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Expert Consultation on the Comprehensive Prevention and Control of Cervical Cancer



Kuala Lumpur, Malaysia
4 – 6 November 2009

SUMMARY

An Expert Consultation on the Comprehensive Prevention and Control of Cervical Cancer was held in Kuala Lumpur, Malaysia from 4 to 6 November 2009. It was organized by the World Health Organization Regional Office for the Western Pacific. There were 29 participating experts from Australia, China, Fiji, Japan, Malaysia, the Philippines, the Republic of Korea and Viet Nam. Representatives from the Johns Hopkins Program for International Education in Gynaecology and Obstetrics (JHPIEGO), PATH, and the International Union Against Cancer (UICC) also attended the consultation.

The objectives of the consultation were:

- (1) to critically review current information and evidence on cervical cancer and its prevention, and examine its relevance among Member States of the Western Pacific Region at different levels of socioeconomic and health systems development, in order to strengthen cervical cancer control efforts; and
- (2) to identify priority actions for Member States for establishing comprehensive cervical cancer control, and to develop a road map for developing and strengthening cervical cancer control programmes.

Background information was provided through five plenary papers from WHO staff on the global and regional status of cervical cancer prevention, laboratory requirements for cervical cancer prevention and control, the WHO recommendations on screening programmes, and the WHO position paper on human papillomavirus (HPV) vaccination. Seven panel sessions were held to address several issues related to comprehensive cervical cancer control, covering the broad and general spectrum of control programme as well as the specific issues related to screening and vaccination. Two group work sessions were conducted: (1) to develop a checklist for assessment of the status of cervical cancer control in countries of the Region, and (2) to develop a road map for countries in the Region for comprehensive cervical cancer control. A number of recommendations and suggestions emerged from the discussions and group work. Participants confirmed that countries in the Western Pacific Region need operational guidelines for a comprehensive cervical cancer prevention and control programme which are based on current needs and capacity.

1. INTRODUCTION

1.1 Background

Cervical cancer remains an important public health problem and is a significant cause of mortality among women, especially in the developing countries, which account for more than 80% of cases. Globally, in 2002, there were an estimated 493 000 incident cases and 1.4 million prevalent cases of cervical cancer, with 273 000 deaths. An estimated 52% of these cases are in Asia and the Pacific. Countries of the Western Pacific Region report varying levels of incidence and mortality. Accurate data are difficult to come by, especially since very few countries have cancer registries. In the Western Pacific Region, 19 countries reported available estimates to *GLOBOCAN 2002*, a cancer database of the International Agency for Research on Cancer.

In April 2007, a biregional consultation was conducted by the World Health Organization Regional Offices for South-East Asia and the Western Pacific in Pattaya, Thailand. The objective of the consultation was to assist countries in making informed decisions on the prevention of cervical cancer. This meeting reviewed the situation in several countries in the two regions.

To respond to the need of countries in the Western Pacific Region, an Expert Consultation on the Comprehensive Prevention and Control of Cervical Cancer was held in Kuala Lumpur from 4 to 6 November 2009. The consultation was organized by the WHO Regional Office, with valuable inputs from WHO Headquarters. A background paper on the current status of cervical cancer control in the Western Pacific Region was developed through desk review.

1.2 Objectives

- (1) To critically review current information and evidence on cervical cancer and its prevention, and examine its relevance among Member States of the Western Pacific Region at different levels of socioeconomic and health systems development, in order to strengthen cervical cancer control efforts.
- (2) To identify priority actions for Member States for establishing comprehensive cervical cancer control, and to develop a road map for developing and strengthening cervical cancer control programmes.

1.3 Participants

Twenty-nine technical experts from Australia, China, Fiji, Japan, Malaysia, the Philippines, the Republic of Korea and Viet Nam participated in the meeting. Representatives from Johns Hopkins Program for International Education in Gynaecology and Obstetrics (JHPIEGO), PATH, and International Union Against Cancer (UICC) also attended the consultation (Annex 1).

2. PROCEEDINGS

2.1 Agenda and programme of the meeting

The agenda of the meeting is shown in Annex 2. The three-day meeting consisted of plenary presentations of background information and context, panel sessions for discussion of relevant issues, and group work to review situations in countries and to develop road maps for them.

2.2 Introduction to the meeting

Dr Narimah Awini, Regional Adviser, Making Pregnancy Safer, WHO Regional Office for the Western Pacific, welcomed the participants to the meeting. This was followed by self-introductions. Reference was made to the biregional meeting in 2006 in Pattaya, Thailand. It was emphasized that countries in the Western Pacific Region expressed a need to have operational guidelines for cervical cancer control, appropriate for each country context. The agenda and programme of the meeting were explained.

2.3 Background and context

Five background papers explained the context of the consultation and served as a platform for the subsequent panel sessions and group work.

- (1) Dr Nathalie Broutet, Medical Officer, Reproductive Health and Research, WHO Headquarters, presented the first background paper on the global scenario of cervical cancer and the different strategies available for cervical cancer prevention and control.
- (2) A summary of the WHO recommendations on comprehensive cervical cancer prevention control, as contained in the WHO publication of the same title, was presented by Dr Khine Sabai Latt, Technical Officer, Gender, Women and Reproductive Health, WHO Regional Office.
- (3) Dr Cherian Varghese, Technical Officer, Noncommunicable Diseases, WHO Regional Office, presented the status of cervical cancer burden in the Western Pacific Region and the opportunities and challenges faced by cervical cancer control programmes.
- (4) Dr Gayatri Ghadiok, Technical Officer, Essential Health Technologies Adviser, Health Technology, WHO Regional Office, presented on laboratory support for cervical cancer screening programmes.
- (5) The fifth presentation by Dr Broutet explained the WHO position paper on human papillomavirus (HPV) vaccination, and recommendations on using HPV vaccine in national immunization programmes.

Issues and concerns identified during the discussion were further deliberated during the panel sessions.

2.4 Panel discussions

The prerequisites for a successful comprehensive cervical cancer control programme include parameters for both primary prevention (health education, vaccination) and secondary prevention (screening), which in turn must be linked to diagnosis, referral and management of cases. This wide spectrum of activities involves several issues and areas of concern. In an attempt to discuss these issues in a structured manner, seven panel sessions were held. Each panel session was opened by the lead presenter, followed by two or three commentators. To guide these panellists, questions were drafted for each panel, and their comments were to some extent related to these questions (Annex 3). The presentations and comments were not designed to be country reports, although panellists found it relevant to relate experiences in their own countries.

2.4.1 PANEL 1: Governance and management for cervical cancer control programmes

Panellists: Dr Kyung Seo (lead), Prof Wang Linhong, Dr Mymoon Alias, Dr Vivien Tsu

- (1) It is important to recognize that cervical cancer is a preventable disease and an important public health priority in countries of the Western Pacific Region. Cervical cancer prevention can be started with whatever programmes or services are available in the country, regardless of the stage of the programmes, but it has to be done systematically. All countries may have to adopt a phased approach with plans for future expansion and scale-up. Doing nothing is not an option.
- (2) Countries should have a national policy and budget allocation for a comprehensive cervical cancer programme.
- (3) Countries should be prepared for change given the dynamic political climate, introduction of new technologies on cervical cancer prevention (e.g. upcoming rapid HPV tests) and price changes of screening tests or HPV vaccines.
- (4) The important role of cancer registries in planning, monitoring and evaluating the programme was emphasized.
- (5) Programme managers must have the required information and data, such as the size of the target population, for the purpose of monitoring and scaling up.
- (6) Integration with other programmes is considered as an appropriate approach. For example, the cervical cancer control programme can be part of a national cancer control programme. It can also be incorporated into the broader agenda of women's health and development, or added as a component of lifestyle and wellness programmes, since this can open opportunities to include more stakeholders and potential sources of additional resources.
- (7) Payment towards screening services should be considered in any health financing mechanism such as health insurance.

2.4.2 PANEL 2: Cervical cancer screening coverage and alternative methods

Panellists: Prof Takashi Fukuda (lead), Dr Malcolm Moore, Dr Cecilia Llave, Prof Lihui Wei

- (1) While there is difficulty in applying a standard definition for coverage, it can be seen from available data that coverage for screening is generally low in most countries of the Region, including high-income countries such as Japan and the Republic of Korea.

(2) It is important to have a standard definition of screening coverage that uses the following formula. However, many countries will find difficulty in getting the data required for this formula.

$$\text{Coverage} = \frac{\text{Number of women screened at least once in the required interval}}{\text{Total number of women at risk in the target population in the required interval}}$$

(3) In determining the age when screening should start and the interval of screening, several factors, especially the number of women to be screened and resources available, should be considered.

(4) The reasons for poor coverage must be studied carefully. If repeated visits and delays in receiving a cytology report are factors, especially in poor-resource settings with poor laboratory services, a single-visit approach such as visual inspection with acetic acid (VIA) and appropriate treatment may be considered. Some women do not come for screening because they prefer a female health worker, or they insist on a doctor and not a health worker to take the smears.

(5) For choice of screening methods, countries that are currently using cytology, which generally has seen low coverage, may consider these options: (1) go on with cytology and try to improve performance and coverage, (2) complement their existing cytology services with visual inspection in areas where it is appropriate, and (3) avail other tests like HPV testing as resources permit. For countries that would like to start a screening programme, they should assess the capacity and resources required for the programme and can consider VIA and treatment as an initial option and plan for scaling up in a phased manner.

2.4.3 PANEL 3: Cost and impact of cervical cancer screening

Panellists: Prof Kobchitt Limpaphayom (lead), Dr Kyung Seo, Dr James Fong

(1) The panel focussed on the question: "If cytology has shown not to be effective and has no impact, what should countries try to do?" The under-performance of screening programmes, as shown through low coverage and no evidence of impact on disease burden, is not necessarily a failure of the screening test used, but could be due to programmatic factors. Screening programmes require a functioning and strong health system. One common constraint faced by many countries is inadequate laboratory facilities for cytology, which is an inherent limitation of cytology-based programmes. Monitoring and appropriate follow-up mechanisms for abnormal results must also be in place, regardless of the screening method used. Thus to impact significantly on disease burden, a successful cervical cancer screening programme requires an organized, rather than an opportunistic approach. The panel also discussed alternative methods of screening, as a continuation of Panel 2.

(2) It is useful for screening programme to be developed with clear phases and identified activities in each phase, which essentially consist of (a) prepare, (b) build, (c) expand, and (d) sustain.

(3) The safety of "see and treat" approaches, especially the use of VIA with or without cryotherapy at the same visit, was discussed, with clarifications given that it is generally safe. It was also clarified that VIA is contraindicated in pregnancy and up to six weeks postpartum, because a speculum examination may not be safe during pregnancy and the results of cytology may not be appreciated due to hormonal changes. Innovative approaches such as "one day screening" in some settings can be explored.

2.4.4 PANEL 4: Laboratory issues, referral and treatment

Panellists: Prof Hayati Othman (lead), Dr Cecilia Llave, Prof Kobchitt

- (1) All screening methods – cytology, VIA, HPV – are useful for cervical cancer screening in the appropriate context; cytology and HPV tests require good quality laboratory services, HPV test is currently expensive, and VIA does not require laboratory services except for cases referred for suspicion of cancer.
- (2) Gaps and challenges were identified, e.g. lack of implementation, auditing and monitoring in laboratories despite existing guidelines. New molecular tests are available and show several advantages, but they are currently costly for many countries.
- (3) Laboratories must have a quality management system and quality assurance. All laboratories need to participate in external quality assessment scheme (EQAS), and laboratory performance measures should be established at the national level.
- (4) Laboratory staff need to be trained, supervised and motivated.
- (5) It is important to establish a registry-based system for referrals, follow-up and monitoring. Innovative approaches in tracking (e.g. bar coding of slides and assignment of unique identifier number) should be considered.
- (6) Other concerns relating to cervical cancer control, not limited to the laboratory and referral aspects, were noted, including: (a) the need for clarity on issues such as screening in pregnancy; (b) the role of circumcision in preventing cervical cancer (uncertain); (c) non-sexual risk factors for cervical cancer; (d) careful use of terminologies (i.e. single visit approach since this may not be applicable to all settings); (e) potential litigation; and (f) varying cost-effectiveness of diagnostic tests depending on the country.

2.4.5 PANEL 5: HPV vaccine: introducing the vaccine

Panellists: Dr Fiona Russel (lead), Dr James Fong, Prof Dorota Gertig, Dr Le Thi Nga

- (1) The panel identified possible challenges in HPV vaccination, including: programme implementation; logistics; handling negative publicity on the vaccine; competing health priorities; and monitoring system for recipients of the vaccines. In general, a lead time of at least six months is required before starting HPV vaccination.
- (2) In view of the age for girls to be vaccinated, a school-based vaccination programme appears to be most appropriate, especially in situations where there is high school enrolment for girls; other settings and opportunities may also be considered, such as clinics and health campaigns in the community. School-based programmes should be used as opportunities to educate teachers and for the vaccinated girls to educate their female household members about cancer control.
- (3) There is a need to establish partnerships with stakeholders (e.g. Ministry of Education, media groups, and professional associations); to emphasize messages about continuing need for screening; and to develop a system for recording, reporting and follow-up.
- (4) As shown by the Australian experience, social marketing, especially through the media, is very important when introducing the vaccine, particularly for catch-up programmes for women over 18 years of age, but it was conjectured that this can require significant resources. The use of a

"champion" such as a dignitary, as done in Australia, can also be useful. There can be instances of negative media coverage; in Fiji, for example, a mopping-up campaign was needed because of a high refusal rate for the second and third doses after a negative media campaign. Programme managers need to plan in advance on how to manage adverse media coverage.

(5) The question of durability of protection from the vaccine was discussed; while this is likely to be long (currently, it is known to be at least nine years), there needs to be more information on this aspect including booster doses, which is expected from ongoing research.

2.4.6 PANEL 6: HPV vaccine: cost and financing

Panellists: Dr Vivien Tsu (lead), Dr Kyung Seo, Prof Takashi Fukuda, Dr Sharifah Izzat

(1) The introduction of HPV vaccine is constrained by cost and lack of financing. Determining the cost of the vaccine is complex and is highly dependent on country-specific factors. It is likely that the cost of the vaccine will eventually go down, as has happened for other vaccines in the past. Competition and economies of scale are likely to enhance this.

(2) Other costs related to vaccination should also be considered, including delivery and infrastructure costs. It was agreed that except for the cost of the vaccine itself, the infrastructural and management costs of a screening programme are far higher than for a vaccination programme.

(3) Possible sources of funding for HPV vaccine and start-up-costs include the government, the Global Alliance for Vaccines and Immunisation (GAVI) for eligible countries, and other donors.

(4) The issue of sustainability was emphasized as countries may be able to start a vaccination programme (such as through a limited availability of vaccines) but will likely face difficulty in sustaining it. Political engagement and successful introduction of other vaccines are factors that will help in sustaining the HPV vaccination programme.

2.4.7 PANEL 7: HPV vaccine: potential impact and challenge

Panellists: Assoc Prof Dorota Gertig, Dr Susan Wang, Dr Fiona Russel, Dr Nathalie Broutet

(1) There is a need to have a reliable information system to monitor and evaluate the impact of the HPV vaccination programme. Process and outcome indicators are needed for monitoring an HPV vaccination programme. Process indicators include vaccination coverage and vaccination safety data. Outcome indicators include prevalence of HPV disease, CIN II-III prevalence and HPV type distribution, positive screening tests and referrals for treatment, and incidence of invasive cervical cancer. WHO is currently developing guidelines on approaches to monitoring the impact of HPV vaccination.

(2) There is a need to establish registries for monitoring and evaluation, namely, a cancer registry, a screening registry and an HPV vaccination registry. A screening registry underpins an organized approach to screening and is critical for improving participation and coverage where a call (invitation) and recall (reminder) system can be established. It can ensure that abnormalities are followed up. It can also create a system of quality assurance for laboratories (positive predictive value, high-grade detection rate, etc.) by making screening histories available for laboratories, doctors and women.

(3) To monitor and evaluate an HPV vaccination programme, guidelines on starting up an information system in a cervical cancer prevention programme should be developed. Minimum requirements for information to be collected should be identified. Linking the programme to the

existing Expanded Programme on Immunization (EPI) database and screening registry, if available, should be explored. Intermediate results to monitor outcome indicators can be collected from laboratories.

2.5 Group work

There were two group work sessions: (1) develop a checklist to assess the situation for comprehensive cervical cancer control in countries, and (2) plan the most appropriate way forward for countries of the Region; for the latter session, countries were grouped into four clusters based on socioeconomic and other relevant parameters.

2.5.1 GROUP WORK 1

The objective of the first group work session was to develop a checklist to help countries to assess their current status and readiness for comprehensive cervical cancer control including HPV vaccination. There were four groupings that represented four major programme areas of cervical cancer prevention control.

- Group 1 - governance, operational mechanism, financing and partnership
- Group 2 - cervical cancer screening tests and laboratory needs
- Group 3 - introducing HPV vaccination
- Group 4 - monitoring and information systems

Based on the outcome of this group work, an assessment checklist was developed (Annex 4).

2.5.2 GROUP WORK 2

The second group work session developed a road map for a cervical cancer prevention programme in the Western Pacific Region. Participating Member States were grouped as follows:

- Group 1 - Australia, Hong Kong (China), Japan, New Zealand and Singapore
- Group 2 - Brunei Darussalam, China, Malaysia, Philippines and Republic of Korea
- Group 3 - Cambodia, Lao People's Democratic Republic, Mongolia and Viet Nam
- Group 4 - Pacific island countries.

Results of the group work are summarized in Annex 5. Although the suggested road maps for each category of countries require greater detail, due to lack of time to deliberate further into them, they will provide the WHO Regional Office and experts with a basis for developing guidelines for countries.

3. CONCLUSIONS AND RECOMMENDATIONS

3.1 Conclusions

The Expert Consultation on Comprehensive Cervical Cancer Control for the Western Pacific Region was held successfully, and the objectives were met. The discussions, observations and recommendations will be used by the WHO Secretariat (Headquarters and Regional Office) with further inputs from experts to provide country-specific support for comprehensive cervical cancer control programmes.

3.2 Recommendations

3.2.1 General recommendations

- (1) WHO should guide countries in implementing effective and efficient approaches in instituting a comprehensive cervical cancer control programme, with both primary and secondary prevention, against the background of the wide diversity among countries in national capacity, resources and performance in prevention programmes.
- (2) Countries should develop a road map for COMPREHENSIVE cervical cancer prevention and control, which requires: introducing/strengthening screening programmes and a well thought-out plan for introduction of the HPV vaccine; recognizing the importance and urgency of starting from whatever point that a country is at; and having a clear plan of time-bound targets within the road map.
- (3) In developing a road map for comprehensive cervical cancer prevention and control, countries should address the issues and make the necessary provisions for: (a) governance and strategic policies, (b) operational strategies, and (c) mechanisms for monitoring and evaluation. Countries should also ensure that there is a clearly identified oversight mechanism supported by a technical advisory group from different disciplines and constituencies related to cervical cancer.

3.2.2 Recommendations for strengthening screening for cervical cancer

- (1) Countries may wish to consider the options available to them for screening: (a) go on with cytology and try to improve performance and coverage, (b) complement their existing cytology services with visual inspection in areas where it is appropriate, and (c) avail other tests like HPV testing as resources permit. Countries that would like to start a screening programme should assess the capacity and resources required for the programme and consider VIA and treatment as an initial option and plan for scaling up in a phased manner.
- (2) It is likely that all countries will have to adopt a phased approach to screening with incremental improvements in coverage and quality, and this will consist of the phases of planning and preparation, building, expanding and scaling up, and sustaining.
- (3) Countries should ensure that appropriate information and data are available for implementation or strengthening of a screening programme, such as the population to be targeted for screening and health systems capacity, so that the screening programme can be planned, monitored and evaluated quantitatively.

- (4) Linking and integrating screening with the other components of cervical cancer control programmes (such as HPV vaccination) and with other relevant programmes (such as control programmes for cancer and sexually transmitted infections, EPI, school and adolescent health) are to be pursued for maximum mutual benefits.
- (5) While it is most urgent to improve the coverage of screening (by any method, but especially by cytology where it exists since many resources are expended on it), countries are advised to ensure they have appropriate data to measure coverage so that there is clarity and harmony in following up and evaluating the programme.
- (6) The method for screening and the interval for screening should be determined based on the current evidence and the situation in each country.
- (7) Countries need to strengthen laboratory services and quality assurance to improve performance of screening programmes if cytology or HPV tests are used.
- (8) The issue of costs, cost-effectiveness and financing mechanisms of screening programmes have to be addressed by all countries by analysing all programme costs and outcomes.

3.2.3 Recommendations for introduction of HPV vaccine

- (1) Whatever the impetus for a vaccination programme, all countries must factor in sustainability in the planning process, bearing in mind that the cost of vaccine is only one component of the costs, and that other programme inputs will have costs.
- (2) The possible delivery mechanisms/entry points for the HPV vaccine need to be evaluated and selected according to the country's situation; possibilities include schools, clinics, campaigns and the community settings.
- (3) Every effort must be made to use the HPV vaccination programme as a platform/opportunity for information and health education, and advocacy for the comprehensive spectrum of prevention and control that includes healthy lifestyles, screening and seeking treatment. Girls who are vaccinated should be used for disseminating information on cancer prevention and control to the adult female members in their households.
- (4) Recognizing that the current vaccine has been monitored for the past nine years only, it is not currently possible to evaluate the durability or period of protection, and countries (with assistance from WHO and other international partners) are encouraged to keep track of this and adapt their country plans accordingly as more data become available.
- (5) Countries should recognize that introduction of the HPV vaccine will entail several requirements on information system and data management.
- (6) Countries embarking on HPV vaccination can consider establishing a vaccination registry where possible, and this can be linked to the other registries (screening registry, pre-cancer registry, cancer registry) where they exist.
- (7) The role of the media should be recognized, and appropriate actions are to be taken to maximize the positive role of the media and prepare responses in anticipation.

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AGENDA

- 1) Opening ceremony
- 2) Introduction to meeting
- 3) Background and current recommendations
- 4) Panel discussion 1: Cervical cancer screening – governance and management, minimum recommendation
- 5) Panel discussion 2: Cervical cancer screening – low coverage and alternative methods
- 6) Panel discussion 3: Cervical cancer screening – cost and impact
- 7) Panel discussion 4: Cervical cancer screening – laboratory issues, referral and treatment
- 8) Panel discussion 5: HPV vaccine – introducing the vaccine
- 9) Panel discussion 6: HPV vaccine – cost and financing
- 10) Panel discussion 7: HPV vaccine – potential impact and challenge
- 11) Group work: Developing a regional strategy with staggered approach for countries at different levels of development/programmatic capacity for cervical cancer control
- 12) Synthesis/report by the secretariat
- 13) Closing ceremony

TEMPLATE FOR THE PANEL DISCUSSIONS

ANNEX 3

TEMPLATE FOR THE PANEL DISCUSSION

Programme areas	Coordinator	Panels sessions	Issues, questions	Panelist
Governance and linkages, national programming	Dr Narimah Awin	P1 – Cervical cancer screening – governance and management, minimum recommendation	Q1 – What should be the national mechanism governing cervical cancer screening?	
			Q2 – How could government integrate cervical cancer screening into other government health services?	
			Q3 – What are the minimum recommendations for instituting screening, which has demonstrated impact on cervical cancer incidence and mortality?	
			Q4 – Should an integrated approach for screening of cancers be adopted – e.g. doing an integrated screening for breast, cervix and colorectal cancers?	
Screening (excl) laboratory, to include methods, approaches coverage, costs, impact assessment	Dr Cherian Varghese,	P2 - Cervical cancer screening – low coverage, alternative methods	Q1 – For countries with existing cervical cancer screening policies but screening coverage remained low, how should government address this issue?	
			Q2 – Should there be a standard definition of screening coverage since the ages and frequency at which screening should be performed vary per country?	
	Dr Sabai Latt	P3 - Cervical cancer screening – cost, impact	Q1 – What should be the criteria for setting the interval (once in life time, three yearly, or five years)?	
			Q2 – Should low-resource countries even try for cytology based screening or a dual track approach (pap smear and VIA) or just focus on VIA?	
			Q3 – Are screening programmes effective for all countries?	

Annex 3

Laboratory	Gayatri Ghadiok	P4 - Panel discussion 4: Cervical cancer screening – laboratory issues, referral and treatment	Q1 – What are the laboratory requirements for introducing comprehensive cervical cancer prevention using the different screening methodologies available?		
			Q2 – What are the challenges and gaps in countries of varying socioeconomic development and within the laboratory networks in those countries?		
			Q3 – What specific mechanisms should be put into place for referral and treatment of abnormalities?		
			Q4 – In places with no treatment facilities, what are the options?		
HPV vaccine introduction	Dr Manju Rani	P5 - HPV vaccine – introducing the vaccine	Q1 – What are the approaches for accessing the target age groups in achieving high coverage?		
			Q2 – Do we know the duration of protection, final impact of cancer incidence?		
			Q3 – Should national programmes issue guidelines for general population for use of HPV vaccine even when it is not introduced in publicly funded programmes?		
			Q4 – Should countries wait for the answers for these remaining questions before starting HPV immunization programmes?		
			P6 - HPV vaccine – cost, financing	Q1 – What is the current market cost of vaccine, current life-time cost of vaccination (~300)? What is the realistic final market price?	
				Q2 – Is current life-time cost of vaccination comparable to current average life-time cost of screening and follow-up treatment?	
				Q3 – How does it compare with cost-effectiveness of screening and other key public health measures especially other reproductive health programmes?	
				Q4 – Financing of HPV immunization – public/private mix or only public?	

Annex 3

		P7 - HPV vaccine – potential impact, challenge	Q1 – What minimum information systems should be put in place by countries considering these programmes? Q2 – Minimum programme monitoring (process indicators) requirements in all countries: systems to record and monitor vaccination coverage by each cohort.	
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CONTENTS

	<u>Page</u>
SUMMARY 1	
1. INTRODUCTION	2
1.1 Background.....	2
1.2 Objectives	2
1.3 Participants	2
2. PROCEEDINGS	3
2.1 Agenda and programme of the meeting	3
2.2 Introduction to the meeting	3
2.3 Background and context	3
2.4 Panel discussions	4
2.5 Group work.....	8
3. CONCLUSIONS AND RECOMMENDATIONS.....	8
3.1 Conclusions	9
3.2 Recommendations	9

ANNEXES:

ANNEX 1 - LIST OF TEMPORARY ADVISERS, REPRESENTATIVES/OBSERVERS AND SECRETARIAT	11
ANNEX 2 - AGENDA.....	15
ANNEX 3 - TEMPLATE FOR THE PANEL DISCUSSIONS.....	17
ANNEX 4 - CHECKLIST FOR ASSESSING COUNTRY CAPACITY AND PREPAREDNESS FOR INTRODUCING OR SCALING UP A COMPREHENSIVE CERVICAL CANCER PREVENTION AND CONTROL PROGRAMME	23
ANNEX 5 - SUMMARY OF GROUP WORK	37

Keywords:

Uterine cervical neoplasms – prevention and control

**CHECKLIST FOR ASSESSING COUNTRY CAPACITY AND PREPAREDNESS FOR
INTRODUCING OR SCALING UP A COMPREHENSIVE CERVICAL CANCER
PREVENTION AND CONTROL PROGRAMME**

ANNEX 4

**CHECKLIST FOR ASSESSING COUNTRY CAPACITY AND PREPAREDNESS FOR
INTRODUCING OR SCALING UP A COMPREHENSIVE CERVICAL CANCER
PREVENTION AND CONTROL PROGRAMME**

WHO-WPRO

Country _____

CONTACT INFORMATION OF THE PERSON COMPLETING THIS CHECKLIST

Name: _____

Position: _____

Organization: _____

Address: _____

E-mail: _____

Phone number: _____

Date Completed: _____

INSTRUCTIONS:

This checklist can be used to assess country capacity and preparedness in introducing or scaling up a cervical cancer prevention and control program. This questionnaire is divided into five sections: (1) demographics; (2) governance and management (3) laboratory services (4) monitoring;and (5) financing to capture the different domains.

All attempts should be made to collate information from multiple sectors relevant for the programme. All questions may not be applicable to all Member States, but these items can be considered at appropriate stages of planning and implementation of cervical cancer prevention and control programmes.

Section 1. Demographics

1.1. Total Population (Pop)	1.2. Total Male Pop	1.3. Total Female Pop	1.4. Total Urban Pop	1.5. Total Rural Pop
(year)				

1.6. No. of Women 30-59 years	1.7. Total no. of females aged 9 years old	1.8. Total no. of females aged 10 years old	1.9. Total no. of females aged 11 years old	1.10. Total no. of females aged 12 years old	1.11. Primary school completion rate among girls

Section 2. Burden of Disease

- 2.1. Incidence rate of cervical cancer _____
- 2.2. Mortality rate of cervical cancer _____
- 2.3. Number of cervical cancer cases managed per year _____
- 2.4. Number of cervical cancer deaths managed per year _____

Section 3. Governance and Management

3.1. Policy

- 3.1.1. Is there a national cancer prevention and control policy? Yes No
 - 3.1.1.1. Does this policy include cervical cancer prevention? Yes No
 - 3.1.1.2. Are there guidelines or protocols that govern the following aspects of cervical cancer prevention and control:
 - a. Screening tests Yes No
 - b. Diagnostic tests Yes No

c. Laboratories Yes No

d. Treatment options for precancerous lesion Yes No

e. Treatment of cervical cancer Yes No

3.1.1.3. Is there a National HPV vaccine policy? Yes No

3.1.1.4. Is there a National guideline on HPV immunization Service delivery? Yes No

3.1.1.5. Is there a National guideline on Health promotion/communication? Yes No

3.1.2. Are there existing policies on:

a. Non communicable diseases Yes No

b. Reproductive and maternal and child health Yes No

c. Women and Gender Yes No

3.1.3. What is the national immunization coverage rate for the following vaccines:

a. Measles _____

b. DTP3 _____

c. HepB3 _____

3.2. Management and Operational Mechanism

3.2. 1.Is there a program for cervical cancer prevention and control? Yes No

3.2.2. Tick the appropriate description of the cervical cancer prevention Organized at the National Level

program and control in your country

Organized at selected areas

(Note: You can tick more than one box)

Opportunistic screening

3.2.3. Is there a responsible office or agency for leading and coordinating a Yes No
cervical cancer prevention program?

3.2.3.1. Name of office or agency? _____

3.2.4. Is there a steering or advisory group for this program? Yes No

3.2.5. Is a referral system available for women who need:

- a. Treatment for precancerous lesion Yes No
- b. Treatment of cervical cancer Yes No
- c. Palliative care Yes No

3.2.6. Are there clinical practice guidelines for the following areas:

- a. Age to initiate screening Yes No
- b. Coverage goals Yes No
- c. Screening interval Yes No
- d. Screening tests to use Yes No
- e. Standard terminology for reporting screening results Yes No
- f. Health Professionals permitted to conduct the screening test and or treatment for precancerous lesion Yes No
- g. Methods to manage women with precancerous lesion Yes No

- 3.2.7. What is the cervical cancer screening test(s) used?
- Cytology Proceed to 3.2.7. Answer on Cytology Services Column
 - VIA Proceed to 3.2.7.2. Answer on VIA Services Column
 - Combination (cytology + VIA) Proceed to 3.2.7. Answer both Columns

3.2.7. Screening Test	3.2.7.1 Cytology Services	3.2.7.2. VIA Services
a. What is the target age group?		
b. What are coverage targets?		
c. Are the screening services managed and delivered at:		
1. Primary	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
2. Secondary	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
3. Tertiary	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
d. Are the treatment services managed and delivered at:		
1. Primary	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No

2. Secondary	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
3. Tertiary	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
e. Do the following health facilities perform screening tests at:		
1. Primary	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
2. Secondary	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
3. Tertiary	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
f. Who performs the screening?		
1. OB-Gyn	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
2. General practitioner	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
3. Nurses	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
4. Midwives	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
5. Others _____	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No

g. What is the total number of health professionals providing screening tests?		
	Cytology	VIA
1. No of OB-Gyn		
2. No of General practitioner		
3. No of Nurses		
4. No of Midwives		
5. No. of community health workers		
h. Is special training offered to the health professional for performing cytology?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
i. Are refresher training courses offered?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
j. How often?		

3.2.8. Are these screening services delivered:

- a. as part of the routine preventive health services for women Yes No
- b. as part of maternal and child health services Yes No
- c. as a special campaign for cervical cancer prevention Yes No

3.2.9. Is there a unique identification number to trace or for call and recall of women who availed of the screening services? Yes No

3.2.10. Is there a government funded HPV vaccination program? Yes No

Proceed to 3.2.11.

3.2.10.1. Is this HPV vaccination program delivered in:

- a. Schools Yes No
- b. Community health centers Yes No
- c. Other (Please specify: _____)

3.2.10.2. Are there communication strategy packages for :

- a. Clinicians & service providers Yes No
- b. Community Yes No
- c. Target groups Yes No
- d. Parents Yes No
- e. Teachers Yes No

3.2.10.3. Is there a training structure/module for:

- a. Clinicians Yes No
- b. Vaccinators Yes No
- c. Communicators Yes No

3.2.10.4. Who performs the vaccination?

- a. General practitioner Yes No
- b. Nurses Yes No
- c. Community health worker Yes No

d. Other (Please specify: _____)

3.2.10.5. What is the total number of persons providing the HPV vaccination services per health professional?

a. General practitioner _____

b. Nurses _____

c. Community health worker _____

d. Others _____

3.2.10.6. Is there available cold chain facility in each health center?

a. National level Yes No

b. District level Yes No

c. Community level Yes No

3.2.11. If there is no national HPV program in the country, is there a plan Yes No to start an HPV vaccination program?

3.2.11.1 By what year? _____

Section 4. Laboratory services

4.1. Are there laboratories offering cervical pathology / histopathology services? Yes No

4.2. Is the laboratory system centralized? Yes No

4.3. No of laboratories offering cervical pathology / histopathology services:

a. At national level _____

b. At sub national level _____

c. Per Health district _____

4.4. Is there a national reference laboratory Yes No

4.5. Is there a regular external quality assessment of cytology? Yes No

4.6. Is there a regular external quality assessment of the histopathology? Yes No

4.7. How many cervical cytology smears does each level of laboratory process on average each year?

- a. National level _____
- b. Sub national level _____
- c. District level _____

4.8. How many cervical biopsy tests does each laboratory process on average each year? _____

4.9. Do all labs report according to the standard international terminology / classification used (eg. Bethesda) Yes No

4.10. Are there cytopathologists/ pathologists in the country? Yes
 No Proceed to 4.11

4.10.1. No. of Cytopathologists/ pathologists in each level of laboratory

- a. National _____
- b. Sub national _____
- c. District level _____

4.10.2. Is the quality of the pathologist's work evaluated and monitored to ensure quality of the biopsy test results? Yes No

4.11. Are there cytotechnicians in the country? Yes No

4.11.1.No. of Cytotechnicians in each level of laboratory

- a. National _____
- b. Sub national _____
- c. District level _____

4.11.2. Is there a program in place for training, continuous updates , re-training, supervision, monitoring performance and evaluation of cytotechnicians? Yes No

4.11.3.Are all smears reported as negative by the cytotechnician re-screened by the cytologist/ pathologist? Yes No

Section 5. Monitoring

5.1. Is it possible to enumerate the target population for cervical cancer screening? Yes No

- 5.2. Is it possible to enumerate the target population for HPV vaccination? Yes No
- 5.4 Are national coverage surveys performed on a regular basis in a standard manner? Yes No
- 5.3. Is there a cancer registry available? Yes No
- 5.3.1. What proportion of the population is covered by cancer registration systems? _____
- 5.4 Is there a central health information system Yes No
- 5.5. Is there a cervical screening registry? Yes No
- 5.6. Is there a public health professional e.g. epidemiologist, responsible for monitoring cervical screening data? Yes No
- 5.7. Is a central list of women with abnormal screening results available? Yes No
- 5.7.1 For what purpose is this list used? Tracking clients
 Follow up or subsequent management
- 5.8. Is it possible to access laboratory records for each woman so that data are available by women screened? Yes No
- 5.9. Are there measures in place to ensure confidentiality? Yes No
- 5.10. Is there a system that links the cervical smears to the biopsy slides Yes No
- 5.11 Are statistical reports on the cervical screening program produced routinely? Yes No
- 5.12. Are these reports available to policy-makers? Yes No
- 5.13. Can you identify the size of the target population for an HPV vaccination program? Yes No
- 5.14. What is the size of the target population for vaccination? _____
- 5.15. Is there an available HPV vaccination register? Yes
 No Proceed to 5.21.
- 5.16 Is there a public health professional e.g. epidemiologist, responsible for monitoring vaccination data? Yes No
- 5.17. Is there a standard vaccination record for use by all immunization providers? Yes No
- 5.18. Since there is a need for vaccine coverage by age and by dose, are the following information recorded:
d. Place where vaccine is distributed Yes No
- 5.19. Has a mechanism been identified for follow up of missed doses? Yes No
a. Date of birth
- 5.20. How are information transferred between screening and vaccination sites? Yes No
b. Date of vaccine administration
- c. Vaccine Dose number Yes No
a. Mail _____

b. Email _____

c. Disk _____

d. Web Access _____

5.21. Is there a system (passive or active) for reporting of adverse events of vaccines by the public and health professionals to a national center? Yes No

5.22. Have case definitions for adverse events of vaccines been identified? Yes No

5.23. Are background rates of relevant diseases known for target age group Yes No

5.24. Is it possible to link to other health data sets to monitor disease rates? Yes No

Section 6. Financing

6.1. Is there a specified budget for cancer prevention and control? Yes No

6.1.1. How much is the annual appropriation specific for cervical cancer prevention and control program? _____

6.2. Is there funding for adolescent health services? Yes No

6.3. Is there a specific budget for non communicable diseases? Yes No

6.4. Is there available budget for Reproductive health? Yes No

6.5. Is there any international assistance supporting cervical cancer control program in your country? Yes No

6.6. Are there local private assistance supporting cervical cancer control program? Yes No

6.7.1. Does the national health insurance cover cervical cancer screening? Yes No

6.7.2. Are women required to pay for cervical screening test:
 Totally
 Partially
 Free

6.8. Is there funding to purchase HPV vaccine? Yes No

6.8.1. Is there funding for operational costs to deliver HPV vaccine?

Yes No

6.8.2. Is HPV vaccination included in health insurance?

Yes No

-END OF QUESTIONNAIRE-

SUMMARY OF GROUP WORK

Summary of Recommended Strategies for Country Groups

Country Groupings	Recommended Strategies
<p>Group 2 (Malaysia, Philippines, China, Brunei, republic of Korea) Scenario: - middle to high income countries - have started cervical cancer prevention program with a national scope</p>	<p>Short term (Year 1)</p> <ul style="list-style-type: none"> • Conduct a situational analysis using the checklist to assess country preparedness for scaling up a cervical cancer prevention program • Formulate an action plan that will address issues on coverage, existing cervical cancer prevention policies, operational, monitoring and evaluation mechanisms • Establish task force <p>Midterm Strategies (Year 2-5)</p> <ul style="list-style-type: none"> • Improve on coverage and quality assurance • Review operations/policy • Develop monitoring system <p>Long Term Strategy</p> <ul style="list-style-type: none"> • Comprehensive programme implementation
<p>Group 3 (Cambodia, Lao PDR, Mongolia and Vietnam) Scenario - middle to low income countries - limited background information about cervical cancer prevention efforts except for Viet Nam</p>	<p>Short term (Year 1)</p> <ul style="list-style-type: none"> • Have a national Policy on cervical cancer prevention • Appoint a senior advisor responsible for the program • Convene a technical Advisory board • Develop operations manual and implementation plan • Ensure adequate and sustainable budget • Establish referral system for treatment; suitable collection sites and laboratory equipments • Have sufficient staff • Implement dual track screening if cytology is already available and working well Cytology- major centers VIA/cryotherapy- rural settings <p>Mid term (Year 2-5)</p> <ul style="list-style-type: none"> • Document cancer burden and strengthen cancer registration • Have public health staff responsible for monitoring and reporting • Improve record keeping • Pilot data collection projects • Provide additional training for smear takers and cytotechnicians (curriculum, qualified trainers, on-site practical training, supervision and monitoring and competency assessment) if cytology is

	<p>available</p> <ul style="list-style-type: none"> • Establish laboratory performance measures and improve quality control (manuals and policies in place, internal and external quality assurance • Set up monitoring system that will enumerate the target population; identify the coverage; get number of women tested; and follow up women with abnormal results <p>Long term</p> <ul style="list-style-type: none"> • Shift to HPV DNA test when price comes down
<p>Group IV- Pacific islands and countries</p> <p>Scenario:</p> <p>Complex scenario given that countries have different resource levels and starting point</p> <p>For New Zealand, French, and US affiliated islands, they are generally well resourced and have effective programs.</p> <p>Tonga, Samoa and Fiji -have reasonable cytology services, to do gap analysis</p> <p>Kiribatu, Nauru and Tuvalu -have small scattered populations, not to do cytology, can benefit from VIA and cryotherapy</p> <p>Solomon and Vanuatu -relatively established referral system for treatment of pre-cancerous lesion, to do VIA and cryotherapy -GAVI eligible and with high incidence of cervical cancer, so to consider HPV</p> <p>Papua New Guinea</p> <ul style="list-style-type: none"> - complex situation with poor coverage of cytology - little government support or capacity 	<p>General recommended strategies:</p> <p>Short term (year 1)</p> <ul style="list-style-type: none"> • Assess the current situation, especially relevant policy and capacity • Develop an operational plan – screening, treatment modalities, referral system, information, etc • Develop training curriculum • Develop communication strategies • Raise general awareness and support • Determine budget and identify financing <p>Mid-term (years 2-5),</p> <ul style="list-style-type: none"> • implement training, information system, equipment and supplies, • evaluate progress and adjust as needed. <p>Long-term</p> <ul style="list-style-type: none"> • Switch to HPV testing or other proven modality • Add on vaccine if not already adopted. <p>Locale Specific Recommended Strategies: Tonga, Samoa and Fiji</p> <ul style="list-style-type: none"> • conduct assessment to identify gaps and preparedness for a cervical cancer prevention program prior to expand screening services those not receiving it. • Review target age groups and identify appropriate frequency/interval • Establish pre-cancer treatment facility since they have gynecologists, they should be trained to do cryotherapy and LEEP. • Have a good EPI system and can adopt vaccine as soon as possible. • In areas that cannot be reached with cytology,

	<p>consider supplementing with VIA.</p> <p>Kiribati, Nauru and Tuvalu</p> <ul style="list-style-type: none">• Capacity for cytology is very minimal. Recommend to use VIA and cryotherapy.• VIA and immediate cryotherapy should be provided by visiting teams that do quarterly EPI and other well child and antenatal care. Where some cytology capacity is available, it can be used to triage after VIA if it does not cause women to be lost to follow-up treatment. Nurse midwives can do cryotherapy, with referral to doctors when LEEP or cone is needed.• Since incidence is relatively low, vaccine may not be an early priority. <p>Solomon Islands and Vanuatu</p> <ul style="list-style-type: none">• Adopt seek and treat approach to be done by nurses given that any specialized care provided by a gynecologist on referral.• early introduction of HPV vaccine should be considered since these countries are GAVI eligible <p>Papua New Guinea</p> <ul style="list-style-type: none">• feasible to introduce VIA through the NGO sector, eg through the professional societies, starting on a small scale and gradually building capacity and support to scale up.• Since the EPI system is weak, vaccine should be considered as a later option.
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Summary of Group Work 1 - Items to be considered in the checklist

Action Topics/Group	Area
<p>1. Policy and Governance Operational mechanism Financing and Partnerships</p>	<ul style="list-style-type: none"> • Availability of support for scaling up prevention strategies by international agreements, regional guidelines, national policies • Availability of data on the burden of disease and magnitude of problem • Presence of a dedicated group of national authorities to support programme • Existence of policy statements that facilitate planning and resource allocation for the programme • Creation of a steering committee or task force, and perhaps a technical or political advisor to influence the program. • Operationalization of the Program: need to develop an operational or management plan to identify all management/operational aspects – screening, diagnoses, laboratory, treatment, palliative care, QA, referrals and linkages. • Availability of a system for collecting data and centralized recall system • Existence of long-term plans – include into nursing and medical training curriculum • Have identified useful stakeholders as influential agents for partnerships.
<p>2. Tests and Labs</p>	<ul style="list-style-type: none"> • Identification of current practices and procedures. • Availability of a matrix to determine the gaps in services against Pap, VIA and HPV testing under a number of factors including: Facilities & infrastructure, Staffing, QA and auditing, Budgeting and resources, Referrals and Follow up, and Data and records
<p>3. HPV Vaccine</p>	<ul style="list-style-type: none"> • Inclusion in Expanded Programme on Immunization and matching with existing EPI standards • Presence of a national guideline on HPV immunization • Availability of trained staff • Existence of an adequate communication strategy • Availability of sustainability plans for procurement of vaccine and budget for delivery strategy
<p>4. Monitoring and Information System, and indicators</p>	<p><u>Monitoring (general)</u></p> <p>Is it possible to enumerate the target population</p> <ul style="list-style-type: none"> • by population census data or • other administrative data sources

Action Topics/Group	Area
	<p>Is there a national/district unique ID for each individual?</p> <p>Is there a central or regional health info system, either specific for cervical screening (register), or other health info sources?</p> <p>Is there a PH professional responsible for monitoring cervical screening and vaccination data?</p> <p>What proportion of the population is covered by cancer registration systems?</p> <p>How is the info transferred between screening and vaccination sites?</p> <ul style="list-style-type: none">• By mail,• e mail,• disk,• web <p><u>Monitoring (vaccination)</u></p> <p>Is it possible to identify the target population where the vaccine will be delivered? Schools, others</p> <p>Is there a standard vaccination record/consent form for use by immunization providers?</p> <p>Is the number of doses distributed and where they are distributed recorded?</p> <p>Are coverage surveys performed on a regular basis in a standard manner?</p> <p>Has a mechanism been identified for follow-up of missed doses?</p> <p>Is there a system (passive or active) for reporting of adverse events by the public and health professionals?</p> <p>Have case definitions for adverse events been identified (eg Brighton Collaboration Centre)?</p> <p>Are there plans for adverse events data to be sent to global monitoring centre?</p> <p>Are background rates of relevant diseases known for the target age groups? Is it possible to link to other health data sets to monitor disease rates?</p> <p>In areas where HPV prevalence surveys are considered, is there a reference lab for HPV genotyping?</p> <p><u>Monitoring (screening)</u></p>

Action Topics/Group	Area
	<p>Is there a cervical cancer screening registry?</p> <p>Is a central list of women with abnormal results available? Is this used for tracking clients, follow up or subsequent management?</p> <p>Is there a standard coding of clinical or laboratory results?</p> <p>Are lab performance measures in place?</p> <p>Are there measures to protect confidentiality?</p> <p>Is there a system to centrally collect histology results?</p> <p>Are statistical reports available to policy makers?</p> <p><u>Indicators (vaccination)</u></p> <p>Coverage = No. of completed courses/No. in target age</p> <p>Adverse events = No. of adverse events/No. doses admin</p> <p><u>Indicators (screening)</u></p> <p>Coverage = No. of women screened at least once in the required time period/ No. of women in target pop (adjust for hysterectomy)</p> <p>No. of tests, No. of negatives, No. of abnormal (in each category – LSIL, HSIL, etc)No. of women with positive results/ No. of women followed up (need to define)</p> <p>Incidence of cervical cancer (by stage and histology subtypes), cervical cancer mortality rates</p> <p>High grade detection rate over 12 months period</p> <p>Positive predictive value = prop of cytology specimens reported as HSIL or higher histology</p>