Developing a Mobile App for Studies of Medication Safety

Sascha Dublin, MD, PhD
August 2017
# Mobile App Study Team

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<th>FDA</th>
<th>Harvard</th>
<th>KP Washington</th>
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### Mobile App Study Team, cont.

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<th>BTC</th>
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<tr>
<td>Shyam Deval</td>
<td>Adam Rauch</td>
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<td>Shanthala Rao</td>
<td>Brian Connolly</td>
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<td>McKinley Hackett</td>
<td>Susan Hert</td>
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<td>Angelica Omaiye</td>
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Outline

Patient Story

Background

Mobile App project

Patient Involvement and its Impact

Conclusion
“The first three months of my second pregnancy, I was really nauseous. It was debilitating. My doctor prescribed me some pills. I got them, but the idea that it was a prescription just freaked me out and I didn't want to put any foreign objects in my body. I don't know what it's going to do to the baby.”

— New mother, Kaiser Permanente Washington
Background: Medications in Pregnancy

- For many medications, we lack adequate information about their safety in pregnancy
- Difficult for women and doctors to make decisions
- Existing study designs have limitations
- Would be a great step forward to be able to collect self-reported information from large numbers of women and link it with electronic health data
- Could a mobile app help us achieve this goal?
Background: FDA Sentinel Initiative

- National system to monitor the safety of medical products
  - Data mostly from insurance claims; some electronic medical records
- Large and representative population
  - 43 million patients with new data being accumulated
- Challenges similar to any large database study
  - Including limited data on pregnancy
- FDA Catalyst: aims to expand Sentinel infrastructure through interactions and interventions with patients and providers
Mobile App Project

▪ Goals
  – Develop a mobile app to collect data directly from patients
  – Develop a secure storage environment for app data that can be used by patients from multiple data partners
  – Recruit a cohort of pregnant women from a Sentinel Data Partner to use the app
  – Demonstrate ability to link app data with Sentinel data; conduct descriptive analyses

▪ Funding: US Department of Health and Human Services via the PCOR Trust Fund
Mobile App Project, cont.

- Provide app to women early in pregnancy
  - Asks about pregnancy history, risk factors, medication exposure
  - Aims to capture outcomes such as miscarriage

- Want to encourage sustained use throughout entire pregnancy

- How do we motivate women to use it consistently for many months?

- We sought patient involvement to make app more useful and engaging
Kaiser Permanente Washington

- Integrated healthcare delivery system in Northwestern US
- Formerly Group Health
- About 630,000 members
- Sentinel Data Partner and scientific collaborator
Patient Involvement

- Two patient advisors on team throughout the project
  - Received an honorarium
  - Initial brainstorming: suggested engagement features
  - Provided input and feedback on materials via phone and email
    (e.g., screenshots, surveys, recruitment brochure)

- Focus group during app development
  - 6 participants including our 2 patient advisors
  - Discussed engagement features; reviewed prototype
Feedback: Focus Group

“The app would be more engaging if it also included helpful information such as strategies for dealing with morning sickness, yoga stretches for back pain, foods to avoid, and a checklist of things to do as you get closer to the delivery date.”
User Acceptability Testing

- 9 people including 2 patients
- Walked through all app screens and functions
- Found bugs and errors (e.g., skip patterns)
- Commented on process, flow, wording
Extended Trial of App

- At least 50 women using the app for about 4 months
- Assess uptake and persistence
- We will interview some women to understand their experiences with the app
- Began recruitment in ? (update with month when known)
Benefits of Patient Involvement

- Learn about how women use apps in pregnancy
- What is an acceptable burden for women? (Answer: 2-3 brief surveys per week)
- Input about all materials that are “patient facing”
  - E.g., survey questions and information about study
  - “Helped to translate the jargon we use here to be more accessible and clear”
Benefits, cont.

- Improve recruitment strategy
  - Understand what would motivate women to participate (*Altruism!*)
  - Contribute to study brochure
  - Participate in study video
Examples of Impact

- App Dashboard: describes activities completed
  - Simplified and focused on information useful to them
- Plan for 2 or 3 brief surveys per week
- Revised study materials including survey questions
- “Wish list” of ideas for future app development
Other Benefits

- Energizes and inspires study team
- Reminds us why we do this work
Learnings About Engaging Patients

- Involve patients early
  - When developing specifications
- Formalize involvement and be respectful of their time
  - Phone calls are convenient for study team but sometimes might be hard for patient advisors to follow
  - Focus groups allow more intense participation
- Email collaboration worked well
When Do You Need Patient Engagement?

- For studies that will require longer or more intense patient participation
- For engaging specific population, e.g. older adults
- To help with recruitment strategy and materials
- To make sure that a study participant’s experience will be reasonable and clear and go smoothly
Conclusion

- Project aimed to develop a mobile app to collect information from patients
- We included patients as advisors to help us make the app more engaging – which hopefully will lead to better data and ultimately, better information about medication safety
- Extended trial of app began in early August; watch for results next year!
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Extra slides – may not use
Background: FDA Sentinel Initiative

Sentinel Initiative

Sentinel Infrastructure

Sentinel System
Routine queries and other activities that use pre-existing data
- PRISM
- BloodSCAN
- ARIA

FDA-Catalyst
Routine queries + interventions and interactions with members and/or providers
Screenshots from App

The FDA is pleased to offer the FDA My Studies app as a tool to gather real-time, contextual data about medication use and other health issues facing the people we serve.

Welcome!

STUDY ACTIVITIES

CURRENT

- One Time
  - Questionnaire about your vitamin use
    - Run: 1/1, 0 done, 0 missed
    - 12:00AM, Jun 22 2017
  - Questionnaire about your race and ethnicity
    - Run: 1/1, 0 done, 0 missed
    - 12:00AM, Jun 22 2017
  - Questionnaire about your pregnancy history
    - Run: 1/1, 0 done, 0 missed
    - 12:00AM, Jun 22 2017
  - Baseline vaccine exposure questionnaire
    - Run: 1/1, 0 done, 0 missed
    - 12:00AM, Jun 22 2017

Congratulations! What is your due date?

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<thead>
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<td>2</td>
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<td>May</td>
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<td>October</td>
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All Slides that follow are templates or extra –no plans to use them currently

- All bulleted copy is 24pt Arial Narrow
  - Second level bullets are 20pt Arial Narrow
- Bulleted copy has initial cap on first word only—no period at the end
- Bulleted copy should not exceed six bullet points
- Text highlights are bold and light blue
Why Engage Patients in Research?

- Learn what questions are most important to patients
  - What outcomes they care most about
  - What exposures or comparisons are most relevant
- Improve the study design and approach
  - E.g., recruitment and retention; study materials
- Plan for dissemination
  - How do the patients you want to reach access information?
  - What kinds of evidence matter to them?
Single Photo or Video Treatment
Applying Designs and Layouts

A. Right click on working area to select from Slide Design or Slide Layout.

B. Inside Slide Design window, rollover desired design and click on pull-down arrow to select from apply menu.

C. Inside Slide Layout window, rollover desired layout and click on pull-down arrow to select from apply menu.

**TIP**
After applying layout, click on Reapply Layout to ensure full conversion.

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Limit use of layouts to Title Only or Title and Text

- Title Only layout must be applied to Segue Slide designs
- Title and Text layout must be applied to Title Slide designs