



Developing a Mobile App for Studies of Medication Safety

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Mobile App Study Team

FDA

- David Martin (PI)

Patient Partners

- Kacie Washington
- Karen Byeman

Harvard

- Juliane Reynolds
- Zac Wyner
- Chayim Herzig-Marx

KP Washington

- Sascha Dublin
- Pedja Klasnja
- Linda Kiel
- Catherine Lim
- Deryn Haug
- Ladia Albers-Junkans
- Several testers

Mobile App Study Team, cont.

BTC	LabKey
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Outline

Patient Story

Background

Mobile App project

Patient Involvement and its Impact

Conclusion

Patient Story

“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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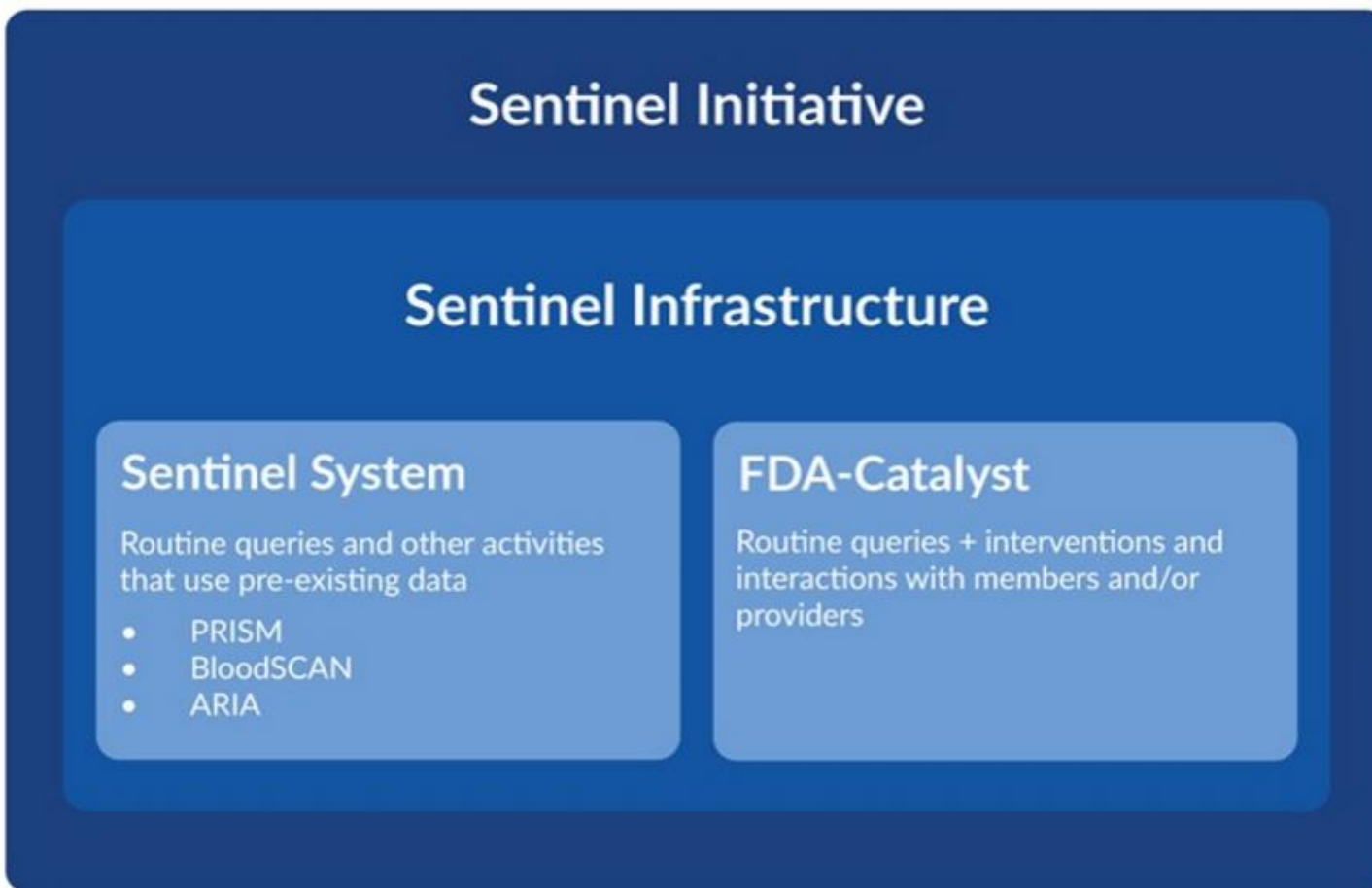
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KP Washington

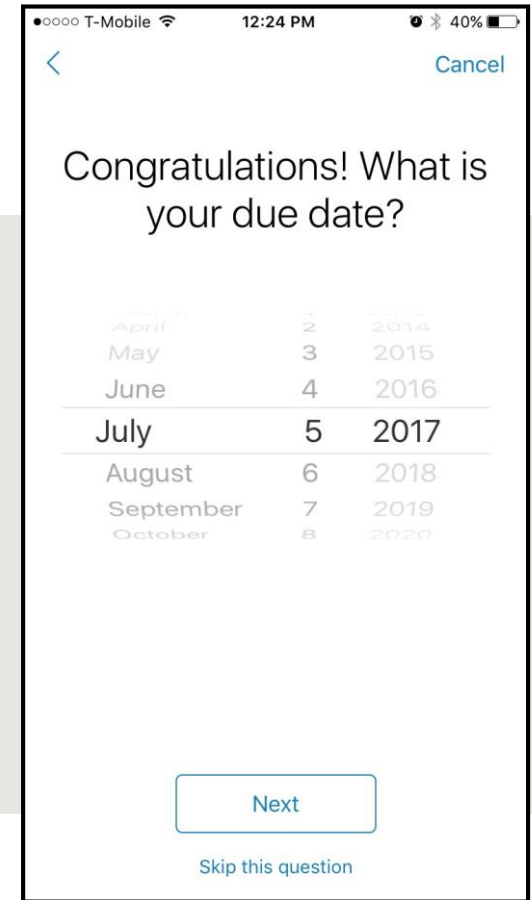
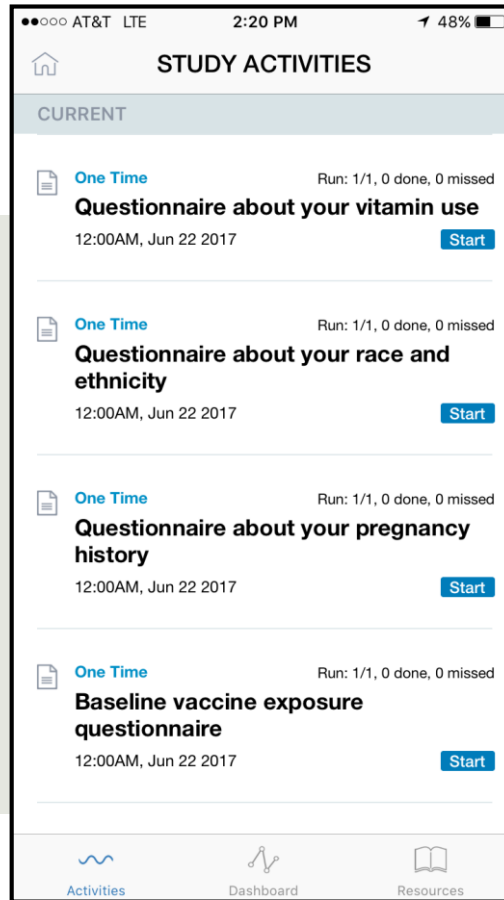
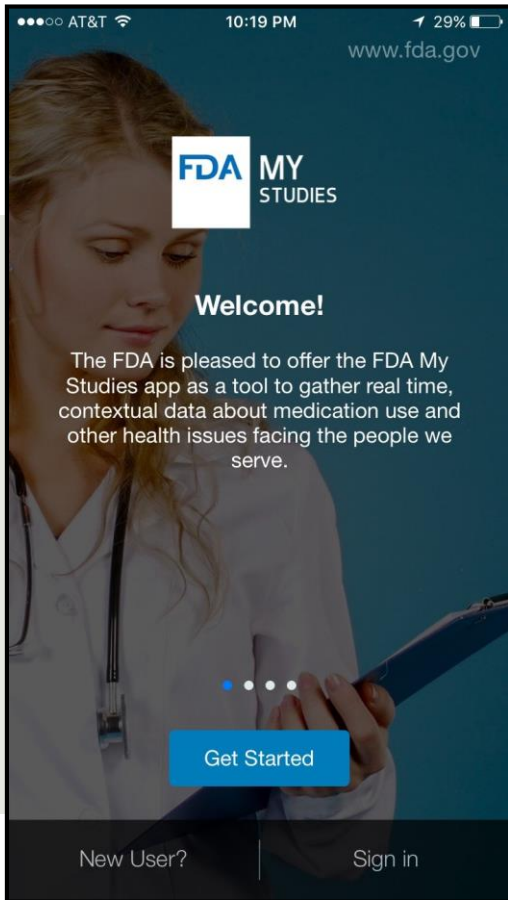
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Extra slides – may not use

Background: FDA Sentinel Initiative



Screenshots from App



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.

RULES

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

The image shows a screenshot of the PowerPoint interface with three callout boxes labeled A, B, and C. Callout A points to a right-click context menu with options: Cut, Copy, Paste, Ruler, Grid and Guides..., Slide Design..., Slide Layout..., Background..., and Slide Transition... Callout B points to the Slide Design task pane, which includes Design Templates, Color Schemes, Animation Schemes, and a 'Used in This Presentation' section. Callout C points to the Slide Layout task pane, which shows 'Apply slide layout:' with 'Text Layouts' and a preview of a slide layout. Below the preview is a menu with 'Apply to Selected Slides', 'Reapply Layout', and 'Insert New Slide'. Two blue callout boxes with white text are positioned to the right: 'TITLE ONLY' points to a 'Title Only' layout preview, and 'TITLE AND TEXT' points to a 'Title and Text' layout preview.