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Relevance of and indications for submitting surgical specimens to the anatomic pathology laboratory: obstetrics/gynecology and urology

English summary

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SUMMARY

Relevance of and indications for submitting surgical specimens to the anatomic pathology laboratory: obstetrics/gynecology and urology

Introduction

Since the publication of the *Organization and Management of Institutions Regulation* (C.Q.L.R., chapter S-5, r. 5)[1] in 1984, section 59 has generally been interpreted in clinical circles to mean that all surgical specimens must be sent to the anatomic pathology laboratory for analysis. This regulatory provision has, for many years, resulted in a large volume of specimens being submitted and analyzed. It is estimated that a significant proportion of these submissions may not be necessary.

To promote optimal utilization of anatomic pathology resources and ensure consistency between institutions, the *Ministère de la Santé et des Services sociaux* asked the *Institut national d'excellence en santé et en services sociaux* (INESSS) to make recommendations to guide clinicians in their decision to submit or not submit certain surgical specimens to the anatomic pathology laboratory, based on the anatomical region, the domain of surgical expertise concerned, and the relevance of an anatomopathological examination. To this end, the project has been divided into six parts: orthopedic surgery and neurosurgery, general surgery, plastic surgery and dermatology (part A); the general surgery subspecialities (part B); obstetrics/gynecology and urology; cardiovascular and thoracic surgery; otolaryngology and maxillofacial and cervicofacial surgery; and ophthalmology. The present report deals with obstetric/gynecologic and urologic surgical specimens.

Methodology

To fulfill the mandate, a systematic review was carried out in the scientific literature and using publications presenting or containing positions, recommendations or guidance on the subject. In addition, contextual information and the perspectives of various stakeholders were gathered to document perceptions of and level of acceptability associated with the selective submission of certain surgical specimens and materials to the anatomic pathology laboratory, and to determine the potential organizational, clinical, ethical and legal issues.

To gather different perspectives, INESSS created an advisory committee consisting of obstetricians/gynecologists, urologists and anatomic pathologists. In addition, electronic surveys were sent to the directors of professional services and OPTILAB co-directors (a clinical laboratory reorganization project) to obtain information on surgical specimen

[1] COMPILATION OF QUÉBEC LAWS AND REGULATIONS (C.Q.L.R.). *Organization and Management of Institutions Regulation*, chapter V, BENEFICIARY'S RECORDS, section 59: "Where any part of a human body or any object is removed during surgery, a written report shall be prepared by the pathologist having examined that part of the human body or object. The original of the report shall be preserved in the beneficiary's record and a copy shall be kept by the laboratory, where an index cross-referenced by beneficiary and by pathology shall be constituted." (O.C. 1320-84, s. 59; O.C. 545-86, s. 25). Available at http://legisquebec.gouv.qc.ca/en/ShowDoc/cr/S-5,%20r.%205/ (consulted on January 7, 2020).

submission practices and anatomic pathology resource utilization in Québec's health-care facilities. The Canadian Medical Protective Association was consulted to validate certain medicolegal issues potentially associated with a change in the procedures for submitting surgical specimens. Information on the impact of selective submission of certain surgical specimens on billing and auditing processes was obtained from the *Régie de l'assurance maladie du Québec*.

The recommendations concerning obstetric/gynecologic and urologic surgical specimens that could be submitted to the anatomic pathology laboratory according to a selective approach are based on a simplified Delphi consultation process with 4 rounds. This process was carried out with the advisory committee in the light of the data and information from the systematic literature review and from consultations with informants and stakeholders, including the aforementioned Canadian Medical Protective Association and RAMQ.

Results

Based on the scientific literature, there is a low risk of missing a clinically significant abnormality (i.e., a fortuitous finding that could have an impact on the patient's management) in omitting an anatomopathological examination of tissue from a voluntary termination of pregnancy, a salpingectomy for a benign indication, a circumcision, or an inguinal hernia repair.

For tissues from a voluntary termination of pregnancy, the sensitivity of an anatomopathological examination is low for the identification of an abnormal outcome, including procedural failure, an incomplete procedure or an ectopic pregnancy. The effectiveness of the surgeon's examination in predicting an abnormal outcome is, in fact, greater than that of an examination by the pathologist.

One study found that a histological analysis failed to identify chorionic villi in 4.2% of ectopic pregnancies confirmed by ultrasound and surgery.

In the case of fallopian tubes, a fortuitous cancer discovery rate of less than 1% is reported for salpingectomies performed during surgery for benign indications in a population at low risk for ovarian cancer.

The results of a histopathologic analysis of foreskin specimens rarely have an impact on patient management. Common indications for circumcision are phimosis, paraphimosis and balanitis xerotica obliterans (BXO). Studies have shown that in more than 83% of cases of lichen sclerosus, the diagnosis was suspected pre- or intraoperatively.

In the case of hernia sacs, the identification of a structure of the reproductive system (epididymis or vas deferens) or cancer is considered clinically significant and varies in frequency from 0 to 0.88%, depending on the study. Only one study reported unexpected cases of cancer (in 0.06%). Identifying epididymal or vas deferens tissue in specimens from inguinal hernia repair in a pediatric patient would have little impact on their immediate management. The clinical course of action is usually to defer treatment in cases where a consequence would occur late (e.g., azoospermia).

Eight guidance documents and practice guidelines were identified in the literature that contained positions or recommendations on procedures for submitting obstetric/gynecologic and urologic surgical specimens to the anatomic pathology laboratory. Some learned societies point out that routine anatomopathological examination of tissues from voluntary terminations of pregnancy is not indicated. However, uterine contents should be visually examined after an abortion, and a histological analysis must be performed when gestational trophoblastic neoplasia or an ectopic pregnancy is suspected. Guidelines from the *Collège des médecins du Québec* stipulate that tissues from a voluntary termination of pregnancy must be sent to the anatomic pathology laboratory for examination.

The Society of Gynecologic Oncology recommends that fallopian tube fimbria in low-risk women undergoing routine salpingectomy be subjected to microscopic examination.

According to the Royal College of Pathologists, foreskins in young boys with no abnormalities require macroscopic examination only. As for the Canadian Urological Association, this group suggests routine histological analysis of foreskins, since the diagnosis of balanitis xerotica obliterans does not always correlate with clinical suspicion.

Policies concerning the selective submission of certain surgical specimens to the anatomic pathology laboratory have been developed by learned societies, including the College of American Pathologists (CAP), government agencies, and teaching hospitals.

No economic evaluation was performed, given the obstacles that would limit the feasibility and scope of such an evaluation in the Québec context, e.g., the inability to determine the number of procedures affected by the desired practice changes and the heterogeneity of current practices.

For the purpose of this report, consultations with experts on the advisory committee allowed for the drawing up of a list of obstetric/gynecologic and urologic surgical specimens for which the level of risk to the patient is considered low. In these cases, an anatomopathological examination is unlikely to provide useful information for managing the patient, and the specimens could be submitted to the anatomic pathology laboratory on a selective basis at the clinician’s discretion. This selective submission list includes: 1) tissues of conception from a normal voluntary termination of pregnancy; 2) rectocele and cystocele repair tissue; 3) tissues from a labiaplasty; 4) normal-appearing foreskins from neonates and boys; 5) hydroceles; 6) spermatoceles; 7) varicoceles; 8) urinary calculi; 9) prostheses, devices, and foreign bodies from the genitourinary sphere; and 10) normal-appearing scars.

Conclusions

The analysis and integration of the data from the scientific literature, the learned society guidelines and positions, and the perspectives of various stakeholders have enabled INESSS to make recommendations concerning the selective submission of certain surgical specimens to the anatomic pathology laboratory. These recommendations should contribute to more judicious utilization of anatomic pathology resources. However, the changes to practice that might result from them will depend on the dissemination and implementation of the recommendations in Québec's health-care facilities. A gradual implementation with the councils of physicians, the directors of professional services, the OPTILAB co-directors and other bodies responsible for the quality of care acting in concert will be needed to facilitate the changes and ensure optimal management of risk and of the quality of medical acts.

FINDINGS AND RECOMMENDATIONS

General findings concerning the submission of surgical specimens to the anatomic pathology laboratory

The analysis and integration of the data from the scientific literature, of the main guidelines and positions of learned societies, and of the perspectives of various experts and decision-makers led to the following findings concerning the submission of surgical specimens to the anatomic pathology laboratory for analysis. These findings are general in nature and apply to each part (i.e., specialty or group of specialties) dealt with in this anatomic pathology relevance project.

Regarding the **clinical utility** of submitting specimens to pathology:

- The routine anatomopathological examination of certain surgical specimens does not provide any useful information for the patient's medical management and should be reserved for unusual clinical presentations in order to clarify the diagnosis or eliminate clinical doubt;
- The probability of a clinically significant fortuitous anatomopathological finding in the specimens of interest in this report is considered to be low (or even anecdotal);
- Systematically submitting specimens to pathology creates a bottleneck in the analysis laboratories and leads to suboptimal turnaround times;
- The recommendations on selective submission by some learned societies have led to a reduction in the workload associated with analyzing specimens of limited or no clinical value.

Regarding the **procedures for submitting specimens** to pathology:

- Several learned societies, such as the American College of Pathologists, have proposed models for the selective submission of certain surgical specimens based on lists of specimens exempted from mandatory submission to anatomic pathology (or exempted from histological examination), in order to promote efficient utilization of anatomic pathology resources;
- Some Québec institutions have already implemented a selective submission policy for certain surgical specimens;
- The lists of specimens exempted from mandatory submission to anatomic pathology (or exempted from histological examination) in the guidance documents examined and by Québec facilities show differences in terms of the number and type of specimens exempted.
- Communicating relevant clinical information (e.g., procedure performed, preoperative diagnosis, unusual intraoperative findings and special concerns) is key to performing an appropriate anatomopathological examination.

Regarding the **professional practice of physicians** who remove specimens:

- There are appropriate ways other than sending a specimen to pathology to verify that a specimen has been removed (e.g., nurse confirmation, surgical notes, etc.).
- The surgeon's notes from the procedure and the surgery report are official documents in which the removal of any specimen during a surgical intervention must be documented and which must be included in the patient's chart. The surgery report must be written or dictated within 24 hours of the procedure.

Regarding the **economic savings** potentially associated with a change in practice in submitting specimens to pathology:

- The savings that could result from a selective submission of specimens to pathology cannot currently be estimated, mainly because of an inability to determine the number of procedures that would be affected by the desired practice changes and because of the heterogeneity of practices between institutions.

Recommendations concerning the submission of surgical specimens to the anatomic pathology laboratory

In light of these findings, INESSS has made a set of recommendations, in collaboration with the advisory and stakeholder committees consulted, aimed at promoting more judicious utilization of anatomic pathology resources without compromising the quality and safety of patient care and services. The first few recommendations are intended to be general in nature and apply to all the surgical disciplines for which specimens are removed and submitted to pathology. These will be repeated for each of the six parts of the pathology relevance project.

The general recommendations are followed by a more specific one for the obstetrics/gynecology and urology specialities: namely, a list of specimens that can be submitted to anatomic pathology on a selective basis. Lastly, recommendations are made aimed at facilitating the implementation and monitoring of the proposed changes.

The relevance of updating these recommendations will be assessed in five years, that is, in 2026.

INESSS's general recommendations[2]
INESSS is of the opinion that certain surgical specimens no longer need to be systematically submitted to the anatomic pathology laboratory for analysis, and that this applies throughout Québec. These specimens could be submitted on a selective basis according to clinical judgment.
To qualify for selective submission, a specimen should: • be on a list of specimens eligible for selective submission to anatomic pathology; and • arise from a surgical procedure for which no neoplastic or infectious process or other significant medical condition, which would warrant an anatomopathological opinion, is suspected by the clinician, based on the pre- and intraoperative findings.
All surgical specimens (organs, tissues, apparatuses, medical devices and foreign bodies) not sent to anatomic pathology must be visually examined by the surgeon to confirm that they do not exhibit any unexpected abnormalities and that the pre- and intraoperative findings are in line with expectations[3, 4].
The surgeon must record the removal, visual examination findings, intraoperative findings, and non-submission of the specimen to anatomic pathology[11, 5] in the patient's medical chart.
The selective submission lists proposed in this report should not, under any circumstances, be used as a substitute for clinical judgment. Therefore, the specimens on these lists can be sent to the anatomic pathology laboratory at any time at the clinician's discretion if there is some uncertainty or concern about the patient's health.

[2] Certain provisions have been made in accordance with current professional standards in Québec.

[3] "All surgery reports must contain information about the procedure performed (preoperative diagnosis, intervention performed, postoperative diagnosis, normal or abnormal findings made during the procedure, including the organs examined and the type of examination, etc.). The surgery report must be written up or dictated within 24 hours" (unofficial translation). Source: *La tenue des dossiers par le médecin en centre hospitalier de soins généraux et spécialisés – Guide d'exercice du Collège des médecins du Québec*, p. 29 (consulted on June 15, 2021).

[4] Biological and biomedical waste disposal standards must be applied to specimens that are not sent to the anatomic pathology laboratory. *Regulation respecting biomedical waste, Environment Quality Act* (chapter Q-2, r. 12, s. 59), available at http://legisquebec.gouv.qc.ca/en/ShowDoc/cr/Q-2,%20r.%2012 (consulted on July 8, 2021).

[5] "At the end of the procedure, the surgeon must add a postoperative note summarizing the surgical findings, the intervention performed, any incidents, blood loss, intraoperative complications, if any, and the patient's condition at the end of the procedure" (unofficial translation). Source: *La tenue des dossiers par le médecin en centre hospitalier de soins généraux et spécialisés – Guide d'exercice du Collège des médecins du Québec*, p. 19 (consulted on June 15, 2021).

INESSS's general recommendations[2]
The relevant clinical information constituting the rationale for submitting a specimen on a selective submission list to the laboratory must be indicated on the examination requisition to guide the anatomopathological investigation[6].
Any surgical specimen that is not on a selective submission list should be sent to the anatomic pathology laboratory for examination.

Recommendations on selective submission specific to obstetrics/gynecology and urology

INESSS recommends that the following surgical specimens be submitted on a selective basis to the anatomic pathology laboratory for analysis, and that this applies throughout Québec.
Obstetrics/gynecology
• Tissues of conception from a normal voluntary termination of pregnancy (VTP) • Rectocele and cystocele repair tissue • Tissues from a labiaplasty
Urology
• Normal-appearing foreskins – neonates and boys • Hydroceles • Spermatoceles • Varicoceles • Urinary calculi
Obstetrics/gynecology and urology
• Prostheses, devices and foreign bodies from the genitourinary sphere • Normal-appearing scars

[6] "All requests for an anatomopathological examination must include mention of the place of origin (hospital, physician's office, operating room, outpatient clinic, etc.) and the patient's identity (last name, first name, address, sex, age, health insurance number and hospital chart number), the date the specimen was removed, the procedure performed, the pre- and postoperative diagnoses, the type and origin of the specimen, and any other relevant clinical information" (unofficial translation). Source: *La tenue des dossiers par le médecin en centre hospitalier de soins généraux et spécialisés – Guide d'exercice du Collège des médecins du Québec*, p. 24 (consulted on June 15, 2021).

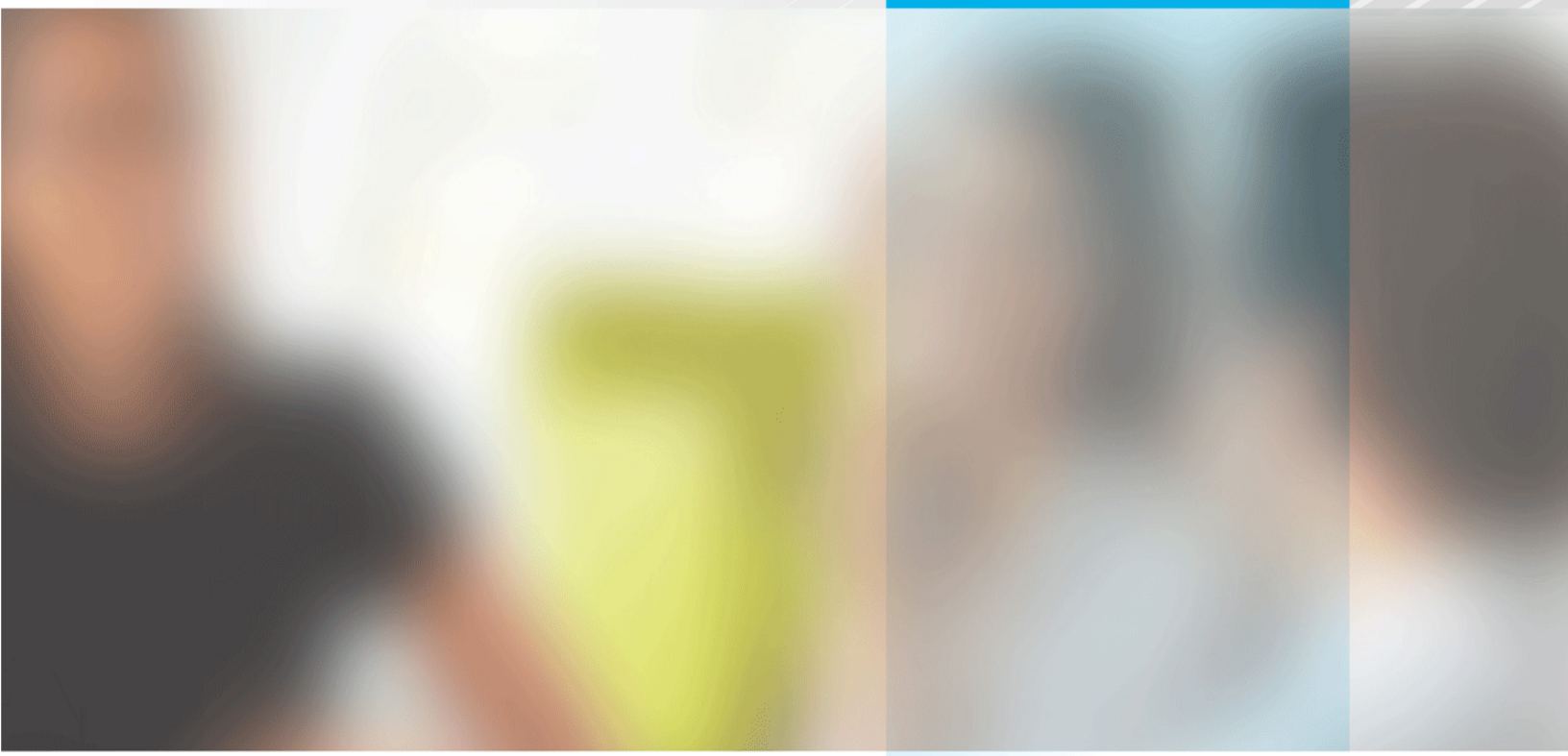
Recommendations promoting the implementation and monitoring of a selective submission process for certain specimens

The selective submission recommendations and lists proposed in this report should be the subject of a structured dissemination and communication process targeting professional orders and associations as well as universities.

A gradual implementation process for the recommendations should be planned to facilitate optimal management of changes. This process should be developed jointly with the councils of physicians, dentists and pharmacists (CPDPs), the directors of professional services (DPSs), the OPTILAB co-directors and other bodies responsible for the quality of care. The process should include the development and implementation of a tool to measure compliance with the recommendations and quality of the practice.

A standardized form should be developed for documenting the removal, appearance (normal or abnormal findings) and the non-submission of a surgical specimen to the anatomic pathology laboratory. The form could be completed by the operating room nurse.

The coding of medical procedures and anatomopathological analysis should be revised and standardized to facilitate the collection and interpretation of medical administrative data and thus make it possible to monitor the optimization measures deployed.



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