Integrating into Clinical Workflow: Success Stories, Best Practices, and Pitfalls

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The Johns Hopkins University School of Medicine

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Disclosures

• Honoraria from the American College of Cardiology for dyslipidemia-related educational activities

• Co-inventor on pending patent filed by Johns Hopkins University for novel method of LDL-C estimation

• Charitable gift to VLDL big data project from Trone Foundation

• Research support from the PJ Schafer Cardiovascular Research Fund, American Heart Association, Aetna Foundation, Fitbug, Google, and Apple, outside the subject matter

• Consulting for Abbott Nutrition, Pressed Juicery, Quest Diagnostics, Sanofi/Regeneron, Amgen, and the Pew Institute
Digital health: plentiful enthusiasm

"I don’t have a Fitbit yet, but I work out hard. Word is these Apple Watches might be a good companion for my workouts. So I’m gonna see, I’m gonna test it out."

– Barack Obama, President of the United States of America

Digital health – “single greatest opportunity of our generation”

– Young Sohn, President and Chief Strategy Officer for Samsung Electronics
"The clinical trenches bear almost no resemblance to what’s being talked about. There are almost no examples of mobile health apps that are being used at scale, wearable sensors that are being used. I do not want all that information, and I’m a technophile."

– Dr. Brennan Spiegel, Director of Health Services Research, Cedars-Sinai Medical Center
Framework for integration (Lobel et al)
Success Stories

- **mActive**
  Ciccarone Center for the Prevention of Heart Disease at Johns Hopkins

- **TEXT ME**
  The George Institute for Global Health

**LEAD(S):**

**Professor Clara Chow**
Director, Cardiovascular Division
Program Director Community, Based Cardiac Services, Westmead Hospital
NHNRC Career Development Fellow and Honorary Heart Foundation Future Leaders Fellow
Professor of Medicine, Western Clinical School, Sydney Medical School, University of Sydney

**Dr Jay Thakkar**
Honorary Fellow
mActive Hypothesis

A fully-automated, fully-mobile, and physician-designed tracking-texting intervention to provide individual encouragement and foster feedback loops increases physical activity.
Week 1
Blind Run-In
N = 48

Phase I
Weeks 2-3
Unblind Tracking
N = 32
Blind Tracking
N = 16

Phase II
Weeks 4-5
Smart Texts
N = 16
No Texts
N = 16
Blind Tracking
N = 16
Eligibility

Inclusions
- Patient at Ciccarone Center
- Aged 18-69 years
- User of a compatible smartphone

Exclusions
- Already using an activity tracker
- Regular leisure-time activity by IPAQ
- Prohibited from normal activity
Interventions

Phase I: Unblinding

- continuous access to activity data via smartphone
Interventions

Phase 2: Smart Texts

- smartphone-delivered coaching
- theory-based, physician-written
- leverage therapeutic relationship
- 3 times/day
  - customized to patient schedule
- booster and positive reinforcement messages
  - individual encouragement, foster feedback loops
- fully-automated using real-time activity data and 16 personal factors with a 10,000 steps/day goal
Outcome measures

• **Primary**
  – Change in accelerometer-measured daily steps

• **Secondary**
  – Change in accelerometer-measured daily activity time
  – Change in accelerometer-measured daily aerobic activity time
    • walking continuously for >10 minutes without breaking for more than a minute
## Baseline characteristics

<table>
<thead>
<tr>
<th></th>
<th>All (n=48) No. (%)</th>
<th>Blind (n=16) No. (%)</th>
<th>No Texts (n=16) No. (%)</th>
<th>Texts (n=16) No. (%)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age, yrs, mean (SD)</strong></td>
<td>58 (8)</td>
<td>60 (7)</td>
<td>58 (8)</td>
<td>55 (8)</td>
<td>0.22</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1.00</td>
</tr>
<tr>
<td>Men</td>
<td>26 (54%)</td>
<td>9 (56%)</td>
<td>9 (56%)</td>
<td>8 (50%)</td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>22 (46%)</td>
<td>7 (44%)</td>
<td>7 (44%)</td>
<td>8 (50%)</td>
<td></td>
</tr>
<tr>
<td><strong>White race</strong></td>
<td>38 (79%)</td>
<td>14 (88%)</td>
<td>12 (75%)</td>
<td>12 (75%)</td>
<td>0.60</td>
</tr>
<tr>
<td>Dog owner</td>
<td>21 (44%)</td>
<td>7 (44%)</td>
<td>9 (56%)</td>
<td>5 (31%)</td>
<td>0.36</td>
</tr>
<tr>
<td>Married</td>
<td>35 (73%)</td>
<td>13 (81%)</td>
<td>13 (81%)</td>
<td>9 (56%)</td>
<td>0.19</td>
</tr>
<tr>
<td>Employed</td>
<td>42 (88%)</td>
<td>13 (81%)</td>
<td>13 (81%)</td>
<td>15 (94%)</td>
<td>0.67</td>
</tr>
</tbody>
</table>
## Baseline characteristics (cont.)

<table>
<thead>
<tr>
<th></th>
<th>All (n=48) No. (%)</th>
<th>Blind (n=16) No. (%)</th>
<th>No Texts (n=16) No. (%)</th>
<th>Texts (n=16) No. (%)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHD</td>
<td>14 (29%)</td>
<td>7 (44%)</td>
<td>5 (31%)</td>
<td>2 (13%)</td>
<td>0.15</td>
</tr>
<tr>
<td>Diabetes</td>
<td>11 (23%)</td>
<td>4 (25%)</td>
<td>5 (31%)</td>
<td>2 (13%)</td>
<td>0.44</td>
</tr>
<tr>
<td>Smoker</td>
<td>1 (2%)</td>
<td>0 (0%)</td>
<td>1 (6%)</td>
<td>0 (0%)</td>
<td>1.00</td>
</tr>
<tr>
<td>Hypertension</td>
<td>24 (50%)</td>
<td>11 (69%)</td>
<td>8 (50%)</td>
<td>5 (31%)</td>
<td>0.12</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>39 (81%)</td>
<td>13 (81%)</td>
<td>14 (88%)</td>
<td>12 (75%)</td>
<td>0.90</td>
</tr>
<tr>
<td>BMI ≥30</td>
<td>31 (6)</td>
<td>33 (7)</td>
<td>30 (5)</td>
<td>30 (7)</td>
<td>0.28</td>
</tr>
</tbody>
</table>

*CHD: Coronary Heart Disease, Diabetes, Smoker, Hypertension, Dyslipidemia, BMI*
# Baseline activity (blind run-in)

<table>
<thead>
<tr>
<th>Activity</th>
<th>Unblind (n=32) Mean (SD)</th>
<th>Blind (n=16) Mean (SD)</th>
<th>Unblind – Blind Mean Difference (95% CI), p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steps, count/day</td>
<td>9094 (4308)</td>
<td>10822 (4337)</td>
<td>-1727 (-4389 to 934), p=0.20</td>
</tr>
<tr>
<td>Activity Time, min/day</td>
<td>88 (46)</td>
<td>102 (44)</td>
<td>-13 (-42 to 15), p=0.35</td>
</tr>
<tr>
<td>Aerobic Time, min/day</td>
<td>11 (18)</td>
<td>18 (19)</td>
<td>-7 (-18 to 5), p=0.24</td>
</tr>
</tbody>
</table>

97% capture of daily activity data throughout the trial
## Phase I

<table>
<thead>
<tr>
<th></th>
<th>Unblind (n=32) Mean (SD)</th>
<th>Blind (n=16) Mean (SD)</th>
<th>Unblind – Blind Mean Difference (95% CI), p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Steps, count/day</strong></td>
<td>408 (2701)</td>
<td>-616 (2385)</td>
<td>1024 (-580 to 2628), p=0.21</td>
</tr>
<tr>
<td><strong>Activity Time, min/day</strong></td>
<td>2 (27)</td>
<td>-6 (26)</td>
<td>8 (-9 to 25), p=0.33</td>
</tr>
<tr>
<td><strong>Aerobic Time, min/day</strong></td>
<td>-3 (12)</td>
<td>-11 (14)</td>
<td>8 (0 to 16), p=0.05</td>
</tr>
</tbody>
</table>
Phase II

<table>
<thead>
<tr>
<th></th>
<th>Texts (n=16)</th>
<th>No Texts (n=16)</th>
<th>Blind (n=16)</th>
<th>Texts - No Texts</th>
<th>Texts - Blind</th>
<th>No Texts - Blind</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean (SD)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Steps, count/day</td>
<td>2334 (1714)</td>
<td>-200 (1653)</td>
<td>-1042 (2202)</td>
<td>2534 (1318 to 3750), p&lt;0.001</td>
<td>3376 (1951 to 4801), p&lt;0.001</td>
<td>842 (-564 to 2248), p=0.23</td>
</tr>
<tr>
<td>Activity Time, min/day</td>
<td>21 (20)</td>
<td>0 (17)</td>
<td>-8 (23)</td>
<td>21 (8 to 34), p=0.003</td>
<td>29 (13 to 45), P&lt;0.001</td>
<td>8 (-7 to 23), p=0.28</td>
</tr>
<tr>
<td>Aerobic Time, min/day</td>
<td>13 (11)</td>
<td>-1 (8)</td>
<td>-3 (10)</td>
<td>14 (7 to 21), P&lt;0.001</td>
<td>15 (7 to 23), P&lt;0.001</td>
<td>1 (-6 to 8), p=0.71</td>
</tr>
</tbody>
</table>
10K step goal attainment

Baseline
- Blind (n=48) 48%
- Unblind (n=32) 41%

Phase I
- Texts (n=16) 81%
- No Texts (n=16) 44%
- Blind (n=16) 50%

Phase II
- Blind (n=16) 44%
TEXT ME Study Overview

- Single Blind RCT
- P: Adults with CHD
- I: Regular ‘one-way’ text messages via SMS over a six month period providing semi-customized advice, motivation, information and support, 4 messages/ wk, random timeslots
- C: Usual Care:
- O: Primary: LDL cholesterol, 2ndary: BP, BMI, Physical activity, smoking, Combined risk factor control
- T: 6 month follow-up
- Setting: Westmead hospital inpatients and outpatients

The Messages

- Messages aimed to provide advice, motivation, information and support and were focused on lifestyle
- Multistage process of development involving clinicians, public health experts, psychologists, feedback from prospective participants.*
- 4 categories 1) General Heart Health, 2) Nutrition, 3) Physical activity, 4) Smoking cessation
- Sending was managed by a custom computerised message management system (MMS)

Examples of Messages

Clara, Exercise is good for your physical & mental health and your quality of life Westmead Hospital (TextMe)

Hi Clara, fish oil capsules & omega-3 enriched foods & drinks can help prevent heart disease Westmead Hospital (TextMe)

Hi Clara, healthy eating means at least 5 serves of vegetables & 2 serves of fruit every day Westmead Hospital (TextMe)

Do you like swimming Clara? It is easy on joints & is very beneficial to your health Westmead Hospital (TextMe)
## Main Results

### Endpoint analyses at 6 months follow-up

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Intervention</th>
<th>Control</th>
<th>Mean difference</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LDL (mmol/L)</td>
<td>2.05 (0.04)</td>
<td>2.16 (0.04)</td>
<td>-0.12 (-0.23 ; -0.01)</td>
<td>0.04</td>
</tr>
<tr>
<td>LDL (mg/dL)</td>
<td>79 (76 – 82)</td>
<td>84 (81 – 87)</td>
<td>-5 (-9; 0)</td>
<td>0.04</td>
</tr>
<tr>
<td>T. cholesterol*</td>
<td>3.89 (0.05)</td>
<td>4.13 (0.05)</td>
<td>-0.24 (-0.38 ; -0.10)</td>
<td>0.0009</td>
</tr>
<tr>
<td>SBP (mmHg)</td>
<td>128.2 (0.8)</td>
<td>135.8 (0.8)</td>
<td>-7.6 (-9.8 ; -5.4)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>DBP</td>
<td>80.5 (0.5)</td>
<td>83.6 (0.5)</td>
<td>-3.1 (-4.4 ; -1.8)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Heart rate (bpm)</td>
<td>67.3 (0.5)</td>
<td>69.2 (0.5)</td>
<td>-1.9 (-3.3; -0.4)</td>
<td>0.0127</td>
</tr>
<tr>
<td>BMI</td>
<td>29.0 (0.1)</td>
<td>30.3 (0.1)</td>
<td>-1.3 (-1.6 ; -0.9)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Waist (cm)</td>
<td>100.6 (0.6)</td>
<td>105.0 (0.6)</td>
<td>-4.4 (-6.0 ; -2.5)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Hip (cm)</td>
<td>101.7 (0.6)</td>
<td>106.3 (0.6)</td>
<td>-4.7 (-6.3 ; -3.0)</td>
<td>&lt;.0001</td>
</tr>
</tbody>
</table>

Analysis of covariance for all parameters

*mmol/L

## Achievement of Guideline Recommended Risk Factor Targets

<table>
<thead>
<tr>
<th>Variable</th>
<th>Intervention (N = 352)</th>
<th>Control (N = 358)</th>
<th>Relative Risk (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. LDL &lt; 2 mmol/L</td>
<td>168/332 (50.6%)</td>
<td>158/342 (46.2%)</td>
<td>1.10 (0.94 - 1.28)</td>
<td>0.2531</td>
</tr>
<tr>
<td>2. BP &lt; 140/90 mmHg</td>
<td>262/331 (79.2%)</td>
<td>189/344 (54.9%)</td>
<td>1.44 (1.29 - 1.61)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>3. Exercising regularly</td>
<td>182/338 (53.8%)</td>
<td>79/351 (22.5%)</td>
<td>2.39 (1.92 - 2.97)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>4. Non-smoker</td>
<td>253/339 (74.6%)</td>
<td>198/354 (55.9%)</td>
<td>1.33 (1.19 - 1.49)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>5. BMI &lt; 25 kg/m2</td>
<td>81/335 (24.2%)</td>
<td>69/349 (19.8%)</td>
<td>1.22 (0.92 - 1.62)</td>
<td>0.1647</td>
</tr>
<tr>
<td>All 5 risk factor targets</td>
<td>15/322 (4.7%)</td>
<td>6/330 (1.8%)</td>
<td>2.56 (1.01 - 6.52)</td>
<td>0.0484</td>
</tr>
<tr>
<td>≥4/5 risk factor targets</td>
<td>93/322 (28.9%)</td>
<td>34/330 (10.3%)</td>
<td>2.80 (1.95 - 4.02)</td>
<td>&lt;.0001</td>
</tr>
</tbody>
</table>
# Benefits of TEXT ME on physical activity over and above cardiac rehab

<table>
<thead>
<tr>
<th></th>
<th>Odds ratio</th>
<th>P value</th>
<th>Mean total PA (met min/wk)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No TM, no CR</td>
<td>Reference group</td>
<td></td>
<td>477 (344 – 610)</td>
</tr>
<tr>
<td>CR Only</td>
<td>1.80 (1.11 – 2.92)</td>
<td>0.018</td>
<td>777 (618 – 937)</td>
</tr>
<tr>
<td>TM Only</td>
<td>4.38 (2.77 – 6.92)</td>
<td>&lt;0.001</td>
<td>865 (725 – 1005)</td>
</tr>
<tr>
<td>TM + CR</td>
<td>7.07 (4.30 – 11.63)</td>
<td>&lt;0.001</td>
<td>958 (802 – 1114)</td>
</tr>
</tbody>
</table>

TM – Texting intervention  
CR – Cardiac Rehabilitation

Best practices

• Automate

• Customize

• Device + drivers

• Link back to hospital/clinic

• Leverage interdisciplinary team
Best practices (cont.): Carefully consider...

- Integration
- Dose and duration
- Alignment with clinical and regulatory guidelines
- Scalability and adaptability (culture, language)
Pitfalls
Digital health monitoring is empowering but not likely an intervention in and of itself

- For an anti-hypertensive trial we wouldn’t just give a BP monitor and not link it to an action and expect improvement

Make the link: new data $\rightarrow$ healthy action
Skipping over fundamental device features

- How comfortable is it?
- Is it accurate?
- How easy is it to use?
Yet:

- Uncomfortable device (Bodymedia), worn only 4 hrs/day
- What was the accuracy of the Bodymedia device?
- Use of other wearable devices in participants?
- No true control group; user experience of standard website vs Bodymedia website?
Validation of the Instant Blood Pressure Smartphone App

Timothy B. Plante, MD; Bruno Urrea, MD; Zane T. MacFarlane; Roger S. Blumenthal, MD; Edgar R. Miller III, MD, PhD; Lawrence J. Appel, MD, MPH; Seth S. Martin, MD, MHS

Validation of the Instant Blood Pressure Smartphone App
Published online March 2, 2016

Available at jamainternalmedicine.com and on The JAMA Network Reader at mobile.jamanetwork.com
Other potential pitfalls

• Increased workload for clinicians
• Not integrated with EMR
• Too complicated / not usable / not actionable
• Loss of privacy
• Lost devices
• Too expensive
• ...
Conclusion

• There are some early success stories but we have a ways to go before the clinical trenches truly resemble what is being talked about

• Best practices include automation, customization, and linking back to the hospital
Thanks!

Ciccarone Center for the Prevention of Heart Disease at Johns Hopkins

smart100@jhmi.edu