Use of a mobile app to capture supplemental health information during pregnancy: implications for clinical research

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Background

Mobile applications ("apps") may be an efficient strategy to improve quality of research about medication safety in pregnancy, but evidence is sparse.

Objective: To describe the feasibility and generalizability of a mobile app for capturing data on health conditions, medication use and other relevant exposures during pregnancy and linking those data to the patient's medical record research database.

Methods

Study Design: Descriptive pilot study collecting data via an app, FDA MyStudies, about health conditions and behaviors during pregnancy

- Post-hoc comparison of pilot participants with a general pregnant population to assess generalizability

Study Setting: Kaiser Permanente Washington (KPWA), an integrated healthcare system in the U.S.

Study Population: Currently pregnant, <36 weeks gestational age, 18-45 years old, English-speaking, and enrolled in KPWA for ≥1 month before last menstrual period (LMP)

- Recruited in September and October 2017
  - Low-touch recruitment outreach of mailed notification; random subset of 50% received follow-up phone call
  - No financial or other incentive to participate
- Participants downloaded app and completed app-based consent
- Enrollment token linked participants to electronic health records (EHR)
- Comparator population constructed from EHR, using original inclusion criteria to identify all eligible women over expanded time period; excluded women enrolled in pilot
  - For assessment of generalizability, excluded all with <6 months pre-pregnancy KPWA coverage

Data Sources: Mobile app-based self-reported questionnaires, KPWA EHR

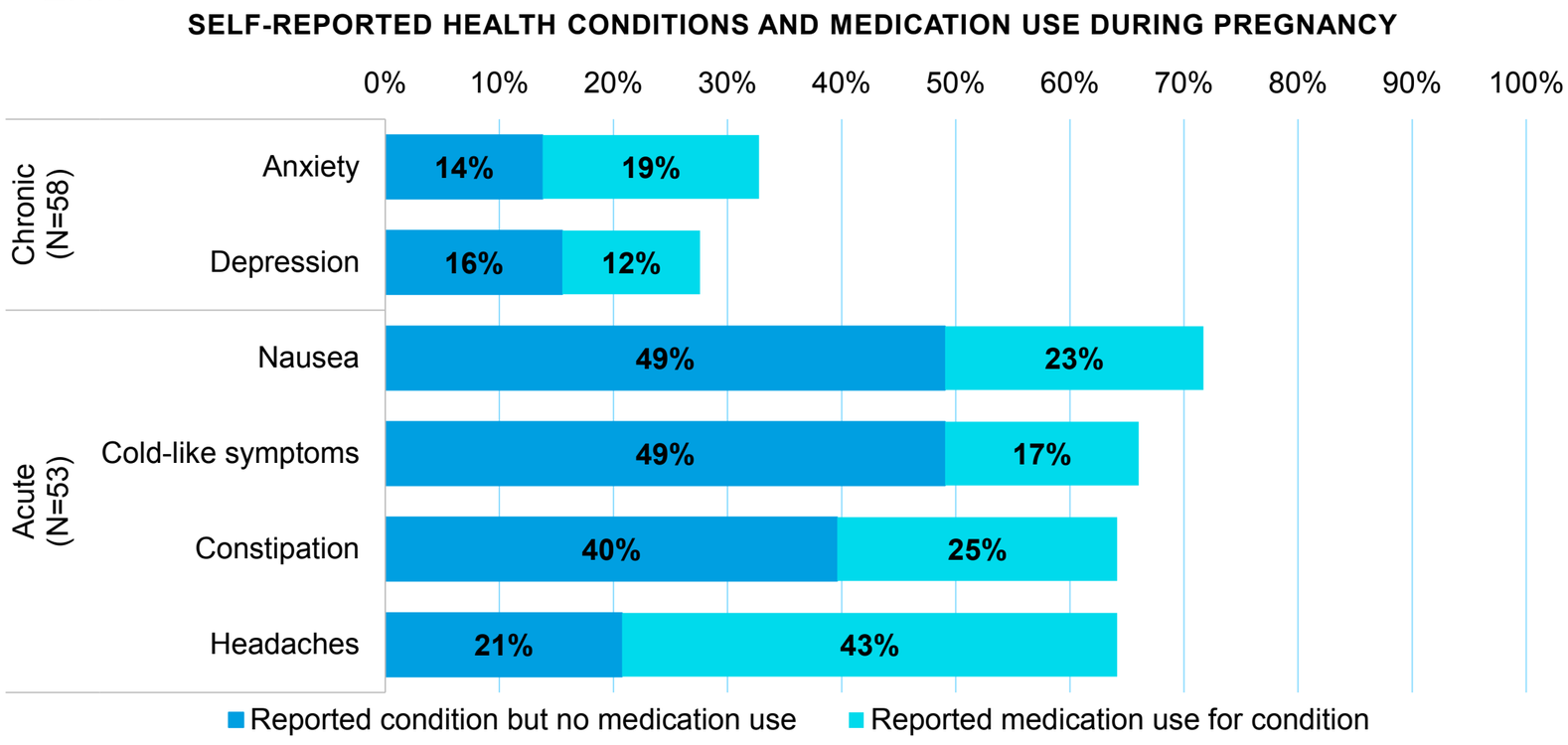
Statistical Analysis: Unadjusted, descriptive summary statistics, with 95% confidence intervals (CI)

Results

Mobile apps provide a feasible way to collect information not routinely found in electronic health records, but women willing to use apps for pregnancy research may differ from the general pregnant population

Feasibility of apps for collecting supplemental data for pregnancy research

- 6% (64/1,070) of women contacted to participate enrolled in pilot study
- High prevalence of self-reported over-the-counter (OTC) medication use not captured in EHR



Generalizability of mobile app pilot participants

	Pilot Participants (N=58)	EHR Population (N=2065)
	% or mean (95% CI)	% or mean
Sociodemographic characteristics		
Age (at LMP, in years)	33 (32.4-34.0)	31
White race	88% (81-95%)	67%
Clinical characteristics		
Comorbid conditions before or during pregnancy		
Anxiety[a]	33% (21-46%)	23%
Depression[a]	34% (22-48%)	20%
Medication use before and during pregnancy		
≥1 prescription medication fills in the 6 months prior to pregnancy		
Antianxiety medication	22% (13-35%)	10%
Antidepressant	19% (10-31%)	9%
≥1 prescription medication fills during pregnancy		
Antianxiety medication	21% (11-33%)	8%
Antidepressant	14% (6-25%)	7%

LMP = last menstrual period; CI = confidence interval

Notes: Confidence intervals are not provided for the EHR population, as this group represents the entirety of the pregnant population. [a]Depression, anxiety and alcohol use disorders were assessed during the 1 year prior to the LMP through delivery

Relative to the EHR population, app pilot participants were:

- Older
- Higher proportion white
- More likely to have depression
- More likely to have filled antianxiety or antidepressant medications

Discussion

- Mobile apps may be a useful tool for supplementing existing research data sources:
  - Exposure to OTC medications, often not captured in electronic health records
  - Detailed timing of exposure to prescription medications; important if pregnant populations are more likely to "self-discontinue" than non-pregnant populations
- Low enrollment (6%) raises concerns for generalizability
  - Pilot participants were older, more likely to be white, and had a higher prevalence of depression and filling of antianxiety and antidepressant medications relative to a general EHR pregnant population
- **Strengths:** Data collection via apps is novel; linkages with KPWA EHR allowed novel analyses including of generalizability
- **Limitations:** Small pilot sample size, generalizability assessment not pre-specified

Conclusion

Mobile apps have great potential to improve evidence on medication safety during pregnancy, but studies relying on mobile apps could have limited generalizability if participation rates are low. Research studies utilizing apps could improve inference by incorporating formal assessments of generalizability at multiple points in the research continuum.

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