovery plans (including postoperative ventilation, pain management, glucose and temperature)
- Nurse(s) review(s) with entire team
 - Instrument / sponge / needle counts
 - Specimen labeling and management
 - Important intraoperative events (including equipment malfunction)
- Changes to post-operative destination?
- What are the KEY concerns for this patient's recovery and management?
- Could anything have been done to make this case safer or more efficient?

Hand-off to PACU / RR, Nursing Unit or ICU

PATIENT INFORMATION

Adapted from the WHO Surgical Safety Checklist, © World Health Organization, 2008

Surgical Safety Checklist: Canada
Version 1, January 9, 2009

Appendix III Surgical Outcomes

COMPLICATIONS AND PATIENT SAFETY

Physicians performing ophthalmic procedures in an IHF are expected to be familiar with the potential complications that can arise both during the procedure, as well as post operatively. This appendix provides a list of complications based on the type of procedure being performed.

Each IHF is responsible for developing and maintaining a quality assurance program. An integral part of such a program includes regular review of complications that have arisen as a result of procedures performed in the IHF. Post-operative complications, however, are often not reported back to the IHF, as many are managed by the referring ophthalmologist or by the IHF surgeon in his/her private office. In order to encourage physicians to report complications to the IHF, sample reporting forms are attached to this appendix. IHFs may consider sending such forms to referring physicians with a copy of the patient's operative report.

GENERAL COMMENTS REGARDING ANESTHESIOLOGY COMPLICATIONS

For many ophthalmic procedures, peri- or retrobulbar anesthesia is required. Unlike topical anesthesia, as is used in cataract surgery, retrobulbar anesthesia can result in rare but potentially very serious complications, such as brainstem anesthesia, retrobulbar hemorrhage, globe perforation, etc. Therefore, an IHF should have treatment algorithms in place to address possible complications.

Furthermore, on occasion, retrobulbar anesthesia may require conversion to general anesthesia in order to proceed with the remainder of the surgery. Accordingly IHFs performing vitreoretinal procedures must employ the use of a qualified anesthesiologist.

GENERAL COMMENTS REGARDING PATIENT SELECTION

A significant number of patients requiring urgent or emergency care have significant co-morbidities. These patients may require hospitalization post-operatively. Algorithms should be in place to address such patient needs.

A. CORNEAL TRANSPLANT SURGERY: POST OPERATIVE COMPLICATIONS REPORT (SAMPLE)

The [IHF name] is committed to offering the highest possible standard of care. Even with excellent care, complications may occur in patients who have undergone corneal transplant surgery. For quality assurance purposes, I would ask that you report any of these complications to [name of IHF Quality Advisor] so that we can review our patient management practices in the facility.

Sincerely,

[Surgeon's Name]

Patient Name: _____

Corneal Transplant Surgery Complications

| Complication | Date of Surgery | Date Complication Reported to Referring Physician |
|---|-----------------|---|
| Persistent epithelial defect | | |
| Wound leak | | |
| Increased intraocular pressure (retained viscoelastic, blood, inflammatory cells) | | |
| Choroidal haemorrhage | | |
| Choroidal effusion | | |
| Cystoid macular edema | | |
| Primary graft failure | | |
| Secondary graft failure (late non-immune endothelial failure) | | |
| Graft rejection (please name) | | |
| Glaucoma | | |
| Epithelial down growth/fibrous ingrowth | | |
| Recurrent of primary disease | | |
| Amblyopia (in pediatric patients) | | |
| Refractive error/astigmatism | | |
| Infection (please name) | | |
| Diffuse ocular infectious process (endophthalmitis, panophthalmitis) | | |
| Suture-related complications (please name) | | |

Complications related to PKP (Penetrating Keratoplasty)

| Complication | Date of Surgery | Date Complication Reported to Referring Physician |
|-----------------------------------|------------------------|--|
| Persistent epithelial defect | | |
| Wound leak/flat anterior chamber | | |
| Iris incarceration into the wound | | |
| Filamentary keratitis | | |
| Formation of anterior synechiae | | |
| Pupillary block | | |
| Hyphema | | |
| Fixed dilated pupil | | |
| Primary graft failure | | |

Complications related to DSEAK Surgery

| Complication | Date of Surgery | Date Complication Reported to Referring Physician |
|---------------------------------------|------------------------|--|
| Hyperoptic shift | | |
| Graft detachment/donor dislocations | | |
| Wound leak/flat anterior chamber | | |
| Pupillary block secondary to air fill | | |
| Persistent epithelial defect | | |
| Interface deposits | | |
| Primary graft failure | | |

Complications related to DALK

| Complication | Date of Surgery | Date Complication Reported to Referring Physician |
|--|------------------------|--|
| Interface infection | | |
| Kaye dots | | |
| Pupillary block | | |
| Fixed-dilated pupil | | |
| Post-keratoplasty atopic sclerokeratitis | | |

B. GLAUCOMA SURGERY: POST OPERATIVE COMPLICATIONS REPORT (SAMPLE)

The [IHF name] is committed to offering the highest possible standard of care. Even with excellent care, complications may occur in patients who have undergone Glaucoma procedures. For quality assurance purposes, I would ask that you report any of these complications to [name of IHF Quality Advisor] so that we can review our patient management practices in the facility.

Sincerely,

[Surgeon's Name]

Patient Name: _____

Glaucoma Filtering Surgery Complications

| Complication | Date of Surgery | Date Complication Reported to Referring Physician |
|-------------------------------|-----------------|---|
| Hypotonia | | |
| High intraocular pressure | | |
| Choroidal effusion | | |
| Aqueous misdirection | | |
| Flat/shallow anterior chamber | | |
| Suprachoroidal hemorrhage | | |
| Bleb leak | | |
| Bleb infection | | |
| Endophthalmitis | | |
| Uveitis | | |
| Dellen | | |
| Hyphema | | |
| Cataract | | |
| Bleb dysesthesia | | |
| Large bleb | | |

Glaucoma Laser Angle Surgery Complications

| Complication | Date of Surgery | Date Complication Reported to Referring Physician |
|--------------------------------|-----------------|---|
| Ocular inflammation | | |
| Intraocular pressure elevation | | |

C. VITREORETINAL PROCEDURES: POST OPERATIVE COMPLICATIONS REPORT (SAMPLE)

The [IHF name] is committed to offering the highest possible standard of care. Even with excellent care, complications may occur in patients who have undergone vitreoretinal procedures. For quality assurance purposes, I would ask that you report any of these complications to [name of IHF Quality Advisor] so that we can review our patient management practices in the facility.

Sincerely,

[Surgeon's Name]

Patient Name: _____

Vitreotomy Complications

| Complication | Date of Surgery | Date Complication Reported to Referring Physician |
|---------------------------------|-----------------|---|
| Elevated intraocular pressure | | |
| Retinal detachment | | |
| Vitreous hemorrhage | | |
| Endophthalmitis | | |
| Cystoid macular edema | | |
| Cataract | | |
| Epiretinal membrane | | |
| Recurrence of primary pathology | | |

Scleral Buckle Complications

| Complication | Date of Surgery | Date Complication Reported to Referring Physician |
|--------------------------------|-----------------|---|
| Elevated intraocular pressure | | |
| Retinal detachment | | |
| Vitreous hemorrhage | | |
| Pain from tight scleral buckle | | |
| Epiretinal membrane | | |
| Infected scleral buckle | | |

Intraocular Injections

| Complication | Date of Surgery | Date Complication Reported to Referring Physician |
|-------------------------------|------------------------|--|
| Elevated intraocular pressure | | |
| Cataract | | |
| Retinal detachment | | |
| Endophthalmitis | | |
| TASS | | |

Intravitreal Injections

| Complication | Date of Surgery | Date Complication Reported to Referring Physician |
|---|------------------------|--|
| Intra-ocular haemorrhage: vitreous hemorrhage, hyphema | | |
| Elevated intra-ocular pressure leading to non-perfusion of central retinal artery | | |
| Endophthalmitis: sterile | | |
| Endophthalmitis: infectious | | |
| Retinal detachment | | |
| Development or progression of cataract | | |
| Sustained elevation of intra-ocular pressure | | |

Appendix IV Diagnostic Ophthalmic A Scan Ultrasonography

Overview

Ultrasound biometry is used to obtain the axial length of the eye. This is used in a formula to calculate the strength of intraocular lens to be implanted in the eye at the time of cataract surgery in order to achieve a specified post-operative refraction.

Clinical Indications

Biometry is indicated in any eye in which cataract surgery with lens implantation is intended. It is also indicated in the second eye to be used to a standard of comparison against the first eye and/or as reference for future cataract surgery and lens implantation.

Requirements for Quality Assurance

In addition to the routine requirements for an ultrasound ophthalmic facility, additional requirements for biometry are:

For each patient there is a record of :

- hard copy of the ultrasound exam record displaying pathology if present
- hard copy of the biometry
- post-operative refraction desired
- lens suggested by biometry

Outcomes

In order to assess the accuracy of the information by the facility at least

- 10% of records must represent:
 - the lens implanted in the eye a post-operative refraction once the eye has stabilized following surgery.

A chart will be supplied for recording this information. It is important for quality assurance that a record of the post-operative refractions be kept. If post-operative refraction is not done at the surgeon's office, there should be a mechanism to retrieve these results.

Appendix V Diagnostic Ophthalmic B Scan Ultrasonography

Overview

The ophthalmic B-scan is a two dimensional ultrasound display based on various levels of sound waves reflected from ocular and periocular tissue. Since a B-scan can define the geometry and the geography of ocular structures, the indications for its use include the following:

- assessment of posterior ocular structure in the presence of obstructed ocular media.
- location and definition of intraocular tumours
- definition of periocular inflammation
- location and definition of intraocular and extraocular foreign material
- evaluation of extra ocular muscles
- definition of global status following penetrating injuries
- definition of retro-orbital or peri-orbital tumours.

Equipment

Most recently manufactured ultrasound machines have a standard interface and CSA approval is required.

The examination should be performed in a consistent manner by a trained technician or practitioner. The equipment components for B-scan ultrasonography may include the following:

- diagnostic A-scan probe (standardized or not standardized)
- corneal thickness A-scan probe
- diagnostic B- scan probe (10 MHz or higher frequency)
- transducer
- pulse emitter
- receiver
- amplifier
- signal processor
- display screen
- measuring gates (A-scan, B-scan calipers)
- image documentation (analogue or digital displays)

Types of Evaluation

- closed or open lid
- immersion B-scan

Standardized echography employs the following:

- standardized diagnostic A-scan
- diagnostic contact B-scan
- standardized examination technique

With standardized echography both the globe and the orbit are systematically scanned. Precise equipment, a formal course of study and on location training are prerequisites.

Materials Used

- sterile methylcellulose or viscous contact lens examining solutions
- topical anaesthetic
- sterile irrigating solution
- sterilizing solution
- tissues
- photographic film or other image capture technology

Probe Placement Sequence

Probe placement sequence could include:

- vertical transverse
- horizontal transverse
- oblique
- longitudinal
- axial

Procedure

The two varieties of examinations include:

- Open eye contact scan
- Closed eyelid examination
- Disadvantages of closed eye examination
 - reduced signal strength
 - eye position being difficult to determine
- Indications for closed eye examination
 - recent eye trauma, surgery or open wound
 - infant and children
 - unco-operative patients.
- Other
 - stand-off scan for anterior segment
 - waterbath immersion scan
- Artifacts can be produced by:
 - incomplete probe contact
 - air bubbles inside the probe, in coupling gel or in the eye

- foreign material.

Requirements for Quality Assurance

In addition to the routine requirements for an ultrasound ophthalmic facility, additional requirements are:

For each patient there must be a record of:

- hard copy of the ultrasound exam record displaying pathology if present.

Outcomes

In order to assess the accuracy of the information provided by the facility, at least 10% of records must be assessed.