Transcript Details
This is a transcript of an educational program. Details about the program and additional media formats for the program are accessible by visiting: https://reachmd.com/programs/diabetes-discourse/an-assessment-of-automated-insulin-delivery-systems-for-t1d/14217/

ReachMD
www.reachmd.com
info@reachmd.com
(866) 423-7849

An Assessment of Automated Insulin Delivery Systems for T1D

Dr. Buse:
Can automated insulin delivery devices help patients better manage their type 1 diabetes? A recent study that compared the efficacy of automated insulin delivery devices, the sensor-augmented insulin pumps, may help us better understand.

Welcome to *Diabetes Discourse* on ReachMD. I'm Dr. John Buse. And joining us to share key insights from his recent research on open-source automated insulin delivery in type 1 diabetes is Dr. Martin de Bock, who's a pediatric endocrinologist at the University of Otago in Christchurch, New Zealand.

Dr. de Bock, thanks so much for speaking with me today.

Dr. de Bock:
Thank you, Dr. Buse. I look forward to our chat today.

Dr. Buse:
Fabulous. So this is a really impressive paper, published in The New England Journal, that compared, sort of do-you-it-yourself automated insulin delivery device open-source device to a commercial sensor-augmented insulin pump. Can you tell us about the significance of the term open-source as you apply that in your study?

Dr. de Bock:
Yeah, sure. So open-source really discusses or opens a concept that we haven't seen a lot in medicine to date where I guess innovation or a new way of doing things is not owned by proprietary organization or a profit organization. So, in this case, if it's open, for example, then anybody can reach that, and that, I guess, is the philosophy of the open-source in diabetes is that they wanted to be able to offer life-changing technology that people with diabetes have developed themselves to be able to reach people before and not wait for the standard regulatory and slow pathway that happens through standard ways of commercialization. So, if you're an end-user or a person with diabetes, you can go and find the algorithm, which is the NAPS program that runs automation on free websites, and you can go to it yourself for free, and then with the support of a community, which is the open community, they'll help you run your own automated system platform to get the best benefits for you as a person with diabetes.

Dr. Buse:
Great. Could you give us a brief overview of what actually comprises this open-source automated insulin delivery system? It's a whole system, in fact.

Dr. de Bock:
Yeah, yeah, it is, and you can build it in many different ways. I guess there are several, or three, main components of any automated insulin delivery system. And that is an algorithm, an insulin pump and a continuous glucose monitor, and all those three things need to talk to each other. So I guess in open-source you can build that in any way you want so long as you can make each bit of technology talk to each other. So you can have a standard proprietary pump that may be enabled with the Bluetooth connection with a smartphone. You can then pop your smartphone with an application that has the algorithm within it and that will also listen to the continuous glucose monitoring and then run the pump according to that algorithm in the smartphone application that you use to drive the automation. So there is a little bit of ability for the end-user to choose which hardware they suit, and also, there's lots of different iterations of those open-source algorithms that you can choose, and you can choose your own wishes.

Dr. Buse:
And what was the sort of range of choices that you used in your study?

Dr. de Bock:
Yeah, yeah, so that's a really good question. So we, because you're in a clinical trial, you have to you have to put some guardrails in. So we used one system for the purpose of the study, so we used the a non-commercialized DANA insulin pump that had two-way Bluetooth, so it allowed the smartphone to drive the pump, and then we used standard Dexcom G6 off the shelf. It's a continuous glucose monitor. And then we actually used a really cheap $100, New Zealand dollars. So what's that, 50 US dollar smartphone to run the application.

Dr. Buse:
And the actual software for the algorithm, does it have a particular source?

Dr. de Bock:
Yeah. So we used an android APS algorithm. So there are, there are sort of three main open-source algorithms that are available that open APS, android APS, and then there's the loop algorithm, which has been published about before.

Dr. Buse:
Very good. And which was the comparator commercial sensor-augmented insulin pump system?

Dr. de Bock:
Yeah, so we allowed the users to choose, so it depended on what system they were on before the study. All participants were previous insulin pump users and that's because when we were designing the study, we thought it was quite a big leap to learn open-source. There was a reputation for it being quite tricky. Although we probably dispelled that myth to a certain degree. So we had people on their own insulin pump, so most of them were actually in New Zealand just because the dominant market share at that point was on Tandem, so most people were using Tandem with a G6, and that was before Basal-IQ or Control-IQ was available, so it was just standard sensor-augmented pump therapy with Tandem pump for the majority of participants who were in the control arm.

Dr. Buse:
For those just tuning in, you're listening to *Diabetes Discourse* on ReachMD. I'm Dr. John Buse, and today I'm speaking with Dr. Martin de Bock about his study focusing on the efficacy of automated insulin delivery devices, open-source automated insulin delivery devices for patients with type 1 diabetes.

So, Dr. de Bock, can you tell us about the top-line futures of your study design and the key findings?

Dr. de Bock:
Yeah, sure. So this was a six-month randomized controlled trial, and this was followed up by another six-month continuation phase that just was recently presented at EASD, but for the purpose of The New England Journal paper, it was a six-month randomized controlled trial, and we compared two arms at the last two weeks of their time using the system, and we found there was a 14 percent overall improvement in time and range, and that there was no age of it, so no matter how old you were, you got that benefit of time and range as the primary outcome. We also found no increase in hypoglycemia, and it was completely safe. We had not a single episode of diabetic ketoacidosis or severe hypoglycemia in either arm of the study.

Dr. Buse:
The study was conducted in New Zealand, and I guess you understand a little bit about the US healthcare system. How should American clinicians think about applying your findings with patients in the US?

Dr. de Bock:
Yeah, this is super interesting. I think that there are significant headwinds in the US due to, I guess, a very strong regulatory framework and parallel to that quite a litigious, I guess philosophy that if should something go wrong, you can end up being quite liable personally as you're a healthcare professional. But you must keep in mind that most, I guess, diabetes societies around the world globally have said that your doctor-patient relationship, your healthcare professional patient or a person with diabetes relationship should probably trump that, and there is, I guess, a degree of allowing civil liberty for the person with diabetes to choose if they wish the style of medicine that works for them. So I guess you've got to look at your own risk and be very careful about how you document that with a person with diabetes in front of you who asks you about open-source alternatives to automated insulin delivery.

Dr. Buse:
Yeah. I mean, I'll just—My personal experience with it is that patients usually become aware of this stuff, and they work with the community to get the materials together. We certainly support these patients with prescribing and helping them with adjusting settings and those sort of things moving forward. I don't know of any lawsuits in the United States to date, but I'm sure that's something that will concern some clinicians.

Dr. de Bock:
Yeah. I guess that's a reflection that the system is safe in real world. And the interesting thing, of course, is that we did the randomized controlled trial at the end of this journey where usually in the standard process of, of innovation you get a randomized controlled trial, then you might get some post world studies, and then you get a, then you get sort of a market-related premise where in this scenario there was, you know, hundreds of millions of end-users safely using the system. And then we did the randomized controlled trial to prove that they were right. So, for that, for that point, I felt that the study was really serving that community of people with diabetes rather than, I guess, the opposite.

Dr. Buse:
Yeah. And, you know, with regards to the comment about how many people perceived this as being very difficult, I take it that for your experienced sensor pump users, making the switch was relatively easy?

Dr. de Bock:
Yeah. Well, there's one extra caveat to that, Dr. Buse, is that, is that in New Zealand, continuous glucose monitoring is not funded, and you can't get it through private health insurance, so actually, the majority, especially the adult participants, were just pump users without true real time CGM. A lot of them are Libre Flash users, just Libre 1 at baseline or not with a sensor at all, so learning CGM and coping with all that was probably more of a challenge than, than running the automated insulin delivery system. And I'm sure you'll know from your own experience, the more you leave automation alone just to do its thing, the better it does so often, actually people who don't want to fiddle too much, who just leave it and be patient to let the algorithm do its magic, you certainly see some great outcomes.

Dr. Buse:
Yeah, that, that last point you made is really critical. The people that I find that don't do well with these systems are the people who want to micromanipulate every, you know, every blood sugar that they see, you know, 20 times a day. If you just let the system do its thing, it usually does a better job than almost any human can accomplish.

Dr. de Bock:
Absolutely agree.

Dr. Buse:
And I think a tip, if you have an older patient that's interested in doing this, in your practice at least, it's their grandchildren that are remarkably helpful in working with the community to get grandpa and grandma set up on these devices. As we close out our discussion, any final thoughts you'd like to share with our audience?

Dr. de Bock:
No, I guess I would just like to thank the community of people with, with type 1 diabetes who have made this whole pathway available for people with diabetes and actually challenging the standard paradigm of innovation in medicine. We're challenging the ways that translation can be sped up and also challenging the framework where there might be profiteering from people's health, and I think that's a really interesting philosophical concept where open-source innovation really empowers people with the condition, and this example is in diabetes, where they can take charge of their own health and get those improvements in a quick and really way for themselves without waiting for the standard regulatory process, which adds cost and time.

Dr. Buse:
That's a great note to end on. I'd like to thank my guest, Dr. Martin de Bock, for providing us his insights on automated insulin delivery devices. Dr. de Bock, it was a pleasure speaking with you today.

Dr. de Bock:
You're welcome. Thank you very much.

Dr. Buse:
For ReachMD, I'm Dr. John Buse. To access this episode and others from our series, visit ReachMD.com/DiabetesDiscourse where you can be Part of the Knowledge. Thanks for listening.