

## **STABILIZATION AND TRANSPORT CASE REPORT**

Patient: Cryonics Institute Member 165, Patient 95

Date: June 25, 2009

Location: Albany, New York

Report prepared by: Catherine Baldwin, Standby Team Leader. Graphics by Mathew Sullivan, Standby Team Member.

### **INTRODUCTION**

On June 20, 2009, cryonics pioneer, Cryonics Institute (CI) member and Suspended Animation (SA) client, Curtis Henderson (CI-95) was admitted to Albany Medical Center in Albany, New York. After consulting with family and physicians, a team from SA was deployed to standby in Albany on June 21.

June 25, Curtis was pronounced legally dead at the Albany Medical Center and was subsequently stabilized and transported to Michigan by the team from SA. The team's activities and data collected are reported below, followed by a brief timeline. Case issues and corrective actions follow that.

### **MEDICAL BACKGROUND**

The patient was an 82-year old Caucasian male, approximately 5 feet 6 inches tall, weighing 175 pounds. He had a history of heart disease and hypertension. He suffered a stroke and had a pacemaker implanted in the year 2000. The pacemaker was replaced in April 2007.

His daily medications prior to admission included:

Coumadin (warfarin), 2mg x3 q.h.s.

Furosemide (Lasix) 40mg x1 q.a.m.

Digitex (Lanoxin) 125mg x1 q.a.m.

Cartia XT 240mg x1 q.d

Sotalol HCl 320mg x1 b.i.d

One month before his hospitalization, he was active and ambulatory.

### **HOSPITAL ADMISSION**

June 7, while visiting his son in New York, the patient complained of pressure and discomfort in his abdomen. He was taken to Kingston Hospital emergency room. CI was notified and subsequently notified SA.

A computerized tomography (CT) scan revealed fluid build up in the abdomen. A paracentesis procedure was scheduled for June 8. Doctors at Kingston Hospital told the patient's family he

was suffering from liver failure and that the ammonia levels in his blood were very high. Creatinine values upon admission were 2.3mg/dL.

June 8, during the paracentesis 6L of liver ascites were removed from the patient's abdomen. Analysis revealed no signs of blood or infection. The patient remained in the hospital for the next 10 days supported with IV fluids and medication to improve his kidney function.

June 18, the patient was discharged to the home of his son with medications and nursing support. Creatinine was 1.2mg/dL, BUN was 44. WBC 7.1.

June 20, the patient's son observed that the patient seemed to be seriously declining and took him to the emergency room of Albany Medical Center. A blood work up at Albany Medical Center found his ammonia levels to be high. Doctors at Albany Medical Center told the family the patient was suffering from liver and kidney failure. He was assigned a bed in the Cardiac Intensive Care Unit (CICU) and the hospital staff was informed of his wishes for cryopreservation. His medical record and CI paperwork were provided to the hospital.

That evening, the family and one of SA's consulting physicians agreed that death was imminent and a standby team should deploy. CI was notified of SA's deployment plans and CI offered the services of its funeral director to make pre-arrangements with a local funeral home to support stabilization and transport efforts. SA accepted this offer of assistance. A New York death certificate was pre-filled at SA and faxed to the CI funeral director. The CI funeral director made arrangements in NY through the Inman Shipping Worldwide network of funeral directors.

The contract perfusion coordinator was notified of the pending case and location and began arranging coverage. A contract surgeon was contacted and arranged to deploy with the team. Back-up team members were alerted.

June 21, five SA standby team members (four staff and one contract surgeon) deployed from Florida to New York. Once at the facility, the Albany Medical Center Medical Director and hospital staff offered their full cooperation and assistance to the team. The CICU's STAT (rapid response) team was available to respond as well as regular nursing staff. A briefing for CICU staff and physicians was held by the Hospitalist and SA Team leader to outline procedures and make preparations.

A cooler of medications and the ice bath with the AutoPulse and ventilator were positioned in the room the patient shared with another patient. The hospital staff provided a stock of ice and small oxygen cylinders. Additional arrangements were made with the staff and security for the team to have 24-hour access to the CICU, prompt pronouncement and immediate signing of the death certificate. The patient was placed on a "no code" status.

The standby team was assigned shifts for 24-hour coverage at the patient's bedside.

June 22, in the morning, the patient's family initiated a palliative care plan. He received O2 by nasal cannula and an IV morphine drip. A telemetry set was put in place to monitor heart rhythm at the nursing station.

The contract perfusionist was notified to deploy to New York.

The pre-arranged local funeral director was contacted. He said his facility was 20-30 minutes by car from the medical center.

A team member then quickly drove the route to the funeral home and pre-positioned the perfusion apparatus in the prep room. A vehicle was rented to accommodate stabilization equipment and procedures en route to the funeral home.

With very limited space in the patient's room, the most critical medications and cardiopulmonary support (CPS) equipment for the first minutes of stabilization were placed at the patient's bedside and the rest of the kit and equipment placed in the vehicle.

One SA staff member departed that afternoon and the contract perfusionist arrived in the evening.

June 23, the patient slipped in and out of consciousness throughout the day. His respiration dropped to four breaths per minute. He had no urine output. His abdomen was visibly distended and there was obvious edema in his upper and lower limbs. He required regular suctioning to keep his airway clear of fluid. By noon, his respiration fell to one breath every 45 to 60 seconds and the heart monitor indicated that his pacemaker was regularly pacing his heart.

The patient's family had been under the impression that the pacemaker was turned off the previous day and now requested that it be shut off. A consulting cardiologist refused, as the patient's heart was now being 100% paced.

June 24, the patient was no longer conscious and his heart continued to be paced by his pacemaker. His family again requested that the pacemaker be turned off. After a meeting of representatives of the Ethics Committee, and Cardiology department, the Medical Director and the family, the Hospitalist attending the CICU was given permission and agreed to shut off the pacemaker before noon. Arterial blood gas values at that time were pH 7.2, pCO<sub>2</sub> 54mmHg and pO<sub>2</sub> 101mmHg.

The contract surgeon departed because of work obligations. A second contract surgeon was scheduled to arrive early Thursday afternoon. Another SA staff member arrived to replace the one who left.

Once the pacemaker was shut off, the patient's heart continued at 60-65 bpm with periods of arrhythmia. At one point during severe arrhythmia, the funeral director was called to come to the medical center in order to be prepared to sign the patient out of the facility after pronouncement; however, the patient's heart rhythm and breathing stabilized after an hour. The funeral director left but said he would have someone available to return to the medical center within 5 minutes.

June 25, the attending physician increased the patient's morphine drip. The patient had now been without food or water for three days. The patient's breathing rate increased to 10 times per

minute. Heart rate increased from 65 to 77 bpm. He remained on O2 (2 lpm) via nasal cannula. Oxygen saturation readings from his pulse oximeter read 97%. Nurses continued to suction fluid from his airway.

In the early morning hours, the patient's breathing increased to 20 times per minute. He regurgitated a yellow opaque fluid and his heart rate fell to 48 bpm. The two SA standby team members in the patient's room called the CICU staff.

At 4:13am, additional standby team members nearby were called to assemble in the patient's room. The funeral director was called. He indicated his travel time to the medical center was 45 minutes and he did not have anyone who could get to the medical center more quickly.

The patient suffered cardiac arrest and was subsequently pronounced legally dead by the attending Hospitalist at 4:17am.

### **INITIAL STABILIZATION**

Heparin (30,000IU) was pushed immediately into the patient's IV line and he was moved to the portable icebath. The patient was intubated with a Combi-Tube and the AutoPulse and automated ventilator with oxygen were started as ice was being packed around the head and neck and groin.

Over the next 20 minutes, the following medications were administered via IV push: Propofol (200mg), Streptokinase (250,000 IU), Vasopressin (100 of 200 IU), S-methylthiourea (400mg), Niacinamide (500mg), Gentamicin (80mg), Ketorolac (7.5mg), and L-kynurenine (1.5gm), along with Epinephrine (1mg) roughly every 3 minutes. Simultaneously, Mannitol (500mL 20%) and Vital-Oxy (70mL) were piggybacked onto the IV line. Within 1 hour post-pronouncement, Aspegic (200mg), an additional dose of Vasopressin, all Vital-Oxy, and all Dextran 40 (500mL) were administered. The glass bottle of Tromethamine (THAM 100mL 1M) had been broken before it could be administered. A back up bottle was administered during transport along with continuing epinephrine every three minutes. Maalox was not administered.

Additional ice was packed around the patient until he was completely covered. His pallor changed from gray to pinkish within a few minutes of initial cardiopulmonary support.

A nasopharyngeal probe and rectal probe with thermocouples were inserted and the patient's Foley catheter assembly was removed. The ice water recirculating pump and Dual Logger were in the vehicle for transport. The Dual Logger was retrieved at 5am when a team member was sent to retrieve additional AutoPulse batteries. At that point the patient's temperatures were approximately 30 C nasopharyngeal and 38 C rectal.

Yellow and then blood-tinged effluent began trickling from the patient's esophageal tube and was suctioned away.

Inflated cuffs on the CombiTube and rectal probe were checked and air added to compensate for cooling.

The funeral director arrived at 5:27am and was ushered inside to the medical center's morgue office to sign the patient out.

### INITIAL TRANSPORT

After completing paperwork, the team moved the patient into the vehicle for transport to the funeral home, approximately one hour and twenty minutes post-pronouncement, at 5:38am. Team members continued to administer Tromethamine and Epinephrine IV push during transport.

Cardiopulmonary support with the AutoPulse and automated ventilation with oxygen continued during transport. Bloody foam began appearing around the patient's mouth during transport and was suctioned clear.

One blood sample was taken and processed on the I-STAT blood analyzer with a limited CG4+ cartridge. Nasopharyngeal temperature was 25C, rectal temperature was 36C. The sample analysis results are shown in the table below.

pH	7.166
PCO2 mmHg	50.3
PO2 mmHg	14
BEecf mmol/L	-10
HCO3 mmol/L	18.2
TCO2 mmol/L	20
sO2%	11
Lac mmol/L	15.08

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25.0°C

pH	7.324
PCO2 mmHg	29.7
PO2 mmHg	6

Sample Type	Ven
PtTemp	25.0
FIO2	30

## CANNULATION

Arriving at the funeral home at 6:35am, the patient was moved from the vehicle into the facility's small embalming room.

The funeral director had not arrived at the facility. The Team Leader prepared the patient's right groin for surgery by swabbing with ChloroPrep and draping with sterile towels. The approximate location of the femoral artery and vein was determined referencing the midpoint along the inguinal crease between the pubic symphysis and iliac crest. Using a #10 scalpel blade an 8cm incision was made at this midpoint, just below the inguinal crease along the longitudinal axis of the leg.

Blunt dissection and electro-cautery were used to clear a 3cm layer of heavy adipose tissue to expose the muscle. Additional blunt dissection clearing 2cm layer of muscle was made through heavy pooling of bright red blood from the surrounding tissues. Hemostasis with surgical sponges was ineffective. After 20 minutes of dissection the femoral capsule and vessels were not visible and a consulting physician was called. He suggested additional adduction of the thigh.

The funeral director for the facility arrived but said that he was unable to assist in raising the femorals and left to locate a Ziegler case for the patient. An affiliated funeral director arrived and was able to direct movement of a muscle mass and identify the vessels before he also left. The vessels were then isolated, separated and cannulated.

The vein was 4-5mm in diameter, dark, thin walled, and fragile. Blood flowed freely from it during cannulation. It was ultimately cannulated with a 15 Fr venous cannula inserted approximately 22cm, after attempts to place larger 21 Fr and 19 Fr were unsuccessful.

Nearly over the top of the vein, was the artery with multiple feeder vessels between the two. The artery was 6-7mm in diameter, light colored, rubbery and heavy walled. Bright red blood flowed freely from it during cannulation. It was cannulated with a 17 Fr arterial cannula inserted approximately 12cm after attempts with a 19 Fr cannula were unsuccessful.

The cannulae were connected to the extracorporeal bypass circuit on the Stockert SCPC mini-bypass system that had been primed with MHP2 organ preservation solution and cooled by the perfusionist. No venous drainage was observed. No bubbles or air locks were visible in the circuit. The perfusionist applied mild suction and the AutoPulse was re-started to assist with

drainage. Still, no venous return could be seen. The venous cannula was slowly backed out while applying suction and automated chest compressions but no return was visible.

Nasopharyngeal temperature was 15C and rectal was 25.6C.

A call was made to CI to determine additional site options for cannulation. A jugular cannulation would not interfere with cryoprotection procedures.

The patient's head was repositioned to the contralateral side and the neck swabbed and prepped for external jugular vein cutdown. The AutoPulse was started to aid location of jugular vein. Pressure to the platysma muscle did not create any obvious jugular pooling. Identification of the external jugular was then made using the mid-point between the angle of the mandible and the top of the clavicle. Using a number 10 scalpel blade, a 3cm incision was made and blunt dissection used to clear the tissue. The jugular was not immediately visible.

A call was made to the funeral director about shipping options and additional surgical assistance. Flight options to accommodate human remains cargo at this time would be limited to Newark Airport. An affiliated funeral director would be available to come to the facility in thirty minutes.

Additional ice was packed onto the patient.

The Ziegler case was delivered by van at 11am.

A funeral director affiliated with the funeral home arrived and offered to quickly cannulate the femoral vein on the patient's left side.

Opening an 8 cm incision and using an aneurism hook for dissection, his field quickly filled with bright red blood. He located the femorals but in separating them, he accidentally cut the artery and multiple feeders between the artery and vein. These vessels were individually ligated and the wound packed while the funeral director enlarged the jugular incision that had been opened earlier and isolated the jugular. A 17Fr venous cannula was inserted into the jugular vein approximately 30cm and connected to the venous perfusion line. Mild suction was applied. Venous drainage was observed.

## **WASHOUT AND PERFUSION**

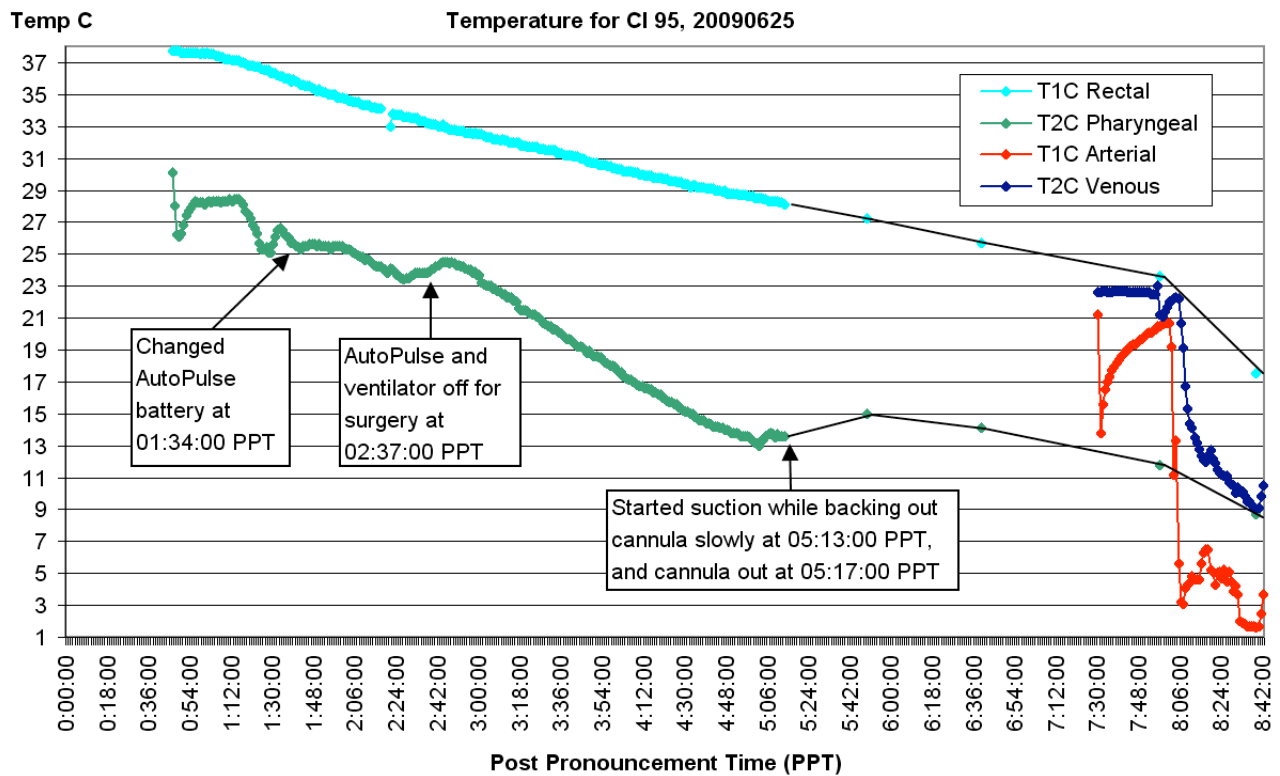
Washout started at 12:11pm. Nasopharyngeal temperature was 11.8C and rectal temp was 23.6C.

After a short period of perfusion, a tourniquet was applied above the left leg wound to minimize leakage of perfusate from this area. To conserve additional perfusate, a second tourniquet was applied with light compression on the tissue around the arterial cannula on the right leg.

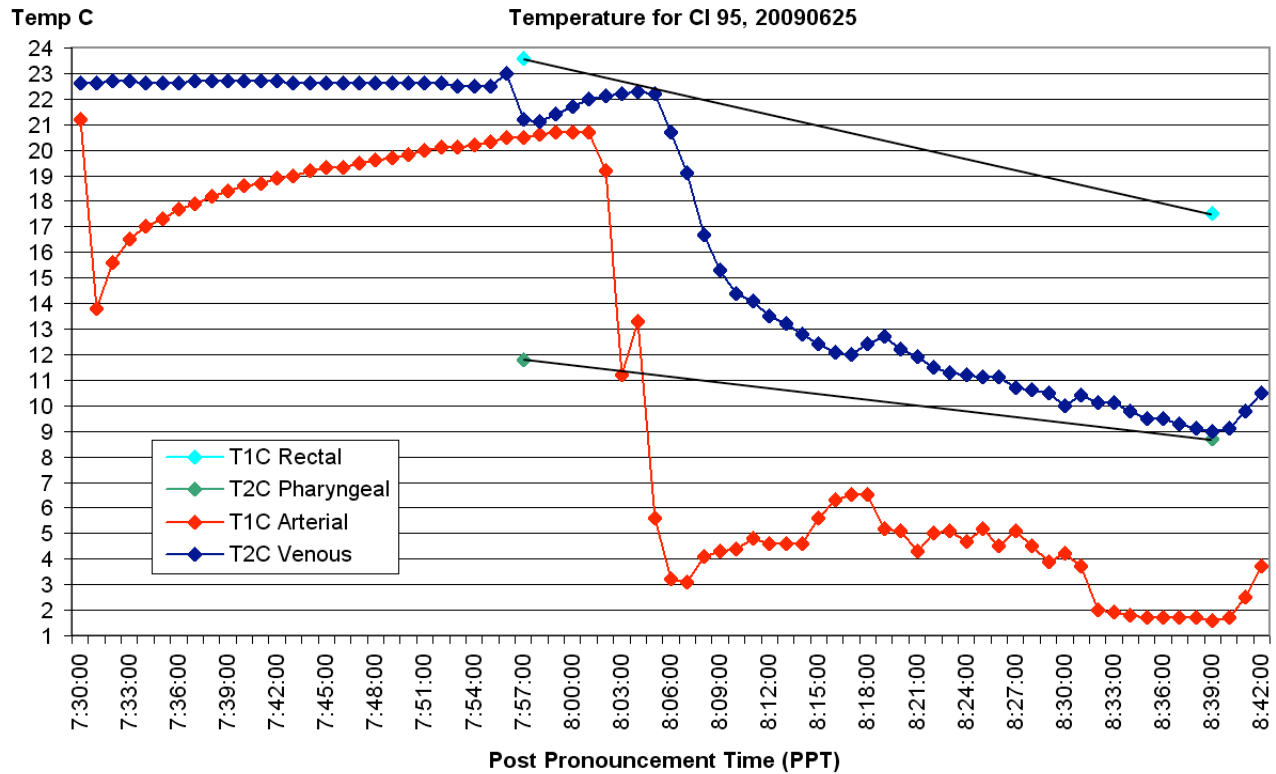
Twenty minutes after washout was initiated, arterial temperature was 4.6C and venous temperature was 13.3C

After 23 minutes on washout, about 14 of 28L of MHP2 had been used and the circuit was closed for cooling recirculation. The remaining perfusate was added slowly during recirculation to maintain circuit volume.

After an additional 20 minutes on closed circuit, arterial temperature was 1.7C and venous was 9.5C. Perfusion was stopped about five minutes later when the last of the perfusate had been used. There was no longer visible edema in the patient's upper or lower limbs. There was no visible change in abdominal distension. Arterial temperature was 1.7C and venous temperature was 8.5C. Nasopharyngeal temperature was 8.7C and rectal temperature was 17.5C. The patient's cooling curve is shown below.







The patient was disconnected from the extracorporeal bypass circuit with the cannulae clamped and left in place. He was then moved from the ice bath to a Ziegler case prepared with external insulation and a body bag with a layer of ice on the bottom. An additional 200 pounds of ice was packed around the patient before closing the body bag and sealing the lid screws of the Ziegler case.

The next available direct flight to Detroit onto which the patient could go would not be until that evening. Its arrival in Michigan would be after cargo offices closed and the patient could not be retrieved until the morning. Instead, arrangements were made for a funeral home employee to drive with the SA team leader and the patient to the CI funeral home north of Detroit, approximately 12 hours by car, without passing through Canada. A mini van was obtained, fueled and the patient loaded. The funeral director provided the transit permit.

The van with the patient departed the funeral home at approximately 3:30pm. Arriving at the CI funeral home at 3am, the Ziegler case was unloaded and moved inside where the patient received cryoprotective perfusion.

## TIMELINE

*Time line assembled from multiple sources. All times are approximate.*

4:17am Patient pronounced legally dead

4:18am 30,000 units of Heparin pushed into his IV line.

4:22am The patient was moved into the ice bath.

4:25am The patient was intubated and the AutoPulse started.

4:31am The automated ventilator was started with an oxygen line attached.

4:56am AutoPulse stopped. Manual chest compressions started. Team member sent to retrieve other AutoPulse batteries.

5:01am Team member returned with AutoPulse batteries and Dual Logger. Manual compressions stopped, AutoPulse started again.

5:27am Funeral director arrived and brought in to sign patient out

5:38am Team departed medical center for funeral home.

6:35am Team arrived at funeral home.

6:37am Team moved patient into funeral home prep room

6:50am The patient's right groin was prepared for surgery

8:00am The vessels were isolated and the vein cannulated

8:23am The artery was cannulated

9:36am Unable to get venous drainage

9:44am Patient prepped for external jugular cut down

11:00am Ziegler delivered

11:13am Funeral director attempts left femoral vein isolation

11:49am Funeral director attempts jugular vein isolation

12:11pm Jugular vein cannulated. Washout started.

12:34pm Circuit closed for recirculation

12:59pm Perfusion stopped.

1:15pm Arrangements made to drive patient

1:50pm Patient packed in Ziegler with ice

2:30pm Vehicle for transport arrives

3:00pm Driver arrives

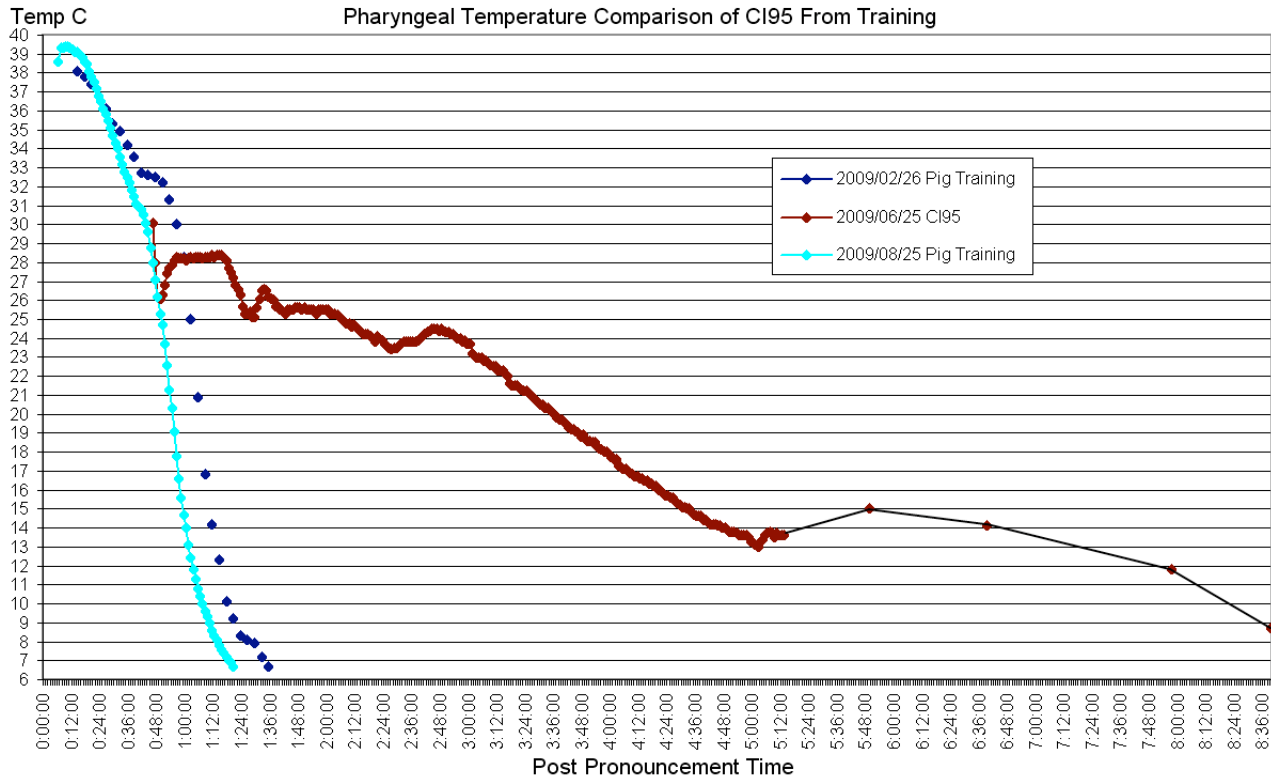
3:10pm Load Ziegler and secure in vehicle

3:30pm Depart for Michigan

### **CASE ISSUES AND CORRECTIVE ACTIONS**

With immediate cooling, CPS and meds, Curtis did not likely suffer much warm ischemia, but not having ice water recirculation was a major error and temperature data were not obtained for the first 40 minutes. His total ischemic time for the first five hours was probably around 1 hour and 20 minutes with cardiopulmonary support and oxygen for half of this time. His cold ischemia was more significant, including 12 hours of transport on ice, which might have been avoided with fewer funeral-home related delays and more rapid cannulation and perfusion. His stabilization cooling curve leaves a lot to be desired when compared to SA's stabilization training cooling curves on 50-60kg pigs where cannulation and perfusion occur within 1 hour post-pronouncement. (See below)

There is a lot of room for improvement.



## ISSUES IDENTIFIED

### DEPLOYMENT AND LOGISTICS

- Arrangements for airline cargo movement of the kits were made the evening before deployment. When the team arrived at the air cargo office at 5am, the agent would not accept the kits because they did not have SA's federal shipper number, account number and had no air bill for the kit, with these numbers included. Attempting to check the kits as luggage, Continental Airlines would not accept two of the Pelican cases containing the ATP and the MHP2 perfusate because they exceeded maximum allowable weight limits. Two team members stayed behind to make shipping arrangements for the remaining kits, while three team members flew on to Albany. Two team members were delayed by 4 hours and critical kits were delayed by 12 hours.

**CORRECTIVE ACTION:** All SA airline cargo accounts must be current and updated with SA's TSA federal shipper number on file. All staff must have access to necessary information and understand in detail, how to arrange efficient shipping for the kits with any airline as baggage or cargo, or with a carrier such as FedEx. *All accounts have now been updated, all team members briefed, all info in hard copy is in team member personal kits and online access is available through Google docs. Kits have been modified so no cases exceed maximum weight for major airlines.*

- After learning the funeral home's director might not have a vehicle that would allow treatment to continue en route to the funeral home, a larger vehicle was rented and outfitted with coolers, battery powered lighting and tie downs for the ice bath.
- The full icebath weight is prohibitively heavy to lift into a vehicle. A standard moving-style ramp was too narrow to accommodate the portable ice bath wheels. A wooden ramp was constructed to facilitate loading.
- Picnic-style styrofoam coolers purchased proved too flimsy when fully loaded with ice.

**CORRECTIVE ACTION:** SA will arrange funeral home services directly. Vehicle type and availability from a funeral home will be determined in advance. Only sturdy plastic coolers will be purchased where available. The next generation portable ice bath will be both lighter and have a wheel width compatible with the common ramp widths without compromising ice bath strength or stability. *SA's new portable ice bath has been prototyped. It is half the weight of the older version and wheels are two inches narrower, like standard medical gurneys. This ice bath is now being constructed for load and stress testing.*

### **FUNERAL HOME SERVICES**

- The Inman-contracted funeral home was not "local" and the distance from the medical center (1 hr drive with the patient) and resulted in one hour delay.
- The Inman-contracted funeral director was unable to respond to the medical center immediately, as agreed, resulting in an additional one hour delay.
- The funeral director's subsequent unavailability to assist with surgery contributed to an additional two-hour delay.
- The Ziegler case to transport the patient was not available until 11am, nearly seven hours after the patient was pronounced.
- The New York death certificate information had to be provided by SA three separate times during the case before getting a transit permit, due to lack of communication between funeral directors.
- The Inman-contracted facility was not an active funeral home. It had no refrigeration for the patient or perfusate, no Ziegler cases on site, and the prep room was dirty, poorly lit and without air conditioning. Temperatures in the prep room during the case approached 85F.

**CORRECTIVE ACTION:** SA will make arrangements with any future cooperating funeral home directly. When possible, the facility will be inspected in advance. Facility managers will be specifically asked about response time at any hour, transit permits and transportation outside of normal business hours, Ziegler cases in stock, and availability to assist with femoral cut down.

Copies of any-pre-filled death certificates will be kept with the patient. *SA has created a one-page document that can be faxed to funeral directors that describes what to expect and the needs that must be met by a funeral home contracted to support a cryonics case.*

## **STABILIZATION**

- One glass bottle of Tromethamine (THAM) broke inside the meds kit during transport. The kit did not leak. The back up bottle had to be used and its location in the vehicle instead of bedside delayed administration and additional buffering by an hour.

**CORRECTIVE ACTION:** Obtain THAM in plastic dispenser bottles or compound in plastic at SA. Keep all meds and backups at bedside. *A soft, removable pouch around the icebath liner perimeter will be used to keep bedside item spares and backups at hand without the need for the large Pelican containers.*

- L-Kynurenine was extremely difficult to get into solution and ultimately required soaking the bottle of citrate/L-K mix in superheated water from a microwave and vigorous shaking for more than 10 minutes.

**CORRECTIVE ACTION:** All team members must be reminded of mixing requirements and to plan for these. Investigate alternate forms of medication. *We currently have the most soluble form of this drug. Testing at SA has shown that water for heating this citrate/L-kynurenine mix must fall in the 105-110F range and the bottle must be immersed for 5 minutes at a time, followed by vigorous shaking until the clumps dissolve.*

- The patient was intubated after he was moved to the icebath. Verification of correct placement (using a stethoscope) could not be done because of the noise in the room. Maalox was not administered through the esophageal portion of the tube. With the ventilator attached, chest movements were observed, but gastric effluent backing up into the esophageal tube precluded the addition of Maalox.

**CORRECTIVE ACTION:** Have bag valve plus stethoscope handy to immediately verify placement of CombiTube. Administer Maalox as soon as ventilator is running.

- Attempting to stack and tape the impedance threshold device (ITV) and CO2 detector on top of the CombiTube, a team member dropped the ITV and it bounced off the ice bath and rolled on the floor under another patient's bed. Even with only the CO2 detector taped to it, the CombiTube with the ventilator attached was not stable, toppled over and kinked the vent hose. The CO2 detector was removed, so neither the ITV nor the CO2 detector were used.

**CORRECTIVE ACTION:** Identify and test existing technology to stabilize CombiTube/ITV/CO2 detector stack or design and test device(s) for doing so. *Existing "collars" for stabilizing airways have been tested and do not support the stack. SA has modified the CombiTube to support the stack and placement of the ventilator to avoid kinking problems.*

- The patient was immediately and completely packed in small cube and chipped ice with some water. Additional water and the “squid” were not added in anticipation of immediately loading the full icebath up the ramp into the vehicle. After Curtis was moved to the vehicle, team members still did not apply additional water and the “squid” during transport. His cooling could have been more rapid if the ice water “squid” had been in his hospital room and applied immediately, or at least in the vehicle.

CORRECTIVE ACTION: Since this issue has multiple sources, it will be addressed by direct arrangements with funeral directors, making sure the “squid” is always at bedside, continuing training, and shift/rest changes to try to minimize fatigue. *A soft, removable pouch around the perimeter of the icebath liner will now hold necessary bedside items, like the “squid,” so they are at hand without the space requirements of Pelican cases.*

- Spare AutoPulse batteries were also placed in the vehicle and had to be retrieved when the patient could not be immediately moved to the vehicle.

CORRECTIVE ACTION: Spare AutoPulse batteries should remain at bedside. *The new icebath liner pouch can accommodate spare batteries, also.*

- Dual Logger temperature recorder was placed in the vehicle and also had to be retrieved later.

CORRECTIVE ACTION: Dual Logger will remain at bedside. *Dual Logger can be placed in the icebath liner pouch.*

- Blood and foam around the patient’s mouth was observed and suctioned away during transport from the medical center to the funeral home, indicating the CombiTube may have become dislodged or the inflation cuffs were not checked after leaving the medical center.

CORRECTIVE ACTION: Additional emphasis will be added during training and evaluation on maintaining airway and proper inflation of cuffs affected by cooling.

- Only one blood sample was collected and processed.

CORRECTIVE ACTION: Additional emphasis and training will be provided on blood sample collection prior to medications administration, during medications administration, following administration and circulation of the entire medications protocol, and at the start of the washout.

## **TEAM SHIFTS, REST AND ACCOMMODATION**

- Team focus and cognition visibly declined with each day on standby. Repeated agonal periods followed by stable periods left everyone ragged and on edge.
- Although the hotel was only five minutes from the medical center, it seemed too far away with cardiac arrest appearing imminent, so people slept in chairs, on top of tables and on the floor of the vehicles.
- Six-hour shifts were not long enough to relax, call family, shower, and sleep.

**CORRECTIVE ACTION:** Where possible, two daily 12 hour shifts with two to three team members will be assigned after a full team and all equipment is in place. Even if there is greater expense, at least one room in the closest hotel possible should be available to team members on a resting period. Regular training and drills will continue to make improve team member skills and make execution of protocols more automatic.

### **CANNULATION AND PERFUSION**

- Prep room was dirty, open to the outside and not air-conditioned
- Temperatures in the prep room during surgery neared 85F.
- 2-0 silk suture on surgical kit inventory was missing from the surgical kit, so less suitable suture in the kit was used
- Retractor was too small to maintain retraction of flesh around incision
- Surgical headlamp shorted out and no high power light was available
- Heavy blood pooling obscured surgical field
- Funeral directors were unable or unavailable to assist with cut-down
- Backup surgeon was unable to quickly locate, dissect and cannulate femorals
- Backup surgeon was unable to quickly locate, dissect and cannulate jugular vein
- AutoPulse was not restarted when there was no surgical activity
- The perfusionist suggested having isopropyl alcohol or rock salt available to drive the perfusion circuit cooling bath to a lower temperature
- The perfusionist suggested having a powered, metered suction device for perfusion use
- Perfusionist pulsed oxygen through the oxygenator briefly at the start of perfusion



CORRECTIVE ACTIONS: SA will make funeral home arrangements directly. Surgical kits will be reinventoried for suture and large retractors. *Completed.* Suture and retractors will be replaced or added in all kits. *Completed.* Surgical headlamp will be replaced with a more durable model. *Completed.* Additional means and techniques for minimizing and controlling blood pooling will be investigated. *Completed.* Backup surgeon will have additional anatomical and surgical training on cadavers and pigs and perform practice surgeries regularly. *Underway.* Additional surgeons and funeral directors with femoral cannulation experience will be recruited to the standby team. *Underway.* SA surgical protocol will be modified to include maintaining CPS when there is no active surgery and/or until the patient reaches at least 20C. *Completed.* Where possible, isopropyl alcohol or rock salt will be purchased prior to perfusion for providing more aggressive cooling for the circuit, when desirable. A compact medical suction device will be added to the air transportable perfusion kits. *Underway.* Perfusionists will be instructed to perform oxygenator flushes with nitrogen or air only and this will be made explicit in the SA Cryonics Perfusion Protocol used by contract perfusionists. *Completed.*

## PERSONNEL

- Vacation scheduling resulted in a one-day gap for replacing an SA staff member on standby.
- One team member came down with a head-chest cold 36 hours into the case. He was isolated, but was not replaced.
- Of five contract surgeons, only two were available to respond to the case in Albany and the team leader was unable to schedule an overlap between the departure of one and the arrival of another. In this gap, the patient was pronounced.
- The perfusion coordinator was not able to schedule continuous coverage for the entire length of the standby.

CORRECTIVE ACTIONS: Staff vacations that overlap will not be approved. Staff members who show any signs of illness during a case will be relieved and replaced by other staff or contractors immediately. Additional surgeons with femoral cannulation experience will be recruited to the standby team. *Underway.* Additional hires or contract changes will be made to assure continuous perfusion coverage on cases. *Underway.*