Nova Scotia Provincial Blood Coordinating Program
Provincial Dental Board of Nova Scotia

Toolkit for Allograft Usage
In Dental Practice

September 29, 2017
A. Preamble

This document has been developed by the Nova Scotia Provincial Blood Coordinating Program in conjunction with the Provincial Dental Board of Nova Scotia to support compliance by dentists practicing in Nova Scotia to the Health Canada Safety of Human Cells, Tissues and Organs for Transplantation Regulations. As described within this toolkit, establishments other than source establishments that discover an unexpected adverse reaction has occurred must report the information to the source establishment or the importer (if applicable) for all suspected or known unexpected adverse reactions associated with a tissue without delay.

This document is divided into sections according to responsibilities the user has:

- Determining whether or not a distributor or manufacturer is licensed by Health Canada;
- Signs and symptoms of an adverse reaction;
- Example cases of adverse reactions to tissues used in dental settings;
- Who to report adverse reactions of transplanted tissue to; and
- How to report adverse reactions.
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B. Reporting Allograft Usage Data: What Dentists Need to Know

Since 2016 dentists have been required to report the number of human allograft tissues transplanted in practice each year to the Provincial Dental Board of Nova Scotia.

Human allograft tissues are commonly used in dental practice today. In 2009, the Health Products and Food Branch Inspectorate of Health Canada adopted the Guidance Document for Cell, Tissue, and Organ Establishments – Safety of Human Cells, Tissues, and Organs for Transplantation. This document was published to assist establishments in complying with Health Canada’s Safety of Human Cells, Tissues, and Organs for Transplantation Regulations, which came into force in 2008.

The Canadian Dental Association published its Guidance Document for Dentists Providing Human Allogeneic Transplants in 2010. This document outlines the specific requirements that pertain to dentists using human allograft tissue products in their practice. The main requirements for dentists utilizing these products in their practice are as follows:

1. To ensure that any human allograft tissue products utilized in practice are obtained from Source Establishments that are registered with Health Canada
2. To ensure that recordkeeping practices capture all of the information required (donor identification code, description of the transplanted tissue, the Health Canada registration number of the source establishment, the notice of exceptional distribution, if applicable, information that allows for identification of the recipient, and documentation of any suspected errors, accidents, or adverse reactions and their investigation) for ten years
3. To ensure that there are procedures in place for reporting suspected errors, accidents and adverse reactions

The Provincial Dental Board of Nova Scotia has a mandate to protect the public interest in matters related to the delivery of dental care. The Board does this by ensuring that only properly trained, licensed individuals provide treatment and that the treatment is of a reasonable standard. The Provincial Dental Board is responsible for the administration of the Dental Act and the Regulations pursuant to the Act. With the privilege of self-regulation comes the responsibility of responsible action.

Part of the responsible action is ensuring that practitioners in Nova Scotia are aware of the regulatory requirements and are adhering to regulations and standards. As such, dentists must provide to the Board, as part of annual license renewal, the number of human allograft tissue products transplanted in practice in the previous calendar year. This is done for the safety of Nova Scotians by ensuring that transplanted tissue products are obtained from Health Canada registered source establishments, and that recipients are easily identifiable in the event of a recall.

Additionally, the number and type of human allografts transplanted by dentists will be shared with the Nova Scotia Provincial Blood Coordinating Program (NSPBCP). The Program collects data on tissue usage in Nova Scotia as part of their participation in the National Cells, Tissues, and Organs Surveillance System.
What products are included in the project?

Below are some examples to help you identify the type of products that fall within this scope:

1. Demineralized bone (Raptos by Citagenix; PentOs Ol Fill by Citagenix, Straumann AlloGraft)
2. Mineralized bone (Mineralized cancellous powder by Synthes)
3. Demineralized bone strips (PentOs Ol Fec by Citagenix)
4. Demineralized bone putty (PentOs Ol Putty by Citagenix, DBM Putty by Synthes, AlloOss Putty with demineralized bone chips by ACE Surgical)
5. Injectable bone morphogenetic protein (INFUSE Bone Graft by Medtronic)
6. Particulate allograft (Puros by Zimmer)
7. Extracellular dermal matrix (DynaMatrix by Citagenix)
8. Acellular dermal matrix (NeoDerm by Citagenix, AlloDerm Regenerative Tissue Matrix by LifeCell; DermanMatrix Acellular Dermis by Synthes)
9. Placental allograft membrane (BioXclude by Citagenix)
10. Any other product that contains human cells

These are some examples of the products that are in scope. If you have other products and are unsure whether they should be counted, you can contact the Nova Scotia Provincial Blood Coordinating Program at (902) 487-0504.

C. List of Registered CTO Establishments

In accordance with the Safety of Human Cells, Tissues and Organs for Transplantation Regulations (CTO Regulations), all source establishments and establishments that distribute or import for further distribution, cells, tissues and organs (CTO), must register with Health Canada. The List of Registered CTO Establishments should be used as a reference tool to identify those establishments that have registered with Health Canada prior to requesting tissues from suppliers.

The List of Registered Cells, Tissues and Organs Establishments can be found at:


Commonly used registered establishments in Nova Scotia include:

- BioHorizons
• Citagenix
• Zimmer BioMet
• Nobel BioCare
• Straumann
• Musculoskeletal Transplant Foundation

Medical devices establishment licences held with Health Canada can be determined by entering the appropriate information in this website: https://health-products.canada.ca/mdel-leim/index-eng.jsp

Commonly used licensed medical device establishments include:
• Dentsply
• Depuy

D. Adverse Reactions to Tissues

Establishments, other than source establishments, that discover an unexpected adverse reaction has occurred must report to the source establishment and the importer (if applicable) all suspected or known unexpected adverse reactions associated with a tissue without delay as well as the NSPBCP.

Upon receipt of the notice above, an importer of tissue is required to notify the source establishment of the adverse reaction.

An unexpected adverse reaction following the transplantation of a tissue includes the unintended and unforeseen transmission of any bacterial, viral or fungal infection (infection disease or disease agents), as well as malignancies or any other disease/disorders (e.g. genetic disorder, immunological disorder, etc.) that is suspected to originate from the donor.

Signs and Symptoms include but are not limited to:
• Chills
• Fever
• Localized tenderness
• Abscess formation
• Osteonecrosis
• Rash
- Pain
- Swelling
- Dry socket
- Bleeding

If the infectious agent was a virus such as HBV or HIV etc., the presentation would of course differ depending on the disease and may be a positive screening test in an asymptomatic patient.

E. Example Cases

<table>
<thead>
<tr>
<th>Tissue</th>
<th>Adverse Reaction(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mineralized cortical powder</td>
<td>Jaw ache/pain, dry socket and premature loss of sutures</td>
</tr>
<tr>
<td>Cortical bone demineralized and dental pericardium</td>
<td>Rash</td>
</tr>
<tr>
<td>AlloDerm</td>
<td>Peri-implantitis, infection of the AlloDerm membrane</td>
</tr>
<tr>
<td>Mineralized allograft cortical/cancellous bone granules</td>
<td>Failed osteointegration of a bone allograft possibly due to a post-operative infection of the graft site</td>
</tr>
<tr>
<td>AlloDerm (acellular human skin graft)</td>
<td>Swelling and bleeding</td>
</tr>
</tbody>
</table>
F. Algorithm for Reporting Adverse Reactions to Transplanted Tissues by Dentists

**Mandatory Reporting**

Standard Statement: All suspected, unexpected Adverse Reactions due to the transplant of minimally manipulated tissue shall be reported by dentists, as required by applicable federal regulations (Safety of Human Cells, Tissues and Organs for Transplantation Regulations).

Is this a suspected adverse reaction due to the use of a minimally manipulated transplanted tissue product?

YES

Is this a suspected adverse reaction due to the use of a transplanted tissue derived medical device or more than minimally manipulated tissue (Have a Drug Identification Number)?

YES

Complete the Cells, Tissues and Organs Surveillance System’s Canadian Transplantation Adverse Event Reporting Form and send to:

A. The Nova Scotia Provincial Blood Coordinating Program (NSPBCP) via fax: (902) 422-0893 or email: jennifer.lefrense@nshealth.ca

Form is available on the NSPBCP website

**Voluntary Reporting**

B. The Manufacturer or Importer, the establishment from whom the tissue was purchased.

You may report any account of an incident, complaint or concern involving a medical device or any suspected adverse reaction to a transplanted or implanted tissue product. Refer to current Health Canada Medical Device Regulations and Guidance Documents


If the product has a DIN, then the adverse reaction would be reported to the Marketed Health Products Directorate as follows: [https://hp-rps.hres.ca/static/content/form-formula.php?lang=en](https://hp-rps.hres.ca/static/content/form-formula.php?lang=en)
G. Canadian Transplantation Adverse Event (TAE) Reporting Form for Tissues

The TAE Reporting Form for Tissues can be obtained by calling The NSPBCP at 902-487-0504 or on the NSPBCP website: https://novascotia.ca/dhw/nspbcp/

Instructions for Completing the Canadian Transplantation Adverse Event (TAE) Reporting Form for Tissues are as follows:

1) Complete the Date of birth and sex fields.

2) Complete the information in regards to your facility. This includes:
   - Name of facility
   - Address
   - Name and contact information of the transplanting dentist
   - Name and contact information of the individual completing the form if different from the transplanting dentist
3) Complete the information in regards to the Source Establishment. This includes:

- Name
- Address
- Contact Person and Health Canada registration number, you must also indicate if they were notified
4) Complete the information in regards to the transplantation adverse event. This includes:

- Date and location of the event
- Tissue type
- Product code
- Supplier name
- Donor ID code
- Expiry date
- Quantity
- Dates of Transplant, Pre-Transplant and Post-Transplant.

**3. DATE AND LOCATION OF THE TAE**

<table>
<thead>
<tr>
<th>LOCATION WHERE TAE WAS RECOGNIZED:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital where graft transplanted/implanted:</td>
</tr>
<tr>
<td>Other facility, e.g. Walk-in Clinic, Home:</td>
</tr>
<tr>
<td>Other Hospital:</td>
</tr>
</tbody>
</table>

**4. SUSPECTED TRANSPLANTED/IMPLANTED TISSUE(S)**

(Note: Pre and Post Transplant/Implant Culture Dates and Results are to be completed by source establishments only)

<table>
<thead>
<tr>
<th>TISSUE TYPE</th>
<th>PRODUCT CODE</th>
<th>SUPPLIER NAME</th>
<th>DONOR ID CODE</th>
<th>EXPIRY DATE</th>
<th>QUANTITY TRANSPLANTED</th>
<th>DATE OF TRANSPLANT/IMPLANT</th>
<th>PRE-TRANSPLANT/IMPLANT CULTURE DATE AND RESULT</th>
<th>POST-TRANSPLANT/IMPLANT CULTURE DATE AND RESULT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day</td>
<td>Month</td>
<td>Year</td>
<td>Day</td>
<td>Month</td>
<td>Year</td>
<td>Day</td>
<td>Month</td>
<td>Year</td>
</tr>
</tbody>
</table>

**COMMENTS (INCLUDING TYPE OF PATHOGEN AND COLONY COUNT):**
5) Complete the clinical history section of the form with as much information as possible.

6) Complete the Clinical Signs section providing as much information as possible.
7) Complete the diagnosis of TAE section. This includes details on:

- the specific event
- severity
- imputability
- outcome
- status of the investigation
8) Complete the conclusion section. The transplanting dentist would sign off on all information documented verifying its accuracy as well as providing a contact number and date/time the report was completed.
Once complete, the TAE Reporting Form should be forwarded to the source establishment or importer (if applicable) as well as the NSPBCP by fax at 902-422-0893 or email to jennifer.lefrense@nshealth.ca.

The source establishment or importer and the NSPBCP may contact you for further information not captured on the form if the situation requires it.

Documentation of submitting the form to the source establishment or the importer as well as the NSPBCP should be kept in the patients file to prove compliance to the regulations.