The Use of mHealth to Manage and Improve Diabetes

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Categories of consumer-facing diabetes mHealth interventions

- Clinical tracking and management
- Sensor provided/analyzed data
- General purpose information
- Games

Current mHealth Research: Defining Interventions, Outcomes and Evidence

Figure 1. The CBDeT Model for Behavioral Treatment Development
Questions Addressed by Translation of Mhealth Research to Practice (Implementation)

• How can we achieve widely accepted and adopted mHealth interventions in a variety of real-world settings?
• What are modifiable mobile interventions consistently accepted and implemented by individuals with varying training and expertise?
• What mHealth elements/dimensions enhance feasibility, provider and patient adherence, and community uptake, producing reliable effects at reasonable cost?
• What mobile interventions assist persons to maintain change over time (lifestyle, medication adherence, weight loss)?

mHealth User behavior

• Determining how to engage health consumers and impact on health behaviors
• Perceived value, burden, consumer engagement are key factors in adoption and abandonment
  - 26% of downloaded health apps used only once
  - 74% abandoned by 10th use

mHealth measurable outcomes

• Clinical outcomes
  - Change in HbA1c
  - SMBG values
• Patient-reported outcomes
  - Quality of life
  - Mobility
  - Engagement
• Health system/population impact/delivery of care
  - Utilization
  - Cost
  - Receipt guideline recommended services
  - Workflow

What Quality of Life Improvements Are Most Important?

mHealth measurable outcomes

• Clinical outcomes
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  - SMBG values
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Case Study: Mobile Prescription Therapy (MPT)

- The first MPT, WellDoc, Inc's BlueStar was launched in 2014 for patients with type 2 diabetes.
- Clinical studies on earlier versions of BlueStar demonstrated a clinically significant reductions of A1C (2.0%, 1.9%) *
- Report here on initial measures of patient engagement based on analysis of de-identified observational data of BlueStar commercial users.


Case Study: Patient Engagement*

<table>
<thead>
<tr>
<th>Age group</th>
<th>Percent of total users</th>
<th>Percent of total engagements</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;60</td>
<td>17%</td>
<td>10%</td>
</tr>
<tr>
<td>50-59</td>
<td>41%</td>
<td>42%</td>
</tr>
<tr>
<td>40-49</td>
<td>20%</td>
<td>19%</td>
</tr>
</tbody>
</table>

Engagement was seen across all age groups with higher than expected engagement in the >60 age group.

Case Study: Patient Engagement

Engagement with various MPT features was high among active users.

<table>
<thead>
<tr>
<th>Total engagements</th>
<th>66,242</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication entries</td>
<td>28,977</td>
</tr>
<tr>
<td>BG entries</td>
<td>11,149</td>
</tr>
<tr>
<td>User notes</td>
<td>3,710</td>
</tr>
<tr>
<td>Labs/exams/screenings</td>
<td>1,521</td>
</tr>
</tbody>
</table>

Case Study: User BG Entries

<table>
<thead>
<tr>
<th>Number of BG entries by meal types (n=11,149)</th>
</tr>
</thead>
<tbody>
<tr>
<td>F</td>
</tr>
<tr>
<td>------</td>
</tr>
<tr>
<td>Number of BG entries</td>
</tr>
<tr>
<td>1403</td>
</tr>
</tbody>
</table>

Users entered BG values across all meal types (F=fasting, BB=before breakfast, AB=after breakfast, BL=before lunch, AL=after lunch, BD=before dinner, AD=after dinner, BT=bedtime)

Case Study: Patient Satisfaction

BlueStar User Satisfaction

<table>
<thead>
<tr>
<th>Important to use</th>
<th>4/5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improved self-management</td>
<td>4/5</td>
</tr>
<tr>
<td>Simple to use</td>
<td>3.75/5</td>
</tr>
<tr>
<td>Likely to recommend</td>
<td>1/0</td>
</tr>
</tbody>
</table>

Internal company data, BlueStar

Case Study: Clinical Outcome

Change in BG values entered between day 1 and day 120

<table>
<thead>
<tr>
<th>Change in mean BG (mg/dL)</th>
<th>fasting</th>
<th>post-prandial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean BG of users was lower after 120 days of use.</td>
<td>x1</td>
<td>16</td>
</tr>
</tbody>
</table>

Fasting BG improved more than post-prandial BG.
Case study: Hyper and Hypoglycemic events

Reductions were seen in MPT users in extreme BG value episodes over time (low BG<70 mg/dL, critical low BG<50 mg/dL, high BG>200 mg/dL, and high high BG>400 mg/dL).


Case study: Clinical Outcomes

<table>
<thead>
<tr>
<th>Group</th>
<th>n</th>
<th>1st AIC&lt;7%</th>
<th>2nd AIC&lt;7%</th>
</tr>
</thead>
<tbody>
<tr>
<td>BlueStar</td>
<td>0.7</td>
<td>11</td>
<td>25</td>
</tr>
<tr>
<td>Control</td>
<td>0%</td>
<td>20%</td>
<td>37%</td>
</tr>
</tbody>
</table>

At the time of the initial A1C reading, 49% of the control group patients had an A1C level within the recommended target versus 16% for BlueStar patients. The time of the second A1C reading, 49% of control group patients had an A1C level within the recommended target versus 37% for BlueStar patients. The control group had no improvement in the number of patients at the target level while BlueStar more than doubled the number of patients within the recommended target level.

Forthcoming AHA Scientific Statement

Current Science on Consumer Use of Mobile Health for Cardiovascular Disease Prevention
A Scientific Statement From the American Heart Association, Circulation, 2015

Forthcoming AHA Scientific Statement

Consumer use of mobile health

- Reviewed studies on the following topics:
  - Weight management
  - Physical activity
  - Smoking cessation
  - Blood glucose control (Type 2)
  - Blood pressure control
  - Lipid management

Review of Evidence for Efficacy

- Searched PubMed for the years 2004 to 2014
- 242 manuscripts identified; 159 reviewed further; 142 excluded; 17 eligible for inclusion; 10 of 17 were international studies
- Similar to other sections of the review mobile technologies may target multiple behaviors singly or in combination to improve numerous clinical and behavioral outcomes.
- Therefore, for this review co-authors agreed should focus on studies with change in clinical metric, HbA1c as the primary outcome, considered the gold standard in diabetes improvement.
Forthcoming AHA Scientific Statement
Consumer use of Mobile Health-Findings

- Large, primary care RCTs of mobile diabetes management are limited
- Smaller studies are addressing feasibility, usability, and acceptability
- Generally identified the following components essential to successful diabetes management: personalized engagement, provision of actionable feedback for consumers, and connection with providers or healthcare systems.
- Additional contributors to usability include mobile technologies to support community health workers and peer-supported self-care behaviors.

Evidence for Efficacy-change in HbA1c

- Significant mean difference in HbA1c change for mHealth interventions compared with control condition met coauthors decision rule of reduction of at least 0.3% as a clinically meaningful treatment effect and a 1% decrease in HbA1c as a clinically meaningful indicator of reduced risk of diabetes mellitus complications.
- Questions remain:
  - optimal frequency of use of systems by patients and providers
  - whether the success of interventions depends on repeated modification of patient’s treatment regimen or
  - ongoing assistance with applying a static treatment plan.

AHA Scientific Statement: Gaps

- Few studies focus on high-risk, underserved, or minority populations.
- Most studies do not report changes in antihyperglycemic medications during the intervention, which may affect change in HbA1c.
- Reviewed studies did not report intervention dose or receipt, e.g., number of SMS messages or push notifications sent and opened by participants.
- Only 1 study reported differences in HbA1c change as a function of different baseline HbA1c levels, important for understanding who will most benefit.

AHA Scientific Statement: Recommendations

- Technology development or intervention development should be considered to meet the needs of specific population groups:
  - older adults with age-related changes (vision or touch),
  - minorities needing culturally sensitive intervention content or materials and approaches,
  - low-income adults who may have inconsistent access to mobile technologies and supplies to support diabetes management.

AHA Scientific Statement: Study Recommendations

- Evaluate technology-supported glucose management for periods >3 months to determine the sustainability of engagement and long-term effects of mHealth interventions in maintaining behavior changes.
- Include clinical, technical, behavioral factors that may influence the initial engagement and ongoing use of mHealth and its associated impact on outcomes.
- Examine other outcomes related to improved diabetes management, quality of life and acceptability of mHealth devices.

AHA Scientific Statement: Recommendations

- Examine the relationships among use of mHealth interventions, HbA1c change and other indicators of improvement, and healthcare use and costs, including consumer and provider costs.
- As more public and private insurers reimburse for the cost of mHealth interventions, evaluation of claims data from these populations may add to our understanding of cost-effectiveness.
Possible “New” Disruptive Research for Evidence on Effectiveness

- Study size
  - Need both large and small
- Setting
  - Primary care where majority of diabetes care provided
  - With-in patient care units or communities
  - Patients as partners in mHealth design and evaluation
- Methods
  - mHealth as data collection tools and interventions
  - Leverage multiple mobile data sources
- Endpoints
  - Patient-oriented
  - Quality of life may be as important than clinical outcomes
  - Health service utilization and cost analyses needed

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