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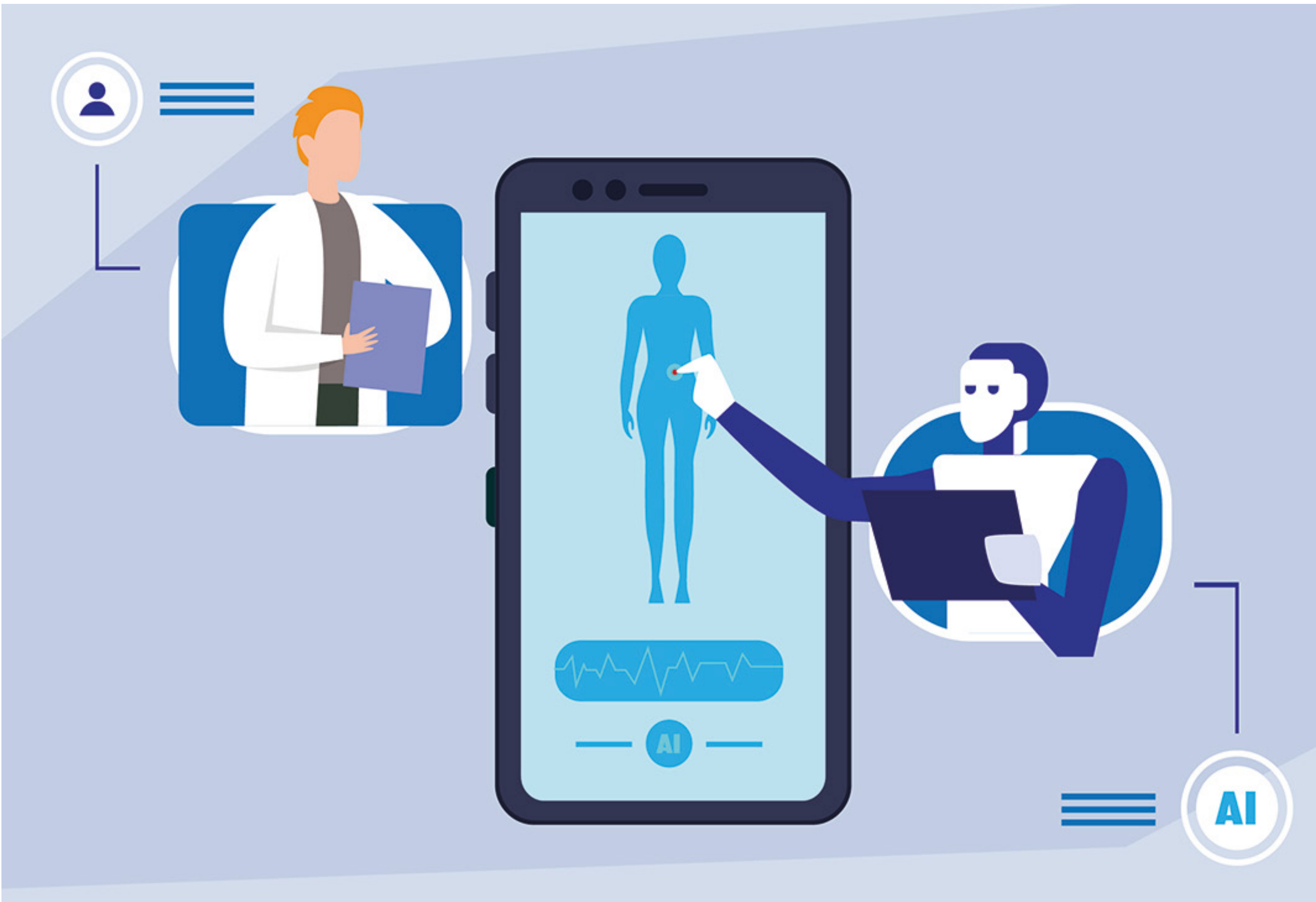

Automated insulin adjustment using artificial intelligence in multiple daily injection therapy

Multiple daily insulin injection therapy (MDI) is the treatment of choice for more than 90% of people with type 1 diabetes (T1DM) and approximately 30% of those with type 2 diabetes (T2DM) in Spain.[1] This basal–bolus regimen requires frequent decisions regarding insulin dosing, representing a substantial daily burden.

People with diabetes (PwD) using MDI spend more than 4 hours per week on self-management tasks and devote more active cognitive time to their diabetes than those not using insulin (1). Between 17% and 60% experience elevated levels of diabetes distress, with emotional and treatment-related domains being the most affected (2). Moreover, longer duration of MDI therapy is associated with a progressive increase in psychological burden (3).

At the same time, health care professionals face increasing workload due to the volume of continuous glucose monitoring (CGM) data, the need for frequent individualized adjustments, and growing health care pressure. A UK national study reported that more than 57% of endocrinology residents experienced burnout, rising to 62.5% in subsequent analyses (4).

Closed-loop insulin delivery systems (AID, Automated Insulin Delivery) have demonstrated clear benefits; however, access remains limited due to cost (approximately €3000–6000/year), technical complexity, and indication restrictions within the Spanish National Health System (SNS) (5). In this context, artificial intelligence (AI) systems applied to MDI represent a scalable alternative capable of reducing both patient burden and health care workload.

COMPONENTS OF AI–MDI SYSTEMS

Intelligent insulin adjustment systems in MDI integrate three main components working in coordination (1, 6).

SMART PENS

These devices automatically record administered insulin doses, injection timing, and calculate insulin on board (IOB), reducing missed doses and improving data recording. Examples include InPen (Medtronic), NovoPen 6/Echo Plus (Novo Nordisk), and Tempo Pen (Biocorp).

CONTINUOUS GLUCOSE MONITORING (CGM)

Provides real-time information on interstitial glucose, time in range (TIR), glycemic variability, and ambulatory glucose profiles (AGP). This information allows algorithms to “visualize” daily patterns and generate data-driven adjustment recommendations.

ARTIFICIAL INTELLIGENCE ALGORITHMS

These use techniques such as machine learning to identify individual patterns, reinforcement learning for dynamic adjustment based on prior outcomes, and Bayesian systems for personalized probabilistic prediction. Algorithms process glucose data, insulin doses, carbohydrate intake, physical activity, and contextual variables to generate individualized recommendations.

This ecosystem is complemented by mobile applications for PwD, delivering real-time recommendations, and web-based dashboards for health care professionals with aggregated analytics and alerts enabling remote monitoring.

ARTIFICIAL INTELLIGENCE SYSTEMS APPLIED TO MDI EMERGE AS A SCALABLE OPTION CAPABLE OF REDUCING BOTH PATIENT BURDEN AND HEALTH CARE WORKLOAD

RECENT EVIDENCE

Recent clinical trials have evaluated these systems in both hospital settings and community-based MDI users.

INCDSS TRIAL (JAMA NETWORK OPEN, 2025)

This randomized clinical trial compared an AI-based system providing real-time recommendations with adjustments performed by expert endocrinologists in hospitalized patients with T2D (1). The algorithm integrated more than 60 electronic health record variables using machine learning.

The system achieved glycemic control noninferior to senior endocrinologists, with a significant reduction in professional workload. Clinicians accepted algorithm recommendations without modification in more than 85% of cases.

BAYESIAN DECISION–SUPPORT SYSTEM (NATURE COMMUNICATIONS, 2025)

This 12-week randomized controlled trial included 41 participants in the experimental MDI group (6). The intervention combined the iBolus mobile application with a Bayesian decision algorithm for basal and prandial insulin adjustment.

Time in range improved, with large but hi- »

NO TRIAL HAS FORMALLY EVALUATED THE IMPACT ON DIABETES DISTRESS USING VALIDATED SCALES OR ON PROFESSIONAL BURNOUT USING INSTRUMENTS SUCH AS THE MASLACH BURNOUT INVENTORY, REPRESENTING A PRIORITY GAP FOR FUTURE RESEARCH

» ghly individualized dose adjustments: 29% increased both basal and prandial insulin, 26% decreased both, 21% increased basal and decreased prandial, and 24% showed the opposite pattern. This heterogeneity highlights the importance of algorithm-driven personalization.

Qualitative interviews identified three key themes: perceived glycemic improvement through personalized dosing reducing trial-and-error and anxiety; the advantage of continuous digital support between visits; and a strong preference for accessing advanced MDI technologies without permanent external devices (6).

CLINICAL OUTCOMES

Overall, studies report the following results (1, 6).

- **Efficacy:** HbA1c reductions of approximately 0.4–0.8%, increases in time in range of 5–15%, and reduced glycemic variability.
- **Safety:** No increase in hypoglycemia rates, with a trend toward reduction. Adverse events are comparable to standard care. Automatic dose recording helps prevent omissions that could lead to ketoacidosis.

For PwD, these improvements translate into more daily time within target glucose range and reduced reliance on trial-and-error insulin adjustments.

PATIENT EXPERIENCE AND HEALTH CARE WORKLOAD

Treatment burden

Participants reported reduced cognitive burden, greater confidence in dosing decisions—especially in non-routine situations—and described the system as a "co-pilot" enhancing autonomy through personalized information without replacing it (6). Continuous support reduced the feeling of being "alone" in daily management.

Health care workload

The iNCDSS system demonstrated a significant reduction in clinician workload by automatically processing multiple variables and generating evidence-based recommendations (1). Pre-analyzed data dashboards allow clinicians to devote more consultation time to therapeutic education, emotional support, shared decision-making, and patient concerns. Efficient remote monitoring reduces travel and increases the frequency of therapeutic contact.

KEY DIFFERENCES VS AID SYSTEMS

Differences in cost and the absence of external hardware make »

CHARACTERISTIC	AID SYSTEMS WITH PUMP	AI SYSTEMS IN MDI
Permanent external device.	Continuous infusion pump.	Smart pen and mobile device.
Type of adjustment.	Continuous automatic basal adjustment with microboluses.	Adjustment recommendations; final decision made by the person.
Estimated annual cost.	Approximately €3,000–€6,000/year.	Approximately €1,000–€2,000/year.
Target population.	Minority with access to pump therapy.	Most people using MDI.
Degree of "democratization".	Access restricted by cost and indications.	Potentially more accessible and scalable in the Spanish National Health System (SNS).

AI–MDI systems more easily scalable to a broader population of insulin-treated patients (1, 6, 5).

APPLICABILITY IN THE SPANISH CONTEXT

Advantages in our setting

Accessibility: applicable to most people using insulin with MDI.	**Scalability:** easy deployment in both specialized care and primary care settings.
Personalization: adaptation to local patterns (meal schedules, lifestyles).	**Integrated telemedicine:** optimization of resources through remote monitoring.

Current barriers

Device cost not yet covered by the SNS.
Need for specific training of health care teams in the supervision of AI-based systems.
Pending integration with electronic health records.
Lack of validation studies in the Spanish population.

LIMITATIONS AND FUTURE PERSPECTIVES

Current studies are limited in duration (<1 year), and specific populations such as older adults, pregnant women, and patients with T2D are underrepresented. Dependence on manual carbohydrate entry and connectivity requirements remain limitations. Regulatory status is heterogeneous, with some systems still under investigation.

Of note, no trial has formally assessed diabetes distress using validated scales or professional burnout using instruments such as the Maslach Burnout Inventory, representing a priority gap for future research (4, 7, 8).

Future directions include integration with physical activity sensors, automated carbohydrate estimation using computer vision, multimodal systems incorporating ketones and inflammatory markers, and validation in special populations. The development of more robust algorithms will enable greater automation while maintaining safety. D

CONCLUSIONS

AI-based systems applied to insulin adjustment in MDI allow optimization of treatment by reducing diabetes burden and improving self-management for PwD, while providing health care professionals with more time to dedicate to therapeutic education.

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