Artificial Pancreas

OVERALL VISION AND LONG-TERM OBJECTIVES
The vision of the Artificial Pancreas (AP) Program is a world where broadly labeled, easy-to-use, discreet devices which automatically regulate blood glucose levels by automated delivery of insulin and/or other drugs with minimal, if any, user interaction, are commercially available, accessible, and affordable. This vision encompasses three categories of objectives:

1. To enable improved outcomes for people with type 1 diabetes (T1D) of all ages and stages.
2. To reduce burden on users, caregivers, and health care professionals (HCPs).
3. To increase affordable access and adoption.

RATIONALE
Artificial pancreas (AP) systems have been shown in numerous studies to improve clinical outcomes for people with T1D and simultaneously ease the burden of self-management. While other sectors of the research community work toward a cure, AP systems leverage mature and ever-improving technology and are, in principle, applicable to a large portion of the T1D population. AP systems have improved tremendously over the years in terms of both technology and accessibility, but there are opportunities for significant improvement that are within reach.

CURRENT STATUS
The first hybrid system, the Medtronic 670G, is currently on the market in the United States, and other similar products are in development. All components of such AP systems have seen significant advancements recently:

- Closed-loop algorithms are becoming more robust while requiring less user interaction
- CGM systems are becoming more accurate (even to the point of replacing BG meters), requiring fewer (if any) calibrations, and being labeled for longer durations
- Insulin pumps are improving in terms of user experience
- Wearables/consumables are improving in comfort and duration

Yet, there remain a number of achievable advancements associated with each of these components.

GAPS AND CHALLENGES

Outcomes
Glucose control is still suboptimal, particularly in postprandial times and during and after exercise. Potential ways to bridge this gap include:

- A transition from continuous glucose monitoring (CGM) being the main algorithm input variable to the incorporation of additional signals/variables
A transition from subcutaneous (SC) systems to more physiological systems (delivery and sensing)
A transition from fast-acting insulin (only) to different and/or better insulins and adjunct drugs
A transition from non-adaptive algorithms to adaptive/learning algorithms

Burden
Current AP systems carry a significant burden for the user, from both on-body and user-experience perspectives. Potential ways to bridge this gap include:

A transition from cumbersome devices to more discreet, miniaturized devices
A transition from frequent replacements of wearables/consumables to longer-lasting, extended-wear systems
A transition from interactions with medical devices to cloud/app-based interactions
A transition from frequent alarms and decision-making to infrequent or no such interactions

Access and Adoption
Certain subpopulations who might significantly benefit from these systems still do not have access to them (e.g., the very young, seniors and pregnant women). Moreover, adoption remains relatively low in those who do have access. Potential ways to bridge this gap include:

A transition from the current state of access to expanded access realized through specialized clinical studies
A transition from the current state of adoption to increased adoption through innovation, more user-friendly systems, lower costs, enhanced demonstration of improved outcomes, and educational efforts
A transition from closed, proprietary communication and data-management frameworks to open, interoperable frameworks utilizing industry-wide standards

MID-TERM GOALS

Improved Outcomes through a Drive toward Full Automation
Specific focuses include:

1. Advanced algorithms using inputs beyond glucose.
2. Physiological delivery and sensing.
3. Adaptive systems leveraging machine learning techniques.
4. Use of faster insulins to close the loop. (Note: The development of a drug is in the purview of JDRF’s Metabolic Control Program; the use of the drug in closed-loop systems is in the purview of JDRF’s Artificial Pancreas Program.)
5. Use of new drugs/adjunct therapies to close the loop. (Note: The development of a drug is in the purview of JDRF’s Metabolic Control Program; the use of the drug in closed-loop systems is in the purview of JDRF’s Artificial Pancreas Program.)
Reduced Burden
Specific focuses include:

1. Lowered on-body burden.
   a. Miniaturization.
   b. Longer-lasting consumables.
   c. Integration of sensor and pump (both devices and infusion/sensing sites).
   d. Less frequent or eliminated sensor calibrations.

2. Improved user experience.
   a. Cloud/app-based functionality.
   b. Less frequent decision-making and device interaction.

Expanded Access and Adoption
Specific focuses include:

1. Expanded labeling to include specific populations, such as the very young, seniors, pregnant women and early/new-onset.
2. Open-protocol systems.
3. Education for both (potential) users and HCPs on CGM and AP systems.

SHORT-TERM OBJECTIVES AND PRIORITIES

1. Incorporate additional inputs into AP algorithms/systems.
   a. Aligned with the mid-term goal of full automation by enabling more robust glucose control under a wider range of conditions.
   b. Aligned with the mid-term goal of an improved user experience by enabling a reduction in user interaction and/or more user-friendly interaction.

2. Develop user-centric innovations, such as miniaturized integrated systems, implantable systems, and improved infusion sets/systems with extended longevity and fault resistance.
   a. Aligned directly with the mid-term goal of an improved user experience.
   b. Aligned with the mid-term goal of a lowered on-body burden by enabling miniature devices and more convenient body attachments requiring less frequent replacements.

3. Continue to push beyond SC insulin-only systems; in particular, investigate the use of physiological delivery/sensing and adjunct drugs.
   a. Aligned with the mid-term goal of full automation by potentially enabling PK/PD more conducive to achieving robust glucose control.
   b. Potentially aligned with the mid-term goal of an improved user experience by enabling reduced frequencies of consumables refills/replacements.
   c. Potentially aligned with the mid-term goal of a lowered on-body burden by eliminating need to deliver insulin SC.

4. Explore the feasibility of open-protocol systems.
   a. Aligned with mid-term goal of an improved user experience by shifting functionality to familiar devices not associated with the disease state and by giving users choices in terms of which components to use.
b. Aligned with the overall vision of increased access and adoption by expediting the creation of and access to innovative technology, by transitioning functionality to familiar devices via familiar processes, by facilitating the generation of large, accessible, informative database, and by encouraging the use of industry-wide communication and data-management standards.

Figure 1 demonstrates how these short-term goals contribute to mid-term goals and, in turn, to the overall vision of the program.

Figure 1. Contributions of short- and mid-term goals to the overall vision of the JDRF Artificial Pancreas Program.