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.

RESULTS: 322 eligible participants (≥1 dose of vaccine, ≥2 serology results ≥2 months post-last dose) had a mean age: 34 years (±12.6). 18.9%, 12.7%, 8.7%, and 7.1% participants had a boosting event of ≥0.4 log units for HPV6, HPV18, HPV16, and HPV11, respectively. Log titre increases were median 0.75-0.98 and maximum 2.20-3.37, depending on HPV type. For HPV16 and 18, there was no significant relationship between the odds of a boosting event and intercourse since last visit, number of sexual partners since last visit, or HIV viral load suppression. There was a relationship between the number of new sexual partners (≥1 vs. 0) since last visit and the odds of immune boosting (for HPV16: p=0.02, OR=4.51, 95%CI=1.25-16.38; for HPV18: p=0.02, OR=2.64, 95% CI: 1.17-5.96).

CONCLUSION: Many participants experienced immune boosting events of ≥0.4 log titre (>50% increase in raw antibody titre). The association between an immune boosting event and having new sexual partners since the previous study visit supports natural boosting occurring as a result of sexual exposure to HPV, even in immunocompromised women.

LEARNING OBJECTIVES: describe natural boosting events in qHPV-vaccinated HIV-positive women.

19 Should women living with HIV be screened for pelvic floor disorder during a routine gynecological care visit?

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OBJECTIVES: This study assesses if women living with HIV experience symptoms related to pelvic floor disorders.

METHODS: From March to April 2019 women attending a dedicated HIV gynecological clinic were offered participation. Thirty patients were approached and 15 (50%) consented. Demographic information was collected. A questionnaire was administered to assess pelvic floor dysfunction, including lower urinary tract symptoms, bowel (evacuation and incontinence), pelvic organ prolapse symptoms, and sexual distress. Symptoms were assessed using 15 questions from two validated questionnaires, the Pelvic Floor Disability Index and Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire. Topic areas assessing function and distress were: lower urinary tract symptoms 5 (33.3%), bowel 5 (33.3%), sexual desire 2 (13.3%) and pelvic organ prolapse 3 (20%). Statistical analyses utilizing t-statistics, chi-squared and fisher's tests, were performed; a p-value less than 0.05 was considered statistically significant.

RESULTS: The mean (SD) age for the study population (n=15) was 45.5 ï‚± 10.5 years, 93% had at least one delivery, and 80% had more than one delivery. Most reporting pelvic floor dysfunction were either White Hispanic 38.5% or Black non-Hispanic 30.8%. There was no significant differences in mean age, marital status, education, income, pregnancy and vaginal deliveries when stratified by the distressed outcomes. Overall, 13 reported pelvic floor dysfunction: 12 (80%) reported pelvic organ prolapse, bowel distress was reported by 8 (57.1%), urinary distress was reported by 13 (86.7%), and 13 (86.7%) reported pelvic floor disorder symptoms. There was an association between urinary distress and pelvic floor prolapse distress symptoms (p=0.029). Significantly more women reported having distress with pelvic organ prolapse distress symptoms 80% (p=0.002) and lower urinary tract symptoms 86.7% (p=0.029). Neither pelvic organ prolapse, nor urinary distress was associated with bowel distress symptoms in this cohort.

CONCLUSION: Women living with HIV present with high rates of pelvic floor dysfunction and report symptoms related to pelvic organ prolapse and the lower urinary tract. Since gynecologic visits in women living with HIV usually have greater emphasis on infection and cancer surveillance, conditions associated with pelvic floor dysfunction may not be routinely addressed. Our findings support routine screening for pelvic floor dysfunction and appropriate referrals.

LEARNING OBJECTIVES: Learners will be able to identify risk factors for pelvic floor dysfunction, including the prevalence of incontinence, urgency, frequency, nocturia and voiding difficulty in women living HIV, which is often underreported

20 When normal isn't normal: heterogeneity in dominant lactobacillus species among women having a nugent score of 0-3

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OBJECTIVES: To describe differences in prevalence, concentration, and relative abundance of five vaginal Lactobacillus species across the spectrum of normal Nugent scores (0-3).

METHODS: This was a secondary analysis of 685 healthy, asymptomatic, non-pregnant, sexually active women, aged 18-45 years enrolled in five studies (one group B Streptococcus vaccine and four vaginal microbicide product trials) between 2003 and 2018. Vaginal swabs and a vaginal smear were obtained at enrollment prior to study product administration. Five species of Lactobacillus (crispatus, vaginalis, jensenii, gasseri, iners) were identified using quantitative PCR. Vaginal smears were evaluated by the Nugent criteria. Relative abundance was calculated by dividing the concentration of a single species by the total concentration of all five Lactobacillus species. Women with Nugent score 0-3 were used in this analysis (n=414). Chi-square for linear trend and Kruskal-Wallis tests were used to evaluate differences in prevalence, concentration (log10 copies/swab), and relative abundance of the five species of lactobacilli across the spectrum of Nugent scores.

RESULTS: Of 685 women, 414 (60.4%) had Nugent score 0-3. These women predominantly self-identified as non-Hispanic white (67.4%) or non-Hispanic black (23.7%), were single (68.4%), and using hormonal contraception (70.3%). Nearly half (48.6%) of the women had a score of 0. The prevalence, concentration, and relative abundance of L. crispatus decreased with increasing score (p=.03, <.001, <.001, respectively), while the concentration and relative abundance of L. iners increased with Nugent score (p<.001). The relative abundance of L. jensenii increased with Nugent score (p=.05) and while prevalence and concentration were highest at a score of 3, this increase was not statistically significant. L. gasseri and L. vaginalis were present in low concentrations and the mean relative abundance remained at <6% and <2%, respectively.

CONCLUSION: In this large subset of women with normal vaginal microbiota by Nugent score, L. crispatus was the predominant Lactobacillus species only among women with Nugent scores of 0-1, while L. iners was the most abundant species in women with scores of 2-3. While L. jensenii has been considered to confer vaginal health benefits, it was the most abundant species in only 18% of women across the Nugent "normal" range. L. vaginalis, L. jensenii and L. gasseri likely have a limited role in vaginal health.