NICE Recommends Medtronic Integrated Sensor-Augmented Insulin Pump As the Only Therapy System to Manage Glucose Levels in Type 1 Diabetes

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Medtronic

- The NICE guidance reviewed two sensor-augmented insulin pump therapy systems and recommends the MiniMed® Paradigm Veo(TM) system for managing glucose levels in people with Type 1 diabetes.[1]
- The MiniMed Paradigm Veo and the MiniMed 640G sensor-augmented insulin pump therapy systems can help to protect against severe hypoglycemia in people with Type 1 diabetes by continuously monitoring glucose levels.
- NICE concluded that the adoption of Medtronic technology has the potential to save a UK health system £1,500 per person per year.[1]

DUBLIN - February 12, 2016 - Today, the United Kingdom's *National Institute for Health and Care Excellence* (NICE) has issued positive guidance for the use of Medtronic insulin pump systems integrated with glucose sensors, for managing Type 1 diabetes and the avoidance of potentially life-threatening hypoglycemic episodes.[1, 2]

The guidance reviewed two sensor-augmented insulin pump therapy systems and recommends the MiniMed Paradigm Veo system for managing glucose levels in people with Type 1 diabetes who experience 'disabling hypoglycemia' - defined as repeated and unpredictable occurrence of low-blood sugar attacks that result in persistent anxiety about recurrence, and is associated with a significant adverse impact on quality of life.[1]

Since the assessment of the MiniMed Paradigm Veo system in the Diagnostics Assessment Programme (DAP), NICE has recognised that in 2015, Medtronic launched a successor system, MiniMed 640G.[3]

Type 1 diabetes is an autoimmune condition in which the pancreas does not produce any insulin.[4] It is a chronic, life-threatening condition that is on the increase. It currently affects around 400,000 people in the UK - 32,500 of whom are children.[5]

A hypoglycemic episode, also known as a 'hypo', is triggered when a person's blood glucose levels are too low.[2] The average individual with Type 1 diabetes suffers approximately two hypos every week.[6] Symptoms including sweating, fatigue, and dizziness, and in severe cases they can lead to seizures, loss of consciousness, and even death.[2] A hypo can be dangerous if not treated immediately and because they often go undetected, night-time hypos can be of particular concern to patients and to parents of children living with diabetes.[7]

The MiniMed Paradigm Veo and MiniMed 640G systems, the only systems to offer low glucose suspend mode, both incorporate continuous glucose monitoring (CGM) technology, providing users with a more complete picture of their glucose levels. The system alerts users when their sensor glucose levels are falling too low or rising too high, and also mimics the human pancreas' ability to suspend insulin delivery automatically - protecting against the risk of ahypo, even when a person is asleep or unable to react.

Adopting the MiniMed Paradigm Veo system may result in the following potential savings:

- £1,500 per person per annum from reduced on-going costs compared to using a stand-alone continuous glucose monitor with an insulin pump (CSII)
- £300-£1,600 for each avoided hospital admission for diabetes with hypoglycemic disorders
- £80-£240 for each avoided Accident & Emergency attendance
- £180 and £230 per ambulance call per patient.[8]

Commenting on the guidance, Consultant Diabetologist of Harrogate District Hospital and ex-Clinical Lead for the NHS Diabetes National Insulin Pump Network, Peter Hammond, stated: "Avoiding episodes of severe or disabling

hypoglycemia (hypos) can be one of the biggest challenges associated with managing Type 1 diabetes. Preventing hypoglycemic attacks, which put the lives of patients at risk and lead to costly A&E admissions and hospitalization, is a priority area for the NHS. The Medtronic system recommended by NICE incorporates sensor technology, continuously monitoring sugar and shutting-off insulin when needed, to reduce the risk of a hypo. Insulin pump therapy systems combined with continuous glucose sensing and automated suspension of insulin delivery can be a lifesaver for those who have lost the ability to recognise when they are experiencing a hypoglycemic episode, and are also very reassuring for parents of children with Type 1 diabetes who fear night-time hypoglycemia. This guidance is extremely positive; acknowledging the latest technology and confirming the vital role of sensor-augmented insulin pump therapy with automated insulin suspend in the effective treatment of Type 1 diabetes today."

"This guidance is a great step forward for ensuring that people with Type 1 diabetes have easier access to the latest technology, which will help those that meet the criteria manage their condition better," said Lesley Jordan, pump user and chief executive of UK Patient Advocacy Group INPUT. "CGM continuously monitors the glucose and alerts the user when the glucose level goes out of the safe range; and low glucose suspend helps prevent the glucose level from dropping dangerously low, which can result in collapse, coma or death. The availability of such advanced technology means those living with Type 1 diabetes may experience less difficulty and risk in their day-to-day lives as a result."

This diagnostics guidance supports the use of the MiniMed Paradigm Veo system for managing glucose levels in people with Type 1 diabetes if:

- they have episodes of disabling hypoglycemia despite optimal management with continuous subcutaneous (under the skin) insulin infusion and
- Medtronic arranges to collect, analyse and publish data on the use of the MiniMed Paradigm Veo system and successor technologies with low-glucose suspend function.[1]

Note to Editors
In accordance with the recommendations, Medtronic will collect, analyse and publish data on the MiniMed Paradigm Veo, MiniMed 640G, and successive generation systems. The data and associated publications will contribute towards future Diagnostic Guidance updates and will include MiniMed 640G. Registration and data uploads will continue to be optional for the patient.

The guidance also requires that the MiniMed Paradigm Veo system should be used under the supervision of a trained multidisciplinary team who are experienced in continuous subcutaneous insulin infusion and continuous glucose monitoring, for managing Type 1 diabetes, if the person or the care-giver:

- agrees to use the sensors for at least 70% of the time
- understands how to use it and is physically able to use the system and
- agrees to use the system while having a structured education programme on diet and lifestyle, and counselling.

About the NICE DAP Process
As part of NICE's work on evaluating medical technologies, the Diagnostics Assessment Programme (DAP) focuses on the evaluation of innovative medical diagnostic technologies in order to ensure that the NHS is able to adopt clinically and cost effective technologies rapidly and consistently.[9]

About NICE Medtech Innovation Briefings
NICE Medtech Innovation Briefings (MIBs) are designed to support NHS and social care commissioners and staff who are considering using new medical devices and other medical or diagnostic technologies. The information provided includes a description of the technology, how it's used and its potential role in the treatment pathway, as well as a review of relevant published evidence and the likely costs of using the technologies. MIBs are designed to be fast, flexible and responsive to the need for information on innovative technologies.[10]

About the MiniMed Paradigm Veo System

Launched by Medtronic in the UK in 2009, the MiniMed Paradigm Veo system combines insulin pump therapy and CGM with a unique capability to automatically suspend insulin delivery temporarily if glucose levels become too low, protecting against the risk of hypoglycemia even when a person is asleep or unable to react.

The system includes an insulin pump with CGM provided by means of a separate sensor and transmitter. The patient uses readings from the monitor in conjunction with occasional confirmatory fingerstick measurements to understand their current glucose level, and program the insulin pump to deliver the appropriate amount of insulin. If data transmitted from the sensor show that the patient's glucose levels have dropped below a defined threshold, the insulin pump automatically suspends insulin delivery for up to two hours, to help protect against hypoglycemic events.

About the MiniMed 640G System
Launched in the UK in 2015, the MiniMed 640G system is designed to help people with diabetes achieve better glucose control through advanced protection from hypoglycemia. With first-of-its-kind SmartGuard(TM) technology, the system is the first in the world to both automatically suspend insulin delivery when sensor glucose levels are predicted to approach a low limit and resume insulin delivery once sensor glucose levels recover. The system includes the Enhanced Enlite(TM) sensor, which continuously monitors glucose levels with accuracy and comfort. It also incorporates an updated insulin pump design to provide convenient diabetes management with a simple user interface, full-colour screen, waterproofing and remote bolus.

About the Diabetes Group at Medtronic (www.medtronicdiabetes.com)
Medtronic is working together with the global community to change the way people manage diabetes. The company aims to transform diabetes care by expanding access, integrating care and improving outcomes, so people living with diabetes can enjoy greater freedom and better health.

About Medtronic
Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 85,000 people worldwide, serving physicians, hospitals and patients in approximately 160 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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[1] NICE Published Guidance http://www.nice.org.uk/guidance/dg21

[2] Diabetes.co.uk: Diabetes and Hypoglycaemia. http://www.diabetes.co.uk/Diabetes-and-Hypoglycaemia.html Last accessed February 2016

[3] NICE Published Guidance http://www.nice.org.uk/guidance/dg21

[4] NHS Choices. Type 1 Diabetes. http://www.nhs.uk/Conditions/Diabetes-type1/Pages/Causes.aspx Last accessed February 2016

[5] Daily Hansard - Westminster Hall. Type 1 Diabetes (Young People). 30 April 2014 : Column 247WH http://www.publications.parliament.uk/pa/cm201314/cmhansrd/cm140430/halltext/140430h0001.htm Last accessed February 2016

[6] McCrimmon, RJ and Sherwin, RS. Hypoglycemia in Type 1 Diabetes. Diabetes 2010; 59(10): 2333-2339

[7] Nocturnal Hypoglycemia: Answering the Challenge With Long-acting Insulin Analogs. *Medical General Medicine*. 2007; 9(2): 38. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1994862/ Last accessed February 2016

[8] NICE Resource Impact Report http://www.nice.org.uk/guidance/dg21/resources/resource-impact-report-2312936173

[9] NICE diagnostics guidance: https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-diagnostics-guidance Last accessed February 2016

[10] Medtech innovation briefings: https://www.nice.org.uk/about/what-we-do/our-programmes/nice-advice/medtech-innovation-briefings Last accessed February 2016

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