Automated insulin delivery: Why pregnancy makes glucose control harder

Written by The Life Science Feed Editorial Team · Published 25 September 2026 · Edited by Mara Voss

Maintaining tight glycaemic control is paramount for individuals with type 1 diabetes, particularly during periods of significant hormonal flux such as pregnancy and the menstrual cycle. These physiological states introduce considerable variability in insulin requirements, often necessitating frequent adjustments to insulin dosing regimens. The challenge lies in achieving optimal glucose targets without increasing the risk of hypoglycaemia, a delicate balance that conventional insulin therapy often struggles to maintain.
Automated insulin delivery (AID) systems, often referred to as artificial pancreases, represent a significant advancement in diabetes management. These closed-loop systems integrate continuous glucose monitoring (CGM) with an insulin pump, using algorithms to automatically adjust insulin delivery based on real-time glucose readings. The goal is to reduce the burden of self-management while improving time in range and reducing glycaemic variability.

KEY TAKEAWAYS

- The Pivot: AID systems offer enhanced glucose control, but their algorithms require careful tuning to account for the unique hormonal shifts of pregnancy and the menstrual cycle.
- The Data: While specific numeric results are not available for CamAPS Liberty in these populations, AID systems generally improve time in range and reduce hypoglycaemia compared to standard therapy.
- The Action: Clinicians should be aware of the need for personalised algorithm adjustments and increased monitoring when patients using AID systems navigate pregnancy or significant menstrual cycle changes.

Individuals with type 1 diabetes face a constant battle to keep blood glucose levels within a healthy range. This struggle intensifies dramatically during pregnancy, where tight glycaemic control is essential for both maternal and foetal health. Poor control increases the risk of pre-eclampsia, macrosomia, preterm birth, and congenital anomalies. The physiological changes of pregnancy, including fluctuating hormone levels and increasing insulin resistance, demand dynamic and responsive insulin management strategies.

The menstrual cycle also introduces predictable, yet challenging, fluctuations in insulin sensitivity. Many women with type 1 diabetes report increased insulin resistance in the luteal phase, leading to higher glucose levels, followed by increased sensitivity in the follicular phase. These cyclical changes can complicate insulin dosing, often leading to periods of suboptimal control and increased distress for patients. Traditional insulin regimens often require patients to anticipate these changes and manually adjust their doses, a task that is both burdensome and prone to error.

The Promise of Automated Insulin Delivery

Automated insulin delivery systems aim to alleviate the burden of manual insulin adjustments by using algorithms to predict and respond to glucose trends. These systems typically consist of a continuous glucose monitor (CGM), an insulin pump, and a control algorithm that communicates between the two devices. The algorithm processes CGM data and automatically adjusts basal insulin delivery and, in some systems, bolus recommendations, to maintain glucose within a target range. This continuous feedback loop can significantly improve time in range and reduce the incidence of both hypo- and hyperglycaemia.

The CamAPS Liberty system, for example, employs a model predictive control algorithm that learns an individual's insulin sensitivity and adapts insulin delivery accordingly. This adaptive learning is particularly valuable in situations where insulin requirements are highly variable. The system's ability to anticipate glucose changes and make proactive adjustments can offer a level of precision that is difficult to achieve with manual management, even for highly motivated patients. For a deeper understanding of how these systems integrate with patient care, consider the Oxford Handbook of Endocrinology and Diabetes.

But the inherent variability of pregnancy and the menstrual cycle pushes even advanced AID algorithms to their limits. The hormonal shifts are not merely static changes but dynamic processes that evolve over days and weeks. An algorithm that performs well in a stable state may struggle to adapt quickly enough to the rapid changes in insulin sensitivity seen during the third trimester of pregnancy or the premenstrual phase. This necessitates a more detailed approach to AID system configuration and ongoing clinical support.

Clinicians must understand that while AID systems automate much of the daily management, they do not eliminate the need for patient education and clinical oversight. Patients still need to enter carbohydrate counts for meals, correct for high glucose levels, and manage pump site changes. The system is a tool, albeit a sophisticated one, that requires active engagement from the user and their healthcare team. This is especially true when considering the unique challenges of insulin resistance and fertility outcomes in related conditions.

Navigating Pregnancy with AID Systems

Pregnancy in women with type 1 diabetes is a high-risk condition requiring intensive management to prevent adverse outcomes. Traditional management often involves multiple daily injections (MDI) or insulin pump therapy with frequent manual adjustments, often guided by continuous glucose monitoring. AID systems offer the potential to simplify this complex regimen and improve outcomes by maintaining tighter glucose control with less effort from the patient.

The physiological changes during pregnancy, particularly the progressive increase in insulin resistance, mean that insulin requirements can double or even triple by the third trimester. An AID system's algorithm must be robust enough to handle these escalating demands. Some systems may require more frequent manual overrides or adjustments to target settings by the patient or clinician to keep pace with these changes. This highlights the importance of close monitoring and proactive adjustments to the system's parameters.

The goal in pregnancy is to achieve very tight glycaemic targets, typically a time in range (TIR) of 70-180 mg/dL (3.9-10.0 mmol/L) of greater than 70%, with minimal hypoglycaemia. AID systems have shown promise in achieving these targets, often outperforming conventional therapy. But the specific algorithms and their adaptability to the unique hormonal milieu of pregnancy can vary. Clinicians need to be familiar with the capabilities and limitations of the specific AID system their patient is using.

Still, the data on AID systems in pregnancy, while encouraging, often comes from smaller studies or real-world evidence.

The long-term impact on foetal development and maternal health requires further investigation. The safety profile, particularly regarding the risk of severe hypoglycaemia, is a critical consideration. While AID systems generally reduce hypoglycaemia, the aggressive targets in pregnancy mean that vigilance is still necessary. This is a topic often discussed in the context of enhancing patient-clinician dialogue around severe hypoglycaemia.

Addressing Menstrual Cycle Variability

The impact of the menstrual cycle on glucose control is a well-recognised but often under-addressed challenge for women with type 1 diabetes. Hormonal fluctuations, particularly oestrogen and progesterone, influence insulin sensitivity. Many women experience increased insulin resistance during the luteal phase (the week or so before menstruation), leading to higher glucose levels and increased insulin requirements. Conversely, insulin sensitivity may increase during the follicular phase, raising the risk of hypoglycaemia.

For patients using AID systems, these cyclical changes can disrupt the system's ability to maintain optimal control. An algorithm that has learned a patient's typical insulin sensitivity may struggle when that sensitivity shifts dramatically for several days each month. This can lead to frustration for patients who expect the system to fully automate their management, only to find they still need to make manual adjustments or experience periods of dysglycaemia.

Some AID systems offer features that allow for temporary target adjustments or increased basal rates during specific phases of the menstrual cycle. Patients can be educated to anticipate these changes and apply pre-programmed settings or communicate with their healthcare team for guidance. This proactive approach can help mitigate the impact of hormonal fluctuations and improve overall glycaemic control throughout the month. The relationship between sex and hypoglycaemia is a complex area that continuous glucose monitoring data is helping to illuminate.

The challenge lies in accurately identifying the timing and magnitude of these cyclical changes for each individual. Menstrual cycles can be irregular, and the degree of insulin sensitivity fluctuation varies widely among women. This necessitates a personalised approach, where patients track their cycles and glucose patterns to inform adjustments to their AID system settings. Education and ongoing support from a diabetes specialist team are essential for optimising AID use in this context.

Optimising AID for Hormonal Changes

Optimising AID systems for periods of hormonal flux requires a combination of patient education, careful system configuration, and ongoing clinical support. For pregnant patients, frequent monitoring of glucose levels and insulin requirements is essential. The AID system's target glucose range may need to be adjusted more aggressively, and basal insulin profiles may require manual overrides or temporary adjustments as pregnancy progresses. Regular communication with the diabetes care team is paramount to ensure timely adjustments.

For menstrual cycle management, patients can be empowered to use features within their AID system that allow for temporary basal rate changes or different target glucose settings during specific phases of their cycle. Tracking menstrual cycles and correlating them with glucose patterns can help identify individual trends and inform these adjustments. Some systems may even offer predictive capabilities that can learn and adapt to these cyclical changes over time, though this remains an area of active development.

The integration of AID systems into routine clinical practice demands that healthcare professionals are well-versed in their operation, limitations, and optimisation strategies. Training for both clinicians and patients is vital to maximise the benefits of these technologies, especially in complex scenarios like pregnancy and menstrual cycle management. The goal is to leverage the automation while still providing the personalised care that these unique physiological states demand.

The open-label design of many real-world AID studies is an obvious caveat. While they provide valuable insights into system performance in everyday life, they lack the rigorous control of randomised trials. The specific algorithms used by different AID systems also vary, meaning that findings from one system may not be directly transferable to another. This necessitates a careful evaluation of each system's capabilities and evidence base when considering its use in these specific populations.

The next generation of AID systems will likely incorporate more sophisticated algorithms capable of learning and adapting to complex hormonal changes with even greater autonomy. This could include algorithms that automatically detect and adjust for menstrual cycle phases or dynamically respond to the rapidly changing insulin demands of pregnancy. The ultimate aim is to further reduce the burden on patients while maintaining optimal glycaemic control, but for now, careful clinical oversight remains essential.

> **CLINICAL IMPLICATIONS**
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> Automated insulin delivery systems are a clear step forward in diabetes management, but their application in pregnancy and during the menstrual cycle is not a set-and-forget solution. Clinicians must recognise that while these systems automate much of the daily grind, they still require intelligent oversight and patient education. Expecting an algorithm to perfectly navigate the hormonal maelstrom of pregnancy or the monthly shifts of the menstrual cycle without intervention is naive.
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> For patients, this means understanding that their AID system is a powerful tool, not a magic bullet. They need to remain engaged, track their cycles, and communicate openly with their care team about glucose patterns. The promise of reduced burden is real, but it comes with the responsibility of active partnership in their own care. The industry, in turn, needs to develop algorithms that are more dynamically adaptive to these specific physiological states, moving beyond static profiles to truly predictive, personalised adjustments.
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> The current state of AID technology, while advanced, still places a significant onus on the clinician to guide patients through these complex periods. This requires a deep understanding of both diabetes physiology and the specific AID system in use. Without this expertise, the benefits of these innovative technologies may not be fully realised, and patients could experience unnecessary periods of suboptimal control. The next iteration of these systems must offer more intuitive and autonomous adaptation to these predictable, yet challenging, hormonal shifts.

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