Steno Diabetes Center Copenhagen

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Guidelines for the use of unauthorized Do-It-Yourself (DIY) medical technologies for the treatment of diabetes

Background for guidelines

Within the diabetes community is a fast-growing movement working to develop Do-It-Yourself (DIY) medical devices to optimize their diabetes treatment. The movement has various names and approaches for developing these devices. The distribution of knowledge and methods occurs primarily via international networks on social media. These DIY medical systems are not approved by regulatory authorities for the treatment of diabetes, and no randomised controlled clinical trials of DIY systems, demonstrating a scientific groundwork for evaluation of the effect and safety of these devises, have been conducted. There are, however, an increasing number of people with diabetes who wish to use DIY systems. Steno Diabetes Center Copenhagen (SDCC) has therefore decided to prepare the following guidelines to clarify the framework for collaboration between people who have chosen to utilize unauthorized DIY medical systems and healthcare professionals at SDCC.

Definition of DIY medical technologies

Commercially available medical systems are subject to EU legislation, and these devices bear the CE mark as proof of compliance with the relevant requirements.

DIY medical systems encompass a variety of diverse technologies created by individuals for their own use in the treatment of diabetes.

These devices are not developed for wider distribution, and as such are not subject to EU legislative requirements for safety or performance.

An example of DIY medical technologies is an artificial pancreas, which automates insulin delivery. This system is comprised of commercially available, authorized components – the insulin pump and the continuous glucose monitor (CGM) – but communication between these devices and the algorithm which controls insulin dosing is developed by the user, resulting in an end product which is no longer covered by the original regulatory approval.

DIY vs. authorized medical technologies

DIY medical technologies are per definition developed by individuals for their own use and have not undergone the same legislative, systematic evaluations as commercially available authorized medical technologies. This does not mean that DIY systems are inherently dangerous to use. However, the manufacturer of these devices cannot be responsible either legally or financially, if any errors in the DIY systems cause injury to the user or a third party. Although a DIY medical system is composed of commercially available components (e.g. insulin pump, CGM), any guarantee or manufacturer's liability are voided when the devices are used in a way other than intended by the manufacturer. Additionally, the individual user of DIY medical technologies must manage any private insurance-related issues consequent to the use of unauthorized medical devices as opposed to authorized medical devices used in accordance with the manufacturer's guidelines for use.

Use of medical technologies at SDCC

Healthcare professionals at SDCC recommend only the use of authorized medical devices for the treatment of diabetes. Healthcare professionals at SDCC may only prescribe authorized medical technologies, which support the treatment methods available at SDCC. They are thus unable to advise on the development, maintenance, or use of DIY devices, and they are unable to prescribe technological components other than those which are part of the authorized treatment program offered at SDCC. Any person choosing to use DIY technologies does so at their own risk for the development and maintenance as well as any effects and side effects resulting from the use of these devices.

Users of medical technologies at SDCC

SDCC recognizes that the current selection of authorized medical devices may not meet the needs of everyone with diabetes. It is SDCC's goal to ensure the best possible treatment for everyone with diabetes, including the highest possible quality of life. For a segment of this population, this may include the use of DIY medical technologies. Healthcare professionals at SDCC may not advise users on aspects of their treatment related specifically to their unauthorized DIY medical devices, however, if a person with diabetes chooses to build a DIY system, they must continue to receive support and care from their diabetes healthcare providers at SDCC for all other aspects of their diabetes care. SDCC encourages users of DIY technology to inform their healthcare providers at SDCC regarding their choice of treatment methods so that the rest of their treatment can be adapted accordingly.

Examples from the meeting between users of DIY systems and healthcare professionals from SDCC

- A person informs their healthcare provider that they have developed a personal DIY medical device and would like to know if they are still eligible to receive treatment at SDCC.

Answer: Healthcare professionals at SDCC recommend only the use of authorized medical devices and may not advise on treatment specific to the DIY device. However, the use of DIY devices does not disqualify an individual from receiving support in other aspects of their diabetes treatment including the prescription of insulin and other medicines, diet, and screening for complications.

- A person wishes to build a DIY medical device but is missing a specific component, which is not available for sale in Denmark. This person asks their healthcare provider for help ordering the component.

Answer: Healthcare providers at SDCC may not help in the procurement of medical equipment other than those systems which are approved by regulatory authorities, and which are commonly offered as a treatment option at SDCC.

- A person using an insulin pump prescribed by their healthcare provider at SDCC, requests a prescription for a CGM. This person wishes to use this commercially available medical devise as a component of a DIY artificial pancreas.

Answer: Healthcare providers at SDCC may provide commercially available medical devices, including CGMs, to people who fulfil the criteria for the use of

this device. If the criteria are not fulfilled, then the device will not be provided despite the person's request.

- A person receiving treatment at SDCC with an authorized insulin pump and CGM requests from their SDCC healthcare provider access to a comparable medical device from another manufacturer because the manufacturers insulin pump and CGM device (as opposed to the pump and CGM devise the person already uses) is compatible with a DIY artificial pancreas, which the person wishes to build.

Answer: Healthcare providers at SDCC may, upon request, switch to another equipment provider, as long as the change is in accordance with standard practice for changing of medical devices. In other words, the request for change should be prompted because of a defective component, or that the healthcare provider recognizes there is a need for a device with other functions.

- A person with diabetes wishes to discuss glucose levels obtained via the use of a DIY artificial pancreas with their healthcare provider at SDCC yet is unsure if this is possible since SDCC does not endorse the use of DIY technologies.

Answer: Healthcare providers at SDCC may provide professional evaluations of, for example, glucose values obtained via a DIY medical device, as well as general advising regarding dosing of insulin and glucose monitoring. SDCC healthcare providers at SDCC may not provide specific advice regarding optimization of DIY medical device settings.

- The parent of a child with diabetes has heard that it is possible to obtain a DIY medical device with remote monitoring of their child's CGM data and ask their child's healthcare provider where they can find additional information.

Answer: Healthcare providers at SDCC may not refer people to sources of information regarding DIY medical devices.