Centre for Healthcare Resilience and Implementation Science

Centre for Health Informatics

Centre for Health Systems and Safety Research
SafeHealthApps

Safety Concerns with Consumer-Facing Mobile Health Applications and their Consequences
Used a mobile health app that diagnosed her with HIV simply by analyzing her fingerprint on the touch screen.

"And she wasn't the only one, there were others that came to us worried about the app and those were just the ones that were willing to speak out."

-Laura de Reynal

FDA GUIDELINES

Medical Devices

Intermediate

Wellness
Background

- A vast amount of mobile apps on the market
- 325,000 health apps currently available on IOS and Android
- Consumer use of mobile health apps is rapidly growing
- Not independently evaluated, regulated or built to any common safety standard
- Limited examination of safety risks and harms posed by health apps

SafeHealthApps

1. Scoping Review of Literature
   • Categorization of Safety Concerns

2. Qualitative Analysis of Safety Reports
   • Classification of Consequences
## Classification of Consequences

<table>
<thead>
<tr>
<th>Harm category¹</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Actual or potential harm</td>
<td>Adverse event - clinical consequence.</td>
</tr>
<tr>
<td>Arrested or interrupted sequence</td>
<td>Near miss – Error detected before it could harm the user.</td>
</tr>
<tr>
<td>Noticeable consequence but no harm</td>
<td>Problem that affected care delivery but involved no harm to the user.</td>
</tr>
<tr>
<td>No noticeable consequence</td>
<td>No affect on care delivery.</td>
</tr>
<tr>
<td>Hazardous event</td>
<td>A problem or circumstance that could eventually lead to an adverse event.</td>
</tr>
</tbody>
</table>

Scoping Review

Objectives

To review studies about health apps and to identify the types of safety concerns and their consequences.
Inclusion Criteria

- 2013 onwards (searched in Jun, 2017)
- Featuring consumer facing mobile health app
- Study design: Systematic reviews, RCTs, Analysis of health apps, Pilot tests
- Safety risk/ adverse event outcome considered
Total records identified through database searching* (n=1944)

Additional records identified through other sources (n=8)

Records after duplicates removed (n=1276)

Erratum/Reply (n=7)

Records excluded (n=1182)
- Not a health app (n=468)
- Not consumer facing (n=148)
- Ineligible study design (n=130)
- Safety not considered (n=357)
- Abstract unavailable (n=31)
- Study protocol (n=43)
- Non English (n=1)
- Letters to editor (n=4)

Titles and abstracts screened (n=1269)

Full text articles assessed (n=87)

Studies included in review (n=48)

Records excluded (n=39)
- Not a health app (n=1)
- Not consumer facing (n=1)
- Ineligible study design (n=4)
- Safety not considered (n=19)
- Full text unavailable (n=11)
- Non English (n=3)

*PubMed (n=631), Web of Science (n=385), Scopus (n=808), Cochrane (n=120)
### Findings

<table>
<thead>
<tr>
<th>Review of App(s)</th>
<th>42</th>
</tr>
</thead>
</table>
| Range of sample size | Apps: 2 – 750  
Users: 1 – 1932 |
| Types of Apps | Wellness: 02  
Intermediate: 38  
Medical Device: 05 |

#### Consumer Engagement Functionalities

- Rewards behavior change: 7
- Enables communication with family or clinician: 10
- Reminds or Alerts patients: 14
- Provides support through social networks: 15
- Provides educational information: 30
- Provides guidance based on user entered information: 31
- Tracks information: 32
- Displays and summarizes user-entered information: 35
Frequently Reported Concerns

κ=0.79 (p<0.001, 95% CI 0.70 to 0.88)

38% of the studies reported absence or lack of sufficient scientific evidence to support the information content of the app.

23% of the studies reported variation in content quality, particularly in clinical information.

23% of the studies reported Diagnostic or calculation errors yielding wrong output.

31% of the studies reported that the apps provided incorrect or incomplete information.

21% of the studies reported Lack of medical professional involvement, in the process of app development.
<table>
<thead>
<tr>
<th>Others</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Inducing unintended negative harms</td>
<td>4</td>
</tr>
<tr>
<td>Lack of regulatory evidence</td>
<td>1</td>
</tr>
<tr>
<td>Anxiety provoking information</td>
<td>1</td>
</tr>
<tr>
<td>Insufficient scope</td>
<td>1</td>
</tr>
<tr>
<td>Inappropriate response to consumers’ needs</td>
<td>1</td>
</tr>
</tbody>
</table>
Consequences (n=22, 46%)

<table>
<thead>
<tr>
<th>Harm category</th>
<th>Frequency</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Actual or potential harm (Adverse</td>
<td>5</td>
<td>Increased alcohol consumption due to competitive drinking games offered</td>
</tr>
<tr>
<td>event)</td>
<td></td>
<td>by apps.</td>
</tr>
<tr>
<td>Noticeable consequence but no harm</td>
<td>14</td>
<td>Inability to accurately monitor step count.</td>
</tr>
<tr>
<td>Hazardous event</td>
<td>3</td>
<td>Substituting a visit to a medical professional with the use of diagnostic</td>
</tr>
<tr>
<td></td>
<td></td>
<td>apps that were found to be erratic.</td>
</tr>
</tbody>
</table>

Consequences vs. Functionality

- Rewards behavior change: 43%
- Provides support through social networks: 47%
- Enables communication with family or clinician: 50%
- Provides guidance based on user entered information: 52%
- Displays and summarizes user-entered information: 49%
- Tracks information: 50%
- Reminds or Alerts patients: 57%
- Provides educational information: 40%
Safety Report Analysis

Objectives

To identify the types of safety concerns with consumer-facing mobile health apps in the hands of users, and their consequences.
Participants and setting

- Consenting Adults (18 years or over)
- Consumers of mHealth apps
- Voluntary participation
- Macquarie University

Design

- Consumers reported safety concerns
- Aug’17 – Nov’17

Tool

- Online Survey
  - Health app
  - Purpose of use
  - Response of app
  - Outcome
  - Demographics

Analysis

- Categorization of concerns by two independent reviewers
- Consequences analyzed using the standard approach

## Findings

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Total participants</td>
<td>162</td>
</tr>
<tr>
<td>Female to male ratio</td>
<td>7:3</td>
</tr>
<tr>
<td>Age distribution</td>
<td></td>
</tr>
<tr>
<td>18-24:</td>
<td>30%</td>
</tr>
<tr>
<td>25-34:</td>
<td>34%</td>
</tr>
<tr>
<td>35-44:</td>
<td>24%</td>
</tr>
<tr>
<td>45-54:</td>
<td>12%</td>
</tr>
<tr>
<td>No. of apps currently using</td>
<td></td>
</tr>
<tr>
<td>None:</td>
<td>11%</td>
</tr>
<tr>
<td>1-3:</td>
<td>76%</td>
</tr>
<tr>
<td>4-6:</td>
<td>12%</td>
</tr>
<tr>
<td>7-9:</td>
<td>0%</td>
</tr>
<tr>
<td>&gt; 9:</td>
<td>1%</td>
</tr>
<tr>
<td>Participants who reported safety concerns</td>
<td>65</td>
</tr>
<tr>
<td>Total safety concerns reported</td>
<td>86</td>
</tr>
</tbody>
</table>
Purposes of using health apps

- Weight loss: 52%
- Help me watch what I eat/Improve what I eat: 51%
- Track how much I sleep: 40%
- Show/teach me exercises: 40%
- Help me relax: 34%
- Track a health measure: 22%
- Keep a diary or log of my symptoms: 10%
- Access health information: 8%
- Remind me to take my medication: 4%
- Check my medical records: 3%
- Help me stop a habit: 2%
- Chat with my doctor/other HCP: 1%

Others: 17%
Reported Safety Concerns

25

Reports were related to
Errors in information tracking
E.g. inaccurate step count and sleep time

17

Reports were related to
Incorrect or incomplete information
E.g. misleading caloric count and absence of exercise instructions

<table>
<thead>
<tr>
<th>Safety Concern</th>
<th>Number of incidents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insufficient scope</td>
<td>6</td>
</tr>
<tr>
<td>Difficulty in accessing content</td>
<td>6</td>
</tr>
<tr>
<td>Lack of geographic customization</td>
<td>5</td>
</tr>
<tr>
<td>Complex or demotivating interface</td>
<td>5</td>
</tr>
<tr>
<td>Inability to interact with other devices</td>
<td>5</td>
</tr>
<tr>
<td>Inappropriate alerts</td>
<td>4</td>
</tr>
<tr>
<td>Addictive in nature</td>
<td>4</td>
</tr>
<tr>
<td>Variation in content quality</td>
<td>3</td>
</tr>
<tr>
<td>Information loss</td>
<td>2</td>
</tr>
<tr>
<td>Errors in calculation</td>
<td>2</td>
</tr>
<tr>
<td>Difficult retrieval of personal information</td>
<td>2</td>
</tr>
</tbody>
</table>
# Reported Consequences

62 safety concerns (72%) were associated with a consequence.

<table>
<thead>
<tr>
<th>Harm category¹</th>
<th>#</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Actual or potential harm (Adverse event)</td>
<td>12</td>
<td>Undesired weight loss, sprain injury, over and under eating, missed medicine dose, risk of self-diagnosis, and inaccurate calorie count resulting in excess consumption. <em>(Minimum Harm²)</em></td>
</tr>
<tr>
<td>Arrested or interrupted sequence (near miss)</td>
<td>20</td>
<td>Google search solved confusion in calorie requirement, user created their own excel sheet to keep record of activity.</td>
</tr>
<tr>
<td>Noticeable consequence but no harm</td>
<td>15</td>
<td>Need to restart tracking, activities not counted towards team goals.</td>
</tr>
<tr>
<td>Hazardous event</td>
<td>6</td>
<td>Inaccurate sleep tracking, inability of the app to address special groups such as dwarfs, and wrong data output.</td>
</tr>
<tr>
<td>No noticeable consequence</td>
<td>11</td>
<td>Need to reboot the hardware, excessive battery consumption</td>
</tr>
</tbody>
</table>


Consumers’ Reactions

- 45 participants (70%) contacted a national authority
- 24 participants (37%) discontinued using the app

Study limitations

- Self-reporting
- Limited to university setting
Conclusion

● Safety of health apps is an emerging issue in public health informatics.

● Incorrect or incomplete information is a commonly reported concern – both in literature and by consumers

● Need to address gaps in current process of app development.
  ○ regulatory framework
  ○ Involvement of HCPs
  ○ Recency check

● Consumer awareness about safe use of apps.
Acknowledgement

UNC
● Dr Javed Mostafa
● Rebecca Kitzmiller
● Heidi Harkins
● Mariell Ruiz

AIHI
● Farah Magrabi
● Enrico Coiera
● Jessica Chen
● Annie Lau
● Liliana Laranjo
● Mi Ok Kim
● Ying Wang
● Denise Tsiros
● Samantha Morris
● Isabella Bozzi
● Study participants
THANKS!

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