# **Alcor A-2798**

# **Case Report**



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### 1. Summary

Information was derived from multiple sources and was all converted to Mountain Standard Time (MST). For de-identification, dates are not shown. T-0 is the date of cardiac arrest (if more than a few moments before pronouncement) or pronouncement of legal death, T-X represents occurrences on dates before T-0, and T+X represents occurrences on dates following T-0.

A-2798 was a 36-year-old member with whole body cryopreservation arrangements. The cause of death on the death certificate was acute respiratory failure. The member was pronounced legally deceased in Pennsylvania at 17:45 hrs on T-0 days in December of 2021.

After stabilization and field washout, the patient was air transported to Alcor for cryoprotection. The patient arrived at Alcor at 21:36 hrs on T+1 days. The cryogenic cooldown was started on T+2 days at 04:34 hrs and terminated at 00:52 hrs on T+11 days. The patient was transferred to long-term maintenance at liquid nitrogen temperature at 14:16 hrs on T+36 days.

## 2. Patient Assessment and Pre-Deployment

The member had been on Alcor's watch list for many months due to a high risk of COVID-19 complications because of an active cancer diagnosis, a heart condition, and a liver condition. The member reported in May that a bone marrow transplant would be performed in June. The member signed up for the Alcor Check-In service to keep in frequent contact. Additionally, the member provided Alcor with documentation showing that a Health Insurance Portability and Accountability Act (HIPAA) Medical Release Form had been completed and notarized. The bone marrow transplant was successful, and the member continued to be monitored closely by both the medical team and by Alcor.

The member was admitted to the intensive care unit (ICU) at a hospital in late November. The member had an unknown respiratory infection which was potentially due to the transplant history. The medical team planned to intubate and sedate the member to provide some rest and relief for the lungs. The member was still alert and talking at the time while on 50% high flow oxygen ( $O_2$ ). But the situation was deemed critical. Two days later the ICU staff ruled out tuberculosis as well as some other bacterial infections. The member was still on the ventilator and heavily sedated.

#### T-3 days

Vancomycin-resistant enterococcus (VRE) was confirmed to be in the member's blood and lungs. The ICU tried multiple antibiotics and stated that they would reevaluate the member's condition two days later and attempt to extubate to see if the member would breathe without assistance



#### T-1 days

At 11:09 hrs the family was given 48 hours to decide on extubating the member. Because the member already had two types of bacteria present in the lungs and blood stream as well as the potential for the kidneys to require dialysis, the family declined an abdominal CT scan since it would use a contrast fluid, and they did not feel the benefits would outweigh the risks to the kidneys.

One of Alcor's strategic partners, Suspended Animation, Inc. (SA), was officially deployed at 15:36 hrs for standby, stabilization and transport (SST), as well as field washout.

#### 3. Deployment

Information was derived from multiple sources and was all converted to Mountain Standard Time (MST), military notation, times in parentheses reflect the SST team's local time.

#### T-0 days

Two members of the SST team arrived at the member's location at 06:12 hrs MST (08:12 EST) the next morning, and their contract surgeon and perfusionist were expected to arrive later that day. The SST team gathered supplies and a rental van prior to heading to the hospital. At 08:11 hrs (10:11 EST), the team arrived at the hospital. The SST team learned that the member was on a ventilator at the maximum flow rate, had internal bleeding, and weighed around 271 lbs. with a height of 5' 7". The team contacted the nurse manager and consulted the hospital's Office of General Counsel for permission to store their equipment and be on standby on the floor.

Overall, the hospital staff was accommodating and cooperative. After making initial contact with the hospital staff and the member's family, the team left the hospital to organize logistics and prep the funeral home operating room, which was roughly 20 minutes away. While unloading equipment at the funeral home, it was discovered that both bottles of Decaglycerol/THAM in the SA Ischemia Kit had been shattered, most likely by poor handling by TSA at the airport. SA ordered two more bottles from their Florida facility, but they were not expected to arrive until the next morning.

At 13:11 hrs (15:11 EST), the team received authorization from the hospital to keep their equipment on standby adjacent to the member's room. SA also coordinated with hospital security and received approval to stage the rental van in the hospital's funeral/morgue receiving area. However, the member's family at this point wanted to place the member on comfort care sooner than expected. SA's contract surgeon was still due to arrive at 15:00 (17:00 EST).



## 4. Standby and Stabilization

Based on the member's condition and vital signs, the member was expected to deteriorate rapidly after extubation. As a consequence, the SST team remained in the hospital. At 15:09 hrs (17:09 EST), SA's surgeon had landed and was enroute to the funeral home. The hospital's current plan at that time was to terminate the member's care at 16:00 hrs (18:00 EST).

At 16:22 hrs (18:22 EST), the hospital staff began gradually shutting down the member's ventilation support. At 16:28 hrs (18:28 EST), the member was down to low/medium pressure support and had a capillary oxygen saturation (SpO2) reading of 45%. At 16:37 hrs (18:37 EST), the member began having short episodes of apnea and at 16:50 hrs (18:50 EST) the member was on the lowest possible ventilation support. At that point, the member's vital signs were also dropping gradually. At 17:08 hrs (19:08 EST), vitals were respiration rate (RR) 26, heart rate (HR) 46 and SpO<sub>2</sub> 55%.

At 17:31 hrs (19:31 EST), the hospital staff assembled to declare pronouncement of legal death, but the attending nurse could detect breath and pulse. A physician was called in to confirm if breath and pulse were absent, and at 17:45 hrs (19:45 EST), the member was officially pronounced legally deceased, and the SST team was given access to the room and the patient to begin stabilization.

An intraosseous device to access the patient's vasculature was placed in the right tibial tuberosity at 17:48 hrs (19:48 EST) while the patient was still on the hospital bed. Three SST team members used the hospital's Hoyer lift to move the patient from the hospital bed into the portable ice bath (PIB). No water was added to the ice bath due to the added weight it would add, and the resulting difficulty lifting the PIB into the rented vehicle and possibly at the funeral home. Ice bags were applied to the patient's head and body. The Autopulse mechanical heart compression device was turned on at 17:51 hrs (19:51 EST) to provide circulatory support and to help optimize cooling, and the first stabilization medication was administered (see the below Table of Medications Administered for the names of the medications, the dosages, and the times of administration). The patient did not need to be intubated because the hospital staff had left the endotracheal (ET) tube in place. When the capnograph was attached it was noted the device time was 8 minutes too fast. The subsequent graph has been amended for this differential.

At 17:55 hrs (19:55 EST), extrication had begun to remove the patient from the hospital. At 18:02 hrs (20:02 EST), the patient was loaded into the rental van. Stabilization procedures continued while the patient was transported to the funeral home. The administration of stabilization medications was started at 18:08 hrs (2022 EST) (see the below Table of Medications Administered for the names of medications, dosages, and times of administration).

At 18:22 hrs (2022 EST), the Autopulse battery gave an audible warning indicating that the battery was running low. At 18:28 hrs (2028 EST), the Autopulse stopped due to a depleted battery and manual compressions were initiated. At 18:29 hrs (20:29 EST), the van arrived at the funeral home, the Autopulse battery was changed, and mechanical compressions were resumed.



At 18:30 hrs (20:30 EST), the patient was rolled into the funeral home in the PIB. Due to the patient's weight, together with the added weight of the ice in the PIB, the total of which was estimated to be 350 to 400 lbs., two wheels on the ice bath snapped off. The PIB had to be lifted and dragged by the team to get it into the operating room. Once in the operating room, the PIB was manually lifted onto the operating table and the administration of stabilization medications resumed. The funeral home had a hoist, but it could not be used because of height limitation (see Discussion section).

At 18:35 hrs (20:35 EST two team members left the funeral home to obtain additional ice. At 18:40 hrs (20:40 EST), the patient's nasopharyngeal temperature (NPT) was 35°C.

#### 5. Field Surgery and Washout

The field surgery and washout procedures were performed with the patient in the PIB. Due to the size of the patient, external cooling was not effective. Alcor was contacted for suggestions on when to start the field surgery and washout. Alcor's Medical Advisor told the team to proceed immediately with the surgery rather than try for additional surface cooling. At 18:56 hrs (20:56 EST), the Autopulse was stopped; both the right NPT and the left NPT were of 34°C. The patient's chest was prepped, and sterile drapes were placed.

The first surgical incision was made in the patient's chest for the median sternotomy at 19:00 hrs (21:00 EST) and deepened to the level of the sternum, which was divided with an oscillating saw. The pericardium was opened, and the cardiac structures were noted to appear grossly normal. However, the heart was severely distended and there was abundant mediastinal fat, limiting exposure of the ascending aorta. Thus, at 19:15 hrs (21:15 EST), a 43/37 dual-stage venous cannula was inserted into the right atrium to drain out part of the blood pool, decompressing the heart and allowing cannulation. Purse string sutures of 3-0 Ethibond were placed in the distal ascending aorta and an 8.5 mm aortic cannula was inserted after making a stab wound inside this purse string.

At 19:17 hrs (21:17 EST), a 21 French (Fr) arterial canula was inserted. At 19:19 hrs (21:19 EST) the cannulae were connected to the cardiopulmonary bypass circuit and open circuit perfusion was initiated. At 19:36 hrs (21:36 EST) closed circuit perfusion was started. Per the perfusionist's report, the maximum flow rate was 7.3 L/min, and the highest line pressure was 75 mmHg. Perfusion and cooling continued until the patient reached a core temperature of less than 5°C. The perfusion pump was stopped at 20:25 hrs (22:25 EST). The temperatures were 4.9°C venous, left NPT 2°C, right NPT 1°C and thoracic 6°C. Air was supplied at 5 L/min to the circuit oxygenator (standard SA procedure since July 2019). The surgeon concluded that a good washout had resulted.

The venous cannula was removed, but at the request of Alcor, the aortic cannula was left in situ and was kinked-off and wrapped with a segment of sternal wire; the proximal end of the cannula was directed into the left chest. The sternum was reapproximated with three #6 stainless steel



wires, followed by running 3-0 Prolene for the skin. The patient was then prepared for transfer to Alcor the following day.

While waiting for the patient to cool and during the washout procedure, team members were on the phone contacting the funeral director, Alcor, and the hospital to confirm the delivery of the Ziegler case and to obtain the electronic death certificate number from the hospital. The Ziegler case would not arrive until 08:00 hrs (10:00 EST) the next morning. It was decided that due to the low temperatures outside (estimated to be 2°C), the patient would be placed in two body bags with water ice and left in the funeral home's locked storage overnight.

Fortunately, the funeral home had their own lifting apparatus that made removal of the patient from the PIB into the body bags much safer and easier (see the Discussion section). At 21:34 hrs (23:34 EST) the patient was packed with approximately 100 lb. of water ice into two body bags before retiring for the night. The team went to the funeral home the following morning to receive the Ziegler case and proceed with the transport process.

## 6. Transport

#### <u>T+1 days</u>

The patient was loaded into the Ziegler case and air tray at 08:00 hrs. The patient was loaded with approximately 100 lbs. of double-bagged water ice and insulated with R19 fiberglass. The patient was then loaded into the transport vehicle.

The physical copy of the transit permit from the funeral director was received at 09:49 hrs. The patient was taken to the airline cargo department and checked in at 11:26 hrs. At 13:00 hrs the flight left for Phoenix, and arrived at 19:22 hrs. The patient was picked up at the airport and loaded into the Alcor vehicle for transport to Alcor.

## 7. Cryoprotectant Perfusion Surgery

The patient arrived at Alcor at 21:36 hrs. The data collection set-up and the circuit tubing had been primed before the patient arrived (see the Discussion section). The patient was moved into the operating room (OR) at 21:46 hrs. A hoist was used to place the patient on the OR table at 21:47 hrs. Ice was placed around the patient's head at 21:50 hrs.

The patient's head was shaved at 21:53 hrs in preparation of making the burr holes. Two burr holes were made to observe the hemispheres of the brain. No shrinkage or swelling was seen until the patient was transferred to cooldown (see the last paragraph of this Discussion section, below). There was leakage from the burr holes onto the table. Approximately 15 liters of B1



were used to continue flushing out the body before starting the cryoprotectant concentration ramp. The venous effluent at the end of washout was nearly clear, but still retained a lot of red blood cells. The temperature thermocouple was not working because of being wet from shifting during transport. A new thermocouple was connected at 21:58 hrs and connected to the computer data acquisition system. The NPT was 4.5°C.

The patient's chest was reopened at 22:08 hrs. The venous cannula had been removed following washout. The inferior vena cava was recannulated at 22:13 hrs and connected to the tubing circuit at 22:14 hrs.

A 21 Fr arterial canula was still in the right atrium and was connected to the tubing circuit at 22:15 hrs. Perfusion was initiated on the arterial circuit at 50 mmHg. The bypass was clamped off at 22:16 hrs. At 22:19 hrs blood clots were removed from the venous return line.

## 8. Cryoprotectant Perfusion

The cryoprotectant ramp was started at 22:27 hrs. At 22:37 hrs the main pump speed was raised to 2.8 liters/minute. The main pump speed was reduced (amount not noted) when the arterial pressure reached 90 mmHg at 22:39 hrs. Computer control of the system was initiated at 22:40 hrs.

Using a Codman perforator, and cooled saline to cool the drill, the right burr hole was completed 22:43 hrs. The left burr hole was completed at 22:44 hrs. The burr hole temperature was 3.8°C.

#### T+2 days

To allow for equilibration of the cryoprotectant in the tissues, the ramp pump was stopped at 00:05 hrs when the refractive index of the effluent reached 30 Brix. At 00:34 hrs it was again noted that there were no signs of brain swelling. The ramp pump was restarted at 00:35 hrs. The temperature of the chiller, reservoir enclosure, and the table were set to  $-3^{\circ}$ C at 00:48 hrs.

#### Sidebar:

Per the cryoprotection protocol, the ramp is to be paused at 30 Brix (50% of the desired terminal concentration) to allow the patient to come to osmotic equilibrium. The cephalic enclosure and the chiller are switched from  $+3^{\circ}$ C to  $-3^{\circ}$ C operation. At the end of the 30-minute pause, the ramp is resumed at the maximum addition rate (maximum without losing total volume in the circuit) to go to 105% of the desired end concentration (52.5 Brix) and held between 102% and 105% concentration until the terminal concentration is obtained.

The refractive index of the venous effluent was measured at 33.75 Brix at 01:03 hrs. The temperature of the chiller was reduced to  $-5^{\circ}$ C at 01:05 hrs to bring the temperature more in line with the target temperature of  $-3^{\circ}$ C. To speed up the perfusion ramp, the volume in the mixing



reservoir was reduced from 10 to 7 liters at 01:13 hrs. The refractive index of the venous effluent was measured at 36.69 Brix at 01:17 hrs.

The venous sampling head was noted at 01:40 hrs to be leaking and the problem was corrected. It was also noted that the GoPro camera in the OR had not been turned on but that the whole-room high-definition camera was on. A new bladder of M22 perfusate was started at 02:04 hrs and it was noted that there was only one bladder left on site. The effluent subtraction line was disengaged at 02:18 hrs because the volume kept dropping. The ramp pump speed setting was increased from 7 to 8 in order to increase the ramp rate at 02:25 hrs and the effluent withdrawal pump was reengaged at 02:33 hrs.

The system temperature had dropped to  $-4^{\circ}$ C. The chiller temperature was set back to  $-3^{\circ}$ C at 02:45 hrs. The ramp pump speed was gradually reduced from 6.5 at 03:05 hrs to 4 at 03:17 hrs, as terminal concentration was approached.

#### Sidebar:

The 30-minute countdown to the termination of cryoprotection is initiated, after which the final sub-zero terminal concentration ramp is resumed. Per the cryoprotection protocol, the normal endpoint criterion for whole body patients is over 100% for over 30 minutes from the venous return and for neuro patients, it is over 100% for over 30 minutes from both jugular veins. The addition pump speed is minimized, with frequent corrections, to compensate for latency.

At 03:18 hrs the refractive index of the venous effluent was measured at 51.5 Brix. The cryoprotective ramp was stopped at 04:06 hrs. The patient was moved into the patient care bay and cryogenic cooling was started at 04:34 hrs.

## 9. Cooling to Liquid Nitrogen Temperature

A computer program was used to initiate cryogenic cooldown at 04:34 hrs on T+2 days, plunging to  $-80^{\circ}$ C and descending thereafter at  $-1^{\circ}$ C/hour to liquid nitrogen temperature. The burr hole thermocouple graph showed an isotherm at approximately  $-25.2^{\circ}$ C.

#### Sidebar:

An isotherm (freezing event) is a period of interrupted temperature descent observed on the time vs. temperature graph of a specimen as the specimen undergoes a phase transition, for example when freezing a liquid to a solid. An isotherm occurs as energy is exchanged to rearrange molecules into the new phase, instead of to change the temperature of the system. In the context of cryonics, an isotherm is undesirable because it is an indicator of ice formation, and therefore incomplete vitrification. The formation of a glassy solid by vitrification, which involves no crystallization, does not express an isotherm.

On T+11 days at 00:52 hrs, an uneventful cooldown was terminated. On T+36 days at 14:16 hrs, the patient was transferred to long-term maintenance at liquid nitrogen temperature.



## **10.** Timeline and Time Summaries

#### Timeline

T-0 days

- 17:45 Pronouncement of legal death
- 17:48 Placement of intraosseous device (EZ-IO)
- 17:50 Start of ice bath cooling (bagged ice only)
- 17:51 Start of mechanical chest compressions
- 17:51 Administration of first medication (200 mg propofol)
- 17:51 Ventilator started (endotracheal tube left in place by hospital staff )
- 18:04 Start transport of patient to location of surgery (funeral home)
- 18:30 Arrival at location of surgery
- 18:56 Termination of cardiopulmonary support (NPT 34°C)
- 19:00 Start or field surgery (median sternotomy)
- 19:19 Start of open circuit washout
- 19:35 Administration of final medication (vasopressin)
- 19:36 Start of closed-circuit perfusion
- 20:25 Completion of closed-circuit perfusion

#### T+1 days

- 11:26 Departure of transport vehicle to airport
- 21:36 Arrival of the patient at Alcor
- 21:58 NPT probes attached to data acquisition system (initial NPT 4.5°C)
- 22:08 Start of surgery (recannulation)
- 22:15 Start of open-circuit washout
- 22:20 Completion of open-circuit washout
- 22:27 Start of cryoprotection
- 22:40 Start of burr hole surgery
- 22:44 Completion of burr hole surgery

#### T+2 days

- 00:05 50% of concentration necessary for vitrification (CNV) achieved
- 00:35 Start of sub-zero terminal concentration ramp (off pause)
- 04:06 Termination of cryoprotection (51.5 Brix)
- 04:34 Start of cryogenic cooldown

#### T+11 days

- 00:52 Completion of cryogenic cooldown
- 14:16 Transfer of patient to long-term maintenance at LN<sub>2</sub> temperature



#### **Time Summaries**

#### **Stabilization**

Event Duration

- **27:51** From the pronouncement of legal death to patient arrival at Alcor: 17:45 hrs on T-0 to 21:36 hrs on T+1
- **00:06** From pronouncement of legal death to start of cardiopulmonary support: 17:45 hrs to 17:51 hrs
- **00:06** From pronouncement of legal death to start of medication administration: Also 17:45 hrs to 17:51 hrs
- 00:22 From start to the end of medication administration: 17:51 hrs to 18:13 hrs

#### Field Surgery and Washout

Event Duration hrs: mins

- **01:15** From pronouncement of legal death to start of surgery: 17:45 hrs to 19:00 hrs
- **00:17** From the start of surgery to end of surgery: 19:00 hrs to 19:17 hrs
- 01:34 From pronouncement of legal death to start of washout: 17:45 hrs to 19:19 hrs
- 01:06 From the start of washout to end of washout: 19:19 hrs to 20:25 hrs
- 02:40 From pronouncement of legal death to end of washout: 17:45 hrs to 20:25 hrs

#### Cryoprotectant Surgery

**Event Duration** 

hrs: mins

- **00:32** From arrival at Alcor to the start of surgery: 21:36 hrs to 22:08 hrs
- 00:19 From the start of surgery to the start of the cryoprotection: 22:08 hrs to 22:27 hrs

#### Cryoprotectant Perfusion and Cryogenic Cooldown

**Event Duration** 

hrs: mins

- **28:42** From pronouncement of legal death to start of cryoprotection: 17:45 hrs on T-0 to 22:27 hrs on T+1
- **00:51** From arrival at Alcor to the start of cryoprotection: 21:36 hrs to 22:27 hrs
- **05:39** From start to the end of cryoprotection: 22:27 hrs on T+1 to 04:06 hrs on T+2
- 00:28 From the end of cryoprotection to the start of cooldown: 04:06 hrs to 04:34 hrs
- **34:49** From pronouncement of legal death to start of cooldown: 17:45 hrs on T-0 to 04:34 hrs on T+1
- 06:58 From arrival at Alcor to the start of cooldown: 21:36 hrs on T+1 to 04:34 hrs on T+2



## 11. Table of Medications Administered

TIME	MEDICATION	DOSE	PURPOSE
<b>T-0 days</b> 17:51 hrs	Propofol	200 mg	Anesthetic; reduces cerebral metabolic demand; reduces the theoretic possibility of increased awareness during aggressive CPS.
17:53 hrs	Sodium citrate	50 mL	Anticoagulant; prevents blood clot formation.
17:54 hrs	Sodium citrate	50 mL	Anticoagulant; prevents blood clot formation.
17:55 hrs	Heparin	50,000 IU	Anticoagulant; prevents blood clot formation.
17:55 hrs	Vasopressin	40 IU total (1st dose 40 IU) Note 1	Vasopressor; increases blood pressure during CPS.
18:05 hrs	Minocycline	200 mg	Antibiotic and neuroprotectant
18:05 hrs	SMT (S-methyl- isothiourea)	400 mg Note 2	Neuroprotectant (iNOS inhibitor); protects the brain from ischemic injury; raises blood pressure.
18:06 hrs	Vital Oxy (w/saline)	220 cc total (1st dose 60 cc) Note 3	Antioxidants: melatonin, vitamin E (D-alpha tocopherol), PBN (alpha Phenyl t-Butyl Nitrone) and anti-inflammatory carprofen.
18:08 hrs	Vital Oxy (w/saline)	220 cc total (2nd dose 60 cc) Note 3	Antioxidants: melatonin, vitamin E (D-alpha tocopherol), PBN (alpha Phenyl t-Butyl Nitrone) and anti-inflammatory carprofen.
18:09 hrs	Antacid	Unknown Note 4	A buffer used to protect the stomach from acid erosion.
18:09 hrs	Vital Oxy (w/saline)	220 cc total (3rd dose 40 cc) Note 3	Antioxidants: melatonin, vitamin E (D-alpha tocopherol), PBN (alpha Phenyl t-Butyl Nitrone) and anti-inflammatory carprofen.
18:12 hrs	Vital Oxy (w/saline)	220 cc total (4th dose 60 cc) Note 3	Antioxidants: melatonin, vitamin E (D-alpha tocopherol), PBN (alpha Phenyl t-Butyl Nitrone) and anti-inflammatory carprofen.
18:13 hrs	Vasopressin	40 IU total (2nd dose 40 IU) Note 1	Vasopressor; increases blood pressure during CPS.
19:35 hrs	Streptokinase	250,000 IU Note 5	A thrombolytic used to break up existing blood clots.

Notes:

1. Vasopressin is a fixed dosage of 40 IU, per dose for two doses. The second 40 IU dose is to be administered concurrently with Vital-Oxy, I.V. Vasopressin is to be administered only if the patient's temperature is above 20°C as it is ineffective at cold temperatures.



2. SMT (S-methyl isothiourea) is a fixed-dose and is a powder, (1 vial = 400 mg) dissolved in 10 mL of saline and injected through a 0.2  $\mu$  filter. SMT is unstable in solution with a useful life of approximately six hours.

3. The medications protocol dilutes 70 mL or less, based on body weight, of Vital-Oxy into 150 mL of saline for a total of 220 cc of diluted Vital-Oxy saline. Each mL of Vital-Oxy contains 194 mg Sigma Cremophor EL (or Sigma Kolliphor EL), 155 mg ethanol, 19.4 mg PBN, 3.24 mg carprofen, 1.55 mg melatonin, and 198 IU vitamin E.

4. An attempt was made to administer 250mL of antacid into the patient's nasogastric tube (NG). However, the working environment of the moving vehicle as well as the small diameter of the NG tube made administration of the antacid difficult. A good portion of the antacid spilled into the ice bath and did not make it into the NG tube. An unknown amount of antacid was administered during transport.

5. The standard administration of streptokinase is 250,000 IU dissolved in 5 mL of 9% sodium chloride and infused through a 0.2  $\mu$  filter. Streptokinase is usually administered with the initiation of the washout procedure.

6. Decaglycerol/THAM was not administered because the two bottles in the medications kit were damaged in transit. It is assumed that they were damaged during the TSA examination of the kits.

#### 12. Discussion

#### SST and Washout

Two Decaglycerol/THAM bottles were broken in transit to the member. Most likely due to the TSA inspection at the airport. Additional padding, as well as hard sided casing has been implemented for large volume medications in glass bottles.

The funeral home had a hoist, but it could not be used to lift the portable ice bath (PIB) with the patient and ice onto the operating table when the patient first arrived because the hoist could not reach high enough to place the PIB onto the table. After the washout, the PIB was lifted off the operating table by the team members and placed on the floor. Then the hoist was used to move the patient out of the ice bath and into the body bags.

The contractor's ice bath has low wheels to be able to load it into a standard minivan for transport to a funeral home. They have additional, tall legs, which can be used if needed, but for most cases the tall legs take more time and manpower to attach so that in most cases it is easier to just lift the ice bath onto an existing OR table.



The patient's weight made moving the PIB difficult and even resulted in two of the casters on the contractor's stainless-steel ice bath breaking off while transporting the patient from the vehicle to the operating room at the funeral home. The two casters that broke were sheared off at the connection from the caster to the pin that holds the caster onto the ice bath. (see the below pictures).







More personnel should have been deployed to assist with lifting a patient of this size. There were a few situations where lifting power was needed and the personnel on site had to make up for that lack. For future cases, the height and weight of the patient needs to be given to the SST team prior to deployment so adequate personnel can be deployed.

The patient remained at the funeral home over night. The data loggers measure their surrounding temperature with an internal sensor. The funeral home room was cooled with a large A/C unit but not specifically refrigerated. It is SA policy to always make the location of surgery (and transport) to be as cold as possible to aid in cooling. Transport to Alcor

The morning after surgery when the patient was loaded into the Ziegler case, no additional ice was needed as the location where the patient was stored overnight was approximately1°C. During transport to the airport, something happened to the loggers. The ambient temperature and the right nasopharyngeal temperature both increased, but the left nasopharyngeal temperature decreased. The reason for this is not known as the team was in transit to the airport cargo area. There were also temperature variations at the cargo area that cannot be explained because the team was not present to observe the handling of the patient. Also, prior to and post-departure of the patient, the loggers stopped working.

In the past, there have been issues with cargo offices leaving patients either in the elements on hot days or indoors on cold days with the indoor temperature controls at comfortable working temperatures. This is why the patients are insulated as well as possible.

The EtCO2 (end-tidal CO2) readings that were obtained are a measure of effectiveness of CPS. The readings were mostly in the normal range (35 to 45 mmHg) indicating that oxygenated blood was being successfully circulated to support metabolism to generate CO2, and that the lungs were being ventilated adequately to remove it. The noisy readings between 18:07 and 18:32 occurred while the patient was transported to the funeral home. The cause of the sudden CO2 buildup upon arrival at the funeral home is unknown but could plausibly have been caused by a transient obstruction of the airway during movement of the patient to prepare for surgery.

#### Surgery and Cryoprotection

The data collection set-up and the circuit tubing had been primed and debubbled before the patient arrived. The whole-body handling gear worked well. The lifting straps to go around the body were not positioned well for the patient's center of gravity (CG), though. Upon arrival the patient was in a mesh lifting harness which could not be removed from under the patient, even with considerable effort. The mesh harness was used for all lifting operations in lieu of the standard lifting straps.

The mixing reservoir volume was between 6 and 8 liters. With the stir bar speed as it was, there were a lot of small bubbles going into the pump. This is a common event, and these were removed by the bubble filter part of the clot filter. Bubbles were never seen in the perfusate line. A large head of foam built up on the mixing reservoir. It would be helpful to have a mixing reservoir with transparent walls, such as polycarbonate but not glass (which can break, and is



avoided in the OR), to look at the vortex and adjust the mixing bar speed to reduce bubble generation and reduce the foam problems.

Unexpectedly, the vascular cross-section became extremely high (vascular resistance = viscosity / vascular diameter ^4) and the main pump with a 1/4" shoe was unable to reach a pressure of 80 mmHg at full speed (~70 mmHg at 2.74 lpm with B1 washout solution). This may be related to the obesity of the patient, as obesity has been associated with increased diameter of vasculature, at least in young men, (Obesity and Overweight Associated With Increased Carotid Diameter and Decreased Arterial Function in Young Otherwise Healthy Men). Eventually the viscosity of the ramp became high enough to achieve the 80mmHg regulating pressure, resulting in a vascular resistance ratio of 4.2. This prompts the question: what part of this is due to change in vascular cross-section and what part to viscosity increase; a viscosity increase of 4x over the course of the cryoprotection does not sound unreasonable. We used to have a 1/4" and a 3/8" shoe in the circuit to select from but dropped the 3/8" shoe because we never needed it.

A number for relative viscosity changes with pressures can be obtained at the beginning and the end of the 3/8" perfusate line, which is rather long, and the pressure at the arterial cannula for pressure regulation by pump speed is already available. Work has been done at Alcor with differential pressure sensors working on measuring liquid nitrogen levels. It could then be determined if the vascular cross-section is changing during the cryoprotection, information worth knowing, especially considering that cryoprotection is about tissue dehydration (most of the pressure drop from arterial to venous is in the capillary beds of the various organs, and it is sensitive ( $d^4$ ) to the capillary diameter).

The pressure drop across a length of cylindrical pipe in laminar flow is linearly proportional to both the fluid viscosity and the flow rate, with diameter and length held constant. The flow rate is calculated from the pump speed, the pressure drop is measured directly, and thus with a change in pressure, the relative viscosity can be measured. A similar method might be used to calculate the vascular resistance of the patient, though the relationships must be complicated by the unknown flow conditions inside the patient. Further research is necessary. From direct measurements elsewhere, M22x1.00 (100% CNV) has a refractive index of 51.5 Brix. The comfortable upper limit suggested by 21st Century Medicine of [M22 perfusate exposure] is 108%, with a calculated RI of 54.2. Mostly keeping below that, the effluent from the body was held around 51.5 Brix for about 45 minutes and the cryoprotection was ended.

The jump from 50% to 108% took about an hour because of the small size of the ramp pump. Since the specification for the jump after the 30-minute pause is "as fast as possible" other methods should be considered to speed things up. One number needed is the total volume of perfusate passed through the main pump between the beginning of the jump and the end of perfusion to see what the cost of single-pass 106% cryoprotectant would be, the simplest solution. (Single pass works for neuro cryoprotection because of the smaller scale but is likely to be hugely more expensive for whole body patients). For reference, the ramp from 0% to 50% in this case took about 20 liters of M22x1.25. The remaining cryoprotection, from 50% to 100% effluent [M22] took about 85 liters at \$220.09/liter. The objective here is to reduce the exposure time to cryoprotectant and the amount of cryoprotectant used).



The refractometer micro adapters leaked due to too high a pump speed and a single return line for two pumps. As viscosity rose, the pressure in the refractometer heads rose until the O-rings unsealed. A reduction in the refractometer pump speed or using separate return lines for both left and right refractometers would have prevented this. The standard tubing set typically uses two return lines, but a temporary set had been constructed for this case on short notice.

By metrics which are generally agreed upon, the cryopreservation appeared to go well. Good flow was sustained for the entire procedure and strong physical effects of perfusion on the patient's body (e.g., sunken eyes, yellowing skin) were observed. However, the patient appeared to have leakage into the abdominal cavity during perfusion, becoming slightly distended. A reasonable volume of effluent was suctioned continuously out of the chest cavity for the entire procedure, though the venous return flow was sustained. The results of cryoprotection on the brain are not known because Alcor cannot conduct CT scans on whole-body patients yet.

When the patient was transferred to cooldown from -80°C, it was noted that a substantial amount of salmon-colored and yellowish fluid (~2-300 ml) had leaked from the burr holes. The brain volume appeared normal through the burr holes at the end of perfusion, in fact there was little to be seen through the burr holes for the entire procedure. There was no sign of extrusion until after of cooldown to -80C.

#### Cooldown

This patient was very obese and presented a challenge for transfer into long-term storage. It was difficult getting the protective sleeping bag sealed around the patient before placing the patient into the liquid nitrogen. Alcor staff will investigate obtaining extra-large sleeping bags for future cases. The size of the patient did not interfere with the Super Dewar open-style backer board, and the straps were long enough to fully secure the patient.



## 14. Graphs and CT Scans

### Graphs provided by SA:







End-tidal  $CO_2$  (EtCO<sub>2</sub>) readings and respiratory rate measured by a CMI PC-900B capnograph while ventilating at 11 breaths per minute during CPS. Normal EtCO2 is 35 to 45 mmHg. The noisy readings between 18:07 and 18:32 coincide with the time period that the patient was being transported to the funeral home.





The anomalous low and noisy readings of the left nasopharyngeal temperature while the patient was checked in as air cargo are assumed to be a malfunction.





#### Graphs provided by Alcor:



Operating room personnel record temperature data during equipment startup as it may help to explain problems encountered (note hours 27 to ~28.5 post-pronouncement). The start of perfusion, start of cryoprotection and end of cryoprotection are marked with event bars. The graph shows the nasopharyngeal and burr hole thermocouples were inserted at 28:15 and 29:08 post-pronouncement.

















#### **Cryoprotectant Distribution (Post-cryopreservation CT scan)**

As this was a whole-body cryopreservation, no post-cryopreservation CT scans were obtained.

