Medication and Vaccination Data from the Healthy Pregnancy Study

Jennifer Radin is an epidemiologist at Scripps Translational Science Institute (STSI) in La Jolla, CA and the principal investigator of the Healthy Pregnancy Study. She will talk about medication and vaccination data collected through this app-based research study. STSI aims to replace the *status-quo* of one-size-fits-all-medicine with individualized health care that is based on the known genetic factors influencing health and disease and that takes advantage of advances in digital technology for real-time health monitoring.

This Healthy Pregnancy Study is a prospective, long-term, multi-year ResearchKit app created in collaboration between STSI and WebMD. The study aims to improve understanding of pregnancy through the collection of both survey and connected device data. The app collects medication (prescribed and over-the-counter) and vaccination data through an initial health history questionnaire and weekly surveys (see Figure). This data can be linked with outcome variables, such as pregnancy complications and diagnoses, symptoms, physiological measurements, activity, sleep, birth outcomes and more. Since the study is run entirely online, new questions can quickly and easily be added to the app at any time. The app is available for download from the iTunes store: https://itunes.apple.com/us/app/webmd-pregnancy/id600535431?mt=8.
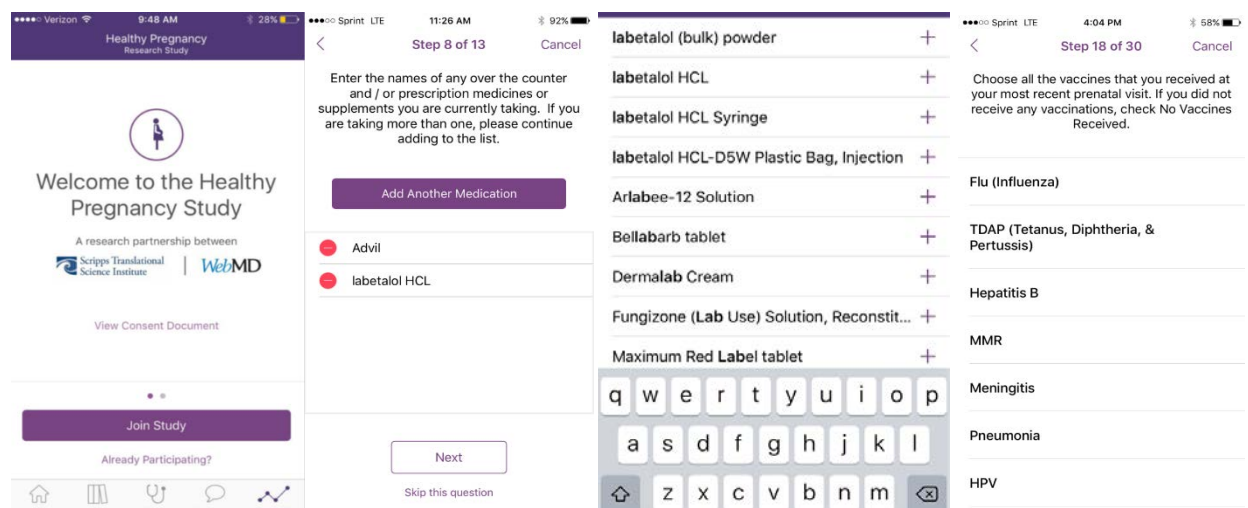

Figure. Healthy pregnancy app screen shots. Left to right: (a) Welcome screen (b) Medications during pregnancy question- health history questionnaire (c) Drop down list of prescribed and over-the-counter medications (d) Vaccinations during pregnancy question- health history questionnaire.

All pregnant women living in the United States, who own an iPhone and are comfortable reading and writing on it in English are eligible to join. However, in the near future, there are plans to expand to the study to Android phones, other languages and countries, and even postpartum women and their babies. As the availability of an increasing array of wireless, connected sensors grows, we also anticipate including a greater amount of automated daily (or even more frequent) collection of multiple parameters such as blood pressure, heart rate, activity, sleep, stress, glucose and more.

Currently, 6 out of the top ten prescribed medications and 2 of the top ten over the counter medications taken by women in the study are FDA category C, meaning animal studies show potential harm and adequate and well controlled human studies don't exist (see Table). The

high prevalence of category C drug use highlights the incredible need to provide women with better evidence based information about drug safety and effectiveness during pregnancy. By crowd-sourcing data from hundreds of thousands of pregnant women through a popular pregnancy app, the Healthy Pregnancy Study intends to fill in important research gaps regarding vaccine and drug safety, interactions, and effectiveness during pregnancy, even for less commonly taken medications.

Table. List of the top ten most prescribed and over-the-counter medications during pregnancy, drug indication, FDA pregnancy category, and percentage of participants taking the drug. Data is from the health history questionnaire, n=1,123.

Prescribed Medications	Over-the-counter

1. Antidepressants (8%)
   a. Zoloft, C (3%)
   b. Prozac, C (1%)
   c. Bupropion, C (1%)
   d. Lexapro, C (1%)
   e. Celexa (1%)
2. Levothyroxine (Thyroid Deficiency), C (5%)
3. Progesterone (Infertility/Prevent Miscarriage), A (2%)
4. Metformin (Type 2 Diabetes), B (1%)
5. Diclegis (Morning Sickness), A, (1%)
6. Adderall (ADHD/Narcolepsy), C (1%)
	1. Prenatal Vitamins (93%)
	2. Allergy (7%)
	   a. Zyrtec, B (4%)
	   b. Benadryl B, (2%)
	   c. Claritin, B, (1%)
	3. Acetaminophen (Analgesic), B (5%)
	4. Aspirin (NSAID/Analgesic), C/D, (4%)
	5. Zantac (Nausea/Heartburn), B (2%)
	6. Tums (Antacid), C (2%)
	7. Probiotic (Healthy Gut), Not Assigned (2%)
	8. Unisom (Sleep), B (1%)