



Guidance Document

Evaluation of Body Cooling at Standard D5.400

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*American Association of Tissue Banks
1320 Old Chain Bridge Road
Suite 450
McLean, Virginia 22101
(703) 827-9582 (703) 356-2198 Facsimile*

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American Association of Tissue Banks
Suite 450
1320 Old Chain Bridge Road
McLean, Virginia 22101
www.aatb.org

For questions on the content of the document, please contact the AATB at:

(703) 827-9582 or (703) 356-2198 (Fax)

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The AATB recognizes the efforts of the following individuals who generously donated their time and expertise to creating this document.

Robert Hinely (co-editor)
Catherine H. Kamm (co-editor)
Daniel Schultz, MD (co-editor)
Scott A. Brubaker (co-editor, AATB liaison)

Kristen Brown
Wayne Daniels, DO
Patricia Darrigan
Gary Flanders
J. Dennis Hancock, MD
Michael Real
Mark Strong

Version 2 update:

Laurie Agle
Michael Gould, MD
Maria Leonard
Mike Real
Dan Schultz, MD
Randy White
Scott A. Brubaker

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AATB GUIDANCE DOCUMENT EVALUATION OF BODY COOLING

I. INTRODUCTION

Self-imposed limitations by tissue banking professionals regarding the time to recover tissue after donor death have existed in the United States for more than two decades. Mention of applying a time limit, and to maintain the body in a cold environment if there is a delay, is found in a publication endorsed by membership in 1984, via the inaugural edition of the AATB's *Standards for Tissue Banking* [1].¹ As it was then and it is now, time limits can depend on the type of tissue to be recovered, additional requirements related to body cooling, and expected functional utility of the tissue. Ideally, recovery should begin as soon as possible post asystole, however, many factors play a role in delays that occur before tissue recovery can begin. Untoward delay, especially in the absence of body cooling, has led to system failures resulting in transmission of bacterial infections (*Clostridium sordellii*) and the death of a tissue allograft recipient [2]. In this case, the donor body was not cooled for 19 hours after death, subjected to a short period of cooling (4 hours), and tissue recovery began approximately 23.5 hours after death [3]. Reports have shown bacterial contamination of tissues to be associated with, or due to, many factors including agonal state of the donor, prolonged intervals from death to recovery, delay of body cooling, pre-and post-mortem trauma, number of recovery personnel, length of recovery times, and variability in procedures [4,5]. Today, transporting a donor body to a dedicated tissue recovery site is commonplace and can cover a considerable distance from the hospital. One study addressed this and the possible warming and cooling rates of a donor body by performing tests on a gel-filled model [6]. Concerns abound regarding the proliferation of microorganisms after death so time to recovery and considerations for body cooling remain highly regarded.

A. History and Purpose

On March 18, 2010, an AATB Bulletin (No. 10-05) was issued that described changes to Standard D5.400 Time Limits for Tissue Recovery [7]. Where time limitations originally referred to when the donor body was not cooled for 15 “consecutive” hours, changes were made to limit when the donor body was not cooled for 15 “cumulative” hours. This change has resulted in interpretation that additional documentation is required. A perceived flaw of allowing up to 15 consecutive hours of non-cooling in some circumstances could theoretically allow for recovery of a donor's tissues to begin with literally only minutes of body cooling having occurred, yet the body was subjected to a non-cooled environment many hours but under 24 hours. The goal of this document is to provide definitions, examples of source documentation, strategies to document cooling intervals, and to provide guidance for various cautionary situations.

¹ In *Standards for Tissue Banking*. American Association of Tissue Banks. 1984; see Standard C1.352 which states “Tissues shall be retrieved as soon after death as is practical. In the event that tissue retrieval cannot be accomplished within hours of death, the remains shall be refrigerated. Specific time limits will vary with each tissue obtained and those time limits shall be at the discretion of the Tissue Bank Director. In order to ensure tissue quality and to avoid delay of funeral services, tissue retrieval should occur within 24 hours following time of death.”

An important aspect of this document includes considerations when assessing the time when the donor was subjected to cooling. An estimate of when the donor's body was subjected to cooling, when an estimate must be used, may be acceptable in certain scenarios. However, policy can differ among individual tissue banks whose Medical Director will ultimately determine donor suitability. Reliable information is expected so an informed decision regarding suitability of the donor can be made. Estimates should be avoided when determining when the body was first cooled after asystole.

The intent of Standard D5.400 [8, and below] is to mitigate and retard microbial proliferation by imposing time limitations and body cooling guidelines. The total time the body was not cooled must be considered when qualifying a deceased donor for suitability. It cannot be assumed that when a body is subjected to some cooling, that the body stays cooled when removed from that environment (and is no longer subjected to cooling).

This guidance was revised to reflect updating to the standard that clarifies the time when recovery begins and that subsequent steps must proceed without delay. To support this, a definition for *Skin Prep* was created for *Standards* and included in this guidance.

The standard, revised twice, is recreated here (with all amendments):

SECTION D - ACQUISITION OF TISSUE: AUTHORIZATION, INFORMED CONSENT, DONOR SCREENING, AND TISSUE RECOVERY AND COLLECTION

D5.000 RECOVERY AND COLLECTION POLICIES AND PROCEDURES

D5.400 Time Limits for Postmortem Tissue Recovery

When Recovery of tissue has begun, subsequent recovery steps must proceed without delay.

- (C, V) Cardiac and vascular tissue *Recovery* and *Processing* time limits (i.e., *Warm* and *Cold Ischemic Times*, *Disinfection Times*, and the *Perfusion Time* [specific to vascular tissues]) shall be established by each individual tissue bank; however, the following upper time limits for initiation of *Recovery* of specific tissue types shall not be exceeded.
- (C) *Warm Ischemic Time* (C) shall not exceed 24 hours from *Asystole* if the body was cooled (e.g., application of sufficient amounts of wet ice or a cooling blanket, cold weather conditions) or refrigerated within 12 hours of *Asystole*. The time limit shall not exceed 15 hours if the body was not cooled or refrigerated. If the body is cooled for a period of time then not cooled for a period of time, the time period the body is not cooled cannot exceed 15 ~~consecutive~~ cumulative hours.
- (V) 1) *Perfusion Time* shall not exceed 12 hours from *Asystole*; and
2) *Warm Ischemic Time* (V) shall not exceed 24 hours from *Asystole* if the body was cooled (e.g., application of sufficient amounts of wet ice or a cooling blanket, cold weather conditions) or refrigerated within 12 hours of *Asystole*. The time limit shall not exceed 15 hours if the body was not cooled or refrigerated. If the body is cooled for a period of time then not cooled for a period of time, the time period the body is not cooled cannot exceed 15 ~~consecutive~~ cumulative hours.

(MS, OA, S)

~~Tissue excision~~ *The Skin Prep* shall ~~commence~~ *begin* within 24 hours of *Asystole* provided the body was cooled (e.g., application of sufficient amounts of wet ice or a cooling blanket, cold weather conditions) or refrigerated within 12 hours of *Asystole*. ~~Tissue excision~~ *The Skin Prep* shall ~~commence~~ *begin* within 15 hours of death if the deceased donor has not been cooled or refrigerated. If the body is cooled for a period of time then not cooled for a period of time, the time period the body is not cooled cannot exceed 15 ~~consecutive~~ *cumulative* hours.

B. Definitions

The following definitions are used in this Guidance Document:

Asystole: The reference time for cardiac death. A documented pronounced time of death is used as ‘asystole’ when life-saving procedures have been attempted and there were signs of, or documentation of recent life (e.g., witnessed event, agonal respirations, pulseless electrical activity). If a death was not witnessed, ‘asystole’ must be determined by the last time known alive (LKA). Asystole will be ‘cross clamp time’ if the tissue donor was also a solid organ donor.

Body Cooling: The placement of a donor body in conditions of cold environment (e.g., mechanical refrigeration such as a morgue cooler, use of wet ice placed on or next to the body of the deceased, or exposure to comparable environmental conditions).

Last Known Alive (LKA): For an un-witnessed death, the last time known alive is the worst-case time used to establish when asystole could have occurred. This includes the time the person was seen or heard, or when they performed an action supported by a record. This would suffice as an equivocal time of having cardiac rhythm or respirations.

Medical Discretion: Under certain circumstances, a written and scientifically rationalized decision by a Medical Director can allow or disallow a particular scenario

Skin Prep: The application of antiseptic solution to decontaminate the skin. This is a continuous process that is performed without delay between steps; it does not include shaving hair, although this can be done if preferred. The manufacturer’s written recommendations must be followed, including that the antiseptic agent should remain in place for the full time.

Source: A written or oral record considered reliable that can be used to support the documentation of when a body was cooled or removed from cooling. A source must be documented. A few examples of source information can include a: Morgue Log Book; Hospital Security Log; a health care professional identified by name, or a specific staff person from the Medical Examiner’s office.

II. RELEVANT SCENARIOS

Q1. I found the cooling date and time as it appears in the hospital morgue logbook. Do I need to note in donor records that the information came from the logbook?

A1. Yes, the source of the information must be noted, whether the communication was from a written record or obtained verbally.

Q2. The morgue's handwritten logbook shows the donor body entered the morgue refrigerator at 0400. The facility's electronic chart describes the donor was taken to the morgue at 0315. Which time do I use and do I need to justify my answer?

A2. The time of 0400 should be used and described as a "worst-case scenario."

Q3. I have a hospital death notification form that shows the body was transferred from the patient's room at 1050 and taken to the morgue. Should I use 1050 for the start of the cooling time?

A3. No. Verification of entry into morgue refrigeration should be sought. If no further documentation exists, a verbal confirmation from a hospital source should be obtained. The name of the individual or the document providing this information must be noted in the donor file. In any case, if this time of entry into cooling will be estimated, this must be noted and, depending on criticality of the information in regard to limits to recovery time, it should be communicated to a responsible person at the tissue bank that will determine donor suitability.

Q4. It is summer time. The hospital does not have a morgue. A hospital representative states they placed bags of ice next to the donor's torso, however there is no documentation by medical staff that supports this. The body is found with bags containing ice in place as expected. Would a verbal time from the hospital staff be appropriate to use?

A4. Yes, the verbal information, including the source of the information can be used and must be documented. If source documents exist that describe measures taken to cool the body, they are preferred.

Q5. The hospital has a morgue logbook that only shows the date the donor was placed in morgue refrigeration. Can I use an approximate cooling time based on conversations with hospital staff?

A5. Yes. Document the verbal source of the information. A notation that the log simply states they "were placed in morgue refrigeration with no time assigned" can be noted but confirmation of the estimation of the time is expected. Otherwise, a worst-case scenario should be used. Example documentation could be: "J. Doe, Security Officer, estimated body to have been placed in the morgue cooler at 0015."

Q6. I am aware that our ME office removes bodies from morgue refrigeration for short intervals to complete their forensic data gathering. Do I need to document each interval to establish cumulative cooling time?

A6. No. It is recognized there will be in and out times by the ME or pathologist for short intervals. Documentation of such time intervals is considered beyond the intent of documenting the 15 cumulative hours of no body cooling. It is acceptable to use the entire ME interval as cooled time, despite intermittent, brief removals for x-rays, exams, specimen collection, etc. The intent of the change, from “consecutive” to “cumulative” regarding 15 hours when no body cooling occurs, did not include an expectation to add excessive documentation requirements that can promote errors. However, adequate documentation is expected so *relevant* periods (i.e. an autopsy), when no body cooling occurred can be realized.

Q7. The hospital has documented in and out cooling times of the donor. The body was transported to the Medical Examiner’s (ME) office, which I know is 30 minutes away. The ME doesn’t document in and out times and no one in that office has documentation regarding when this donor was taken in and out of cooling, however they follow a standardized work protocol. The ME staff reports bodies are routinely removed from cooling at 0800, however, the autopsy may not begin for 2-3 hours. Can I piece together cooling times based on common sense and the practice the ME follows?

A7. It is best practice is to show due diligence to find the information from either documentation or via interview. If neither is available, then an estimation of times can be utilized. It should be noted that the times are estimates. Example of Documentation: “Factual cooling times at the ME office are unavailable. Times are estimates based on the coroner’s stated practice per J. Doe, ME staff.” See the following example of a documentation method:

Asystole: Date 3/15/11 Time 1900

Donor Cooling:

| Date In | Time In | Date Out | Time Out | Total Non-Cooled Time | Source (list for In Time / Out Time) |
|---------|---------|----------|----------|-------------------------|--------------------------------------|
| 3/15/11 | 2000 | 3/16/11 | 0800 | 1 hour | Trans. Sheet/J. Doe, ME Staff |
| 3/16/11 | 1300 | 3/16/11 | 1700 | 5 hours | J. Doe/Trans Sheet |
| | | | | Total 6 hours estimated | |

Q8. Can cooling the body using wet ice during transportation be counted towards additional cooling time?

A8. Yes. Utilizing bags of wet ice placed along the lateral aspect of the torso and between or on top of the thighs can serve the purpose of cooling the body. Documentation of this should include the name and title of the person who reported the times this was done and the number of ice bags used.

Q9. Does a death occurring in a cold environment (a decedent lying in a snow bank, or a hanging that occurred in a park during the winter and at night) allow for discretion and consideration as “cooled time?”

A9. Yes. Medical director discretion, documentation of known environmental temperatures (via the internet for weather sites for that locale, or other references) can be utilized to show the body was subjected to cool temperatures. Allowances for temperature should be documented with supportive, written rationale.

Q10. Can discretion be used when evaluating acceptability when a calculated postmortem interval has minimally exceeded the 15 hours uncooled time or tissue recovery time limits (i.e., Skin Prep)?

A10. Yes, however, this scenario would require comprehensive documentation by the Medical Director, possibly in consultation with a knowledgeable physician such as a pathologist or Medical Examiner to rationalize why the time intervals are inaccurately exceeded by the worst case estimations, or failure to account for comparable conditions to wet ice cooling. Discretion, for example, can include exposure to cold temperatures due to the environment. Discretion could include providing evidence of a shorter postmortem interval by the Medical Examiner or medical personnel observations (e.g. degrees of algor, rigor, livor, a core body temperature taken) at the time of their assessment.

Q11. Considering that the body cooling parameters are met, what is the expectation for the timing of tissue recovery when the skin preparation process overlaps the 15- or 24-hour time limits for recovery?

A11. The *Skin Prep* is performed with the same diligence as used for operative procedures, allows for maximum antisepsis, and occurs without interruptions. The recovery in such situations immediately follows the skin preparation.

Q12. Why is the death note and/or pronouncement note not sufficient documentation for time of Asystole for some donors?

A12. Time of pronouncement/Time of death may be different from time of *Asystole* depending on the scenario:

- a) The donor is ‘Do Not Resuscitate/Comfort Measures Only’ status prior to death on a unit without cardiac monitoring.

- b) The donor was hospitalized, cared for in a nursing home or in hospice (at home or at a facility) for several days prior to death. The only documentation provided regarding care of the donor within 24 hours of death is the pronouncement note.
- c) Conflicting times of death in care records vs. death records. Actual Time of Death/Last Seen Alive time is unclear.
- d) The donor is an organ donor. Pronouncement time and time of death is the time of brain death. *Asystole* is the time of cross clamp (clinical death).
- e) The death was not witnessed and the decedent was simply found and pronounced. Use of “Last Known Alive” time as defined in this Guidance Document ensures the donor was recovered within acceptable time limits.

III. SPECIAL CONSIDERATIONS

Donors who appear, based on reported asystole, LKA, or body cooling, to be within appropriate time requirements may have signs of accelerated post-mortem interval (decomposition). This can manifest as unexplained skin slippage, unexplained green discoloration (often seen first in the right lower quadrant of the abdomen), unexplained bloating, or putrefactive odor. These accelerated postmortem changes usually arise from hyperthermia due to inordinately warm environmental conditions, or underlying bodily conditions (e.g. a significant infection, brain lesion, or drugs leading to altered temperature regulation). Accelerated postmortem decomposition may also occur when exposed to environments of high bioburden near death (e.g. drowning in dirty water). Observation of changes such as those described above must be documented at physical assessment.

IV. SAMPLE DOCUMENTATION METHODS

Example I

| | Source | Date | Time (Military) | Non-Cooled Time |
|---------------------------|------------------------|------------------|-----------------|-------------------|
| Asystole (see definition) | <i>Pronouncement</i> | <i>4/11/2011</i> | <i>2300</i> | |
| Cooling Start | <i>M. Doe, RN</i> | <i>4/12/2011</i> | <i>0523</i> | |
| Cooling End | <i>Transport Sheet</i> | <i>4/12/2011</i> | <i>1315</i> | |
| | | | | <i>6hrs23mins</i> |
| Cooling Start | | | | |
| Cooling End | | | | |

Example II

| | | | | | |
|--|-------------|-------------------|--|---|------------------------------|
| Date/Time of Asystole: | | Cooled? Y N | | Total Time from Asystole to Recovery: _____Hrs. _____Mins. | |
| Cooling Information | Date | Time | Calculated Time Out of Cooling | | Source of information |
| Cooling Started | | | Elapsed Time from Death to Cooling: _____Hrs. _____Mins. | | |
| Out | | | | | |
| In | | | _____Hrs. | _____Mins. | |
| Out | | | | | |
| In | | | _____Hrs. | _____Mins. | |
| Out | | | | | |
| Initial Incision | | | _____Hrs. | _____Mins. | |
| Total Calculated time out of cooling (must be less than 15 hours) | | | _____Hrs. | _____Mins. | |

Example III

Asystole: Date _____ Time _____

Donor Cooling:

| Date In | Time In | Date Out | Time Out | Total Non-Cooled Time | Source (list for In Time / Out Time) |
|---------|---------|----------|----------|--------------------------|---|
| | | | | | |
| | | | | | |
| | | | | Total ___hours estimated | |

V. References

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