Monitoring Pill Taking using WisePill

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WisePill

- Pill insert
- Status lights
Openings

• Openings
  – A signal is sent to server every time device is opened
  – If not on network, opening data are stored and transmitted later
  – Does opening $\Rightarrow$ pill taking?
    • Assume no “show and tell”
  – Does No opening $\Rightarrow$ No pill taking?
    • Assume pills not removed for later use
    • Assume device is functional
Heartbeat

• Heartbeats
  – Indicates device is functional
  – Sent 1x/day between 1-2 am if device is on network; heartbeat is not stored
  – Reasons for no heartbeat:
    • Off network
    • Device not functional (out of battery, broken)
    • Non-compatible SIM card
Adherence

• “Adherence” = # days opened/# days functional
• To calculate “adherence” we need to know if device was functional on a given day

<table>
<thead>
<tr>
<th></th>
<th>Heartbeat</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Opening</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>No</td>
</tr>
</tbody>
</table>
Example

Person-days followup  20,330
  >1 opening        14,632
    no opening     5,698
      heartbeat   2,099
    no heartbeat  3,599

• “Adherence”? 
  14632/20330 = 72% biased low?
  14632/(20330-3599) = 87% biased high?
# HPTN study

Percentage of WisePill devices with any heartbeat following randomization

<table>
<thead>
<tr>
<th>Percentage</th>
<th>Site 1</th>
<th>Site 2</th>
<th>Site 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>0%</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td>44 (25.9%)</td>
</tr>
<tr>
<td>&gt;0% and &lt;=50%</td>
<td>1 (0.6%)</td>
<td>1 (0.6%)</td>
<td>25 (14.7%)</td>
</tr>
<tr>
<td>&gt;50% and &lt;=85%</td>
<td>11 (6.1%)</td>
<td>3 (1.7%)</td>
<td>38 (22.4%)</td>
</tr>
<tr>
<td>&gt;85% and &lt;100%</td>
<td>158 (88.3%)</td>
<td>80 (44.7%)</td>
<td>63 (37.1%)</td>
</tr>
<tr>
<td>100%</td>
<td>9 (5.0%)</td>
<td>95 (53.1%)</td>
<td>0 (0.0%)</td>
</tr>
</tbody>
</table>
Fixes?

- Eliminate all days with no heartbeat (regardless of opening)
  - Okay, if small proportion
- Only eliminate day if last day with heartbeat indicated low battery
  - Not reliable (enough)
- Only eliminate day based on user reports of travel, lost device, malfunctioning device
  - Not systematically collected
  - Reliability?
Conclusions

- Important to understand limitations of device
- If few days with no heartbeat, “adherence” estimate unbiased
- If many days with no heartbeat …
  - If heartbeat data ignored, adherence is biased low
  - Attempt to identify and remove days with noncompatible SIM card
    - If large proportion of days with no heartbeat remains, may be impossible to estimate adherence without bias
- Electronic monitoring is not a panacea for measuring adherence!