Parents want solutions **now**

"I don't know of more motivated patients than the parents of a diabetic child," says Lenka Petruželková. To improve the quality of life for their children, they created an open source system providing automatic insulin delivery. Although it has not passed any official certification and its use has not been certified, Lenka Petruželková nevertheless decided to help the families and now they are working together on official testing.

What is life like for parents of young diabetics?
Very difficult. When you have a small child with diabetes, you wake up every night, sometimes several times, both to feed and to inject so that the compensation is the best it can be – the quality of life suffers. You either withdraw from normal activities and the child has excellent blood glucose levels, or you lead a normal life, but with worse levels. Luckily, continual monitoring sensors are available, and these have greatly improved the quality of life for patients and their loved ones.

How do these sensors work?
The patient has a tiny probe installed with an enzyme, and it continually senses the current level of sugar. The reading is not from the blood but from the subcutaneous skin, which correlates well with blood glucose levels. The sensor sends data to a receiver, which is at the moment a smartphone, which we all have. It clearly shows not only the current blood glucose level but also its trend – whether it's going up or down. As a result, you know what to expect in the near future and how to prepare for fluctuations. If you have low blood glucose and the arrows are pointing downward, you can eat in time to avoid hypoglycaemia. Everyone is looking forward to when they are able to connect the sensor to an insulin pump that physiologically mimics the pancreas better than an insulin pen. Unfortunately, at this time families control the pump according to a doctor's instructions.

There's nothing like this on the market yet?
There's only a single product available in the world but it's not available in the Czech Republic yet. That's why a parent association named "We are not waiting" was started. It has some clever people in it who themselves created and are gradually improving an algorithm that can work with the sensor and switch off the pump according to blood glucose levels. It can send a bolus [Editor's note: a single dose of insulin provided before food] or otherwise respond. It works like a closed loop.

Does the parent then need to manually operate the pump?
They don't have to. Everything is controlled via the mobile app. You connect the app with a transmitter that detects the level of glucose and communicates with the insulin pump. Every five minutes a new blood glucose reading is performed and the algorithm calculates what is likely to develop over the next few minutes and how much insulin needs to be increased or decreased to get as close as possible to the optimal blood glucose reading. This command is sent to the insulin pump via Bluetooth, and the pump itself executes it. Only the oversight function remains with the parents.

So then the control doesn't take place via the insulin pump?
No. And imagine that you're a 17 year old girl, you have a dress and you have to pull out a pump somewhere quickly… At that moment, you're only interested in being discreet. Then the main advantages of having it controlled by a smartphone or smart watch start to become clear. Teenage patients are an extraordinarily difficult group for us, because at that age they're dealing with personal issues. Compensation isn't important for them.

What prevents the system you've described from being adopted on a mass scale?
The problem is the open source program's lack of certification. We cannot officially recommend it without this certification and proof of its safety.

Wouldn't it be simpler to test the system to prove its safety?
We're already trying to do that. In cooperation with the engineer Miloš Kozák, the father of one of our patients, who turned this procedure into a user-friendly and simple mobile application, we tested the algorithm in a pilot study that showed very promising results. After all, doctors tend to be very sceptical of patients' ideas, but here it turned out that the system works and that it's worth it to listen to patients.

Our goal is to adapt the algorithm into an official form so that we can gain the approval of the State Institute for Drug Control to conduct a prospective study in a home environment to prove the system's safety and effectiveness. Then an official product can be made that would be easily available for all patients.

What made you take on this difficult task?
I think all patients should be entitled to the same approach, and I can't accept the fact that although a closed circuit pump has existed in the USA for three years now, it still has not reached us. So I support any other product that would increase competition on the market and force companies to innovate faster and bring the latest available technologies to our market immediately.

I had two options – to close my eyes and pretend that the patients' solution did not exist – or to get familiar with it and find out if it worked. I chose the second option. The driving force for me is motivated parents who want the best for their children and who go for the best possible results.

How long can it take to get all the necessary stamps of approval? For child patients, every month can certainly play a role.
We quietly hope that we'll be able to have launched the study this fall, because we have everything prepared. We even got a grant from the Technology Agency of the Czech Republic. We also have to get the approval of all the international companies whose sensors and pumps we're using. The study will last for nine months, and then we will have certification. However, it will be beneficial to verify that the system is effective and safe.

There are around one million patients in the Czech Republic with diabetes. That still isn't an interesting target group for companies?
Although this figure may seem high, it's a negligible number in terms of the worldwide number of diabetics. In the Czech Republic, we are at the mercy of the big global players.

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