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Challenges in Therapeutic Education for Closed-Loop Systems

In recent years, technology applied to diabetes treatment has brought about a revolution, both for people with diabetes and for the health care professionals involved. As with the rapid technological evolution seen across society, regulation or systematic approaches to its use often emerge afterward, as a response to unmet and identified needs.

At present, several years after the initial boom of hybrid systems, we can reflect, based on experience and a forward-looking perspective, on the challenges therapeutic education in diabetes faces in an ever-changing landscape.

WHAT IS A HYBRID SYSTEM OR CLOSED-LOOP SYSTEM?

A semi-automatic system in which a glucose sensor and an insulin pump are interconnected via an algorithm that adjusts the necessary insulin dose every few minutes. It is currently the most advanced treatment for type 1 diabetes mellitus.

ABUNDANCE OF OPTIONS: A THREAT?

The variety of systems available and their constant updates pose a challenge, especially for healthcare professionals, who need thorough training to provide quality care to users. This requires time that we often lack during the workday.

Perhaps this explains the fact that, in a survey we launched on social media last January, 14 of the 44 professionals who responded (32%) identified independence in training (i.e., not relying on the manufacturer for patient training) as the main challenge in the face of the growing range of hybrid systems.

Nevertheless, the growing range of closed-loop system models is an advantage for people with diabetes, as each offers different features and capabilities, allowing us to select the one best suited to the specific needs of each individual (e.g., portability, sensor replacement frequency, glycemic control targets, mobile device management, etc.).

As health care professionals, technological advances aimed at improving the overall health of the people we serve are undoubtedly good news. The challenge lies in restructuring our work plans to adapt to this evolving reality.

EQUITABLE ACCESS TO CLOSED-LOOP SYSTEMS

Unfortunately, the presence of multiple closed-loop systems on the market does not mean that all individuals with type 1 diabetes mellitus have access to this variety—or even to a single model. The Spanish Diabetes Federation (FEDE) conducted a survey directed at representatives from all diabetes federations integrated within FEDE, analyzing four pillars of equitable access to integrated or closed-loop systems: treatment personalization, indication, information, and the number and training of healthcare professionals.

The results for each axis were as follows:

1. ***Treatment Personalization:*** A total of 78% believed that the public procurement model in their autonomous community restricted health care professionals from choosing the system best suited to their patients' needs. Nearly 45% felt that individuals could not jointly decide with their healthcare provider on the model that best fit their needs.

2. ***Indication:*** Nearly 45% reported that the same prescription criteria were not used across hospitals in their autonomous community. A total of 100% agreed that specific indications should be included in the national portfolio of health services.

3. ***Information:*** A total of 83% stated that the Health Administration did not proactively communicate new instructions and/or indications periodically. A total of 73% indicated that the relevant health portal did not have updated information.

4. ***Number and Training of Health care Professionals:*** A total of 72% felt that the lack of qualified professionals and training programs for closed-loop systems, both for professionals and patients, could be a barrier to prescribing this treatment.

The National Agreement for Equitable Access to Closed-Loop Systems was, therefore, established (1), which called for:

1. Integration of closed-loop systems into the national health service portfolio.

2. Indication of these systems for all indi- »

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viduals undergoing multiple daily insulin injections who wish to improve their disease control, with the only limitations being their ability to use these systems correctly and their commitment to utilizing them as efficiently as possible.

AUTONOMY IN TRAINING

The technical specificity of each system and ongoing updates create a constant and in-depth training need for health care professionals to help users make the most of these systems. Commercial companies provide training support during the implementation process for users. In some cases, this support is offered by healthcare professionals; in others, it is provided by industry professionals who are not healthcare practitioners. Consensus guidelines clearly state that the prescription and initiation of these systems must be conducted by trained, committed, and experienced healthcare professionals through structured educational programs (2).

A study titled Analysis of the Current Situation of Nurses in Therapeutic Education in Spain (February-September 2023) was conducted by the Therapeutic Education Working Group of the Spanish Society of Diabetes (SED). It surveyed a total of 1871 nurses (from primary and hospital care). Regarding whether the pharmaceutical industry participated in patient education for diabetes technology implementation, nearly 43% of hospital care respondents (where closed-loop systems are usually implemented) reported significant involvement, which raises concerns that training may, in many cases, be delegated.

Barriers Perceived by Diabetes Educators. Diabetes educators (professionals typically responsible for training system users) face several barriers, including lack of time, staff, and opportunities for professional development, insufficient space for group education sessions, lack of recognition and respect for their responsibilities, insufficient understanding of the specificities of each system, and challenges in managing appointment schedules. Addressing these barriers is urgent to restructure care and ensure quality services for those who rely on our attention.

MANAGING EXPECTATIONS AND RESPONSIBILITIES

Sometimes, both professionals and users may be blinded by "clinical enthusiasm," leading us to underestimate the impact of using these systems and the responsibilities they entail.

It is important to recognize that closed-loop systems can significantly improve glycemic control and quality of life (e.g., reducing fear of hypoglycemia and improving sleep quality) (3). However, achieving these benefits requires ensuring several key practices:

- Replacing the infusion set at the recommended frequency, rotating the infusion site, and avoiding areas with lipodystrophies.
- Trusting the system ("letting it do its job"), responding to alarms, and replacing the sensor when necessary.
- Accurately estimating carbohydrate amounts and administering boluses with the recommended timing before meals.
- Avoiding the input of false carbohydrate values.
- Activating the physical activity mode when engaging in exercise, ideally 60–90 minutes in advance.

Depending on the hybrid system model, adhering to these points can become

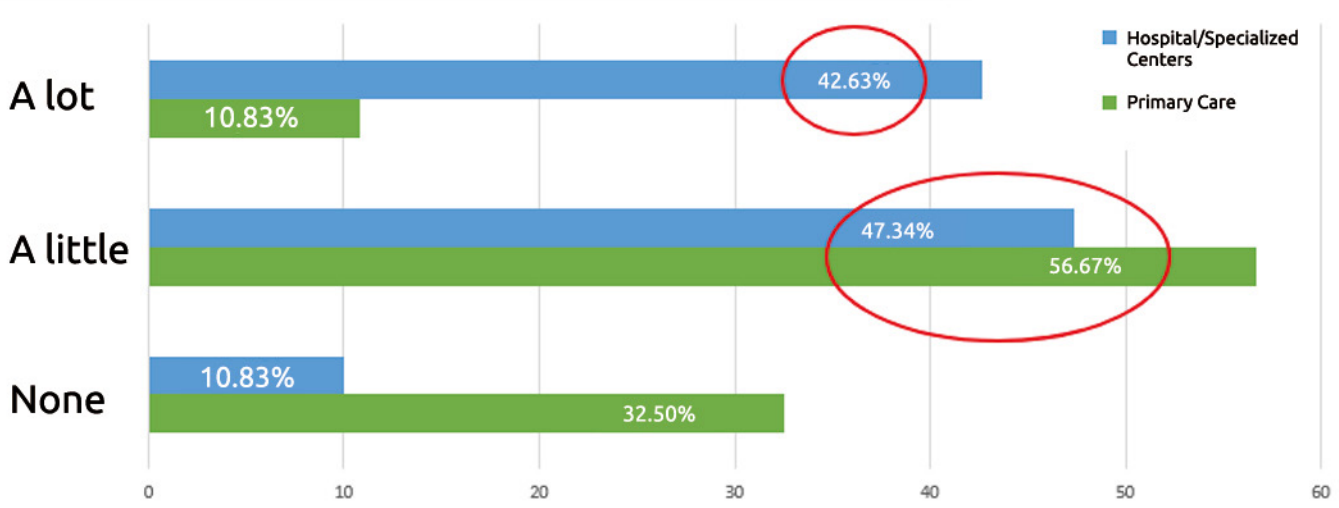

FIGURE 1. Answers to the question: "Does the pharmaceutical industry participate in educating individuals on the implementation of diabetes technology?" included in the survey from the study Analysis of the Current Situation of Nurses in Therapeutic Education in Spain, 2023.

» even more critical. For instance, in systems that recalculate insulin requirements based on the total administered over the past few days, extending the use of a cannula beyond the recommended time can impair insulin absorption. This may cause the system to overestimate insulin needs, leading to hypoglycemia once the cannula is replaced. Reinforcing these behaviors, along with addressing potential issues with infusion sets (e.g., cannula blockages, adhesive allergies, or injection site inflammation), is particularly important over time with these systems.

We must also consider the impact on body image from using an insulin pump and sensor, especially at the beginning. Similarly, the potential interference of alarms with daily life or sleep is a factor. Discussing these aspects during consultations and addressing common questions about everyday situations and potential disconnections will help set more realistic expectations for new treatments.

IDENTIFYING COMMON BASICS

A practical approach to hybrid systems involves identifying their common key points and unique features, guided by the paradigm proposed by Laurel Messel, known as CARES (4) (Table 1).

Answering these questions will help guide the initiation of these systems. Tables outlining the characteristics of each system currently available in our setting have already been developed. These resources can be found in the article by Daría Roca, published in this same journal: https://www.revistadiabetes.org/tecnologia/conocimientos-basicos-en-terapia-integrada-que-debemos-saber-en-caso-de-que-falle-el-sistema. D

C: calculate	• How does the algorithm calculate insulin administration? • Which components of insulin administration are automated?
A: adjust	• How can the user adjust insulin administration? • Which parameters can be adjusted to modify automatic insulin administration? • Which parameters are fixed?
R: revert	• When should the user switch back to manual mode? • When will the system exit automatic mode?
E: educate	• What are the key educational points for proper device usage? • How can users remain in automatic mode most of the time? • Where can users and professionals find additional training?
S: sensor/tracking	• What are the relevant sensor characteristics for each device? • What features does the system offer for remote monitoring and cloud-based data sharing?

TABLA 1

CONCLUSIONS

Therapeutic education in diabetes must evolve to incorporate the technological advancements of closed-loop systems. Ensuring structured educational programs, promoting equitable access, and providing specific training are essential to address current and future challenges. The organization and systematization of the educational and logistical process will contribute to better diabetes management and significantly improve the quality of life for users of these systems.

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