

Data Acquisition in the ICU

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Intro

Over the past few decades the anesthesia community has led the way in monitoring advancements leading to improvements in patient management and safety. However, there are still errors being made at the bedside and we are still plagued by isolated monitors that do not act as part of a coordinated system.

For the past four years, we have been part of the US Army's Hospital of the Future program and have been investigating ways to address some of the remaining problems with a focus on "systems of monitors". We are working with a wide group of collaborators to help develop the Integrated Clinical Environment (ICE) standard that is being promoted by Dr. Julian Goldman and the Medical Device Plug-and-Play organization (www.MDPnP.org). This article describes some of the problems we are addressing in both the acquisition of data and the use of data and our approach to solving them. We are focusing our particular developments in neuromonitoring as we believe the unique requirements of this area provide the most challenging environment to carry out such a development. Much of what we are doing requires a collaborative effort and we welcome participants.

Problems to Overcome for the Hospital of the Future

The problems we are addressing are as follows:

- **Medical device connectivity:** we need monitors to connect easily to provide a central integrated source for monitored information that can be integrated with other information
- **Alarms:** we need multi-parametric "smart alarms" that operate with a higher specificity than those we currently use
- **Continuity:** we would like to have continuous data from the time of injury through to the ICU
- **Use of information:** we would like to configure our monitoring workstations with the tools and applications that adapt our system to the patient and the particular needs of the clinician
- **Learning content:** we would like to capture the short-lived learning opportunities that exist in surgery and critical care and serve up brief, highly targeted learning modules to take advantage of these opportunities
- **Consistency of care:** we would like to provide guidance where necessary to even out the imbalances in training or experience to increase the consistency of care
- **Regulatory:** we need to develop such a system to ensure high quality and patient safety and to remain within regulatory expectations

The Goal

Our work, funded by both NIH and the Army, has been to define a series of hardware and software components that can be selected and connected to create an "interoperable environment" for medical devices as well as software-based "application modules". The inputs and outputs of each component are defined, openly available, and based on published standards where applicable. Once defined, the modules could be created by any company or institution to create a "vendor neutral" industry. The modules will permit the creation of an interoperable environment in a variety of settings.

A computer analogy is helpful in defining our end point. When purchasing accessories for your computer, you rarely have to worry whether they will connect...whether it's a printer, scanner, camera, or mobile phone. The same with software. For example most photo processing software doesn't care where you got the images because there is a common format for images (actually several which are easily interchanged). In general, each type of component (printers, routers, cameras, etc.) is available from a variety of vendors thus the environment is "vendor neutral". Similarly, in neuromonitoring, we would like all monitors to provide their data in a common format and we would like to use that data as input to independently produced software modules

(e.g. multi-parametric alarms, an index of autoregulation, etc.)...very similar to how computers work. That's the goal.

Approach to the Problem

The logical approach to this problem is to develop standards from which manufacturers could develop medical devices and other system components such that they interoperate...as in the computer analogy. Two standards stand out in their applicability: ISO/IEEE 11073 which addresses medical device connectivity and ASTM F-2761 which addresses the formation of a patient-centric, integrated clinical environment (ICE). Unfortunately, the problem is far from solved. The IEEE standard has been around for a decade or more but has seen limited adoption (and some sections are already obsolete) and the ASTM standard is in its infancy. Standards work, though necessary, is tedious, often thankless, and by nature a slow process. Thus, it will be a while before both of these standards are either updated or complete.

So how can we make progress apart from the standards work? We are working on a "bottom up" approach in parallel to the standards work. Standards development can be considered a "top down" approach since they must consider all users, applications, and scenarios. They are highly consensus based and take time. Our "bottom up" approach narrows the target to one application area (neuromonitoring) in which we develop a comprehensive, interoperable, information environment. The idea is to follow the spirit of the existing standards (adopting them where possible) and feed back what is learned to these organizations to help with the standards. We (and many others) have learned the "devil is in the details" when it comes to connecting medical devices into a coordinated system. These valuable details are often lost when standards are developed without this type of experience.

Medical Device Connectivity

Our first goal is to get devices connected so that they are speaking the same language and sending data that is identified in a common way (e.g. ventricular ICP is identified consistently by all devices). Our assumption is that we will be waiting a long time for manufacturers to adopt any uniform communications standards so we are developing an adapter that converts the device protocol to ISO/IEEE 11073 (Figure 1). We are also developing software that will receive the data as well as educational aids for understanding the standard.

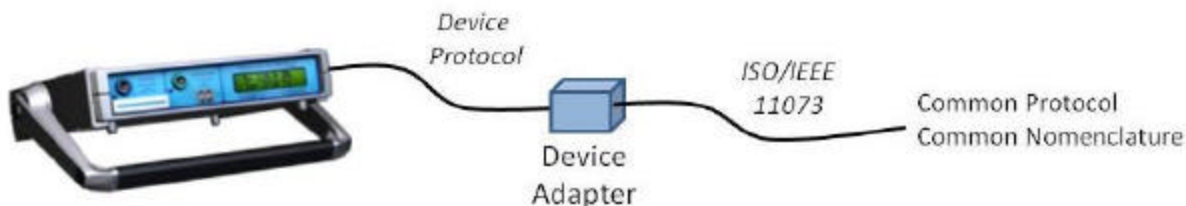


Figure 1. Use of an adapter to convert medical device data into a standard format.

Using a common protocol for all devices provides two advantages:

- Developers of the "receiving software" need only develop one "device driver"...that of ISO/IEEE 11073 and from then on, the system can communicate with any device that adopts this protocol, without having prior knowledge of the device. This results in "plug-and-play" an essential feature of an integrated monitoring system.
- Data is now received in a standard format and using a common terminology. For example, brain tissue oxygen would always be called "PbtO2" (or whatever is finally decided). The big advantage of standardizing a nomenclature is that software can be developed independently of this system that can

use this data (without having to collect the data itself). Similarly, PhotoShop on a computer can use pictures from your digital camera because a common nomenclature is used for the files.

In neurocritical care we have seen several systems that collect data from monitors and then use it for various display and analysis applications (ICM+, ICUpilot, BedMaster, CNS Monitor, and others). These companies had to write the same device interfaces when what they were really focusing on were the data analysis or integration techniques. The availability of a common protocol (and adapters for those devices not adopting it) will allow such companies to focus on their areas of expertise and not be burdened with writing device drivers.

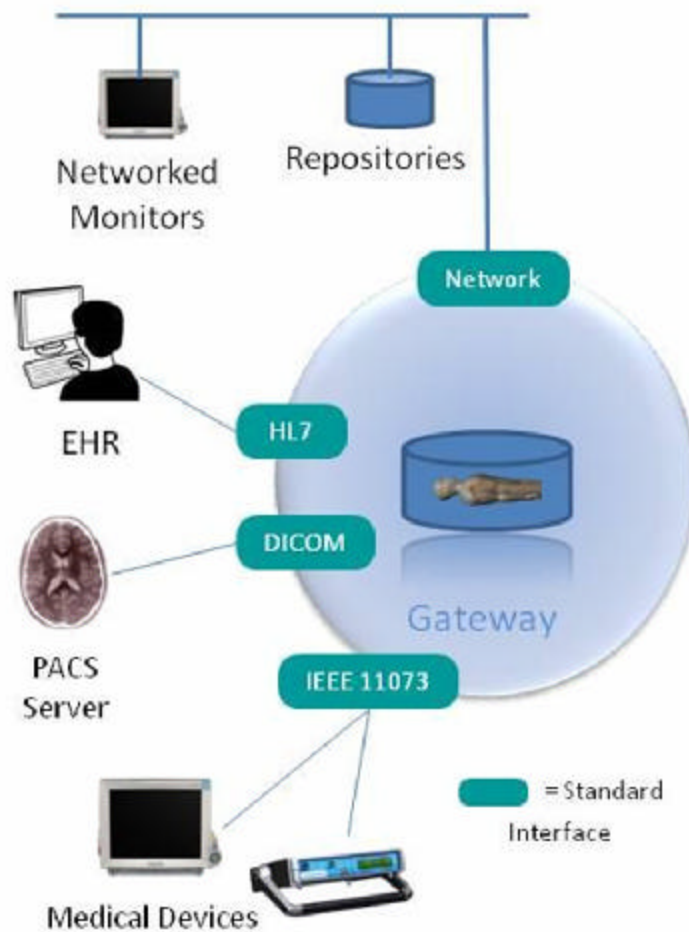


Figure 2. Completing the data collection to build a comprehensive data set.

Collecting data from other sources (Figure 2) is generally easier since there are standards that exist. Images are transferred using the DICOM standard and patient demographics and other information in the medical record is communicated via HL7. We have labeled this “component” of the system a Gateway and it corresponds to the “Network Controller” in the ICE standard terminology.

Integrated Clinical Environment

Once we have this patient-centric data set, the approach is to write core software (the Supervisor in Figure 3) which builds an “information architecture” around the patient. The Supervisor is written such that applications and tools can be “plugged-in” to the system and use the data collected. Thus, an “Alarm Manager” could let the user develop multi-parametric alarm strategies that would alarm with more precision than at present with every monitor acting in isolation. It would help to avoid “alarm fatigue” caused by too many false alarms and contribute to a safer environment. Knowing the status of a device (which the device adapters can provide) can help with other types of alarms such as making sure the ventilator is turned on following bypass or taking of x-rays (a rare but still occurring error that can be fatal).

Other plug-ins could be decision support modules as well as practice guidelines. We call this section the Supervisor to follow the terminology in the Integrated Clinical Environment.

Many interesting functions can be carried out with an architecture as described. One, which we are investigating with NIH funding, is the linking of instructional content to guidelines or care paths. We are using an open source guideline format called Proteus in our Supervisor. We are also creating modular instructional content using a standard format called SCORM (Sharable Content Reference Model). We are using metadata on the guideline steps to link that step, with the help of a knowledge base (ontology), to reference material that you might need to carry out that step. Figure 4 shows a step in a guideline for therapeutic hypothermia where the temperature data from cooling can be superimposed on an ideal temperature profile. The buttons at the bottom are dynamically linked to content based on the keywords of that step. Since cooling is to take place instructions are available for setting up the cooling unit. An feature such as this evens out the disparities in the training and experience of personnel and contributes to a higher consistency of care.

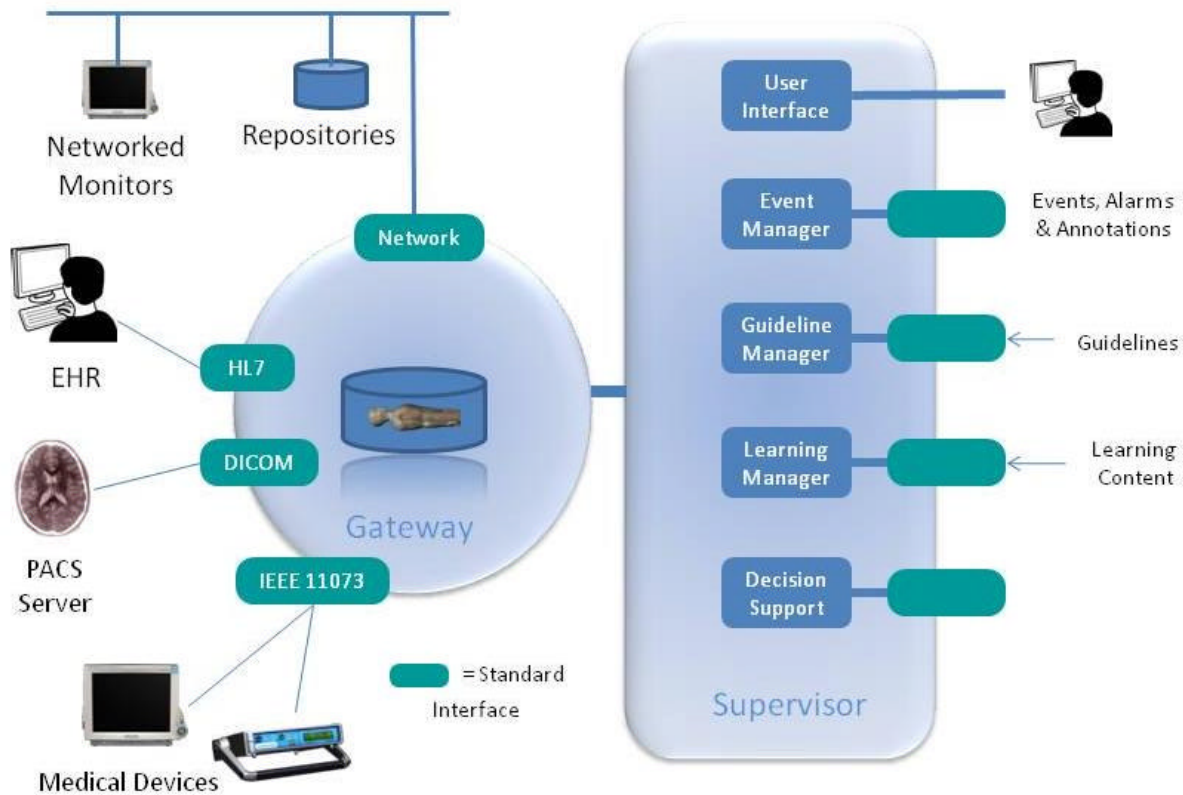


Figure 3. The right hand section illustrates the Supervisor software that permits “plug-ins” to configure the system to the needs of the clinician. Some standards (green rounded rectangles) have yet to be identified.

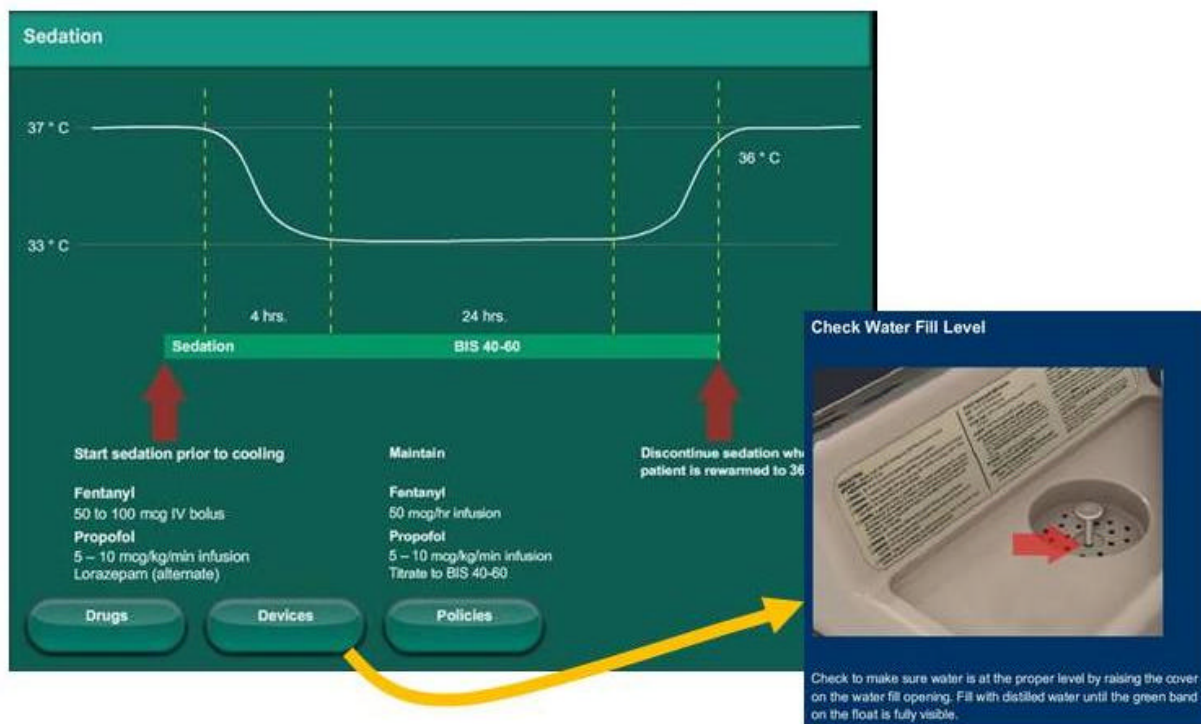


Figure 4: A guideline step and the instructional content linked to it.

As mentioned before, a significant advantage with developing a modular, standards-based approach is that separate companies (or individuals) can create products for the “uses” of the information without having to worry about collecting the information. This is like developing an app for an iPhone to manage the pictures in the phone without having to build the phone itself (seems simple, but medical informatics is a bit behind the rest of technology). There are obviously quality, safety, and regulatory hurdles we may have to overcome and we are addressing these issues in our work.

The Power of an Annotated Database

Once a continuous, comprehensive, and time-synchronized data set can be collected from each patient, it can be annotated as to clinical features. The power of such a database is seen in the MIT-Beth Israel Hospital Arrhythmia Database started in the mid-70s. The database consisted of a large number of highly annotated ECGs and after a few years of existence became the de facto standard to which developers of arrhythmia algorithms tested their detection methods. It ushered in a quality metric for these algorithms that is now required by regulatory agencies. This database has become a national resource.

In a like manner, such a database for neurocritical care (and neuroanesthesia) could greatly aid in the validation of new metrics (alarms, detection methods, autoregulation indices, etc.). The regulatory requirements for “plug-in metrics” are, at most, uncharted, but the more proactive we can be in developing quality modules, the better.

Such a database would also be a significant research and teaching tool. There are efforts underway to collect a database such as this such as from Urban Ungerstedt (using ICUpilot), from Cambridge (using ICM+), and via the BrainIT group in Europe. These are commendable efforts all with similar vision. A plea would be to adopt a common nomenclature and collection parameters (where it makes sense) or to be able to transfer the data to a standard format.

Barriers

There have been some significant barriers to adopting a unified information architecture and one has certainly been from industry where their closed systems mean you buy everything from one vendor. This may be changing as vendors seem to be moving more towards the development of open architecture...possible from customer demand.

The FDA is another barrier in that there is no pathway through the device approval process for such things as medical device plug-and-play. If approved, a vendor could test their product to a standard protocol (such as ISO/IEEE 11073) instead of testing every possible device connection (as our company currently has to do with its multimodal data collection system).

Progress

This information architecture or similar one can address many of the problems facing clinical monitoring today. The development needs to be done in a collaborative fashion and with a wide enough consensus such that it will be adopted. Efforts are being made on several fronts such as the work on Common Data Elements project at NINDS and the database activities mentioned previously. As mentioned previously, the neurocritical care community is an ideal setting for exploring and developing these concepts. The results will not only help neurocritical care, but has the potential to significantly advance healthcare informatics.

If you are interested in contributing to this project, contact Dick Moberg (dick@moberg.com).