College of Physicians and Surgeons of British Columbia

Position Statement

Handling Patient Requests for Return of Explanted Medical Devices, Human Tissue or Specimens

DETAILS

Department/program: Non-Hospital Medical and Surgical Facilities Accreditation Program

Date: September 6, 2019

PURPOSE

Position statements from the College provide background information and express or clarify the College's intent on a particular matter. They are intended as guidance for stakeholders in areas where events are evolving or changing rapidly, the implementation of processes and procedures may be premature, the implementation of a guideline or standard may not be necessary, another credible body (i.e. professional association) has already established guidelines or standards, or it is timely to communicate the College's broad intent before or as policies and procedures are developed.

This document addresses handling patient requests for return of explanted medical devices, human tissue or specimens in non-hospital facilities.

BACKGROUND

The *Environmental Management Act* (EMA) sets out the requirements for the introduction of waste into the environment and the Hazardous Waste Regulation, under the EMA, sets out the requirements for the proper handling and disposal of hazardous waste including biomedical waste.

The NHMSFAP standards require that health-care waste be safely and appropriately managed and that the return of explanted medical devices be appropriately managed. In addition, the NHMSFAP standards provide guidance on the issue of returning explanted medical devices and specimens to patients and assert not to return these to patients.

However, cultural and personal preferences of the patient may influence the handling of explanted medical devices, human tissue and specimens

POSITION

The NHMSFAP Committee is responsible for establishing accreditation standards, policies, rules, procedures and guidelines for the NHMSFAP to ensure the delivery of high-quality and safe services in non-hospital facilities.

While there is no provincial or federal law which specifically refers to whether explanted medical devices, human tissue or specimens can or cannot be returned to the patient after removal, the NHMSFAP Committee does not support the practice of returning explanted medical devices, human tissue or specimens to patients for several reasons including:

- Infection prevention and control (i.e. infectious disease risk, cleaning, decontamination and sterilization for each type of explant)
- Proper disposal of biomedical waste (i.e. autoclaving, incineration)
- Post-market surveillance requiring return of the medical device to the manufacturer
- Availability of options other than release to the patient (i.e. viewing, photographing)

Considerations, hazards and risks

- Non-hospital facilities should have policy and procedures in place for the handling of patient requests for the return of explanted medical devices, human tissue and specimens.
- Options other than releasing the explanted medical device, human tissue or specimen to the patient should be considered and are preferred (i.e. viewing, providing a photograph).
- Consideration should be given to the hazards and risks of release (i.e. infection prevention and control, handling and disposal of biomedical waste).
- Human tissue or specimens required for pathology should not be released.
- Human tissue or specimens that contain cytotoxic, pharmaceutical, chemical or radioactive waste should not be released.
- Human tissue or specimens that may pose an infectious disease risk (e.g. hepatitis B, multi-resistant bacteria) should not be released.
- Medical devices that are required to be returned to the manufacturer should not be released.
- Authorization for the return of medical devices, human tissue or specimens to a patient should only be granted by the medical director of the non-hospital facility.
- The medical director should consult the patient's physician and an infection prevention and control practitioner in determining whether to authorize the return of medical devices, human tissue or specimens to a patient. Consultation with a risk manager and/or legal counsel can also be considered.
- The medical director's decision authorizing or denying the return of the explanted medical device, human tissue or specimen to a patient should be documented in the patient's medical record including the reason for the decision.
- The details of the release of the explanted medical device, human tissue or specimen to a patient should be documented in the patient's medical record (i.e. date, what is being returned, to whom it was given, how it is contained, information about safe handling and disposal (i.e. return to the non-hospital facility for appropriate disposal) etc.).

REFERENCES

Association of periOperative Registered Nurses (AORN). Guidelines for perioperative practice 2018 edition. Denver, CO: AORN; 2018. Guideline for specimen management; p. 439-68.

Canadian Standards Association. Cells, tissues, and organs for transplantation: general requirements – 3rd ed. Toronto: Canadian Standards Association; 2017. CSA Standard: Z900.1-17.

Canadian Standards Association. Handling of health care waste materials – 4th ed. Toronto: Canadian Standards Association; 2015. CSA Standard: Z317.10-15.

Government of British Columbia. Hazardous waste legislation & regulations [Internet]. Victoria: Government of British Columbia; 2018. [cited 2019 May 14]. Available from:

https://www2.gov.bc.ca/gov/content/environment/waste-management/hazardous-waste/legislation-regulations

Operating Room Nurses Association of Canada (ORNAC). The ORNAC standards, guidelines, and position statements for perioperative registered nurses. 13th ed. Toronto: CSA Group; 2017. 469 p.

CONTACT

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