Designing for the Critical Care Environment

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About GlySure Limited
In 2001, a landmark study published in the New England Journal of Medicine revealed that Tight Glycemic Control (TGC) in critically ill patients (even those without diabetes) significantly reduced morbidity and mortality (cutting mortality by 34%, blood transfusions by 50%, renal failure by 41%, and sepsis by 46%).

However, over the past decade, while a dozen key opinion leaders have published statements on the need for continuous glucose monitors to facilitate safe and effective TGC, no one player has developed technology that enables clinicians to effectively, continuously, and accurately monitor patient blood glucose levels throughout their length of stay. Enter GlySure. GlySure has developed continuous glucose monitoring technology that meets the decade-long demand for TGC. GlySure recently conducted human use trials that prove that its system can measure glucose levels across the entire human physiological range with an extremely high degree of accuracy and repeatability, which is key to effectively implementing TGC. The company is now starting its European clinical regulatory trials.

Converging factors have driven clinicians to re-evaluate the benefits and risks of insulin therapy. For over a decade, insulin has been #1 on the MedMarx list of hospital harmful medication errors, impelling clinicians to take greater caution with its administration. Over that same time period, there has been growing interest in the benefits of maintaining tight glycemic control (TCG) in critically ill patients (see "About" sidebar), with studies demonstrating that TCG can significantly reduce morbidity and mortality in the intensive care unit (ICU).

This clash between benefit and risk has placed added pressure on ICU staff to safely and effectively monitor blood glucose levels. In an article published in the American Journal of Critical Care, author Daleen Aragon [1], RN, Ph.D., CCRN noted, “Although most nurses endorse tight glycemic control, the work associated with it is burdensome and costly...Easier clinical methods for monitoring blood glucose levels are needed.”[1]

While there is a wide array of glucose measurement systems developed for use in home diabetes and in the clinical lab, the ICU presents a unique set of challenges, from the intensity of the nurses’ work environment to the fragile state of their patients.

Rather than trying to stretch existing technology to fit into the ICU, GlySure Limited [2] built its technology from the ground up to address the specific needs of the critical care environment, developing a continuous blood glucose (CBG) monitoring system to facilitate TGC. To ensure that its CBG monitors met the challenge of the ICU, GlySure took into consideration a broad range of factors in its product design and development, including the demanding ICU environment, work patterns of ICU clinicians, the critically ill nature of ICU patients, and the data requirements of today’s information-driven healthcare industry.

Designing for the Critically Ill Patient

Critically ill patients present a number of challenges to effective monitoring. Various disease states complicate blood chemistry, compromise perfusion, and cause fluctuating blood pressure levels, heart rates, body temperatures, available oxygen, and pH. Furthermore, the pharmaceuticals used to treat these conditions can skew body chemistry and vital signs, adding to the complexity. By nature, these patients are unpredictable and can change without warning. The complicated nature of these patients and multiple treatments places high demands on nursing time and labor. Surveys of ICU clinicians repeatedly highlight that in order for ICU CGM to be successful, it must not only provide accurate continuous measurement but also be simple to set up, easy to use, and integrate effectively into patient care.

Chemistry

The core of any glucose monitoring system is the detection technology or chemistry. The main requirement for an effective CMG chemistry is to be highly selective and reversible for glucose in the bloodstream across the physiologic range. The blood itself is essentially a soup comprised of thousands of different materials, all of which could theoretically interfere with the signal, producing either a falsely high or low glucose value.

In critically ill patients, the challenges are even more complex. Patients in various disease states produce materials in their bloodstreams that do not normally exist in healthy patients. For example, kidney failure patients have a variety of metabolized materials in their blood. Complicating matters are the thousands of different drugs used to treat patients in the ICU, which metabolize in the blood and change its chemistry.

In addition to facilitating effective monitoring for multiple days in the intensive care setting, the chemistry needs to be robust enough to maintain its accuracy over time. These multiple needs lead to the selection of a designer chemistry—developed to be highly selective and accurate for glucose while at the same time having longevity to allow monitoring throughout a patient’s stay in the ICU.

Lab and healthy volunteer testing can't come close to simulating the ICU environment. That is why GlySure has tested its CBG system in many different patient types, conditions, and co-morbidities to ensure that it works as intended, regardless of what materials reside in the bloodstream.

Access Point
GlySure chose to deliver its CBG monitoring system sensor through a central venous catheter (CVC) because nearly all ICU patients have a CVC catheter in place, and the CVC provides direct access to the patient’s core blood flow, which is critical to obtaining accurate blood glucose readings. Furthermore, the use of an existing CVC facilitates a minimally invasive approach, as it does not require any additional access sites into the patient.

Small and Strong
While GlySure had to design a sensor small enough to fit down a narrow catheter, it also had to ensure that this small sensor had high strength and mechanical reliability. This was accomplished through the use of high-end material science and manufacturing processes, such as incorporating a 100-micron strengthening wire that terminates in the tip and distal ends of the sensor to provide added strength and durability.

GlySure also had to provide a safe and effective way to prevent blood from clotting to the sensor while it resides in the bloodstream. While the use of heparin was an obvious solution, many hospitals are minimizing heparin use as it poses the risk of heparin-induced thrombocytopenia (HIT), an immune system response that can lead to major clotting problems. To overcome this issue, we used a covalently bound heparin derivative on the surface of our sensor, which ensures that the device can stay in the bloodstream, clot free, throughout its use without releasing heparin into the body.

Designing for the Critical Care Environment

Suffering from life-threatening conditions, critically ill patients are vigilantly observed by a multidisciplinary team of caregivers. Subjected to frequent vital sign spot checks and continuous monitoring, including blood pressure, heart rate, temperature, and blood oxygen saturation, these patients are tethered to a variety of both invasive and non-invasive equipment, presenting a jungle of wires, tubes, and cords at the bedside. GlySure had to take these environmental factors into consideration when designing its CBG monitor so that it would present true benefits to the caregiver, rather than imposing an additional burden. Anyone who has spent time in an ICU knows that the last thing a nurse wants is another alarm.

Size and Space

In an already crowded, intense environment, the size and space of GlySure's CBG monitor was an important consideration. Rather than forcing the clinical staff to designate a specific stand or shelf for our monitor, we designed it to fit onto an existing IV pole where it can be used alongside infusion pumps and other devices.

There is a great deal of debate in the industry around monitor size. Some feel strongly that monitors must be designed as small as possible to save space at the bedside, while others prefer a larger screen that is easy to read. When determining the size of GlySure's CBG monitor, we took into consideration not only space but also user requirements. Because the monitor provides a continuous trace of blood glucose levels throughout a patient's length of stay, the nurse at the bedside needed a reasonable size screen to easily see the trace and numerals at the head of the bed when standing eight to ten feet away at the foot of the bed. So while the monitor is pole mounted and out of the way, the display is large enough to provide a clear resolution for the caregiver.

Calibration

ICUs are staffed tightly all over the world and nursing time is precious. When designing our CBG monitoring system, we wanted to make less work for the nursing staff, not more. To do this, we created a system that calibrates itself, rather than requiring the nurse to perform a multi-step rigorous process.

GlySure's CBG sensor is packaged in a small, sterile calibrator pod, about the size of an iPhone. The tip of the sensor is housed inside this pack. The caregiver simply connects the sensor and calibrator pod to the monitor at the bedside. The monitor runs its software and the sensor calibration is performed just prior to use.

True Continuous Monitoring

No one can deny that ICU nurses have a tough job. They must be ever vigilant in monitoring extremely ill patients who require constant, complex care. If we could predict which patients would have problems and when they would occur we wouldn't need to put them in intensive care. Providing a true continuous solution that provides a minute-by-minute trend with minimal user intervention provides constantly up-to-date information and frees up nursing time for patient care

Patient Management

Another benefit of a continuous approach to blood glucose monitoring over intermittent monitoring is that it supports more efficient and effective patient management. True continuous monitoring provides a minute-by-minute trend that shows where the patient has been and where he/she is going along with direction and rate of change.

This becomes extremely useful in providing predictive alerts. Rather than waiting to sound an alarm when a patient has become hypo- or hyperglycemic, the GlySure monitor uses predictive algorithms to notify the nurse with a tone or blinking light that his/her patient is likely to go out of range, providing the caregiver enough time to properly manage the patient’s care. Offering caregivers a predictive trend rather than an urgent alarm enables them to address the issue at their convenience in the course of care, rather than forcing them to drop everything and rush to the bedside. Nurses also appreciate not having yet another noisy and disruptive monitor vying for their time in the ICU.

Data Output

In an environment such as the ICU where multidisciplinary teams are caring for patients, we had to ensure that our CBG system offered all of the necessary data for patient management in a way that suited diverse clinical needs. We found that clinicians wanted plasma or whole blood numbers, while nurses were more interested in patient trending data with which to make decisions—so we offer both.

In regard to the display, nurses wanted a simple tool that they could use to measure and manage patient glucose levels, rather than deep analytics. Through our display, the nurse can set upper and lower glucose limits so that he/she can add insulin if the patient’s glucose is too high and add glucose if it is too low. We also provide a continuous trace so that the nurse can monitor the patient’s glucose level trending, as well as numerals so that he/she can access instantaneous glucose levels.

While bedside clinicians mainly want to access the display to understand where a patient’s glucose level was, where it is now and whether there is an upward or downward trend, we can also apply other metrics to blood glucose readings, such as rates of change and how long glucose values are outside a particular limit. Researchers and others interested in this data can access it by using menu options on the monitor display.

For the healthcare facility, we had to consider how the data within our system would flow out to various information management systems. Facilities have a wide range of systems—some antiquated, some modern, and each with their own connections. We had to build into our system access points that would support all of the various ways in which a facility could retrieve the data—from network connections to legacy RS232 connections to USB ports. In today’s data driven environment, a medical device manufacturer must ensure that its technology is enabled and ready to go out of the box so that hospitals can get the data they need when they need it.

[1] Am J Crit Care July 2006 vol. 15 no. 4 370-377

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[2] http://www.glysure.com/