EVA System®

America's Cervical Cancer Crisis

Why Low-income and Medically Underserved Women Are Bearing the Burden and How to Improve Access to Care

MobileODT
Mobile Optical Detection Technologies

Unequal access and opportunity for high-quality health care

When it comes to saving their lives from cervical cancer, not all women in America have equal access, or equal opportunity to appropriate health care. Recent research has shown women from ethnic minorities in America suffer from cervical cancer incidence and mortality rates that are significantly higher than white women.[1] Despite the national increase in cervical cancer screening over the last half century, which has led to a 75% decline[2] in mortality from the disease, rates of cervical cancer deaths among women in underserved populations remain vulnerable. Of those American women who will be diagnosed with cervical cancer at some point during their lifetime, and the thousands who die each year from the disease, a disproportionate burden falls on medically underserved communities who face economic, cultural, linguistic or location-based barriers to care, such as in inner-city or rural areas.

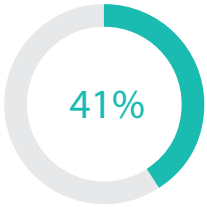
As a virus-associated disease, cervical cancer spreads throughout a population propelled by the Human Papillomavirus (HPV). While the virus itself is randomly distributed throughout the population, shockingly, a 2017 study found black women and white women in the United States are dying from cervical cancer at rates 77% and 47% higher than previously thought, respectively.[3] Furthermore, black women are being diagnosed at a later age than white women which has been attributed to lack of access to "timely, appropriate and high-quality care."[4] Most alarmingly, black women are dying of cervical cancer at a rate 41% higher than white women.[5]

Meanwhile, Hispanic women, referring to persons of Mexican, Cuban, Puerto Rican, South or Central American, Dominican, or other Spanish descent, have the highest incidence of cervical cancer in the United States, especially around the Texas-Mexico border, lower Mississippi valley[6] and southern Appalachia,[7] [8] with rates 40% higher than those in non-Hispanic whites. Native American women are nearly twice as likely to develop cervical cancer as white women.[9] For these women, the remarkable success of the Pap smear at curbing cervical cancer as experienced by white urban women is still out of reach.

We believe there is an end in sight to these tragedies. From our experience, building digital tools for healthcare providers in 26 countries around the world, it is possible to address the lack of culturally-appropriate education about cervical health, and the constraints on resources for healthcare outreach that further entrench these seemingly intractable disparities in a cost-effective manner.[10]

While the US healthcare system is often thought of as the most advanced of its kind, the medical care experienced by underserved communities lacks many of the advances made in addressing global health concerns in less developed nations.

This short report provides an overview of recent research into the state of cervical cancer among underserved women in America, information about toolkits made available in low-resource settings worldwide, and finishes with an overview into the technologies now available to enable healthcare providers to better extend the benefits accrued to those American women in the US for which cervical cancer is no longer a leading cause of death.



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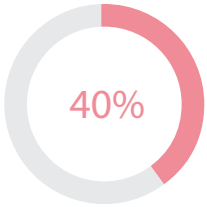


Hispanic women have highest incidence of cervical cancer with rates 40% higher than white women.

1 https://www.cdc.gov/cancer/hpv/statistics/cervical.htm
2 https://www.cancer.gov/about-nci/organization/crch-d/about-health-disparities/resources/excess-cervical-cancer-mortality.pdf
3 http://onlinelibrary.wiley.com/doi/10.1002/cncr.30507/abstract
4 http://onlinelibrary.wiley.com/doi/10.3322/caac.21340/full
5 https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/cancer-facts-and-figures-for-african-americans/cancer-facts-and-figures-for-african-americans-2016-2018.pdf
6 http://msdh.ms.gov/msdhsite/_static/44,0,236.html
7 http://www.arc.gov/assets/research_reports/AnalysisofHealth-DisparitiesIntroductionExecutiveSummary.pdf
8 https://www.arc.gov/appalachian_region/CountyEconomicStatusandDistressedAreasinAppalachia.asp
9 https://www.americanindiancancer.org/cervical

Cervical Cancer Still Threatens American Women

Until recent research highlighted the disparities in mortality rates from cervical cancer in the United States, cervical cancer in America was generally thought of as a disease of the past. Over the past five decades, since the introduction of the Pap smear and universal guidelines that recommend regular screening for women, cervical cancer screening rates have increased substantially and mortality rates in the US have declined by more than 75% in the past fifty years,[11] driving cervical cancer from the one of the most common causes of cancer death for women to the 21st.[12] We now know that women in underserved populations are not experiencing those benefits. Of the approximately 132.44 million women at risk for cervical cancer in the United States, it is estimated that only 80.5% of women are screened, leaving approximately 25.8* million women across America untested for the deadly, but easily preventable disease.[13]

25.8M US women are not screened for cervical cancer

It is well known that most cervical cancers develop following infection by high-risk strains of human papillomavirus (HPV), leading to 12,900 new HPV-related cases diagnosed each year in the United States, an average of 35 women a day.[14] [15]

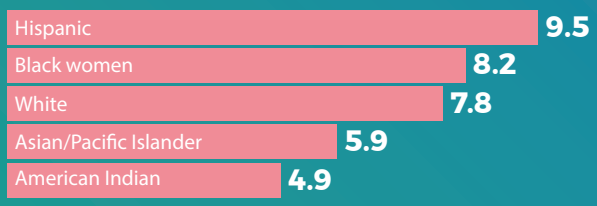
35 women per day are diagnosed with HPV

Whilst efforts to vaccinate young teens and adults against this sexually transmitted infection (STI) are ongoing, it will take several generations to halt the spread of HPV, and there is a crucial need for effective screening programs that allow clinicians to visualize and examine the cervix of HPV-positive individuals to detect any changes, which could lead to the development of precancerous lesions, and cervical cancer if not treated early. Though cervical cancer is a slow growing cancer that can take up to twenty years to develop,[16] broad-based screenings form the most reliable strategy to reduce prevalence and mortality rates, which disproportionately affect underserved communities. More than 50% of new cervical cancer cases occur in women who not been screened in the past five years, or have never undergone a screening.[17]

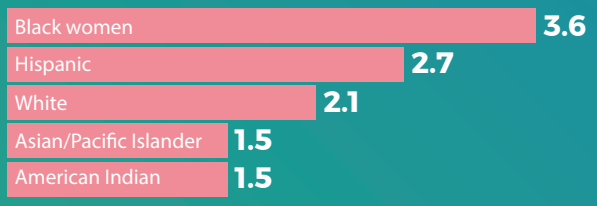
10 http://onlinelibrary.wiley.com/doi/10.1002/cncr.20508/full
11 https://www.cancer.gov/about-nci/organization/crch-d/about-health-disparities/resources/excess-cervical-cancer-mortality.pdf
12 https://seer.cancer.gov/statfacts/html/cervix.html
13 http://www.hpvcentre.net/statistics/reports/USA_FS.pdf
14 https://www.hpv.com/hpv-related-cancers-and-diseases
15 http://www.hpvcentre.net/statistics/reports/USA_FS.pdf
16 http://www.who.int/mediacentre/factsheets/fs380/en
17 https://www.cdc.gov/vitalsigns/cervical-cancer/index.html

The Centers for Disease Control (CDC)[18] reports that in 2014, Hispanic women had the highest incidence rate of cervical cancer of all women, followed by Black, White, Asian/Pacific Islander (A/PI), and American Indian/Alaska Native (AI/AN) women. The rate of death was highest for black women, followed by Hispanic, White, Asian/Pacific Islander and American Indian/Alaska Native.

A detailed look at statistics
Incidence of cervical cancer per 100,00 population shows:



Mortality from cervical cancer per 100,00 population shows:



Not only is incidence and mortality higher for black women than for white women, but the 5-year relative survival rate is lower in blacks than in whites for every stage of diagnosis for most cancer sites.[19] The overall 5-year relative survival rate for cervical cancer is 58% for black women, compared to 69% for white women.[20] Another contributing factor is that black women are diagnosed later than white women. The median age of cervical cancer diagnosis is 51 years for black women compared 48 years of age for white women. Those three crucial years can mean the difference between a treatable cancer, and one that is terminal.

Screening programs are trying to break this entrenched pattern of health disparities with varying rates of success.

The National Breast and Cervical Cancer Early Detection Program (NBCCEDP)[21] is one of the most successful screening programs for medically underserved populations in the country, yet only 6.5%[22] out of this eligible population of women have been screened. That represents only 705,970 women out of 9.8 million women that need access to screening, a disparity that falls disproportionately on the backs of minority and low-income women.

Only **705,970** women out of
9.8 million underserved women are
getting cervical cancer screenings.

Despite the best efforts of the NBCCEDP, federally qualified community health centers and Planned Parenthood, many low-income, uninsured women are not being screened. This leaves cancers to grow undetected over many years. A study published in Gynecologic Oncology[23] found that women who entered the NBCCEDP who did not have regular Pap tests, "had a higher rate of high-grade histological lesions and invasive cervical cancers at later stages than women screened more recently."

The NBCCEDP[24] says, "Deaths from breast and cervical cancers could be avoided if cancer screening rates increased among women at risk. Deaths from these diseases occur disproportionately among women who are uninsured or underinsured. Pap tests are underused by women who have no regular source of health care, women without health insurance, and women who immigrated to the United States within the past 10 years."

Authors of the study said major obstacles to regular screening like access to transportation and lack of a regular primary care provider, "are associated with late-stage of cervical cancer at diagnosis". Many medically underserved women continue to use the ER as their primary source of health care, which means they do not have consistent access to family doctors or OB-GYNs who can perform cervical cancer screenings. The adoption of innovative care delivery systems, like mobile cervical cancer programs, which can reach underserved communities closer to their places of residence and daily life, and in accessible locations such as community centers instead of medical clinics, can substantially advance efforts to improve care.

18 https://www.cdc.gov/cancer/cervical/statistics/race.htm
19 http://onlinelibrary.wiley.com/doi/10.3322/caac.21340/full
20 http://onlinelibrary.wiley.com/doi/10.3322/caac.21340/full
21 https://www.cdc.gov/cancer/nbccedp/about.htm
22 https://link.springer.com/article/10.1007/s10552-015-0524-5
23 http://www.sciencedirect.com/science/article/pii/S0090825815301657
24 https://www.cdc.gov/cancer/nbccedp/about.htm

Overcoming the barriers of access to care

Removing barriers to screening means addressing and resolving many types of obstacles; financial, cultural, interpersonal and educational. As efforts continue to find new ways to improve screening rates, many states including Utah[25], Ohio[26] and Georgia[27] have launched programs to educate women about the importance of screening. These programs expand access to screening for low-income and uninsured women and in some cases help them to navigate the healthcare system as a whole, complimenting coverage provided by the Affordable Care Act, Medicaid and Medicare coverage in all 50 states.

Partnerships between community organizations, expanded outreach and education efforts, and free screening programs, can be some of the most effective interventions to increase cervical screening rates. Community-based screenings at community centers instead of clinic settings may take advantage of a combined PAP/HPV test and mobile colposcopy approach, which has proven to be a successful and advantageous solution for improving screening in underserved populations.[28] No singular intervention will work for all population subgroups. Therefore, interventions should incorporate a variety of locations, languages and types of providers. Outreach located at community centers rather than clinical settings, can be some of the most effective because they target groups with persistent screening disparities.[29]

Major obstacles standing before the expansion of these programs are similarly experienced by healthcare providers around the world in developing economies. Chief among these include lack of access to transportation to and from clinical services, poor access to expertise that can provide women with a confident diagnostic decision, no local access to therapeutic options if and when needed, and an absence of a regular primary care provider that can regularly ensure a woman is properly screened.[30] Many medically underserved women continue to use the emergency room (ER) as their primary source of health care, which means they do not have consistent access to family doctors or OB-GYNs who can perform Pap smears.

If women do manage to undergo a Pap smear and test positive for abnormalities, they also face limited access to specialist care, with a shortage of clinicians suitably trained to serve as expert colposcopists. Women's health providers should band together to address this enormous gap.

25 https://cancerutah.org/cancers/cervical-cancer
26 https://www.odh.ohio.gov/en/health/cancer/bccp/bcanc1
27 https://dph.georgia.gov/breast-and-cervical-cancer-program-eligibility-information
28 http://onlinelibrary.wiley.com/doi/10.1002/cncr.20508/full
29 http://onlinelibrary.wiley.com/doi/10.1002/cncr.20508/full
30 https://www.cdc.gov/cancer/nbccedp/about.htm

A screening program that can reach a far greater percentage of those women across America who require screening should address the following:

- Ensure local availability of clinical services
- Enable local access to expertise for diagnostic decision-making
- Provide direction to the nearest therapeutic resources when required
- Leverage appropriate telemedicine solutions to engage experts that are not locally available
- Expert review with regular, local check-ins with a primary healthcare provider to ensure follow-up to clinical recommendations

Setting up these four pillars to hold up any cervical cancer screening program for low-resource individuals across the US will require the application of new resources and different approaches to care provision. The increased emphasis on training for Nurse Practitioners, and the adoption of innovative care delivery systems, like mobile cervical cancer programs, promise to reach underserved communities closer to their places of residence and daily life, and can substantially advance efforts to improve care. So too can the expansion of training on colposcopy for other Advanced Practice Professionals, which can ensure that any woman who has a Pap sample taken will also have the opportunity to follow-up on her test results with a local clinician who can address the matter-at-hand and lead the screening process towards a successful conclusion.

While thermocoagulation, cryotherapy, and other low-risk and easy to apply interventions to address precancerous lesions have been passed over in higher resource settings in the United States in favor of LEEP, it may be worth re-thinking the **'Single Visit Approach'** taken by healthcare organizations across remote and rural areas worldwide. The 'Single Visit Approach' assumes that the best intervention to reduce the burden of cervical cancer is one that can be applied when the woman is already in the room.

Until now, guidelines for the identification and treatment of cervical cancer have been standardized across the United States, but the research studies this particular paper has been based upon have sparked a conversation about varying the guidelines according to level of risk. We have observed worldwide that the greatest risk to a woman's health is loss-to-follow-up, when a positively screened or diagnosed woman is lost to the system, and does not access available care due to a variety of circumstances that may include fear, shame, economic anxiety, or social pressure. **Loss-to-follow-up, far more than a lack of available technology or health-care infrastructure, is an addressable and solvable challenge** – one that by solving can mean the difference between life and death for women who have already engaged with cervical cancer screening efforts one way or another. Addressing loss-to-follow-up will require new program infrastructure, and new technology.

How technology can help access to care

While the American healthcare system often sets itself apart by those served by the World Health Organization, it may be wise to review its recommendations by the WHO for a good screening program:

- **Accurate:** the result of the test is correct
- **Reproducible:** repeating the same test will give the same result
- **Inexpensive:** affordable to the health system in terms of both financial and human resources, and to all patients and their families in terms of access to necessary services
- **Relatively easy:** uncomplicated to perform and to provide follow-up care for women with abnormal results
- **Acceptable:** well-tolerated by both the patient and the provider
- **Safe:** the test procedure and management of screen-positive subjects have no or minimal adverse effects
- **Available:** accessible to the entire target population.

Providing quality cervical cancer screening to low-income and underserved women across the United States will require healthcare providers to stretch their regular way of doing business and focus efforts on building a new model for healthcare delivery that can save thousands of lives every year.

There are a number of technological and service efforts that take these WHO values as their guiding principles, and ensure that US quality standards are met through the application of these values. Since 2012, we have worked with healthcare providers worldwide and observed how they have maximized their resources and applied every ounce of their beings to ensure that every woman can access the care she deserved. Over this five-year period we have worked to co-develop new tools for these healthcare providers working to serve the underserved in the US and around the world, and the result is embodied by our Enhanced Visual Assessment (EVA) System, a toolkit we make available so that healthcare providers can focus on expanding care, and EVA can enable them to provide care wherever their programs are needed.

At the most basic, healthcare providers across the United States are using the EVA System as a mobile colposcope, a traditionally-required tool used during cervical cancer diagnosis for the magnified viewing of the cervix for diagnosis and treatment. What we have learned, however, is that the colposcope functionality is only one of the many tools a healthcare provider needs to expand cervical cancer screening and treatment programs to the underserved, and to close the gap between the current reality and a world where every woman in America, no matter her race, ethnicity or socio-economic status, shares the same access to care and opportunity for a long life.

Using the WHO recommendations as a foundation for developing that toolkit, the EVA System uses its colposcope to enable a broad set of support services to help healthcare providers extend their programs.

ACCURATE: the EVA System helps the healthcare provider ensure the result of the test is correct by integrating a set of online-enabled quality assurance tools, including remote review by supervisors and peers, and the ability for a remote clinician to call-in over live video to help provide additional insights into cases where the local healthcare provider expertise may be limited.

REPRODUCIBLE: the EVA System helps ensure that repeating the same test will give the same result by making the records from examinations available securely online for immediate review, so consensus may be agreed upon by the healthcare team – without requiring all of the members of that team to be present in the same clinic.

INEXPENSIVE: the EVA System is affordable to the health system in terms of both financial and human resources, and made available at a fraction of the current cost of colposcopes. Its integrated digital services make collaboration and supervision possible that would have previously required travel and logistics expenses.

RELATIVELY EASY: the EVA System was built with the familiar Android smartphone interface, so healthcare providers familiar with the use of mobile phones will find it uncomplicated to perform and to provide follow-up care for women with abnormal results.

ACCEPTABLE: as an FDA-cleared device and set of software, meeting all of the security and privacy regulations required by some of the largest hospital systems across the US, the EVA System has been well-tolerated by both the patient and the provider in a variety of settings.

SAFE: the EVA System test procedure and management of screen-positive subjects minimizes false negatives by ensuring the data used to make diagnostic decisions is available to healthcare providers across the continuum of care, and that supervisors and peers can catch false positives without having to physically examine the patient. By enabling the capture of patient contact information even in clinics without existing electronic medical records systems – or when patients move across networks and their electronic medical records are not available – EVA can securely and anonymously educate and encourage women to return for care, to ensure that their disease is addressed early enough to treat.

AVAILABLE: as a portable, affordable, and holistic solution for cervical cancer programs, the EVA System can be made accessible to the entire target population at a minimal cost, enabling healthcare providers to focus the majority of their resources on providing direct care to patients instead of purchasing and maintaining expensive equipment.

Having a technology that holds these WHO values at its core is crucial to ensure the healthcare infrastructure to address cervical cancer is made available to women across economically disadvantaged areas and within minority populations. Yet it is only the beginning. As remarked above, a significant additional hurdle in ensuring that every woman not only has access but is effectively addressed by cervical cancer programs, is an adjustment in operations that tackles loss-to-follow-up. Often lacking regular physical presence of expertise, and comprehensive electronic medical records, cervical cancer programs for disadvantaged women may inadvertently exacerbate loss-to-follow-up due to the limitation of resources they have available to diagnose and treat the woman when she is in the clinical environment and effectively deliver that woman to the next level of care. Since these disadvantaged women are often limited in their ability to travel and take time off work, any additional time or distance requirements to complete their diagnosis or treatment will significantly increase the risk a woman will be lost to follow-up, and that her disease, if present, will develop into cervical cancer.

It is because of this that the EVA System has built a secure online system around remote support and supervision to ensure that decisions can be made by local medical providers in the room while the woman is at the point-of-care. Recognizing that the visualization of the patient is only a component of a continuum of care, EVA's online tools have been built to help healthcare providers reduce referrals and recalls as much as possible, and to work as close to a Single Visit Approach as available to that clinic at that time.

Breaking the barriers to care, together

Of all the health disparities that exist, a lack of screening for preventable cancers is perhaps the most tragic. Breaking the barriers to cervical cancer screenings requires the ongoing determination of healthcare organizations, non-profits, state and federal governments. The high incidence and mortality rates demand impactful policy and aggressive public outreach. It requires a comprehensive system-wide approach to screening. Individual healthcare systems can further this advocacy by picking up the mantle and employing innovative technologies that directly reach people in need, matching the needs of underserved populations and closing the gaps in care caused by healthcare disparities.

Assistive technologies such as the EVA System can help providers from inner cities to the most remote rural areas of the country perform expert-level screenings for the early detection and treatment of cervical cancer. It delivers benefits for providers, policy makers, healthcare systems and patients. It can expand services, improve care and potentially decrease the incidence and mortality of cervical cancer.

We aspire for a day where healthcare providers capitalize on technology to streamline cervical cancer screening and treatment, so that every American woman has the same access to quality care. We are committed to building the tools to help health providers improve access to care and believe innovative, disruptive technology can support the implementation of effective community screening programs, which can reach populations in need and rid disparities that are unnecessarily costing thousands of lives.

About MobileODT

MobileODT is reinventing visual diagnostics at the point-of-care with the EVA (Enhanced Visual Assessment) System for colposcopy. The portable and affordable EVA System enables clinicians to provide on-the-spot assessment via smart image capture and patient management tools along with secure online consultation features for expert review. Used in over 27 countries for cervical cancer screenings, EVA is enabling more women's health workers to save more lives in the US and around the world.

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