Washington, D.C., USA, 29 September-3 October 2008

Provisional Agenda Item 4.2

CD48/6 (Eng.) 7 August 2008 ORIGINAL: ENGLISH

REGIONAL STRATEGY AND PLAN OF ACTION FOR CERVICAL CANCER PREVENTION AND CONTROL

- 1. The Regional Strategy and Plan of Action for Cervical Cancer Prevention and Control aims to address the high burden of disease and the limited impact of current screening programs in low resource settings. This paper illustrates the cost-effective approaches available for comprehensive cervical cancer prevention and control, including a complete package of services: health education, screening, diagnosis and treatment; and depending on affordability, sustainability and country preparedness, HPV vaccination. An integrated approach for cervical cancer prevention is required across existing programs on adolescent health, sexual and reproductive health, immunization and cervical cancer control. The priority is to fortify programs and evaluate whether and how new technologies and methods, such as new screening techniques, behavioral, educational and preventive programs and HPV vaccines can be used to improve the effectiveness of current programs.
- 2. There are an estimated 27,500 deaths in the Americas from cervical cancer per year, representing an economic loss of approximately US\$ 3.3 billion. It is a disease of inequities which disproportionately affects poor women. Cervical cancer mortality rates are seven times greater in Latin America and the Caribbean (LAC) than in North America. As illustrated in Annex A, Bolivia, Haiti, and Paraguay are among the countries with the highest cervical cancer rates.
- 3. Previous mandates on this topic include: the World Health Assembly resolution on *Cancer Prevention and Control* (WHA58.22), which urges Member States to give priority to cervical cancer and emphasizes that the control of cervical cancer will contribute to the attainment of international development goals and targets related to sexual and reproductive health; the PAHO 47th Directing Council Resolution on the *Regional Strategy and Plan of Action on an Integrated Approach to the Prevention and Control of Chronic Diseases, including Diet, Physical Activity, and Health* (CD47.R9)

which provides a framework for cancer control; the World Health Assembly resolutions on a Global Strategy for Reproductive Health (WHA57.12) and on the Prevention and Control of Sexually Transmitted Infections (WHA59.19) which recognize the burden of human papillomaviruses (HPV) and provide frameworks to address HPV, cervical cancer and other gynecological morbidities.

- 4. Cervical cancer is caused by persistent infection with high risk types of human papillomaviruses (HPV), a sexually transmitted infection. HPV types 16 and 18 are the most common types of HPV found in cervical cancer and together account for about 70% of the cervical cancer cases in the Americas. Co-factors contributing to the development of cervical cancer include: young age at sexual initiation, increasing number of sexual partners, coinfection with sexually transmitted infections (Chlamydia or Herpes simplex virus), low socioeconomic status, immune suppression, tobacco use, high parity, and long-term use of oral contraceptives. Women from vulnerable and disadvantaged groups are at higher risk of cervical cancer, including indigenous women, women residing in rural areas, and sex workers.
- 5. HPV is a common infection and most people aquire the infection at some time in their lives. Peak incidence of HPV infection is usually in the adolescent period, soon after the onset of sexual activity, and the majority of HPV infections clear up spontaneously within two years. In the Americas, the estimated prevalence of HPV is 15.6% among women in the general population. Only a small portion of women infected with high risk HPV types develop precancerous cervical lesions that can progress to cancer. The natural history of the disease yields opportunities for prevention throughout the lifecycle. In adolescents, health information and education about healthy sexual behaviors, including delayed sexual initiation, reduced number of sexual partners and condom use, as well as cervical cancer prevention is critical. In adult women, screening for precancerous cervical lesions, followed by treatment of the lesions, has been the most effective way to halt the progression to invasive cancer.
- 6. PAHO has been working in partnership with the Alliance for Cervical Cancer Prevention (ACCP) since 1999, and with a global coalition, Cervical Cancer Action, since 2007 to advocate for and strengthen cervical cancer prevention in low resource settings. Demonstration projects were established using alternative screening approaches in El Salvador, Peru, and Suriname, which provided evidence on the effectiveness of these alternative approaches. Technical assistance was also provided to over 10 countries in the Region to strengthen their existing cytology screening programs, and a subregional program was established through CAREC which helped to improve the quality of and access to screening programs. With respect to cancer treatment, PAHO has a longstanding history of working in the Americas to improve radiotherapy services and strengthen cancer treatment capacity.

- 7. In the Americas, cytology screening (Pap test) has been in place for over 30 years, either through opportunistic screening or through organized screening programs. Yet countries in LAC have not experienced the same declines in mortality rates as those observed in North America. A few countries in the Region, such as Chile, Costa Rica, and Mexico, have observed reductions in cervical cancer rates, which have been attributed to improvements in the coverage, organization and quality of their screening programs. It has proven to be difficult to mount and sustain high quality screening programs in low resource settings.
- 8. The failures of screening programs in LAC can be characterized not only by factors related to the screening technology, but also health service access, and community perspectives. Gender considerations are particularly important, as women's sociocultural, economic, religious, educational status and ethnicity influence their access to information, demand, and utilization of cervical cancer prevention services. Other key factors include:
- low awareness among women and men of the importance of screening;
- limited access to diagnostic services and treatment for pre-cancer;
- inadequate capacity for surgical and radiotherapy treatment for women detected with invasive cancer.
- 9. Alternative screening technologies: Several cervical cancer screening technologies have been developed, partly as a response to the challenges of cytology screening. These screening technologies include visual inspection with acetic acid (VIA) and HPV DNA test which have demonstrated test performance equal to or better than the Pap test¹. The immediate results of VIA testing enables a single visit approach linking screening with pre-cancer treatment and this approach has shown to significantly reduce mortality rates. Several countries in the Region, such as Bolivia, Colombia, Costa Rica, Guatemala, Mexico, and Peru, are currently using alternative screening approaches. It is, therefore possible that an expansion of different screening approaches can be adopted in countries, depending on health system access, availability of laboratory services, and human and financial resources.
- 10. *HPV vaccines:* The currently available HPV vaccines include a quadrivalent vaccine containing genotypes 6, 11, 16 and 18, and a bivalent vaccine containing genotypes 16 and 18. In clinical trials, both vaccines have demonstrated safety, high immunogenicity and over 90% effectiveness in preventing infection and precancerous lesions from HPV types 16 and 18 when given to adolescent females prior to sexual

¹ Technical note: The test sensitivity of HPVDNA test (Hybrid Capture II) is 66%-99%; VIA test sensitivity is 67%-79%; and the Pap test sensitivity is 47%-62%. The specificity of the Pap test is superior to the other screening tests.

debut. Both vaccines have a private sector price of approximately \$360 for the required three dose regimen. The vaccines have been licensed for use in females aged 9-26 years, based on data from efficacy and immunogenicity trials. The vaccines have shown a duration of protection of at least 6 years (this being the longest published follow-up period) and maybe much longer. Further follow-up studies of at least 14 years are planned to evaluate the duration of protection. Additionally, clinical data is still being gathered on the HPV vaccine efficacy in boys.

- 11. HPV vaccines are not a substitute for health education and screening. A comprehensive cervical cancer program will need to include all components of health education, screening, diagnosis, treatment and palliative care, even after HPV vaccines can be introduced based on affordability, sustainability and all necessary preparations for new vaccine introduction (e.g. train providers, reinforce the cold chain, strengthen laboratories). It is particularly important that programs continue to include information for adolescents about preventing HPV and other sexually transmitted infections and healthy sexual behavior, as well as screening for women to detect precancerous lesions caused by HPV types not included in the vaccines and to protect those who have not been vaccinated.
- 12. In recognition of the availability of HPV vaccines, Resolution CD47.R10 of the PAHO Directing Council, *Regional Strategy for Sustaining National Immunization Programs in the Americas*, urged Member States to expand the legal and fiscal space and identify new revenue sources to sustainably finance the introduction of new vaccines, including HPV vaccines.
- 13. Twenty-eight countries in the Americas have licensed the HPV vaccine and Canada and the United States are currently implementing the vaccine in immunization programs. Costa Rica, Mexico, and Peru are testing the HPV vaccine in demonstration projects or research trials. The affordability of the HPV vaccines for public health programs remains a challenge, in addition to the preparatory requirements to introduce the vaccine as part of a comprehensive cervical cancer program. The current HPV vaccines are in the process of WHO pre-qualification for new vaccines, which would enable purchases in developing countries via United Nations agencies. In the meantime, PAHO has developed a framework for country-based policy decisions on new vaccine introduction through its ProVac Initiative.
- 14. The purpose of the Regional Strategy is to improve country capacity for the sustained implementation of comprehensive cervical cancer prevention and control programs, with the goal of reducing incidence and mortality. The components of the Strategy are as follows: health information and education; screening of asymptomatic women and pre-cancer treatment; invasive cervical cancer treatment and palliative care; and evidence-based decision-making on whether and how to introduce the HPV vaccines.

- 15. This proposal calls upon the Pan American Sanitary Bureau and PAHO Member States to collaborate, and in partnership with other organizations including women's groups, to develop and/or strengthen cervical cancer prevention and control programs according to the needs and situation of the country. The strategy calls for integrating cervical cancer into existing primary health care programs, including sexual and reproductive health and adolescent health programs. The following seven point plan of action is proposed, with the immediate priority being to strengthen current programs and consider the introduction of new technologies and approaches to improve their effectiveness.
- (a) Conduct a situation assessment: In the absence of current strategic information, collect information on sexual health; assess the current investments and coverage, follow-up and quality of the screening program; assess the HPV, cervical precancer and cancer burden in the country; and examine the adolescent and community perspectives, beliefs and needs related to cervical cancer prevention and control. This information would help inform decisions on whether and how to modify cervical cancer policies and practices, and also serve as a baseline for monitoring program impact.
- (b) Intensify information, education and counseling: Increase awareness about cervical cancer and HPV infection prevention and promote healthy sexual behavior among adolescent populations, women and men, and health professionals; and engage communities in prevention services, focusing on women from disadvantaged and vulnerable groups including women residing in rural areas, indigenous women, and sex workers. This involves empowering women and informing people on cervical cancer, its causes and prevention methods; promoting screening; increasing awareness of signs and symptoms; and reducing fear, embarrassment and stigma. Health education is most effective if provided in community settings, with the support and involvement of families, community leaders, youth groups, women's advocacy and support groups, the nongovernmental sector, and the media.
- (c) Fortify screening and pre-cancer treatment programs: In settings with sufficient resources to sustain quality Pap test screening and to guarantee timely and appropriate follow up for women screened positive, strengthen screening programs by: (1) improving the quality of screening tests, and consider introducing HPV DNA testing; (2) increase the screening coverage of women in the at-risk age group (>30 years); and (3) increase the proportion of timely and appropriate follow-up care for women with abnormal screening test results.

In settings where resources are not sufficient to sustain quality Pap test screening, and where there are high rates of women who do not have access to timely and

appropriate follow-up care, consider incorporating a single visit screen and treatment approach. This involves screening women, for example with visual inspection with acetic acid (VIA) followed by immediate treatment of precancerous lesions using cryotherapy. This can be easily administered in primary health care services or through outreach campaigns.

- (d) Establish or strengthen information systems and cancer registries: Establishment of an information and surveillance system is essential for ongoing monitoring of cervical cancer program performance, including coverage, screening test results and follow up diagnosis and treatment, as well as to assess the pre-vaccine burden of HPV, pre-cancer and cervical cancer and to monitor the impact, safety and effectiveness of HPV vaccines.
- (e) Improve access and quality of cancer treatment and of palliative care: Surgery and radiation therapy are the recommended treatment modalities for invasive cervical cancer, resulting in cure rates of 85% to 90% in early stages (12-15). Investments are needed to ensure that radiation therapy and surgery are available and accessible and linked to screening programs so that women detected with cancer can be treated appropriately and cured.

Palliative care services are an integral component of cancer control programs. This involves providing symptom control and pain relief, access to opioids, palliative radiation therapy, and spiritual and psychosocial support to patients and families.

- (f) Generate evidence to facilitate decision-making regarding HPV vaccine introduction: As countries decide whether and how to introduce the vaccine into public health programs, evidence to inform their decisions will need to be gathered and several issues will need to be taken into account. PAHO, through the ProVac Initiative will work with countries to enhance the national capacity to make evidence-based vaccine introduction decisions through a five-year program of scaled up work. Issues to consider in making these policy decisions include the following:
 - the burden of HPV related disease and prevalence of specific HPV genotypes in the country, population groups most affected, and competing health priorities;
 - affordability, sustainabilty, cost effectiveness and community acceptability;
 - target population and age group for vaccination, for example whether to vaccinate females only or both girls and boys;

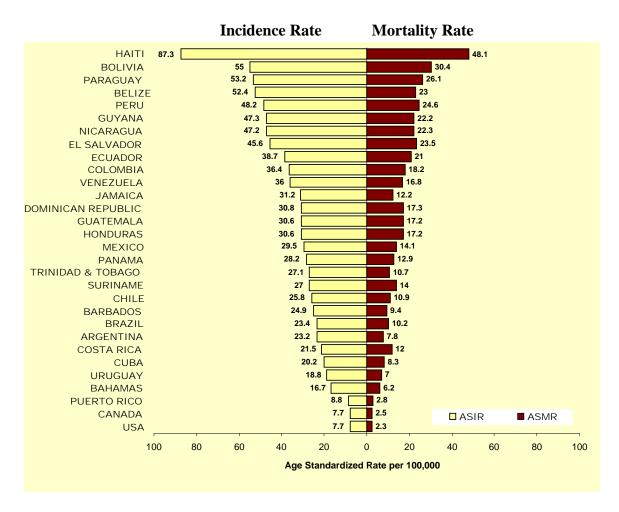
- strategy for equitable vaccine delivery, for example whether to use a school-based approach, a family-community approach, etc;
- the capacity to sustain vaccine delivery, achieve high vaccination coverage and monitor vaccine impact;
- access and quality of cervical cancer screening and treatment services.
- (g) Advocate for equitable access and affordable comprehensive cervical cancer prevention: Widespread access to the HPV vaccine will depend on having an affordable vaccine price and ensuring the necessary preparations for introducing a vaccine as part of a comprehensive cervical cancer program. Advocacy is needed to educate about HPV and cervical cancer as well as to encourage affordable HPV vaccines. Partnerships and collaboration across multidisciplinary health professional groups are needed to strengthen the primary care services, sexual and reproductive health and immunization programs, in preparation for HPV vaccine introduction and to ensure a comprehensive approach to cervical cancer.
- 16. To implement the Regional Strategy and Plan of Action, partnerships with community, national, and international organizations will be developed or strengthened, including across the UN system with agencies such as UNFPA and UNAIDS. The initial focus will be on working in those subregions and countries with the highest mortality rates from cervical cancer. Within countries, more intensified efforts will be in those areas/districts with the highest mortality rates and in populations with disadvantaged and vulnerable groups. The Secretariat will mobilize resources and undertake efforts in an interprogrammatic manner to ensure the successful and sustained implementation of the Strategy.

Action by the Directing Council

17. The Directing Council, after reviewing the information provided, is invited to consider adoption of the resolution recommended by the 142nd Session of the Executive Committee in Resolution CE142.R13 (see Annex D).

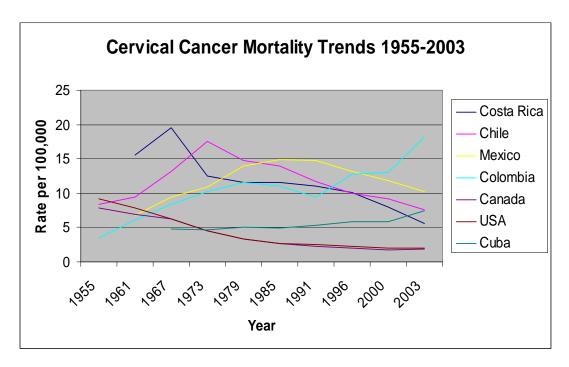
Annexes

Cervical Cancer Age Standardized Incidence and Mortality Rates: The Americas



Source: Ferlay et al, Globocan 2002, International Agency for Research on Cancer.

Cervical Cancer Mortality Trends Age Standardized Rates: Selected Countries, 1955-2003



Source: PAHO Mortality database, 2007.



PAN AMERICAN HEALTH ORGANIZATION

Pan American Sanitary Bureau, Regional Office of the

WORLD HEALTH ORGANIZATION

CD48/6 (Eng.) Annex C

ANALYTICAL FORM TO LINK AGENDA ITEM WITH ORGANIZATIONAL AREAS

1. Agenda Item: Item 4.2 **2. Agenda Title:** Regional Strategy and Plan of

Action for Cervical Cancer Prevention and Control

3. Responsible Unit: Non-communicable Diseases, Area of Health Surveillance and Disease Management

(HDM/NC)

4. Preparing Officer: Silvana Luciani

5. List of collaborating centers and national institutions linked to this Agenda item:

WHO Collaborating Centre on Cancer Policy and Communications, University of Wisconsin Regional RedPAC Reference Laboratory for Cervical Cytology, University of Chile

6. Link between Agenda item and Health Agenda of the Americas:

This agenda item is in accordance with the area of action in the Health Agenda of the Americas on reducing the risk and burden of disease. This agenda item is also linked to the area of action on diminishing health inequalities among countries and inequities within them, as cervical cancer disproportionately affects the poor and vulnerable populations.

7. Link between Agenda item and Strategic Plan 2008-2012:

This agenda item is linked to several Strategic Objectives:

SO 1 (to reduce the health, social and economic burden of communicable diseases);

SO 3 (to prevent and reduce disease, disability and premature death from chronic noncommunicable conditions);

SO 4 (to reduce morbidity and mortality and improve health during key stages of life);

SO 12 (to ensure improved access, quality and use of medical products and technologies).

8. Best practices in this area and examples from other countries within AMRO:

The field of cervical cancer prevention is rapidly changing with new scientific evidence on cost-effective alternatives to cervical cytology (Pap test) programs, which have experienced many challenges in LAC; and with the availability of new HPV vaccines.

Since the 1950s when Pap test screening programs were first introduced, Canada and the USA have experienced significant mortality reductions, in the magnitude of 75%. This impact has been attributed, in large part to the organization and high quality of cytology testing (1, 2). Significant mortality reductions have not been experienced in Latin American and Caribbean countries, despite cytology screening services. Only a few countries in the Region, namely Chile, Costa Rica, and Mexico have reported reductions in cervical cancer rates, attributed to improvements in the organization and quality control of the cytology screening program (3).

Several countries, including Colombia, Costa Rica, Mexico, and Peru have tested alternative screening approaches, including visual inspection screening with Acetic Acid (VIA), and HPV DNA testing. HPV

DNA testing has proven to be more sensitive than Pap testing in accurately detecting pre-cancerous lesions; VIA performs equal to or better than the Pap test in detecting pre-cancerous lesions; and has the added advantage of offering women an immediate test result, and can be linked immediately to pre-cancer treatment in a single visit in primary care settings. This approach of VIA screening followed immediately by cryotherapy treatment for precancerous lesions has demonstrated a 35% reduction in cervical cancer mortality in a 7 year period(4).

Many countries have begun to introduce these alternative screen and pre-cancer treatment approaches into their cervical cancer prevention program, but considerable more work is needed to improve the quality of cytology screening programs, and/or scale up alternative approaches; achieve high screening coverage for women in the at risk age group (>30years); and assure complete follow up diagnosis and treatment.

9. Financial implications of Agenda item:

This Regional Strategy and Plan of Action for Cervical Cancer Prevention and Control would require \$7 million over 7 years for implementation.

142nd SESSION OF THE EXECUTIVE COMMITTEE

Washington, D.C., USA, 23-27 June 2008

CD48/6 (Eng.) Annex D

ORIGINAL: ENGLISH

RESOLUTION

CE142.R13

REGIONAL STRATEGY AND PLAN OF ACTION FOR CERVICAL CANCER PREVENTION AND CONTROL

THE 142nd SESSION OF THE EXECUTIVE COMMITTEE,

Having considered the proposal of the Director on the Regional Strategy and Plan of Action for Cervical Cancer Prevention and Control (Document CE142/10),

RESOLVES:

To recommend that the Directing Council adopt a resolution along the following lines:

THE 48th DIRECTING COUNCIL,

Having considered the proposal of the Director on the Regional Strategy and Plan of Action for Cervical Cancer Prevention and Control (Document CD48/6);

Noting the World Health Assembly resolution on cancer prevention and control (WHA58.22, 2005), which urges governments to develop comprehensive cancer control programs and recommends the prioritization of cervical cancer prevention and control programs;

Recalling Resolution CD47.R9 (2006) of the 47th Directing Council on the Regional Strategy and Plan of Action on an Integrated Approach to the Prevention and Control of Chronic Diseases, which includes cancer as one of the priority chronic diseases;

Cognizant that there are an estimated 27,500 deaths in the Americas from cervical cancer, caused mainly by persistent infection with some genotypes of the human papilloma virus (HPV), and recognizing that although cervical cancer can be prevented and controlled through a comprehensive program of health education, screening, diagnosis, treatment, and palliative care, it continues to cause premature mortality and disproportionately affects women in the lower economic strata, revealing the existing health inequities in the Region;

Recognizing that current efforts and investments are not resulting in significant declines in the cervical cancer burden in most countries of Latin America and the Caribbean;

Recognizing that cost-effective HPV vaccines can become a component of a comprehensive cervical cancer prevention and control program;

Recognizing that the Pan American Health Organization, together with the Global Alliance for Cervical Cancer Prevention, has been assessing innovative approaches for cervical cancer screening and treatment of precancer lesions, and has generated new evidence and new knowledge on cost-effective strategies that can greatly improve cervical cancer prevention programs, particularly in low resource settings, and that PAHO has been supporting evidence-based decision-making by countries regarding HPV vaccine introduction; and

Aware that the prevention and control of cervical cancer could contribute to the attainment of international development goals,

RESOLVES:

- 1. To urge Member States to:
- (a) approve the framework of the Regional Strategy and Plan of Action for Cervical Cancer Prevention and Control, designed to improve capacity for sustained implementation of comprehensive cervical cancer prevention and control programs, with the goal of reducing incidence and mortality;

- (b) give priority on the national public health agenda to cervical cancer prevention and control, consider allocating appropriate resources, and work to strengthen current programs so they have an integrated approach;
- (c) revitalize and upgrade cervical cancer prevention and control programs to effectively utilize new evidence-based technologies and approaches, particularly in settings where access is challenging and resources are constrained;
- (d) undertake age-appropriate social communications strategies to heighten awareness about risk factors for cervical cancer and its preventability among adolescents and women, and engage communities in cervical cancer prevention efforts, with a special focus on empowering women from disadvantaged and vulnerable groups, including indigenous women;
- (e) develop and implement the actions recommended in this Regional Strategy and Plan of Action which are appropriate to the circumstances in their respective country and that address primary prevention, screening and precancer treatment, diagnosis and treatment of invasive cervical cancer, and palliative care;
- (f) strengthen health systems based on primary health care so that effective cervical cancer prevention and control programs may be delivered in close proximity to communities and with an integrated approach to primary and secondary prevention;
- (g) consider the studies available and local or subregional research data to make evidence-based policy decisions for the introduction of HPV vaccines, cognizant of the need for sustainability;
- (h) whenever possible utilize the PAHO Revolving Fund for Vaccine Procurement, since it plays an instrumental role in the introduction of new vaccines in the Americas;
- (i) establish and foster strategic partnerships with institutions in all appropriate sectors in order to moblize financial, technical and other resources that will improve the effectiveness of cervical cancer prevention and control programs.
- 2. To request the Director to:
- (a) provide technical assistance to Member States in an interprogrammatic manner in the revitalization of comprehensive cervical cancer prevention and control programs, incorporating new cost-effective technologies and approaches and to monitor the advancements and report periodically on achievements;

- (b) raise awareness among policymakers and health professionals in order to increase political, financial and technical commitments to cervical cancer prevention and control programs;
- (c) advocate for more equitable access to new technologies (HPV tests, HPV vaccines);
- (d) develop new or strengthen existing partnerships within the international community for resource mobilization, advocacy, and collaboration to improve cervical cancer prevention and control efforts in the Region.

(Ninth meeting, 27 June 2008)

Washington, D.C., USA, 29 September-3 October 2008

CD48/6 (Eng.) Annex E

Report on the Financial and Administrative Implications for the Secretariat of the Resolutions Proposed for Adoption by the Directing Council

1. Resolution: Regional Strategy and Plan of Action for Cervical Cancer Prevention and Control.

2. Linkage to program budget

Area of work

Expected result

Strategic Objective 3.0

RER 3.1, 3.2, 3.5, 3.6

3. Financial implications

a) Total estimated cost for implementation over the lifecycle of the resolution (estimated to the nearest US\$ 10,000; including staff and activities):

\$7 million over 7 years.

b) Estimated cost for the biennium 2008-2009 (estimated to the nearest US\$ 10,000; including staff and activities):

\$1 million.

c) Of the estimated cost noted in (b) what can be subsumed under existing programmed activities?

\$150,000.

4. Administrative implications

- a) Implementation locales (indicate the levels of the Organization at which the work will be undertaken and identify the specific regions, where relevant):
 - PAHO Washington, DC, PAHO/WHO representative offices, and CAREC.
 - Implementation would begin in several priority countries, which are among those with the highest rates of cervical cancer: Belize, Bolivia, El Salvador, Guyana, Haiti, Honduras, Nicaragua, and Paraguay.
- b) Additional staffing requirements (indicate additional required staff full-time equivalents, noting necessary skills profile):
 - 2 FTEs: medical officer and public health program manager.
- c) Time frames (indicate broad timeframes for the implementation and evaluation):

2008-2015 (7 years).

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