



## Closing in on a Closed Loop?

*Dr. Liam Pender*

Short of a cure, the availability of an artificial pancreas medical device that would regulate blood sugar is the most desired breakthrough diabetics foresee on the horizon. At a recent diabetes technology conference, it appears that remote patient monitoring and wireless device connectivity are driving this initiative as much as improved sensors, algorithms and insulin.

Recently I attended my first *Advanced Technologies & Treatments for Diabetes (ATTD) Conference*, an event entirely focused on technology to treat diabetes. Not only was the conference inspirational, so too was the venue, the wonderful city of Paris.

The organizers of this event are driven to advance the goal of an artificial pancreas and all presentations were focused on that objective.



To diabetics, the expression 'closed loop' is synonymous with an artificial pancreas. There are three pieces of technology that are needed to create a closed loop system:

- continuous glucose monitoring (CGM) **sensors**

- software control **algorithms** that take those glucose values and decide on what insulin dose to issue to the patient
- **insulin infusion pumps** that issue the doses to the patient.

None of these three technologies are new, but all of them improve incrementally year over year. At ATTD there were presentations and data on more accurate sensors, results from algorithms that better mimic the natural operation of a functioning pancreas and updates on faster acting insulin.

As recently as 2011, artificial pancreas clinical trials using electronics to regulate patients' blood glucose were carried out exclusively in hospitals. Photos and videos from these trials show individual patients attached to carts of electronic instruments confined to hospital beds. While the patients appear pleased to put aside their usual vigilance, it is also very obvious that a portable system is required.

Now, just two years later, this picture has greatly changed. Clinical trial results presented at the ATTD Conference showed much larger trial groups and three distinct improvements.

1) Firstly, the subjects were **mobile**.

The CGM sensors have always been small and worn on the body, and in these new trials all are connected wirelessly to the platforms running the algorithms. These platforms are an array of smartphones, tablets and notebooks – all battery operated and portable. The insulin pumps also communicate wirelessly with the platforms to receive their dosing instructions.

In one recent study involving a children’s camp, the only inconvenience was wearing a small back-pack to carry the notebook.

Yet, it is this availability of small, portable, battery-operated, wirelessly-connected computing platforms that allows patients to move untethered from a hospital bed. This is not a diabetes-technology innovation -- it is an advance from consumer electronics.

1) Secondly, patients were **monitored remotely**.

The new mobile computing platforms are equipped with a menu of radios; Bluetooth, Wi-Fi, and Cellular. From the platform real-time data detailing the status of the patient and equipment is uploaded to the internet and pushed to caregivers so that human intervention can be immediate, if needed. This is particularly important as hypoglycemia is a potential risk in artificial pancreas design.

This real-time remote monitoring of data is an advance from outside diabetes. It is equivalent to GPS fleet tracking or monitoring seniors living alone. However, it is also a key factor in accelerating a closed loop artificial pancreas system.

2) Thirdly, the regulatory bodies are **pushing the agenda**.

Late last year, the FDA published guidance on submissions for IDEs and PMAs of artificial pancreas systems. Their guidance was recognition that device manufacturers were innovating in this space and needed regulatory direction. Almost simultaneously, an integrated closed loop system with low glucose suspends (LGS) functionality was approved for sale in Europe.

During a recent visit with a client to the FDA in Maryland, the staff was encouraging us to submit the required documentation so they could approve an IDE and move on; the agency is motivated, as is the market.

As you think about how today’s wireless medical devices in a connected world will give freedom and independent living to chronic disease sufferers and to seniors, consider how your current product development challenges could leverage these three technologies. Take action and call Egret Technologies. We look forward to hearing from you.

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