cpsa
COLLEGE OF PHYSICIANS
& SURGEONS OF ALBERTA

Termination of Pregnancy Standards

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1.0 Preamble

This document addresses privileges and standards for Termination of Pregnancy, and is intended to supplement the CPSA's standards for *Non-Hospital Surgical Facilities.*

2.0 Physician Privileges

2.1 Abortion procedure privileges shall be limited to gestational ages for which a qualified preceptor attests that the applicant is competent to perform.

2.2 Physicians performing trans-abdominal ultrasound for gestational dating in an abortion facility shall have completed a minimum of fifty (50) such studies in a facility approved by Council and provide the CPSA with evidence of his or her satisfactory performance.

2.3 Physicians performing trans-vaginal ultrasound for gestational dating in an abortion facility shall have completed a minimum of fifty (50) such studies in a facility approved by Council and provide the CPSA with evidence of his or her satisfactory performance.

3.0 Counseling and Consent

3.1 Prior to the performance of any abortion services, the patient shall be provided with information and counseling in conformance with the following standards:

1. all verbal and written educational information details covering the abortion services, after-care and contraception methods shall be readily understandable to the patient;

2. the educational information shall accurately describe the alternatives to abortion and the attendant risks of abortions including but not limited to hemorrhage, infection, continued pregnancy, and adverse emotional / psychological consequences;

3. emotional and psychological support shall be provided by trained staff within the facility or shall be offered by way of referral to a qualified outside resources; and

4. the patient shall be interviewed by an objective informed empathic person in the facility who is trained in counseling for this purpose and who will review and document the extent of counseling received and the patient's decision in the record.

3.2 The consent process shall include an opportunity for the patient to discuss all aspects of the procedure with the physician who will perform it.

3.3 Before proceeding, the patient shall affirm in writing that she understands the procedure and its alternative, risks and benefits and freely wishes to have the abortion.

4.0 Diagnostic Testing

4.1 The diagnosis of pregnancy shall be confirmed pre-operatively by one or more of the following methods:

1. urine beta-hCG
2. serum beta-hCG
3. ultrasound

4.2 The gestational age shall be determined within two weeks of the abortion procedure and shall be documented in the record indicating the method of determination.

4.3 Rh immune globulin (RhIg) administration shall be offered to all Rh-negative women not known to be immunized to the D antigen.

4.4 Prior to the administration of RhIg, the patient's Rh type shall be determined either by a laboratory accredited by the College of Physicians & Surgeons of Alberta or by the facility on-site.

4.5 For facilities performing Rh typing on-site, the medical director of the facility is required to ensure compliance with the relevant requirements of the current version of the CPSA Laboratory Accreditation – Transfusion Medicine Standards:

- Personnel training and competency assessment
- Pre-examination sample identification
- Examination procedure (Rh typing)
- Quality assurance of examination procedures
- Blood product (RhIg) traceability

4.6 The patient's antibody screen, and confirmation of the patient's Rh type (if performed by the facility) shall be performed by a laboratory accredited by the College of Physicians & Surgeons of Alberta.

5.0 Use of Diagnostic Ultrasound

5.1 A physician approved to perform medically-induced abortions and to use diagnostic ultrasound in an approved facility is permitted to use ultrasound to:

1. confirm intrauterine pregnancy and determine gestational age; and
2. detect retained products

5.2 Images obtained by ultrasound and their interpretation shall be retained in the patient's clinical record.

5.3 The physician shall inform patients as to the limitations of the ultrasound study in that it is used only to confirm and date a pregnancy and/or to detect the presence or absence of uterine abnormalities pertinent to the abortion procedure.

5.4 Approval to perform ultrasound is subject to periodic review by the CPSA to determine the quality of the studies and the resulting care to patients.

6.0 Approved Procedures

6.1 Abortion procedures in approved facilities shall be limited to gestational ages of not greater than twenty (20) weeks / 0 days.

6.2 Methods used to terminate a pregnancy shall be limited to:

1. Methotrexate/Misoprostol in early pregnancy;
2. Dilatation and Suction Evacuation up to sixteen (16) weeks / 0 days;
3. Dilatation and Evacuation up to twenty (20) weeks / 0 days.

7.0 Confirmation at Completion of Procedure

7.1 Upon completion of the abortion procedure the physician shall confirm termination of the pregnancy and estimate the gestational age by a gross examination of all tissue obtained and document those findings in the medical record.

7.2 When insufficient tissue or incomplete products of conception are obtained, the patient shall be evaluated with further diagnostic testing.

8.0 Discharging the Patient

8.1 The facility shall comply with the CPSA's standards for discharging patients after sedation or anesthesia (Standards for Non-Hospital Surgical Facilities).

9.0 Annual Statistical Reporting

9.1 In addition to annual statistical reporting to the CPSA required of all NHSFs, facilities performing abortions shall report to the CPSA the information in regard to complications and outcomes required for membership with the National Abortion Federation.

10.0 Additional Drugs and Blood Products for Abortion Facilities

10.1 In addition to the drugs listed in appendix A of the CPSA's NHSF Standards and Guidelines, facilities performing abortions shall have the following drugs available:

- Oxytocin
- Carboprost tromethamine
- Misoprostol

10.2 Facilities performing abortions shall also have the following blood product available:

1. Rh(D) Immune Globulin (RhIG)

10.3 The following additional drug is recommended but not required:

1. Flumazenil

11.0 Ultrasound Services

11.1 Personnel

11.1.1 All physicians who perform and/or interpret ultrasound shall be accredited by the CPSA.

11.1.2 A sonologist shall be on site for all ultrasound examinations.

11.2 Images

11.2.1 All archived images shall be identified with the following:

a. Patient name
b. Second patient identifier
c. Date of birth
d. Facility name
e. Date of examination

11.2.2 All electronically stored images shall be readily available, for printing, when required.

11.2.3 All electronically stored images should be maintained for a minimum of 10 years.

11.3 Quality Assurance

11.3.1 All quality control results shall be reviewed by the physicians approved for ultrasound.

11.3.2 All corrective actions shall be recorded.

11.3.3 All quality control results shall be retained for at least 2 years.

11.4 Safety

11.4.1 The manufacturer's guidelines for maintenance and quality control of equipment shall be followed.

11.5 Infection Prevention and Control

11.5.1 There shall be a written protocol for the cleaning and disinfection of endo-cavity probes.

11.5.2 The "Guidelines for Cleaning and Preparing Endocavitary Ultrasound Transducer Between Patients" of the College of Physicians & Surgeons shall apply. (Appendix A)

11.5.3 There shall be no re-use of critical or semi-critical medical equipment labeled as single-use by the manufacturer.

11.6 Manuals

11.6.1 There shall be a manual outlining the facilities quality assurance policies.

11.6.2 The quality assurance manual shall be reviewed annually.

11.6.3 The quality assurance manual shall be accessible to staff.

11.6.4 A physician accredited by the CPSA to perform and interpret ultrasounds shall be consulted for manual development and maintenance.

11.6.5 The quality assurance manual shall include sections on quality control for:

a. Ultrasound equipment

Appendix A - Guidelines for Cleaning and Preparing Endocavitary Ultrasound Transducer Between Patients[i]

The purpose of this document is to provide guidance regarding the cleaning and disinfection of trans-vaginal and trans-rectal ultrasound transducers.

All sterilization/disinfection represents a statistical reduction in the number of microbes present on a surface. **Cleaning is an extremely important part of equipment and instrument reprocessing and is necessary to permit maximum efficacy of subsequent disinfection and sterilization processes.** Cleaning of transducer probes must be followed by a disinfecting procedure to ensure a high degree of protection to patients from infectious disease transmission, even if a disposable barrier covers the instrument during use.

Medical instruments fall into different categories with respect to potential for infection transmission. The most critical level of instruments are those that are intended to penetrate skin or mucous membranes. These require sterilization. Less critical instruments (often called "semi-critical" instruments) such as endocavity diagnostic probes that simply come into contact with mucous membranes require a minimum of high-level disinfection.

Although endocavitary ultrasound transducers might be considered even less critical instruments because they are routinely protected by single use disposable probe covers, leakage rates of 0.9% - 2% for condoms and 8% - 81% for commercial probe covers have been observed in recent studies.[ii] For maximum safety one should therefore perform cleaning and **high-level disinfection** on the transducer between each use and a probe cover or condom should be used as an aid to keeping the transducer clean.

There are four generally recognized categories of disinfection and sterilization.

Sterilization is the complete elimination of all forms of microbial life including spores and viruses.
Disinfection is the selective removal of microbial life and is divided into three classes:

> **High-Level Disinfection** – Destruction/removal of all micro-organisms except bacterial spores;
> **Intermediate-Level Disinfection** – Inactivation of Mycobacterium Tuberculosis, bacteria, most viruses and most fungi and some bacterial spores;
> **Low-Level Disinfection** – Destruction of most bacteria, some viruses and some fungi. Low-level disinfection will not necessarily inactivate Mycobacterium Tuberculosis or bacterial spores.

The following specific recommendations are made for the use of endocavitary ultrasound transducers. Users should review the Health Canada Infection Control Guidelines – Hand Washing, Cleaning, Disinfection and Sterilization in Health Care to be certain that their procedures conform to the principles for disinfection of patient care equipment. Always refer to the manufacturer instructions.

1. CLEANING – After removal of the probe cover, wipe off any residual gel or debris from the probe with a damp cloth. Immerse the probe in water (only the part of the probe that is safe to immerse) according to manufacturer's instructions and clean with medical grade detergent or enzymatic cleaner. Consider the use of a small brush especially for crevices and areas of angulation depending on the design of your particular transducer. Rinse the transducer thoroughly with clean tap water under the surface of the water, and then dry the transducer with a soft lint free cloth.

2. DISINFECTION – Cleaning with a detergent/water solution as described above is important as the first step in proper disinfection since chemical disinfectants act more rapidly on clean surfaces. However, the additional use of a high-level liquid disinfectant will ensure further statistical reduction in microbial load. Because of the potential disruption of the barrier sheath, additional high-level disinfection with chemical agents is necessary. Examples of such high level disinfectants include but are not limited to:

    ⇒ 2.4-3.2% glutaraldehyde products (a variety of available proprietary products including "Cidex", "Metricide", or "Procide");

    ⇒ Non-glutaraldehyde agents (proprietary products include "Cidex OPA [o-phthalaldehyde]", "Cidex PA [hydrogen peroxide & peroxyacetic acid]").

    ⇒ 7.5% Hydrogen Peroxide solution

    ⇒ 2% Accelerated Hydrogen Peroxide (AHP) (e.g. Resert)

    ⇒ Hydrogen peroxide vapour system (e.g Trophon EPR Sonex vapour High level disinfectant, GE Canada). This product must be used in a dedicated system according to manufacturer's instructions.

    All disinfectants shall have a Drug Identification Number (DIN) or Natural Product Number (NPN) from Health Canada and be approved for use in Canada.

    Other agents such as quaternary ammonium compounds are not considered high level disinfectants and should not be used. Isopropanol is not a high level disinfectant when used as a wipe and transducer manufacturers do not generally recommend soaking transducers in the liquid.

    The high level disinfection contact conditions, such as duration of soak, temperature of disinfectant solution, concentration testing and changing of solutions, cleaning of trays, etc. must be in accordance with manufacturer directions. Practitioners should consult the labels of proprietary products for specific instructions. They should also consult instrument manufacturers regarding compatibility of these agents with transducers. Many of the chemical disinfectants are potentially toxic and many require adequate precautions such as proper ventilation, wearing personal protective equipment (PPE) (chemically resistant gloves, face/eye protection, etc.) and thorough rinsing to remove chemical residue before reuse of the transducer.

3. PROBE COVERS – When in use the transducer should be covered with a single-use barrier. If the barrier used is a condom, it should be non-lubricated and non-medicated. Practitioners should be aware that condoms have been shown to be less prone to leakage than commercial probe covers, and have a six-fold enhanced AQL (acceptable quality level) when compared to standard examination gloves. They have an AQL equal to that of surgical gloves. Users should be aware of latex-sensitivity issues and have available nonlatex-containing barriers.

4. ASEPTIC TECHNIQUE – Reprocessed transducers must be stored in a clean, dry protected area when not in use. For the protection of the health care worker, all endocavitary examinations should be performed with the operator wearing clean procedure gloves throughout the procedure. Gloves should also be worn when handling used probes, when removing the condom or other barrier from the transducer and to clean the transducer as outlined above. When removing the barrier or condom, care should be taken not to contaminate the probe with secretions from the

patient. At the completion of the procedure, gloves should be removed and hands should be thoroughly washed with soap and water.

Note: Obvious disruption in condom barrier integrity does NOT require modification of this protocol. Following these guidelines take into account possible transducer contamination due to a disruption in the barrier sheath.

In summary, routine high-level disinfection of the endocavitary transducer between patients, plus the use of a probe cover or condom during each examination is required to properly protect patients from infection during endocavitary examinations. Whenever chemical disinfectants are used, precautions must be taken to protect workers and patients from the toxic vapours and contact with the disinfectant.

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[i] Amis S, Ruddy M, Kibbler CC, Economides DL, MacLean AB. Assessment of condoms as probe covers for transvaginal sonography. J Clin Ultrasound 2000;28:295-8.
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[ii] Health Canada, Infection Control Guidelines: *Hand Washing, Cleaning, Disinfection and Sterilization in Health Care,* Canada Communicable Disease Report (1998), Volume 24S8.

