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Submission of surgical specimens to the anatomic pathology laboratory: relevance and indications

Orthopedic surgery and neurosurgery

English summary

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SUMMARY

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INTRODUCTION

Issue and background

Since the publication of the *Organization and Management of Institutions Regulation* (C.Q.L.R., chapter S-5, r. 5) in 1984, section 59 has generally been interpreted in Québec's clinical circles as meaning 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 a certain level of consistency between institutions, the *Ministère de la Santé et des Services sociaux* (MSSS) 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 and area of surgical expertise concerned, and on the relevance of an anatomopathological examination. To this end, this project has been divided into six parts, each of which has examined a surgical specialty or group of related specialties: orthopedic surgery and neurosurgery; general and plastic surgery; obstetrics, gynecology, and urology; cardiovascular and thoracic surgery; otolaryngology and maxillofacial and cervicofacial surgery; and ophthalmology. The present report deals with surgical specimens and materials from orthopedic surgery and neurosurgery.

Decision question

Which **orthopedic surgery** and **neurosurgery** specimens could be part of a selective anatomic pathology submission process, that takes into account situations where the pathologist's report is unlikely to provide any useful information for patient management?

METHODS

To fulfill this mandate, a rapid, structured review was carried out in the scientific literature and using publications presenting or containing positions, recommendations or guidance on the subject. 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 examine potential organizational, clinical, ethical and legal issues.

To gather different perspectives, INESSS created an advisory committee consisting of orthopedic surgeons, neurosurgeons and anatomic pathologists. In addition, electronic surveys were sent to the directors of professional services and OPTILAB co-directors, to obtain information on surgical specimen submission practices and anatomic pathology resources utilization in Québec's healthcare facilities. The Canadian Medical Protective Association (CMPA) and the *Régie de l'assurance maladie du Québec* (RAMQ) were consulted to validate certain medicolegal issues potentially associated with selective submission of surgical specimens to anatomic pathology and to examine the impact this change in practice could have on the billing and auditing process for medical procedures.

The recommendations concerning orthopedic surgery and neurosurgery specimens that could be submitted to the anatomic pathology laboratory according to a selective approach are based on a simplified Delphi consultation process with three rounds. This process was carried out with the advisory committee members in the light of the data and information collected from the literature review and from informant and stakeholder consultations.

RESULTS

Clinical utility of the anatomopathological examination of orthopedic surgery and neurosurgery specimens

The scientific literature review yielded 30 studies that compared the clinical and anatomopathological diagnoses of orthopedic surgery or neurosurgery specimens, i.e., material from arthroscopies and joint arthroplasties, corrective procedures for the foot or hand (hammertoe, hallux valgus and thumb osteoarthritis), neuromas, synovial cysts, tissue from discectomies and laminectomies, and orthopedic implants removed during procedures. Most of these studies (26/30) were retrospective cross-sectional and based on medical chart review.

According to the studies reviewed, the probability of a clinically significant anatomopathological finding, i.e., one that would lead to a change in patient management, is between 0% and 1.6% for joint tissue. One of these studies, a systematic review with meta-analysis, observed a probability of 0.04%. The indications for submitting joint tissue include an unusual clinical presentation, a history of dysplasia or malignancy, a case involving a controversial primary diagnosis, unexpected intraoperative findings (e.g., synovial hyperplasia or a suspicious cortical or medullary bone lesion), and prosthetic revision to identify the cause of a loosening (aseptic or septic).

Furthermore, according to the retained studies, the probability of a clinically significant anatomopathological finding upon examining material from corrective surgery for hammertoe, hallux valgus or thumb carpometacarpal osteoarthritis is nil.

According to the studies reviewed, the probability is also nil for material from the excision of synovial cysts and Morton's neuromas. However, according to the United Kingdom's Royal College of Pathologists (RCP), this material needs to be examined histologically

because of the risk of juxta-articular synovial sarcoma, epithelioid sarcoma and other similar pathologies.

In cases of routine discectomy or laminectomy, where no neoplastic or infectious process or other condition of concern is suspected, the probability of a significant fortuitous finding is between 0% and 0.1%.

Learned society positions and recommendations

Eleven learned society publications were identified concerning the procedures for submitting surgical specimens to the anatomic pathology laboratory for analysis.

According to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), exceptions to mandatory submission to pathology have been permitted since 1991, provided that the exception does not compromise the quality of care, that there is an alternative means of verifying the specimen resection, and that the specimen collection is documented in an authenticated surgery report (or other official report).

A few learned societies, such as the College of American Pathologists (CAP), have published lists of specimens whose submission to pathology is optional. Some have also drawn up lists of specimens to be sent for a gross examination only.

In addition, according to the Royal College of Pathologists (RCP), certain diagnoses traditionally made by histopathology are now based on other methods with superior sensitivity and specificity.

In Canada, lists of specimens for which submission to the pathology laboratory or histological examination is optional have been published by health authorities in Manitoba, Saskatchewan and British Columbia.

Perspectives of experts and other stakeholders

Regarding orthopedic surgery and corrective or reconstructive neurosurgery, the expert and stakeholder consultations highlighted the following:

- Surgical specimens are rarely submitted for diagnostic confirmation or support, but rather to document the medical procedure or as a requirement under section 59 of the Regulation.
- The systematic anatomopathological examination of surgical specimens, regardless of the type of procedure performed and the clinical context, would constitute inappropriate resource utilization.
- An anatomopathological examination should be reserved for unusual clinical cases to clarify the diagnosis or reassure the surgeon.
- The selective submission of certain specimens should improve the turnaround time for patients whose management depends on the anatomic pathology report and promote more judicious resource utilization.

- Lists of specimens that can be submitted according to a selective approach should be established on the basis of scientific evidence, rather than fear of potential lawsuits.
- The specimens on the proposed lists are considered at very low risk of affecting the patient, and not submitting them should not compromise the quality of care.

The expert and stakeholder consultations also highlighted the following regarding selective submission of certain specimens:

- The removed specimens should be visually examined by the surgeon to verify that there are no unexpected abnormalities. The findings of this examination should be included in the surgical notes and entered into the patient's medical chart.
- If there is some uncertainty or concern about the patient's health, there should be the option of sending specimens on the lists to pathology. The clinical information justifying their submission to pathology should be clearly indicated on the requisition.
- RAMQ has shown openness to considering other ways of auditing certain surgical procedures for which no specimens are submitted to anatomic pathology.
- The collaboration of professionals in the care units concerned and the involvement of the Councils of Physicians, Dentists and Pharmacists (CPDPs), the directors of professional services (DPSs), the OPTILAB co-directors and the bodies responsible for the quality of processes will be necessary for the implementation and sound management of this change.

Expert consultations using the simplified Delphi method

Consultation with the advisory committee's experts using the simplified Delphi method resulted in a list of 10 orthopedic surgery and neurosurgery specimens for which an anatomopathological examination is unlikely to provide any useful information for patient management and which, in the clinicians' judgement, could be submitted to the anatomic pathology laboratory in a selective manner. This list has been translated into a recommendation.

Economic evaluation of the selective submission of surgical specimens to the anatomic pathology laboratory

No economic evaluation was carried out because of the obstacles limiting the feasibility and scope of such an evaluation in the Québec setting (e.g., the inability to determine the volume of procedures that would be affected by the desired practice changes and the heterogeneity of current practices). Some possible solutions for potentially performing such an analysis in the future were identified and translated into recommendations.

FINDINGS AND RECOMMENDATIONS

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 orthopedic surgery and neurosurgery specimens to the anatomic pathology laboratory for analysis.

Regarding the **clinical utility** of submitting these 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 optional submission by some learned societies have led to a reduction in the workload associated with analyzing specimens considered to have little or no clinical value.

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

- Several learned societies have proposed models for the selective submission of certain surgical specimens based on established lists, 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 proposed for selective submission or for gross examination only in the guidance documents examined and by Québec facilities show differences in terms of the number and type of specimens specified;
- 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 medical 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 volume 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 orthopedic surgery and neurosurgery specialties: namely, a list of specimens that can be selectively submitted to pathology. 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[1]
INESSS is of the opinion that it would be fair and reasonable to no longer systematically submit certain surgical specimens to anatomic pathology laboratories 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 examination, 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 the anatomic pathology laboratory 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[2, 3].
The surgeon must record the removal, visual examination findings, intraoperative findings, and non-submission of the specimen to anatomic pathology in the patient's medical chart[2, 4].
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.
The relevant clinical information justifying submitting a specimen on a selective submission list to anatomic pathology must be indicated on the examination requisition to guide the anatomopathological investigation[5].
Any surgical specimen that is not on a selective submission list should be sent to the anatomic pathology laboratory for examination.

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

[2] "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). *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).

[3] 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/fr/ShowDoc/cr/Q-2,%20r.%2012 (consulted on July 8, 2021).

[4] "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). *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).

[5] "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). *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).

Selective submission recommendations specific to orthopedic surgery and neurosurgery

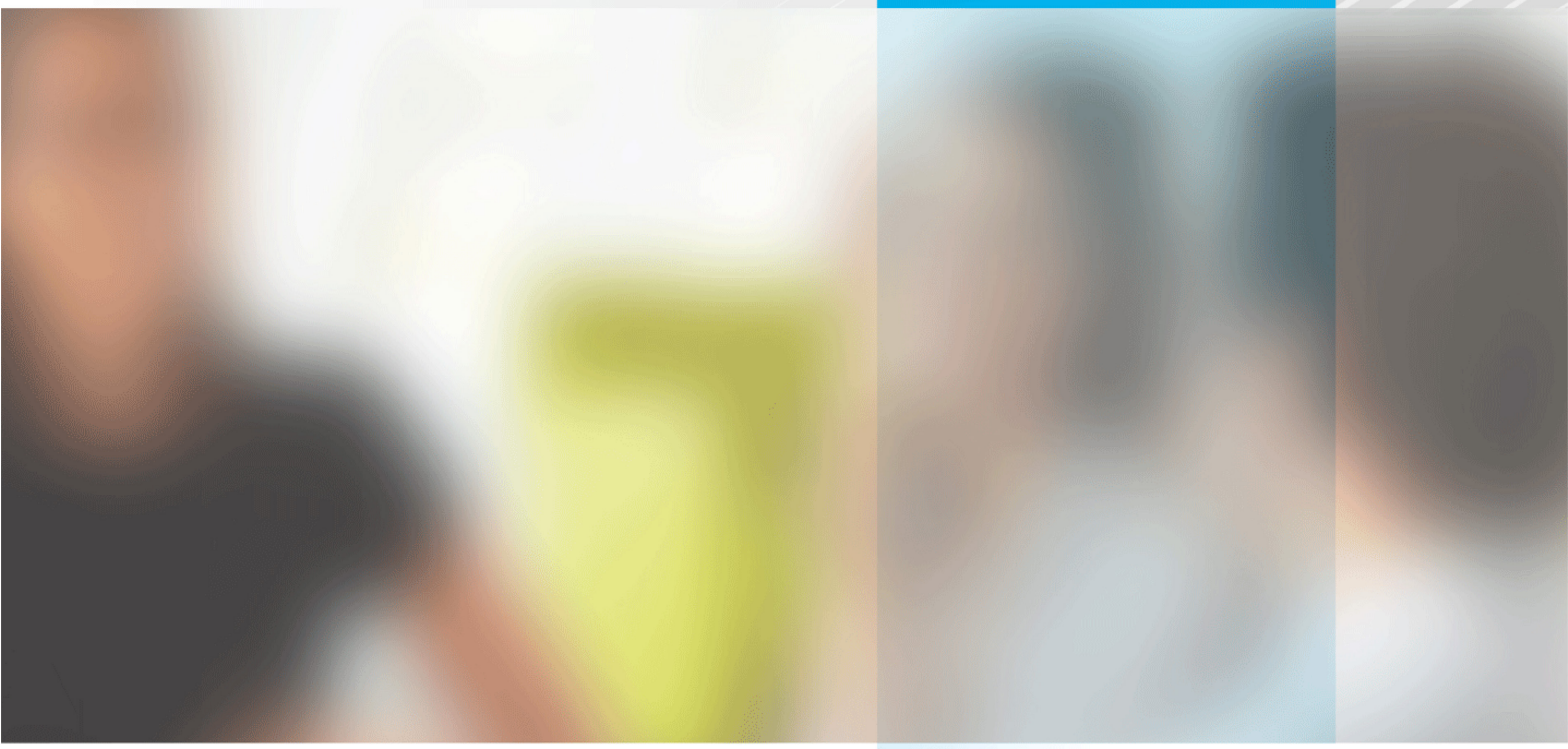
INESSS recommends that the following surgical specimens be submitted on a selective basis to the anatomic pathology laboratory for analysis, and that this applies throughout Québec.

INESSS's selective submission recommendations
Orthopedics
• Specimens from routine orthopedic procedures for the correction, repair or reconstruction of a joint or functional deformity • Amputated supernumerary fingers or toes • Specimens from a traumatic amputation or an elective amputation for non-neoplastic reasons (e.g., trauma, ischemia or chronic infection) • Tissues from debridement for a known cause • Nails of normal macroscopic appearance • Excess autologous graft material
Neurosurgery
• Bone fragments from a craniotomy • Specimens from a laminectomy, a discectomy or other routine spinal surgery*
Apparatuses, devices and other nonbiological materials
• Medical or orthopedic implants, devices and material removed during surgery • Foreign bodies

* With the exception of material from the surgical treatment of diastematomyelia or neural tube dysraphism for which there are differential diagnoses and to confirm the type of tissue excised.

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 CPDPs, DPSs, 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 analyses should be revised and standardized to facilitate the collection and interpretation of medico-administrative data and thus make it possible to monitor the optimization measures deployed.



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