Appendix 1
Quality of Patient Care in Cryonics: A Systematic Approach

Introduction

The term "patient care" requires little explanation in mainstream medicine. When a patient is admitted to a hospital for a routine medical procedure there is usually an obvious expectation of what the desired outcome should be – even to people without a medical background. The hospital employs qualified personnel to ensure that the intended procedure conforms to protocol, and medical practice and internal and external entities make sure that good practices are adhered to.

In cryonics, however, a common belief is that the only meaningful test of efficacy of a cryonics procedure is whether the patient is revised in the future. In the most fundamental sense this is correct, but framing the issue of quality care in cryonics this way obscures the fact that cryonics consists of several specific procedures that are aimed at a specific outcome for which data can be collected to evaluate how well the delivery of this procedure confirmed to its stated objective.

In this document we will propose a general framework to evaluate patient care in cryonics, translate these objectives into distinct objectives for each major procedure, and discuss its physical, logistical, educational, and staffing implications.

Long Term Care

Alcor's mission statement states that maintaining "the current patients in biostasis" as its first and fundamental goal. This objective is so fundamental that it could potentially conflict with placing new patients in biostasis or conducting research to improve cryopreservation procedures. Since this fundamental goal pertains to patients already in biostasis it is no longer possible to improve their (physical) condition relative to the time when they were placed in liquid nitrogen. One recent caveat to this observation concerns Alcor patient's that are currently stored at intermediate temperatures (ITS). Poor maintenance and anticipation of future ITS needs could result in additional fracturing if those patients are placed in regular liquid nitrogen dewars.

In a general sense, however, providing good patient care in the case of long term care means maintaining patients at cryogenic temperatures. This objective does not mean a "passive" continuation of existing physical storage arrangements. For example, dewars are expected to have a finite lifespan and money will need to be set aside for future changes. New dewars can be designed to reduce liquid nitrogen boil off and reduce the cost of long-term patient care (for example, the gradual replacement of the Bigfoot dewars by Alcor's Super dewars). Alternative storage options and emergency procedures will need to be drafted in case manufacturers and suppliers no longer want or can deliver storage vessels to Alcor. Alternative storage locations need to be considered in case there are political or economical reasons for abandoning the current storage facility.

Two important measures to ensure Alcor can deliver on its most fundamental mandate include the creation of a legally and financially separate patient care trust and the creation of a full-time patient care taker. The care trust ensures that patients will be shielded from the day-to-day organizational and financial challenges of a membership and service delivery organization. The full-time patient caretaker's sole responsibility is to maintain the patient's in cryostasis, documentation, and report to the cryonics organization (and its care trust) on potential developments that can reduce the cost and enhance the safety of Alcor patients.

Cryopreservation

The common denominator of all Alcor patents is that they are cryopreserved. But the variable that matters for evaluating the quality of care is how well they have been *cryoprotected*. For a patient the degree of ice formation can range from a straight freeze (cryopreservation without cryoprotection) to complete vitrification (solidification without ice formation). Elimination of ice formation (or minimization of ice formation in whole body patients) is a minimal requirement of Alcor's cryopreservation protocols but it by no means exhausts its mandate.

It is important to distinguish here between Alcor's long-term research objective and what is possible with current technologies. Alcor's long-term objective is to develop (or implement) reversible cryopreservation, or human suspended animation. Reversible cryopreservation would allow a critically ill patient to be placed in biostasis without causing any further damage that was not reversible by contemporary means. Alcor's research goal is to conduct or collaborate on research to narrow the gap between human suspended animation and its current cryopreservation capabilities.

What we should require from a cryopreservation protocol evolves and is based on reasonable extrapolations from contemporary cryobiology research. At the time of writing we should expect cryoprotection of the patient with a vitrification solution that can (a) eliminate ice formation at realistic cooling rates, (b) preserve the fine structure of the brain, and (c) recover some viability in cryopreserved isolated brain slices as a marker of minimal biochemical disturbance.

Elimination of ice formation can be assessed by subjecting (neuro) patients to CT scans. Preservation of the fine structure of the brain can be assessed by obtaining microliter samples of the patient's brain for electron microscopy. These brain samples can also be subjected to viability assays such as the K/Na ratio assay. It is important to recognize here that our current understanding is that elimination of ice formation and preservation of the fine structure of the brain is possible but that obtaining high viability readings from brain samples of patient's is not yet within our reach. Our current belief is that in very good cases viability of the brain is lost during the early to mid-stages of cryoprotective perfusion because of cryoprotectant toxicity and CPA-induced dehydration of the brain. This means that for a typical cryonics case conducted under good condition we should collect evidence that we achieved the first two objectives (vitrification and ultrastructural preservation) and support research and development aimed at maintaining viability throughout the whole cryoprotection procedure by further reducing cryoprotectant toxicity, eliminating CPA-induced brain shrinking, and optimization of cryoprotection protocols. At this point each case report should contain CT scans and electron

micrographs to document the degree of vitrification and ultrastructural preservation achieved in a (neuro) patient, if applicable.

Stabilization

As the word “stabilization” suggests, the aim of this set of cryonics procedures is to stabilize the condition of the patient from the moment of pronouncement of legal death. That means that, ideally, there will be no further deterioration to the patient’s physiological functioning and condition of the brain. Since cryonics procedures can only start after pronouncement of legal death, the initial (pre-mortem) state of the patient is usually beyond the cryonics organization’s control. It is important to recognize this because proper evaluation of casework should describe this initial state as its benchmark.

In a good cryonics case, where the patient has not been diagnosed as brain death, and where response can be begun promptly, the objective of stabilization procedures is to keep the brain viable by *contemporary* medical criteria. One helpful way to describe this mandate is that upon completion of stabilization procedures it should be possible to *reverse* those procedures and recover brain function.

Keeping the brain viable by contemporary medical criteria is something that cannot be measured in a straightforward matter because at the completion of stabilization procedures the temperature of the brain is not able to support meaningful whole brain function. What can be done is to take microliter brain biopsies and subject these tissue samples to viability measurements. These measurements in turn can be compared to brain biopsies obtained after the completion of cryoprotective perfusion to understand how cryoprotection affects viability. The sample samples can subsequently be processed for electron microscopy to obtain information about the ultrastructure of the patient’s brain.

Another means to ensure that stabilization procedures are successful in keeping the patient viable is to collect blood samples (pH, electrolytes etc.) and end tidal CO2 readings throughout the procedure. Collecting temperature data during all parts of cryonics procedures is essential because the temperature profile of a patient is a reasonably good indirect measure of brain injury (or lack thereof). Each patient case report should include a presentation of monitoring data and discuss the reason for not being able collect some of this information if this occurred.

Readiness and Deployment

Since its inception it has been routine in cryonics to document stabilization and cryopreservation procedures. When it comes to readiness and deployment, however, policies have often changed from administration to administration - if documented policies existed at all. Since a cryonics organization’s state of readiness and deployment policies have profound effects on its ability to timely respond to a patient and the quality of care a patient will receive, a credible quality control – and assurance program should be extended to readiness and deployment as well.

Some of the questions that need to be addressed include: who is responsible for local and non-local cases? What are the conditions for deploying a local or remote team? What is the composition of a deployment committee and should all parties have equal say in deployment

decision (such as for-profit independent contractors)? What is the minimum number of team members required to do the full stabilization protocol? What is the likelihood of having multiple deployments and cases at the same time? What is the role of local (volunteer) teams? Should complete sets of standby kits be deployed to local groups with a lot of members? What makes a region eligible for respectively a cryonics first aid kit or a full set of kits? Which procedures should be only be done by medical professionals and which procedures can be done by all trained individuals?

When a cryonics organization answers these questions and incorporates them in a set of policies and protocols, then a formal quality control program will have a framework to evaluate the state of readiness at a cryonics organization, and thus the ability to respond to cases in a consistent and reliable manner.

Training

Like readiness and deployment policies, the training of volunteers and medical professionals can greatly benefit from a set of formal policies, eligibility criteria, and written teaching materials. A review of the history of cryonics training at Alcor reveals a plethora of different approaches ranging from the teaching of members and volunteers to do the most advanced procedures (i.e. surgery, whole body blood washout) to not providing any training at all to non-professionals. A detailed review of cryonics training options and curricula is beyond the scope of this manual, but we want to make a few observations.

The transition from a volunteer-driven standby to employing team made up of medical professionals does not eliminate the need for providing cryonics training. While medical professionals may be certified and competent to do a specific cryonics procedure (surgery, extracorporeal perfusion, IV placement) they may not be familiar with other aspects of our procedures, or how specific procedures work together to produce a specific outcome. It is therefore important for Alcor (or its contractors) to organize periodical cryonics training courses and to provide relevant reading materials and updates.

A second reason why the use of professionals in cryonics does not exempt a cryonics organization from conducting training is that there will still be cases in which the professional standby organizations will not or cannot deploy a standby a team in time. Such a situation does not necessarily indicate poor readiness at the standby organization but can also reflect a rapid decline of the patient or challenges to get to the patient in time due to weather or logistical obstacles. In these circumstances local members and volunteers may have do the initial or all parts of a cryonics stabilization. Teaching local members basic cryonics “first aid” protocols and how to assist a professional standby team is essential for a cryonics organization that covers a country as large as the United States, not to speak of other countries.

It is increasingly recognized in cryonics that using members/volunteers and medical professionals is not mutually exclusive and the nature of cryonics today necessitates a model in which local volunteers cooperate, complement, or sometimes even replace a professional standby team. This “hybrid” model of standby implies that a cryonics organization creates different levels of protocols and training curricula. A proper quality control- and assurance program in cryonics

needs to address both the local / volunteer part of cryonics as well as overseeing the use of medical professionals.

Staffing

The staffing of a cryonics organization is a complex topic and we confine ourselves here to making some observations pertaining to the quality of case work and quality control. Currently, Alcor's financial situation allows for the deployment of staff with a medical or scientific background. It is important that the core of Alcor's (local) standby team is made up of at least two individuals with a strong EMS, nursing, or scientific background. When these individuals are a part of Alcor's staff, case work is always a priority and complex coordination of volunteers and contractors is reduced. These staff members should take a leading role in standby equipment maintenance, team composition and deployment, training, standbys and the collection and gathering of case data. In a cryonics organization with a high case load it is important that these individuals are not distracted from these responsibilities by other responsibilities such as extensive writing tasks like case reports.

When generous funding is available in cryonics it is tempting to "recruit" competent staff members to work for (for-profit) cryonics-associated companies so they can focus full-time on research. When this happens, it is important that the cryonics organization creates a structure to interact with, and benefit from, the work of such individuals and that an open line of communication is retained between these organizations and Alcor.

If funding permits, a growing cryonics organization should employ a full-time quality control officer whose sole responsibility it is to maintain a constant level of care, improve procedures, and write or delegate the production of high quality case reports. Ideally, participation of this officer in cases is limited to ensure impartiality. If the cryonics organization contracts with other organizations for standby or other services it should require that this officer has the right to observe all cases and receive all data.

Meta-Analysis

An important reason for writing case reports is that the data that have been collected and analyzed in case reports (and patient files) can form the basis of a comprehensive meta-analysis to discover patterns, trends, and opportunities for protocol improvements. As of writing, there have been several attempts to look at the quality of care by reviewing selected case reports, data, and video footage but so far, no attempt has been made to look at all Alcor's case data with the aim of understanding the evolution of care, problematic areas, and opportunities for protocol- and policy changes. In principle, it is possible to extend the idea of meta-analysis to cover areas such as protocols, state of readiness, and training. An important reason for doing a comprehensive meta-analysis, followed by periodical updates is that it allows the cryonics organization to develop a series of benchmarks that can be used to manage today's expectations and future directions.

One useful tool for future case reporting and case reporting is to develop a single outcome measure that can be quickly consulted to understand the quality of the case. Some rigorous attempts have been made to create such a measure to estimate the total amount of ischemic exposure in a patient. Such a measure can then be entered as one element in a compound measure that includes other relevant data such as the degree of ice formation and fracturing events. It is important to note here that such a compound measure does not distinguish between events that were within and beyond a cryonics organization's control. For example, a case in which a family member hid the death of a patient for a week would render a very low score, but this poor outcome cannot not be attributed to the cryonics organization. Overall case measures are important, but context is important, too.

Quality Control Table

The following table lists specific items that need to be addressed / evaluated in any proper cryonics quality assurance / quality control program. This list is not exhaustive and other items could be added to guide quality control management and case reporting.

Readiness	**Stabilization**	**Cryoprotection**	**Cryopreservation**
Personnel	Cooling rate	Weight gain/loss	Ice formation (CT)
Protocols	End-Tidal CO2	Brain dehydration (CT)	Fracturing
Documentation	Blood gases	Pressure	Temp. Maintenance
Training	CPS data	Refractive Index	
Kit Maintenance		Viability (K/Na)	
Local groups		Ultrastructure (EM)	