Exclusive coverage from the ADA 2020 Event
ADA 2020: Abbott Expects CGM To Reduce Insulin Needed For Type 2 Diabetes

Executive Summary
Research presented at this year’s virtual American Diabetes Association meeting demonstrated the benefits of continuous glucose monitoring for those with type 2 diabetes not taking insulin. Mahmood Kazemi, divisional VP for global medical and scientific affairs at Abbott’s diabetes care tells Medtech Insight how he sees CGM technology transforming the future of diabetes management.

For individuals with type 2 diabetes, continuous glucose monitoring (CGM) devices may one day become the standard of care, according to Abbott Laboratories Inc.

At this year’s American Diabetes Association (ADA) virtual meeting, the company presented data to support the use of CGM systems in individuals with type 2 diabetes, whether they use insulin or not. Mahmood Kazemi, Abbott’s divisional VP for global medical and scientific affairs at Abbott’s diabetes care business, told Medtech Insight the data would have “revolutionary” implications for diabetes management.

“We knew the benefits of our technology in people with type 1 and type 2 diabetes who are using insulin but are also now expanding into new populations of individuals with type 2 diabetes who are not yet on insulin therapy,” Kazemi said.

At the ADA meeting, Eden Miller of St. Charles Hospital in Bend, OR, presented a study of people with type 2 diabetes using Abbott’s FreeStyle Libre CGM system. The study subjects were either using oral medication or a long-acting/basal insulin for their diabetes management or no insulin therapy, a population that has not benefited from CGM in previous studies.

Miller’s group analyzed HbA1c, the average blood sugar over a period of three months, from baseline to six months and baseline to 12 months after initiating glucose control with the FreeStyle Libre system. Results demonstrated overall lower HbA1c levels associated with the use of Abbott’s technology, specifically a 0.8% drop after six months, from 8.5% to 7.7%, and 0.6% drop after one year of glucose control with FreeStyle Libre, from 8.5% to 7.9%.

For individuals with type 2 diabetes, who are not using insulin, the glucose control with the FreeStyle Libre system was associated with A1c reduction that would normally be seen with the addition of insulin therapy. “I think this is quite dramatic because if a patient has type 2 diabetes and is not hitting their glycemic goal on their current oral medication regimen, this data offers a compelling argument that instead of adding insulin, physicians can consider adding in a CGM like FreeStyle Libre to allow the individual to have a better sense of their glycemic profile,” Kazemi said.

“What we showed with these abstracts is that, in fact, looking at very important real-world evidence from real-world users of our technology in the US, that the use of the technology is associated with significant benefit in terms of clinical outcome including lower A1c values,” said Kazemi.

If lifestyle, diet and activity changes take place that improve glycemic control, then there is potential
to avoid the need for insulin or other medications entirely. “It becomes quite challenging when you’re trying to look at what would be the next step in progressing someone’s therapy if they’re not hitting their glycemic goal.

CGM therapy have very few side effects compared to prescription medication and offers more choices of treatment in diabetes care.” The data also showed a reduction in acute diabetes events, which can lead to hospitalization.

**RELIEF Study**

Additional data from Abbott’s RELIEF study in France showed that the use of FreeStyle Libre produced lower A1c levels and reduction in diabetes ketoacidosis (DKA).

“This is a severe complication for individuals with diabetes which can be not only costly, but life-threatening,” said Kazemi.

In the study, researchers assessed nationwide reimbursement claims data in France of 74,158 people living with diabetes, including 33,203 people with type 1 diabetes and 40,955 people with type 2 diabetes. Overall, annual DKA rates dropped by 52% in those with type 1 diabetes and 47% in those with type 2 diabetes when using the FreeStyle Libre system.

Greatest reductions in DKA-related hospitalizations occurred in people who did not conduct traditional fingerstick testing, as well as those who performed fingersticks more than five times per day, regardless of previous test strip usage.

In those who did not do fingersticks, results showed decreases in DKA-related hospitalizations of 60% and 51% in people with type 1 and type 2 diabetes, respectively. For people who performed fingersticks more than five times per day, findings showed drops of 59% for people with type 1 diabetes and 52% for people with type 2 diabetes.

**New FDA Clearance For FreeStyle Libre 2**

Abbott is now preparing to launch its next-generation FreeStyle Libre 2 device, following clearance and integrated continuous glucose monitoring [iCGM] designation from the US Food and Drug Administration on 15 June.

The platform can now continuously transmit glucose data every minute and features optional real-time alarms to alert when glucose is high or low. A pediatric indication is also included that allows use of the technology in children aged four and above.

“There is a certain population within the diabetes community, such as children or individuals who may not be able to feel low glucose levels. Those individuals can now hopefully benefit from the real-time alarms in Freestyle Libre 2,” Kazemi said.

Unlike rival Dexcom’s G6 CGM, cleared by the FDA in March 2018, the Libre 2 iCGM designation is not intended to be used with automated insulin dosing (AID) systems. Dexcom’s CEO Kevin Sayer told Medtech Insight he believes the G6 is “far superior” to FreeStyle Libre 2 as it can connect with any product. (Also see “ADA 2020: CGM Maker Dexcom Gains CE Mark, Launches G6 Pro While Rivalry With Abbott Builds” - Medtech Insight, 16 Jun, 2020.)

The two companies are leading players on a mission to capture the CGM market. While concern was raised over the lack of connectivity, Kazemi said Abbott will expand FreeStyle Libre 2 to connect with AID systems.

“We know this capability is of interest to a rather
small segment of the diabetes population. If you look at the numbers of people using AIDs, it's very small. But we are aware that this is a population that may grow in the future, so we are certainly working on seeing how we can have that availability. Our device has unsurpassed accuracy than others on the market and we are offering all of that with the real-time optional alarms at a very attractive price point,” according to Kazemi.

Just days before the ADA meeting, Abbott rival Dexcom announced its G6 CGM received CE marking in Europe for attachment on the back of the upper arm. The device has already been available in Europe since 2018 for wear on the abdomen. In July, Dexcom will also launch its single-use professional G6 Pro CGM in the US. (Also see “Dexcom Now Offers Providers G6 Pro Continuous Glucose Monitoring Systems” - Medtech Insight, 8 Jun, 2020.)

According to analysis by Informa’s Meddevicetracker, “Diabetes Management: Blood Glucose Monitoring Devices Market,” sales of CGMs are expected to surpass revenue volume of traditional blood glucose meters (BGMs) by 2021. By 2023, CGMs are expected to reach total sales of $9.3bn, nearly triple the volume of blood glucose meters, which are expected to reach $3.5bn by 2023.

Despite Abbott’s AID contraindication, market analysts responded favorably to the announcement.

“This does not have a significant impact on Abbott’s market opportunity,” wrote Marie Thibault of BTIG in a 15 June research note. “We have confirmed this does not impact the company’s integration partnerships with Insulet Corp. and Tandem Diabetes Care Inc. These partnerships and development timelines remain on track. We expect Libre 2 to extend Abbott’s high-sales growth in the diabetes business.”
ADA 2020: Medtronic Explains Strategy To Return Growth To Diabetes Business

Executive Summary
Medtronic will launch its next-generation MiniMed 780G insulin pump while continuing to develop complementary technologies to close the competitive gap with its rivals in the diabetes market.

Medtronic PLC expects the launch of its next-generation MiniMed 780G hybrid closed-loop system will mark the start of the turnaround for its diabetes business.

During the virtual American Diabetes Association conference on 11 June, Medtronic announced the CE mark for its MiniMed 780G, indicating it for the treatment of type 1 diabetes in people ages 7 to 80 years. Medtronic plans to begin shipping the 780G this fall in select European countries.

The 780G is the same Bluetooth-compatible hardware as Medtronic’s MiniMed 770G, but it has an upgraded control algorithm which company will provide for free to users who already have the MiniMed 770G. Without the 780G software update, the 770G runs the same algorithm as the company’s flagship MiniMed 670G.

Medtronic said it filed for US Food and Drug Administration approval for the 770G in May, but has not publicly shared when it expects to file for US regulatory approval of the 780G.

The CE mark is good news for a business that has been short of good news lately.

Medtronic reported revenues of $2.37bn for fiscal 2020 ended 24 April, representing less than 1% year-over-year growth, including a 7% year-over-year decline in revenue during the fourth quarter of fiscal 2020. (Also see “ACC 2020: Medtronic’s Resolute Onyx DES Meets Goals In US/Japan High Bleeding Risk Patients” - Medtech Insight, 9 Apr, 2020.)

Meanwhile, Medtronic’s rivals in the diabetes care device market have been rapidly taking market share. In 2019, Abbott’s diabetes care business grew almost 36% to $2.52bn; Dexcom’s revenues grew 43% to $1.48bn in 2019; and Tandem Diabetes Care reported $362m in 2019 revenues, representing a 97% year-over-year increase. (Also see “Market Intel: After A Year Of Partnerships, Insulin Pump Manufacturers Will Face Fierce Competition In 2020 “ - Medtech Insight, 9 Dec, 2019.)

Medtronic’s diabetes group president Sean Salmon discussed the company’s strategy to “reinvigorate” the company’s diabetes business during an online investor meeting held on 12 June to coincide with the ADA meeting.

“We have some work to do to get this business back to growth and we’re certainly committed to returning ourselves to very strong growth,” Salmon said. “But we do have considerable strengths that we can leverage, including our long history in this business, our deep connections and relationships we have with health care providers, and the extent of our organization.”

Salmon took over the leadership of the diabetes business in October 2019 after previously leading Medtronic’s coronary and structural heart
“The emphasis of our strategy is on the entire customer experience,” he added. “It’s not just the products. It’s how they all work together and how our support network and really every touchpoint that a patient is going to encounter.”

Making Medtronic’s diabetes business more competitive is one of the top priorities for Medtronic CEO Geoff Martha, who took over the top job at the company in April. (Also see “Medtronic CEO Omar Ishrak Announces Retirement; Geoff Martha Will Be New CEO” - Medtech Insight, 28 Aug, 2019.)

“We haven’t really managed that business well,” Martha said during the Bernstein Strategic Decisions Virtual Conference on 29 May. “But we put a new leadership in there and we’ve taken a hard look at it ... I feel really good about the pipeline.”

To accelerate its diabetes pipeline development, Medtronic announced a $337m investment from Blackstone Life Sciences to support research and development in its diabetes group.

In a 15 June note, SunTrust analyst Robinson Humphrey wrote: “The company has invested organically in the business and its pipeline, and taken appropriate steps to support and stabilize its position as a market leader, [but] the strategy from here will hinge on improving the entire customer experience with product innovation.”

780G Reduces “Hassle Factor” Of 670G

Martha stressed the importance of the 780G for Medtronic’s growth strategy of its diabetes business, because users generally regard the company’s previous-generation insulin pump system, the MiniMed 670G, as harder to use than competitors’ devices. “We just have to get the 780G out the door and eliminate some of the hassle factor of our current product,” Martha said.

People who used the 670G reported that they did not feel as safe running the device in automatic mode as they were running it in manual mode, Salmon explained. In manual mode, the 670G creates many alarms and alerts, including unnecessary alarms in the middle of the night. The 780G aims to eliminate extraneous alarms that interrupt patients’ lives, he said.

“That user experience is something we focus on and we continue to work on,” Salmon said.

Incorporating technology Medtronic obtained by acquiring DreaMed Diabetes in 2015, the 780G algorithm automates the delivery of both basal insulin and correction boluses every five minutes to help people with diabetes avoid blood glucose highs and lows. It can be controlled by compatible iOS and Android smartphones via Bluetooth connectivity with an app that reports real-time glucose data and trends.

Patients who used the 780G in clinical studies reported that it made their life easier, because the regular insulin bolus adjustments reduce the burden on patients to measure their carbohydrate intake, Salmon said.

“We know three-quarters of patients find carb counting to be difficult to do. For those who actually do it, maybe two-thirds of those folks get it wrong and missed boluses, no matter how attentive you are.”

The 780G also lets the user personalize their glucose goals with an adjustable target setting as low as 100 mg/dL, which is lower than any other advanced hybrid closed-loop system available,
according to Medtronic.

“The number one request that we get on our algorithms [from users] is that they want to target more normal levels of glucose,” Salmon said. “They want to set a lower target, and, of course, they want to be able to do that safely.”

Medtronic is also developing the Personalized Closed-Loop insulin pump system, which will automate insulin delivery and provide insights and predictive diagnostics unique to the individual user to simplify.

The software that runs the Personalized Closed-Loop system is largely based on artificial intelligence technology developed by Nutrino Health, which Medtronic acquired in 2019.

The FDA granted the Personalized Closed Loop system breakthrough designation in February 2019. The company has previously said that it expects to submit clinical data supporting the Personalized Closed-Loop system to the FDA in the second half of fiscal 2021, which begins in January of calendar 2021.

Better Sensors, User-Friendly Design
The 780G is compatible with Medtronic’s next-generation glucose sensor, an upgraded version of its Guardian Sensor 3, that the company is temporarily referring to as “Project Zeus.”

The Project Zeus sensor accurately tracks blood glucose without requiring the user to calibrate it several times a day with fingerstick blood tests, Salmon explained.

By comparison, the FDA-approved labeling for the current version of Guardian Sensor 3 states it is not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a fingerstick may be required and that a confirmatory fingerstick test with blood glucose meter is required prior to making any adjustments to the user’s diabetes therapy, Medtronic said.

The company hopes the FDA will approve the Project Zeus sensor with labeling stating it requires just one calibration per day. Outside the US, Medtronic hopes it will be approved with a “non-adjunctive” labeling, indicating that users can rely on the information from the sensor without a confirmation fingerstick test.

Salmon said Medtronic has completed collecting the clinical data that it will need to submit for US regulatory approval for Project Zeus sensor, but it has not provided an expected approval date or brand name.

The company is sponsoring a US clinical trial of the Synergy sensor, which is disposable, smaller, and easier to wear than the Guardian Sensor 3.

In a 14 June report, Wells Fargo analyst Larry Biegelsen wrote that adding a sensor with the “non-adjunctive” labeling would help Medtronic sell the 780G to the Medicare population, which makes up about 15-20% of diabetes patients in the US. But he believes 780G will not be competitive without a better sensor.

“Medtronic’s [insulin pump sales] will continue to be held back by an inferior continuous glucose monitor sensor,” Biegelsen explained. He pointed out that both Zeus and Synergy require at least occasional fingerstick calibration by the patient, while Abbott’s FreeStyle Libre and Dexcom’s G6 CGM devices do not require fingerstick calibration. “Some of the clinicians believe given [that] Zeus still has the same sensor as Guardian 3 – but a different algorithm – the gap will not close
competitively until Medtronic’s Synergy sensor comes out,” he wrote.

Medtronic is also developing a more durable infusion set, the part of the insulin pump system that delivers insulin under the skin. Medtronic’s current-generation infusion set must be changed every two to three days, but its Extended infusion set relies on a new adhesion technology and on a proprietary approach to minimize insulin degradation, according to the company.

At the ADA meeting, Medtronic presented study results showing the improved insulin stability provided by the Extended set contributes to better infusion site performance and reduction in hyperglycemia due to occlusions and that wearing the Extended set could save users five to ten vials of insulin per year that is currently being thrown away during two-day or three-day infusion set changes.

The Extended infusion set is already approved for marketing in Europe. Now Medtronic is sponsoring a US pivotal trial to support FDA approval. Medtronic said it is the only infusion set on the market labeled to be used for up to seven days.
ADA 2020: Tandem Wins FDA Nod For T:Slim Pump Technology In Children; Positive Feedback on Studies

Executive Summary
After announcing positive results at the American Diabetes Association conference and an expanded FDA approval for its insulin pump delivery system, Tandem Diabetes Care's CEO outlines its path forward.

In a recent six-month study of children ages six to 13 with type 1 diabetes using the t:slim X2 pump with Control-IQ technology, users' sensor time in range rose 67% compared to 53% in the control group using sensor-augmented pump (SAP) alone.

Overnight, children who used the Control-IQ technology stayed in range 80% of the time compared to 54% in the control group. The data was presented at this year’s International Conference on Advanced Technologies and Treatment for Diabetes in Madrid, Spain. The time in range, or amount of time a person spends with blood glucose levels a healthy target range, is 70-180 mg/dL.

“The thing that's meaningful about this is that when you look at that group, if you look at the stratification of A1Cs by age, the adolescents and young adults really have a hard time controlling their blood sugar,” Tandem's CEO and president John Sheridan said during a 17 June company management call with analyst Jayson Bedford from Raymond James & Associates. A1C, which is taken with a blood test, evaluates an average of blood glucose levels as a percentage of red blood cells over the past two to three months.

Sheridan said the data presented at the ADA conference showed “substantial improvement in time and range with this group.”

Findings from a six-month multicenter randomized study comparing Tandem’s t:slim pump with Control-IQ technology and Dexcom’s G6 CGM to SAP therapy, showed that the closed-loop control system improved time in range by 11%, reduced A1C by 0.33%, dropped mean

With new study results presented at this week’s virtual American Diabetes Association (ADA) meeting followed by approval from US regulators to expand the indication for its t:slim X2 insulin pump with Control-IQ technology system, Tandem Diabetes Care Inc. is hoping for brighter days ahead.

The San Diego,CA-based insulin pump maker announced on 17 June that the US Food and Drug Administration has approved an expanded indication for its t:slim X2 insulin pump with Control-IQ technology to children ages six and older. The product was previously approved for use in patients aged 14 and older and has been on the US market since January.

Tandem’s t:slim system with Control-IQ technology integrates Dexcom Inc.’s G6 continuous glucose monitoring (CGM) system. It is designed to help increase time in range (70-180 mg/dL) and requires no fingersticks for calibration. Tandem says its system simplifies diabetes management for younger patients by predicting glucose levels ahead and adjusting insulin delivery accordingly to prevent highs and lows. (Also see “ADA 2020: CGM Maker Dexcom Gains CE Mark, Launches G6 Pro While Rivalry With Abbott Builds” - Medtech Insight, 16 Jun, 2020.)
glucose by 13, and decreased hyperglycemia by 10%, according to professor Sue Brown from the Virginia Health System who presented the data at the ADA conference on 13 June.

Sheridan told the analyst he walked away from the conference feeling “strengthened.”

“I thought that the data that we presented for the real-world data as well as the pediatric data just showed that we have the superior product on the market,” he said. “And clearly, when you look at the sensor and the pump in terms of the ease of use, no finger sticks, we feel very confident in our competitive position going forward with the product we’ve got today.”

He noted that the real-world Control-IQ study was cut short, because Tandem had to submit the data to the ADA in March.

“We were able to look at about 1,600 people who had one month not using Control-IQ followed by one month where they used Control-IQ. And in that group, we saw time and range improvement of 10% going from the high-60s to the high-70,” he said. “We’re very pleased with that result. And I think that, as we just talked about, the pediatric data was also very, very encouraging.”

Tandem’s chief administrative officer Susan Morrison said, there are nearly 200,000 people with type 1 diabetes under the age of 20; globally there are about 1.1 million people under the age of 20 who have type 1 diabetes of which 100,000 kids are under the age of 15.

Sheridan said: “We’re really hoping that this has a meaningful impact on that performance over time because people do talk about how this trend hasn’t really improved, but there really haven’t been devices out there that has shown the ability to do that. So I believe that Control-IQ for this population is very important.”

Abbott Partnership

Last October, Tandem also announced a new partnership with Abbott Laboratories Inc. to integrate diabetes solutions that combine Abbott’s glucose sensing technology with Tandem’s insulin delivery systems.

Abbott, a competitor of Dexcom, announced at this year’s ADA meeting that its FreeStyle Libre 2 gained FDA clearance as an integrated CGM system for managing diabetes in children ages 4 and above and adults.

Dexcom was the first company to establish the integrated continuous glucose monitoring designation in March 2018 with the FDA de novo classification of the G6 and Tandem’s t:slim X2 insulin pump was the first to receive the FDA clearance in a new device category called alternate controller enabled (ACE) infusion pumps in 2019. The special controls allow ACE pumps to be integrated with any external device. However, the FreeStyle Libre 2 is not authorized to be used with automated insulin dosing systems. (Also see “Tandem Wins FDA Clearance On First Stand-Alone Glycemic Controller” - Medtech Insight, 19 Dec, 2019.)

Sheridan said during the call: “When we announced the fact that we plan to work with Abbott, we didn’t specifically indicate which technology we are planning to work with,” adding that “I think people assumed it was Libre 2 because of the timing of the submission.”

He said right now Tandem is working with Abbott on an agreement.

“Once we have the agreement in place, we can
then begin to get the technical teams together and begin to understand what that implementation is going to look like,” he said. “And at the same time, I know that Abbott is going to be working to address this, because clearly they want these systems to also be used in automated insulin delivery products.”

**Covid-19 Impact**

Leigh Vosseller, Tandem’s chief financial officer, said the firm has been “seeing more strength than we had anticipated when we set the guidance number” at the end of April, for both the domestic and international markets.

She now expects that Tandem will exceed $85m in revenues in the second quarter. For the first quarter ended March 31, the company reported $97.9m in revenues.

Tandem, like many other medtechs and health systems, also benefitted from a wider adoption of telehealth in the US during the COVID-19 pandemic. And Sheridan expects demand for virtual training and virtual visits to continue to grow.

“We have a consumer-based business model and also we basically think that the use of telehealth has really helped the adoption of Control-IQ,” Sheridan said. “I think that both the physicians and the people that are living with diabetes see the benefit of doing it this way. So, I think it’s going to be a part of therapy management and training for a long time.”

Internationally, distributors continue to see demand and have been placing “pump replenishment orders.” Also, more people are aware of Tandem and other products, Sheridan pointed out.

“And we also believe that we’re seeing some positive performance because of the entrants into these new markets,” he said.

Though Vosseller also cautioned that “we’re still seeing pressure on the business.”

Sheridan also expects more people to convert from multiple daily injections (MDI) to pump therapy. He noted that after a substantial drop in 2019, the amount of people who moved from MDI to pump therapy doubled, driven by technological advancements and very accurate sensors “that are small and don’t require fingersticks and last longer.”

He expects a 50% pump market penetration in the next three to five years and also expects that continuous glucose monitoring companies will be able to achieve their goal of a 70% penetration rate.

Today, about half of Tandem’s insulin pump users also use CGMs, said Morrison. She added these numbers are likely to go up with users realizing the benefits of CGM information.

Tandem also remains on track to launch its next-generation t:sport insulin delivery system in 2021.

Sheridan said the pump will have an improved algorithm but could not comment on whether it will have advanced features such as customizable targets.

Sheridan noted that the company plans to continue on its path set pre-COVID – including expanding manufacturing, significant investment in R&D, building out its product pipeline over the next two to three years and investing in technology solutions that make all departments more efficient and focusing on remote training.
ADA 2020: US Pivotal Trial Data Support Medtronic’s Next-Gen Insulin Pump

**Executive Summary**
Clinical data presented during the virtual ADA meeting show Medtronic’s MinMed 780G hybrid closed-loop insulin system, an upgraded version of the company’s 770G system, improved patients’ ability to keep their blood-glucose levels within target range.

New 90-day results from the US pivotal trial of Medtronic PLC’s MiniMed 780G insulin pump show the next-generation system safely improves users’ “time in range” (70-180 mg/dL) – the percentage of time the users’ blood glucose is near the optimal level – without increasing hypoglycemia.

Primary investigator Anders Carlson of the Park Nicollet International Diabetes Center in Minneapolis presented results from the US pivotal trial during the online American Diabetes Association online conference on 12 June.

The results from the trial will support a submission to the US Food and Drug Administration later this year. The 780G has gained the CE mark and Medtronic expects to launch the device in Europe this fall.

In the study, 157 subjects – including 39 adolescents – used the 780G with the glycemic control set point at either 100mg/dL or 120mg/dL for 45 days and then used it with the other set point for the next 45 days.

There were no cases of severe hypoglycemia or diabetic ketoacidosis during the study.

The average time in range increased from 69% at baseline to 75% with an overall time below range of 1.8%. When the device was set to the 100 mg/dL target, subjects with an active insulin time of two hours had an overall time in range of 79% and an overnight time in range of 87%. The results across all pump settings exceeded international clinical consensus time in range targets set by the ADA and Advanced Technologies & Treatments for Diabetes, according to Carlson.

The 780G’s autocorrection feature contributed 22% of all bolus insulin and the patients used the 780G’s SmartGuard closed-loop function 95% of the time. The SmartGuard closed-loop function automatically suspends insulin delivery when glucose levels are approaching the pre-set lower limit and resumes delivery of basal insulin once glucose levels recover, according to Medtronic.

Survey results show 96% of study subjects found the 780G to be easy to use. The survey results also showed that 780G requires 46% fewer fingerstick calibration tests than the 670G.

“We often hear from our patients about wanting lower glucose target settings and there is certainly a desire to see that represented more in the current marketplace,” Carlson said. “I’m pleased to see this next-generation closed-loop system continuing to improve in that direction.”

Also at the ADA meeting, Martin de Bock from the University of Otago in Christchurch, New Zealand, presented data from a randomized cross-over clinical trial comparing the 780G to sensor-augmented pump therapy with predictive low glucose management. The four-week trial enrolled
59 subjects aged seven to 80 years, including those with less-controlled diabetes.

The study met primary endpoints of increasing overall time in range.

Compared to those treated with the predictive low-glucose management algorithm, the patients who used the 780G showed significant improvement in overall time in range (70.4% vs 57.9%) and overnight time in range (74.9% vs 59.2%) due largely to a 12% reduction in hyperglycemia.

Survey results showed 95% of the 780G users believed it was easy to use and 85% said it improved their quality of life.

Commenting on Medtronic’s presentation in a 14 June report, Wells Fargo analyst Larry Biegelsen pointed out that results of this pivotal trial are similar to the results of the pivotal trial of Tandem Diabetes Care Inc.’s Control IQ system, an automated insulin delivery system that integrates Tandem’s t:slim X2 insulin pump and Dexcom Inc.’s G6 continuous glucose monitor with an algorithm that automatically adjusts basal insulin delivery.

The Control IQ pivotal trial was a six-month, 168-subject trial showing the Control IQ system improved users’ time in range by an average of 2.6 hours. The FDA cleared Control IQ Control-IQ technology in December 2019. (Also see “Tandem Wins FDA Clearance On First Stand-Alone Glycemic Controller” - Medtech Insight, 19 Dec, 2019.)

“Clinicians will likely interpret the results between the two systems similarly,” Biegelsen wrote.
Executive Summary
Dexcom's CEO explained the company's strategy for continued growth, including marketing opportunities for its G6 and G6 Pro continuous glucose monitors and plans for the next-gen G7 CGM.

Just days before the 12 June start of the 80th virtual American Diabetes Association meeting, continuous glucose monitoring (CGM) company Dexcom Inc. announced its G6 CGM received a new CE marking in Europe and the launch of its G6 Pro CGM in the US.

The San Diego, CA-based CGM leader also recently gained temporary permission from US regulators to market its G6 CGM device in hospitals during the COVID-19 pandemic, which Dexcom's CEO Kevin Sayer sees as another important market opportunity for CGM.

Rivalry
Dexcom's rival Abbott Laboratories Inc. announced on 15 June that its next-generation FreeStyle Libre 2 gained US Food and Drug Administration clearance as an integrated CGM (iCGM) system to help adults and children ages 4 and older manage their diabetes. (Also see “Market Brief: Abbott, Dexcom Help Drive Continuous Glucose Monitoring Market; 30% Expected Growth by 2023 “ - Medtech Insight, 26 Dec, 2019.) Freestyle Libre 2 from Abbott

Dexcom was the first company to establish the iCGM category in March 2018 with the FDA de novo classification of the G6 and until now has been the only CGM maker to hold this status. Dexcom's G6 has been integrated with two insulin pump systems – Tandem Diabetes Care Inc.'s Control IQ system and Insulet Corp.'s Omnipod 5, powered by Horizon – both of which presented positive data at this year's meeting. (Also see “Market Intel: CGM Market Competition And Device Interoperability Were Hot Topics At ADA2019” - Medtech Insight, 3 Jul, 2019.)

Some industry insiders see Abbott's iCGM clearance for the FreeStyle Libre 2 as impacting Dexcom's business, but Sayer pointed out that, for now, Abbott's FreeStyle Libre 2 is not authorized for use with automated insulin dosing systems and also does not offer some of the same features.

“We still believe our G6 is far superior to Libre 2,” Sayer told Medtech Insight. He noted that while Abbott's Libre 2 received iCGM clearance, it cannot be integrated with other insulin pumps. (Also see “Market Intel: Bigfoot Biomedical, Beta Bionics Getting Pumped To Introduce Next-Gen Artificial Pancreas “ - Medtech Insight, 18 Dec, 2019.) Freestyle Libre 2 from Abbott

“‘If you have iCGM but can't interconnect, what is it exactly that we have? I don't know the answer to that question,” Sayer said. “We, with our iCGM designation, can connect with any product.”

Abbott told Medtech Insight that the Libre 2 can connect with certain technologies, such as insulin pens. Abbott also has partnerships with Tandem and Insulet to integrate its Libre system. It also has existing partnerships with Bigfoot Biomedical Inc. and Novo Nordisk AS.
The Libre 2 list price is $54 for the sensor and $70 for the reader; the same as for the company’s flagship FreeStyle Libre 14-day CGM. The device will be made available to pharmacies and durable equipment makers in the coming weeks.

Abbott said it will work on future use of the Libre 2 with automated insulin dosing algorithms.

“Abbott is focused on creating future-forward health technologies that simplify how people living with diabetes manage their condition so they can live their best lives,” said Jared Watkin, senior vice president, Diabetes Care, Abbott. “As diabetes care becomes more interoperable, we’re developing more connected approaches to improve care.”

Sayer said he’s been anticipating Abbott’s Libre 2 clearance for a while.

“We are still in a very good position and we are certainly prepared.”

**Trial Delay**

Like most medtechs, Dexcom has felt the impact of COVID-19 on its R&D operations. The company announced during its first-quarter earnings call on 28 April that it would delay the pivotal trial of its next-generation G7 CGM by at least six months.

Sayer reiterated to Medtech Insight that the company will stick to its six-month delay right now, citing some of the difficulties in getting trials started during this time of uncertainty.

“The study for these products requires a patient to be in clinic for 12 to 15 hours and drawing blood every 15 minutes and running their glucose values up and down,” he said. “We have some questions yet to answer, for example, the social distancing. If a clinic used to run four people at a time, are they going to run two, three, one? [And] How many patients can we get into a clinic and then how many new clinics can we get up and started.”

He said answering these questions will take time. Dexcom also has not projected a date for the launch of the G7, because the schedule of the studies has not been laid out. Sayer anticipates that the trial will enroll “hundreds of patients” and would not include fewer patients than the G6 trial, which included roughly 400 people; the number of clinics participating in the trial will depend on how many patients they will be able to serve.

Compared to the G6, the G7 is smaller with a shorter sensor, which makes it more comfortable for patients to wear, Sayer said. It also has no transmitter component. He added the G7 was designed for automated manufacturing, which Dexcom did not have in place until now and will begin implementing with its G6 device.

“We think ultimately we can continue to take costs out of the system and make it more affordable for our patients as well,” Sayer said. “G6 was a huge upgrade from G5, if you ask any of our patients – we’re going to do the same thing again [with the G7].”

Initially, Sayer expects that the G7 will not be priced below the G6 sensor. But he hopes to bring the cost per day down for patients, which he pointed out has been the case for the firm’s flagship G6, which also continues to be improved upon. Dexcom plans to file for FDA clearance for the G7 for attachment on the upper arm or abdomen and as an integrated CGM device, he said.

On 9 June, Dexcom announced it received the CE mark in Europe for its G6 for attachment on the back of the upper arm, providing patients more
choice on how to wear the system. The G6 has been available in the EU since 2018 for wear on the abdomen. This February it also received the CE mark for use during pregnancy.

Sayer noted that some patients have been using the device off-label on the back of the arm and the data from these patients is very encouraging. He noted that Dexcom has not done a formal study on upper arm wear for regulatory clearance in the US.

“We think that the back of the arm label combined with the pregnancy [label] is going to be a great product offering for us in that market,” Sayer noted.

But reimbursement for CGM remains challenging and differs from one country to another. For example, in Germany and Scandinavia reimbursement for CGM is very strong, “so we have very good usage there,” Sayer said. In other parts of Europe, “reimbursement is a little more spotty, but it is getting better.”

Dexcom is also working on getting reimbursement in Canada and Australia, where the G6 is also approved; in Japan, where the G6 was also recently approved for marketing, Dexcom plans to do more work on the data and analytics side before launching it there.

**Growth Markets**

On 8 June, the company also announced that it will start shipping its G6 Pro CGM to health care providers on 6 July. The device is the first and only single-use professional CGM for users two years and older that gathers data for 10 days and is marketed to health providers as a way to introduce patients who may or may not be familiar with the concept of CGMs or are reluctant to wear such a device to gain a better understanding of how CGM works. The FDA cleared the G6 Pro last October. (Also see “Dexcom Now Offers Providers G6 Pro Continuous Glucose Monitoring Systems” - Medtech Insight, 8 Jun, 2020.)

Then in April, both Dexcom and Abbott gained permission from the FDA to bring their respective CGMs – the G6 and Freestyle Libre 14-day system – into hospitals for the duration of the pandemic. Until now, CGMs have not been approved for use in hospitalized patients.

Hospitals will be able to use the devices to remotely monitor patients with diabetes, which helps minimize their exposure to COVID-19 patients and preserve the use of personal protective equipment.

Sayer told Medtech Insight earlier that he sees the hospital market as a big market opportunity.

“We have always believed our product belonged in this market,” Sayer said. It started working on a device for hospital use in the early 2000s, but shelved the project, because it could not “reach the level of performance that we’ve reached now.” The company is now gathering data and is in discussions with the FDA to gain clearance to bring its CGM into hospitals permanently.

The hospital market is different than shipping and selling to a direct patient channel and required Dexcom to implement a new infrastructure, including a new customer-support team. Sayer said the company already gained some lessons from this new distribution channel.

“We learned we need to be more specific in our training,” he said. “We’ve learned this is going to be a great market for us over time, [but] it’s going to be a different market and require different
thought, different distribution, different software solutions.”

In 2019, Dexcom had a strong year with a 43% revenue growth from the year before. Last year, its US revenue grew 42% and its international revenue grew 48%. Total revenues reached $1.5bn in 2019.

Wells Fargo’s Larry Biegelsen is also optimistic about the CGM market.

“Overall, we believe this year’s ADA meeting as positive for CGM in the coming years,” he wrote on 15 June in his analyst note. He noted that Abbott on 14 May filed three new trademarks for a product called Libre Sense, which is described as “sensors for non-medical purposes.”

“If Libre Sense is an over-the-counter product for people without diabetes, it could open a potentially large, new market for continuous glucose monitors for both Abbott and Dexcom,” he wrote.

Sayer is equally optimistic and said that CGM is also showing promise in type 2 diabetes patients as data presented at the conference have shown.

“There was a lot of type 2 data presented even for people not intensively using insulin showing that CGM in these patient cases is a wonderful outcome for patients,” he said. “By giving these patients information they can make the lifestyle changes and they can stick to make them healthier.”

“Dexcom technology continues to be at the center of this meeting,” he said. “We continue to be very important to the data that’s presented.”

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