Digital Health: Evaluating the Evidence, Identifying Gaps, Producing Better Science

Workshop at the 23rd Annual Meeting of the International Society for Pharmacoeconomics and Outcomes Research

May 21, 2018

Structure of the Workshop

• Overview of the Landscape of Digital Health

• Learning from the Past: Evaluating the State of Evidence
  – Facilitated Discussion

• Designing Real-World Digital Health Studies to Better Meet End User Needs
  – Facilitated Discussion
The Landscape of Digital Health
Digital Health Tools

- Health System Disease Management Apps
- Consumer Mobile Apps
- Consumer Wearables
- Connected Biometric Sensors
- Web-based Interactive Programs
- Text Messaging or Email
- Personal Health Records
- Telemedicine and Virtual Physician Visits
- In-Home Connected Virtual Assistants
- Smartphone Cameras
- Clinical Trial Patient Information Collection Tools
Digital Health Apps by Category 2017

2015 100% = 165,000 apps; 2017 100% = 315,000 apps

WELLNESS MANAGEMENT

<table>
<thead>
<tr>
<th>Category</th>
<th>2015</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dist and Nutrition</td>
<td>13%</td>
<td>60%</td>
</tr>
<tr>
<td>Lifestyle and Stress</td>
<td>19%</td>
<td>12%</td>
</tr>
<tr>
<td>Exercise and Fitness</td>
<td>40%</td>
<td>30%</td>
</tr>
</tbody>
</table>

HEALTH CONDITION MANAGEMENT

<table>
<thead>
<tr>
<th>Category</th>
<th>2015</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthcare Providers/Insurance</td>
<td>48%</td>
<td>40%</td>
</tr>
<tr>
<td>Medication Reminders and Info</td>
<td>27%</td>
<td>11%</td>
</tr>
<tr>
<td>Women’s Health and Pregnancy</td>
<td>10%</td>
<td>8%</td>
</tr>
<tr>
<td>Disease Specific</td>
<td>16%</td>
<td>9%</td>
</tr>
</tbody>
</table>

Disease-Specific Apps by Therapy Area

- Mental Health and Behavioural Disorders, 28%
- Diabetes, 16%
- Nervous System, 7%
- Heart / Circulatory System, 11%
- Cancer, 5%
- Musculoskeletal System and Connective Tissue, 7%
- Digestive System, 4%
- Respiratory System, 5%
- Skin and Subcutaneous Tissue, 3%
- Endocrine, Nutritional and Metabolic Diseases, 3%
- Pain, 4%
- Eyes & Ears, 4%
- Infectious and Parasitic Diseases
- Urogenital System, 3%
- Other, 1%
- Kidney Disease, 1%
- Hematology, 1%

Sources:
42 Matters, Jul 2017; IQVIA Apptitude Database, Jul 2017; IQVIA Institute, Jul 2017

Note: All data points rounded to whole numbers. Numbers may not sum to 100% due to rounding. 2017 data includes 11,216 unique apps with 11,249 categorizations. 2015 data includes 24,012 apps with 24,088 categorizations. 2015 includes uncategorized apps from 2015 publication senior. 2017 includes all apps with categorization.
Digital Health in the 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
- Condition Education & Management
  - Self-Monitoring
  - Remote Patient Monitoring
  - App-Enabled Rehabilitation Program

Condition Monitoring
- Prescription Filling & Compliance
  - Prescription Discounts
  - Prescription Filling
  - Medication Management & Adherence
  - Digital Therapeutics
  - Disease treatment

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

Number of Published Digital Health Efficacy & Effectiveness Studies
Total: 571 Efficacy Studies Between 2007-2017 (YTD)

Source: AppScript Clinical Evidence, August 14, 2017
Notes: Analysis excludes accuracy database studies. Only includes studies with hard outcomes. ‘Observational Study’ includes all trials examining interventional value or impact of an app excluded from the other three categories regardless of design.

Source: IQVIA Institute, Sep 2017
Number of Clinical Trials Including Digital Health Technologies, By Type

![Bar chart showing number of trials and average enrollment by type]

- **Mobile Apps and Messaging**: 357 trials, N = 1156
- **Sensors**: 159 trials, N = 192
- **Web Apps**: 35 trials, N = 3175
- **Telemedicine**: 14 trials, N = 99
- **Other**: 24 trials, N = 296

Total trials: N = 540 Unique Trials

Sources: Clinicaltrials.gov, Feb 2017; IQVIA Institute, Jul 2017

Notes: Total percent exceeds 100% due to inclusion of multiple digital health types in a single trial; Connected devices connected to an app, EMR or other interface; Mobile apps include use of phones to deliver text messages; Other includes offline computer apps, tablet video or virtual interaction programs; Web apps are presumed to be mobile accessible.


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Learning from the Past: Evaluating the Evidence of Impact of Digital Health on Patient Outcomes

mHealth Applications for Chronic Disease Self-Management: Evidence Map for PCORI

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Definition of self-management interventions

Aim to equip patients with skills to actively participate and take responsibility

▶ in the management of their chronic condition
▶ in order to function optimally through at least knowledge acquisition and
▶ a combination of at least two of the following:
  ■ stimulation of independent sign/symptom monitoring,
  ■ medication management,
  ■ enhancing problem-solving and decision-making skills for medical treatment management,
  ■ changing their physical activity, dietary, and/or smoking behavior

Jonkman et al. (2016)

mHealth Interventions

▶ Electronic
▶ Communication between a patient or caregiver and the healthcare system
  ■ over a distance
  ■ rather than within a clinic/hospital setting.
Process

- Interviewed experts who research and implement mHealth applications (Technical Expert Panel)
- Developed protocol
- Performed literature searches, screening, data extraction
- Created evidence maps

Map Demonstration