NON-HOSPITAL MEDICAL AND SURGICAL FACILITIES ACCREDITATION PROGRAM

Accreditation Standards

Allografts

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INTRODUCTION

An allograft is tissue taken from one person for transplantation into another person after it has been processed. Allograft use in non-hospital facilities may include but is not limited to: bone void fillers (e.g. demineralized bone matrix), bone wedges (e.g. allopure™), costal cartilage (e.g. Profile®), acellular hydrated dermis (e.g. Alloderm®, Allomax®, BellaDerm®), acellular peritoneum matrix (e.g. Meso BioMatrix®) and tendons (e.g. Gracilis Tendon, Achilles Tendon). Allografts may be used in procedures that include but are not limited to: anterior cruciate ligament (ACL) repair, joint reconstruction in the knee and ankle, articular cartilage repair, rhinoplasty, breast augmentation, mastopexy (Meso BioMatrix®), cervical spine fusion, and dental procedures. The collection of tissues from patients for a tissue bank may not be performed at a non-hospital facility.

Non-hospital facilities are end-user establishments; they are not tissue banks. Therefore, allografts that require refrigeration or freezing are to be ordered and received into inventory only as needed (i.e. either on the day of or the day prior to surgery). If an allograft requiring refrigeration or freezing is not used and/or the surgery is cancelled/postponed, the allograft should be returned to the supplier. Non-hospital facilities are not to store allografts requiring refrigeration or freezing beyond 48 hours. However, non-hospital facilities may maintain “in-house” inventory (i.e. store beyond 48 hours) of allografts which can be stored at ambient temperature.

Non-hospital facilities are not required to register with Health Canada as they do not recover, screen, test, process, label, package or distribute allografts. Non-hospital facilities do not forward allografts onto another establishment (i.e. another non-hospital facility) with the exception of returning an allograft to the source establishment or distributor.

ALO1.0 ALLOGRAFTS

ALO1.1	**Allografts are appropriately stored and managed.**	
ALO1.1.1	**M**	An allograft order is written by the physician. *Guidance: Legislation restricts the sale, distribution and use of allografts to (or on the order of) a physician, dentist, oral maxillofacial surgeon or podiatric surgeon. A patient specific order is written for allografts which includes the type(s) of allograft(s) requested along with (if necessary) any specifications (e.g. length, width). The physician order sheet clearly identifies the patient with two unique patient identifiers and is signed by the surgeon. This order is then used to fill out the source establishment/distributor allograft request (order) form which typically includes the name of the non-hospital facility, name of the requesting surgeon, date of surgery and type(s) of allograft(s) requested along with (if necessary) any specifications (e.g. length, width).*
ALO1.1.2	**M**	Allografts are obtained from a source establishment (i.e. tissue bank) registered with Health Canada. *Guidance: The establishment where the allograft(s) are obtained from holds current registration for Cells, Tissues and Organs for transplantation (CTO) with Health Canada. In addition to being registered with Health Canada, it is recommended that the source establishment be accredited by the American Association of Tissue Banks (AATB). Copies of each source establishment's registration is on file at the facility. This is usually posted on the source establishment's website and can be printed by the end-user establishment (i.e. non-hospital facility). When the registration certificate expires, the facility file is updated with the current registration and the expired registration is retained for, at minimum, 16 years.*
ALO1.1.3	**M**	Allografts are stored in an area not accessible to patients and non-authorized personnel. *Guidance: Allografts that require refrigeration or freezing are ordered and received into inventory only as needed (i.e. either on the day of or the day prior to surgery) and are to remain in their shipping container with the tamper seal intact until needed (i.e. just prior to surgery). If the allograft requiring refrigeration or freezing is not used and/or the surgery is cancelled/postponed, the allograft should be returned to the supplier. Non-hospital facilities are not to store allografts requiring refrigeration or freezing beyond 48 hours. Non-hospital facilities may maintain "in-house" inventory (i.e. store beyond 48 hours) of allografts which can be stored at ambient temperature.*
ALO1.1.4	**M**	Allografts are stored in the appropriate conditions prior to transplant. *Guidance: Allografts must be stored in accordance with the package insert (manufacturer's instructions for use) for temperature conditions and packaging conditions (e.g. outer packaging, container seals). Allografts that require refrigeration or freezing are ordered and received into inventory only as needed (i.e. either on the day of or the day prior to surgery) and are to remain in their shipping container with the tamper seal intact until needed (i.e. just prior to surgery). Storage (i.e. longer than 48 hours) of allografts requiring refrigeration or freezing is not acceptable. If the allograft requiring refrigeration or freezing is not used and/or the surgery is cancelled/postponed, the allograft should be returned to the supplier.*
ALO1.2	**Allografts are safely implanted.**	

ALO1.2.1	**M**	Allografts are verified before induction of anesthesia. *Guidance: The allograft transportation container is inspected and the allograft is not used if: the tamper seal is damaged or not intact, if the container has any physical damage, if the container label or identifying bar code is severely damaged, not readable or is missing, if the allograft has not been stored in the appropriate conditions, or if the expiration date shown on the container label has passed. The name, identification (i.e. bar code, label) and (if necessary) specifications (e.g. length, width) of the allograft are verified against the physician allograft order, the shipping form/packing slip and the allograft packaging. In addition, the allograft is confirmed during the surgical safety checklist briefing.*
ALO1.2.2	**M**	Consent is obtained from the patient prior to transplantation of any allograft. *Guidance: The consent discussion explains the proposed treatment and use (or potential use) of an allograft. The procedure(s) to be performed listed on the consent form includes the use (or potential use) of an allograft. There are no reports of disease transmission during the 30-year history of using freeze-dried bone allografts. However, there have been four cases of HIV following procedures using fresh-frozen bone allografts.*
ALO1.2.3	**M**	Allografts are prepared in accordance with their package insert. *Guidance: Some allografts need to be rehydrated or thawed prior to use.*
ALO1.2.4	**M**	Allografts are single-use only. *Guidance: Excess or unused allograft is discarded in accordance with standards, legislation and regulation for biomedical waste.*
ALO1.2.5	**M**	Excess or unused allograft is discarded in accordance with standards, legislation and regulation for biomedical waste. *Guidance: Allograft that has been rehydrated or thawed and not used within the time period specified by the package insert is discarded in accordance with standards, legislation and regulation for biomedical waste. Also see the NHMSFAP Waste Management standard.*
ALO1.3	**Allograft records are accurate and facilitate the tracking of each allograft from its source establishment to its final disposition.**	
ALO1.3.1	**M**	Allograft records are maintained. *Guidance: The facility must be able to trace all allografts from their source establishment (e.g. tissue bank) to their final disposition (i.e. implanted into a patient, returned to supplier, destroyed/disposed). Records include the receipt voucher or the copy of the purchase order provided by the supplier, a description of the allograft (i.e. name), the donor identification code, the registration number of the source establishment, the notice of exceptional distribution (if any), the date received into inventory, and information about the final disposition (i.e. recipient, return, destruction/disposal) of the allograft. Allograft records must also specify their outcome including any complications, technical problems, errors, accidents and adverse reactions, their investigation and any corrective action taken, and their reporting to the source establishment/distributor and the College in accordance with the bylaws for patient safety incidents. Allograft implant information (i.e. allograft description, donor identification code, location) is also documented in the recipient's medical record in accordance with the NHMSFAP Medical Records and Documentation standard. However, it is not necessary to document full traceability information (i.e. from source establishment to final disposition) in the recipient's medical record. Allograft records are filed sequentially and can be easily retrieved. Allograft records are maintained for, at minimum, 16 years.*

ALO1.3.2	**M**	Allograft records include a source establishment/distributor disposition form for each allograft. *Guidance: The disposition form (i.e. allograft tracking record) should include a description of the allograft (i.e. name), the donor identification code and the name of the source establishment. The attaching of an allograft identification label provided by the source establishment/distributor to their generic disposition form is acceptable. These records are maintained for, at minimum, 16 years.*
ALO1.3.3	**M**	Allograft final disposition is documented. *Guidance: A log is kept to track the final disposition of all allografts from time of receipt from the source establishment (e.g. tissue bank) to their final disposition (i.e. implanted into a patient, returned to supplier, destroyed/disposed). Each allograft received into inventory at the facility is documented in a log. The log includes a description of the allograft (i.e. name), the donor identification code, the registration number of the source establishment, the notice of exceptional distribution (if any), the date received into inventory and information about the final disposition (i.e. recipient, return, destruction/disposal) of the allograft. If implanted in a patient, the log includes recipient identifying information (i.e. two unique patient identifiers), a unique recipient identification code (i.e. for traceability), name of the surgeon, and date of the procedure. If the allograft is returned to the supplier or destroyed/disposed, the records include the date the allograft was returned or destroyed/disposed. These logs are to be maintained for, at minimum, 16 years.*
ALO1.3.4	**M**	Errors, adverse events or technical problems are documented. *Guidance: Allograft records must specify their outcome including any complications, technical problems, errors, accidents, complications and adverse reactions, their investigation and any corrective action taken, and their reporting to the source establishment/distributor and the College in accordance with the bylaws for patient safety incidents. To demonstrate this, for example, the allograft log (final disposition log) could include a column to indicate the outcome of the allograft. In the event of a complication, technical problem, error, accident or adverse event, this column would be marked to indicate an incident (i.e. yes or no/not applicable) and it would alert personnel that documentation of the event, investigation and any corrective action taken and reporting to the source establishment/distributor and the College would be on file at the facility. These records are maintained for, at minimum, 16 years.*
ALO1.3.5	**M**	The allograft log includes a unique identification code to identify the recipient of the implant. *Guidance: Information about the final disposition of the allograft must be provided to the source establishment or distributor. If the allograft was implanted in a patient, the source establishment or distributor is provided with a unique recipient identification code so that its records link the donor to the recipient in the event of a lookback or recall notification. The unique recipient identification code should not be derived from or related to information about the patient (i.e. date of birth, provincial personal health number, medical record number, address, phone number). The non-hospital facility's allograft log facilitates correlation of the unique recipient identification code with the patient name.*

ALO1.3.6	**M**	The final disposition of the allograft is communicated to the source establishment or distributor. *Guidance: Information about the final disposition of the allograft is provided to the source establishment or distributor. If the allograft was implanted in a patient, the source establishment or distributor is provided with a unique recipient identification code so that its records link the donor to the recipient in the event of a lookback or recall notification. If there are any complications or technical problems with the allografts, this is also communicated to the source establishment or distributor and documented in the allograft log/records. Copies of the allograft tracking forms returned to the source establishment/distributor or records of electronic submission are on file at the facility. These records are maintained for, at minimum, 16 years.*
ALO1.4	**Policies and procedures contain all of the information necessary for the safety of patients, staff and visitors.** *Intent: Policies and procedures ensure that activities/procedures are performed consistently and accurately by all personnel within the non-hospital facility.*	
ALO1.4.1	**M**	There is policy and procedures for allografts. *Guidance: The policy and procedures outline the ordering, receipt, storage and safe use (i.e. single-use, preparation, consent) of allografts, the return of allografts to the source establishment/distributor, and the required record keeping.*
ALO1.4.2	**M**	There is policy and procedures for the investigation and reporting of incidents involving allografts. *Guidance: The policy and procedures outline the investigation of complications, technical problems, errors, accidents or adverse reactions involving allografts, the reporting of complications, technical problems, errors, accidents or adverse reaction involving allografts to the source establishment or distributor and any corrective action taken. Allograft incidents that reach the patient, both no harm and harm events, are also reported to the College in accordance with the bylaws for patient safety incidents. Investigation and reporting of incidents involving allografts are maintained for, at minimum, 16 years.*
ALO1.4.3	**M**	There is policy and procedures for lookback notifications and recall of allografts. *Guidance: The policy and procedures outline the regulated health professional(s) responsible for lookback and recall activities, acknowledgement of lookback or recall notification, notification of the physician of the patient or the patient directly if required, and quarantining of allografts in inventory until final disposition is determined. A lookback is the tracing and testing of allograft recipients in cases where the allograft is determined to be potentially contaminated with a blood-borne infection. A recall is a notification by the source establishment or distributor when a quality problem requiring action has been identified. Lookback notification and recall records are maintained for, at minimum, 16 years.*

Summary of changes	
2019-07-04	The following changes were made: • New title (formerly Bone, Bone Products, Cells and Tissues). • Introduction added to clarify that non-hospital facilities are considered end-user establishments; not tissue banks and therefore, non-hospital facilities may not store allografts requiring refrigeration or freezing beyond 48 hours. • Clarified that allografts are to be verified before induction of anesthesia. • Clarified that the allograft log is to include a unique identification code to identify the recipient of the implant. • Substantial format changes and guidance added.

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