ORIGINAL ARTICLE

Why Expectations Will Determine the Future of Artificial Pancreas

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Introduction

AFTER MUCH ANTICIPATION, artificial pancreas (AP) technology is finally a commercial option for individuals with type 1 diabetes (T1D). AP is defined here as any system that automates the calculation of insulin delivery based on sensor glucose levels, from hybrid closed-loop therapy to future fully closed-loop or bihormonal systems.¹ As companies move devices through the product development pipeline, options for people with T1D will likely increase exponentially in the upcoming decade.

There is little doubt that AP systems can improve glycemic control in individuals with T1D. A recent meta-analysis of 24 randomized controlled clinical trials of AP systems showed an overall 13% improvement in time in target range, and a 35-min per day reduction in hypoglycemia.² The Medtronic 670G pivotal trial, although uncontrolled, likewise demonstrated increased time in target range with 11% increase in adolescents and 7% increase in adults, with 35% and 46% decrease in hypoglycemia, respectively.³ While this often-quoted statistics highlights the impact of AP, such data do not equip clinicians with meaningful information about who to recommend for AP therapy, or what to communicate to patients about AP practicalities. Many patients also utilize nonclinical online sources to satiate their curiosity of AP without the knowledge of their providers or diabetes educators. Closed-loop discussions, speculations, and recommendations are a constant on social media platforms, online diabetes forums, and within diabetes support groups. This is outside the control of the diabetes provider, but nonetheless magnifies the importance of the clinician's role: to be able to critically assess the appropriateness of AP therapy for an individual, educate competently on AP, and most importantly, set appropriate expectations for AP in the real world.

Why Expectations Are Paramount

Before the era of AP, expectations were noted to play a role in insulin pump satisfaction and continuance,^{4–6} continuous

glucose monitoring (CGM) use,^{7,8} and sensor-augmented pump therapy.⁹ As diabetes technology advances in an upward trajectory, expectations take a more extreme course of highs and lows: with each new advancement, expectations soar with idealism and then fall, tempered by the reality of what that generation of technology can and cannot deliver. The buildup starts with marketing and spreads with innovators and early adapters who have higher risk tolerance and are more likely to overlook hassles of a new system for the sake of novelty.¹⁰ After more collective experience with these devices, a firm understanding of capabilities and limitations take shape, and expectations stabilize among clinicians and patients alike. Not surprisingly, it is in the upsurge and peak of expectations that the largest mismatch with reality exists, and patients are at their highest risk of discontinuing therapy due to disappointment and frustration they had not anticipated.

True-to-life expectations are paramount to the uptake and continuance of AP therapy, and are fortunately within the realm of clinician influence. There is theoretical precedent for the predictive power of expectations, described most simply in the technology acceptance model (TAM).¹¹ The TAM was developed 30 years ago, conceptually derived from the theory of reasoned action, a well-established psychological/behavioral theory that helped explain volitional human behavior such as voting, exercise, and condom use.¹² Davis and colleagues transformed these concepts into a technology-centric model,¹¹ which has been adapted and applied across disciplines, from information technology and e-commerce^{13–16} to health science and medicine.^{17–20}

The core constructs of the TAM are straightforward: “perceived usefulness” of a device and “perceived ease of use” of the device will lead to the behavioral intention to use the device. These constructs are familiar to diabetes providers and educators; however, we often use alternative language: the “benefits of technology” and the “burden of technology.” These perceptions—or expectations—of AP devices inform the decisions of both clinician and patient. Van Bon et al.²¹ used the TAM as a framework to assess user expectations with future AP systems, also incorporating trust as a

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central component. They found that 89% of individuals thought an AP would be useful, and 87% thought it would be easily handled. As this study was conducted many years ago, the results were based on hypothetical systems and do not reflect current expectations with AP. Nonetheless, the constructs were valid in pointing to behavioral intention to use a system.

Mismatched Expectations with AP

AP systems are not the optimal choice for all individuals with T1D, just as there is no “one size fits all” for diabetes care. When patients are persuaded to use AP based on unrealistically high expectations of usefulness and ease of use, they may experience dissatisfaction with the device that does not live up to the expectations. Discontinuation of AP due to frustration is disruptive to the clinical care of T1D, consuming valuable clinical resources and patients’ time, money, and peace of mind. This can be largely avoided by increasing understanding of AP before device initiation.

One study investigated user expectations of AP after using a precommercial version of the 670G system in 32 individuals (ages 14–40 years) at 3 academic centers.²² Many of the subjects had high expectations of the AP before use. This included a perception that the device would be more “hands off,” that they could eat unrestricted without glycemic excursions, or that the system would require minimal interaction. Others articulated more moderate expectations, understanding system burdens such as bolusing requirements and blood glucose checking. Interestingly, there was a key difference between these two groups. The group with mismatched high expectations had less knowledge about AP therapy on entry to the trial, whereas the subjects with more realistic expectations had more previous knowledge of AP than the high expectations group. The implications of this study are simple: when individuals are equipped with better information, they are more likely to set appropriate expectations on the perceived usefulness and ease of use of an AP system. According to the TAM, this will predict intention to use the technology, and likely continued use of the device.¹¹

This has been observed in clinical care as well. As an example, at our large academic diabetes center, one 14-year-old adolescent asked to start the AP he had read about online that would take care of his 14% glycated hemoglobin (HbA_{1c}) while simultaneously eliminating all the work of diabetes: “no more checking, no more bolusing, it does it all.” He believed that his problems with diabetes would be solved by AP within 6 months. Without serious readjustment of his unrealistic expectations, this patient would have become quickly frustrated and disappointed by the actual system performance and be at high risk for discontinuation. In contrast, other patients show a better understanding of insulin pumps and glucose sensors and ask nuanced questions about additional AP functionality and tasks. Still others express moderate hope in hypoglycemia protection due to their understanding of low suspend systems, while keeping an open mind about capabilities for hyperglycemia mitigation. Overall, the expectations are tied to experience and knowledge level.

Clinician Responsibility to Set Appropriate Expectations

If perceived usefulness and perceived ease of use (conventionally, benefits, and burden) are central to whether individuals embrace AP, diabetes clinicians have a crucial responsibility: to help set these expectations appropriately. This is done by as-

sessing patients’ knowledge of AP and equipping them with information reflecting the real potential gains and hassles of an AP system. Clinicians should ask unambiguous questions related to both usefulness (expected glycemic goals, glucose control, hopes for AP) and ease of use (learning curve, daily interaction with AP, troubleshooting), with more suggestions in the accompanying Figure 1. This discussion should commence when patients start to consider AP therapy, and continue through AP system initiation and throughout use. Here are potential points to consider when guiding expectations.

Usefulness

The usefulness of AP is largely in improved glycemic control. This is a realistic expectation for some people—those who struggle with overnight control, hypoglycemia, or persistent hyperglycemia. Studies with the current system show a reduction in HbA_{1c} of 0.5% in adults and 0.6% in adolescents after 3 months, while significantly reducing hypoglycemia and improving overnight glucose levels.³ Improved glycemic control is not equivalent to perfect control, however, and often the expectations for improvement can be off by an order of magnitude. A parent recently came to our clinic suggesting she may discontinue the AP system if her child continued to have glucose values >140 mg/dL overnight. Her expectations needed significant resetting to understand the current state of the technology and reasonable goals for therapy. Furthermore, individuals who take scrupulous care of their diabetes may achieve better glycemic outcomes than those seen with current AP systems, making improvement an unlikely goal for a subset of users.² Future systems will likely show greater improvement in glycemic control, as new algorithms may include customizable glucose targets, optional meal boluses, activity and sleep data, or incorporation of bihormonal therapy. For the current AP system and the future systems, consider carefully if AP may have glycemic benefit for your patient as you discuss the utility of AP.

Similarly, AP may be useful in improving quality of life for some, but not all people. AP can grant peace of mind to individuals who worry about hypoglycemia or have hypoglycemia unawareness by tangibly reducing occurrences.^{2,3,23} AP can also give users confidence that their glucose levels are being managed even when they are not actively making insulin dosing decisions. On the contrary, quality of life could be diminished by worries associated with AP. These might include concerns over whether the system is working, disagreeing with automated dosing, or finding ways to “trick” the system to perform differently. For individuals who prefer to be in complete control of all aspects of their diabetes care regimen, AP will likely bring disappointment and frustration. This includes the “Type A+” patients who will struggle to disengage from compulsive diabetes care and insulin decisions they cannot see (due to proprietary “black box” calculations) or change. Consider these patient characteristics when setting AP expectations, and assess ability or willingness to give partial control over to an AP system.

Finally, patients must understand the algorithm constraints of any AP system as they set expectations for usefulness. A quick survey of social media demonstrates individuals trading advice on letting the current 670G system “learn their body” or “learn their diabetes” as if the current AP algorithm considers meal-times, exercise schedules, dietary choices, or diurnal hormone patterns. While future AP designs may do this, the current system

FIG. 1. Clinician-guided questions to assess patient expectations of Artificial Pancreas. AP = Artificial Pancreas.

only incorporates historical total daily dose to tune the algorithm.^{24,25} This is all that the system “learns.” AP systems are likely to increase in sophistication and customization, even to the point of incorporating modular algorithms or dual hormone infusion with insulin and glucagon. Several patients at our clinic have expressed waiting for future systems that will include more customization of targets and algorithm parameters so that they are able to fine-tune and subsequently trust the system more. By understanding the general nature of AP intelligence, patients can adjust expectations for system adaptation over time. This will necessarily be different for every future system, prompting re-adjustment of expectations and education with each device.²⁶

Ease of use

Patients considering AP need to understand the daily/monthly/yearly maintenance of an AP system. Usability includes time and commitment required for training, cost of device, number of fingersticks needed, troubleshooting frequency, ability to customize and silence alerts, capability for remote monitoring, replacement frequency of components (both disposables and durable equipment), and adequacy of support. These will all factor into whether the system is perceived as easy to use. The current commercial system requires 2+ calibration blood glucose levels per day, is not currently indicated to replace blood glucose checks for insulin dosing, requires regular troubleshooting to maintain operation,²³ and does not facilitate commercial remote monitoring. This is a demanding trade-off considering other commercially available CGMs (not AP) are factory calibrated (requiring no blood glucose calibrations), last for 10–14 days, and require little user maintenance. The trade-off, of course, is worth it when there are tangible benefits to AP use.

Consider that some individuals may see reduced burden if they are used to intensively checking blood glucose levels (6–10 times per day) but are open to giving control over to the AP system. These individuals include the classic “type A” personalities, who are scrupulous with diabetes care but not as compulsive as previously mentioned “type A+” personalities. Patients currently using continuous subcutaneous insulin infusion or CGM may also already anticipate hassles associated with device wear, but it is unknown if this places them at an overall advantage when adapting AP therapy. TAM theory suggests that it will, and more studies are needed to explore this. Overall, individuals who anticipate the workload constraints of AP will likely adapt to the technology more easily than those who expect the system to run itself.²² Hopefully future AP systems will increase ease of use by eliminating CGM calibration (already a reality for some CGMs), reducing troubleshooting tasks, and increasing sensor duration. In the meantime, clinician-guided expectations will allow individuals to engage the system with eyes open and tolerate the hassles of use to gain better glycemic control or better quality of life.

Conclusion

There is still much to be learned about incorporating AP into clinical care. Future research will elucidate best practices, including appropriate indication for AP, patient selection characteristics, and optimal education strategies. All of these, however, will be contingent on provider and patient expectations of the system, setting the course for successful use.

The 670G has been on the market for 1 year, and clinicians and patients are better informed of what to expect, the rollercoaster wave of expectations having quelled. This is a place of progress for both clinician and patient. The next

technological advancement will likely come soon, generating a new wave of high expectations and initial disappointments. As clinicians, we can prepare for this by cautiously tempering the expectations of our patients, orienting them to the likely reality of future advancements being incremental over the current reality. By setting appropriate expectations for the utility and ease of use for near-future devices, we place our patients at a significant advantage. Informed consumers of AP technology will likely be the ones to persist with the technology and reap benefits long term. As clinicians continue to learn who will be best candidates and appropriately recommend AP therapy, our success with AP will continue to improve. In the meantime, expectations reign paramount in patient intention to utilize AP technology.

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