Postpartum HPV Vaccination: Acceptability, Uptake and Immunogenicity

Study Protocol & Statistical Analysis Plan

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Investigator Studies Program (MISP) Protocol Template	
Requirements for Submitting a Full Proposal	
Section #1 - MISP Protocol Identification	
Study Title:	Postpartum HPV Vaccination: Acceptability, Uptake and Immunogenicity
Request Date:	March 21, 2017
Institution Name	University of Alabama at Birmingham
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2.1 Objectives & Hypotheses

Human papillomavirus (HPV)-related cancers are on the rise in the United States. Furthermore, greater than 90% of cervical cancer cases are attributable to HPV, and cervical cancer disproportionately affects women of color in both incidence and mortality. Due to low HPV vaccine uptake in the US, innovative approaches to vaccinating vulnerable populations are necessary in order to maximize the cancer prevention potential of this vaccine. The puerperium is a time period when women are engaged in the healthcare system and have almost universal access to affordable health care. Two prior studies have shown that postpartum HPV vaccination is acceptable to patients, and high rates of vaccination were achieved in these primarily Hispanic populations. However, data show that the immune response in young women is less robust than in adolescents, and no studies have examined immunogenicity in postpartum women specifically. We propose an HPV vaccination pilot study in women who receive postpartum care at University of Alabama at Birmingham (UAB) hospital. UAB hospital serves a diverse population of patients, of whom 48% are African Americans and 16% are Hispanics. We will examine the acceptability, uptake and immunogenicity of the vaccine in the postpartum setting. For the purpose of this study, *acceptability* is defined as willingness to receive the HPV vaccine. *Uptake* is defined as actual receipt of the vaccine.

The specific aims are:

1. To examine the acceptability and uptake of HPV vaccination in postpartum women at UAB across white and African American patients
2. To evaluate the immunogenicity of the HPV vaccine in postpartum women

Outcomes:

Primary:

- Rates of vaccination uptake in postpartum patients across the racial/ethnic groups approached for study

Secondary:

- Serum titers of anti-oncogenic HPV subtypes (6,11,16,18,31,33,45,52,58) at baseline compared to 1 month after the third dose
- Factors associated with vaccine uptake or refusal and those associated with vaccine series completion

Exploratory:

- Serum titers of anti-oncogenic HPV subtypes of postpartum women compared to a historical age-matched control group, if data is available from Merck

Pending results of this study, widespread roll-out of a postpartum vaccination program for all women at UAB may be implemented. If successful, additional funding may also be sought for long-term follow-up of these patients. The results of this study could support and encourage uptake of postpartum HPV vaccination program at other institutions and in equally or more diverse populations.

2.1.1 Clinical Hypotheses

Aim 1: Offering postpartum women the HPV vaccine will increase the HPV vaccination rates from baseline
Aim 2: Postpartum women will achieve seroconversion of the nine anti-oncogenic HPV types included in Gardasil 9 by month seven
Aim 2.1: Antibody titer levels will be compared to a historical age-matched cohort

2.2 Background & Rationale, Significance of Selected Topic & Preliminary Data

2.2.1 Background

Human papillomavirus (HPV) oncogenic subtypes are associated with cervical, vulvovaginal, anal and oropharyngeal cancer, as well as their associated precancerous conditions. These HPV-related diseases are a major cause of morbidity and mortality in the United States (US) and worldwide – there are over 12,000 new diagnoses and 4,000 deaths from cervical cancer alone annually in the US. While cervical cancer rates are stable thanks to widespread adoption of screening via Pap tests and HPV testing, the overall rate of HPV-related cancers is on the rise in the US, with over 38,000 men and women diagnosed with HPV-related cancers (including cervical, vulvovaginal, anal, penile and oropharyngeal) every year.[1] Cervical cancer disproportionately impacts racial/ethnic minority women, women living in poverty, those without health insurance, and those living in certain underserved geographic regions of the US.[2-5]

The Gardasil HPV vaccine was developed for primary prevention of HPV-related cancers and their pre-

cancerous conditions, and has been FDA approved in the US since 2006 for use in women and girls ages 9-26 Despite being one of only two vaccines available to prevent cancer (the other being Hepatitis B), uptake of the HPV vaccine has been slow. Healthy People 2020 established a goal of 80% vaccination completion rate for girls and boys ages 13-15.[6] However, as of 2015 in the United States, only 62.8% of eligible girls ages 13-17 completed the first dose of the HPV vaccination, with 41.9% finishing all three doses.[7] The Centers for Disease Control and Prevention (CDC) officially made the recommendation to vaccinate boys in 2011, but in 2015 only 48.9% of eligible boys age 13-17 completed the first dose, with only 28.1% finishing the series. In Alabama, 57.7% of girls received the first dose and 40.8% received three doses. In contrast, rates of vaccination for the two other vaccines routinely given in adolescence are much higher, with 81.3% and 86.4% of adolescents age 13-17 receiving ≥ 1 dose of the meningococcal and Tdap vaccines, respectively.[7] The CDC recommends that a boys and girls between the ages of 11 and 12 receive the HPV vaccine; however, Gardasil and Gardasil-9 are FDA approved for women up to the age of 26. Current guidelines recommend two doses to children ages 9-14, and three does to adolescents and young adults ages 15-26.[8]

Low rates of HPV vaccination are attributed to multiple barriers including but not limited to cost, convenience, patient and parental attitudes towards vaccines in general and in particular, the link between the HPV vaccine and sexual activity.[9-13] Due to the low vaccine uptake in adolescence, there is still a large proportion of young women ≤26 years old who have not received the vaccine. Despite the fact that many young adults have already been exposed to the HPV virus through sexual activity, data have shown that HPV vaccination still provides protection from oncogenic virus types and can prevent cervical dysplasia in these women.[14] While increasing vaccination rates in the pediatric population remains a focus, capturing these patients who have aged out of the pediatric clinics but are still eligible for vaccination is also important. One proposed setting for capturing at-risk women is during the immediate postpartum period.

2.2.2 Postpartum Vaccination

Pregnancy is a time of increased patient engagement in the health care system and consequently, greater health care coverage. Many women who are otherwise uninsured have access to care under Medicaid during pregnancy and for 6-8 weeks postpartum making it an excellent opportunity to maximize disease prevention.[15-17] However, despite being eligible for the vaccine, very few postpartum women are receiving it.[18] Wright et al.[19] in New York and Berenson et al.[20] have described successful postpartum HPV vaccination programs, with a focus on racial/ethnic minorities (especially Hispanic/Latina) and publicly insured patient populations. Both groups have reported high rates of vaccine uptake and acceptability by patients, with 75% of patients approached by Berenson's group receiving at least 1 dose of the vaccine. 97% of patients surveyed by Wright et al. reported that they. Vaccine series completion rates were lower than initiation rates, with Wright et al. achieving a 31% 3-dose completion rate, and Berenson achieving a 57% 3-dose completion rate with the addition of patient navigators to assist with follow-up. Although these series completion rates not ideal, given that these are patients who would otherwise not receive any HPV vaccine doses, vaccine coverage in these populations were substantially improved with postpartum intervention. Qualitative data from nurses and doctors who participated in the Texas vaccination program demonstrated that providers generally supported the postpartum vaccination program and believed that patient education was key to achieving high vaccine uptake levels.[21] While there is limited data on vaccine reception and breastfeeding in humans, animal data have not shown increased risk to breastfed offspring from Gardasil-9.[22] Vaccines were provided to women who were lactating in one previous study, with similar rates of vaccine uptake in both breastfeeding and non-breastfeedin mothers, with no adverse outcomes reported.[20]

2.2.3 Racial Differences in Vaccination

The previously studied postpartum populations had larger proportions of Hispanic patients (73% and 49%) than African American (12% and 21%) patients.[19,20] In contrast, of the women who delivered at UAB in 2016, 48% were African American and 16.2% were Hispanic - with 68% of women who followed up in the postpartum period being African American. That our intended population of study is predominantly African American is important given racial disparities in cervical cancer outcomes. While both Hispanic and African American women have higher cervical cancer incidence rates compared to white women, African American women are more likely to be diagnosed at a higher stage and have higher mortality from cervical cancer than are white and Hispanic women.[3,5] Furthermore, there are racial differences in HPV vaccination uptake and postpartum vaccination uptake.

Rates of HPV vaccination initiation in 2015 for Hispanic (68.4%) and African American (66.9%) adolescent girls were significantly *higher* than in white girls (59.2%, $p<.05$), and 3-dose completion rates for

Hispanics were significantly higher than for whites (46.2% vs. 39.6%, p<.05).[7] The high rates of postpartum vaccine acceptance in previously mentioned study populations may reflect these higher rates of vaccination in Hispanic women. Some studies have shown that African American women may be less likely to believe that the are at risk for cervical cancer.[5] Qualitative data have shown that African American woman may be more skeptical about HPV vaccination than Hispanic women.[23] A 2014 study by Berenson et al. using a survey to assess acceptability of the HPV vaccine found that unvaccinated African American women were more likely to state that they could not afford the vaccine and that they were afraid of vaccine side effects compared to white or Hispanic women (p=0.001).[24] Decreased rates of postpartum Tdap vaccination in African American women have also been shown.[25,26] Healy et al. showed that while overall acceptance rates were high, African American women refused the Tdap vaccine postpartum at higher rates than Hispanic or white women, and were three times more likely to refuse the vaccine for non-medical reasons (p=0.003).[26] Our study will examine acceptabili and uptake in a population that is predominantly African American to determine barriers or facilitators to expanding HPV vaccination coverage in this at risk population.

2.2.4 Immunogenicity

Data have shown that the immune response to HPV vaccination in girls is non-inferior to that in young women and that antibody titers are actually higher in girls ages 9- to 15-years old.[27] This difference in immune response to the vaccine has not been shown to contribute to a difference in efficacy between the two age groups.[28] Pregnancy and the puerperium are time periods of substantial fluctuations in the immune system, with relative immunosuppression during pregnancy.[29] However, there are no existing data on the efficacy or immunogenicity of the HPV vaccine when administered in postpartum women. Vaccination in the postpartum period is not uncommon, with women routinely receiving MMR, Tdap and influenza vaccines in the hospital or a postpartum visits.[26] Limited data on these vaccines in postpartum women demonstrate adequate immunogenicity compared to non-pregnant women. Sperling et al. evaluated rates of seroconversion, defined a ≥ 4-fold increase in hemagluttination inhibition (HI) antibody from baseline titers, in pregnant and postpartum women after receiving a trivalent influenza vaccine. Rates of seroconversion were lowest in the first trimester and postpartum (54.8% each compared to 69.6% in the third trimester), but these differences were not statistically significant (p=.23).[30] This study will evaluate the immunogenicity of the Gardasil-9 vaccine in this population of postpartum women. We hypothesize that our data will show adequate seroconversion compared historical controls and provide support for postpartum HPV vaccination.

2.3 Study Design

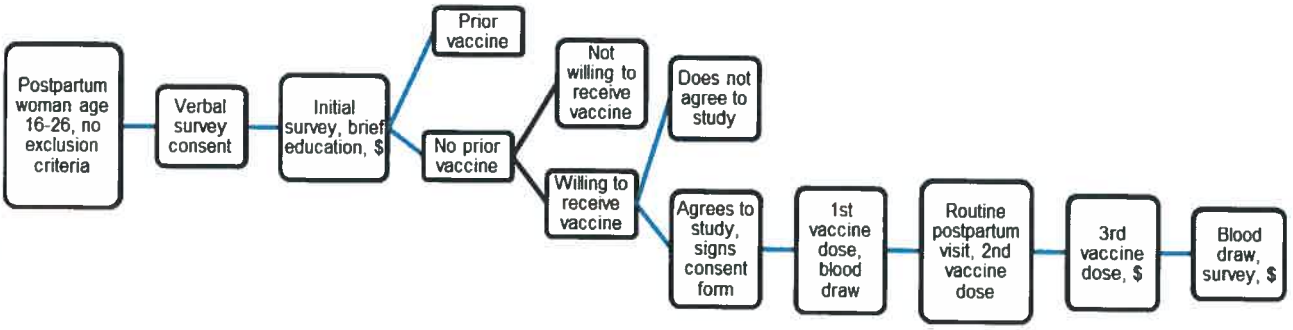
This project will be a single center exploratory study of postpartum patients who receive their care in th UAB Health system. Patients will be recruited at the Women and Infants Center at UAB immediately postpartur The study will consist of 4 stages: recruitment, survey, vaccination and serum samples in the hospital. Follow-u visits will then be conducted at 6-8 weeks postpartum and 6 months postpartum for the subsequent vaccine doses. One final blood test and survey will be conducted at 7 months postpartum (See Figure).

Patient Population

- **Inclusion criteria:** age 16-26 (under Alabama law, when a women under the age of 19 is pregnant, sh is considered an adult capable of consenting to medical treatment.), postpartum day 1-4, vaginal or Cesarean delivery
- **Exclusion criteria:** Fetal demise or miscarriage, autoimmune disorder, HIV, Hepatitis B/C, chronic steroid use, preeclampsia

- Spanish speaking patients: Due to the exploratory nature of our project and the lack of study personnel who speak Spanish, we have opted to exclude Spanish-speaking patients. Since the majorit of Hispanic patients seen at UAB are monolingual, we are excluding Hispanic patients. We recognize the importance of including Spanish-speaking patients in any study that examines racial/ethnic differences in health care decision making, and we plan to include this population in any future HPV vaccination research or interventions.

2.4 Study Flowchart



2.5 Study Procedures

Women age 16-26 who received their prenatal care at the UAB Obstetrics Complication Clinic (OBCC) or a Health Department will be identified on admission for labor and screened for participation. Of the approximately 4000 annual deliveries at UAB hospital, over 50% of those patients received their prenatal care a one of these locations, >74% of whom receive government-funded health care. These women will be approached on the postpartum unit in the 24-96 hours following delivery by study staff (including research assistants and nurses) and asked if they would like to participate in an interviewer-administered survey on HPV vaccination, for which verbal consent will be obtained). Patients will then fill out a survey via in-person intervie with study personnel that addresses perceived risk of HPV and HPV-related cancers, barriers that have prevented the patient from receiving the vaccine to that point and history of abnormal Pap tests or cervical dysplasia. Patients will be briefly educated on the HPV vaccine using a standard education script. Surveys will use Health Behavior Model (HBM) constructs as a framework. The HBM has successfully been used to examin patient decision making in the past, including pregnant women's attitudes towards vaccination.[31,32] At the end o this survey, patients will be asked whether they have ever received the HPV vaccine, and if not if would be willing to accept the HPV vaccine prior to leaving the hospital if it were offered to them. If they indicate that they would accept the vaccine, they will be asked to participate in a study to receive the vaccine and undergo two blood draws to test the body's immune response to the vaccine. They will be able to decide at the time of recruitment or any time prior to the day of discharge. Women who agree will then sign a consent form for this portion of the study. See the study flowchart above for a graphical representation of the recruitment, consent and testing process and timeline. Some demographic information will be gathered from the initial survey, and additional clinical data will be abstracted from the medical record, including gestational age at delivery, delivery type, and pregnancy or delivery complications such as pre-eclampsia, postpartum hemorrhage and chorioamnionitis.

For patients who agree to participate in vaccination stage:

First dose: Patients who agree to receive the vaccine will be discharged from the postpartum unit and escorte to the infusion center in the same building. The first of three Gardasil-9 doses will be administered in the deltoic as a 0.5-mL intramuscular injection, and one vial of blood will be drawn by a research nurse for baseline titers.

Second dose: Their postpartum visit will be scheduled 6-8 weeks later in the outpatient research unit affiliated with the OBCC. One reminder call will be performed prior to this visit. At the postpartum visit, the patient will receive routine prenatal care and will receive the second dose of the Gardasil-9 during this visit.

Third dose: Prior to leaving the postpartum appointment, a return visit 4 months later will be scheduled to receive the 3rd dose of the vaccine. This will be a nurse-only visit, where the patient receives the vaccine. Reminder calls will be performed prior to this visit.

Final blood draw: A final blood draw will be scheduled one month after the third vaccine dose. One vial of bloc will be drawn and a final survey will be performed at this time. This survey will be similar to the first, and will include questions about their experiences receiving the vaccine postpartum.

For all outpatient appointments, patients will receive reminder phone calls or text messages (per patient

preference) prior to their appointment by study staff, as well as reminders if they miss an appointment.

Baseline and month seven serum samples will be tested for vaccine HPV type antibodies by type-specific competitive Luminex immunoassay (cLIA) through Merck Research Laboratories. As described in the literature[27] subjects will be defined as anti-HPV 6/11/16/18/31/33/45/52/58 positive if her anti-HPV serum level ≥30, ≥16, ≥20, ≥24, ≥10, ≥8, ≥8, ≥8, or ≥8 milli Merck units (mMU)/mL for the 9 types, respectively. This protoc will be similar to that conducted by Kumar et al. with immunosuppressed transplant patients who received the HPV vaccine.[33] Patients who demonstrate seroconversion of types 6, 11, 16 and 18 at baseline will not receive further doses and will not be tested at the 7-month mark as these patients will be assumed to have previously received the vaccine. Seven month titers of our cohort will be compared to a historical Merck cohort and non-inferiority will be demonstrated based on Geometric Mean Titers (GMT) with a 95% confidence interval lower bound of >0.67 for each of the 9 subtypes.[27,28]

Incentives
Postpartum patients who agree to vaccination will receive $10 upon initial recruitment, $20 at the third return visit with administration of the third vaccine dose, and $20 at the final visit.

Data Storage and Safety
Data from surveys and medical record will be recorded and maintained securely in REDCap. All patient identifying information will be removed prior to data analysis and before data is shared outside of encrypted servers for with non-study personnel.

Research Team
- PI: Warner Huh, MD: Professor, Division of Gynecologic Oncology
- Sarah Dilley, MD, MPH: Fellow, Division of Gynecologic Oncology
- Alan Tita, MD: Professor, Division of Maternal Fetal Medicine
- Isabel Scarinci, PhD, MPH: Professor, Division of Preventive Medicine
- Akila Subramaniam, MD, MPH: Assistant Professor, Division of Maternal Fetal Medicine
- Charles A. Leath III, MD, MSPH: Associate Professor, Division of Gynecologic Oncology
- Sejong Bae, PhD: Professor of Biostatistics Division of Preventive Medicine
- Daniel Pasko, MD: Fellow, Division of Maternal Fetal Medicine
- Rachel LeDuke, MSN: Administrative Director of MFM Research
- Gloria Adams, RN: Research Nurse

2.6 Study Duration

Study activities for the primary outcome from recruitment to data collection, data analysis and manuscript preparation are estimated to take 12 months.

Activities	Months											
	0	1	2	3	4	5	6	7	8	9	10	11
Recruitment	X	X										
Vaccination – Dose 1	X	X										
Vaccination – Dose 2		X	X	X								
Vaccination – Dose 3							X	X	X			
Blood Draw	X	X						X	X	X		
Survey	X	X						X	X	X		
Analysis										X	X	
Manuscript Preparation												X

2.7 Statistical Analysis and Sample Size Justification	Sejong Bae, PhD, a Professor of Medicine in the Division of Preventive Medicine will be providing guidance wit statistical analysis. **Sample Size Justification:** This is a feasibility study focused on HPV vaccination among postpartum women, with an ultimate goal to demonstrate 3-dose completion vaccination rates that are comparable to those of other postpartum completion rates. Vaccine initiation and three dose completion rates gleaned from prior postpartur vaccination studies[19,20] are estimated to be up to 75% for one dose initiation and 45% for 3 dose completion. In order to demonstrate at least a 50% completion (+/-10%) of three doses, approximately 100 patients will need t initiate vaccination with 50 completing the 3 doses, to have 95% confidence at alpha of 0.05. We anticipate tha approximately 80% of patients will agree to complete the initial survey, of whom 25% of women have already received the HPV vaccine at baseline (based on data from Berenson et al.[20]). Therefore at least 200 patients w be approached in order to recruit 170 patients who will undergo the initial survey, 130 of whom will be eligble fo the second portion of the study, approximately 75% of whom will initiate the vaccination series. **Statistical Methods**: Final results will be determined to be statistically significant when the accompanying test yields a two-tailed p-value of ≤0.05, recognizing that many associations will be considered hypothesis generating. The primary analysis will be estimating the vaccine initiation and completion rates. Demographic ar vaccination rates will be summarized using descriptive summary statistics overall and by different subgroups, such as race, as well as corresponding 95% confidence intervals. Descriptive and Chi square statistics will be used to explore the HPV vaccination status and patient characteristics, survey responses, and other variables c interest. Multivariable logistic regression will be used to assess association between patient characteristics, survey responses, and vaccination rates. **Immunogenicity:** Descriptive statistics will be used to assess rates of seroconversion as described above. Geometric Mean Titers of samples at 7 months will be compared to historical controls. As this is a pilot study, w will perform exploratory analyses.
2.8 Specific Drug Supply Requirements	Medicaid in pregnancy (also known as SOBRA) in the state of Alabama funds the Gardasil-9 vaccine ir the immediate postpartum patient and through 60 days after delivery in the outpatient setting. 75% of our patier population is estimated to have Medicaid, although the proportion of these with SOBRA Medicaid (versus Medicaid for Parents) is unknown. The first two doses of the vaccine for the majority of patients will be purchased locally as a marketed product, and bulk supplies will not be required. Drug supply is requested from MSD for any patients who are uninsured, and those who no longer have insurance coverage for the 3rd dose of the Gardasil-9 vaccine. We estimate that this would include 40 vaccine doses. We acknowledge that a limitation of our study is the lack of generalizability of access to the third dose c Gardasil. In the current healthcare system access to Medicaid outside of pregnancy is state-dependent, and it i especially limited in states that have not expanded Medicaid under the Affordable Care Act (such as Alabama). Outside of being enrolled in a study, there are several approaches that pregnant women who lose Medicaid coverage after the immediate postpartum period may be able to use to access the third vaccine dose. Pregnan adolescents age 18 or younger would qualify for the Children's Health Insurance Program (CHIP) and Vaccines for Children (VFC). In Alabama, women age 19-26 qualify for SOBRA when their household income is 146% or less of the Federal Poverty Limit (FPL). For women whose household income is 18% or less of FPL, they qualif for Medicaid for Parents if they are US citizens and their child lives in the home with them. Alternatively, womer who do not qualify for Medicaid may quality for Special Enrollment into an affordable Blue Cross Blue Shield plan via the ACA insurance marketplace, with premium tax credits based on income. Finally, women could app for the Merck Patient Assistance Program to obtain the third vaccine dose if they do not access health insurance. Unfortunately, these approaches may not be sufficient or for all patients. We hope that our data will further support the need for vaccine coverage and access to Medicaid under healthcare reform.
2.9 Adverse Experience Reporting	Adverse experiences will be reported as per the Model Study Agreement

2.10 Itemized Study Budget	See separate attachment
2.11 References	1. Viens LJ HS, Watson M, et al. . Human Papillomavirus–Associated Cancers — United States, 2008–2012. *MMWR Morb Mortal Wkly Rep 2016.* 2016;65:662-666. 2. Amini A, Jones BL, Yeh N, et al. Disparities in disease presentation in the four screenable cancers according to health insurance status. *Public Health.* 3. Beavis AL, Gravitt PE, Rositch AF. Hysterectomy-corrected cervical cancer mortality rates reveal a larger racial disparity in the United States. *Cancer.* 2017:n/a-n/a. 4. Collins Y, Holcomb K, Chapman-Davis E, Khabele D, Farley JH. Gynecologic cancer disparities: A report from the Health Disparities Taskforce of the Society of Gynecologic Oncology. *Gynecologic Oncology.* 2014;133(2):353-361. 5. Downs LS, Smith JS, Scarinci I, Flowers L, Parham G. The disparity of cervical cancer in diverse populations. *Gynecologic Oncology.* 2008;109(2, Supplement):S22-S30. 6. US Department of Health and Human Services OoDPaHP, US Department of Health and Human Services, & Office of Disease Prevention and Health Promotion. Healthy people 2020. 2010. 7. Reagan-Steiner S YD, Jeyarajah J, et al. National, Regional, State, and Selected Local Area Vaccination Coverage Among Adolescents Aged 13–17 Years — United States, 2015. *MMWR Morb Mortal Wkly Rep.* 2016;65:850-858. 8. CDC recommends only two HPV shots for younger adolescents [press release]. October 19, 2016 201 9. Holman DM BV, Roland KB, et al. Barriers to human papillomavirus vaccination among us adolescents A systematic review of the literature. *JAMA Pediatrics.* 2014;168(1):76-82. 10. Hough-Telford C, Kimberlin DW, Aban I, et al. Vaccine delays, refusals, and patient dismissals: a surve of pediatricians. *Pediatrics.* 2016. 11. Rambout L, Tashkandi M, Hopkins L, Tricco AC. Self-reported barriers and facilitators to preventive human papillomavirus vaccination among adolescent girls and young women: A systematic review. *Preventive Medicine.* 2014;58:22-32. 12. Watts LA, Joseph N, Wallace M, et al. HPV vaccine: A comparison of attitudes and behavioral perspectives between Latino and non-Latino women. *Gynecologic Oncology.* 2009;112(3):577-582. 13. Widdice LE, Bernstein DI, Leonard AC, Marsolo KA, Kahn JA. Adherence to the HPV Vaccine Dosing Intervals and Factors Associated With Completion of 3 Doses. *Pediatrics.* 2011;127(1):77. 14. Group TFIS. Prophylactic Efficacy of a Quadrivalent Human Papillomavirus (HPV) Vaccine in Women with Virological Evidence of HPV Infection. *Journal of Infectious Diseases.* 2007;196(10):1438-1446. 15. D'Angelo DV, Le B, O'Neil ME, et al. Patterns of Health Insurance Coverage Around the Time of Pregnancy Among Women with Live-Born Infants--Pregnancy Risk Assessment Monitoring System, 29 States, 2009. *Morbidity and mortality weekly report. Surveillance summaries (Washington, D.C. : 2002)* 2015;64(4):1-19. 16. D'Angelo DV, Williams L, Harrison L, Ahluwalia IB. Health Status and Health Insurance Coverage of Women with Live-Born Infants: An Opportunity for Preventive Services After Pregnancy. *Maternal and child health journal.* 2012;16(0 2):222-230. 17. Markus AR, Rosenbaum S. The Role of Medicaid in Promoting Access to High-Quality, High-Value Maternity Care. *Women's Health Issues.*20(1):S67-S78. 18. Kilfoyle KA, Rahangdale L, Dusetzina SB. Low Uptake of Human Papillomavirus Vaccine Among Postpartum Women, 2006–2012. *Journal of Women's Health.* 2016;25(12):1256-1261. 19. Wright JD, Govindappagari S, Pawar N, et al. Acceptance and compliance with postpartum human papillomavirus vaccination. *Obstetrics & Gynecology.* 2012;120(4):771-782. 20. Berenson AB, Rahman M, Hirth JM, Rupp RE, Sarpong KO. A human papillomavirus vaccination program for low-income postpartum women. *American Journal of Obstetrics and Gynecology.* 2016;215(3):318.e311-318.e319. 21. Gross TT, Rahman M, M. Wright A, et al. Implementation of a Postpartum HPV Vaccination Program ir a Southeast Texas Hospital: A Qualitative Study Evaluating Health Care Provider Acceptance. *Materna and Child Health Journal.* 2016:1-10. 22. GARDASIL 9 Package Insert. In: Administration FaD, ed2016. 23. Scarinci IC, Garces-Palacio IC, Partridge EE. An examination of acceptability of HPV vaccination amor

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2.12 Publication Plan	We anticipate two publications and 2-4 abstracts to be developed from this project. Target journals including Gynecologic Oncology, Vaccine, American College of Obstetricians and Gynecologists (ACOG Green Journal) and the American Journal of Obstetrics and Gynecology (AJOG). Meetings where we would consider presentin study results include the Society of Gynecologic Oncology, ACOG and the Society for Maternal Fetal Medicine.
2.13 Curriculum Vitae	See separate attachment for CV References: J. Michael Straughn Jr., MD: jstraughn@uabmc.edu Charles A. Leath III, MD: cleath@uabmc.edu Karen Adams, MD: adamsk@ohsu.edu
2.13 Protocol Submission for Investigator-Initiated Studies	U.S. protocols should be submitted by US investigators directly or through the Global Research Specialist at www.merckiisp.com Non U.S. protocols should be submitted to the MSD office by the investigators.