Cervical Cancer Screening in Developing Countries Position Statement

Dr. Eric Suba
Dear Ann,

Thank you for your kindness and encouragement. The intent of the proposed statement is to combine two important educational messages:

1. Screening programs for cervical neoplasia should be established before vaccination programs for HPV.

For one reason:
-- It will not be known for many years whether HPV vaccination will work or, in the worst case, do harm. (1)

2. All screening programs for cervical neoplasia will require at least some cytology.

For two reasons:
-- Women with positive screening tests for cancer understandably desire to know whether or not they truly have the disease. Therefore, screening programs based on visual or HPV primary screening tests will require cytology for triage of women with positive screening tests for followup confirmatory testing. 'Screen and treat' programs based on visual or HPV primary screening tests linked to immediate ablative treatment theoretically eliminate all programmatic requirements for cytology but fail to provide confirmatory testing and for that reason alone will find limited acceptance among women and among health care providers in any setting.

-- Cytology is the only primary screening test appropriate for women of all ages. Due to unacceptably high false-positive rates, HPV tests are not appropriate for women under 30 in developed countries and will not be appropriate for women over 30 in many developing-country settings due to the higher prevalence rates of HPV infection among women over 30 in many developing-country settings. (2) Due to unacceptably high false-negative rates, visual screening tests are not appropriate for postmenopausal women. (3)

All the best,
Eric

References:


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Dear Eric,

Thank you for championing cervical cancer screening on a global basis. Your efforts on behalf of cervical cancer prevention have been incredible and I am pleased that you have are going to be a contributor to the Global Health Council Meeting.

Your proposed statement on cervical cancer screening that you would like the ASC Executive Board to endorse reads: "Papanicolaou cytologic screening services (with or without liquid-based collection systems, and/or HPV testing services, and/or visual screening services) should be provided in any setting where cervical screening is appropriate but unavailable, with consideration given to HPV vaccination after, rather than before, full coverage of target demographic groups by screening services has been achieved." I would like to clarify that the intent of the proposed statement is that Papanicolaou test cervical cancer screening should be performed prior to the introduction of vaccination services in areas where no cervical cancer screening exists. In other words, establish cancer screening programs prior to vaccination programs. Please set me straight if I have misinterpreted the proposed statement.

We will consider your proposed statement at our upcoming Executive Board meeting this spring. Let me know if there is further background or information to present with this statement. Thank you for all your work on behalf of the women of the world. I hope your upcoming Global Health Council meeting is a success.

Regards,

Ann T. Moriarty, MD

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To the ASC Executive Board:

The position statement noted below will be discussed at a 2-hour policy roundtable during the annual Global Health Council Meeting in Washington DC.

Included in the discussion will be mention of a successful cervical cancer prevention effort in Vietnam. To my knowledge, this may be the first report in the United States of cervical screening being associated with a decisive impact on health outcomes in any developing country.

For the reasons outlined in the abstract provided below, I request that the Executive Board consider modifying the ASC position statement on cervical cancer prevention in developing countries to state:

“Papanicolaou cytologic screening services (with or without liquid-based collection systems, and/or HPV testing services, and/or visual screening services) should be provided in any setting where cervical screening is appropriate but unavailable, with consideration given to HPV vaccination after, rather than before, full coverage of target demographic groups by screening services has been achieved.”

I will be happy to answer any questions you may have.

Sincerely yours,

Eric Suba

Patient-Centered Policy for New Cervical Cancer Prevention Technologies

Eric J. Suba, MD, Department of Pathology, Kaiser Permanente Medical Center, 350 Saint Joseph’s Avenue, San Francisco, CA 94115 Stephen S. Raab, MD, Department of Pathology, University of Colorado Health Sciences Center, 12605 East 16th Avenue, Aurora, CO 80045; Viet/American Cervical Cancer Prevention Project, 2295 Vallejo Street, San Francisco, CA 94123

Background

Cervical cancer is the leading cause of cancer-related death among women in developing countries. After documenting in 1996 that the Vietnam War had contributed to the problem of cervical cancer in Vietnam,(1) we participated in a volunteer grassroots effort to establish a nationwide cervical cancer prevention program in Vietnam(2) and performed root cause analysis of real-world obstacles to successful cervical cancer prevention in developing countries.(3)

Policy Overview and Relevant Issues

Currently there is no consensus policy regarding cervical cancer prevention technologies for developing countries. The debate over appropriate policies for cervical cancer prevention in developing countries may be considered part of a larger debate, articulated previously by President Jimmy Carter,(4) over whether the global health community has become enamored with the promise of new technologies at the expense of delivering available preventives today.

Current Efforts and Implications

Papanicolaou cytologic screening is feasible anywhere cervical screening is appropriate.(3) Cytology is the only primary screening test appropriate for women in all age groups and will be a required confirmatory testing component for HPV or visual primary screening tests.(3) The introduction of cytologic screening services in southern Vietnam was associated with a reduction in cervical cancer incidence rates from 29.2/100,000 in 1998 to 16.5/100,000 in 2004 (Figure 1). Critical real-world obstacles to successful cervical cancer prevention in developing countries involve people far more than technology and present themselves as puzzles with the structure of the “prisoner’s dilemma” in game theory: cervical cancer prevention programs fall when participants uniformly pursue rational self-interest, but succeed when at least some participants act in manners at least partially contrary to rational self-interest.(3) Developing countries should allocate their limited resources toward screening, rather than HPV vaccination, until the possibility has been excluded that HPV vaccines may be ineffective for cervical cancer prevention.(5) Creating access to HPV vaccines for some will reduce access to screening for others which, from a public health perspective, is not a prudent compromise.

Conclusions

Based on lessons learned in Vietnam we propose a patient-centered global consensus policy: Papanicolaou cytologic screening services (with or without liquid-based collection systems, and/or HPV testing services, and/or visual screening services) should be provided without further delay in any setting where cervical screening is appropriate but unavailable, with consideration given to HPV vaccination after, rather than before, full coverage of target demographic groups by screening services has been achieved. Alternative policies would delay the implementation of cervical screening services in some settings pending the unlikely realization of cytology-free preventive approaches with decisive advantages over approaches incorporating some cytology, and are not consistent with the patient-centered public health goal of improving health outcomes as rapidly as possible among as many women as possible.

Figure 1. Cervical cancer incidence rates in Vietnam, 1996-2004. (6,7,8,9) Population-based Pap screening was introduced to Ho Chi Minh City during 1998 but has not yet been introduced to Hanoi.
Dear Dr. Mody:

As followup to comments you recently posted on the ASC listserv, I formally request that the ASC Executive Board update its intellectual support for Papanicolaou cytologic screening in developing countries by endorsing the following statement:

"Papanicolaou cytologic screening should be implemented in settings where screening for cervical neoplasia is appropriate (and where no screening services exist) before, rather than after, locality-specific evaluations of less-traditional preventive methods have been completed."

Attached to this email are copies of statements previously endorsed by the ASC Executive Board.

An earlier statement, contained in Dr. Celeste Powers’ letter dated January 2005, reads:

"Papanicolaou cytologic screening should be implemented in settings where screening for cervical neoplasia is appropriate and where no screening services currently exist."

The statement currently endorsed by the ASC Executive Board, contained in Dr. Marshall Austin’s letter dated April 2005, reads:

"The Papanicolaou cervical cancer screening test represents the most significant contribution to the reduction of suffering from human cancer. As the leading national organization promoting and advocating for cytopathology, the American Society of Cytopathology endorses world wide cervical cancer screening for all women, using the conventional Papanicolaou test, or other technologies (as appropriate for the economy, culture, and infrastructure of the underserved region) that have been proven to effectively detect and prevent cervical cancer."

For the reasons outlined in a publication also attached to this email the ASC statement of January 2005 appears to be more scientifically accurate than the ASC statement of April 2005.

I therefore entreat the Executive Board to endorse the statement proposed in this communication, which more closely resembles the ASC statement of January 2005 than the statement currently endorsed by the ASC.

Otherwise, I entreat the Executive Board to re-adopt the statement originally adopted in January 2005.

I will be happy to answer any questions you may have.

Sincerely yours,

Eric Suba

*Suba EJ, Donnelly AD, Furia LM, Huynh ML, Raab SS; Viet-American Cervical Cancer Prevention Project. Cervical cancer prevention for all the world’s women: genuine promise resides in
January 12, 2005

Eric J. Suba, M.D.
Kaiser Permanente Medical Center
1200 El Camino Real
South San Francisco, CA 94080

Dear Dr. Suba

The ASC Executive Board met on November 16 and re-endorsing the intellectual concept of pap screening in d

The ASC Executive Board endorses the following state

“Papinalacou cytologic screening should be impleme

dd screening for cervical neoplasia is appropriate and whe

The Executive Board and I wish you the best in your re

Please let me know if you have any questions.

Sincerely,

Celeste N. Powers, M.D., Ph.D.
April 25, 2005

Eric J. Suba, M.D.
Kaiser Permanente Medical Center
1200 El Camino Real
South San Francisco, CA 94080

Dear Dr. Suba:

In November, the ASC Executive Board reviewed your intellectual concept of pap screening in developing cou Board has developed an official position statement on 1 countries,

On April 17, 2005, the ASC Executive Board approved

“The Papanicolaou cervical cancer screening text repre contribution to the reduction of suffering from human national organization promoting an advocating for cyto Society of Cytopathology endorses world wide cervical women, using the conventional Papanicolaou test, or of appropriate for the economy, culture and infrastructure that have been proven to effectively detect and prevent

The Executive Board and I wish you the best in your re population.

Please let me know if you have any questions.
Cervical Cancer Prevention for All the World’s Women: Genuine Promise Resides in Skilled Quality Management Rather Than Novel Screening Approaches


The debate over the best route for cervical cancer prevention in developing countries may be considered part of a larger debate over whether the global health community has become enamored with the promise of new approaches at the expense of delivering available preventives today. Pap screening, which is feasible anywhere cervical screening is appropriate, is the only intervention currently available for the prevention of cervical cancer in developing countries, and the Pap test will be an essential component of future novel preventive approaches. Cervical cancer vaccination, the long-term effectiveness of which is uncertain, will not eliminate screening requirements and is currently not affordable in developing countries. Root cause analyses, which may appropriately inform the best routes for improving health in developing countries, document that failures of cervical cancer prevention efforts are not attributable to factors specific to the Pap test but to lapses in programmatic quality management to which all screening tests are vulnerable. The genuine promise of cervical cancer prevention for all the world’s women therefore resides in skilled quality management rather than novel screening approaches. We propose a global consensus policy by which Pap screening services will be provided in any setting where cervical screening is appropriate but unavailable, with consideration given to novel preventive approaches as they mature. Opportunity costs, borne by the underserved, are associated with prioritizing research on new approaches in any setting where established preventives are feasible but unavailable. Diagn. Cytopathol. 2007;35:187–191. © 2007 Wiley-Liss, Inc.

Key Words: cervical cancer prevention; developing countries; quality management; Bill and Melinda Gates Foundation

We applaud the dedication that Dr. Wright and the Alliance for Cervical Cancer Prevention (ACCP) have applied to research on novel screening approaches for cervical cancer prevention in developing countries, and we appreciate the opportunity to address concerns stimulated by a previous publication on behalf of the Viet/American Cervical Cancer Prevention Project (VACCPP). The hope of scientific and technological breakthroughs in medicine offers opportunities and promise that are intuitively appealing. However, it is prudent to balance this hope against the observations that most of the world’s premature deaths, including those related to cervical cancer, can be prevented with available interventions, and that what is not clear is how to make these interventions more widely available to the people who need them. The current discussion may be considered part of a larger debate, articulated bluntly by President Jimmy Carter, over whether the Bill and Melinda Gates Foundation has become enamored with the promise of science and new technologies at the expense of delivering available preventives today. Although ideological commitments to novel technologies as the best route for improving health outcomes in developing countries have been characterized by others as being potentially harmful, it is plausible that ideological commitments to other categories of public health interventions may also be potentially harmful. Root cause analyses, rather than ideological commitments, may therefore be employed to inform the best routes for improving health outcomes in developing countries.
countries, for the same reasons that compulsive diagnostic workups are employed to inform the best routes for improving health outcomes among individual patients. Given the commitment of the Bill and Melinda Gates Foundation to a relatively small staff to monitor the impact of programs it funds, academic debate will facilitate a deeper understanding of the root causes underlying global health challenges that will enhance the humanitarian impact of the unprecedented, transformative generosity of the Gates and Buffett families.

**The Promise and Challenges of Skilled Quality Management and Novel Screening Approaches**

Pap screening, when fully successful, reduces cervical cancer rates by 60–90% within 3 yr of introduction to populations that have not previously been screened; these reductions in incidence and mortality are consistent and dramatic across populations. Past and current failures of cervical cancer prevention efforts in both developed and developing countries are not attributable to factors specific to the Pap test, but to lapses in programmatic quality management and failures in political will to which all screening tests are vulnerable. Root cause analysis documents that real-world obstacles to successful cervical cancer prevention in developing countries involve people far more than technology, and that novel screening approaches may reinforce obstacles to success. Dr. William Foege, senior medical advisor to the Bill and Melinda Gates Foundation, has suggested that a lack of management skills appears to be the single most important barrier to improving health throughout the world. Because technological improvements to the Pap test are unlikely to be associated with improved long-term clinical outcomes, we suggest that the genuine promise for cervical cancer prevention for all the world’s women resides in skilled quality management, the goal of which is to confirm that women in targeted demographic groups are screened and receive appropriate follow-up, rather than in novel screening approaches.

It is encouraging that Dr. Wright et al. do not challenge the observation that Pap screening is feasible anywhere that cervical screening is appropriate. Because there appears to be a genuine lack of support for cervical cancer prevention efforts within the political structures of many developing countries, incorrect beliefs that Pap screening is not feasible in low-resource settings where cervical screening is appropriate may empower apologists for the status quo. We have advocated making Pap screening services available without further delay, anywhere cervical screening is appropriate but unavailable, not because the Pap test will forever remain the most effective preventive option in all settings but because, in any setting, it is both prudent and strategically necessary to implement Pap screening before rather than after completing research on either human papillomavirus (HPV) vaccines or what may become an endless series of novel screening approaches. VACCPP maintains that research on novel screening approaches in certain low-resource settings may be appropriate, provided that such research is conducted subordinate to, rather than in place of, the development of Pap screening services in the same settings. Opportunity costs, borne by the underserved, are associated with prioritizing research on novel health interventions in any setting where established interventions are feasible but unavailable. That research on novel health technologies in developing countries may be more compatible with market forces than with public health goals adds additional complexity to the situation. For example, the partnership between ACCP’s coordinating organization and Digene Corporation, which manufactures and markets HPV tests, presents potential conflicts of interest.

It might be acknowledged that, despite a substantial investment of time and resources, the promise for the humanitarian impact of novel screening approaches has not yet been realized. Although Dr. Wright et al. understandably believe that there are multiple ways to prevent cervical cancer, ranging from HPV vaccines to visual and HPV screening strategies, Pap screening remains the only preventive option currently available to public health authorities responsible for cervical cancer control in developing countries. Prophylactic HPV vaccination, the long-term effectiveness of which is uncertain, will not protect women already infected by HPV. Moreover, HPV vaccination may reduce but will not eliminate requirements for screening, and is currently not affordable in low-resource settings. HPV tests, currently priced at $20–$30, are also not affordable for use in low-resource settings. Research involving HPV tests collected from women in developing countries but shipped to American reference laboratories for analysis therefore raises justifiable concerns of commercial exploitation, particularly when data generated in this manner are used to market HPV tests in the United States. When analyzed in developing-country laboratories, HPV tests present difficulties with reproducibility and accuracy comparable to those of Pap tests. Although the quality of visual testing degrades more rapidly than either cytologic or HPV testing, quality management procedures, including uniform criteria for reporting visual test results, have not been established for visual primary screening methods, which are understandably recommended for use only in pilot projects and are not appropriate for postmenopausal women in any setting. It is therefore uncertain whether novel screening approaches will eventually provide any decisive advantages over currently available cytologic screening methods.

It is difficult to reconcile these observations with the central founding assumption of ACCP that noncytologic screening methods, rather than Pap screening, constitute the most likely solution to the problem of cervical cancer.
in developing countries. ACCP’s founding assumption, which might more appropriately be considered a hypothesis, was adopted without benefit of root cause analysis or academic debate. The assumption presents a significant source of potential bias against cytology, and undermines efforts by progressive public health leaders to develop essential Pap screening services in developing countries. ACCP was founded in 1999 with a gift of $50 million from the Bill and Melinda Gates Foundation. That ACCP’s founding assumption may constitute a service differentiation strategy used to successfully compete in a donative market environment adds additional complexity to the situation, as it becomes difficult to challenge founding assumptions under such circumstances.

Cervical screening tests are appropriately characterized as complementary, rather than competitive. Visual and HPV tests are essential triage components of cytology-based screening programs. Cytology will be an essential triage component of future single-visit or multiple-visit programs based either on HPV or visual primary screening tests, because of the low specificity of the noncytologic tests. The issue of which combination of screening tests will be most appropriate for any particular setting will be addressed by quality management methods utilizing real-world locality-specific laboratory data. In settings where single-visit screening is desired, combined-modality ‘screen and treat’ would appear to offer significant advantages over purely cytologic, visual, or HPV ‘screen and treat.’ Pap tests collected from women prior to visual tests or together with HPV tests could be analyzed immediately only for women with positive visual or HPV test results. Women with Pap tests showing high-risk lesions would receive immediate excisional, rather than ablative, treatment. Pap tests from women with negative visual exams or negative HPV tests would be processed routinely and every attempt would be made to recontact women with abnormal Pap test results. Combined-modality ‘screen and treat’ would greatly reduce quantitative requirements for mobile cytology laboratories and, unlike purely visual ‘screen and treat,’ would produce physical evidence on which to base meaningful program audits. The existence, let alone effectiveness, of purely visual ‘screen and treat’ programs will not be verifiable outside of research settings, with problematic implications for program management and sustainability.

Combined-modality ‘screen and treat’ would not require administering ablative treatment to women before excluding the possibility of invasive carcinoma, which is a shortcoming of purely visual and HPV ‘screen and treat’ strategies that may substantially limit their desirability in real-world settings. ACCP studies of purely visual and HPV ‘screen and treat’ have included careful follow-up testing, including cervical biopsies, to evaluate screen-positive women for the possibility of invasive neoplasia. This level of follow-up care will not be available in real-world settings, where screen-positive women will be informed that they have a positive screening test for cervical cancer, that cryosurgery will probably render it impossible for anyone to determine whether cancer is present, and, if cancer is in fact present, that cryosurgery will be ineffective. Individuals with positive screening tests for cancer desire to know whether or not they truly have the disease, and it is puzzling that Dr. Wright et al. do not acknowledge the psychological harm that may be endangered by absolutely ‘cytology-free’ screening strategies that fail to provide desired confirmatory testing. It is disquieting that ACCP and the American College of Obstetrics and Gynecology have endorsed as ‘safe and effective’ absolutely cytology-free screening strategies that would necessitate regular acts of uncontested medical malpractice were they to be implemented in the United States.

No-screening arms would not be considered appropriate in randomized trials of cervical screening performed in the United States, and no-screening arms were not included in ACCP randomized trials of cervical screening performed in South Africa. Dr. Wright et al. cite the approval of ethical review boards as justification for the inclusion of no-screening arms in ACCP randomized trials currently being performed in India. However, because the shortcomings of ethical review boards in protecting the safety of human research participants have been adequately documented, the responsibility for the design and conduct of any study involving human participants appropriately rests with the study investigators themselves.

ACCP has documented the expected finding of increased detection rates of early-stage curable cancers among women in the screening arms of the ongoing Indian trials. Absent any more compelling justification than that offered by Dr. Wright et al., women currently enrolled in the no-screening arms of ongoing ACCP trials should be reassigned to screening arms in order to avoid needless risk of harm and to prevent future disaffection of underserved groups.

Monetary Costs of Cervical Screening: Academic and Sociopolitical Considerations

Dr. Wright et al. correctly indicate that the cost-effectiveness study we performed for Pap screening in Vietnam did not include costs for curative or palliative treatment. We did not include these costs because they are incurred in any setting whether or not cervical screening programs exist. The decision not to include costs for curative treatment in our analysis constituted a bias against the cost-effectiveness of Pap screening in Vietnam, because Pap screening in a variety of settings has been associated with reduced costs for curative treatment in screened populations relative to unscreened populations. There is no consensus regarding all items that should be included in
cost-effectiveness studies. Costs for training, quality control activities, recruitment of women for participation in screening programs, and increasing marginal costs to provide services in remote areas will impact the cost-effectiveness of cervical cancer prevention irrespective of the screening test(s) actually used. However, although the inclusion or exclusion of these items will impact total program costs and cost-effectiveness, their inclusion or exclusion has a more limited impact on the unit cost of screening tests.

A more critical distinction between VACCPP and ACCP cost-effectiveness studies resides in VACCPP’s use of time-motion studies, rather than local fee schedules, to determine the unit cost of screening tests. All health workers, including cytologists, have incentives to increase net reimbursement. We find that these incentives may produce inflated prices for Pap tests that may be reflected in local fee schedules. In 1996, VACCPP was presented with local fee schedules for Pap tests in Vietnam that, from the perspective of VACCPP participants with prior experience in medical laboratory cost analysis, lacked face validity. Successful cervical cancer prevention programs require negotiated solutions to the ‘prisoner’s dilemma’ of game theory, as programmatic failures occur when participants uniformly pursue rational self-interest, while programmatic successes occur when at least some participants act in manners partly contrary to rational self-interest. The decision by Vietnamese physicians to utilize time-motion studies, rather than local fee schedules, to determine the unit cost of Pap tests in Vietnam constitutes one example of a negotiated solution to the prisoner’s dilemma. The use of time motion studies in conjunction with a systems approach in Vietnam allowed groups of health workers prone to competition to view themselves in relation to other categories of workers, to their own shares of program costs and responsibilities, and to the programmatic goal of improving health outcomes among women. That cervical cancer in Vietnam is, in part, a legacy of the Vietnam War added additional complexity to the negotiations as publication of data linking war to disease was delayed for 8 yr in an attempt to ease the process of reconciliation by offering what most would acknowledge to be a remedy in advance of what some will perceive to be an accusation. By acting in manners partly contrary to rational self-interest, Vietnamese physicians enabled de novo establishment of Pap screening services in Vietnam by dispelling paradoxical yet commercially useful beliefs that Pap tests in developing countries such as Vietnam are expensive. ACCP’s responses to decisions made in Vietnam are not entirely consistent with a characterization that ACCP works to strengthen cytology services in settings where they are appropriate.

Time-motion studies render transparent the sociopolitically delicate connection between salaries and unit costs of labor-intensive items such as screening tests. A 2002 ACCP cost-effectiveness study used time-motion studies, based on a local annual wage rate of $2,000 for nurses, to determine that the unit cost of a visual screening test in Thailand is $0.92. The same ACCP study, using local fee schedules, determined that the unit cost of a Pap test in Thailand is $7.50. We have suggested that a unit cost of $7.50 for a Pap test in Thailand lacks face validity because it mathematically implies a local annual wage rate of $75,000 for cytologists. A 2001 ACCP study determined that the unit cost of a Pap test in South Africa is $10.00, implying a local annual wage rate of $100,000 for cytologists, which may be valid in light of South Africa’s unusual socioeconomic structure. ACCP studies have uniformly used local fee schedules, rather than time-motion studies, to determine unit costs for Pap tests in developing countries. We encourage ACCP to adopt a single standard, and to use time motion studies to determine the unit costs of visual, HPV, and cytologic tests in future cost-effectiveness studies of cervical screening and HPV vaccination. Overestimates of unit costs for Pap tests in any setting spuriously enhance the apparent desirability of both noncytologic screening methods and HPV vaccines.

Conclusion: An Appeal for Patient-Centered Consensus

We entreat Dr. Wright et al. to endorse a global consensus policy by which Pap screening programs will be established without delay and developed in any setting where cervical screening is appropriate but unavailable, with consideration given to vaccines and to novel screening approaches as research on novel preventive approaches is completed. The alternative policy, which would be to delay the implementation of Pap screening services in some settings pending the unlikely realization of absolutely cytology-free preventive approaches with decisive advantages over approaches incorporating some cytology, is enamored with the promise of new approaches at the expense of delivering available preventives today and is not an appropriate course for improving health outcomes in developing countries. Because the Pap test will be an essential triage component of ‘screen and treat’ or multiple-visit screening programs based on HPV or visual testing, it is in the interests of those promoting HPV and visual primary screening methods to support the establishment of Pap screening services in any setting. By achieving consensus on a patient-centered policy by which to develop cervical cancer prevention programs among underserved communities, we will achieve a milestone in genuinely assuring cervical cancer prevention for all the world’s women.
References


