Recommendations on practices related to tissue exemption and release – *final report, Pathology Early Quality Initiative (EQI) #2.*

10 August 2016

THE COLLEGE OF PHYSICIANS AND SURGEONS OF ONTARIO

Ontario
Cancer Care Ontario

Quality Management Partnership

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1. Background

1.1 The Quality management partnership

The Quality Management Partnership (the Partnership) is a collaboration between CCO and the College of Physicians and Surgeons of Ontario (CPSO). The Partnership is implementing provincial quality management programs (QMPs) for pathology, colonoscopy and mammography.

These provincial QMPs include evidence-based provincial standards and guidelines, which apply to all providers, settings and health service areas where the service is performed; quality reporting at the provincial, regional, facility and physician levels; a three-tier clinical leadership structure; and resources, tools and opportunities to support physicians and care teams to continuously improve the quality and consistency of care provided to patients across the province.

Further detail about the Partnership, including its first provincial report on the quality of these three health services, *Building on Strong Foundations: Inaugural Report on Quality in Colonoscopy, Mammography and Pathology,* is available at www.qmpontario.ca.

1.2 Early Quality Initiatives – Pathology

Guided by clinical leads and Expert Advisory Panels (EAPs) for each health service area, early quality initiatives (EQIs) were undertaken in 2014/15 with the aim of advancing the Partnership's mandate for each service area.

The Pathology EQIs recommended by the pathology EAP and initiated in 2014-15 include:

- EQI #1: The production of a baseline quality report for pathology
- EQI #2: Development of recommendations to inform practices related to tissue exemption and tissue release
- EQI #3: Identification and assessment of options for improving communication within pathology diagnostic reporting

1.3 Pathology EQI #2

Introduction

In the design phase, the pathology Expert Advisory Panel discussed the clinical utility of some pathologic investigations. As one of the core goals of the Partnership is to standardize processes and decrease variability, an EQI that comprehensively examined the literature and legislative requirements around tissue exemption was identified as of potential value to the field. The goal was to provide the most up to date information available in the literature for facilities to use in critically examining their own local processes, streamline practices and find efficiencies. It was also hoped that this would be a very early start to consider the clinical utility of conducting microscopic examination on specimens commonly received at laboratories.

The second component of this EQI stemmed from discussions related to patient safety and the patient experience. Most patients do not interact with the laboratory, but when they do, it may be to request tissue to be released to them or their designate for personal, cultural or religious reasons. Therefore, the goal of this EQI was to review, summarize and make recommendations as appropriate to standardize safe practices around release of tissue directly to patients.

Objectives:

1. Undertake an environmental scan of legislation and literature related to tissue exemption.
2. Compare tissue exemption and release practices in Ontario to other jurisdictions.
3. Undertake an environmental scan of legislation and current practices related to tissue release to patients.
4. Summarize the information and make recommendations as appropriate.

Overall Research Approach:

The following evidence-informed process was used:

- A clinical working group (CWG) was established to guide the EQI work. The CWG included the Partnership's provincial lead for pathology, pathologists, pathologists' assistants and laboratory administrators (for a list of CWG members, see Appendix C).
- A legislative scan was conducted to review legislation governing tissue exemption and tissue release in particular jurisdictions.
- Communication with specific institutions and focused online searches helped us to identify best practice educational materials including guides, templates and forms to help Ontario laboratories improve practice.
- Three questions related to tissue exemption and five questions related to tissue release practices in Ontario were included on the Quality Management Partnership Pathology Baseline Survey (Pathology Baseline Survey). This survey was conducted by a separate working group dedicated to Pathology EQI#1.

The CWG was consulted throughout the research process to refine the search, provide advice about the nature of findings in relation to the scope of the environmental scan, identify gaps where necessary, determine when data was saturated (i.e. when there was enough information for the CWG to be able to summarize data and consider recommendations), and guide the development of this report.

This report details the research and recommendations related to EQI #2 on informing practices related to tissue exemption and release.

2. Tissue Exemption

2.1 Approach to research

The following working definition was developed in collaboration with the CWG and adopted to guide the research on tissue exemption:

> *Tissue exemption refers to standardized practices that would eliminate pathology examination by category (e.g. hernia sac, optic lens, placenta), in the absence of clinical indication. In other words, tissue that is removed in a hospital by a licensed medical practitioner but not submitted to the pathology laboratory.*

The CWG indicated that there would be value in providing information and guidance to the profession not only about tissue exempt as defined above, but also tissue that could safely be exempt from microscopic examination (i.e., tissues submitted to the pathology laboratory but for which microscopic examination would be of minimal clinical utility after careful gross examination).

The following research approaches were used in collecting and analyzing information relevant to tissue exemption.

Environmental Scan

The environmental scan included:

1. a legislative scan to source examples of legislation guiding tissue exemption in Canada, Ireland, Britain and Australia; and,
2. a focused search to source best practices, policies, tools and/or guidelines regarding tissue exemption.

The environmental scan was conducted using the following search terms: *tissue exemption lists; list of exempt specimens; submission of tissue to pathology, surgical pathology specimens for gross examination only, surgical specimens exempt from microscopic examination.*

The environmental scan was conducted using:

a) Online searches for examples of national and international tissue exemption lists from hospitals across Canada, the EU, Ireland, Britain, the United States (U.S.), and Australia

b) Email inquiries requesting legislative/regulatory examples, best practices, policies, tools and/or guidelines were sent to
   (i) five Ontario physicians recommended by CWG members;
   (ii) six international regulatory bodies and departments of health in the UK, Australia, and New Zealand; and
   (iii) the author of *Routine ordering of Primary Pathology Examinations in Canada – Environmental Scan, the Canadian Agency for Drugs and Technologies in Health (CADTH) -2014,* a key text for the project obtained through the online search.

c) Focused institutional inquiries: To supplement the legislative scan, a number of academic institutions were asked to provide their local policies and exemption lists, which provided insight into exemptions at the institutional level. This was deemed useful in the absence of broader jurisdictional legislative examples, best practices, policies or tools/guidelines.

Information collected through the environmental scan was synthesized into tables for easy comparison of legislative differences in tissue exemptions for jurisdictions for which such information exists. These tables are presented in Appendices A and B and discussed in section 2.3 (findings, tissue exemption).

Current State Assessment

CCO's Pathology and Laboratory Medicine Program (PLMP) conducted a Pathology Baseline Questionnaire (baseline survey) on behalf of the Partnership in the Spring/Summer of 2015. The purpose of the survey was to obtain an accurate and thorough assessment of the uptake of select, high-priority recommendations derived from the Standards2Quality (S2Q) Guidelines and endorsed by the pathology EAP. Three questions relevant to tissue exemption were included on the Pathology Baseline Survey.

Surveys were received from 78 out of the 80 histopathology sites in Ontario in total (98% response rate). At the time data was analyzed for the purposes of this report, surveys were received from 77 of the sites. The resulting analysis is presented in the findings section of this report.

Strengths and Limitations

Very limited results were obtained from the environmental scan either through online searches or the subsequent inquiries sent to regulatory bodies and departments of health. Namely:

- The Royal College of Pathologists of Australasia indicated that there is no legislation in Australia governing which specimens should be sent to pathology;
- No response was received from the UK or Ireland.
- No national legislation was found for the U.S., although the online search identified some state-based legislation (included in the table summarizing legislative findings in Appendix A).
- Most hospitals and medical centres, including larger hospitals and medical centres such as the Mayo Clinic, do not make their policies or guidelines available online. However, this challenge was somewhat mitigated through the Pathology Baseline Survey, where respondents were solicited to provide anonymized copies of their policies and guidelines regarding tissue exemption and release.
- The author of the Canadian Agencies for Drugs and Technologies in Health (CADTH) report *Routine ordering of Primary Pathology Examinations in Canada – Environmental Scan (2014)* confirmed the lack of access to this information.

Given the lack of legislative examples, policies, best practices, tools and guidelines regarding tissue exemption, the information collected and synthesized through this project begins to address a gap in this area of knowledge pertaining to standardized practices in eliminating pathological examination by category, in the absence of clinical indication.

Analysis of the responses to question 52 on the Pathology Baseline Survey indicated that the wording of the question was confusing. The question of whether tissues specified "should be exempt" was not consistently answered by respondents (i.e., some respondents who indicated that the specimen was already exempt did not also select the answer option "should be exempt," whereas some respondents chose both). As a result, the data regarding whether or not specimens "should be exempt" on this question was not meaningful and has been left out of the findings for tissue exemption.

2.2 Findings —Tissue Exemption

Environmental Scan

Canadian legislative exemptions were sourced from the 2014 CADTH report*, Routine ordering of Primary Pathology Examinations in Canada – Environmental Scan (2014)*, which identified the following nine provincial or territorial legislative examples that regulate exemptions from pathological examination of human tissues removed by surgery or curettage:

- Alberta *(Hospitals Act)*
- Manitoba *(The Hospitals Act)*
- New Brunswick *(Hospitals Act)*
- Northwest Territories *(Hospital Insurance and Health and Social Services Administration Act)*
- Nova Scotia *(Hospitals Act)*
- Nunavut *(Hospital Insurance and Health and Social Services Administration Act)*
- Ontario *(Public Hospitals Act)*
- Prince Edward Island *(Hospitals Act)*
- Saskatchewan *(The Regional Health Services Act)*

No relevant regulations or policies were found for British Columbia, Quebec, Newfoundland and Labrador or the Yukon.

The CWG felt it was important to remember that the Ontario Public Hospitals Act (PHA) section on tissue exemptions is directed at surgeons:

> *"Where the tissue removed is an arm, finger, foot, hand, hemorrhoid, lens, leg, prepuce, tonsil, toe, toenail, tooth, the tissue shall not be sent to a laboratory unless the surgeon conducting the operation requests an examination and report on the tissue."*

In addition to Canadian legislative examples as identified through the CADTH 2014 report, the legislative scan also found two legislative examples from the U.S., namely Illinois and Pennsylvania. Furthermore, a number of institutions indicated that they follow the College of American Pathologists (CAP) guidelines in the absence of relevant regulation. Therefore, specimens identified as exempt from pathological examination on the CAP list, although not legislative in nature, were included in our synthesis of relevant legislative findings (see Appendix A for a complete list of specimens contained in these sources and a summary of which specimens are exempt in which jurisdictions).

The environmental scan also produced a number of local exemption lists and policies used at select academic institutions across Canadian and the U.S. (five Canadian and 12 American institutions in total – see Appendix B).

The findings from the environmental scan were used to create a list of specimens submitted to or exempt from pathology across a number of jurisdictions and individual laboratories. The findings also provided the CWG with insight into the type of examination generally performed (e.g., gross only or routine microscopic examination) across jurisdictions and institutions.

This information was used by the CWG to generate a comprehensive list of specimens to be considered for a gross only examination by Ontario laboratories.

Current State Assessment

This section presents the results of the questions related to tissue exemption that were included in the Pathology Baseline Survey.

Table 1 presents the percentage of survey respondents that report routine submission of this specimen to the lab for accessioning and examination (N=76).

Table 1	
Specimens exempt in Ontario *(Source: PHA)*	**% of survey respondents that report submission of this specimen to the lab for accessioning and examination *(Source: Pathology Baseline Survey)***
	(N=76)
Foreskin	49%
Tooth	44%
Hands	43%
Legs	41%
Optic lens	41%
Fingers	36%
Toenail	35%
Tonsil	33%
Toe	31%
Hemorrhoid	27%
Arm	25%
Feet	25%

Note: Only 6.5% of Ontario facilities (5 out of 76 sites) indicated that they do not routinely receive any of the specimens that are exempt from pathological examination as per the PHA.

Comments received in response to this question indicated that the onus on submitting these specimens is on operating surgeons although the laboratory may not require them to be submitted. Comments indicated that “some surgeons may routinely submit some of these specimens as part of their personal practice beliefs/philosophy” even if the laboratory does not require the specimen to be submitted. One respondent also indicated that “it should be mandatory to submit all tissues and samples collected [and/or] removed by surgeons,” at least for a gross examination.”

Table 2 below presents a list of additional specimens that are exempt from routine pathological examination in other Canadian provinces, and the percentage of survey respondents that believe these

specimens should also be exempt from routine pathological examination in Ontario (i.e., should not submitted to the laboratory routinely).

Table 2: % of Ontario sites that believe select specimens listed below should be exempt from routine pathological examination

Specimens exempt in other provinces of Canada *(Source: Pathology Baseline Survey)*	% of survey respondents that believe specimen should be exempt in Ontario *(Source: Pathology Baseline Survey)*
	(N=74)
Vein strippings	70%
Foreign bodies (incl. bone plates, nails, screws)	64%
Bone fragments & ligaments	62%
Bony ossicles (ear)	60%
Ribs removed incidental to chest surgery	58%
Cartilage, External Ear	58%
Amputation stumps	55%
Tendon segments	52%
Blood clots	52%
Vaginal wall fragments	51%
Intervertebral disc	47%
Adenoids	45%
Varicocele	42%
Semilunar cartridges	41%
Nasal Septa when removed for obstruction only	40%
Placenta	34%
Frenum	32%
Hydrocele sac	27%
Hernial sac	26%
Scar tissue	23%
Liposuction material	19%
Meningocele sac	19%

Comments from four sites indicated that the decision to submit to pathology should be based on clinical indication. One respondent noted that any tissue that is removed from the human body should be sent to pathology but receive a gross only examination as necessary. The CWG considered this data in generating the list of specimens to be considered for a gross only examination by Ontario laboratories (see section 2.4).

Table 3 below presents the percentage of sites at which the listed specimens are currently exempt/ not exempt from microscopic examination.

Table 3

Specimen *(Source Pathology Baseline Survey)*	N	% of Ontario sites where specimen is exempt from routine microscopic exam *(Source: Pathology Baseline Survey)*	% of Ontario sites where specimen is not exempt from routine microscopic exam *(Pathology Baseline Survey)*
Abdominal pannus	63	38%	56%
Adenoids <16 years of age with no significant clinical history	64	42%	44%
Bone (hip, knee, etc.) for osteoarthritis	66	61%	27%
Breast implant with no soft tissue	65	77%	15%
Foreign Bodies (including bone plates, nails, and screws)	72	78%	14%
Foreskin <16 years of age with no significant clinical history	64	22%	56%
Hernia sac	63	6%	81%
Intrauterine device with no soft tissue	68	75%	12%
Limb or digit from traumatic amputation (no evidence of infection or other pathology)	66	44%	38%
Liposuction material	66	56%	27%
Nasal septum cartilage and bone for clinical history of deviated septum	62	39%	47%
Stone of any sort – ureteral, bladder, gallbladder	69	74%	17%
Tonsil <16 years old with no significant clinical history	65	38%	43%
Varicose veins	57	47%	37%
Other, please specify			

Note: Those respondents who specified "other" specimens that are exempt or should be exempt from routine pathological examination at their facilities listed the following specimens: bunions, fingernails, gallbladder if for stone only, gangrenous digits, intervertebral disc, knee cartilage, lens, normal uncomplicated placenta, shoulder joint, teeth, uvula for sleep disorder

The CWG considered this data in generating the list of specimens to be considered for a gross only examination by Ontario laboratories (section 2.4).

2.3 Discussion – Tissue Exemption

Tissue Exemptions to the Laboratory

Across Ontario, respondents to the survey indicated that many specimens that are legislatively exempt from submission to the pathology laboratory are in fact submitted and examined.

The environmental scan showed that a number of specimens currently not exempt under Ontario's PHA are exempt from pathological examination in other Canadian provinces (Table 2). Respondents to the survey believe that many of these specimens should be exempt from routine pathological examination in Ontario as well. In order to make specific recommendations about this, a more fulsome stakeholder engagement process would be required. The CWG considered these specimens in the list of specimens suggested for primary pathological examination only (figure 1.) [1]

Tissue Exemptions from Microscopic Examination

The list of specimens suggested for primary pathological examination only was generated after the CWG reviewed the findings from the environmental scan, current state assessment and considered the clinical value of a microscopic examination of these tissues.
For a detailed synthesis of findings from the environmental scan, please see the tables in appendices A and B. These tables detail:

- a full list of specimens that were included in the scan (Appendix A and B, combined);
- the number of jurisdictions included in the scan (Appendix A);
- the number of specific institutions included in the scan (Appendix B), and;
- the type/level of pathological examination (i.e. gross only or routine pathological examination) each of these jurisdictions/sites perform on the listed specimens. (Appendix A and B)

The list of specimens suggested for primary pathological examination only is meant to provide information for facilities to develop facility-based guidelines for primary/gross only pathological examination. While facilities may determine that any number of the specimens on this list may be exempt from microscopic examination, ensuring a process for careful gross examination is important. Facilities should use this list as a guide to review and adapt appropriately to their clinical environment.[2]

[1] Specimens organized alphabetically, except appliances, which are grouped together at the end of the list.
[2] Although "Placenta" and "body cavity fluids (pleural and ascites)" were identified as exempt in some academic institutions *(see Appendix B),* upon discussion, the CWG removed them from this list given that those tissues are submitted to pathology by institutions for specific reasons and usually warrant routine pathological examination.

Figure 1: Suggested specimens for primary pathological/ gross examination only

Suggested Specimens for Primary Pathological/ Gross Examination only

1. Abdominus Pannus
2. Adenoids
3. Adipose tissue/ Liposuction material
4. Amputation stumps
5. Appendix epididymis
6. Appendix testis
7. Arteries and veins (peripheral vascular bypass)
8. Arthroscopy shavings
9. Artificial heart valves
10. Atherosclerotic plaques
11. Bezoars
12. Blood clots
13. Bone (hip, knee, etc.) for osteoarthritis
14. Bone fragments and ligaments
15. Bony ossicles
16. Breast implant with no soft tissue
17. Calculi
18. Cartilage (external ear)
19. Cataract removed by phacoemulsification
20. Fecaliths
21. Fetus <20 weeks gestation, without clinical indication or fetal autopsy request
22. Fingernail
23. Foreign bodies (e.g. bone plates, nails, screws)
24. Frenum/frenulum
25. Hernial sac
26. Hydrocele sac
27. Intervertebral disc
28. Intrauterine device with no soft tissue
29. Iris removed at time of peripheral iridectomy
30. Liposuction material
31. Meningocele Sac
32. Meniscus
33. Mucus
34. Nasal Septa (removed for obstruction only)
35. Normal skin
36. Penile implant
37. Pharyngoplasty (uvula) specimens removed for sleep apnea
38. Ribs removed (incidental to chest surgery)
39. Scar tissue
40. Semilunar cartridges
41. Stone of any sort - ureteral, bladder, gallbladder
42. Tattoo
43. Tendon segments
44. Therapeutic radioactive sources
45. Vaginal wall fragments
46. Varicose veins
47. Variocele
48. Vein strippings
49. Appliances:
    a. Dental appliances
    b. Medical devices not contributing to patient illness, injury or death
    c. Orthopedic appliances and mechanical devices
    d. Prosthetic devices

2.4 Recommendations – Tissue Exemption

The CWG considered the possibility of recommending changes to the Public Hospitals Act and concluded that a deeper understanding of the current state of tissue exemption practices in Ontario and consultation with the surgical and pathology community would be needed. As such, regulatory change was considered out of scope for this EQI.

The recommendations should not supersede existing institutional policies that may be unique for various reasons; however, the CWG anticipates that facilities will use the recommendations to review their current practices regarding tissue exemption.

Examining tissue exemptions either with surgical colleagues or in the context of maximizing "gross examination only" list within an institution may assist facilities to streamline workload related to specimens of little or no clinical value, while making time for other specimens.

Recommendations
Recommendation 1: Laboratory Directors should engage in a collaborative process with surgical colleagues at their facility, to review the tissues that are exempt from submission to pathology as per the *Public Hospitals Act* (PHA) in order to promote awareness and appropriate use of pathology Laboratory resources. Through this collaborative process, it is recommended that facilities develop/amend policies to: i. encourage surgeons to reduce the submission of specimens listed as exempt from being submitted to pathology, unless clinically indicated or as required by the operating surgeon ii. encourage laboratories to define the rationale and procedure for accepting PHA-exempt specimens for pathological examination In addition, such a policy may also: iii. define the procedure for documenting disposal and notifying the submitter when an exempt specimen is submitted iv. define the procedure for documenting the removal and disposal of tissue not submitted to pathology
Recommendation 2: Facilities should develop a policy to define which specimen types will receive a gross only examination, as appropriate for their clinical environment (see *Figure 1*). A microscopic examination should be conducted on specimens included in such a policy, if deemed necessary based on a meticulous gross examination of the specimen.
Recommendation 3: It is recommended that laboratory directors communicate policies with clinical and hospital administrative colleagues to promote awareness and appropriate use of resources

3. Tissue Release

3.1 Approach to Research

In order to guide the development of recommendations for tissue release, the following working definition was developed in collaboration with the CWG and adopted to guide the research on tissue exemption:

> *Tissue release refers to the release of tissue (wet tissue and other objects) for personal use (source or family).*

The following research approaches were used in collecting and analyzing information relevant to tissue release.

Environmental Scan

The environmental scan included:

1. a legislative scan to identify Canadian and international legislation dealing with tissue release

2. an online search conducted to identify how hospitals and laboratories manage human tissue release (e.g. the release of the placenta to patients)

The online search was conducted using the following search terms: *release of tissue/body parts to patients, releasing human tissue to patients, release of human tissue, discard of surgical specimens*

3. Key informants were consulted to gather information about the reasons for tissue release requests and to gain insight into various cultural reasons for the request for tissue release. Contact was made with the following agencies:
    - Association of Ontario Midwives
    - Toronto Public Health
    - St. Michael's Hospital
    - Trillium Health Partners
    - Six Nations Birthing Centre
    - Southwest Aboriginal Health Access Centre
    - Seventh Generation Midwives

Current State Assessment

In order to compare results of the environmental scan with current Ontario practices regarding tissue release, three questions were included on the Pathology Baseline Survey.

Information collected through the survey was analyzed using basic descriptives and is presented in the findings section below.

Strengths & Limitations:

Generally, limited results were obtained through the online search. Most hospitals and medical centres do not make their policies or guidelines available online.

Better results were obtained through direct contact with key informants. Requests to key informants produced a number of local or regional policies, procedures, guidelines and forms.

3.2 Findings — Tissue Release

Environmental Scan

Summary:

The objective of the environmental scan was to source information about legislation and policy regarding the release of tissue that has been removed from the patient (surgical tissue) for the patient's personal use. The purpose of the search was to find information within the Canadian federal, the Ontario and the international contexts, including the European Union, the British Commonwealth and the U.S.

While the search produced very limited results, they can be categorized as findings relating to:

i. general tissue release;
ii. the use of environmental/ other legislation used to guide policy/ practice of tissue release; and
iii. the specific release of placental/ fetal tissue.

General Tissue Release: We were unable to identify legislation that directly addresses the release of surgical tissue to individuals/ patients for personal use in any of the jurisdictions included in the search. While health legislation was identified in most jurisdictions, it is directed most often at the regulation of organ donation and research specifically, and thus not relevant for our purposes.

Where healthcare providers do have local policies to address tissue release, there were a number of barriers to accessing such policies for our use.

Environmental/ other legislation used to guide tissue release as biomedical waste: The release of tissue is sometimes addressed using environmental or other legislation for guidance on the handling of biomedical materials. For example, see the *Ontario Environmental Protection Act*, quoted below. We were unable to identify a comprehensive list of any other legislation used to indirectly guide the release of surgical tissue.

Placental/ Fetal Tissue Release: Tissue release legislation regarding the release of placenta appears to be an emerging area of activity as witnessed by the recent attempt of the European Food Safety Authority (EFSA) to classify placenta as a "novel food" which could affect release of the placenta to individuals as well as the business of placenta encapsulation. A number of jurisdictions in the U.S. have also begun enacting legislation to address the release of placental tissue to patients (detailed below) and a number of Canadian healthcare providers, including healthcare providers in Ontario, currently address requests for the release of placental tissue and/or fetal tissue (for burial) through policies at the local (institutional) level.

The following summarizes the findings related to tissue release in the Canadian, Ontario and relevant international contexts.

Canada:

No Canadian federal legislation that directly or indirectly regulates the release of surgical tissue to individuals was found.

Ontario:

Ontario does not have specific legislation regarding the release of tissue to patients; however, the *Environmental Protection Act, R.S.O. 1990, c E19 – Reg. 347: General Waste Management* regulates how "industrial waste" must be transported and disposed of (meaning, "waste, other than municipal

waste" including those from "clinics that provide medical diagnosis or treatment"). However, in instances where the tissue being requested is not considered "discard" or medical waste, this legislation may not prove relevant.

Despite the lack of provincial legislation regarding tissue release, it appears that a number of healthcare providers in Ontario have policies to ensure the safe release of placental/ fetal tissue to patients should it be requested.

International:

Similar to the Canadian and Ontarian context, we found a lack of legislation that directly regulates the release of surgical tissue to individuals. For example, the government of Western Australia's Department of Health Policy for the Release of Human Tissue and Explanted Medical Devices notes that "[n]either State nor Commonwealth legislation explicitly authorizes or prohibits the release of human tissue to an individual.[3]"

At the state level in the U.S, there has been some jurisdictional interest in legislating the release of placental/ fetal tissue. A survey of placenta legislation by state was completed by Courtney Durfee in 2010 to better understand the state and regional variations in placenta release regulations and protocols as well as how placenta encapsulation services are addressed within each state. In 2006, the state of Hawaii enacted a law stating "upon negative findings of infection or hazard after appropriate testing of the mother, the human placenta may be released by the hospital to the woman from whom it originated or to the woman's designee. The department shall stipulate appropriate measures for the safe release of human placenta" (*Haw. Rev. Stat. § 321-30: Hawaii Statutes - Section 321-30: Human placenta).* In 2014, Oregon enacted House Bill 2612, *a Bill for an Act relating to postpartum procedures; amending ORS 459.400*, which indicates that a postpartum mother and certain persons may remove a placenta from a healthcare facility in certain cases and pursuant to rules adopted by Oregon Health Authority. The state of Texas has also introduced *An Act relating to the possession and removal of a placenta from a hospital or birthing center* in 2015, although it has not yet been enacted.

Where the release of tissue is regulated using environmental/other legislation for guidance on the handling of biomedical materials/waste, the conclusion regarding surgical tissue seems to be permission by omission. For example, the Commonwealth of Massachusetts Department of Public Health, in a memo to hospitals, cites the State Sanitary Code, noting that "…the definition of medical waste includes only 'discarded' materials. Therefore, the retention of placental tissues by patients is not expressly prohibited.[4]" Another example identified through the search is the English Worcestershire Acute Hospitals NHS Trust *Guidelines on Releasing Removed Body Parts (Human Tissue) to the Patient*, which cite the *Human Tissue Act 2004* in much the same way but are not restrictive to placentae.[5]

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[3] Government of Western Australia, Department of Health. Policy for the Release of Human Tissue and Explanted Medical Devices. No date.

[4] Memo from Lauren Smith, Medical Director and Chief Medical Officer, Massachusetts Department of Public Health to CEOs of hospitals licensed to provide maternal and newborn services, October 25, 2010, citing 105 CMR 480.000: Minimum Requirements for the Management of Medical or Biological Waste (State Sanitary Code, Chapter VIII).

[5] Worcestershire Acute Hospitals NHS Trust, Releasing Removed Body Parts (Human Tissue) to the Patient, WHAT-TWI-004, v2, December 18, 2013.

While Toronto Public Health has no policy on placenta burial, it would be considered "prohibited waste" under Municipal Code Chapter 844. As such, placentae could not be put out for collection with garbage or organics. On the other hand, Municipal Licensing and Standards indicate that there are no restrictions against burying or composting human placenta on one's personal property.

Current State Assessment

This section presents the results of the questions related to tissue Release that were included in the Pathology Baseline Survey.

- 75% of sites (N=77) currently have a policy in place regarding the release of tissue to patients
- 50% of sites (N=77) have a process in place to provide patients with information about the risks associated with formalin fixed tissue
- 62% of sites (N=77) receive requests for tissue release up to five times a month. An additional 8% of sites indicate that they receive requests for tissue release more than five times a month
- The most commonly released tissues include placenta (released by 45% of sites); products of conception, including fetus and endometrial curettings (released by 40% of sites); and gallstones (released by 40% of sites).

3.3 Discussion – Tissue Release

Although an emerging area of activity, there is a lack of specific legislation that regulates the release of tissue for patients for personal use. While the release of tissue to patients may be indirectly addressed via environmental legislation or regulations regarding handling of biomedical waste, these regulations do not directly deal with the release of tissue to patients. In Ontario, 8% of laboratories (N=77) receive requests for tissue release more than five times a month. A further 62% indicated that they receive requests for tissue release up to five times a month. 25% of Ontario laboratories currently do not have a policy in place to address the release of tissue to patients. Further, 50% of laboratories do not have a process in place to inform patients of the risks associated with formalin fixed tissue.

3.4 Recommendations

Based on the synthesis of findings, the CWG recommends the following regarding tissue release:

Recommendations
Recommendation 1: All Ontario laboratories must have a policy/procedure in place to handle requests for release of tissue to patients.
Recommendation 2: All Ontario laboratories must have a process in place to provide written information to patients about the risks associated with formalin-fixed tissue, if such tissue is being released.
Recommendation 3: Any release of tissue to a patient, including the summary of advice provided regarding the risks of formalin-fixation, should be documented and kept on file in the laboratory.

Appendix A: Specimens exempt from pathological examination: A comparison of existing regulations in Ontario, other Canadian provinces and selected exemption lists from the U.S.

Specimen Type	Canadian provinces						United States		
	Ontario (PHA)	Alberta	Saskatchewan	Manitoba	Northwest Territories	Nunavut	CAP	Illinois	Pennsylvania
Adenoids		✓		✓			Gross only		
Amputation stumps — secondary		✓	Gross only by surgeon	✓					
Arm	✓		Gross only by surgeon		✓	✓			
Blood clots		✓							
Bone Fragments and ligaments		✓		✓			✓	✓	
Bony ossicles (ears)		✓		✓			✓		
Cartilage, external ear (plastic)		✓		✓			Gross only	✓	
Cataracts removed by phacoemulsification							✓	✓	✓
Extraocular muscle from surgical procedures							Gross only		
Finger	✓	✓	Gross only by surgeon	✓	✓	✓			
Fingernail		✓		✓			✓	✓	
Foot	✓		Gross only by surgeon		✓	✓			
Foreign bodies (including bone plates, nails, and screws)		✓		✓			✓	✓	✓
Frenum					✓	✓			
Hand	✓		Gross only by surgeon		✓	✓			
Hemorrhoid	✓		Gross only by surgeon		✓	✓			
Hernial sac		✓	Gross only by surgeon	✓	✓	✓	Gross only		
Hydrocele sac		✓		✓					
Intervertebral disc		✓		✓					
Leg	✓		Gross only by surgeon		✓	✓			
Meniscus							Gross only		
Meningocele sac		✓		✓					
Nasal septa when removed for obstruction only		✓		✓					
Optic lens	✓	✓		✓					✓
Placenta				✓			✓		
Prosthetic devices							Gross only		
Prepuce	✓	✓	Gross only by surgeon	✓					

Specimen Type	Canadian provinces						United States		
	Ontario (PHA)	Alberta	Saskatchewan	Manitoba	Northwest Territories	Nunavut	CAP	Illinois	Pennsylvania
Ribs removed incidental to chest surgery		✓		✓			✓		✓
Scar Tissue		✓		✓				✓	
Semilunar cartridges		✓		✓					
Tendon segments removed incidental to orthopedic procedures		✓		✓					
Tissue expander/implants							Gross only		
Toe	✓	✓	Gross only by surgeon	✓	✓	✓			
Toenail	✓	✓		✓			✓	✓	
Tonsil	✓	✓	Gross only by surgeon	✓	✓	✓	Gross only		
Tooth	✓	✓	Gross only by surgeon	✓	✓	✓	✓	✓	✓
Vaginal wall fragments (plastic repair)		✓		✓					
Varicocele		✓		✓			Gross only		
Vein strippings		✓		✓					
Normal Skin							✓	✓	✓
Dental Appliances							✓	✓	
Fat removed by liposuction							✓		
Bone donated to the bone bank							✓		
Intrauterine contraceptive devices without attached soft tissue.							✓		
Medical devices such as catheters, gastrostomy tubes, myringotomy tubes, stents, and sutures that have not contributed to patient illness, injury or death.							✓		
Orthopedic hardware and other radio-opaque mechanical devices							✓		
Saphenous vein segments harvested for coronary artery bypass.							✓		✓
Therapeutic radioactive sources							✓		
Traumatically injured members that have been amputated and for which examination for either medical or legal reasons is not deemed necessary							✓		✓
Specimens known to rarely, if ever, show pathological change, and removal of which is highly visible postoperatively									✓
Calculi									✓

Specimen Type	Canadian provinces						United States		
	Ontario (PHA)	Alberta	Saskatchewan	Manitoba	Northwest Territories	Nunavut	CAP	Illinois	Pennsylvania

Notes:
**The province of BC does not have a provincial exemption list or regulation, but there are specific lists for some individual institutions which are presented in another table.
**The province of Newfoundland has a policy on tissue exemption which refers to exemption lists currently being used in British Columbia health institutions (as an example). Those exemption lists are presented in the table which summarizes academic and health institution data.

The analysis of relevant legislation included in Table 1. also identified the following caveats on microscopic/histological examination:

Illinois/Pennsylvania:
A list of tissues which routinely require microscopic examination shall be developed in writing by the pathologist with the approval of the medical staff:
Illinois Administrative Code, Title 77 Public Health, Chapter P Department of Public Health, Subchapter b Hospital and Ambulatory Care Facilities, Part 250, Hospital Licensing Requirements, Subpart E Laboratory, 250.5P0. Laboratory Services, Section g.1, Pennsylvania Code, P35.P5. Surgical specimens

Nova Scotia Hospital Regulations, NS Reg 16/79 Section 11:
1. A physician shall not destroy tissues removed from a patient during an operation or curettage
2. All tissues removed from a patient during an operation or curettage shall be sent, together with a short history of the case and a statement of the findings to a laboratory where a pathologist shall carry out a gross examination of the tissue
3. A histological examination of such tissue shall be carried out upon the request of the physician, or if the gross examination suggests a pathological condition, which can only be confirmed by a histological examination
4. A laboratory report on every such tissue examination shall be sent to the hospital in which the operation or curettage to remove the tissue took place
5. The Board of an individual hospital on the recommendation of its medical staff, may authorize the exceptions to this regulation for certain tissues or specimens or classes of tissues and specimens which are deemed by the Board of the hospital not to require pathological examination

Saskatchewan: The Hospital Standards Regulations, P980 Section 56(1)(7)
Any tissues or sections of tissues removed during a surgical procedure or curettage shall be immediately set aside by the surgeon operating and shall be forwarded with a short history of the case and a statement of his findings for examination by a pathologist. Any tooth, tonsil, prepuce, haemorrhoid, Hernial sac, finger, toe, hand, foot, arm, or leg removed or amputated, shall not so be forwarded unless the surgeon or hospital desires a special examination; but a gross description of the tissue shall be noted in the report of the operation.

New Brunswick Hospital Regulations, NB Reg 92-84 Section 52(1-4)
1. A regional health authority shall
    a. take possession of all human tissue and foreign bodies removed from any person during an operation or curettage in a hospital facility, and
    b. obtain a statement from the surgeon, or and maxillofacial surgeon or dental practitioner who removed the human tissue and foreign bodies, setting out the reason for removal of the human tissue and foreign bodies together with relevant clinical data
2. The statement obtained under paragraph (1)(b) shall be suitably identified and kept with the human tissue and foreign bodies at all reasonable times
3. Where a regional health authority takes possession of any human tissue or foreign body, or shall cause the human tissue or foreign body
    a. to be identified at the time of the removal by a member of the medical staff; and
    b. to be sent for examination to a hospital laboratory
4. A regional health authority shall ensure that human tissue and foreign bodies removed from a patient during an operation or curettage are
    a. examined at least in gross to determine if any further examination is required and
    b. disposed if in accordance with the policies approved by the board of trustees

Appendix B: Specimens exempt from pathological examination: A comparison of exempt specimen across select laboratories in Canada and the U.S.

Note: The following table complements Appendix A insofar as it provides additional context regarding specimens that are exempt at the institutional level (i.e. individual laboratories) across Canada and the U.S. This information was collected during the environmental scan, given the lack of jurisdictional legislation regarding tissue exemptions.

Specimen	How many out of the five Canadian laboratories contacted exempt this specimen (N=5)	How many out of the twelve American laboratories contacted exempt this specimen (N=12)
Adenoids	**4** *(2 conduct gross only)*	**4**
Adipose Tissue	**1**	**1**
Arteries and Veins from peripheral vascular bypass procedures	**2***(1 conducts gross only)*	**6**
Arthroscopy Shavings	**3** *(1 conducts gross only)*	**4** *(1 conducts gross only)*
Artificial heart valves	**1** *conducts gross only*	**4** *(1 conducts gross only)*
Atherosclerotic plaques	**1** *conducts gross only*	**3** *(2 conduct gross only)*
Blood clot	**None**	**1**
Body cavity fluids (pleural and ascites)	**None**	**2**
Bone Chips (e.g.: arthrodesis)	**1**	**2**
Bone for Bone Banks	**1**	**3**
Bone Fragments (including bunions and femoral heads) and ligaments	**4** (*2 conduct gross only)*	**8**
Bony ossicles (ears)	**1**	**4**
Calculi	**1**	**3**
Cartilage	**2**	**6** *(1 conducts gross only)*
Cataract removed by phacoemulsification	**5** *(1 conducts gross only)*	**8**
Dental Appliances	**1**	**4**
Drains and Tubes	**1**	**1**
EGross onlytraocular muscle and tendon tissue removed during surgery	**1**	8 *(1 conducts gross only)*
Fat contents from liposuction	**2** *(1 conducts gross only)*	**11**
Fecaliths	**1**	**1**
Fingernail	**2**	**8**
Foreign bodies (including bone plates, nails, and screws)	**3** *(1 conducts gross only)*	**9** *(1 conducts gross only)*
Intervertebral discs	**2** *(1 conducts gross only)*	**5**
Intrauterine contraceptive devices without attached soft tissue	**3** *(2 conduct gross only)*	**5**
Medical devices not contributing to patient illness, injury or death (e.g. catheters, pacemakers, gastrostomy tubes, stents, sutures)	**2**	**9** *(1 conducts gross only)*
Meniscus	**4** *(2 conducts gross only)*	**5** *(2 conduct gross only)*
Normal Skin	**2**	**5**
Orthopedic appliances and mechanical devices (hardware)	**2** *(1 conducts gross only)*	**10** *(1 conducts gross only)*
Placenta (unless abnormal)	3	8
Prosthetic devices	**1** *conducts gross only*	**4** *(3 conducts gross only)*
Stones (kidney, gall bladder, ureter)	**2** *(both conduct gross only)*	**1** *conducts gross only*
Tissue from Septal Reconstruction and Intranasal Antrostom	**1**	**4**
Tissue or skin from cosmetic procedure	**2**	**10**
Vaginal wall fragments	**3** (*1 conducts gross only)*	**4** *(1 conducts gross only)*
Varicose Veins	**4** (*2 conduct gross only)*	**4** *(1 conducts gross only)*

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