EXPLORING VIRTUAL CLINICAL TRIALS: Lessons from Clinical Care

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Virtual Clinical Trials: Challenges and Opportunities
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Overview

- What is Livongo?
- Challenges of remote chronic condition management
- Real-world Evidence research partnerships
- Use of digital tools for clinical research and medical product development
What is Livongo?
The Health and Cost Impact of Chronic Conditions Is Overwhelming

135 MILLION Americans have chronic conditions

73% of people with diabetes also have hypertension

46% Hypertension

14% Diabetes

33% Prediabetes

$327B Cost of diabetes

$131B Cost of hypertension

$44B Cost of prediabetes

75% of US healthcare spend is on chronic conditions

2. Statistics About Diabetes, American Diabetes Association, 2018
3. Vital Signs:...of Uncontrolled Hypertension (MMWR), CDC, 2012
4. Medical Care Expenditures for Individuals with Prediabetes, NCBI, 2017
For many Americans living with chronic conditions the **confusion, complexity, and cost** of the healthcare system is overwhelming and has resulted in them ignoring their health and conditions.

This is Noisy Healthcare.
Applied Health Signals: AI + AI
Livongo Health Programs & Devices

Livongo for Diabetes
2015

Livongo DPP
Powered by Retrofit
2018

Livongo for Hypertension
2019
Applied Health Signals: AI + AI
We Support All People with Chronic Conditions

People with chronic conditions are very diverse and their needs evolve over time

Maria (51) T2D, overweight
Just changed medications

John (54) T2D, HTN
Facing a complication

Britt (42) T2D, HTN
Doesn’t think checking is needed

Max (25) T1D
Diagnosed for 10 years, feels like an expert
Over 400+ Organizations Provide Livongo for their Employees/Members
Challenges of Remote Chronic Condition Management
Are We Observing the Right Person?
How Do We Create Meaningful Health Signals?

- HbA1c is gold standard lab test for assessing diabetes health status and risk stratification
- Livongo measures individual blood glucose values
- Created concept of “Observability”
- Increased our ability to observe health status of 25% -> 53% of our members

Estimated A1c for Livongo population. Mean BG converted to A1c using ADAG model.

Data Science Approach to Monitoring Health Status for a Diabetes Population, Oral Presentation, American Medical Informatics Association Summit, San Francisco, CA - March 15, 2018
How do we best coordinate care for members?

We surround members with the resources to get and stay healthy.
How do we best coordinate care for members?

- Livongo CDEs and member support refer members to Pharmacists
- Livongo can access data including Rx history (Upcoming in Q3)
- Pharmacists can refer members to enroll in Livongo

Livongo Clinical Website
Access members’ profile information, BG data and alerts

Livongo API
Display of Livongo data into Partner native system (BG data and Health Summary Report)

- Livongo CDEs recommend members see their provider regularly and for any medical decision

Livongo Clinical Website
Access members’ profile information, BG data and alerts and Health Summary Report

Livongo API
Display of Livongo data into Partner native system (BG data and Health Summary Report)

- Livongo CDEs and member support refer members to Care Managers
- Health Plan / Care Manager can refer members to enroll in Livongo
- Warm transfer to Livongo member support

Livongo Clinical Website
Access members’ profile information, BG data and alerts and Health Summary Report

Livongo API
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Member Engagement Reports
Receive member level usage data to assess enrollment, activation, and usage to support incentives and coordination
Real-World Evidence Research Partnerships
What is Real-World Evidence?

“We believe it refers to information on health care that is derived from multiple sources outside typical clinical research settings, including electronic health records (EHRs), claims and billing data, product and disease registries, and data gathered through personal devices and health applications.”

NEJM 375;23, December 8, 2016
What is the financial impact of a remote diabetes digital management program offering a connected blood glucose meter, digital and in-person CDE coaching at one year?
Other Examples of RWE Research

• Evaluation of Diabetes Patient Empowerment and Diabetes Distress With Real-World Patient Outcomes using the Livongo for Diabetes Platform

• Exploration of Blood Glucose Variability and Medication Use in a Real-World setting for Livongo members with Type 2 Diabetes

• Retrospective *In Silico* Evaluation of Glycemic Pattern Recognition System in the Livongo population Using Insulin
Use of digital tools for clinical research and medical product development
Remote Collection of Health Device Data for Research

- More convenient for research participants
- Less expensive for researchers
- Allows for more frequent assessments
- Consider impact of Hawthorne Effect - *the alteration of behavior by study participants due to their awareness of being observed*
  - BG checking patterns are different for some of our members when they are in “airplane mode”
  - Sharing BG values with friends, family, healthcare providers yields improved and sustained outcomes
Thank you!

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