An implementation tool for healthcare professionals and local providers to consider opportunities for implementing first-void urine (FVU) based self-sampling for cervical cancer screening in their setting and population

Purpose: The aim of this tool is to enable healthcare professionals (HCPs) and providers to become active stakeholders in improving access to HPV screening by identifying opportunities for FVU self-sampling within their patient population. The tool was developed using a phased approach with input from subject matter experts.

Instructions for use: The tool will guide you through a series of 22 questions within five themes:

- Theme 1. The value of self-sampling
- Theme 2. Existing healthcare structures
- Theme 3. Key stakeholders
- Theme 4. Evidence available
- Theme 5. Barriers and facilitators to implementing urine-based self-sampling

Work through the tool alone or as a team answering all the relevant questions. Skip any questions that are not relevant to your context. There is a call to action at the end of the tool.

Additional resources: On the final page, you will find references to some useful resources.

Theme	Questions to consider	Responses
Value of self-sampling	1) What are the key demographic groups (or patient characteristics) within my patient group? [e.g. race/ethnicity, age, education, socioeconomic status, with/without health insurance, religious/cultural practices/experience of trauma, etc.] 2) Are there data on cervical cancer rates or cervical screening coverage in my area that can help me/us understand where there is an unmet need for screening and who are the underserved groups? 3) Is there any observable or documented evidence in my field/work that describes the unmet need and how self-sampling might impact it and/or considerations driving preference for self-sampling? 4) What are some potential benefits of using self-sampling for cervical cancer screening in my population?	
Existing healthcare structures	5) What data exists to inform how people are currently accessing cervical cancer screening in my population? 6) How are people without health insurance accessing screening? 7) How and where could self-sampling best complement existing health screening structures? 8) Do we know why some people are not screening using the existing provision?	

Theme	Questions to consider	Responses
Stakeholders	9) Who are the key cervical cancer screening stakeholders in my region? [e.g. providers, healthcare professionals, patients, laboratory, etc.] 10) What individuals or groups would be affected by the introduction of self-sampling? How will they be affected? 11) Which patient subgroups would most benefit from the availability of self-sampling? 12) Who could help shape how self-sampling is implemented in my region? 13) Are there any groups outside the healthcare sector that would benefit from getting involved? 14) Which of these stakeholders do I already know or could approach?	
Evidence	15) What evidence is available already about urine self-sampling for HPV primary-based cervical cancer screening including acceptability, safety, accuracy, clinical benefit, cost-effectiveness, urine stability, storage and transportation recommendations etc.? 16) What other evidence is needed to shape how self-sampling is offered and/or to support implementation in my setting/region? 17) What other evidence could I generate?	

Theme	Questions to consider	Responses
Barriers and facilitators to implementing urine-based self-sampling	18) What are the individual / system-level barriers to implementing self-sampling in my region? How could I help overcome any of these barriers? 19) How can I improve equity and access to self-sampling? 20) What system-level changes may be needed to facilitate self-sampling? 21) How can barriers specific to new technologies be addressed? [e.g. standardising language, easy instructions for patients, etc.] 22) Who do I know or could reach out to who might be able to help overcome other barriers?	
Taking action	• What additional information do I need to answer these questions – where can I find this information? • Now that I have some answers, what are the next steps needed to take action? • Who else can I collaborate with to advance this action plan?	

Resources

Listed below are some resources you might find helpful as you work through the tool and decide on the next steps for taking action.

Category	Example references
Information on screening	• Fontham *et al*. Cervical cancer screening for individuals at average risk: 2020 guideline update from the American Cancer Society. CA Cancer J Clin. 2020 Sep;70(5):321–46. https://doi.org/10.3322/caac.21628 • CDC. Behavioral Risk Factor Surveillance System (BRFSS). https://www.cdc.gov/brfss/index.html
Examples of available services for women with no insurance	• Wong FL, *et al*. CDC National Breast and Cervical Cancer Early Detection Program: Increasing Access to Screening. J Women's Health 2002. 2019 Apr;28(4):427–31. https://doi.org/10.1089/jwh.2019.7726 • Find a Screening Program Near You, NBCCEDP. CDC. 2023. https://www.cdc.gov/breast-cervical-cancer-screening/about/screenings.html • FQHC Associates. What is a Federally Qualified Health Center (FQHC)? www.fqhc.org/what-is-an-fqhc
Example of regional trials for HPV self-sampling	• Winer RL, et al. Effect of Mailed Human Papillomavirus Test Kits vs Usual Care Reminders on Cervical Cancer Screening Uptake, Precancer Detection, and Treatment. JAMA Netw Open. 2019 Nov 6;2(11):e1914729. https://doi.org/10.1001/jamanetworkopen.2019.14729 • Pretsch PK, et al. Effect of HPV self-collection kits on cervical cancer screening uptake among under-screened women from low-income US backgrounds (MBMT-3): a phase 3, open-label, randomised controlled trial. Lancet Public Health. 2023 Jun 1;8(6):e411–21. https://doi.org/10.1016/S2468-2667(23)00076-2 • Kobetz E, et al. A Randomized Trial of Mailed HPV Self-Sampling for Cervical Cancer Screening among Ethnic Minority Women in South Florida. Cancer Causes Control CCC. 2018 Sep;29(9):793–801. https://doi.org/10.1007/s10552-018-1055-7

Category	Example references
Examples of disparities and determinants of under-screening	• United States Cancer Statistics: Data Visualizations. Available from: https://gis.cdc.gov/Cancer/USCS/#/AtAGlance/ • National Cancer Institute. SEER*Explorer Application. Available here: SEER*Explorer Application (cancer.gov) • Jensen B, *et al*. Sociodemographic Determinants in Cervical Cancer Screening Among the Underserved West Texas Women. Womens Health Rep. 2023 Apr 19;4(1):191–201. https://doi.org/10.1089/whr.2022.0050 • Zeno EE, *et al*. Racial and ethnic differences in cervical cancer screening barriers and intentions: The My Body My Test-3 HPV self-collection trial among under-screened, low-income women. PLoS ONE. 2022 Oct 13;17(10):e0274974. https://doi.org/10.1371/journal.pone.0274974 • Suk R, *et al*. Assessment of US Preventive Services Task Force Guideline-Concordant Cervical Cancer Screening Rates and Reasons for Underscreening by Age, Race and Ethnicity, Sexual Orientation, Rurality, and Insurance, 2005 to 2019. JAMA Netw Open. 2022 Jan 4;5(1):e2143582. https://doi.org/10.1001/jamanetworkopen.2021.43582 • Zhao G, *et al*. Health Insurance Status and Clinical Cancer Screenings Among U.S. Adults. Am J Prev Med. 2018 Jan;54(1):e11–9. https://doi.org/10.1016/j.amepre.2017.08.024
Examples of evidence for urine-based self-sampling	• Rohner E, *et al*. Racial and Ethnic Differences in Acceptability of Urine and Cervico-Vaginal Sample Self-Collection for HPV-Based Cervical Cancer Screening. J Women's Health 2002. 2020;29(7):971–9. https://doi.org/10.1089/jwh.2019.8132 • Leeman A, *et al*. HPV testing in first-void urine provides sensitivity for CIN2+ detection comparable with a smear taken by a clinician or a brush-based self-sample: cross-sectional data from a triage population. BJOG. 2017 Aug;124(9):1356-1363. https://doi.org/10.1111/1471-0528.14682 • Meers N, *et al*. Storage and transport recommendations for first-void urine samples. Novosanis. Available at: https://novosanis.com/sampling-solutions/colli-pee-urine-stability

This tool was created by Aquarius Population Health, an independent consultancy based in London, UK. More information about our work can be found on our website AquariusPH.com or by emailing info@aquariusph.com.