Non-Hospital Medical and Surgical Facilities Accreditation Program

ACCREDITATION STANDARDS

Allografts

Introduction

No.	Description

ALO1.0 ALLOGRAFTS

No.		Description
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.*

No.

No.		Description
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.*

No.		Description
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.*

References

American Academy of Orthopedic Surgeons. Use of musculoskeletal tissue allografts [Internet]. Rosemont, IL: American Academy of Orthopedic Surgeons; 2011 [cited 2019 Mar 25]. Available from: https://www.aaos.org/globalassets/about/bylaws-library/information-statements/1011-use-of-musculoskeletal-tissue-allografts.pdf

Canadian Standards Association. Cells, tissues, and organs for transplantation: general requirements. 3rd 3d. Toronto: Canadian Standards Association; 2017. CAN/CSA Standard: Z900.1-

Revision history

Date	Revisions