Online ExclusivesDiabetic Care Technology Is at a Standstill

By Emily L. Cross, Ph.D., Director of Media and Communication, TecMed Inc. | February 23, 2016

What needs to happen to get things moving again?

In the U.S. alone, over 37 million patients are diagnosed with diabetes, but technology is unable to keep pace with the growing demand due to a number of factors.

Related Online Exclusives

- Is My FDA 510(k) PMN Compliance Data Sufficient to Meet CE Regulations?
- Electroplating Innovation Used to Enhance Braided Catheters
- Disrupting Healthcare Through the Internet of Things
- Sounding Board: Device Tax Suspended, but What's Next?

A hard and firm rule of diabetes is self-care. Diabetics know that proactive self-care requires 24-hour, round the clock attention to avoid complications. Yet, this hard and fast rule is commonly only practiced in theory and oftentimes, neglected in practice. Maintaining the intricate diet and necessary exercise; vigilant measurement of blood glucose; paying attention to dental care, foot care, and eye care; and ensuring that medications are taken to regulate blood pressure and cholesterol can be overwhelming. Diabetes is a disease that requires a complete overhaul of lifestyle for most people and as we all know, a life overhaul is much easier in theory than in practice. Alas, diabetics also are intimately aware that without precautions, complications will arise and lead them to a hospital bed.

Although nobody wants to end up in the hospital, it is assumed, perhaps once again in theory, that the technology available to our medical experts will lead to a direct progression of necessary care and ultimately, revived health. In practice, especially for people struggling with diabetes, this is far from the truth.

In the U.S. alone, over 37 million patients are diagnosed with diabetes (according to the International Diabetes Foundation).

In fact, on a global scale, one in 12 adults have diabetes. Predictions are that by the year 2040, over 640 million adults worldwide will have diabetes (again, according to the International Diabetes Foundation). Without the intent to induce fear, today we know that one person dies every six seconds from complications associated with diabetes, while the actual direct deaths associated from diabetes sat at 1.55 million in 2014. That equates to about 5.3 million people a year.

Let's tie these ideas together.

Emily L. Cross, Ph.D. is director of media
and communication at TecMed Inc.

We know that the diabetes epidemic is explosive. We know that self-care for diabetics is necessary and tedious. We know that due to the increasing number of people with diabetes, the number of diabetic patients being admitted to hospitals is also growing at unprecedented rates. What is not so openly recognized are the problems diabetics encounter when they are admitted to hospitals and critical care units. As diabetics head to the hospital, the expectation is that help is near and the technology to solve the health problems plaguing the patients is accessible.

Yet, they are not.

In the last several years, the U.S. government has recognized that there have been an unacceptably high number of adverse patient outcomes for diabetics who are admitted to the hospital for a myriad of reasons. The problems that arise with the use of these meters—the traditional fingerstick meter most of us are so aware of—include increased patient morbidity, increased patient mortality, and increased bacteria and infections. Additionally, irreversible damages to the core functions of the body—nerve damage, autonomic instability, and cardiac arrhythmia—are also concerns. In fact, many of these adverse events can be directly connected to the use of glucose meters.

Quite simply, there is poor glucose management due to technology that doesn't serve patients or their providers adequately. With poor glucose management, patients can't get better and have longer stays in critical care units and the hospital. Outside of the negative impact this has on patient well-being, it also radically increases medical costs by billions of dollars annually.

Currently, the standard for acceptable blood glucose measurements has a 40-point variable in terms of accurate measurements. The new 2016 measurement standards (which will be put into play in June 1) have a 30-point variability. We can accept that this is an improvement, but there is little hope that it will have a major impact on patient safety. Perhaps increasing the point variability to only 25 percent, which is the laboratory expectation of accuracy in measurement, will improve patient outcomes more notably.

This wide variance of blood glucose measurement accuracy standards is one of the primary causes as to why so many patients suffer additional maladies or spend extra time in hospital care units. The significant variance means that medical practitioners truly can't make the decisions they need to make to provide for the health demands fluctuating blood glucose requires. Even with improved measurement mandates, the gap will not do much to solve the problems of blood glucose measurements and improved patient outcomes in critical care and hospital units.

A little known company (which admittedly, I represent) has the technology that patients, patient advocates, and medical practitioners need to actually make the therapeutic decisions that lead to better patient outcomes. This little company is

struggling to bring its technology to market.

What we know is that there is a need for more stringent regulations for blood glucose monitoring, regulations that even supersede the improved standards that will come to fruition this summer. We also know that improved blood glucose measurement capabilities will save lives and money. We also know that the technology we need exists, yet isn't available to U.S. markets.

Yet.

The pipeline from research and development to market is long, complicated, and often littered with extraneous steps. Currently, stuck in research pipelines are products at various stages of development that can potentially answer patients' needs here in the United States and abroad. Speaking to diabetes and blood glucose measurement alone, we know that we need higher levels of innovations and a cleaner path from development to market to provide for improvements in patient care and patient outcomes. The technology currently available does not meet new government mandates. Even the elusive technology that does meet mandates is not readily available, and quite frankly, doesn't answer the true medical demands of patients or allow for medical practitioners to make immediate therapeutic decisions to improve patient outcomes.

What needs to happen is some sort of "coming together of minds." Government regulations demand more accuracy, yet do not provide for a clean-cut path for products to be brought to market. Medical practitioners, patients, and patient-care groups are pushing for greater blood glucose measurement accuracy, but seem to lack the power to bring much needed improved technology to market. The small businesses that have the intellectual property to answer the demands of government, medical practitioners, and patients need greater access to resources to bring their technology to market and into the hands of the people who would most benefit from it.

We are at a stand-off.

Someone has to give a little to ensure that we do what we need to do—whether it be from a government regulatory perspective or from a patient advocacy position. It seems that we are all treading water at both ends of this innovation standstill.

We all want to move forward. We all want to improve patient care. We all want to save lives. Somehow, we need to find the missing puzzle piece to make this vision a reality.