Navigating the Roadblocks: Identifying the Complexities and Challenges of Artificial Pancreas in Management of Type 1 Diabetes Mellitus

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Background & Objectives

Despite of significant scientific breakthroughs in managing type 1 diabetes mellitus (T1DM), there are still numerous intangible challenges that need to be addressed. This systematic review of literature aimed to comprehend and communicate the current barriers in initiation and usage of Artificial Pancreas (AP).

Methods

A systematic review adhering to PRISMA guidelines was conducted searching Embase® and MEDLINE® using the interfaces Embase.com and PubMed. Publications from last five years (1st Jan 2019 – 31st Dec 2023) reporting challenges associated with use of AP in management of T1DM were included. English only publications without any restriction of study design or geography were assessed. Relevant evidence from included studies was extracted and summarized.

Results

- A total of 812 records were retrieved from the biomedical databases
- After deduplication, 631 records underwent title/abstract screening, followed by full-text screening of 191 publications, leading to inclusion of 20 unique studies. Four relevant studies were added from bibliographic searching. Finally, 24 unique publications were included with 22 journal articles and 2 conference abstracts
- Four major challenges were observed impeding successful use of AP including technical complications (n=17), followed by psychosocial factors (n=9), economic burden (n=6), and lack of learning curve/training (n=3) (**Figure 1**)

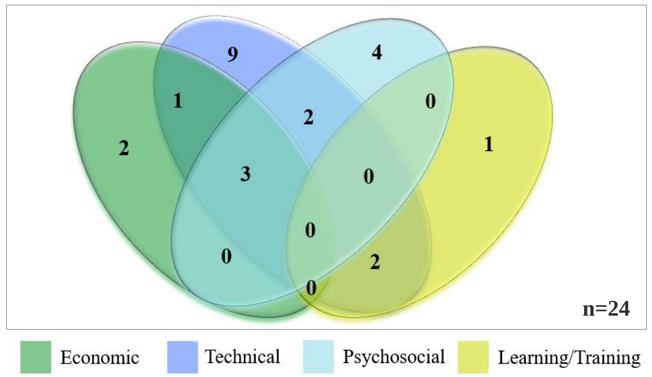

Figure 1: Distribution overview of AP challenges

Table 1. Key insights from studies reporting Economic challenges

Study name	Details of complications
Ebekozien et al., 2023	• Across most age groups, patients with private insurance experienced a larger favorable HbA1c reduction than those who were publicly insured
Kubilay et al., 2023b	• Affordability issues (indirect financial loss due to frequent HCRU leading to work loss/productivity; lack of government subsidies to meet high long-term expenses of AP utility) • Retirement-related issues (delaying retirement to afford AP, waiting for government subsidies before starting AP, working extra days to pay for AP)
Addala et al., 2020	• Patients with lowest SES exhibited lowest AP use
Farrington et al., 2020	• Affordability issues raised by clinicians
Messer et al., 2020a	• Caregiver expressed expense/reimbursement as one of the four most common challenges and reason for AP discontinuation (too expensive to afford, insurance coverage-related issues)
Messer et al., 2020b	• Cost/insurance-related concerns

Table 2. Key insights from studies reporting Technical challenges

Study name	Details of complications
Akiyama et al., 2023	• Frequent alarms and need for calibration
Kesavadev et al., 2023	• Connectivity issues with the sensor, cannula blockage kinking for those using insulin Fiasp, and too many alarms
Kubilay et al., 2023a	• Sensory inaccuracy • Disruptive overnight alarms
Kubilay et al., 2023b	• Technology access barriers in older individuals • Usability issues (sensory accuracy, sound of alarms, AP attachments and operation of the system)
Mizokami-Stout et al., 2023	• Sensors falling off or malfunctioning, frequent alarms, high number of calibrations with a glucometer
Sehgal et al., 2023	• Sensor-related issues • Challenges with digital integration of AP with phones
Farrington et al., 2022	• Tighter eligibility constraints in terms of the greater technical challenges and user input required for successful operation of Aps
Kimbell et al., 2022	• Inappropriate size/weight of AP for infants and toddlers
Vijayanand et al., 2022	• Frequent alarms and exits out of auto mode
Dubose et al., 2021	• Sleep disturbances because of nighttime alarms
Wang et al., 2021	• Frequent alarms, excessive user input, sensor quality issues • Checking the pump often to monitor its activity
Messer et al., 2020a	• Calibration related issues, high alarm frequency, time consumption for operating the system, technological difficulties (error alarm and malfunctioning)
Messer et al., 2020b	• Excess time requirement in device management
Wong et al., 2020	• Excessive robust information of glycemic data leading to concerns with information analysis
Zabinsky et al., 2020	• Dissatisfaction with ease of initial set-up and troubleshooting
Grando et al., 2019	• Physical design/structure, user input and alert frequency, difficulty in use, non-flexible settings
Musolino et al., 2019	• Device size, battery performance and connectivity issues

Table 3. Key insights from studies reporting Learning/Training challenges

Study name	Details of complications
Kesavadev et al., 2023	• Challenge in counting carbohydrates intake before meals and snacks due to lack of knowledge
March et al., 2021	• Inadequate guidelines and training to caregivers
Grando et al., 2019	• Limited understanding of the system and interpreting downloaded data

- Inadequate financial support impacted the willingness of patients and caregivers to adopt AP and continued long term use (**Table 1**)
- Among the technical complications, device size and malfunctioning, frequent alarms, and impaired algorithmic predictions were the most reported ones (**Table 2**)
- Lack of learning curve due to the overwhelming pool of knowledge leads to frustration and exhaustion, which negatively impacts trust (**Table 3**)
- Device complexity was identified as one of the contributors to the emergence of psychosocial challenges (**Table 4**)

Table 4. Key insights from studies reporting Psychosocial challenges

Study name	Details of complications
Kubilay et al., 2023b	• Frustration in older patients due to lack of financial support, reliability issues, sound of alarms, device complexity
Rankin et al., 2022	• Adolescents expressed distress regarding the visibility of AP and, restrictions to activities such as swimming
Wang et al., 2021	• Frustration due to high frequency of alarms and user input, sensor problems, inadequate responsiveness to hyperglycemia
Farrington et al., 2020	• Worry of clinicians about the potential impacts of AP on some users' psychological status, making users 'more anxious' • Unrealistic expectations (over-dependence of patients on the system)
Merzon et al., 2020	• Co-morbid neuro-psychiatric disorders included diagnosis of depression, ADHD leading to withdrawal of system
Messer et al., 2020b	• Discomfort with wearing the device on the body • Diabetes distress, and depressive symptoms
Tanenbaum et al., 2020	• Context-dependent trust (users trusted the system more to manage diabetes overnight than to handle meals and exercise) • Trust issues related to system accuracy, dependence on system, high frequency of alerts, and past experiences with certain device brands
Wong et al., 2020	• Concerns about receiving unwanted attention due to device use • Hassle of wearing device all the time • Nervousness to rely on technology
Gonder-Frederick et al., 2019	• Higher levels of emotional diabetes distress may increase the probability of negative experiences with technology

Conclusions

- The evidence provides an understanding of design, cost, psychosocial factors and training-related challenges faced by end-users
- Recognition of these challenges can help biotech/pharmaceutical companies advance their technological capabilities and enable healthcare providers develop better and structured training programs

Abbreviations: ADHD: Attention deficit hyperactivity disorder; AP: Artificial pancreas; HbA1c: Glycated hemoglobin; HCRU: Healthcare cost and resource use; PRISMA: Preferred reporting items for systematic reviews and meta-analyses; SES: Socio-economic status; T1DM: Type 1 diabetes mellitus

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