Reporting allograft usage data: what dentists need to know.

Effective the 2016 licensing period, dentists will be asked annually to report the number of human allograft tissues transplanted in practice each year.

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 Allogenic 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:

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 record keeping 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 interests 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 Regulations. With the privilege of self-regulation comes the responsibility of responsible action.

Part of responsible action is ensuring that practitioners in Nova Scotia are aware of Regulatory requirements and are adhering to Regulations and Standards. As such, we are now asking practitioners to provide the Board, as part of your annual license application or renewal, with the number of human allograft tissue products transplanted in your practice in the previous calendar year. This is to ensure 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. 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 are in scope:

1. Demineralized bone (Raptos by Citagenix; PentOs OI Fill by Citagenix; Straumann AlloGraft)
2. Mineralized bone (Mineralized cancellous powder by Synthes)
3. Demineralized bone strips (PentOs OI Flex by Citagenix)
4. Demineralized bone putty (PentOs OI Putty by Citagenix; DBM Putty by Synthes; AlloOss Putty with demineralized bone chips by ACE Surgical)
5. Injectible 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; DermaMatrix Acellular Dermis by Synthes)
9. Placental allograft membrane (BioXclude by Citagenix)
10. Any other product that contains human cells

These are just some examples of 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) 487-0505.