

Consortium on Law and Values in Health, Environment & the Life Sciences 2019-20 Proposal Cover Page

To use checkboxes, place cursor on box; right click; select Properties; select Checked under Default value

Applicant Information

Applicant name(s):	Serena Xiong, MPH	Email:	xiong455@umn.edu
Project title:	HPV Self-Sampling in Primary Care Clinics in Minnesota: A Pre-Implementation Study		
Department:	Epidemiology & Community Health	College:	School of Public Health
Degree program:	PhD in Social/Behavioral Epidemiology		
Faculty advisor:	DeAnn Lazovich, PhD	Faculty advisor email	lazov001@umn.edu <input type="checkbox"/> No advisor
Dept. Head:	Dianne Neumark-Sztainer, PhD, MPH, RD	Dept. Head's email:	neuma011@umn.edu
Dean:	John R. Finnegan Jr., PhD	Dean's email:	finne001@umn.edu

How did you hear about this funding opportunity?

ACCU Consortium website The Brief Dept. email/newsletter Law School email Other

Funding

Total amount of funding requested: **\$7,000 (maximum)**

Executive summary (maximum 200 words)

Since the implementation of cervical cancer screening methods, such as cervical cytology or Pap test, cervical cancer rates have been declining. Nevertheless, racial/ethnic disparities in cervical cancer screening continue to exist, and are caused by a wide range of factors, including limited awareness about HPV and cervical cancer, difficulties accessing health care services, and cultural or religious beliefs. Self-sampling techniques for the collection of HPV specimens have been proposed as an effective alternative to overcome some of these barriers. Most research in this area, however, has focused on mail-in self-sampling kits, and has overlooked the potential to help address cervical cancer screening equity in primary care. The overall goal of this study is to develop an understanding of multilevel perspectives on the implementation of an HPV self-sampling practice in primary care settings in Minnesota by 1) interviewing key health care personnel from health systems across the state of MN, and 2) surveying minority female patients across the state of MN on their perspectives of HPV self-sampling. This study will make a unique contribution in describing health systems and clinicians' and patients' perspectives on the adoption and implementation of an HPV self-sampling practice in primary care clinics.

Approvals

Check all appropriate approvals required for your proposal. It is not necessary to have all approvals at the time of proposal submission; however, approvals must be obtained prior to receipt of funding. If you have applied for approval but have not yet received it, indicate that below.

IRB required?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	<input checked="" type="checkbox"/> If yes, is application pending?	Approval date or number:
Other/s required?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	<input checked="" type="checkbox"/> If yes, is application pending?	Specify type of approval: CPRC (Cancer Protocol Research Committee)

Checklist—for reviewer use only. DO NOT COMPLETE.

- The proposal is 1000 words or less excluding budget, biographies, references and citations.
- The proposal includes a work plan with a specific timeline using months or quarters to identify work to be done and completion dates.
- The proposal includes a 1-2 paragraph biography of the applicant and all co-investigators.
- The budget form is complete including the funds sought for this project, other pending applications for this project, and the amount/source of matching or other funds.
- The applicant's faculty advisor is copied on the application email. Professional students w/o advisors check No Advisor.
- All necessary approvals are pending or received.

BACKGROUND

In 2019, approximately 13,000 cervical cancer cases were diagnosed in the US.¹ As the second highest annual medical expenditure for US women (\$37.7 billion),² it is imperative that public health efforts are employed to address the burden of cervical cancer. Since implementation of cervical cancer screening, via Pap tests, cervical cancer rates have declined.^{3,4} However, Pap tests are still underutilized by many minority women due to limited awareness about HPV and cervical cancer,⁵⁻⁹ difficulties accessing health care services,¹⁰ and cultural or religious beliefs.¹⁰⁻¹³ Self-sampling techniques, the process of collecting a vaginal sample by oneself, have been proposed as an effective alternative to overcome these barriers.¹⁴⁻²⁰ In many countries with national cancer screening programs (e.g., Chile), HPV self-sampling has been shown to successfully reach women who delay or opt out of cervical cancer screening.²¹⁻²⁸ Many women in these studies also reported a high acceptability of HPV self-sampling,²⁶⁻²⁸ suggesting that this test is an effective strategy to increase cervical cancer screening among women who may be resistant to Pap tests.

In 2018, the US Preventive Services Task Force recommended that women ages 30-65 can undergo primary HPV testing every 5 years.²⁹ However, health systems have experienced slow onboarding with this screening recommendation. Fortunately, HPV self-sampling can be used to facilitate patient-initiated primary HPV testing, but this approach has not gained strong traction in the US. Implementing this new intervention will require a multilevel (individual, community) and interdisciplinary (public health, medicine) understanding of how health systems can be changed to achieve better and equitable cancer screening outcomes for women. To date, no such studies have examined how HPV self-sampling can be adopted into routine care in primary care settings.

STUDY AIMS

The proposed study will be the first of its kind to describe health systems and clinicians' and patients' perspectives on the adoption and implementation of an HPV self-sampling practice in primary care clinics. The specific aims are as follow:

AIM 1: To conduct 30 key informant interviews with health systems leaders, primary care clinicians, and clinic staff to inform the implementation of an HPV self-sampling practice in primary care clinics in MN. Guided by the Consolidated Framework for Implementation Research (CFIR), these key healthcare personnel will be asked to describe multilevel barriers and facilitators to the implementation of HPV self-sampling in primary care settings. **Hypothesis 1:** The CFIR approach will enable health systems leaders, primary care clinicians and clinic staff to identify key multilevel factors required for the successful implementation of a routine HPV self-sampling practice in MN. *Funding for Aim 1 is currently being supported through the Division of Epidemiology and Community Health.*

AIM 2: To conduct an online survey of 335 racially/ethnically-diverse women across the state of MN on their awareness, self-efficacy, and preferences of HPV self-sampling. **Hypothesis 2:** Racially/ethnically-diverse women will report a low level of HPV self-sampling awareness, a high level of self-efficacy to conduct an HPV self-sampling test, a high preference for clinic-based HPV self-sampling; and a high preference for HPV self-sampling over Pap test. *Funding for Aim 2 is being requested through this Consortium Award application.* Study methods for Aim 2 are described below.

STUDY METHODS

AIM 2: Study Population. Three hundred thirty-five (N=335) women (ages 30-65 years) will be recruited through Minnesota Community Care (MCC) clinics, a large federally-qualified health center in St. Paul, MN with high populations of racially/ethnically diverse female patients (Letter of Support received 1/2020). Women will be recruited onsite in the lobby rooms of MCC clinics where they will complete the survey in real time. The survey (in English, Spanish, Hmong, and Somali) will be administered via iPad using the REDCap system. Interested women will first complete an online eligibility screener then the survey. For women who are unable to complete the survey at the clinic, they will be provided with a study brochure with links to the online screener and survey. **Study Measures.** The 20-item survey includes 16 sociodemographic questions (age, country of origin, religious orientation, yearly income, education level, relationship status, employment status,

BIOGRAPHIES OF APPLICANT & CO-INVESTIGATORS

Serena Xiong, MPH (PI) is a doctoral student in the Social and Behavioral Epidemiology program at the University of Minnesota School of Public Health. Prior to entering graduate school, she worked as a Health Services Program Coordinator for Hmong American Partnership, wherein she was responsible for coordinating a breast cancer and cervical cancer screening program for Hmong women. Through this navigator role, she gained intimate experience of how to navigate health systems and effectively work with minority women around sensitive health topics. Ms. Xiong also has several years of experience on health disparity projects and cervical cancer prevention interventions, including leading the design and implementation of a recent mobile application intervention to educate Hmong families about HPV vaccinations. In several of these research projects, she also managed, analyzed, and collected survey data through REDCap and is well-verse in using this database. Ms. Xiong will serve as the Principal Investigator (PI) for the project (her dissertation research) and her dissertation committee will serve as co-investigators.

DeAnn Lazovich, PhD (Academic Advisor, Co-I) is an Associate Professor in the Division of Epidemiology and Community Health at the University of Minnesota School of Public Health. Dr. Lazovich has applied both qualitative and quantitative methods to understand cancer prevention, screening, treatment and survivorship. She also has conducted both etiologic and intervention studies, using various observational (descriptive, case-control, cohort) and randomized controlled study designs. While she has studied various cancers, and a range of risk behaviors and screening tests, she has particular expertise in melanoma skin cancer and skin cancer prevention. She is currently principal investigator for the Iowa Women's Health Study, and is an active member of an interdisciplinary team working to establish a new, Minnesota-based cohort, known as the 10,000 Families Study. As Ms. Xiong's primary dissertation advisor, she will provide oversight of the project to ensure methodologic rigor and engage with Ms. Xiong frequently to ensure the project is carried out in a timely and valid manner.

Rebekah Pratt, PhD (Project Advisor, Co-I) is an Assistant Professor in the Department of Family Medicine and Community Health at the University of Minnesota Medical School. Dr. Pratt has an extensive background in cancer prevention, primary care, implementation science, qualitative methods and health disparities. Dr. Pratt will provide expertise in qualitative methods, particularly in relation to interviews, including in relation to data collection, analysis and dissemination. Additionally, Dr. Pratt will help to facilitate recruitment of primary care professionals through her extensive networks in family medicine and the Minnesota Practice Based Research Network in primary care. Dr. Pratt has expertise in health disparities research, including community-partnered research with minority communities. She will support the recruitment of minority women to the survey component of this proposed work. Dr. Pratt will also work with Ms. Xiong to provide mentorship and training to ensure the project is successfully completed.

Rahel Ghebre, MD, MPH (Dissertation Committee Member, Co-I) is an Associate Professor in the Department of Obstetrics, Gynecology and Women's Health (OBGYN) at the University of Minnesota Medical School. Dr. Ghebre has extensive experience in conducting and implementing cervical cancer prevention (e.g., screening and HPV vaccination) interventions, including being the PI of a recently completed HPV self-sampling pilot study in Somali women in MN. Her content expertise in HPV self-sampling coupled with her experience in working with minoritized populations will help to guide the proposed study and its survey questions to be culturally-appropriate for the target populations of racially and ethnically diverse women. Having implemented several clinic-based interventions, Dr. Ghebre will also provide alternative recruitment support and strategies to the Ms. Xiong.

REFERENCES

1. American Cancer Society. (2019, January 8). *Key Statistics for Cervical Cancer*. Retrieved from <https://www.cancer.org/cancer/cervical-cancer/about/key-statistics.html>.
2. Soni, A. (2011). *Top 10 most costly conditions among men and women, 2008: Estimates for the US civilian noninstitutionalized adult population, age 18 and older*. Agency for Healthcare Research and Quality.
3. IARC Working Group on the Evaluation of Cancer-Preventive Strategies, & International Agency for Research on Cancer. (2005). *Cervix cancer screening* (Vol. 10). Diamond Pocket Books (P) Ltd..
4. Kitchener, H. C., Castle, P. E., & Cox, J. T. (2006). Achievements and limitations of cervical cytology screening. *Vaccine*, 24, S63-S70.
5. Abakporo, U., Hussein, A., Begun, J. W., & Shippee, T. (2018). Knowledge, Beliefs and Attitudes of Somali Men in Olmsted County, Minnesota, US, on the Human Papillomavirus Vaccine and Cervical Cancer Screening: January 17, 2015. *Journal of Immigrant and Minority Health*, 20(5), 1230-1235.
6. Downs Jr, L. S., Scarinci, I., Einstein, M. H., Collins, Y., & Flowers, L. (2010). Overcoming the barriers to HPV vaccination in high-risk populations in the US. *Gynecologic Oncology*, 117(3), 486-490.
7. Otanez, S., & Torr, B. M. (2018). Ethnic and Racial Disparities in HPV Vaccination Attitudes. *Journal of Immigrant and Minority Health*, 20(6), 1476-1482.
8. Carroll, J., Epstein, R., Fiscella, K., Volpe, E., Diaz, K., & Omar, S. (2007). Knowledge and beliefs about health promotion and preventive health care among Somali women in the United States. *Health Care for Women International*, 28(4), 360-380.
9. Al-Amoudi, S., Cañas, J., Hohl, S. D., Distelhorst, S. R., & Thompson, B. (2015). Breaking the silence: breast cancer knowledge and beliefs among Somali Muslim women in Seattle, Washington. *Health Care for Women International*, 36(5), 608-616.
10. Pavlish, C. L., Noor, S., & Brandt, J. (2010). Somali immigrant women and the American health care system: discordant beliefs, divergent expectations, and silent worries. *Social Science & Medicine*, 71(2), 353-361.
11. Bigby, J., Ko, L. K., Johnson, N., David, M. M., Ferrer, B., & Boston, R. E. A. C. H. (2003). A community approach to addressing excess breast and cervical cancer mortality among women of African descent in Boston. *Public Health Reports*, 118(4), 338.
12. Khaja, K., Lay, K., & Boys, S. (2010). Female circumcision: toward an inclusive practice of care. *Health Care for Women International*, 31(8), 686-699.
13. Degni, F., Suominen, S., Essén, B., El Ansari, W., & Vehviläinen-Julkunen, K. (2012). Communication and cultural issues in providing reproductive health care to immigrant women: health care providers' experiences in meeting Somali women living in Finland. *Journal of Immigrant and Minority Health*, 14(2), 330-343.
14. Hobbs, M. M., Van Der Pol, B., Totten, P., Gaydos, C. A., ... & Schachter, J. (2008). From the NIH: proceedings of a workshop on the importance of self-obtained vaginal specimens for detection of sexually transmitted infections. *Sexually Transmitted Diseases*, 35(1).
15. Arrossi, S., Thouyaret, L., Herrero, R., Campanera, A., ... & EMA Study Team. (2015). Effect of self-collection of HPV DNA offered by community health workers at home visits on uptake of screening for cervical cancer (the EMA study): a population-based cluster-randomised trial. *The Lancet Global Health*, 3(2), e85-e94.
16. Wright Jr, T. C., Denny, L., Kuhn, L., Pollack, A., & Lorincz, A. (2000). HPV DNA testing of self-collected vaginal samples compared with cytologic screening to detect cervical cancer. *JAMA*, 283(1), 81-86.
17. Zhao, F. H., Lewkowitz, A. K., Chen, F., Lin, M. J., ... & Li, S. M. (2012). Pooled analysis of a self-sampling HPV DNA test as a cervical cancer primary screening method. *Journal of the National Cancer Institute*, 104(3), 178-188.
18. Arbyn, M., Verdoodt, F., Snijders, P. J., Verhoef, V. M., ... & Hillemanns, P. (2014). Accuracy of human papillomavirus testing on self-collected versus clinician-collected samples: a meta-analysis. *The Lancet Oncology*, 15(2), 172-183.

19. Winer, R. L., Feng, Q., Hughes, J. P., Yu, M., ... & Koutsky, L. A. (2007). Concordance of self-collected and clinician-collected swab samples for detecting human papillomavirus DNA in women 18 to 32 years of age. *Sexually Transmitted Diseases*, 34(6), 371–377.
20. Ogilvie, G. S., Patrick, D. M., Schulzer, M., Sellors, J. W., ... & FitzGerald, J. M. (2005). Diagnostic accuracy of self-collected vaginal specimens for human papillomavirus compared to clinician collected human papillomavirus specimens: a meta-analysis. *Sexually Transmitted Infections*, 81(3), 207-212.
21. Gravitt, P. E., Belinson, J. L., Salmeron, J., & Shah, K. V. (2011). Looking ahead: A case for human papillomavirus testing of self-sampled vaginal specimens as a cervical cancer screening strategy. *International Journal of Cancer*, 129(3), 517-527.
22. Stewart, D. E., Gagliardi, A., Johnston, M., Howlett, R., ... & Mai, V. (2007). Self-collected samples for testing of oncogenic human papillomavirus: a systematic review. *Journal of Obstetrics and Gynaecology Canada*, 29(10), 817-828.
23. Gupta, S., Palmer, C., Bik, E. M., Cardenas, J. P., ... & Goddard, A. D. (2018). Self-sampling for human papillomavirus testing: increased cervical cancer screening participation and incorporation in international screening programs. *Frontiers in Public Health*, 6, 77.
24. Madzima, T. R., Vahabi, M., & Lofters, A. (2017). Emerging role of HPV self-sampling in cervical cancer screening for hard-to-reach women: focused literature review. *Canadian Family Physician*, 63(8), 597-601.
25. Smith, J. S., Des Marais, A. C., Deal, A. M., Richman, A. R., Perez-Heydrich, C., Yen-Lieberman, B., ... & Brewer, N. T. (2018). Mailed human papillomavirus self-collection with Papanicolaou test referral for infrequently screened women in the United States. *Sexually Transmitted Diseases*, 45(1), 42.
26. Anderson, C., Breithaupt, L., Des Marais, A., Rastas, C., Richman, A., Barclay, L., ... & Smith, J. S. (2018). Acceptability and ease of use of mailed HPV self-collection among infrequently screened women in North Carolina. *Sexually Transmitted Infections*, 94(2), 131-137.
27. Ortiz, A. P., Alejandro, N., Pérez, C. M., Otero, Y., ... & Romaguera, J. (2012). Acceptability of cervical and anal HPV self-sampling in a sample of Hispanic women in Puerto Rico. *Puerto Rico Health Sciences Journal*, 31(4), 205.
28. Tisci, S., Shen, Y. H., Fife, D., Huang, J., ... & Qiao, Y. L. (2003). Patient acceptance of self-sampling for human papillomavirus in rural China. *Journal of Lower Genital Tract Disease*, 7(2), 107-116.
29. US Preventive Services Task Force. (2018). Screening for cervical cancer us preventive services task force recommendation statement. *JAMA*, 320(7), 674–686.
<https://doi.org/https://doi.org/10.1001/jama.2018.10897>

PROPOSED BUDGET AND BUDGET JUSTIFICATION

Project Title: HPV Self-Sampling in Primary Care Clinics in Minnesota: A Pre-Implementation Study

Provide justification along with costs.		Requested funding	
Category & Instructions	Justification	Amount	
1	Your stipend (maximum amount is \$5,000)	A stipend is requested to support the PI (SX) in conducting on-site/in-person recruitment, data management and analysis, and manuscript writing.	\$2500
2	Speaker honoraria (for colloquia)	___ speakers x \$ _____ honorarium	\$0
3	Supplies & Services <i>Identify and explain use here or in the body of your proposal.</i>	Compensation for survey respondents are requested, being \$10 gift card per participant, for approximately 335 participants, for a total cost of \$3350. Printing of study brochures is also being requested for a total cost of \$150.	\$3500
4	Equipment <i>Identify and explain use. Allowable only if the equipment is necessary for this project. All equipment must be given to your dept. at the completion of your project.</i>	Purchase of an iPad (with WiFi capability) for survey data collection is requested for a total cost of \$1000.	\$1000
5	Travel <i>Indicate the purpose of the travel, estimated dates of travel, transportation, housing and allowable per diem costs (see travel.umn.edu).</i>		\$0
TOTAL BUDGET			\$7,000 (maximum)

Other funding: List other or matching funding you have requested for this project.

Funding source	Amount
EpiCH J.B. Hawley Student Research Award (received; funds will be used to pay for transcription fees and incentives for Aim 1)	\$7,500