PRimary CarE PrAgmatic, Real World Experience for Automated Insulin Delivery (PREPARE 4 AID) in Patients with Diabetes

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Background

- **Automated Insulin Delivery (AID**) systems allow people with insulin-treated diabetes to achieve glycemic targets.
- These devices typically require considerable patient and staff time, which is often not feasible in primary care (PC) settings.
- The **iLet Bionic Pancreas (iLet)** takes minimal time to initiate.
- It is **FDA cleared** for type 1 diabetes (T1D) but has **not** been studied in diverse PC settings or in patients with type 2 diabetes.
- Our previous study with 40 adults with T1D (20 PC, 20 endocrinology), deployed in-person or via telehealth revealed:
  - Similar target glycemic outcomes between subgroups
  - **97%** of iLet users achieved average glucose (AG) <183mg/dL (HEDIS measure of <8)
  - Similar amounts of insulin used with the iLet and at screening, even as the AG was reduced.
  - No increase in hypoglycemia
- This study will assess iLet initiation by primary care providers who are *less* experienced with diabetes technologies.

Objective

To evaluate the **safety** and **efficacy** of the iLet Bionic Pancreas System prescribed by primary care providers in patients with insulin-treated diabetes (type 1 and type 2), impact on **quality of life** and **treatment satisfaction**, and **experience** and **satisfaction** of providers with prescribing the device.

iLet® Bionic Pancreas (Beta Bionics, Inc., Concord, MA)

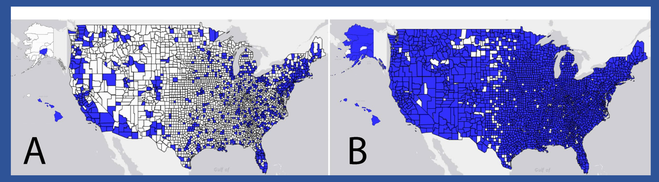
- ❖ Uses perpetual autonomous adaptation to fully automate insulin delivery.
- ❖ Only requires input of the patient's body weight for initiation.

Does not require:

- ❖ Insulin therapy decisions on the part of the patient or provider
- ❖ Patient numeracy
- ❖ Individual dosing information to initiate

People with diabetes need more accessible evidence-based technologies for their care.

Delivery *through primary care (B)* can help reach more patients with diabetes through virtual methods and can provide greater access for patients who do not have access to endocrinologists (A).



Our previous study showed intensive, endocrinology-specific and in-person resources are *not required* for effective iLet deployment.

Planned Outcomes

Primary

- **Superiority** for reduction in HbA1c at 13wks
- **Non-inferiority** for median glucose time <54 mg/dL

Secondary

Compare iLet to routine care At baseline & 13wks

Hierarchical:

- Average TIR
- Mean CGM glucose
- Average TAR >180
- Average TAR >250
- Average glucose SD
- Median TBR <70
- Median TBR <54
- Average glucose CV

Other

Participants:

- Diabetes distress
- Fear of hypoglycemia
- Emotional well-being
- Benefits & burdens of AID system use

Providers/Practices:

- Experience & satisfaction with the iLet

Study Design

Consent and Screening
n=138; 99 from CU; 39 from MGH
- People with insulin-treated diabetes
- Age 18-89 years

Baseline Assessment
- Blinded CGM (10 days)
- Surveys
- A1c, weight, pregnancy test

Randomization

iLet Bionic Pancreas (n=93)	Routine Care (n=45)
Randomized Control Trial (RCT) – 13 weeks	
• Train on iLet • Surveys • A1c, weight, pregnancy test	• Train on glucose meter • Surveys • A1c, weight, pregnancy test
Mid Period Follow-up	
End RCT • Surveys • A1c, weight, pregnancy test • Transition to routine care	**Observational Extension Phase (OEP) – 13 weeks** • Train on iLet • Surveys • A1c, weight, pregnancy test
	Mid Period Follow-up
	End OEP • Surveys • A1c, weight, pregnancy test • Transition to routine care

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