Commentary
Volume 6:3, 2022

Journal of Hepatology and Pancreatic Science

ISSN: 2573-4563 Open Access

A Commentary on Artificial Pancreas Systems

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Description

Self-management of diabetes is a demanding, delicate, and yet essential task that people with diabetes must carry out every day to prevent harmful glycaemic episodes. In order to improve the management of diabetes, modern systems have been developed, such as the artificial pancreas (AP) and decision support systems. The continuous glucose monitor (CGM), insulin pump, and algorithm that controls the artificial pancreas work together to keep blood sugar levels within the permissible range (70-180 mg/dL). The development of an artificial pancreas based on insulin is envisioned to lead to a fully automated system that does not require user input at any time during the day. Postprandial glucose management is a key obstacle to achieving this goal with an artificial pancreas. Studies have demonstrated that AP systems can manage the postprandial rise in glucose that occurs when modest meals (such as 30 g) are skipped. The level of control is, however, substantially worse with larger meals [1]. Because meals must be notified ahead of time to maintain proper control, the existing artificial pancreas system is categorised as a hybrid closed-loop system.

In hybrid closed-loop systems, meal announcements must be initiated by the user, which might result in less-than-ideal results. In the ideal situation, the user predicts the meal size correctly by calculating carbohydrates and transmits that information to the AP system before eating. Due to the delays in subcutaneous insulin delivery, this must be done. However, numerous studies have revealed that people with diabetes frequently forget or reschedule their insulin boluses for meals. This might be attributable to elements in a regular routine including diabetes discomfort, stress, and forgetfulness, among others. These studies generally demonstrated a significant correlation between HbA1c levels and late and missed meal boluses. Over time, this rise in HbA1c levels may cause a decline in quality of life. Furthermore, between 20% and 59 % of meal quantities are often estimated incorrectly by those with diabetes [2,3].

DIY artificial pancreas system (DIY APS) users are on the rise despite the recent development of more commercial hybrid closed-loop devices. There are probably several causes for this, but one is that system development does not always equate to user accessibility. For instance, only four commercial systems exist in the United Kingdom that have received the necessary regulatory clearances, and depending on the location of the PWD, not all of them are accessible through the NHS or to all PWDs. Another issue is that some DIY customers won't transfer to the new commercial systems because they appreciate the versatility and adaptability provided by the DIY systems. As a result, not only do DIY APSs appear to be here to stay for the foreseeable future, but new DIY systems (like FreeAPSX) are joining the competition and building on the success of those that are already out there (OpenAPS, AndroidAPS, and Loop).

These DIY systems are made up of three parts: an insulin pump to deliver insulin, a continuous glucose monitor (CGM), which provides glucose readings, and a smartphone/small computer that runs an algorithm and gathers data. Once connected, the resulting system calculates and administers insulin doses automatically. Improvements in blood-glucose management and a decline in anxiety related to hypoglycemia are benefits cited by users [4].

Despite the fact that the use of DIY systems has continued to rise, they have not gone through the standard regulatory approvals procedures. Thus, DIY APSs provide a number of legal challenges for users, developers, and healthcare experts that have not yet received enough attention [4,5]. The servers that house the software and building manuals for the various DIY APSs are situated outside of the EU and the UK. The end effect is that "both legally and in practise, DIY APSs fall through a regulatory gap," as two of us have remarked elsewhere. This indicates that the typical approval and manufacturer registration processes do not include them. However, in current practise, the legal obligations and responsibilities of physicians and other actors with regard to DIY APS generally fall under the law of negligence. This is despite the fact that there is larger regulatory confusion about the status of DIY APS that has to be resolved.

Conflicts of Interest

The authors declare no conflict of interest.

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Date of Submission: 02-May-2022, Manuscript No. hps-22-70620; **Editor assigned:** 04-May-2022, PreQC No. P-70620; **Reviewed:** 18-May-2022, QC No. Q-70620; **Revised:** 23-May-2022, Manuscript No. R-70620; **Published:** 30-May-2022, DOI: 10.37421/2573-4563.2022.6.189

How to cite this article: Herrero, Georgiou. “A Commentary on Artificial Pancreas Systems” Hepatol Pancreat Sci 6 (2022): 189.