EXEMPTION OF SPECIMENS FROM ROUTINE SUBMISSION TO PATHOLOGY LABORATORIES: RECOMMENDATIONS IN THE CANADIAN CONTEXT

CONTENTS

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INTRODUCTION

It is standard practice to send any tissue or organ removed during a medical procedure to a pathology laboratory. Policies regarding exemption of certain specimens—diverting them directly to biohazardous waste incineration—vary widely between places. These policies are shaped by legal regulations, local conventions, and evidence of diagnostic value. This last factor, especially relative to cost, should be central to decision making on this topic, given the growing focus on improving efficacy, saving money, and reducing waste within the Canadian healthcare system.

For each type of specimen, the following monetary, environmental, and human workload costs should be considered: cost of transport to laboratory; cost of routine accessioning and workflow in the laboratory; cost of specimen preservation (refrigeration or fixation) for recommended four weeks after final report;[1] cost of fixative and its environmentally responsible recycling or disposal; [...] cost of paraffin, cassettes, slides, and stains; cost of long-term archiving; cost of over-diagnosis and follow-up on non-specific "findings"; and maybe most importantly, pathologists' assistant, histotechnologist, pathologist, and support staff time.

For each type of specimen, the following utility factors should be considered: diagnostic value of gross examination; necessity and diagnostic value of microscopic examination; pre-test probability of uncovering unexpected pathology; pre-test probability of uncovering clinically actionable pathology; sensitivity of pathologic examination; risks associated with missing certain pathologies; and alternatives to examination in the laboratory.

There is no consensus cutoff for what percentage of unexpected pathology warrants examination of all cases in a category. Some have argued that even a pick-up rate of less than 0.5% (in gallbladders) is important,[2] whereas others have argued the opposite for a similar diagnostic yield (in "benign" hysterectomies).[3]

LEGAL FRAMEWORK

The requirement to submit specimens is covered in most provinces in health ministerial regulations made under their respective *Hospital Acts*. As a typical example, the Prince Edward Island *Hospital Management Regulations* specify that: "A surgeon shall not dispose of any tissues removed from a patient during a surgical operation or curettage [and] shall ensure that all tissues removed from a patient [...] together with adequate clinical data, are sent to a pathologist for examination and report."[4]

Most provinces that have regulations do allow for some tissues to be automatically exempt. For example, in Nova Scotia, "On the recommendation of its medical staff, a hospital may authorize exceptions [...] that the hospital considers do not require pathological examination." [5] This is similar to the wording in PEI's regulations.[4]

Several other provinces, however, have specified within their regulations exactly which specimens may be exempted. For example, in Saskatchewan, the only allowed exceptions are: "Any tooth, tonsil, prepuce, haemorrhoid, hernial sac, finger, toe, hand, foot, arm or leg removed or amputated."[6] Other provinces with legally defined exemption lists include Alberta,[7] Manitoba,[8] Ontario,[9] and New Brunswick.[10]

The Quebec regulations imply that all human body parts and objects removed during surgical procedures, without exception, must be sent to a pathology lab for examination and formal reporting by a pathologist,[11] although recent provincial policy has been developed to the contrary.[12]

British Columbia does not appear to have enacted regulations on this topic, and so policy making by default falls to hospitals and/or health authorities. The BC Agency for Pathology and Laboratory Medicine has defined a list of "Specimens Not Required for Submission to Pathology for Examination."[13]

PREVIOUS WORK ON THIS TOPIC

In 1999, the College of American Pathologists published results of a large survey on pathology exemption practices and found a wide range of specimen exemption policies across 413 mostly American laboratories.[14] The economic factors that may influence exemption lists in the United States are likely different from those in Canada.

In 2014, the Canadian Agency for Drugs and Technologies in Health (CADTH, recently renamed CDA: Canada's Drug Agency) released an environmental scan of Canadian practices based on both provincial regulations and a limited survey of pathology laboratory directors.[15] A project was undertaken by Ontario's Quality Management Partnership, who published "Recommendations on practices related to tissue exemption and release" in 2016,[16] although it is unclear whether hospitals have been able to implement these fully due to standing provincial regulations.

The largest pathology lab in Nova Scotia applied "Choosing Wisely" principles to successfully expand their exemption list in 2020, with corresponding human workload and cost savings.[17]

In Quebec, there has been a recent initiative to develop extensive and detailed recommendations related to anatomical pathology exemption lists.[12] According to online sources, for example a memo from Optilab Montreal-CUSM, these have been adopted in practice,[18] notwithstanding previously mentioned provincial regulations.

The Royal College of Pathologists in the United Kingdom has also published guidelines covering this and topics related to reducing pathology testing of "limited or no clinical value."[19]

ENVIRONMENTAL SCAN

Table 1 presents a relatively current summary of pathology exemption lists, based on regulations and guidelines from most Canadian provinces as well as the UK recommendations. No reference was found for either Prince Edward Island or Newfoundland and Labra
dor. The Canadian territories do not have their own pathology laboratories. The exact wording in these references varies; for specifics, please consult the cited primary sources. Exceptions to the exemptions (i.e. tissues that should in fact be submitted to the pathology lab) are noted with asterisks for each row, and common qualifiers or examples are noted.

This environmental scan reveals some discrepancies and inconsistencies between what various jurisdictions consider to be "human tissues" as well as between what regulations or policy may specify and what is observed in common practice. For example, the BC policy[13] exempts fecaliths and renal calculi, and the NB regulation[10] exempts bezoars; these arguably are not human tissues and therefore may not need to be mentioned in most exemption lists. Fingernails and/or toenails are inconsistently mentioned in these lists, probably not because their examination is required but because they are so inconsequential as to not merit mention.

Some lists specifically mention medical and non-medical foreign bodies, but for example, Ontario's regulations do not,[9] probably because they are written specifically to cover "tissues."

Some lists specifically exempt placentas from uncomplicated pregnancies and deliveries; others do not mention placentas at all even though it is common practice throughout North America for only selected placentas to be examined by a pathologist.[20] For example, Alberta's regulations do not exempt placentas; however, Alberta Precision Laboratories policy clearly allows for some placentas to be discarded without pathology examination.[21]

GENERAL PRINCIPLES

Laboratory resources, including pathologist and staff time, should be allocated where possible in proportion to the diagnostic and clinical importance of specimens.

Environmental impacts of laboratory workflows and diagnostic processes should be minimized where possible.

Not all tissues, organs, and/or objects removed from a patient during an operation or other medical procedure require submission to a pathology laboratory.

Both costs and diagnostic utility should be considered when formulating exemption lists.

RECOMMENDATIONS

1. **Exemption lists should be co-developed by pathologists and relevant clinicians**. Both pathologists and clinicians should be in agreement on the reasoning behind exempting certain types of specimens. Proceduralists discarding tissues should understand their responsibility for documentation, including explicit documentation of disposal rather than submission to pathology.

2. **The pathology laboratory should receive, examine, and report on any specimen specifically requested by a clinician**, even if it qualifies for automatic exemption, provided adequate clinical history and appropriate clinical indication has been communicated. Clinicians should be empowered to ask for a pathologist's examination whenever there is any suspicion of unusual pathology and should not automatically discard any specimen, even if allowed, without consideration.

   The requirement for clinical history to be provided by submitting clinicians is legally codified in most provinces' regulations. For example, in Ontario, specimens must be accompanied by "a short history of the case and a statement of the findings of the operation";[9] nevertheless, real-world adherence to this standard has been shown to be poor and apparently decreasing over time.[22]

3. **Laboratories should not require routine submission of medical and non-medical foreign objects and materials**. Some specimens for which a police warrant for production are anticipated (ex. bullet fragments) may require safeguarding; hospitals should decide on the most appropriate way to store these securely. Situations involving possible medical device malfunction should be handled on a case-by-case basis in accordance with the principles of Vanessa's Law.[23]

4. **Laboratories should not require routine submission of normal-appearing tissue removed incidentally for access or a functional procedure** where there is an extremely low likelihood of incidental important pathology. For example, mediastinal fat removed before cardiac surgery, extraocular muscles from strabismus surgery, elective circumcisions, and pieces of leftover autologous vein graft from a vascular procedure are all extremely unlikely to reveal clinically important histologic abnormalities.

5. **Laboratories should not require submission of specimens for which clinical diagnosis or macroscopic examination by the proceduralist is sufficient.** A plastic surgeon performing liposuction for cosmesis can be entrusted to recognize and weigh normal adipose tissue. An orthopedic surgeon performing a joint surgery will record their intraoperative findings in the operative note, and in routine cases of degenerative joint disease, there is little to be gained from a second examination in the pathology lab. A vascular surgeon's observation of atheromatous plaque burden inside a carotid artery is unlikely to be improved upon by histologic examination. A physician performing an elective first trimester surgical abortion can recognize normal products of conception and understand in which scenarios submission to the pathology laboratory is indicated.[24]

   That said, there are some "normal" tissues that should be submitted for limited microscopic examination (for example, macroscopically normal breast tissue), given the small possibility of unsuspected pathology.[25]

6. **Laboratories should limit the use of gross-only examinations.** If "gross only" documentation in the laboratory is sufficient, is there a good reason why gross examination as recorded in the operative note is insufficient? In the 1999 College of American Pathologists survey, more than 50% of laboratories were routinely handling certain specimens as "gross only" examinations (teeth, lenses, foreign bodies, and medical devices).[14] It is unclear what is the added documentary value of this macroscopic examination other than perhaps revenue generation for the laboratory.

   There are likely very few circumstances in which the gross room examination is value added. One exception being gross examination of embryofetal remains from spontaneous abortions — gynecologists will generally not have capacity to do examinations for dysmorphism or growth parameters in the operating room after dilatation and curettage.[24]

7. **Laboratories should implement conditional, rather than routine, pathologic examination for certain types of specimens**. This approach is commonly used to guide clinicians and pathologists regarding which placentas can be discarded versus which should be examined by a pathologist.[20] A similar approach could be used for other specimens; for example, medically indicated circumcisions in pediatrics are commonly done for hypospadias (no benefit of microscopic examination) and balanitis xerotica obliterans (which should be confirmed microscopically in order to guide surgical follow up). Many laboratories use age-based cutoffs for some specimens (example, tonsils) that are highly unlikely to harbour malignancy in younger patients in the absence of other clinical reasons for suspicion.

8. **Laboratories operating with legally mandated exemption regulations should be aware of their obligations** but should not be compelled to do more of an examination of submitted specimens than is strictly required. For example, if a provincial regulation requires submission of large limb amputations with peripheral vascular disease, brief documentation of the specimen size and laterality will likely suffice in most instances.

   That said, pathologists working under these regulations should advocate to their provincial Ministers of Health to amend regulations stipulating submission and exemption requirements. Instead, regulations should be amended to include language like that in PEI, which allows flexibility for health authorities or hospitals to, "with the advice of the medical staff, establish policies authorizing the disposal of specified types of tissue without an examination and report by a pathologist."[4]

CONCLUSION

Specific recommendations on which specimens to exempt are evolving. Each jurisdiction (laboratory, health authority, province) should consider the recommendations above in formulating a list and can use the specimens listed in **Table 1** as a useful starting point for discussions. Ideally, evidence, shared knowledge, consensus, and a commitment to appropriate resource utilization should guide decision making on this matter.

It is anticipated that these exemption lists may generate some lively debate. Many pathologists (and some clinicians) will have anecdotes about important unexpected pathology found in innocuous "routine" specimens, and pathologists as a general rule are inclined to a high degree of accuracy and sensitivity in our work. However, as in everywhere else in medicine, perfect sensitivity can usually only be achieved at very high expense, and we should strive to find appropriate balance. Resource constraints and environmental impacts should motivate laboratories and health systems to critically develop and continually reassess evidence-based routine pathology exemption lists.

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Table 1: Specimens exempt from automatic submission to pathology laboratories in various jurisdictions

Specimen	BC[13]	AB[7]	SK[6]	MB[8]	ON[9]	QC[12]	NB[10]	NS[17]	UK[19]	Comments
Ophthalmologic										
Lens and/or cornea	X	X		X	X	X	X	X		
Other small tissue portions without diagnostic relevance						X	X	X		Ex. Epiretinal membrane, extraocular muscles, eyelid skin
Head & Neck										
Tonsils & adenoids	X*	X*	X	X*	X	X*			X*	*Exemption below age cutoff (range 16-40 y) or suspicion of malignancy
Nasal septum / turbinates		X		X		X				If removed for obstruction
Middle ear ossicles	X	X		X		X				
Tympanic membrane						X				With normal appearance
Ear cartilage		X		X			X			From cosmetic/plastic procedure
Teeth	X	X	X	X	X	X		X		
Cardiovascular										
Thrombus, clot, hematoma	X*	X				X		X		*Submit thrombus or hematoma from CNS
Aneurysm contents, atheroma						X		X		
Varicose veins	X	X		X		X		X		
Autologous vascular graft						X	X			Leftover from bypass procedure
Mediastinal fat for cardiac access						X				
Orthopedic										
Finger and/or toe amputation	X	X	X	X	X	X		X	X	Non-tumour amputation
Limb amputation	X		X		X	X		X	X	Non-tumour amputation
Re-amputation stump	X	X	X	X	X	X		X	X	
Arthroplasty	X				X	X		X	X	Uncomplicated degenerative joint disease
Pieces of bone, cartilage, ligament and/or tendon	X	X		X	X	X		X		Routine non-tumour orthopedic procedures
Rib for thoracic access	X	X		X		X		X		
Fingernails & toenails	X	X		X	X	X		X		
Spine surgery										
Intervertebral disc	X	X		X		X		X		
Meningocele sac	X	X		X						
Abdominal / general surgery										
Hernia sac	X	X	X	X						
Hiatal hernia						X				
Hemorrhoid	X		X		X					
Ostomy revision / closure	X					X				After non-oncologic surgery
Gynecologic & obstetric										
Placenta	X			X			X	X	X	Uncomplicated pregnancy & delivery
Products of conception	X					X		X	X	Elective termination of pregnancy
Tissue from urogynecologic procedure	X	X		X		X				
Labiaplasty						X				
Urologic										
Varicocele and/or hydrocele	X	X		X		X				
Vas deferens							X			From elective sterilization
Foreskin	X*	X	X	X*	X	X*	X*	X*	X*	*Exemption below age cutoff (range newborn – 25 years)
Plastic surgery										
Abdominal pannus	X					X		X		
Fat from liposuction	X					X*	X			*Should be weighed by surgeon
Wound debridement	X					X		X		
Scar tissue	X*	X		X		X*				*With no history of malignancy in area
Benign-looking superficial lesions						X				Ex. skin tags, skin cysts, pilonidal disease
Normal tissue removed during plastic surgery	X*					X*				*Exception: Normal breast tissue should be sampled
Other										
Medical devices, hardware, foreign material	X	X		X		X*	X	X*		*Exception: prosthetic valves and/or breast implants should be submitted.
Non-medical foreign bodies	X	X		X		X	X	X		With no forensic significance
Research or tissue bank specimen	X						X	X		
Extra tissue from tissue/organ harvest/transplant						X*				*Exception: submit pneumoreduction tissue from lung transplant

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