

Independent Health Facilities

Clinical Practice Parameters and Facility Standards

Obstetrics & Gynaecology: Induced Abortion



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.

Independent Health Facilities

Clinical Practice Parameters and Facility Standards

Obstetrics & Gynaecology: Induced Abortion



THE
COLLEGE
OF
PHYSICIANS
AND
SURGEONS
OF
ONTARIO

First Edition, April 1992

Second Edition, May 1993. Reviewed and Revised again in February 1997.

Members of the Obstetrics/Gynaecology Task Force:

Dr. Arthur Leader, Chair, Ottawa

Ms. Sharon Dore, Hamilton

Dr. Diana Ingram, Hamilton

Dr. Kay Lie, Toronto

Dr. Mel Petersiel, Willowdale

Dr. John Tyson, Mississauga

Dr. Cecil Wright, London

A special subcommittee of the Task Force was constituted for the purpose of developing additional clinical practice parameters and facility standards for facilities performing Dilatation and Evacuation procedures. These members include:

Dr. Arthur Leader, Chair - Ottawa

Ms Lynne Julius, Thunder Bay

Dr. John Lamont, Hamilton

Dr. Henry Morgentaler, Toronto

Third Edition, April 2006

Members of the Obstetrics/Gynaecology Task Force:

Dr. Henry Muggah, Chair - Hamilton

Dr. Deborah Copes, Toronto

Ms Sheila Collins, Hamilton

Ms Lynne Julius, Kitchener

Dr. Nathan Roth, Toronto

Published and distributed by the College of Physicians and Surgeons of Ontario. For more information, contact:

Daniel J. Klass MD, FRCP (C)
Associate Registrar
Director, Quality Management
The College of Physicians and Surgeons of Ontario
80 College Street
Toronto, Ontario M5G 2E2

Toll free (800) 268-7096
(416) 967-2600 ext. 403
email: dklass@cpsso.on.ca

Contents

Clinical Practice Parameters and Facility Standards

Clinical Practice Parameters and Facility Standards

Preface

Purpose of Clinical Practice Parameters	v
Role of the College of Physicians and Surgeons	vi
Responsibilities of the College	vii
Updating this Document	vii

Volume 1 **Facility Standards**

Chapter 1 **Staffing a Facility**

Overview	1
Quality Advisor	1
Providing Surgical and Medical Services	2
Qualifications of Physicians	2
Physician Responsibilities	3
Training Physicians in Ultrasound Procedures	3
Training Staff in Emergency Procedures	3
Providing Nursing Care	4
Providing Counselling Services	4
Services Provided by Paramedical and Paraprofessional Staff	4

Chapter 2 **Policies and Procedures**

Overview	5
Developing Policies and Procedures	5

Chapter 3 **Facilities, Equipment and Supplies**

Overview	7
Providing a Safe Environment	7
Physical Environment	7
Providing a Sanitary Environment	7
Using Sterile Techniques	8
Observing Body Fluid Precautions	8
Disposing of Products of Conception and Biomedical Waste	8
Available Equipment	8
Intra-operative and Post-operative Equipment and Therapeutic Agents	9
Monitoring Equipment	9
Resuscitation Equipment	10
Other Equipment	10

Chapter 4 **Documenting Health Care**

Overview	11
Documenting Information	11
Documenting the Visit	11
Maintaining Documentation	12
Compiling Statistical Information	12
Chapter 5	
Monitoring Quality of Care	
Overview	15
Monitoring Care	15
Indicators which are Monitored	15
Complications which are Monitored	15
Documenting Long Term Outcomes	16
Evaluating Satisfaction of Care	16

Volume 2 Clinical Practice Parameters

Chapter 6	
Diagnosing a Pregnancy	
Overview	19
Confirming the Diagnosis	19
Determining Gestational Age	19
When the Gestational Age is Questionable	19
Preparing the Medical History	19
Conducting the Physical Examination	20
Recording the Diagnosis	20
Providing Support and Education to the Woman	20
Pre-termination Assessment	21
Other Screening Procedures	21
Performing Pelvic Ultrasound	21
Ultrasound Performed by a Physician	21
Ultrasound Performed by a Technologist	22
Chapter 7	
Protocols for Care	
Overview	23
Written Protocols of Care	23
Women who are at Risk	23
Termination Protocols	23
Documenting the Procedure	24
Following-up with the Woman	24
Tissue Samples	24
Fetal Tissue from Dilatation and Evacuation	24
Chapter 8	
Providing Emergency Services	
Overview	25
Providing Emergency Care	25
Chapter 9	
Providing Diagnostic Services	
Overview	27
Providing Diagnostic Services	27
Appendix I	
Independent Health Facilities Act - Ontario	

Regulation 346/04 Amended O. Reg. 57/92

Quality Advisor and Advisory Committee	29
Standards	30
Records of Employees	31
Patient Records	32
Books and Accounts	34
Notices	35
Miscellaneous	36

Appendix I **Parameters for the Use of Local Anaesthesia with Sedation by Non-anaesthesia Physicians**

Overview	37
Definitions	37
Analgesia and Anxiolysis	37
Sedation and Analgesia	37
Physician Education	37
Patient Selection	38
Drug Administration/Patient Monitoring	38
Equipment	39
Drugs	39
Emergency Routines	40

Bibliography

Preface

The Independent Health Facilities Act (IHFA), proclaimed in April 1990, and 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 specialities. 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.

When a facility is licensed by the Ministry of Health it will receive the appropriate parameters and standards. To further the role of facilitator, the College will work with and assist physicians in developing their own quality management/improvement programs. The first assessor education seminar was held in January, 1992 at which time many of the physicians who had indicated their interest in becoming inspectors/assessors were more fully informed of the assessment process. Additional seminars will be scheduled in the future as required.

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 adhered 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.

Independent Health Facilities: Clinical Practice Parameters and Facility Standards: Induced Abortion

Volume 1

Facility Standards

Chapter 1 Staffing a Facility

Overview

Professional medical and nursing services are provided by appropriately qualified and licensed health professionals.

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 physically present at the independent health facility on a regular basis, at least once every month, and be available for consultation at any time when services are provided with documentation kept of all visits.
- seek advice from other health professionals where necessary to ensure that all aspects of the services provided through the independent health facility are provided in accordance with generally accepted professional standards.
- consult with the quality advisory committee at least semi-annually if the independent health facility has more than six full-time staff equivalents including the quality advisor, otherwise at least annually, and to document the substance of the discussion, 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 nursing staff working in the independent health facility.
- performance of any professional or technical staff who do not have sufficient qualifications for the procedures being performed but who are being permitted to practise because of special circumstances.
- 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.
- facility’s policies regarding the maintenance of all appropriate clinical records, including their maintenance for the required length of time.

- 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 these requirements as set out above.

Providing Surgical and Medical Services

Surgical services are provided in a safe environment and are performed by qualified physicians.

Surgical services performed in an independent health facility are aspiration and dilatation and evacuation procedures performed under local anaesthesia with or without sedation by qualified physicians.

Early medical abortion (in the first trimester) may be provided in an independent health facility.

Note: Instillation procedures for pregnancy termination are not currently appropriate for independent health facilities.

Qualifications of Physicians

Termination of pregnancy is performed only by an appropriately trained physician who is licensed in the Province of Ontario. The physician may be deemed as appropriately trained:

- after attending a training program designated by the College of Physicians and Surgeons of Ontario

or

- was performing abortions in an independent health facility prior to June 2, 1988; and was grandfathered under the IHF Act prior to licensure

or

- if he/she has satisfactorily demonstrated to the Quality Advisor of a licensed facility his or her ability to perform an abortion.

or

- if he/she is licensed and has privileges to perform such procedures at an Ontario hospital.

Dilatation and evacuation procedures at 13 weeks gestation and beyond are performed by physicians appropriately trained in performing dilatation and evacuation procedures and managing their complications, in a facility that is equipped with ultrasound readily available to the operating area.

Local anaesthesia and sedation are used under the direct supervision of a responsible physician. The surgeon will have a trained assistant in the room for monitoring and assistance with drug administration.

Physician Responsibilities

A physician is responsible for the care of the woman from the time of surgery until discharge

Discharge criteria from a physician exist to determine the woman's readiness for discharge

A licensed physician qualified in resuscitation is present or immediately available until all women have been discharged.

Training Physicians in Ultrasound Procedures

Educational training in ultrasound procedures for the purpose of assessing gestational age consists of a one month training program to demonstrate proficiency in a facility or its equivalent providing abortion care. During the training period, the physician has the opportunity to correlate ultrasonographic findings with:

- pre-operative assessment (bi-manual examination)
- intra-operative monitoring (e.g. D & E procedures)
- post-operative monitoring (e.g. findings of the examinations of products of conception)

It is recommended that to demonstrate proficiency a minimum of 100 such cases in total be scanned.

Training Staff in Emergency Procedures

The staff of the facility is prepared to deal with emergencies.

A protocol exists for non-medical emergencies such as fire.

All new staff are oriented to the facility, emergency equipment and emergency protocols.

Staff trained in basic cardiopulmonary resuscitation are present in the facility during the hours of operation.

Providing Nursing Care

Nursing acts are performed only by nurses who have current registration with the College of Nurses of Ontario.

Providing Counselling Services

Counselling services may be provided by trained professionals or by appropriately trained para-professionals.

Services Provided by Paramedical and Paraprofessional Staff

Paramedical and paraprofessional staff provide non-professional services.

Chapter 2 Policies and Procedures

Overview

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

Developing Policies and Procedures

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

There is documentation to indicate who 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 on the routine preparation of patients
- consents
- delegated acts
- scope and limitation of diagnostic services
- patient booking systems
- infection control

Note: Each Independent Health Facility should obtain a copy of “College of Physicians and Surgeons of Ontario Infection Control in the Physician’s Office 2004 Edition:”. This document is available on the College’s Website www.cpso.on.ca under Publications.

- latex anaphylaxis
- maintenance of patient records (*see Appendix 1, IHFA- Ontario Reg, 57/92 amended to O. Reg. 14/95*).
- confidentiality
- safety precautions with regards to electrical, mechanical, fire and internal disaster.
- Material Safety Data Sheets (MSDS) sheets for all chemicals maintained in the facility.
- written job descriptions for each category of employee

Chapter 3 Facilities, Equipment and Supplies

Overview

The facility provides a functionally safe environment.

The facility complies with provincial building codes and fire regulations, and occupational health and safety governing workplace hazards.

Providing a Safe Environment

An emergency power source is available to provide light to areas where direct care is provided in the event of power failure.

The facility contains fire-fighting equipment to control a limited fire.

Safety checks of all electrical equipment are carried out on installation and at regular intervals.

The facility is designed to permit emergency transfer from the operative area to another facility if necessary.

Physical Environment

Surgical services are performed in a safe environment where:

- the space is adequately lit and ventilated
- if D & E procedures are offered there is additional recovery space provided to accommodate a longer recovery period.
- an emergency power source is available to provide light to areas where direct care is provided in the event of a power failure and to complete a surgical procedure
- universal body fluid precautions are observed
- appropriate sterile technique is practised.
- cardiac life support in the form of equipment and staff trained in basic cardiopulmonary resuscitation are available.
- arrangements exist for emergency transfer to hospital.

Providing a Sanitary Environment

The facility provides care in a sanitary environment.

The facility is clean and properly maintained.

Toilet facilities are available for staff, visitors and women being seen or undergoing the procedure.

Operating areas, and areas where the woman's assessment is carried out have facilities for hand washing.

Food service is in compliance with public health department requirements.

Using Sterile Techniques

Operative procedures and invasive procedures are carried out using sterile technique.

Observing Body Fluid Precautions

All personnel in the facility observe universal body fluid precautions in accordance with current CDC recommendations for Prevention of HIV Transmission in Health Care Settings.

Disposing of Products of Conception and Biomedical Waste

All products of conception and biomedical waste are disposed of in accordance with the current Guidelines for the Handling and Disposal of Biomedical Wastes from Health Care Facilities and Laboratories, Ontario Ministry of Environment or, in the case of stillborns, in accordance with the Vital Statistics Act, Government of Ontario.

Available Equipment

Equipment, supplies and technology permitting adequate assessment of the woman are available and includes:

- diagnostic tests for pregnancy use
- diagnostic pelvic ultrasound
- gynaecologic examining accessories and instruments
- diagnostic tests for haemoglobin, Rh factor and STD screening

- consideration should be given to screening women at risk for hepatitis and HIV infections
- basic medical equipment such as stethoscopes and sphygmomanometers.

Intra-operative and Post-operative Equipment and Therapeutic Agents

Equipment, supplies and therapeutic agents facilitating the safe intra-operative and post-operative care of the woman are immediately available.

Intra-operative real time ultrasound is available for all D & E procedures.

Functional and electrically safe vacuum aspiration equipment, as well as conventional instruments for dilatation and curettage and D & E procedures, are available in sufficient quantity so that individually sterilized conventional and suction instruments and new tubing are available for each procedure.

Note: The tubing between the patient and the collection bottle is replaced with new tubing for each procedure.

Suction equipment is designed to prevent reverse pump action, and the suction bottle is large enough to contain all fluids to minimize chance of backflow into the tubing.

Sedatives, narcotics, local anaesthetics, as well as reversal drugs and resuscitative drugs are immediately available.

Oxygen is available.

Other inhalational agents are restricted to nitrous oxide.

Monitoring Equipment

Monitoring equipment is available for women receiving sedation and includes:

- pulse monitor
- sphygmomanometer
- oximeter

Resuscitation Equipment

Resuscitation equipment includes, but is not limited to:

- stethoscope
- sphygmomanometer
- oral airway
- laerdal bag or equivalent
- oropharyngeal suction or dedicated equivalent
- IV equipment
- large bore intravenous catheter such as a 16 gauge
- syringes, needles, tape
- drugs:
 - epinephrine 1 : 1000 (1 ml ampoule)
 - diazepam, 10 mg ampoule
 - diphenhydramine hydrochloride, 50 mg ampoule
 - 50% dextrose/water, 50 ml ampoule.

Other Equipment

Adequate supplies of intravenous fluids, drugs, syringes, needles, intravenous equipment, sterile gloves and sterile sponges are available.

Osmotic cervical dilators are available.

Appropriate instruments necessary for dilatation and evacuation procedures are available if midtrimester abortions are performed.

Equipment to facilitate tissue evaluation is available.

Equipment is available for instrument sterilization.

Anti D Immune Globulin is available for administration to all Rh negative women.

A stretcher is available for emergency situations.

Chapter 4 Documenting Health Care

Overview

Health records facilitate the prompt retrieval of information. A system for processing, maintaining, storing, retrieving, distributing health records is established as described in IHF Regulation (*See Appendix 1 - Independent Health Facilities Act- Ontario Regulation 346/04- Amended to O.Reg. 57/92*).

Health records are:

- legible
- completed in a timely manner
- organized in a systematic manner

Documenting Information

The health record facilitates the continuing care of the woman. Each record contains appropriate information to identify the woman including her:

- name
- date of birth
- address
- phone number

Documenting the Visit

Each record contains documentation of all aspects of a woman's visit, for example:

- counselling
- history
- examination
- tests, including ultrasound
- intervention
- follow-up arrangements

Documentation of each visit includes:

- date
- nature of interaction, for example:
 - counselling
 - physical exam
 - operative procedure
 - drug administration
- signature or initials of responsible practitioner including their professional designation

The history, physical exam and pre-operative assessment including determination of gestational age are present on the health record prior to the performance of the procedure. This documentation will have occurred within two weeks prior to the procedure.

An informed consent is obtained and documented prior to the procedure.

The woman's status prior to and following the surgery is documented.

The procedure is documented and dated with the time and dosage of all drugs used and the signature of the responsible physician.

Products of conception obtained are examined at the conclusion of the procedure and there is documentation that products of conception were obtained.

Maintaining Documentation

There are policies regarding:

- the release of information
- the retention of active health records
- the retirement of inactive health records

Health records are maintained in a confidential and secure manner.

Compiling Statistical Information

Health record keeping facilitates quality assurance programs.

The facility compiles annual statistical information including, but not limited to the number of abortions:

- performed

- performed at each gestational period
 - less than or equal to 12 weeks
 - 13 to 16 weeks
 - 17 to 20 weeks
 - greater than 20 weeks

The facility maintains a record of known complications.

Chapter 5 Monitoring Quality of Care

Overview

There is an ongoing quality management program designed to objectively and systematically monitor and evaluate the quality and appropriateness of care, to improve care, and to resolve identified problems.

Monitoring Care

There is a planned and systematic ongoing process for monitoring, evaluating and improving the quality, appropriateness and outcome of care provided to women and includes:

- defining who is responsible for monitoring and evaluating activities
- establishing who is responsible for monitoring indicators and clinical criteria
- determining frequency of monitoring
- implementing an action plan to improve care or correct identified problems.

Indicators which are Monitored

The monitoring process is designed to identify patterns or trends in care, as well as single clinical events that warrant evaluation.

Indicators that are monitored include, but are not limited to:

- number of women seen and counselled
- number of procedures performed
- number of procedures at each gestation:
 - calculated by LMP
 - and by best clinical estimate
- number of procedures at each gestational age
- number of known follow up outcomes (short and long term)

Complications which are Monitored

Complications that are monitored include, but are not limited to:

- failed abortion with continuing pregnancy or requiring second procedure
- incomplete abortion

- perforation
- haemorrhage >500cc
- infection requiring IV antibiotics
- pulmonary embolus
- laparotomy
- any complication resulting in hospitalization
- death.

Documenting Long Term Outcomes

Any long term outcomes that are known should be documented so that trends may be noted.

Evaluating Satisfaction of Care

The woman's satisfaction of care is evaluated.

Independent Health Facilities: Clinical Practice Parameters and Facility Standards: Induced Abortion

Volume 2

Clinical Practice Parameters

Chapter 6 Diagnosing a Pregnancy

Overview

A diagnosis of pregnancy is confirmed in each woman offered services. Gestational age is determined accurately prior to offering a procedure. An adequate history and physical examination are conducted to determine any co-existing medical conditions or other factors which might affect the procedure or outcome.

Confirming the Diagnosis

Diagnosis of pregnancy is confirmed by one of the following:

- urine pregnancy test
- serum BHCG
- pelvic ultrasound

Determining Gestational Age

Gestational age is determined by one of the following:

- diagnostic pelvic ultrasound is preferred
- bimanual pelvic examination is acceptable if consistent with dates.

When the Gestational Age is Questionable

When gestational age is in question, or intrauterine pregnancy is uncertain, diagnostic pelvic ultrasound is performed.

Note: Pelvic ultrasound may be used in first trimester procedures (equal to or less than 12 weeks). Pelvic ultrasound should be used in second trimester procedures (equal to or greater than 13 weeks).

Preparing the Medical History

The medical history includes, but is not necessarily limited to:

- gynaecological history
- history of significant medical conditions
- family history
- history of allergies
- documentation of current medications
- functional enquiry.

Substance abuse and cigarette smoking are documented. The history is documented in a systematic and legible manner in each health record.

Conducting the Physical Examination

A physical exam which includes, but is not limited to, the following parameters is documented in a systematic and legible manner:

- pulse
- blood pressure
- abdomen
- pelvic assessment

Recording the Diagnosis

A diagnosis of pregnancy gestation and the presence or absence of any risk factors are clearly indicated on the health record.

Providing Support and Education to the Woman

Educational information that is readily understandable to the woman is available regarding the procedure, aftercare and contraception.

Educational information is both verbal and written

Decision-making counselling assuming no predetermined outcome is offered to the client and is documented.

The woman's individual and freely chosen decision to pursue pregnancy termination is assessed privately.

Emotional and psychological support is provided as needed by trained staff.

Pre-termination Assessment

Appropriate pre-termination assessment screening is performed on all women.

Routine pre-termination assessment screening for all women identified as pregnant and at no risk (no co-existing medical conditions or other factors which might affect the procedure or outcome) includes, but is not limited to:

- haemoglobin
- Rh factor

Other Screening Procedures

These screening procedures may be carried out and the appropriate follow-up accordingly arranged. They are:

- rubella
- sickle cell testing
- serology for syphilis
- electrolytes
- cervical cytology

Protocols exist for additional pre-operative screening for women at risk for example:

- blood coagulation disorders
- malignant hyperthermia.

Women at risk for sexually transmitted diseases are either screened with cervical cultures or treated appropriately. Consideration should be given to screening women at risk for hepatitis and HIV antigen using new rapid assays where available.

Performing Pelvic Ultrasound

Pelvic ultrasound is performed by health professionals as an integral component of abortion care.

Ultrasound Performed by a Physician

A physician performing abortion procedures performs an ultrasound to:

- confirm intrauterine gestation

- determine the gestational age
- assist in the evacuation process
- confirm that no residual products of conception are present.

Ultrasound Performed by a Technologist

A trained assistant other than the physician performing abortions performs an ultrasound under the supervision of the physician to:

- confirm intrauterine gestation
- determine the gestational age.

Chapter 7 Protocols for Care

Overview

The woman is provided with accurate information about the procedure and its risks and benefits. The woman is provided with all information necessary to facilitate her care and aftercare.

Written Protocols of Care

Care is conducted according to written protocols. Written protocols of care exist for pre-operative, intra-operative and post-operative care of the woman at no risk and the woman at risk.

Women who are at Risk

Specific protocols address the care of the following women at risk (women in whom medical conditions or other factors might affect the procedure or outcome) and includes but is not limited to:

- anaemia
- blood coagulation disorders
- diabetes
- heart disease
- hyperemesis gravidarum
- malignant hyperthermia
- morbid obesity.

Termination Protocols

Written protocols exist for:

- early medical abortion
- surgical abortion less than or equal to 12 weeks
- surgical abortion 13 to 16 weeks

- surgical abortion 17 to 20 weeks

Note: In relation to D & E after 13 weeks, protocols exist for sufficient dilatation of the cervix through use of multiple osmotic dilators (e.g. laminaria), misoprostol or other methods.

Documenting the Procedure

All aspects of intervention are documented in the record in a systematic legible format and signed by the responsible individual.

Following-up with the Woman

Arrangements are made for appropriate follow-up subsequent to the procedure.

Tissue Samples

Under physician supervision, tissue obtained from the abortion is examined to establish termination of an intrauterine pregnancy.

Tissue from an abortion where chorionic villi or fetal parts cannot be identified grossly is submitted for microscopic examination as soon as possible with an appropriate mechanism in place to retrieve the pathological report and notify the patient of outcome.

Gross examination of tissue where fetal parts and chorionic villi can be seen is noted in the health record.

Fetal Tissue from Dilatation and Evacuation

Fetal tissue from dilatation and evacuation procedures beyond 13 weeks gestation is examined for complete evacuation of all major fetal parts. Foot length is measured.

Fetal tissue from dilatation and evacuation procedures should be disposed of in accordance with current legislation; that is, Vital Statistics Act, Government of Ontario in the case of a stillborn, or in accordance with the current *Guidelines for the Handling and Disposal of Biomedical Wastes from Health Care Facilities and Laboratories, Ontario Ministry of the Environment*.

Chapter 8 Providing Emergency Services

Overview

Emergency care appropriate to abortion procedures is provided.

Providing Emergency Care

The facility has the capability to transfer a woman immediately to a hospital in the case of an acute emergency. Where D & E services are provided, the facility has immediate access (within 30 minutes) to a full service hospital (with blood banks, intensive care unit and operating room).

Staff trained in basic cardiopulmonary resuscitation are on site in the facility until all women are discharged post-operatively.

The facility has drugs and emergency protocols appropriate for medical emergencies which include, but are not limited to:

- haemorrhage
- anaphylactic shock
- cardiac arrest
- seizures

A physician is immediately available until all women are discharged from the facility.

The facility provides all women with verbal and written information on discharge. There is a 24 hour contact number through which a woman can obtain emergency care, both physical and psychological, for any problem arising related to an abortion.

The pre-operative assessment screens for the women at risk so she may be cared for appropriately, whether in the facility or in a hospital setting.

Chapter 9 **Providing Diagnostic Services**

Overview

Medical laboratory and pathology services, and diagnostic services are appropriate to the needs of the women and support the facility's clinical activity.

Providing Diagnostic Services

Services are provided in a timely manner.

Dated reports for all diagnostic services performed are part of the health record.

A written protocol addresses the facility's procedure for reviewing and acting on diagnostic tests.

All diagnostic services are carried out in a safe manner which includes the use of sterile technique, observation of universal body/fluid precautions, and the appropriate disposal of all products of conception and biomedical waste.

Appendix I Independent Health Facilities Act - Ontario Regulation 346/04 Amended 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 initialed 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 Parameters for the Use of Local Anaesthesia with Sedation by Non-anaesthesia Physicians

Overview

This appendix provides guidelines for the use of local anaesthesia with sedation by non-anaesthesia physicians in an IHF performing induced abortion. Use of parenteral medication for anxiolysis, sedation, and anaesthesia presents risks which are dependent on the level of sedation and depression of airway protective reflexes.

Definitions

The following levels of sedation are appropriate for use in such a facility by non-anaesthesia physicians:

- analgesia and anxiolysis
- sedation and analgesia.

Analgesia and Anxiolysis

Decrease in or elimination of pain and anxiety in a conscious patient. The patient is easily awakened by normal or softly spoken verbal commands and is oriented when awake. She is able to hold a conversation. All vital signs are stable, there is no significant risk of losing protective reflexes, and the patient is able to maintain pre-procedure mobility.

Sedation and Analgesia

A state of depressed level of consciousness in which a patient is able to maintain a patent airway independently and continuously and can be aroused by physical stimuli. These patients are unable to hold a conversation, but respond to commands by appropriate action or brief verbalization.

Physician Education

Physician education must be adequate for the level of sedation being practiced in the facility.

In any facility where parenteral sedation is used, physician education should include, in addition to the qualifications required for the performance of the procedure itself:

- basic CPR
- documented number of cases done under supervision
- verification by the Quality Advisor that the physician understands and is capable of maintaining the level of sedation which the staff and facility are prepared for.

In addition, if Sedation and Analgesia are used, physician education should include:

- Advanced Cardiac Life Support (ACLS)
- periodic updates, including airway management.

Patient Selection

Patients are assessed for conditions that would put them at increased risk of cardiorespiratory compromise during parenteral sedation. Such conditions might include:

- cardiac or pulmonary disease
- morbid obesity
- marked anaemia
- habituation to anxiolytic or narcotic medications
- impairment of hepatic or renal function affecting drug metabolism
- concurrent use of medications that are not compatible with the facility's anxiolytic and narcotic medications
- lack of IV access.

Final selection of sedation level is made by the physician taking into account individual patient risk factors, physician training, and facility preparedness.

Drug Administration/Patient Monitoring

Medications for anxiolysis and sedation are chosen with consideration of their duration of action, their known safety profile, and ease of dosage adjustment to prevent over sedation. In general, these will be narcotics and/or benzodiazepines with a short half-life and no active metabolites.

The facility has a formulary and protocols which govern the medications and doses used, the maximum level of sedation to be attained, and the procedure for monitoring and if necessary reversing the level of sedation.

The physician is responsible for determining the dosage and timing of administration of sedative and anxiolytic medications in each individual patient.

There is a suitably trained assistant to the surgeon in the room for drug administration and monitoring.

Monitoring may consist of maintaining verbal contact with the patient, measurement of heart rate and blood pressure, and use of monitoring equipment as set out below.

Equipment

The following equipment is available whenever any parenteral sedation is administered:

- blood pressure apparatus
- source of oxygen
- laerdal bag or equivalent
- suction
- SAO₂ oximetry
- oral airway
- IV equipment.

In addition, if sedation and analgesia are used, equipment should include:

- ECG
- intubation equipment

Drugs

The following drugs are available whenever parenteral sedation is administered:

- sedatives and narcotics
- local anaesthetics
- reversal drugs

In addition, if sedation and analgesia are used, drugs should include:

- resuscitative drugs

Emergency Routines

Emergency routines are established for the following:

- oversedation with loss of ability to respond to verbal communications
- anaphylaxis
- respiratory or cardiac arrest
- other routines as appropriate to the facility.

Bibliography

A Clinician's Guide to Medical and Surgical Abortion, Churchill Livingstone, 1999.

Clinical Policy Guidelines, 2005; National Abortion Federation; 1755 Massachusetts Avenue, NW; Suite 600; Washington, DC 20036. (available at www.guidelines.gov)

Clinical Practice Parameters and Facility Standards - Obstetrics & Gynaecology Induced Abortion - Second Edition, May 1993 - College of Physicians and Surgeons of Ontario.

Practice Guidelines for Sedation and Analgesia by Non-anaesthesiologists, *Anesthesiology* April 2002.