Blueshift RESEARCH **REPORT**

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Medtronic Losing; Dexcom, Abbott, Insulet Winning in the Diabetes Market

Companies: ABT, DXCM, MDT, MNKD, PODD, SENS, TNDM

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Report Type: ☑ Previously Covered ☑ Full Report

Ratings: **ABT** 4/5 **DXCM** 4/5 **MDT** 2.5/5 **TNDM** 4/5 **PODD** 4/5

Research Question:

Are any of the diabetes wearables market's key players setting themselves apart and gaining significant share?

Summary of Findings

- The diabetes wearable market is growing and its key device providers are secure in their market-leading positions. These companies also have tremendous growth opportunities if the pharmacy distribution channel is expanded and third-party payers and Medicare continue to underwrite and support the use of wearable devices for the large Type 2 diabetes patient population.
- Dexcom Inc.'s (DXCM) G6 is expected to continue to dominate the continuous glucose monitoring (CGM) market with the Type 1 patient population. When its G7 is approved, Dexcom is expected to continue that dominance and make meaningful inroads into the Type 2 diabetic population. Dexcom is praised for its accuracy, dependability, and ability to integrate with other devices.
- Abbott Laboratories' (ABT) FreeStyle Libre will also remain a top CGM provider and is the preferred CGM in the Type 2 patient group. When approved in the U.S., the Libre 3, which will be able to integrate with insulin pumps, is expected to drive additional growth. Libre's strengths are its low cost and ease of use.
- Tandem Diabetes Care Inc.'s (TNDM) t:slim X2 with Control-IQ Technology combined with Dexcom's G6 continues to be the leading technology in the insulin pump space. Its next-gen t:sport, expected to be approved later this year, will keep Tandem well ahead of the competition.
- Insulet Corp.'s (PODD) Omnipod is gaining share and has moved beyond mainly being an excellent device for children to favored by active adults. Insulet's next-gen Omnipod 5 (formally known as Horizon), when launched, will integrate with both Dexcom's G6 and Abbott's Libre and has the potential to be disruptive in the market.
- Medtronic PLC (MDT) continues to lose share and patient trust in both the CGM and insulin pump markets. Still, some sources said the company's medical device might and its next-gen MiniMed 780G should allow it to be competitive in the future.
- Several competitors were discussed as offering promising technology, including CeQur SA's Simplicity insulin patch, V-Go (Zealand Pharma A/S/ZEAL), Beta Bionics' iLet, Medtronic's InPen, and Bigfoot Biomedical's collaboration with the DIY diabetic community—but nothing is considered to be disruptive near term.
- Headwinds challenging expansion into the Type 2 population include the use of AstraZeneca PLC's (AZN) Farxiga and Novo Nordisk A/S' (NVO) GLP-1 agonist Victoza, which can delay the use of insulin for these patients.

Silo Summaries

1) Endocrinologists/Members of their Medical Team

Two endocrinologists and one of two physician assistants specializing in providing care to diabetics see **the Type 2 patient population as a major growth opportunity for CGM. One said within the next five years CGM use will explode and become a consumer product. Another commented that when Medicare supports the use of CGM in the Type 2 population, growth will take off. Dexcom's G6 and G7 and Abbott's Libre 2 and 3 are expected to dominate the CGM market. The pump market will be dominated by Tandem, with Insulet gaining prominence because of its pharmacy vs. DME distribution. Medtronic continues to lose share and is considered well behind the competition.**

2) Nurse Educators

Two nurse educators expect **significant growth in the use of CGM for both Type 1 and 2 diabetic patients. One source said it will be a consumer product within 10 to 15 years. Pump use is expected to continue growing** but will face significant challenges, including insurance coverage, high out-of-pocket costs, patient reluctance to wearing a device, and the guidance from diabetic organizations to delay the use of insulin in the Type 2 patient population. **Both sources favor Libre 2, which has the low cost and ease of use competitive advantage. Both sources acknowledge Medtronic and Tandem as the leading insulin pump manufacturers.** One source said Medtronic is favored at their clinic, the other said Tandem has the advantage of updateable software.

3) Diabetes Sales Channel and Competitors

Four of the five sources representing competitive wearable diabetes devices think **significant growth near or higher than published projections will occur. Dexcom and Abbott are expected to continue to dominate the CGM market. In the insulin pump space, Tandem is the clear and dominant provider, Insulet's Omnipod is gaining with active adults, and one source said when it can integrate with CGM it could be disruptive. Medtronic is losing share and patient confidence.**

4) Industry Specialists

Growth in CGM at 38% sounds correct but double-digit growth in the pump sector is a stretch. Gaining market share in Type 2 diabetes patients has been more difficult than companies expected. Only 25% are insulin dependent and the majority of Type 2 patients simply do not need constant glucose monitoring.

Continuous Glucose Monitoring and Insulin Pump Market

	CGM Market Growth	Insulin Pump Market Growth	Wearable Adoption by Type 2 Patients
Endocrinologists/Members of their Medical Team	↑	↑	↑
Nurse Educators	↑	↑	↑
Diabetes Sales Channel and Competitors	↑	↑	↑
Industry Specialists	↑	↑	↑

Background

Blueshift Research's past coverage of the diabetes space has been overwhelmingly positive for all the major players, with the exception of Medtronic, which was experiencing share losses due to a recall and its older technology. Our Sept. 3, 2020 insulin pump report noted that CGM and insulin pump markets are both expected to experience accelerated growth over the next two years, driven by the increasing incidence of diabetes, improved awareness of the disease and its treatments by both providers and patients, technology advancements, collaborations, and DIY organization pressure. Sources discussed growth rates from 10% to 75%. Tossing the extremes, the average expected growth rate was 23%. Past Blueshift coverage of the CGM and insulin pump markets includes our March 26, 2020, report citing Dexcom as the leader in the CGM market. The Oct. 23, 2019, report update revealed Dexcom's and Tandem's growth trends would not be disrupted over the next six to 12 months and Blueshift's June 19, 2019, Tandem report and April 25, 2019, Dexcom report reflected positive findings.

Blueshift's ongoing research found the continuous glucose monitoring and insulin pump market experiencing strong and increasing demand, despite the negative impact and volatility the COVID-19 pandemic has had on other medical device companies. The pandemic is driving rapid adoption of telehealth and virtual care as patients and the companies that make devices are all trying to benefit from the significant increase in tech-driven services and wearable devices. In the diabetes space, Dexcom, Abbott, Medtronic, Tandem, and Insulet have all experienced solid performance and growth, and each has plans for new product launches and collaborations in 2021. What is unknown is if any of these providers can significantly disrupt the current share balance.

CGM and insulin pump market expansion expectations are running high, thanks to the explosive adoption and use of telehealth and virtual care during the pandemic. According to a survey from SVB Leerink of endocrinologists and nurse practitioners, CGM patients are projected to jump by 38% in 2021 and 29% in 2022. Another survey by SVB Leerink projects insulin pump use to expand by double digits. Type 2 diabetics are being targeted as the primary growth driver for CGM devices, as that market is large, under-penetrated, and growing.

After delaying the G7 launch due to COVID-19's disruption of its clinical trials, Dexcom said it plans to submit the G7 for FDA approval as soon as possible in 2021 and plans for a limited launch late in the year. The G7 will be thinner, provide longer wear time, be less costly to produce, and is expected to appeal to some of the Type 2 patient population.

After launching the Libre 2 in the U.S. in 2020, Abbott is planning an update in 2021 to the Libre 3. The new device will be smaller and provide a real-time glucose reading every minute on a compatible mobile app, compared to Libre 2's flash readings.

In the insulin pump market, Tandem's Control-IQ technology was the first FDA-cleared algorithm for use with a fully interoperable, automated insulin dosing system in 2020. This year the company is expanding the launch of Control-IQ in Canada, Germany, and France. Tandem is also working on a mobile bolusing feature and making progress on its t:sport insulin pump, which should be commercialized in early 2022.

Medtronic is the only provider in the diabetes space offering both a CGM and insulin pump. Plans call for a 2021 U.S. launch of its next-gen MiniMed 780G pump system, which is currently available in Europe. Medtronic has also entered into a cross-patent agreement with Tandem, which should help both companies.

Continuous Glucose Monitoring and Insulin Pump Market

Insulet plans a limited launch for its Omnipod 5 insulin pump during the first half of 2021. The company recently presented data at the Endo 2021 meeting, indicating that the Omnipod 5 is highly effective in treating the traditionally hard-to-control pediatric population. The device incorporates the Dexcom G6 CGM system.

Seemingly, the only headwind that could disrupt the growth and expansion of the diabetes market would be further outbreaks of COVID-19, which would slow device approvals as the FDA has committed to addressing the needs of fighting the pandemic ahead of other device and pharma approvals. There is also an element of the medical community questioning the expansion of CGM into the Type 2 diabetes patient population, as there is limited evidence that it leads to better outcomes.

Current Research

Blueshift Research assessed whether any of the diabetes wearables market's key players are setting themselves apart and gaining significant share. We employed our pattern mining approach to establish five independent silos, comprising 12 primary sources (including six repeat sources) and three secondary sources focused on the CGM and insulin pump market. Interviews were conducted May 17–June 4.

1) Endocrinologists/members of their medical team (4)
2) Nurse educators (2)
3) Diabetes sales channel and competitors (5)
4) Industry specialists (1)
5) Secondary sources (3)

Next Steps

Blueshift Research will continue to research the major diabetic CGM and pump companies as they move into the Type 2 patient population to determine who is gaining share. We will also review the next-gen products from each provider to determine if any have the potential to disrupt the current market alignment.

Silos

1) Endocrinologists/Members of their Medical Team

Two endocrinologists and one of two physician assistants (PA) specializing in providing care to diabetics see the Type 2 patient population as a major growth opportunity for the use of CGM. One source said within the next five years CGM use will explode and become a consumer product. Another commented that when Medicare supports the use of CGM in the Type 2 population, growth will take off. The other PA does not expect growth for either CGM or insulin pumps to be rapid and make significant inroads with the Type 2 diabetic population. Dexcom's G6 and G7 and Abbott's Libre 2 and 3 systems are expected to continue to dominate the CGM market. Dexcom was praised for its accuracy and dependability and, when approved in the U.S., the G7 is expected to enhance that market-leading position. Libre's ease of use and low cost will continue its viability in the CGM space. The insulin pump market will continue to grow, but at a slower pace than the CGM market. The two sources that commented had differing opinions on the insulin-using Type 2 patient population's future use of pumps—one said it is a huge opportunity and Insulet is well positioned, while the other said Type 2 insulin users are more apt to adopt the insulin pen vs. a pump. The pump market will continue to be dominated by Tandem, with Insulet gaining prominence in part because of its pharmacy distribution vs. DME distribution. Medtronic continues to lose share and is considered well behind the competition. Beta Bionics is still considered a future player in the space but one source noted its yet-to-be-FDA-approved closed-loop system using both insulin and glucagon is unlikely to catch on.

Key Silo Findings

CGM and Insulin Pump Market Conditions

- 3 expect significant diabetes wearable device growth for both Type 1 and 2 diabetics.
  - 1 said they expect all diabetics to use CGM in the near future, with the Type 2 patient as the next frontier.
  - 1 said if Medicare gets on board, wearable device use for Type 2 patients will soar.
  - 1 said CGM use for Type 2 patients will "explode" over the next five years. However, insulin pump use in the Type 2 population will be limited, as pens are favored.

- 1 said the published growth expectations and penetration of the Type 2 population for CGM and insulin pump use are exaggerated; however, the market will be stable.

CGM Competitive Landscape

- Dexcom's G6 and, eventually, G7 and Abbott Libre 2 and 3 are expected to continue to dominate the CGM market.
  - Dexcom was praised for its accuracy and dependability.
  - Libre was praised for its low cost and ease of use.

Insulin Pump Competitive Landscape

- Tandem dominates the insulin pump market and that is expected to continue.
- Insulet's Omnipod is gaining share, in part because of its distribution through the pharmacy channel.
- Medtronic continues to lose share and is considered well behind the competition technologically.
- Beta Bionics is considered a future competitor; however, its insulin and glucagon pump is unlikely to gain significant traction.

1) Major university academic and research endocrinologist; repeat source

All diabetics will use CGM in the near future and those choosing not to "wear" will be the exception. For the next few years, Tandem followed by Insulet will have the best insulin pumps. Beta Bionics is still some time off. Medtronic has inferior products but its very large sales force allows it to push products. For CGM, Dexcom will continue to lead the market but Libre has a place. There is no real data to support use and reimbursement for the non-insulin-dependent Type 2 patients but that is the next frontier.

Sept. 3, 2020, interview summary: This diabetic research-focused endocrinologist sees continued growth of insulin pumps as more products come to market that are easier to use, better integrated, and more competitive in pricing. Tandem is the leader. Medtronic has work to do and Insulet growth opportunities are more limited. He does not perceive much growth over the next two years with Type 2 patient adoption. Next year Beta Bionics could make waves in the market—he thinks they will launch as an insulin pump and, probably one year later, will integrate glucagon.

March 26, 2020, interview summary: This source believes the recall will cause Medtronic sales to continue to decline until they have a new product on the market. Tandem is the leader and sales of its Control-IQ pump will continue to grow. Both Beta Bionics and Tidepool Loop will be important but will not be on the market for more than a year.

Oct. 23, 2019, Dexcom-Tandem interview summary: This source sees Dexcom and Tandem as both well positioned to remain dominant for the foreseeable future. The Control-IQ and t:sport pump are significant innovations for Tandem's future, as is the recently announced partnership with Abbott. Interoperability is the way of the future. The new partnerships for Abbott with Tandem and Omada Health may be a future threat to Dexcom.

CGM and Insulin Pump Market Conditions

- "I really can't speak to growth rates but I do foresee CGM being used for all diabetics in the near future. Of course, there will always be some people that do not want to 'wear' something—but this will be the exception."
- "There is no real data for the Type 2 non-insulin-dependent diabetic patient using wearables but that is the next frontier."

CGM Competitive Landscape

- "Dexcom is the best of the CGM and the G7 should strengthen its position. Dependable, best accuracy, and new product should reduce the patient burden."
- "Libre 2 not as versatile but relatively cheap and easy to use. It has its place."
- "Eversense [from Senseonics Holdings Inc./SENS] involves a procedure and is not a viable option at this time."
- "Medtronic has an inferior device."
- "Generally speaking, Medtronic has inferior products but they have a very large sales force that can really push stuff and will always be a factor."

I do foresee CGM being used for all diabetics in the near future. … There is no real data for the Type 2 non-insulin-dependent diabetic patient using wearables but that is the next frontier.

Major university academic and research endocrinologist

Insulin Pump Competitive Landscape

- "For pumps, in the next years I would say the 'best' products will be Tandem and Insulet, followed by Medtronic. Beta Bionics is still some time off and I don't know how they will stack up, as it depends on what other products look like at the that time."

2) Physician assistant that manages insulin pump patients at a major university clinic; repeat source

This Type 1 diabetic and primary care provider for pump users at a major university diabetes clinic thinks Dexcom's and Libre's CGM market dominance will continue. Libre's ease of use and Dexcom's accuracy are the key to their market leadership. In the pump space, Tandem's rapid growth is expected to continue, due to strong endorsement from users and its excellent reputation. Medtronic continues to lose share and is considered a second-tier device. Type 2 diabetics that require insulin are a huge opportunity for pump manufacturers and Insulet's Omnipod distribution through the pharmacy channel is a significant competitive advantage. Beta Bionics' approach—using both insulin and glucagon for its closed-loop system—is not expected to catch on because the new insulins are faster acting and reduce the need to introduce glucagon. Bigfoot Biomedical's work with Tidepool called "loop" is considered worth keeping an eye on and its collaboration with Medtronic's InPen is also considered a positive.

Sept. 3, 2020, interview summary: This provider is a long-time Type 1 diabetes patient, which gives her added insight into the clinical and lifestyle considerations of various technologies and products. She is a primary provider within the division of endocrinology at a major private university-based research institution in the Southeast who manages all of their pump patients and is considered the division's pump expert. She indicates that Tandem's and Insulet's current growth rates are likely to continue. Tandem's reputation, technology, lifestyle, and broad insurance coverage are driving its growth. Insulet is popular with active diabetics and parents with diabetic children. Insurance coverage is the driver in a patient's decision process regarding which system they will use. While technology development is important, it is fairly irrelevant if the patient's insurance company does not cover that company's products. Dexcom CGM will maintain is lead domestically, while Eversense's CGM is gaining traction outside the United States.

March 26, 2020, interview summary: This source has both personal and professional experience with all of the major pump manufacturers. At her clinic Medtronic pumps are considered second tier. Confidence in Medtronic's pumps is declining, as is their market share. Tandem is the pump of choice for the younger population and is expected to gain share until the next technology breakthrough emerges. She does not actively steer her patients to any one manufacturer but relies on the recommendations of her nurse educators and patient preferences related to their lifestyles.

CGM and Insulin Pump Market Conditions

- "The more and more people who use Tandem, the faster it keeps growing. This is a very well socially connected group of people who rely on the recommendations of their diabetic friends. Tandem has a wonderful reputation."
- "While we were talking, I found the data about the prevalence of the two types of diabetes. Type 2 accounts for about 90% of all diabetes in the U.S., Canada, and Europe, with Type 1 as 5% to 10% and the remainder the rare genetic forms of diabetes (MODY, etc.). So, whichever pump company can reach the Type 2 community the fastest will have the best monetary gain. Right now, it seems like Omnipod has the advantage here because they are generally covered under a pharmacy benefit instead of medical/DME, making it easier for providers to prescribe and patients to get."
- "Private insurers are covering these devices pretty well, with the exception of United Health Care that has a contract with Medtronic. If Medicare gets on board better for the Type 2 patients, the market will soar. They are currently only covering devices for patients who require at least three shots daily."
- "There has been quite a bit of talk about Beta Bionics' development of a closed-loop system using both insulin and glucagon. I really don't think that this will take off. It just won't be necessary because there are new fast-acting insulins being developed (e.g., [Eli] Lilly [and Co./LLY] has a new one called Lyumjev). The problem with insulin is that is does not act fast enough but, with Lilly's new product and others like Humalog, insulin titration is getting to be more effective and is certainly easier than introducing glucagon into the equation."

CGM Competitive Landscape

- "Dexcom and Libre will continue to be the leaders in the future. Libre is easier to place and to use, so is preferred by the primary care providers. Dexcom's accuracy and reporting are superior, so they are preferred by diabetologists."

Insulin Pump Competitive Landscape

- "Not much has changed since we talked last. There are a couple DIY efforts going on but they are very small in comparison."
- "Medtronic is still losing market share and that will continue. They just can't compete with Dexcom and Libre, who will continue to lead and gain even more share."
- "When I get new Medtronic patients, frequently they won't even know that there is newer, better technology available. When they learn about what is available, every one of them has switched."
- "At our institution, Medtronic is considered to be a second-tier device. They offer no advantages, except perhaps familiarity to long-term users, and have some disadvantages that they say they are working on but don't seem to be making any real headway."
- "Some of the new pumps can accommodate pre-set bolus injections so that the patients don't have to calculate the carbs that they are eating and do the math in their heads. It is effective and just a lot easier. Please understand that confidence and ease of use are huge drivers in this field."

Dexcom and Libre will continue to be the leaders in the future. Libre is easier to place and to use, so is preferred by the primary care providers. Dexcom's accuracy and reporting are superior, so they are preferred by diabetologists.

Physician assistant that manages insulin pump patients at a major university clinic

Miscellaneous

- "Keep an eye on Bigfoot. They are working with the DIYers and Tidepool to develop a closed-loop system. They have helped fund a study that will be going to the FDA shortly with a product called 'loop'."
- "Bigfoot and InPen [owned by Medtronic] are also developing smart pens that are designed to make the insulin injection process better controlled and easier for patients who prefer to do their own injections."

3) Endocrinologist and researcher at a leading nonprofit diabetes research institute

CGM use will explode in the medium term (more than five years) with the publication of better and more personalized disease management potential in the Type 2 diabetes population. CGM will ultimately become a consumer product. For Type 1 patients in the U.S., pump utilization has essentially reached saturation. The main opportunity lies in converting pump users to closed-loop systems and Tandem offers a very good option. Within the next five years, most Type 1 patients will be on a closed-loop system. Type 2 patients are more likely to adopt pen injectors but InPen is at a clear disadvantage because it does not display the insulin dose. Patch technology is not well developed. GLP-1 drugs that control glycemic control in addition to supporting weight loss and improved metabolic parameters are poised to shift the Type 2 market from device options.

CGM and Insulin Pump Market Conditions

- "I think there will be an explosion in Type 2 patients utilizing CGM in the medium term because new research, yet to be published, clearly demonstrates the insights we can gain for people with metabolic abnormalities. This insight will lead to more effective, personalized care and preventive, more cost-effective disease management."
- "Pump utilization has reached saturation for Type 1 in the United States. I also do not believe pump systems will be of much interest for Type 2 patients, especially because pen injectors will become more available."

CGM Competitive Landscape

- "The sheer volume of people at risk of Type 2 diabetes is crying out for more effective lifestyle interventions. I expect that in the not too distant future, CGM will become a consumer product."

Insulin Pump Competitive Landscape

- "The main opportunity for pumps relies on a closed-loop system. Tandem has a very good option and they may gain market share but most people who convert to closed loop are already on a pump, so they are not capturing a naïve population."
- "The majority of Type 1 patients will be on a closed-loop system within five years."
- "InPen has a major Achilles heel, as it does not display the insulin dose given."
- "The patch technology has been around for a while but it has not progressed. It is not developed enough to be an effective tool."

Miscellaneous

- "95% of diabetes patients are Type 2. Newer drugs, e.g. GLP-1, appear quite effective with glycemic control and offer the added benefit of weight loss and improved cardiometabolic parameters. These drugs will squeeze the system."

4) Physician assistant managing diabetic patients at a dominant academic research and quaternary medical center in the south

The talk about the potential for rapid increase in market growth for insulin pumps and CGMs is just talk and the optimism for the opportunity with Type 2 patients is overblown. The applicability of using monitors for Type 2 patients is there but is not a dependable and rational market-driven situation. Using diabetes wearables is a much more personal decision-making process on the part of patients than anything else. No monumental innovation is on the horizon but, as companies gradually develop devices that can work together more flexibly, they are the ones who will dominate. Medtronic is losing share, as almost no new patients are choosing its devices; it is well behind the competition.

CGM and Insulin Pump Market Conditions

- "Dexcom G7 is looking really interesting but it isn't FDA approved yet. Any partner with Dexcom has been leading the field and will continue. These are very impressive combinations."
- "The talk about an artificial pancreas is just that—talk. This isn't where the technology and management of patients is going to be going. The use of rapid-acting insulin with micro-boluses will obviate the need for developing an insulin/glucagon combination technology. There just won't be the need for the incredibly complex systems required to develop an artificial pancreas."
- "I see the market as being fairly stable as I am looking into the foreseeable future. Type 1 patients are generally comfortable with where they are and are very few in numbers in comparison to Type 2 [patient]s. Most Type 2 patients aren't pump candidates, as they won't agree to carb counting. Some are candidates for monitors, but not all. Again, it's largely lifestyle and comfort that will determine their use of this technology."

CGM Competitive Landscape

- "I don't agree with [38% growth for CGM this year] at all. CGM use in Type 2 patients may increase somewhat in the next couple of years but, due to many factors—including how primary care providers manage them vs. how endocrinologists manage them, to cost/reimbursement issues, lifestyle, comfort with technology, willingness to count carbs, and otherwise being interested in being deeply involved in their disease management, etc.—the Type 2 CGM market will grow conservatively. The Type 2 use of pumps is not really going anywhere in the foreseeable future."

Insulin Pump Competitive Landscape

- "Tandem, which is now looping with Dexcom, is the absolute leader in the market, in my opinion. The others are OK but are not innovating fast enough to keep up."
- "Medtronic was the first but is losing market rapidly. Almost no new patients are choosing them and many long-time users are switching as soon as they can."
- "Omipod's tubelessness has and will continue to attract the younger, more active patients. Don't underestimate the importance of lifestyle issues in the decision making by patients here."
- "There is some innovation going on with CGMs but nothing that looks earthshaking at all. I don't see any significant breakthroughs on the horizon. Maybe the most innovative actions coming up are the new looping combinations of various pumps and monitors. The more flexibility, the better, from a competitive position."
- "While there is some amount of pricing pressure, the insurance coverage is starting to be getting pretty good, so decisions by patients are tending to be more related to lifestyle and comfort with technology."

> **Tandem, which is now looping with Dexcom, is the absolute leader in the market, in my opinion. The others are OK but are not innovating fast enough to keep up.**
>
> *Physician assistant managing diabetic patients at a dominant academic research and quaternary medical center in the south*

Miscellaneous

- "In order to safely manage someone on a pump, the provider has to have the ability to download the data and be able to understand and manage a large amount of information. If that doesn't exist, as is the case in many primary care settings, the whole approach to the use of technology vs. the old standard way of using injections will continue to hold down the growth of technology. This isn't so much the case when an endocrinologist is the managing provider. So the mix of who the providers are will also directly impact the expansion of this technology."

2) Nurse Educators

Two nurse educators expect significant growth in the use of CGM for both Type 1 and 2 diabetic patients. One source said it will be a consumer product within 10 to 15 years. Pump use is expected to continue growing but will face significant challenges, including insurance coverage, high out-of-pocket costs, patient reluctance to wearing a device, and the guidance from diabetic organizations to delay the use of insulin in the Type 2 patient population in favor of Farxiga and GLP-1 agonist Victoza. Both sources favor Libre 2, which has the low cost and ease of use competitive advantage. Dexcom offers high accuracy and ease of monitoring a patient's condition. Eversense is considered to be at a disadvantage because it has to be implanted, which is not performed by nurse educators. Both sources acknowledge Medtronic and Tandem as the leading insulin pump manufacturers. One source said Medtronic is favored at their clinic, the other said Tandem has the advantage of updateable software but they added that the Medtronic MiniMed 780G, when approved, would match that feature. Insulet's Omnipod is not offered at VA diabetic facilities. InPen is considered strong technology with solid data. One said MannKind Corp.'s (MNKD) fast-acting, inhaled insulin Afrezza is experiencing a renaissance with Type 2 diabetics.

Key Silo Findings

CGM and Insulin Pump Market Conditions
- 2 expect continued growth for the CGM market.
  - 1 said growth will be huge, including the Type 2 population.
  - 1 said 35% growth will be attained and CGM will be a consumer product within 10 to 15 years.
- Insulin pump usage is expected to grow but there are headwinds, including third-party coverage, high out-of-pocket costs, patient reluctance to wearing a device ,and guidance for Type 2 patients to avoid insulin as long as they can.

CGM Competitive Landscape
- 2 sources favor Libre because of its low cost and ease of use.
- Dexcom was cited as offering high accuracy and easy monitoring of a patient's condition.
- Eversense is considered at a disadvantage because of the implanted sensor, which patients are not positive about and which cannot be performed by a nurse educator.

Insulin Pump Competitive Landscape
- 1 said Medtronic is the leading pump at her clinic, with Tandem second.
- Tandem's downloadable software feature is considered a competitive advantage but Medtronic's 780, when approved, will match it.
- Omnipod is not offered at VA clinics.
- InPen has solid data and is considered a solid technology.

Miscellaneous
- MannKind's fast-acting, inhaled insulin Afrezza has resolved its dosing issue and is gaining with Type 2 diabetics.

1) Diabetic nurse educator and CDCES in the VA system in the Great Lakes area; repeat source

This source expects huge growth with Type 2 diabetic patients of CGM, similar to the 30% (non-insulin-dependent) to 55% (insulin-dependent) range in her clinic. She prefers the Libre 2 for its price and ease of use but also views the Dexcom G6 as valuable, due to its accuracy and ease for monitoring patients. The Eversense by Senseonics is a device the nurse educators cannot place/implant. Regarding insulin pumps, Medtronic remains the top choice in the clinic, with Tandem second. The VA does not carry Omnipod and little interest in it has been shown.

Sept. 3, 2020, interview summary: This outpatient nurse educator sees continued growth in the CGM market, with the Libre 2 as a marketplace disruptor for CGM. Non-integration with insulin pumps is not a major concern and will be worked out. The insulin pump market will see significant growth and should move to 30% of all Type 1 diabetics, with Tandem as leader. This source believes Medtronic has lost support but should rise to the occasion and resolve their MiniMed problems. Insulet patients remain pleased with the product and the company should continue with its current growth.

Tandem should continue to grow at 15%. Type 2 patient growth will be significant for CGM but this source does not foresee growth in the pump market in the next 2 years for this segment.

March 26, 2020, interview summary: Medtronic has been very active in following up after the recall and is inspecting all MiniMed pumps. This source has not seen any patients switching from the MiniMed due to the recall but believes that, if there have been switches, they would be to the Tandem t:slim X2. The MiniMed 600 series has historically had many patient complaints due to the frequency of calibration and problems with accuracy. The t:slim X2 Control-IQ system is exciting, and they believe it will gain healthcare professional support over its competitors.

June 19, 2019, Tandem interview summary: Most of the people with diabetes at this facility are older and have Type 2 diabetes, so they would not qualify for a pump. Patients who use a pump are losing interest in Medtronic's 670G because they have experienced or heard complaints about the system's frequent and lengthy alerts. This VA decided to add Tandem's t:slim to its formulary because they heard it was easy; however, they are having difficulty getting Tandem's sales reps and educators to come to their facility. Patients are also anxious to try the Dexcom, which they have heard positive things about. Their patients are not particularly interested in wireless, although some ask for an Omnipod, and some express interest in a closed-loop system.

CGM and Insulin Pump Market Conditions

- Did not discuss.

CGM Competitive Landscape

- "I am sure we have the data to support the huge growth in CGM use. I believe the growth in Type 2 diabetes that has been projected to peak at 30% of non-insulin users and 55% of insulin users in Type 2 is happening. I am not sure about the exact statistics but I see the growth on the clinical side."
- "Libre 2 has an advantage in its lower price and it is quite easy to use."
- "Senseonics' Eversense has a disadvantage in that diabetes educators cannot place it, as it requires a more complex procedure."
- "Dexcom's strength is its accuracy and ease of monitoring patients."

Insulin Pump Competitive Landscape

- "Since COVID, I have not been working as much with pumps. I would say that the Medtronic is the best for us, Tandem second best. Insulet would be the last but please note the VA does not carry the Omnipod at this time."

I am sure we have the data to support the huge growth in CGM use. I believe the growth in Type 2 diabetes that has been projected to peak at 30% of non-insulin users and 55% of insulin users in Type 2 is happening. I am not sure about the exact statistics but I see the growth on the clinical side.

Diabetic nurse educator and CDCES in the VA system in the Great Lakes area

2) Clinical nurse educator

CGM will grow 35% year over year and become a consumer product within 15 years. Insulin pump market growth will align with bolus insulin-dependent patients. Early pump utilization is becoming the standard of care for Type 1 patients to improve time-in-range. Challenges with Type 2 patient expansion include insurance, out-of-pocket costs, reluctance to wear a device, and the new AACE (American Association of Clinical Endocrinology) and ADA (American Diabetes Association) guidelines delaying the use of insulin in these patients. Inpatient CGM utilization beyond diabetes is an untapped market, highlighted by the recent COVID-19 crisis. Libre sets the standard for consumer CGM convenience. The Eversense implantable CGM is at a disadvantage as a direct result of the implantation requirement. Medtronic and Tandem are the big pump players, with the latter having the software upgrade advantage, although Medtronic is expected to introduce this feature. Most pumpers stick with the brand recommended by their endocrinology team. InPen has shown some compelling data, with results similar to hybrid closed-loop systems. Game changers will include the introduction of glucagon and insulin pumps (whatever CGM is integrated will have a distinct advantage), agnostic pump integration, and faster acting insulin pump compatibility. Inhaled insulin is something to watch.

CGM and Insulin Pump Market Conditions

- "40% year-over-year growth in CGM may be a little aggressive. It is probably more like 35%. CGM will become even more normalized and the prices will come down, akin to the fingertip oxygen sensors that one can now purchase at any drug store for $25 to $45. Consumerization of over-the-counter CGM technology is coming in the next 10 to 15 years."

- "Insurance qualification, coverage, and out-of-pocket costs remain factors that limit market expansion."
- "I have no strong sense for the growth of pumps but it will be aligned with CGM growth among Type 1 and [mealtime] insulin-dependent patients overall."
- "The American Association of Clinical Endocrinology and the American Diabetes Association both have statements supporting weight neutrality in Type 2 diabetes management. They recommend delaying the use of insulin in the population as long as possible because of the associated weight gain. They are pushing early and aggressive intervention with therapeutics including Farxiga and GLP-1 agonist Victoza that juice Type 2 patients just enough to avoid insulin use."
- "Where once someone needed to fail with daily multiple injections, insulin pumps are now the standard of care for Type 1. More endocrinologists are pushing early pump use in this population. We are learning that if we can get time-in-range to 70%, we're significantly reducing adverse events and comorbidities. Pumps are not a luxury for these patients."
- "Hybrid closed-loop systems provide a means to significantly improve glycemic control. Patients learn what foods are kryptonite for them specifically and how to address it. This would never be possible without these systems."
- "Living with insulin-dependent diabetes is like doing a science experiment every day. Patients are expected to act like an organ of the body but the calculations can be tough. Most cannot adequately manage with just four finger sticks a day. Wearables allow for immediate and ongoing feedback. Without a CGM, a patient cannot track what is happening in real time and adjust for optimal disease management."

> **40% year-over-year growth in CGM may be a little aggressive. It is probably more like 35%. CGM will become even more normalized and the prices will come down … Consumerization of over-the-counter CGM technology is coming in the next 10 to 15 years.**
>
> *Clinical nurse educator*

- "Type 2 diabetes incidence is on the rise, but so is latent, adult-onset autoimmune Type 1 diabetes. It puts a lot of pressure on primary care providers to get more educated and proactive, whereas these doctors have historically been timid about having anything to do with insulin management."
- "COVID has really pushed the reliability of CGM to more accurately track glycemic patterns of inpatients for more than just diabetes (e.g., cardiac patients). The inpatient market is relatively untapped and companies like Glytec are improving the utilization with proprietary algorithms for decision support (instead of the typical basal/bolus approach, which can be dangerous). When we actually get to more value-based purchasing in the hospital, there will be acute interest in tight glycemic control to avoid adverse events with the higher associated care costs."
- "The two-week (insurance covered) CGM diagnostic trials are very limited in value. The data is hidden during the two weeks and only reviewed with the doctor at the end of the process, which severely limits the utility and learning. The magic of CGM is the ability to react in real time."

CGM Competitive Landscape

- "Libre set the standard for consumer CGM convenience: accuracy over 14 days, with the convenience of an adhesive so people can take a shower."
- "When closed-loop (glucagon plus insulin) pumps become available, they will be the driving force for Type 1/bolus-mealtime insulin-dependent patients. Integration will be the competitive differentiator for CGM devices."
- "There is a real psychological barrier against something inserted into the body. This is not true just for pumps. The Eversense (90-day) implantable CGM has a real ick factor to it."

Insulin Pump Competitive Landscape

- "Agnostic pump integration would be game changing. The Tidepool do-it-yourselfers are a clear indication that the diabetes community is tired of being held captive by the manufacturers."
- "Medtronic and Tandem are the big pump players. The greatest benefit to Tandem is the ability to download updates but the Medtronic 780 is expected to have this feature also. Most pumpers stick with their original pump brand. It is usually the one favored by, and familiar to, their endocrinologist practice. Those care teams are typically most strongly influenced by the relationship and quality of service of their sales representatives."
- "InPen recently published data showing very similar results to hybrid closed-loop systems for glycemic control using the Smart Pen multiple daily injections. It is a slick technology."
- "Another game changer will be when faster-acting insulin is available for use with a pump system. The current 'fast-acting' insulin is well and good but patients should still be bolusing."

Miscellaneous

- "The Afrezza inhaled insulin for Type 2 diabetics is experiencing a renaissance. It is super rapid onset and out of the system within 90 minutes. The incidence of post-prandial hypoglycemia is also very low. It originally fell out of favor due to limitations in dosing, which has been resolved. I do not, however, see much commercial mention of the product."

3) Diabetes Sales Channel and Competitors

Four of the five sources representing competitive wearable diabetes devices think significant growth near or higher than published projections will occur. The one dissenter said the projected growth numbers are overstated, as manufacturers are exaggerating the opportunity. He added that the CGM market is semi-saturated and the products are becoming commoditized. For insulin pumps, he said growth could reach low double digits; however, 6% to 7% growth is likely. Dexcom and Abbott are expected to continue to dominate the CGM market, with Type 1 patients favoring Dexcom and Type 2 patients preferring Abbott's Libre. In the insulin pump space, Tandem is the clear and dominant provider, Insulet's Omnipod is gaining with active adults, and one source said when it can integrate with CGM it could be disruptive. Medtronic is losing share and patient confidence but one source noted that the company is a major player and will continue to be a factor, while another said the 780 should be more competitive with Tandem. Several different companies expected to make gains in the diabetes wearable market include Bigfoot, CeQur, V-Go, Beta Bionics, and InPen; however, no one is expected to disrupt the current market dynamics.

Key Silo Findings

CGM and Insulin Pump Market Conditions

- 4 said insulin wearable device use will grow near or higher than published projections.
- 1 said the use of wearables will grow but not at the projected levels, which are exaggerated.

CGM Competitive Landscape

- Dexcom and Abbott are expected to continue to dominate the CGM space. Dexcom will lead in the Type 1 patient population, while Abbot's Libre will dominate in the Type 2 group.

Insulin Pump Competitive Landscape

- Tandem is the dominant insulin pump provider.
- Insulet's Omnipod is gaining share with active adults. One source added that when it integrates with CGM it could be disruptive.
- Medtronic is losing share and patient confidence. One source said because of Medtronic's size it will continue to compete; another said the approval and launch of the 780 will make it more competitive.
- Several companies were discussed as having an opportunity to gain share in the diabetes wearable space, including Bigfoot, CeQur, V-Go, Beta Bionics, and InPen, yet no company is expected to significantly disrupt the current market alignment.

1) Insulin pump sales professional in the Southeast

CGM growth will be higher than projected and pump growth will be in the 10% to 20% range. CGM market growth will be with Dexcom—the leader—and, secondly, Abbott. Dexcom's G7 and Abbott's Libre 3 will facilitate growth, patient acceptance, and ease of reimbursement. Aesthetically, G7 will help to overcome the G6 device look and reduce the burden/clumsiness of the G6. If it is able to penetrate the pharmacy channel, this will be well received by patients. With insulin pumps, this source feels the Omnipod 5 can be a disruptor, as it is tubeless and preferred by the active diabetic. Tandem will continue to be strong clinically and aesthetically but its drawbacks are purchasing via DME channel and its operating system can be complicated. Medtronic products are substandard today but the company is huge, known, and trusted brand that is not going away. New players are Bigfoot, CeQur, and Modular Medical Inc. (MODD). Beta Bionics is an unknown.

CGM and Insulin Pump Market Conditions

- "Type 2 is a big market—[there are] 1.5 million Type 1 vs. 15+ million [Type 2] patients. [There is a] lot of advertising and lot of market access for Libre 2. Dexcom distribution is more through DME. Freestyle looks more low profile whereas Dexcom looks more medical device. Libre 2 is scanning and reading every one minutes, whereas G6 is every five minutes. Libre 3 is even smaller—[it is available] currently in Europe. CGM is so instant and easy, they come factory calibrated and very easy to set up and use."

- "I'm sure the data to support Type 2 CGM use is out there; [it] lies in many different places. It is generally understood [that there are] benefits for all diabetics, not just Type 1."
- "[There is] no real pricing pressure at this time. Omnipod has such great coverage and ads in Facebook, social media, and all media. This has put pressure on reimbursement and availability, as payers and pharmacy coverage is great. Most patients pay little or nothing at all. Anthem [insurance] covers [it]. Omnipod is a pod but generally classified as a pump that is covered. [Patient pay a] $5 copay for 90 days."
- "Omnipod is for active athlete kinds. [It] was branded for pediatrics initially but [is] an advantage for active adults. Eros is the classic Omnipod and can loop. Dash Omnipod can be monitored remotely. Data is read on an iPhone. Omnipod 5 is coming out in 2021 [and] will be a 'pump' with the G6 tied in. Algorithm is in the pod."
- "I believe that the Omnipod 5 [which is dropping the Horizon name] with its tubeless system and great coverage combined with G6 breakthrough could become a disruptive device. Eventually it could be integrated with the Libre 2/3 as well. [It] will be sold through the pharmacy channel."
- "Bigfoot Unity will be good for those who don't want the pump and use the smart pen. [It is a] good way to start therapy when you are not ready for a pump. [It can be] combined with Libre 2."
- "[I] think you will see the device market explode. [There are lots of] different pumps."
- "CeQur [is a] patch pod style system. The three-day bolus device is FDA cleared for adults requiring insulin and is currently in a pilot launch stage in 2021. [They are] working with select physicians and centers to bring this innovative technology to patients. The CeQur Simplicity device will be available broadly soon [and] has been tested in three clinical studies that demonstrated the device is effective, safe, and easy to use."

> **I see the Omnipod 5 as being the biggest disruptor. [It is] tubeless and the app allows the patient to move and do anything they want. A PDM [personal diabetes monitor] is needed when you need a bolus but there are other new products coming—startups and newer versions. Medtronic is also in the background and could easily reappear.**
>
> *Insulin pump sales professional in the Southeast*

- "Modular Medical is another new one that is a pod—the Pivot. They are on track for a third-quarter 2022 launch with a simple disposable system."
- "InPen is Medtronic's smart pen and t:sport is what's coming from Tandem in a low profile, high quality pump. App control [is] from your phone or watch."
- "Tidepool is also trialing with current users many approaches that are outside of the FDA approvals."
- "Regarding the growth numbers, I think the CGM growth should be higher for the Type 1 diabetics. All Type 1 patients should be on CGM and, with ease of reimbursement and pharmacy channel, this should grow more."
- "Type 2 diabetic numbers for CGM are closer to what I see."
- "Pump growth should be 10% to 20% as only a third of Type 1 patients are on pumps. Endocrinologists still start Type 1 patients initially on orals before moving to insulin. The FDA recommends pumps, not pods. The majority of the pod business, like Omnipod, is coming from Type 2 patients."

CGM Competitive Landscape

- "Companies that use the pharmacy channel are making it that much easier for the caregivers and patients. These will move forward faster than non-pharmacy channel. Medtronic sensors are garbage now. [They have to] calibrate four-plus times a day [and can be] very disruptive to the patients. But watch out for them because they are investing and could revive their franchise. Dexcom has a large profile that catches on clothes or things you get close to and looks like a medical device, which, for many Type 1 patients, is not cool. The G7 size-wise should be much better. Today the Libre is a lower profile than the G6 and easier to wear and not have to fuss. Once Libre is integrated with their app, then this will be a huge advance."
- "[While] Dexcom catches on clothes and looks a little medical, the app and reliability is great."
- "Abbott [has] no app but [does have a] low profile [and is] easy to obtain and less expensive."
- "Medtronic [has a] garbage sensor and calibration but [it is a] big company that is everywhere."
- "[For] Eversense, finding an physician to do the procedure is an obstacle, as is getting reimbursement—[patients are] never sure who covers it. Implanting is minor surgery that a nurse does not perform. [The] advantage is no skin irritation, [which is] critical for some patients."

- "Abbott and Dexcom, especially with their new versions, are both poised to experience significant growth. Dexcom is posed to be a bigger winner but Libre is close."

Insulin Pump Competitive Landscape

- "I see the Omnipod 5 as being the biggest disruptor. [It is] tubeless and the app allows the patient to move and do anything they want. A PDM [personal diabetes monitor] is needed when you need a bolus but there are other new products coming—startups and newer versions. Medtronic is also in the background and could easily reappear."
- "Medtronic's CareLink system for monitoring patients is easy to work but hard to get data uploaded. The company's advantage is size and having money to spend. It's a known entity, trusted."
- "Tandem [is] really sleek and doesn't look like a device—it looks like an MP3 player. [The] updates [for] t:slim [are] automated, [which] is really slick. [Its] weakness is it can be complicated and it's still mainly in the DME channel with contracts and a load of administrative stuff that is burdensome. Like all [of the options], it has its idiosyncrasies."
- "Bigfoot Unity [is] pen based. Good for beginners but not for the long haul."

2) Diabetes clinical sales and service specialist

Only 25% of qualified patient currently use CGM—there is definitely room for growth. Dexcom holds a leadership position in the Type 1 diabetes space due to its accuracy, while Abbott Libre is more common among Type 2 users where the pharmacy benefit does not adhere to Medicare CGM qualification criteria. Approximately 25% of insulin-dependent diabetes patients use a pump. This figure has been steady for the last 20 years despite technology advances and new competition. The reasons for pump market sluggishness are multifactorial and include insurance coverage, limited time and experience at the primary care level, lack of awareness, and patient reluctance to wear a pump. Half of Medtronic pumpers use Dexcom CGM, despite the lack of hybrid loop integration, because of the superior accuracy. The Dexcom 7 with sensor and transmitter in one device is an appealing advantage and will likely encourage this trend. There is a lot of buzz about Insulet's Horizon pump but it is not expected to appreciably grow the pumper market size. Wearables, including CeQur's Simplicity and V-Go are interesting but limited. The Bigfoot Biomedical pen with Libre integration is appealing to existing Type 2 Libre patients and could serve to capture market share. The largest hinderance to device adoption is strict qualification criteria and out-of-pocket expense.

CGM and Insulin Pump Market Conditions

- "Approximately 25% of patients who inject insulin are currently using a pump. This percentage has remained steady over the last 20 years regardless of advances in technology and increased competition. There are several reasons for this, including: challenging Medicare/insurance coverage criteria, related out-of-pocket expenses, lack of time and expertise at the primary care level, overall lack of device awareness at the patient level, and general resistance to wearing one."
- "There are a lot of patients who simply refuse to consider an insulin pump. While it really helps to improve glycemic control, it's a lot of work and inconvenience for the patient. Injections are easier. Many people do not want to wear one. But, in my experience, once a patient does get on a pump, they wish they had done it sooner."
- "The Type 2 market is significantly impacted by a lack of coverage. Medicare criteria is strict (documented self-monitoring four-plus times per day, injections three-plus times per day) which eliminates more than half of the potential users and people are unwilling or unable to pay out of pocket."
- "Of those Type 2 patients on CGM, many use the Abbott Libre. Abbott has successfully made a dent in this market through the pharmacy benefit channel, where stringent qualification criteria is not a factor."
- "Only 25% of qualified patients have CGM now, so I do believe CGM use will grow. It is a great tool. Patients really do want an accurate and convenient CGM. But I do not expect the pump market to grow considerably simply based on historical trends."
- "From a pain and inconvenience standpoint, finger sticks are the worst. This is why there is much less patient pushback against using a CGM."
- "Some of the wearables are interesting but limited: CeQur Simplicity (three-day patch for bolus/mealtime) and V-Go (daily patch for basal and bolus—covered by Medicare Part D pharmacy benefit)."
- "Bigfoot Biomedical recently introduced a pen that works with Abbott Libre, which could be appealing to Type 2 patients in particular."

> **Dexcom CGM is definitely favored by the Type 1 diabetes patients. Many Type 2 diabetes patients use Abbott Libre.**
>
> *Diabetes clinical sales and service specialist*

CGM Competitive Landscape

- "Dexcom CGM is definitely favored by the Type 1 diabetes patients. Many Type 2 diabetes patients use Abbott Libre."
- "The Dexcom 7 will integrate sensor and transmitter in one device, which will be appealing."

Insulin Pump Competitive Landscape

- "Right now the only hybrid closed-loop systems available are Tandem (with Dexcom CGM) and Medtronic. Except for the very diehard Medtronic loyalists, patients are excited to switch to Tandem/Dexcom because it is much more accurate and user friendly."
- "We in the diabetes community believe that half of the Medtronic pumpers use Dexcom CGM. This is not an optimal (hybrid closed-loop) system, however, as it is not working as designed with non-integrated components."
- "The Insulet Omnipod tubeless pump has definitely had a positive impact for pumpers. If the release had not been delayed, they would have been a bigger competitor to Tandem. I thought when Omnipod was released that the percentage of pumpers would finally grow beyond 25% but there has been no significant increase."
- "There is a lot of buzz about Insulet's Horizon pump—tubeless, smartphone operated, and integrated with Abbott and Dexcom."

Miscellaneous

- "We have a great sick-care system but a not so great well-care system. Abbott and Dexcom are trying hard: lobbying to get the device criteria changed at the Medicare level. But these kinds of changes take years. And the trickle down to third-party carriers takes even longer."
- "Abbott and Dexcom are advertising heavily to consumers, focused on solutions to avoid the dreaded finger sticks. It drives physicians crazy. The doctor wants to be the one to bring up CGM/pumps and the patients have no idea about the strict criteria for coverage."
- "More market penetration comes back to the money. The device cost is not a one and done, there are consumables to consider. Patients simply will not or cannot pay out of pocket."
- "As far as the non-diabetes CGM utilization goes, it could be an interesting tool for elite athletes but it seems like a very niche market."

3) Sales manager for insulin pump manufacturer; repeat source

The diabetes wearable market is experiencing explosive growth and is saturated with great products. There is tremendous excitement for new products which will substantially improve patient lives. Dexcom should be the big winner in CGM due to its accuracy and better outcomes. Libre 3 integrating with Tandem will be a boost to Libre. In pumps, Tandem should be the growth leader and the t:sport will have the biggest impact on pump growth. Medtronic has lost the confidence of patients and health care professionals—it promises fixes to problems but does not deliver. Switches from Medtronic are primarily to t:slim. Omnipod will add promotional resources when Omnipod 5 is released but integration will still not be ideal. Bigfoot and Beta Bionics are not there yet.

<u>Sept. 3, 2020, interview summary</u>: This experienced diabetes device sales leader sees positives with the introduction of Abbott's Libre 2 and continued growth with both CGM devices and insulin pumps. Libre 2 should be able to work out the integration issues and will disrupt the CGM market. Insulin pump growth will continue. A guarded estimate of 25% growth of Tandem pumps is reasonable, due to CGM growth, integration, and partnerships across the market. Medtronic is struggling to regain user confidence and the MiniMed 680 is not enough to turn them around. Insulet is far behind the leaders but will be boosted when the Horizon platform is approved. Beta Bionics will be a future player and will impact this market within the next two years. Studies are showing that Type 2 patients benefit from pumps and future growth is predicted in this market.

<u>March 26, 2020, interview summary:</u> This source said promoting Tandem's new t:slim X2 is "a salesperson's dream." Tandem sales focus on the new Control-IQ product and the reception has been incredibly positive. Patients on the older Basal-IQ product can upgrade to the new Control-IQ pump for free. Endocrinologists and their staff are initiating discussions on switching from MiniMed on every call and Medtronic is losing patients.

<u>Oct. 23, 2019, Dexcom-Tandem interview summary</u>: There are few disruptors to change either Dexcom's or Tandem's growth rates. Tandem should have few negative factors for at least the next year. Dexcom should continue to grow, as new competitive products are not ready to release and are subject to FDA processes. Both companies have positive developments that continue to improve their products.

June 19, 2019, Tandem interview summary: Tandem's continued growth and future are very positive, due to its easier to use t:slim X2 with Basal-IQ technology and the strong product pipeline. Market leader Medtronic is losing its grip, as the 670G pump is complicated to teach and learn, leading to higher discontinuation rates. Tandem is putting the burden on the machine—not the patient. The Animus exit is favoring Tandem, as its CGM and infusion sets are the most compatible. Tandem is expanding its field presence and has added a team focused on renewals to improve its 50% renewal rate.

CGM and Insulin Pump Market Conditions

- "[It is an] explosive market [that] is already saturated with great products. [There is] incredible excitement for G7 and Libre 3, [which will be] easier and [with a] focus on Type 2. Dexcom has always been focused on Type 1 but expanded into Type 2 and the pharmacy distribution channel."
- "Omnipod is pushing into the Type 2 market. Patients [are] not educated on their product and [they are] stretching their resources tremendously, resulting in patients not doing as well as they should. Omnipod does not have automated delivery and is not integrated with CGM. [I] anticipate they will add resources once the Omnipod 5 is approved. Medtronic has burned a lot of bridges and just had a big layoff. The old Medtronic stronghold accounts are few and far between. MiniMed770 and new products have not performed and the trust, once a mainstay, has eroded tremendously. A majority of new patients choosing the Tandem pump are Medtronic patient switches."
- "There are studies with CGM and pumps to support the Type 2 patients."
- "GLP-1 growth into Type 1 and Type 2 is being actively researched [but it is] still early and, due to lack of evidence, a lot of insurance will not cover, thus hindering its use. [It is] not a determining factor at this time. "
- "I Haven't seen pricing pressures on pumps or CGM."
- "I Don't see a big breakthrough or major change in market share in the near future. The new version of the current products is the biggest change coming."

CGM Competitive Landscape

- "There is great excitement for the new products, patient-wise. The new releases will improve patients' lives substantially."
- "Eversense has not taken up much in my area. It's not as much implanting the device but removing it is the bigger issue and every 90 days you are removing and replacing the device."
- "Dexcom has better outcomes, better accuracy, just a better product. Libre 2/3 will grow, as it is easy and cheap but not the quality of the Dexcom CGM."
- "G7 should be the big winner. When Libre and Tandem integrate—with the release of Libre 3—that should give Libre a boost and they will also enjoy good growth. "
- "Medtronic has lost the trust of the community."

> **[It is an] explosive market [that] is already saturated with great products. ... Dexcom has always been focused on Type 1 but expanded into Type 2 and the pharmacy distribution channel. ... Omnipod is pushing into the Type 2 market. ... Medtronic has burned a lot of bridges and just had a big layoff. The old Medtronic stronghold accounts are few and far between.**
>
> *Sales manager for insulin pump manufacturer*

Insulin Pump Competitive Landscape

- "t:sport should have the biggest impact in the pump market. Medtronic has lost the confidence of the users and healthcare professionals. Too much burden, too many promises of how they will fix their problems—and the subsequent products were no better. Physicians and patients have taken the position on Medtronic as, 'I'll believe it when I see it."
- "Tandem's Control-IQ is amazing—life-changing, game-changing without changing the lifestyle of the patient. Just the device changes their life. Tandem's customer support is very strong. Even during COVID, reports are that patients raved about how good its support was remotely and that they were served incredibly. [They have a] great pipeline, great new system updates. [Tandem's] weakness [is that the] t:connect software needs improvement but updates without getting a new pump is great. Next generation will address t:connect shortcomings."
- "Tandem uses some pharmacy channel but primarily a DME process."
- "Omnipod's strength is they own a niche market with the tubeless system. [Their] weakness is integration with CGM. New Omnipod 5 not a big advance. One study showed good outcomes but it comes often with bolusing eight times a day. One has to question the outcomes, [which] look good—but is that because of all the boluses? That is tremendous burden on the patient."
- "[There is] not a lot of excitement about the Bigfoot Unity. It's for patients who are afraid of the pump, I guess, but after manually applying the pen with high frequency, patients tend to accept the pump."

- "Beta Bionics [is] not out there [and there are] not a lot of strengths [for it]. [The] pump is bigger but patients can put into the system when they are having a small, medium, or large meal—but [that is] not a big advantage. [It] will have a splash in the markets where it was studied but I assume those splashes will be limited."

4) Diabetes specialty rep with 14 years of experience including recent employment as a Medtronic territory manager; repeat source

CGM growth in 2021 has been in the 35% to 40% range and this source does not expect a drop-off in 2022. A major children's hospital is an example of where all newly diagnosed diabetes patients start on CGM to guide the decision of when or whether to deploy an insulin pump. He predicts slower insulin pump growth as the Type 2 patients move from metformin to GLP-1 insulin choices that do not require pumps. Dexcom will continue to lead in growth and Tandem's Control-IQ technology with the t:slim is the leader, as it is "the complete package." Medtronic has fallen out of favor with many endocrinology practices and the Type 1 community. Poor performing devices have led to layoffs in many departments that interface with health care professionals and patients. Omnipod has made gains in the adult sector and Bigfoot competes for the smart pen market.

Sept. 3, 2020, interview summary: This source experienced a drop-off in Medtronic insulin device sales, while watching Dexcom and Abbott flourish in CGM and Tandem lead in insulin pumps. He believes Tandem's t:slim will grow more than 15% over next 18 to 24 months if it does not have production problems. Medtronic just announced its intention to acquire Companion Medical and its InPen—a smart insulin pen that integrates with a companion app. This will help get Medtronic back in the game. Beta Bionics should have a major impact in this time period. Rumors are that Roche Holding AG (RHHBY) will re-enter the pump market with a slightly modified older product. Insulet's Omnipod will not be a big factor and will continue as a niche player.

Oct. 23, 2019, Dexcom-Tandem interview summary: There are no substantial market changes expected for the next six to 12 months for the growth of Tandem's or Dexcom's products. There are two potential future disruptors: First, Abbott's deals with Tandem and Omada Health have the potential to impact Dexcom's growth but are subject to FDA approval, which pushes this out at least 12 months. Second, the additional CGM to pump interfaces may confuse patients and diabetes educators having to deal with additional combinations and cross-company issues. This may benefit Medtronic, which has both devices under one roof.

June 19, 2019, Tandem interview summary: Tandem's success is related directly to Dexcom's G6 CGM compatibility and Tandem's juvenile diabetic use. Tandem has not been in the market long and, as many other big companies have exited the market, one cannot be sure about its future success. The greatest opportunity is with Type 2 diabetes patients but there is much resistance with payers to cover costs with these patients.

Growth of the CGM market for 2021 should be about as projected, in the 35% to 40% range. I disagree with the 2022 projection of 29%—it should be greater, at least as big as the 2021 rate.

Diabetes specialty rep with 14 years of experience including recent employment as a Medtronic territory manager

CGM and Insulin Pump Market Conditions

- "The biggest factor in the device space is CGM and the facilitator of growth is largely in the hands of reimbursement. Type 2 patients start on metformin and the next step should be GLP-1. With this, CGM should be used but the question remains: Will the Type 2 patients be covered?"

CGM Competitive Landscape

- "Growth of the CGM market for 2021 should be about as projected, in the 35% to 40% range. I disagree with the 2022 projection of 29%—it should be greater, at least as big as the 2021 rate."
- "An example of a growth driver for CGM is Children's National Hospital in Washington, DC. Every child diagnosed and started on therapy is started on a CGM regardless of the selection of insulin therapy. They use this to assess at what point the patient is ready for a pump."
- "Dexcom G6 and G7 should dominate the growth of GCM. Compared to the competition, it does not ask for a lot of calibration nor alerts."
- "Libre 3 should be a boost to the Libre line and help to accelerate its growth."

- "Eversense has never really taken off. The implantation is a barrier and, as a more durable device, is not very appealing. If they had a 12-month duration between implanting, this would be an advantage and would put them in a much better competitive position."

Insulin Pump Competitive Landscape

- "I don't perceive pump growth as being strong in the Type 2 patient area. The standard of care is to start with metformin and, if another step is needed, healthcare professionals should be adding a GLP-1 class of drug. GLP-1 only works in a glucose-dependent manner. You don't see hypoglycemia with GLP-1 use. ADA and AACE guidelines support this."
- "I don't have a strong feeling for what the growth of pumps will be in the next 18 months."
- "Tandem is the best insulin pump device on the market. Their Control-IQ system with the t:slim is the complete package."
- "Bigfoot will compete well vs. Medtronic and their smart pens. They are having success with pediatrics with their pens."
- "Omnipod is gaining ground in the adult sector and I see it with the Type 2 patients."
- "Medtronic is promoting strongly to gain share with Type 2 patients. Reimbursement for Type 2 is difficult whether they are insulin-dependent or not. "
- "Medtronic pumps have fallen out of favor in many endocrinology practices. Long-time practices and patients have switched to Tandem."
- "I knew many of the territory managers, the inside case managers, and specialists at Medtronic. Many of them do not work there anymore. I would say 50% of the people I trained with at Medtronic do not work there anymore. Their upcoming new version of the pump is reported to have a lower profile CGM with better infusion sets. Including me, many of us in the industry are Type 1 diabetics who wore the Medtronic devices but have switched to Tandem. We had to calibrate the product with finger sticks maybe four times a day."
- "The Medtronic 780 should better compete with Tandem and their IQ system."

5) Diabetes device executive and development engineer

CGM growth rates are significantly overstated. The Type 1 market is semi-saturated and Type 2 adoption faces considerable headwinds, including patient reluctance and primary care inexperience. Pump growth may reach into the low double digits. New consumer-focused CGM technologies are well funded but exaggerate the opportunity, as CGM is commoditized at this point. Chasing accuracy is unreasonable, as most CGMs are comparable. The greatest differentiators now are cost and convenience. There is nothing on the horizon for pumps that is particularly interesting. Tandem is eating Medtronic's lunch—not based on outcomes, but more on patient preference. Companies to watch are Omnipod, Bigfoot Medical, and InPen. More rapid-acting insulin will fundamentally change the dynamics and, although the technology exists, a commercial offering is not available. There are several companies in stealth mode working on novel diabetes device technologies.

CGM and Insulin Pump Market Conditions

- "40% year-over-year growth for CGM is significantly overstated. The industry grew approximately 25% the previous year and the Type 1 opportunity is already semi-saturated. Type 2 has major headwinds in that people are reluctant to wear devices and the primary care system is not well versed in true diabetes disease management."
- "Getting Type 2 patients on a pump is problem ridden: from their own reluctance to wear a device and no need for constant management to the primary care diagnosis and disease management process. At the primary care level, insulin is treated like a medication akin to a statin. There is an attitude that if a patient misses a day, it is not a problem. But this is not how insulin works. There is a difference between taking a medication and managing a disease."
- "Year-over-year growth in insulin pumps may reach the low double digits but it would be no surprise if it is only 6% to 7%."
- "The entire diabetes industry is not very innovative. It can be hard to see where things are going but it will change long term. Short term there will be some shifting between competitors."
- "New consumer-based CGM companies/products have great funding ($10 to $30 million) and everyone involved wants to believe in the huge opportunity. But there is a big difference between wearable watches and rings and something that you stick in your body that delivers a limited benefit."

- "Insulin pumps are getting much better and they will continue to advance but the industry undersells the challenge of wearing an insulin pump. When you show the same patients a smart pen technology, they get excited."
- "There are companies and technology in the diabetes space that are currently in stealth mode that will offer very appealing, novel solutions."
- "CGM companies chasing accuracy are on a fool's errand. Accuracy used to be the big competitive metric but the major players are similar at this point. As long as the accuracy is good enough (no one checks their readings with a finger stick for accuracy), there will never be negative feedback."

There are companies and technology in the diabetes space that are currently in stealth mode that will offer very appealing, novel solutions.

Diabetes device executive and development engineer

CGM Competitive Landscape

- "CGM is commoditized at this point. Mean absolute relative difference [MARD, the average of the absolute error between all CGM values and matched reference values] is the most common metric used to assess the performance of CGM systems. But the CGM systems are becoming much more comparable and the differentiators change as the market evolves. Now the most compelling competitive advantages are wearability/convenience and cost."

Insulin Pump Competitive Landscape

- "Medtronic 780G pump is good but needs to be paired with a better CGM. Medtronic is aware of this. Their Synergy Sensor [which is an all-in-one sensor-transmitter, disposable CGM] will be a much better wearable option for their pump."
- "I do not see anything in pumps that is particularly interesting. They fight over algorithms but that does not really matter. Tandem has control-to-range. Medtronic has control-to-target, which is actually a better approach, but the Tandem is strongly preferred by patients. Outcomes used to be the metric but not so much anymore. Tandem is eating Medtronic's lunch."
- "I like what Beta Bionics is doing but the dual-hormone approach will not change the world."
- "More rapidly acting insulins will fundamentally change the dynamics to allow for full integration. In theory, the technology already exists and I have seen one [stealth] company's data—but there are no commercial offerings ready for launch in the short term."
- "Companies to watch are Omnipod Horizon with its closed-loop system. Bigfoot Biomedical has an amazing business model. They make the doctor more money, which makes up for their inability to record insulin dose and the need to charge the pen every two weeks. Companion InPen is another, better technology smart pen device and it keeps a charge for an entire year."

4) Industry Specialists

Growth in CGM at 38% sounds correct but double-digit growth in the pump sector is a stretch. Gaining market share in Type 2 diabetes patients has been more difficult than companies expected. Only 25% are insulin dependent and the majority of Type 2 patients simply do not need constant glucose monitoring. Pump qualification is even more burdensome and the DME process is complex and cumbersome. CeQur's latest financing has got it on the move and it plans to take advantage of the literature that supports insulin-dependent Type 2 need—both basal and bolus. Tandem is hot and has a lot of interest in the market. If Insulet's new G5 is as good, it will gain market share. Beta Bionics' iLet is interesting but is not expected to launch any time soon. Nemaura Medical Inc. (NMRD) BEAT technology utilizes a Libre-like CGM and three-day patch technology. When launched in the U.S., it is expected to be priced similarly to finger stick glucose management.

Key Silo Findings

CGM and Insulin Pump Market Conditions

- 1 of 1 said CGM growth of 38% is attainable, with a percentage of growth coming from the trend of two-week, clinic-monitored usage. Insulin pump double-digit growth is unlikely.
- 1 said penetrating the Type 2 market provides significant challenges, as most patients do not need constant glucose monitoring and insulin users face burdensome payer qualifications and complex acquisition procedures through the DME system to secure a pump.

CGM Competitive Landscape

- 1 said CGM growth will continue. Two-week, clinic-monitored trial CGM usage is a growth area.

Insulin Pump Competitive Landscape

- Tandem is “hot” with its IQ technology and is generating a lot of interest.
- CeQur Simplicity is on the “move” with its three-day insulin patch.
- Omnipod 5, when launched, could gain share if equal to Tandem.
- Beta Bionics is promising but not yet available in the U.S.
- Nemaura BEAT, when available in the U.S., will offer competitive technology at affordable pricing.

1) Biotechnology consultant and diabetes expert; repeat source

CGM and Insulin Pump Market Conditions

- “Year-over-year growth of 38% for CGM might be a little high but definitely in the ballpark. Double-digit growth for pumps is aggressive.”
- “It has been more difficult for companies to gain market share with Type 2 than they imagined. A patient has to be on insulin [which only 25% of Type 2 patients are] before they qualify for CGM coverage. Then there’s the fact that most Type 2 patients really do not have a need for constant glucose monitoring, as is the case for Type 1.”
- “There is still the challenge of reimbursement for pumps in Type 2. They have to be on basal and bolus insulin. If they are on Medicare, good luck.”
- “The CGM market will continue to grow in Type 1 and some Type 2. One of the growth areas for CGM is a two-week trial with a clinic-owned CGM device to evaluate glycemic control and help educate patients. This is becoming more common and is reimbursed.”

CGM Competitive Landscape

- “Where CGM companies have demonstrated benefit with clinical trials, they are getting coverage. But most Type 2 patients cannot even spell DME—they get all their supplies through the pharmacy. DME paperwork is complex and cumbersome. The insurers like it that way because it gives them control. Getting into the pharmacy channel is a process.”

Insulin Pump Competitive Landscape

- “CeQur is on the move. They received more than $100 million in financing. Many insulin-dependent Type 2 patients are basal only but the literature suggests they need bolus [mealtime] also, which is what the CeQur patch addresses.”
- “Tandem is hot as hell with their IQ technology. It has a lot of interest in the marketplace. It works very well but the cost and DME paperwork are a significant burden.”
- “Insulet is getting ready to launch its G5. If it is anywhere as good as Tandem, they will definitely gain market share. But, of course, the patients already need to be using CGM.”
- “Both Tandem and Insulet have signaled interest in the Type 2 space but they need to get the reimbursement barriers reduced. Insulet may have a better chance, since they have lower upfront cost.”
- “Tandem works very well for Type 2 but the cost [and reimbursement challenges] and the DME paperwork is a real burden.”
- “Insulet just hired a VP for the Type 2 market.”
- “The Beta Bionics wearable iLet [bionic pancreas] is promising but is not launching the U.S. any time soon.”
- “Nemaura Medical BEAT technology includes a Libre-like CGM and three-day patch insulin delivery system. It is CE-market approved but not yet available here in the U.S. It is expected to offer low upfront cost and be priced on par with finger stick blood glucose management.”

> **Tandem is hot as hell with their IQ technology. It has a lot of interest in the marketplace. It works very well but the cost and DME paperwork are a significant burden.**
>
> *Biotechnology consultant and diabetes expert*

Secondary Sources

These three secondary sources focus on Cornell research sponsored in part by Novo Nordisk, first time official guidelines published by the AACE addressing diabetes device technology and the prediction of a diabetes device market revolution.

June 2 Cornell Chronicle article

Research being conducted at Cornell University and sponsored in part by Novo Nordisk is progressing on an implantable cell therapy device that secretes insulin.

- "A Cornell-led research team's improved cell therapy device effectively secreted insulin and controlled blood sugar in diabetic mice for up to six months – showing promise for the possibility of an effective, complication-free treatment for Type 1 diabetes, a chronic disease with no known cure."
- "The research group, led by associate professor Minglin Ma from the Department of Biological and Environmental Engineering in the College of Agriculture and Life Sciences, partnered with stem cell biologists at Washington University School of Medicine in St. Louis to identify how to protect these islets to let them do their job safely."
- Cornell doctoral student Xi Wang is the first author of the group's paper, 'A Nanofibrous Encapsulation Device For Safe Delivery of Insulin-producing Cells to Treat Type 1 Diabetes,' published June 2 in Science Translational Medicine. Postdoctoral researcher Daniel T. Bowers also contributed to the report.
- "Type 1 diabetes – which afflicts roughly 1.6 million Americans, including nearly 200,000 children and adolescents – causes insulin-producing pancreatic cell clusters (islets) to be destroyed by the body's own immune system. Past research has shown that islets can be grown from stem cells and implanted into the body, but they need to be able to secrete insulin in response to blood sugar while also being protected from the body's immune and autoimmune responses."
- "Ma's team implanted a device containing islets or human stem-cell derived, insulin-secreting cells into diabetic mice, reversing their diabetes. By doing so, they eliminated the need for drugs to suppress the immune system from attacking islets."
- "'The combined structural, mechanical and chemical properties of the device we used kept other cells in the mice from completely isolating the implant and, essentially, choking it off and making it ineffective,' Ma said. 'The implants floated freely inside the animals, and when we removed them after about six months, the insulin-secreting cells inside the implants were still functioning. And importantly, it is a very robust and safe device.'"
- "Think of the device as a tiny, micro-porous cage, about the width of several strands of hair, that gets implanted into the abdomen. The mesh of the cage safely encloses the islets to secrete insulin in response to blood sugar levels and gives them a steady flow of nutrients and oxygen to keep them alive, but protects them from the immune cells that are too big to get through."
- "Additional research will be needed to scale up this treatment for human application, as well as to determine how fibrosis – wound healing that can cause scar tissue development around the device and choke the islet cells – could be further mitigated."
- "This work was supported by Novo Nordisk, the Hartwell Foundation and the Juvenile Diabetes Research Foundation. Additional funding was provided by the National Institute of Diabetes and Digestive and Kidney Diseases of the National Institutes of Health."

May 31 Medscape article

Diabetes management technologies now have official guidelines issued by AACE that could pave the way for broader third-party coverage.

- "The American Association of Clinical Endocrinology (AACE) has issued its first-ever official guidelines addressing the use of advanced technologies in the management of people with diabetes."
- "The guidelines cover use of continuous glucose monitoring (CGM), insulin pumps, connected pens, automated insulin delivery systems, telemedicine technologies, and smartphone apps. They also address safety considerations, special situations such as hospitalization, and implementation in clinical practice."
- "They were presented on May 28 during the American Association of Clinical Endocrinology (AACE) Virtual Annual Meeting 2021 and simultaneously published in *Endocrine Practice*."

- "Previous AACE guidance on the clinical use of insulin pumps and CGM over the past decade has been published in the form of consensus or position statements rather than official evidence-based guidelines, task force cochair George Grunberger, MD, of the Grunberger Diabetes Institute, Bloomfield Hills, Michigan, explained."
- "In an AACE podcast, Grunberger said the guidelines will likely become a 'living' document, along the lines of the American Diabetes Association's (ADA) annual Standards of Care, as 'any cutoff date is arbitrary. More and more papers will be published on these technologies…This is certainly not a static field.'"
- "In the meantime, task force cochair and author Jennifer Sherr, MD, PhD, a pediatric endocrinologist, said she hopes the guidelines will help to reduce insurance company barriers to use of the currently available technologies."
- "'I am very hopeful that these guidelines will also encourage payers to change their stance. And I think that we as a community can continue to advocate and inform them of these guidelines so they can appropriately change their coverage practices,' added Sherr, of Yale University School of Medicine, New Haven, Connecticut."
- "In the guidelines, CGM is 'strongly recommended for all persons with diabetes treated with intensive insulin therapy, defined as three or more injections of insulin per day or the use of an insulin pump.' For those with diabetes who use CGM, 'priority metrics' include a 'time in range' of greater than 70% from 14 days of active use. Targets for mean glucose should be individualized, with glycemic variability 36% or lower."
- "Further specific CGM target metrics are given for people with type 1 diabetes, older/high risk individuals, and for pregnant women. The recommendations align with those issued in a 2019 joint consensus statement on CGM time-in-range endorsed by several organizations, including AACE."

May 17 Medical Device Network article

A diabetes device market revolution is predicted that will be led by expanded use of CGM in the type 2 patient population.

- "Although Covid-19 has affected the diabetes devices sector, data evidence shows a growth of the CGM market, which is expected to continue in 2021."
- "The Covid-19 pandemic has impacted the diabetic care devices market, although not as severely as other medical markets that are closely related to elective surgeries. According to GlobalData analysis, the diabetes care devices market, covering continuous glucose monitors (CGM), insulin pens and insulin pumps, was worth over $19.0bn in 2020 and is expected to grow to $25.4bn by 2025, driven by the strong performance of the CGM market."
- "Abbott Diabetes Care reported strong growth of 29% against 2019, reaching $3.3bn globally in 2020. The new-generation FreeStyle Libre 3 launched in Europe last year and is expected to increase revenue by over 20% in 2021. The total revenue of Dexcom, the other CGM leader, grew 31% over 2019, driven by a record number of new patient additions due to growing awareness from healthcare providers and patients. The growing trend continues in 2021. In the first quarter, led by FreeStyle Libre sales of nearly $830m, sales from Abbott Diabetes Care increased 23.6% against Q1 2020. Similarly, revenue from Dexcom grew 25% versus the same quarter in 2020. The robust growth of the CGM market is driven by market expansion and increased awareness, as well as ongoing new-generation product launches globally. Medtronic's MiniMed 770G, the first hybrid closed-loop pump system approved by the US Food and Drug Administration (FDA), launched across 26 countries and had strong growth in Q4 2020. The device combines a continuous glucose monitor and an insulin pump to regulate a patient's insulin. With the approval of its MiniMed 780G system in the EU, the closed-loop pumps market is likely to have mid-single-digit growth in 2021."
- "The collaborations between insulin delivery and CGM manufacturers are closer in 2021. To complete with MiniMed 770G, Abbott is working with Insulet to develop a platform to integrate its CGM sensing technology with Insulet's patch pump, Omnipod. The platform allows glucose data from a CGM sensor to send to Omnipod and automatically adjust insulin delivery to a patient. Bigfoot Biomedical Inc recently received FDA 510(k) clearance for its Bigfoot Unity. The system features connected smartpen caps that work in conjunction with FreeStyle Libre 2 to recommend insulin doses for patients using insulin pens. Additionally, digital technology and new models of diabetes care have been rapidly deployed to meet the challenges of the pandemic. Dexcom's CLARITY clinic software provides healthcare professionals with a web-based portal to view their patients' CGM summary data. The clinical usage of CLARITY has increased greatly to serve patients with diabetes in response to the pandemic."
- "GlobalData anticipates the continued growth of the CGM and closed-loop pumps market will be over 20% in 2021 due to technological development and increasing awareness. Additionally, CGM usage will expand from type 1 diabetes and type 2 diabetes on intensive insulin therapy to broader populations including non-intensive type 2 diabetes, pre-diabetes, pregnancy and the hospital market."

Additional research by James Boland, Pam Conboy, and Bruce Wicks.