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S9

Assessing the Feasibility of Monitoring Influenza Vaccine Safety in Pregnant Women Using Text Messaging

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Objective: Discuss the feasibility of using text messaging for vaccine adverse event surveillance in pregnant women.

Background: Inactivated influenza vaccine (IIV) is recommended for all pregnant women.[1] Monitoring IIV safety, including in pregnant women, is an important part of both seasonal vaccine programs and pandemic influenza plans. Although no evidence suggests that IIV is associated with increased risk for adverse events in pregnant women vaccinated later in pregnancy, data are limited for women vaccinated in the first trimester.[2] Most post-licensure vaccine studies do not capture non-medically attended events that may be clinically important and could affect future vaccination decisions.[3] Of US adults, 90% have a cell phone.[4] Text messaging programs can rapidly collect individualized data on both medically-attended and non-attended events. While we successfully demonstrated the use of text messaging for vaccine adverse event reporting in children[5], and others have demonstrated its use as a one-time query post-vaccination in pregnant women[6-7], the feasibility of its use to monitor post-vaccine events throughout pregnancy has yet to be studied.

Methods: The objective of this study was to assess the feasibility and accuracy of using text messaging to assess health status of pregnant women post-influenza vaccination through the end of pregnancy. We conducted a prospective observational study, in four practices in New York City, of pregnant women with a gestational age (GA) < 20 weeks at time of IIV vaccination who had a cell phone with text messaging; women with high risk pregnancies were not excluded. Most (80.2%, n=166) eligible women enrolled; 97.1% screened had text messaging. Messages were sent on: 1) days 0-2 (vaccination day and the next 2 days) assessing post-vaccination fever, 2) days 7, 14, 28, 42 assessing short-term events in the mother, and 3) from day 70 through participant-reported pregnancy end (monthly, then biweekly, then weekly). Messages included both fixed-choice (presence of vaginal bleeding, contractions, and/or fever) and open-ended responses. Final messages assessed pregnancy and neonatal outcomes, if applicable. Visit information was abstracted from electronic medical records (EMR), and study satisfaction assessed via an exit survey. Outcomes included response rates, d0-2 fever (T≥100.4F; 38C), reported pregnancy-related events and birth/neonatal outcomes.

Results and Conclusion: Median age was 32 years +/-6.2, GA at enrollment was 8.9 weeks +/-3.9; 57.8% were Latino, 33.1% Spanish-speaking, 21.7% publicly-insured and 27.1% uninsured at enrollment. 90.4% had unlimited text messaging plans. D0-2 text message response rates were high (89.7%-95.2%); one participant reported a d0-2 fever. D7-42 response rates ranged from 83.0%-89.1% with 11 unique text message reports of vaginal bleeding (eight of which were also in the EMR); four of contractions (all also in EMR). D70-259 response rates remained high (80.0%-91.7%). There were six unique reports of vaginal bleeding (three also in EMR); 25 of contractions (13 also in EMR). There were seven other unique pregnancy-related events, most commonly hypertension and diabetes; all also in EMR. Most (84.9%;n=141) completed the study (131 reported delivery, 10 reported no longer pregnant). Two fetal losses were not in the EMR, no additional losses were identified in the EMR. Of the 131 births reported, 86.2% had an EMR note confirming delivery. Most (96.9%) reported GA (30-42 weeks) including eight premature births (all confirmed in EMR). All reported a birthweight (1505–4545 grams). There were two other premature births in the EMR for women that had stopped texting. Ten reported neonatal problems, most commonly jaundice (nine confirmed in EMR). Nearly all (94.6%) would take part in a future text message study; 14.2% reported taking part affected how they felt about vaccine safety, all positively.

In addition to determining feasibility of text messaging, our study showed no unexpected adverse events among the pregnant women. Given the high response and retention rates, this study demonstrated the feasibility of text messaging for active vaccine safety surveillance sustained throughout pregnancy.

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S10 An Efficient Method for Vaccine Safety Surveillance

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Objective: Identify an efficient method of studying vaccine safety that can be applied to resource poor areas.
Background: Ongoing surveillance to assess and monitor vaccine safety is critical worldwide. Methods must be practical and efficient in order to monitor numerous vaccine-adverse event pairs.
Methods: We summarized immunization data on our health population by age, gender and dates of all vaccines. We used this summarized data to calculate expected vaccine exposures in case centered studies. Risk sets consisting of cases and all matched controls are constructed from the summarized immunization data on the entire population, with matching on age, sex, and the same vaccine in the 9 months prior to the onset of the case. We applied a case-centered logistic regression model to estimate the Odds ratios (ORs) of vaccination within the exposure interval vs. the comparison interval, with confidence intervals and p-values. The method uses only vaccinated people in the analysis, thus controlling for differences in vaccinated vs. unvaccinated individuals. By anchoring to the date of onset, it also controls for time-varying confounding, such as seasonality. We applied this method for Erythema multiforme following vaccines of any kind, using automated data from 2007-12.
Results and Conclusion: Odds ratio (OR) of any vaccine and subsequent EM was 0.88 (95%CI 0.35-1.88). ORs for MMR, IPV, DTaP, and Hepatitis B were all zero. For PNCV7 and PNCV13, ORs were 1.36 (0.41-3.53) and 1.33 (0.06-7.92) respectively. ORs, 95% CIs, and p-values were calculated for all vaccines. We demonstrated the utility of this approach using summarized, automated data. The approach could be tailored to any population with known age and vaccine dates. Cases must be found, confirmed, and their immunization dates recorded, but a random sample of cases, and using weekly (or possibly monthly) rates with age groupings would suffice. This method could be considered in areas of limited resources, as long as rates of immunization by age and week are recorded.

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