How useful are handheld ECG monitors?

Introduction

• Mobile electrocardiography (ECG) devices w/Smartphone apps are intended to be used by patients to collect healthcare data that needs to be reviewed, and potentially interpreted, by a clinical expert.
• Patients without clinical knowledge must be able to use them safely and effectively, so we assessed patient usability.
• Two primary usability questions:
  – how long does it take to collect a valid ECG reading?
  – how easy is it to share data captured by these devices?

Objectives

Overall: Assess reliability, safety and utility of two handheld ECG monitors

Human Factors: assess usability of devices and the smartphone software used with them

Method

• While lead tester observed & recorded time, each participant read instructions and then completed six tasks:
  – Open application (show pics of screens!)
  – Record an ECG (using a simulator to generate signals)
  – Add a pre-selected note
  – Add a custom note
  – Email a PDF report of a recorded ECG
  – Review a recorded ECG

Technology

• Two different handheld ECG devices, both of which can be used with either Android or iPhone devices, were included.
  – Kardia Mobile by AliveCor, Inc.: ECG check by Cardiac Designs™
  – Each device was tested using two different phones:
    – Samsung Galaxy Note II, running Android version 4.4.2
    – iPhone 4s running iOS 9.3.5
• We used a Fluke Biomedical MPS450 Patient Simulator, which generates many different physiological waveforms, to provide ECG data consistent with a person with atrial fibrillation

Participants

• 18 ECRI employees split across two groups (Android, iPhone)
• Group assignment based on self-reported familiarity with phones.
• Participants familiar with both types were assigned to balance the group sizes: two were placed in Android group, one in iPhone group

Results

Results 1

System Usability Scores

<table>
<thead>
<tr>
<th>Android</th>
<th>iPhone</th>
</tr>
</thead>
<tbody>
<tr>
<td>72.2</td>
<td>75.0</td>
</tr>
</tbody>
</table>

Compliance times graph (add error bars)

Results 2

System Usability Scores

<table>
<thead>
<tr>
<th>Kardia</th>
<th>ECG Check</th>
</tr>
</thead>
<tbody>
<tr>
<td>66.1</td>
<td>72.0</td>
</tr>
</tbody>
</table>

Scenario Completion Times

<table>
<thead>
<tr>
<th>Android</th>
<th>iPhone</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.4</td>
<td>4.1</td>
</tr>
</tbody>
</table>

Results 3

Kardia

• Great educational materials and analysis supplementary information.
• Ability to rotate and zoom on screen showing recordings was helpful.
• Android phone had to be very close to device for it to be detected; no indicators on device that can be used to troubleshoot connection issues
• Allows users to enter, but does not send, additional contextual information beyond waveform and instant analyses
• ECG check
  – Automatically includes additional contextual information provided by user in reports emailed from phones.
  – Difficult to figure out how to send newly captured recording in an email.
  – Recording doesn’t report beats per minute.
• Requires connection to internet to generate and store a recording.

Discussion

• Conclusions
  – The devices had similar usability scores and scenario completion times, but their user experiences were very different.
  – User experience varied not only for different devices, but also for different phone types.
  – The specific usability issues we found are important for potential purchasers, so they can assess if they are likely to have trouble using the devices.
  – Concern
    – Unclear how use of this class of devices will impact a) communication between patients and health providers, and b) provider workflows.
  – Recommendations
    – Develop best practices or guidance about how health providers should talk to patients about devices meant to be used outside a clinical setting to generate data that needs to be interpreted by a medical professional.
    – Doctors need to tell patients when and how they will access emailed reports
    – Patients need to learn enough about waveforms to understand whether they need to seek help instead of just emailing reports.