Digital Therapeutics: Improving Outcomes for Patients with Chronic Diseases

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Outline of Presentation

• Introduction
• Digital DPP
• Overview of digital health
• Digital Therapeutics: A new class of therapies
• How digital therapeutics can bring value comparable to medications/devices
• Example of a digital therapeutic for adults with chronic diseases
  • Better Choices, Better Health (BCBH)
• Q & A

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Canary Health: Leader in Digital Therapeutics

- **Mission:** Decrease the frequency and severity of chronic conditions
- **Tech-Enabled Service:** Deliver digital therapeutics
- **Differentiated:** Increase self-efficacy to self-manage life and chronic conditions
- **Partnering:** Work with Community-Based Organizations, Health Plans, Providers and pharma/device companies
- **Impact:** Our digital diabetes prevention, self-management support, and caregiver programs have engaged more than 65,000 people
Why Digital DPP Works

- Rigorous CDC oversight and recognition
- Faithful to DPP model and implementation
- Available 24/7/365
- Level of engagement / coach interactions
- Attractive to individuals who can’t or don’t want to join in-person groups
- Easy to implement & administer by host organization
- Digital outreach approaches effective and low cost
- Utilization, engagement, outcome data for analysis
Virtual Lifestyle Management (VLM) Delivers Diabetes Prevention Program

- Year-long digital lifestyle change & weight loss intervention
- 16 weekly core / 8 monthly maintenance lessons
- Dynamic behavioral goal-setting, planning and tracking
- Digital health professional coaching – secure messaging, moderated chat
- Group dynamic
- Developed with PITT & UPMC – creators of original DPP
- Launched in 2006 (currently version 6)
- More than 50,000 users; average age 55 years old
- CDC fully recognized
- Covered by commercial insurance, MediCal, not Medicare
Epidemic of chronic diseases persists despite massive investments in healthcare, medications, drug delivery systems and monitoring devices.

Organizations accountable for health of a population have invested in chronic condition management and population health programs, however, much still needs to be done to:

- Improve quality
- Drive deeper patient engagement
- Deliver lasting outcomes that matter
- Ensure reduced utilization and costs
- Digital Health and Digital Therapeutics: Leading the way to improved outcomes
Digital Health Tools

- Health System Disease Management Apps
- Consumer Mobile Apps
- Consumer Wearables
- Connected Biometric Sensors
- Text Messaging or Email
- Smartphone Cameras
- Web-Based Interactive Programmes
- Personal Health Records
- Telemedicine and Virtual Physician Visits
- In-Home Connected Virtual Assistants
- Clinical Trial Patient Information Collection Tools
Digital Health in Patient Journey

- **Wellness & Prevention**
  - Exercise & Fitness
  - Diet & Nutrition
  - Lifestyle & Stress
  - Stress Management
  - Sleep/Insomnia
  - Smoking Cessation
  - Alcohol Moderation

- **Symptom Onset and Seeking Care**
  - Patient Experience Tools
    - General Healthcare Information
    - Symptom Checking
    - Finding a Clinician
    - Managing Clinical and Financial Information
    - Social Media

- **Diagnosis**
  - Physician may recommend app-supported disease management programmes, connected sensors for remote monitoring, or apps for any use case across the patient journey.

- **Condition Monitoring & Management**
  - Self-Monitoring
  - Remote Patient Monitoring
  - App-Enabled Rehabilitation Programme

- **Treatment**
  - Prescription Filling & Compliance
    - Prescription Discounts
    - Prescription Filling
    - Medication Management & Adherence

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Disease Specific App by Therapy area
Digital Therapeutics: A New Class of Therapies

Digital services
- Support and improve patient habits and behavior
- Independent of traditional pharmaceuticals
- May have peer-reviewed evidence
- Not regulated by the FDA

Adjunctive Digital Therapies
- Adds value to existing pharmaceuticals
- Improves clinical benefit (e.g., adherence)
- May require FDA approval

Drug-replacement / enhancement
- Direct, clinical benefit
- Standalone (e.g., insulin dosage recommendations)
- Approved and regulated by FDA similarly to traditional therapies
Promising Interventions to Reach Right Care Control Targets for Heart Attack, Stroke, and Diabetes Prevention and High Quality Management

Patient Activation
- Stress reduction, medication adherence, healthy sleep, nutrition & physical activity, smoking cessation
  - Evidence-based patient education (e.g., Project DULCE; Stanford Patient Self-Management)
  - Motivational interviewing and evidence-based media messaging

Clinical Pharmacists on Care Team
- CA Dept. Public Health White Paper
- HRSA.gov/patientsafety

Patient Centered Practice Redesign
- Team-Based Medical Home
- Un-blinded Performance Feedback
- Web Supported High-Tech Enabled Biometrics Screening (BP, LDL, HBA1c, Coronary Calcium CT Scan Score)
- Optimized Clinical Connectivity For Rapid Treatment Timely Continuous Care—Not Episodic

Protocols
- Nationally Endorsed Guidelines (ACC, ADA)
- NICE UK (eg. chest pain)
- Bundled Medication Therapy (Aspirin, Statin, Hypertension Agents)

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Example of a Digital Therapeutic

Better Choices, Better Health®

Chronic Disease Self-Management Program
Key Characteristics of Any Medical Therapy

1. Target population(s)
2. **Mechanism of action**
3. Active ingredient(s)
4. Contraindications
5. Role with other treatments
6. Patient requirements for success
7. Side effects
8. Outcomes
Mechanism of Action: Increase Self-Efficacy

- “Self-efficacy is the belief we have in our own abilities, specifically our ability to meet the challenges ahead of us and complete a task successfully.” (Bandura 1997; Akhtar, 2008)

- “Self-belief does not necessarily ensure success, but self-disbelief assuredly spawns failure.” Albert Bandura

- “If I have the belief that I can do it, I shall surely acquire the capacity to do it even if I may not have it at the beginning.” Mahatma Gandhi

- "Whether you think you can, or think you can’t....you’re right” Henry Ford

“You have brains in your head and feet in your shoes, you can steer yourself in any direction you choose!”

Dr. Seuss
Individuals’ Characteristics Based on Degree of Self-Efficacy

People with a strong sense of self-efficacy:

- View challenging problems as tasks to be mastered
- Develop deeper interest in the activities in which they participate
- Form a stronger sense of commitment to their interests and activities
- Recover quickly from setbacks and disappointments

People with a weak sense of self-efficacy:

- Avoid challenging tasks
- Believe that difficult tasks and situations are beyond their capabilities
- Focus on personal failings and negative outcomes
- Quickly lose confidence in personal abilities
Examples of individuals with strong self-efficacy

• A woman who has accepted a job in a role she has never performed before but feels she has the ability to learn and perform her job well.

• A man who has had bad luck with relationships so far, but retains a positive outlook on his ability to connect with his upcoming date.

• An entrepreneur who pours her heart and soul into establishing her business, but quickly moves on to her next great idea when her business is hit with an insurmountable and unexpected challenge.

• A man who is struggling to manage his chronic illness but feels confident that he can get back on track and improve his health by working hard and following his doctors’ recommendations.
Key Elements Leading to Increased Self-Efficacy

1. **Mastery**: Gaining experience when we take on a new challenge and succeed.

2. **Vicarious experience** (Social Modeling): Having a role model to observe and emulate.

3. **Verbal persuasion** (Social Persuasion): Being impacted by the words we hear.

4. **Psychological Responses**: Being influenced by context and overall health and well-being

5. **Visualization** (Imaginal experiences): Imagining future success to build belief succeeding is possible.

#1-4  Bandura; #5 Maddux
Increasing Self-Efficacy

1. Accelerates behavior change (e.g. adherence)
2. Reduces depression, anxiety and stress-related disorders
3. Lessens perceived pain
4. Slows cognitive decline
5. Diminishes social isolation
6. Increases health program participation
7. Improves system navigation

Which improve quality of life, reduce the incidence and burden of chronic conditions and decrease healthcare costs.
Example of a Digital Therapeutic
# Key Characteristics of Two Therapeutics

**Insulin and BCBH**

<table>
<thead>
<tr>
<th><strong>Target population</strong></th>
<th>Patients with diabetes who require insulin</th>
<th>Adults with chronic conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mechanism of Action</strong></td>
<td>Replace missing or ineffective hormone</td>
<td>Increase self-efficacy to self-manage</td>
</tr>
<tr>
<td><strong>Active ingredient(s)</strong></td>
<td>Insulin type (chemical structure)</td>
<td>User's experience</td>
</tr>
<tr>
<td><strong>Contraindications</strong></td>
<td>Insulin allergy</td>
<td>None</td>
</tr>
<tr>
<td><strong>Role with other treatments</strong></td>
<td>Needs healthy lifestyle and specific diet</td>
<td>Adjunctive to traditional clinical care and case management</td>
</tr>
<tr>
<td><strong>Accept</strong></td>
<td>Accept blood glucose testing and carb counting</td>
<td>Cognitively intact; digital access; able to use email</td>
</tr>
<tr>
<td><strong>Side effects</strong></td>
<td>Hypoglycemia/hyperglycemia</td>
<td>None</td>
</tr>
<tr>
<td><strong>Outcomes</strong></td>
<td>Life-saving, prevents complications and early death</td>
<td>Improves clinical outcomes, saves cost</td>
</tr>
</tbody>
</table>
BCBH Mechanism of Action and Active Ingredients Supported by Three Decades of Research from Stanford Patient Education Research Center

- Dr. Kate Lorig’s foundational research documenting central role of Self-Management Support
- Originally Developed CDSMP at Stanford (Chronic Disease Self-Management Program)
  - Worldwide deployment in 30 countries; 17 languages
  - Over 1 million participants
  - Hundreds of papers documenting impact on adults with variety of chronic conditions (e.g. arthritis, diabetes, depression, multiple chronic conditions)
  - Evolving based on relevant national standards, new information, wisdom from studies, and technological innovations
Increase Self-Efficacy to Improve Self-Management

- Connects life priorities to health outcomes
- Enhances coping with emotions/depression
- Improves friends and family relationships
- Supports healthy lifestyle change
- Enhances communication with clinicians
- Drives therapy adherence

Improved Self-Management

- Improves health status and reduces use of health resources
- Directly improves health outcomes
- Augments benefits of clinical care
- Integrates into clinical care
BCBH Target Population

For adults living with one or more chronic conditions which require daily self-management.
BCBH® Active Ingredients:
Interactive Six-Week Workshop

**Foundational**
- Self-Management Principles
- Goal Setting / Action Planning
- Relaxation
- Pain Management
- Problem Solving

**Supporting**
- Difficult Emotions
- Physical Activity
- Weight Management
- Fatigue Management
- Sleeping Well
- Communication
- Medications
- Evaluating Treatment Plans
- Working with Healthcare Team
- Depression

**WEEKLY TOPICS**
- Guided Lessons
- Action Planning
- Peer Support Peer Facilitation
- Cycles for 6 weeks
- Peer Facilitation

**Moderated Discussions**
- Action Planning
- Peer Support Peer Facilitation
- Cycles for 6 weeks
- Peer Facilitation

Workshop Topics
Demonstration
BCBH Evidence of Impact

• Anthem type 2 diabetes study
• Real-world, self-management support, in-person and digital therapeutic intervention
• Unique multi-organizational partnership
• Large sample- statistical & clinical significance
• Variety of reliable and valid outcome measures
• Generalizable to other populations
BCBH Improves Clinical and Economic Outcomes

2014-2016 Anthem-Stanford study

N = 1,242 (1,010 digital; 232 in-person)
Type 2 diabetes
16% > 65 years old
Mean age=57; private insured 94%;

- **Significant Clinical Impact (6 and 12 months)**
  1. Increased self-efficacy
  2. Decreased A1C 0.45% at 12 months
  3. Decreased A1C 1.27% at 12 months (Initial A1C>9%)
  4. Reduced incidence of Depression 27%
  5. Improved Medication Adherence by 16%
  6. Increased Exercise 43 minutes Per Week

Benefits of Diabetes Self-Management for Health Plan Members: A 6-Month Translation Study
doi:10.2196/jmir.5568

A Diabetes Self-Management Program: 12-Month Outcome Sustainability From a Nonreinforced Pragmatic Trial - Lorig,KL; J Med Internet Res 2016 | vol. 18 | iss. 12 | e322
• Reduced 12 month all-cause healthcare utilization and costs in year post intervention
• Reduced ED, pharmacy, inpatient and outpatient services
• Decreased claims across variety of co-morbid conditions
• Decreased healthcare utilization for co-morbid conditions - minimal change for diabetes-related utilization
• Lower costs in the year post intervention (unadjusted)
• Total cost savings attributed to intervention was $815 in year post intervention
• Delivered 3:1 return on investment

How BCBH is Being Used Now

- Stand-alone element of disease management program
- Part of well-being initiatives from employers
- Coordinated digital and in-person program as part of clinical care
- Integrated element of a chronic condition / population health program
- Embedded in partner’s condition management digital therapeutic program
Q & A

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User Experience

Screenshots of BCBH

For live demo go to https://goo.gl/Av6R5g
For participant story go to: https://vimeo.com/192045797
Choose Workshop & Get Ready To Start

- Workshops start at least every other week
- Participants choose best workshop date
- 25-30 to workshop
- Self-test before workshop to baseline and guide
Guided Experience with Clear Home Page

- Program “tunnels” users to key tasks
- Options to dive deeper
- Strong satisfaction for users with various technical skill levels
- Mobile friendly
Interactive Learning

- Multi-media lessons cover key self-management topics
- Weekly content dosed to engage and build self-efficacy
- Can review at any time
Personal Action Planning

- Personal goal focused
- Proprietary Stanford approach to support action planning
- Builds confidence, self-efficacy supporting long-term behavior change
Discussion Center Engages Workshop Community

- Participants post to group discussion board
- Provide support
- Tell stories
- Facilitator coaches monitor discussion and provide support
Celebration Board

- Participants celebrate their successes
- Group supports the celebration
- Reinforces success and behavior change
Alumni Community

• After six-week workshop participants can join broad alumni community
• Ongoing interaction and support
“I’ve had Type 2 diabetes for 9.5 years...I have achieved a lot in my life, but before the program I didn’t feel like a winner.... my inner self knew I wasn’t doing that well. I wasn’t guaranteeing myself longevity...what was critical about BCBH was the support: Support from the participants, support from the facilitators and support from the materials. They see you follow through on your action plans and celebrate when you do... The material and facilitators – everything about the program – was high quality....the program was fun and enjoyable because I learned something new every week."
“BCBH is a total program. It includes reading, discussing, questioning and above all establishing goals and objectives in a systematic methodology...You make better choices for yourself.... You interact with other people, some who have far more difficult circumstances than you do – it inspires you to share with them and to act yourself to improve your health. ....I have lost 45 pounds....All 20 of my recent lab tests were normal. My diabetes and arthritis are under good control or in remission. Life can be so good!”
"Better Choices gives you literally hundreds of ideas, and doesn't ask you to do all of them, but pick a couple that you want to do. In combination with the support you get from the group - it worked. Before the program, I was on a bunch of medications. I'm on 1/3 of those medications now. Better Choices, Better Health has been more valuable to my health, mental health and well-being than any other thing I've tried in years."