16 U.S. women's views on delaying pregnancy for the purpose of participating in biomedical research

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OBJECTIVES: Pregnant women are excluded from a majority of infectious disease trials, and contraception requirements are standard inclusion criteria. While often motivated by a desire for fetal protection, both practices may be implemented without a robust risk/benefit assessment or attention to women's values and preferences. For women with positive or uncertain pregnancy intentions, such requirements may be a determining factor in their trial participation decisions and have significant implications for their lives. As women's perspectives on these issues are important and underexplored, we investigated factors affecting women's willingness to delay pregnancy in order to participate in biomedical research.

METHODS: We conducted in-depth interviews with pregnant or recently pregnant women receiving prenatal and/or infectious disease care at one of three US academic medical centers as part of two larger, separate studies. Transcribed responses to a question exploring women's general willingness to delay pregnancy for the purposes of research participation were pooled and coded for emergent themes.

RESULTS: Out of 63 women, 35 stated that they would not delay pregnancy for research participation, whereas 19 would consider doing so and 9 were unsure. Women provided varied reasons for not wanting to delay pregnancy, including a view that pregnancy cannot be planned, not wanting to change pregnancy plans for a study, and advanced maternal age. Reasons cited for willingness to delay pregnancy for participation included if the study was of personal significance or benefit, and that pregnancy was already planned, e.g. due to birth spacing intentions or partner preferences.

CONCLUSION: Women expressed a range of considerations around delaying pregnancy to participate in biomedical research. More than half of participants would not alter their pregnancy plans, citing other, higher priority factors affecting pregnancy timing, but one in three women would consider changing pregnancy plans. In order to optimize recruitment of women for participation in trials, the research community should consider how best to support women's preferences when designing studies, including how inclusion and exclusion criteria affect women's reproductive lives and ability to participate in biomedical research. We discuss potential approaches that support women's reproductive autonomy while achieving an appropriate and considered risk/benefit ratio.

LEARNING OBJECTIVES: 1) Identify the range of considerations influencing women's willingness to delay pregnancy in order to participate in biomedical research 2) Articulate potential alternative approaches to supporting greater reproductive autonomy in biomedical research while achieving a positive risk/benefit ratio for women of reproductive age.

17 Retrospective review of maternal and neonatal outcomes of third trimester gravidas with influenza-like illness during the 2017-2018 influenza season

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OBJECTIVES: To evaluate the characteristics of illness and maternal and neonatal outcomes of women presenting with influenza-like illness in the third trimester of pregnancy.

METHODS: This was a retrospective cohort study of pregnant women evaluated for influenza-like illness in the third trimester of pregnancy during the 2017-2018 influenza season, who subsequently delivered at our hospital. Influenza-like illness was defined as upper or lower respiratory symptoms for which a provider ordered an Xpert Flu/RSV XC assay (Cepheid, Sunnyvale, CA). Fever was not a required inclusion criterion. Women testing positive for RSV, diagnosed with pyelonephritis, and those undergoing prolonged admission to the hospital for non-influenza related indications were excluded from analysis. We compared presenting symptomatology, influenza vaccination, hospital admission, and obstetric and neonatal outcomes among third trimester gravidas with positive versus negative rapid influenza tests.

RESULTS: A total of 423 pregnant women were evaluated for influenza-like illness in the third trimester between September 1, 2017 and March 31, 2018. Of these, 85 (20%) were excluded from analysis. Of the remaining 338 women, 136(40%) tested positive for influenza A or B, and 202(60%) tested negative. Odds of influenza vaccination were 50% lower in flu-positive women (63% vs 77%, OR 0.49 (0.30, 0.79)). Compared with flu-negative women, flu-positive women were more likely to report fever, cough, myalgias and pharyngitis, among other symptoms. While odds of fever were higher among flu-positive gravidas, fever was reported or measured in only 56% of confirmed cases. Flu-positive women had 2.47 times higher odds of hospitalization and over 7 times higher odds of ICU admission relative to flu-negative women. There were no significant differences in delivery or neonatal outcomes among third trimester gravidas with respiratory symptoms evaluated for influenza.

CONCLUSION: Forty percent of third trimester gravidas with respiratory symptoms evaluated for influenza during the 2017-2018 flu season tested positive for influenza A or B. Diagnosis of influenza was more common among women without vaccination. Pregnant women with influenza are at high risk for significant respiratory symptoms, hospital admission, and ICU admission when diagnosed in the third trimester.

LEARNING OBJECTIVES: Learners will be able to identify characteristics of illness and potential risks among mothers with influenza-like illness in the third trimester of pregnancy.

18 A natural immune boosting effect among HPV-vaccinated women living with HIV

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OBJECTIVES: To assess whether or not natural immune boosting to HPV occurs after vaccination.

METHODS: Women living with HIV participating in a multi-centre study of the qHPV vaccine with up to 8 year follow up provided ongoing clinical data including information on potential HPV exposures. Antibody levels were quantified (competitive Luminex immunoassay) at 0/2/7/12/18/24/36/48/60/72/84/96 months post 3-dose vaccination. Mixed-effects logistic regressions were used to assess factors associated with increases in antibody log titre with only increases of $\geq$0.4 log considered due potential assay variability.