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# Roadmap to Prepare National Action Plans for the Implementation of Organized Cervical Cancer Screening Programmes

in Eastern Europe and Central Asia

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## Abbreviations

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<b>CAWG</b>	Capacity Assessment Working Group
<b>CIN</b>	Cervical Intraepithelial Neoplasia
<b>CME</b>	Continuing Medical Education
<b>ECCA</b>	European Cervical Cancer Association
<b>EECA</b>	Eastern Europe and Central Asia
<b>KABPWG</b>	Knowledge, Attitudes, Beliefs and Practices Working Group
<b>PHC</b>	Primary Health Care
<b>PRWG</b>	Policy Review Working Group
<b>QA</b>	Quality Assurance
<b>SCO</b>	Screening Coordination Office
<b>SOP</b>	Standard Operating Procedure
<b>UNFPA</b>	United Nations Population Fund

# Acknowledgements

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This roadmap is based on the Assessment of Capacities for the Implementation of Organized Cervical Cancer Prevention Programmes in Eastern Europe and Central Asia, which was also initiated, supported and coordinated by the UNFPA EECARO and undertaken by the ECCA. It considers the institutional capacity development priorities identified in the assessment and addresses the recommendations discussed and agreed during the consultations between the UNFPA EECARO and the UNFPA COs.

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# 1. Executive Summary

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Compared to Western Europe, cervical cancer rates are substantially higher in Eastern Europe and Central Asia (EECA), where some 40,000 women develop and about 20,000 women die from this disease every year.<sup>1,2</sup> The principal reason for this disparity is the lack of effective organized cervical cancer prevention programmes in these countries.<sup>3</sup> Well-organized cervical screening programmes can reduce cervical cancer incidence and mortality by up to 80 per cent,<sup>4,5</sup> while combining cervical screening with HPV vaccination could produce reductions of up to 90 per cent.<sup>6</sup> However, these benefits will only be realized by well-organized programmes with high coverage (75 per cent or more) of the target population and strict quality assurance (QA) of all health services required to deliver the programmes.<sup>7</sup>

The United Nations Political Declaration from the High-Level Meeting of the General Assembly on the Prevention and Control of Non-Communicable Diseases<sup>8</sup> prioritized, *inter alia*, the prevention of cervical cancer, and this has further motivated many EECA countries to move forward with programmes to address this disease. The United Nations Population Fund (UNFPA), the UN agency leading on cervical cancer prevention, undertakes various activities at the global, regional and country levels to support the implementation of cervical cancer prevention policies and programmes. In support of this objective, the UNFPA published *Comprehensive Cervical Cancer Prevention and Control: Programme Guidance for Countries*, which led to cervical cancer prevention being included in the UNFPA EECA Regional Programme for 2014-2017, as well as in the respective country programmes for the UNFPA Country Offices in this region.

It is essential to approach the needs of the countries in the EECA region in a harmonized and efficient manner. Therefore, an analysis of the current situation in each country was commissioned by the UNFPA EECARO and undertaken by the EECA with support from the respective UNFPA Country Offices and national experts in each country. The resulting *Assessment of Capacities for the Implementation of Organized Cervical Cancer Prevention Programmes in Eastern Europe and Central Asia* was then used to prepare a policy brief, *Preventing Cervical Cancer in Eastern Europe and Central Asia*, and both documents were used to facilitate evidence-based policy dialogue, synchronize planning of cervical cancer prevention activities across the region and to ensure the harmonization of capacity-building, knowledge-sharing and advocacy activities at the regional and national levels.

To continue this process of facilitating cervical cancer prevention in the EECA region, this *Roadmap for the Implementation of Organized Cervical Cancer Screening Programmes in the UNFPA Eastern Europe and Central Asia Region* was prepared to summarize the overall process for developing plans to implement organized cervical screening programmes and provide specific details about the key actions that need to be undertaken. This report focuses on the implementation of cervical screening programmes, and HPV vaccination will be covered in a separate document.

When considering the implementation of cancer screening programmes, several key factors must be recognized:

- Cancer screening programmes must be well organized, coordinated and quality-assured. Without these elements, they will produce suboptimal or no reductions in cancer rates while still consuming substantial health-care resources.
- While cancer screening programmes can produce substantial benefits, they also inevitably produce a range of harms for the people being screened. The principal objective of a well-organized screening programme is to both maximize the benefits *and* minimize the harms.
- The foundation of an organized screening programme is a central administration with the authority, resources and budget to ensure:
  - Broad and equitable coverage of the target population;
  - Adherence to the recommended screening age range and interval;
  - Optimal coordination and quality of all the services involved in the screening programme from recruitment to the follow-up and treatment of people with a positive screening test result.
- The vast majority of central administration actions are the same for all cancer screening programmes.
- Screening programmes for different cancers are not all equally effective:
  - Breast screening aims to detect asymptomatic cancers in their early stages when they can be more easily and effectively treated, but the best screening programmes can reduce breast cancer mortality by only 20-25 per cent.
  - Cervical screening aims to detect *precancerous* lesions at a stage when they can be easily removed using simple outpatient procedures to prevent cancer from developing. Cervical screening therefore reduces both new cases and deaths from cervical cancer, with the best programmes reducing rates by up to 80 per cent.
  - Colorectal screening also works by detecting precancerous lesions so it can reduce both new cases and deaths from colorectal cancer. However, the best programmes will reduce rates by only 18-20 per cent.
  - Prostate screening has not been shown to produce any reductions in prostate cancer deaths, and all major international organizations now recommend *against* population-based prostate screening.

Therefore, while breast and colorectal cancers can be more common than cervical cancer, cervical screening's far higher efficacy and the fact that it reduces both new cases and deaths means the most cost-effective approach in the majority of EECA countries would be to first implement an organized cervical screening programme and then, when the required administrative structures are operating effectively, progressively expand them to include breast and colorectal cancers.

A further consideration is that the implementation of any new health programme is challenging because health systems are complex networks with many interconnected components and with each component having many stakeholders, including the public targeted

by the programme. As a result, the implementation process must do more than simply account for the clinical or scientific elements of the new programme and must also account for the interests, motivations and alliances of these stakeholders. It is therefore essential to identify all stakeholders that will be involved in the operation of the new programme and actively engage them in its design, planning and implementation to ensure that:

- Their knowledge of the realities of health-care delivery and utilization in the country in question is accounted for, so the programme will be well adapted to the local context.
- The people who will be required to manage and provide the services will have ownership of the programme and a personal interest in its success.
- Stakeholders with leadership potential can be identified and provided with further training as needed to fulfil leadership roles within the new programme at the national, regional or district levels.

A particular consideration with screening programmes is that while their cost-effective operation requires a large proportion (75 per cent or more) of the target population to be regularly screened,<sup>9</sup> they specifically recruit people who are not sick and therefore have little motivation to see a health-care provider. Meanwhile, the political and economic changes in the EECA region over the past 25 years have led to a fundamental change in the locus of responsibility for one's health from the state to the individual, so the decision to attend for screening is now entirely personal. As a result, any real or perceived barriers to accessing screening services will decrease participation rates, so these programmes need to be designed to optimize their accessibility, convenience and appeal to the target population. In addition, they need to be supported by effective educational and promotional programmes that will motivate participation.

In most EECA countries, PHC facilities constitute the largest health-care networks, so accessibility can be maximized if screening is delivered at this level. People with abnormal screening test results can then be referred to the secondary or tertiary levels for follow-up, as such abnormal results indicate the presence of disease, and so individual motivation to attend should be higher. However, accessibility is not the only factor that influences screening participation, and it is also necessary to provide services that are convenient and welcoming so people are not discouraged from attending. To do this, it is essential to understand the knowledge, attitudes, beliefs and practices of both health-care providers and the target population so this information can be used to design client-oriented services and health education/promotion programmes to maximize screening participation.

In summary, this means that implementing a successful organized cervical screening programme in the EECA region is particularly challenging. It therefore requires the active engagement of all national stakeholders from the very beginning of the process, and then national expertise must be complemented by support from intergovernmental organizations such as the World Health Organization (WHO), UNFPA Country Offices and the UNFPA EECA, international organizations such as the ECCA, as well as partner organizations in other countries that have already developed successful cervical screening programmes and are willing to share their expertise. This roadmap sets out the process by which this can be achieved.

## 2. Cervical Cancer Screening

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### 2.1 The Principles of Cancer Screening

The objective of cancer screening is to identify people within an asymptomatic target population who have precancerous lesions or early-stage cancers so treatment can be started early to reduce morbidity and mortality. Therefore, cancer screening is a complex multistep process that includes:

- Identification and characterization of the screening target population.
- Recruitment for screening by direct (invitational) and indirect (public health education and promotion to raise awareness and encourage participation, primary health-care counselling, etc.) methods.
- Pre-screening counselling and assessment of individual cancer risk.
- Conducting screening tests.
- Processing screening tests.
- Using screening test results together with an individual's personal history and clinical profile to plan subsequent care:
  - Routine recall for screening.
  - Short recall for rescreening.
  - Referral for follow-up tests or treatment.
- Assessment of follow-up results, planning subsequent care, and monitoring patient compliance until the person is eventually returned to routine screening recall or is discharged from the screening programme.

Cancer-screening programmes can yield substantial benefits, such as up to 80 per cent reductions in cervical cancer incidence and mortality. However, optimal reductions in cancer rates will only be seen if a large proportion (75 per cent or more) of the target population is regularly screened, all the component services are of high quality, all the services are efficiently coordinated and all people with a positive screening test are followed up to establish a definitive diagnosis and to treat any clinically relevant disease.<sup>10, 11</sup>

An important consideration is that while cancer-screening programmes can provide substantial benefits, they can also cause a wide range of harms.<sup>12</sup> These harms are rare in well-organized programmes, but screening is applied to entire populations, so the number of people affected can still be very large. The harms inherent in cancer screening programmes are summarized in **Table 1** below.

**Table 1: Harms Inherent in Cancer Screening Programmes**

1	False negative screening test results leading to delays in cancer diagnosis or treatment.
2	False positive results leading to unnecessary stress, anxiety and invasive diagnostic procedures that carry a risk of complications.
3	Overdiagnosis through the identification of disease with no true malignant potential or that would not become clinically relevant during the individual's lifetime.
4	Overtreatment through the treatment of disease with no true malignant potential or that would not become clinically relevant during the individual's lifetime.
5	Unnecessary adverse sequelae such as premature membrane rupture and premature delivery in women who have been treated for cervical intraepithelial neoplasia (CIN).
6	Unnecessary costs arising from all of the above, which take health-care resources away from services that could otherwise provide greater benefits for the population.

## 2.2 Opportunistic vs. Organized Cancer Screening

### 2.2.1 Opportunistic Cancer Screening

Opportunistic screening occurs when people are screened at their own request or while visiting a doctor for other reasons, but there is no system in place to recruit patients, monitor their screening or follow-up attendance, coordinate service provision or ensure that all the component services are of high quality.

Opportunistic screening can produce substantial disease reductions, but these are seen only in high-resource countries where a large proportion of the target population regularly interacts with the health system, there are reliable mechanisms for patient referral and follow-up, and the health services are all of high quality.

Nonetheless, even in these settings, opportunistic screening has been shown to overscreen women from higher socioeconomic groups who are at lower risk of developing cancer but underscreen women from vulnerable groups who are at higher risk. This is an important issue because every screening test has an optimal screening interval that has been set to maximize the benefits and minimize the harms. Therefore, screening too frequently provides little additional protection but does increase potential harms and the costs for the health-care system, while underscreening obviously provides less protection. As a result, opportunistic screening yields suboptimal disease reductions (or even no disease reductions at all), increases the harms of screening, perpetuates or increases health inequalities and wastes health-care resources.

### 2.2.2 Organized Cancer Screening

Organized screening programmes are designed specifically to maximize the benefits while minimizing the harms for the populations being screened. The foundation of an organized screening programme is a central administration with the authority, resources and budget to ensure:

- Broad and equitable coverage of the target population.
- Adherence to the recommended screening age range and interval.

- Optimal coordination and quality of all the services involved in the screening programme from recruitment to the follow-up and treatment of people with a positive screening test result.

As a result, organized cancer screening programmes provide the optimal balance between benefits and harms of screening, ensure that the benefits are equitably delivered across the entire target population and deliver the most cost-effective disease reductions. For these reasons, the various European guidelines for breast, cervical and colorectal screening all state that screening should only be delivered through organized programmes. The key elements of an organized screening programme are summarized in **Table 2**.

**Table 2: Key Elements of an Organized Cancer Screening Programme**

1	An official policy document that specifies the structure and operation of the screening programme (the Cervical Screening Guidelines).
2	A central administration (the Screening Coordination Office) with the authority and resources needed to coordinate all elements of the screening process, including recruitment, recall, follow-up, monitoring and quality assurance (QA).
3	A stable budget sufficient for the ongoing costs of all of the services required to deliver the programme.
4	Access to an up-to-date database of the target population for recruitment, recall and QA.
5	A central screening registry to collect, store and analyse the data needed to manage the programme (target population identification and contact data, screening call or recall attendance, screening test results, follow-up procedure/test results, treatment outcomes, etc.).
6	Access to cancer registry data for QA and screening programme audits.
7	Evidence-based training curricula, clinical guidelines, standard operating procedures (SOPs), performance indicators and standards.
8	A comprehensive QA system covering the entire screening process from initial recruitment until return to routine screening recall or discharge from the screening programme.
9	Primary, residency and continuing medical education (CME) modules on cancer screening for health-care providers.
10	Health education and health promotion programmes for the general public to motivate screening programme participation.
11	Mechanisms to identify and recruit people from vulnerable groups.

### 3. Implementing New National Health-Care Programmes

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The implementation of any new health programme is challenging because health systems are complex networks with many interconnected components and with each component having many stakeholders, including the public targeted by the programme. As a result, the implementation process must do more than simply account for the clinical or scientific elements, but must also account for the interests, motivations and alliances of these stakeholders.<sup>13-15</sup> An evaluation of PHC reform in Bosnia and Herzegovina identified several elements that were essential to the adoption and diffusion of the reforms:<sup>16</sup>

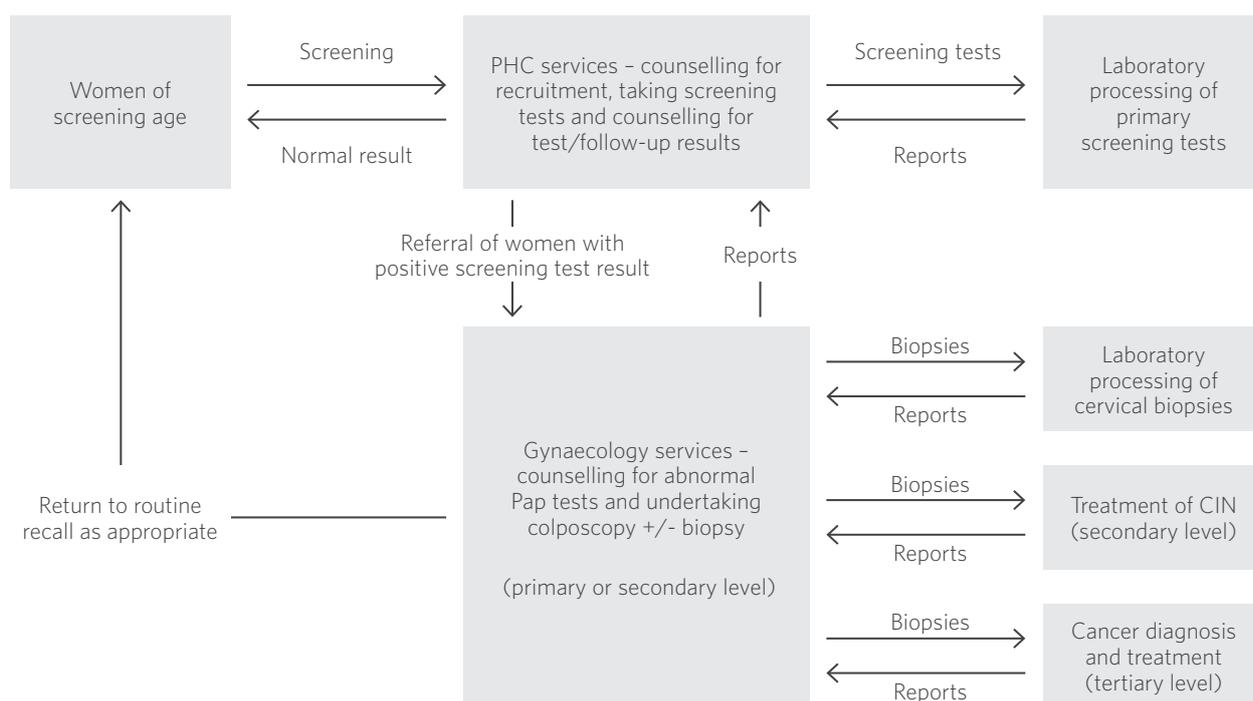
- Regular interaction and communication between the implementers and stakeholders.
- Recognizing the interests of the stakeholders and aligning programme benefits with their interests.
- Recognizing the interests of the public and aligning programme benefits with their interests.
- Ensuring that all stakeholders fully understand the benefits that will be realized.
- Allowing for the reforms to be adapted to the local context was described as “critical”.

A special consideration with population-based screening programmes in the EECA region is that while they require a large proportion (75 per cent or more) of the target population to be regularly screened,<sup>17</sup> they specifically recruit people who are not sick and therefore have little motivation to see a health-care provider. Meanwhile, the political and economic changes in the EECA region over the past 25 years have led to a fundamental change in the locus of responsibility for one’s health from the state to the individual, so the decision to attend for screening is now entirely personal. As a result, any real or perceived barriers to accessing screening services will decrease participation rates, so these programmes need to be designed to optimize their accessibility, convenience and appeal to the target population. In addition, they need to be supported by effective educational and promotional programmes that will motivate participation.

In most EECA countries, PHC facilities constitute the largest health-care networks, so accessibility can be maximized if screening is delivered at this level. People with abnormal screening test results can then be referred to the secondary- and tertiary-level health facilities for follow-up, as such abnormal results indicate the presence of disease, so individual motivation to attend should be higher. However, accessibility is not the only factor that influences screening participation, and it is also necessary to provide services that are convenient and welcoming so people are not discouraged from attending. To do this, it is essential to understand the knowledge, attitudes, beliefs and practices of both health-care providers and the target population so this information can be used to design client-oriented services and health education/promotion programmes to maximize screening participation.

For cervical screening, this means that implementing an organized screening programme is particularly challenging because it requires the coordinated interaction of multiple health services at all levels of the health system so the number of stakeholders is large and the interactions between them complex (see **Figure 1**). This also means that capacity-building needs to address all the required services simultaneously, as suboptimal performance of any service or poor coordination between the services will reduce the programme's effectiveness, even to the point that it has no effect at all but still consumes substantial health-care resources.

Figure 1: Cervical Screening Algorithm



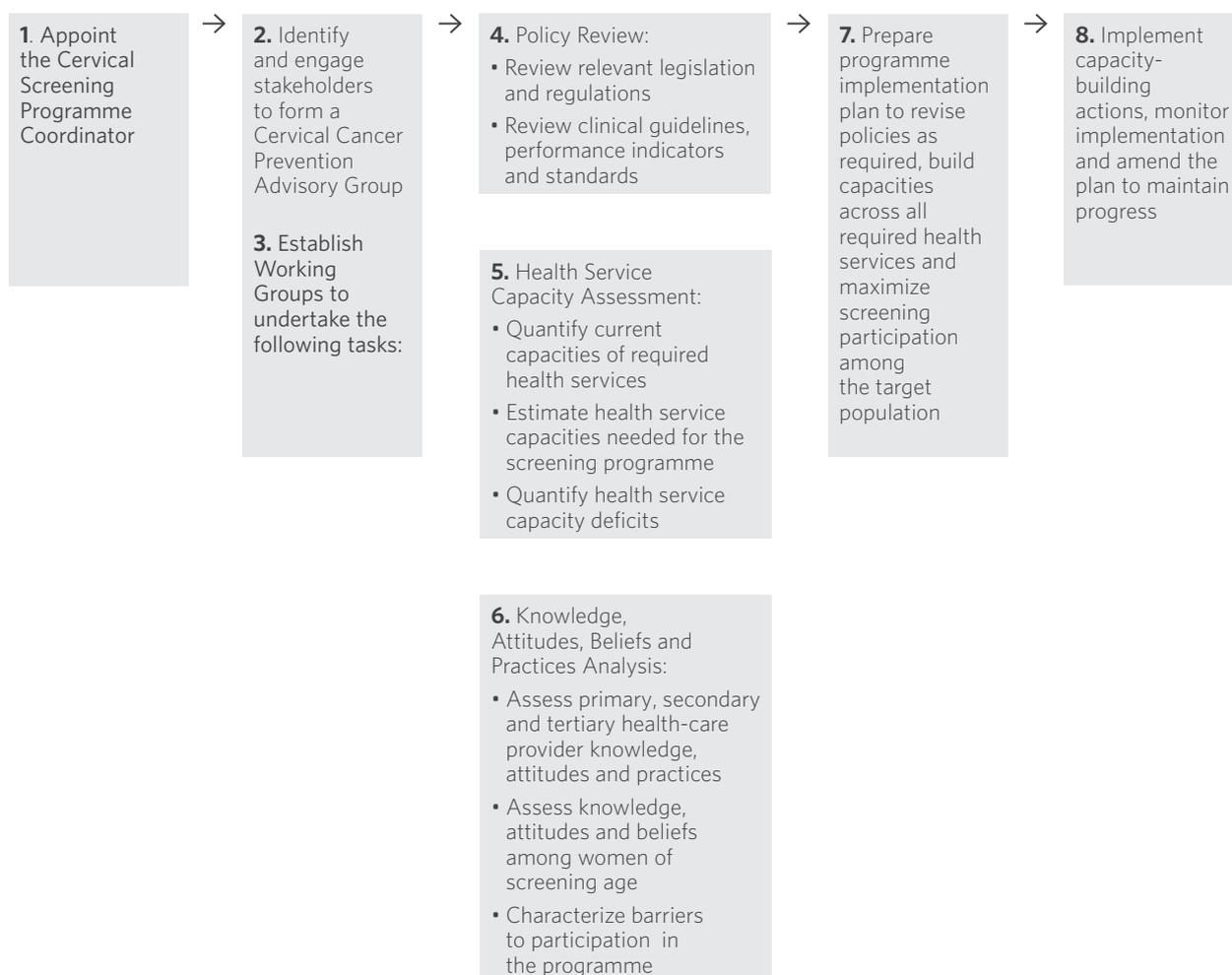
A final consideration is that implementing an organized cervical screening programme (with a focus on client-oriented services, the coordinated interaction of multiple health services, the efficient exchange of personal medical information between health services and strict QA) will demonstrate the importance of these procedures to health-care providers at all levels of the health system and encourage their application to other health services, which will contribute to strengthening the overall health system.

## 4. Summary of the Process of Planning an Organized Cervical Screening Programme

Planning the implementation of an organized cervical screening programme starts with the appointment of a Cervical Screening Programme Coordinator, who will:

- Identify and engage all relevant stakeholders to form a Cervical Cancer Prevention Advisory Group.
- Form working groups to collect and analyse the data required to prepare the implementation plan.
- Lead the stakeholders through the process of designing, planning and implementing the programme.

Figure 2: Key Steps to Preparing a Plan to Implement an Organized Cervical Screening Programme



## 4.1 Appoint a Cervical Screening Programme Coordinator

### 4.1.1 Objectives

To have a person with the required knowledge and skills officially appointed and given the authority needed to successfully lead a diverse group of stakeholders through the process of designing, planning and implementing an organized cervical screening programme. To increase accountability, this should be the same person who will also be responsible for managing the screening programme once it has been implemented.

### 4.1.2 Actions

A person with appropriate qualifications, skills and experience will be officially appointed as the Cervical Screening Programme Coordinator. This position requires a medically qualified professional with clinical experience in one or more of the required health services (PHC, cytology/pathology, gynaecology/colposcopy, gynaecological oncology, etc.), as well as in the administration of a cancer screening service or a population-based public health programme. This experience must be from the country implementing the screening programme, as a detailed knowledge of health-care delivery in the country is essential. In addition, a good working knowledge of English is required, as the Programme Coordinator will need to communicate with organizations in Western Europe to facilitate the exchange of documents, knowledge and skills. Depending on the qualifications of the person selected, additional training (such as exchanges with organized cervical screening programmes in other countries) could be arranged through the WHO, UNFPA EECARO, ECCA and other partner organizations to strengthen their knowledge and skills, and enhance their authority within their home country.

## 4.2 Stakeholder Identification and Engagement

### 4.2.1 Objectives

To identify all stakeholders that will have a role to play in the operation of the organized cervical screening programme and actively engage them in its design, planning and implementation to ensure that:

- Their knowledge of the realities of health-care delivery and utilization in the country is accounted for so the programme will be well adapted to the local context.
- The people who will be required to manage and provide the screening services will have ownership of the programme and a personal interest in its success.
- Stakeholders with leadership potential can be identified and provided with further training as needed to fulfil leadership roles within the screening programme at the national, regional or district levels.

### 4.2.2 Actions

The first task of the Programme Coordinator will be to identify and engage all relevant stakeholders. The stakeholders that should be involved in this process will depend on the structure of the health system in the country, but will likely include representatives of some or all of the following organizations:

- The national Ministry of Health, including departments responsible for PHC, gynaecology/colposcopy, cytology/pathology, oncology, public health and health education.
- Regional or municipal Departments of Health, including departments responsible for PHC, gynaecology/colposcopy, cytology/pathology, oncology, public health and health education.
- National, regional or municipal health insurance programmes.
- National, regional or municipal health QA programmes, including agencies responsible for establishing clinical performance indicators and standards, facility standards, etc.
- Medical universities and colleges, including the departments of family medicine, gynaecology/colposcopy, cytology/pathology, oncology, public health, health education, nursing and midwifery.
- Medical associations or societies for family physicians, gynaecologists/colposcopists, cytologists/pathologists, oncologists, public health practitioners, health educators, nurses and midwives.
- Private-sector providers of relevant medical services (taking screening tests, follow-up of abnormal screening tests, treatment of CIN, treatment of cancer).
- Non-governmental organizations (NGOs), health mediators, patient groups, etc. involved in assessing health knowledge and awareness among providers and women, improving health service access and utilization among vulnerable groups, improving women's health, reproductive health, disease prevention, cancer prevention, etc.

Representatives of all relevant organizations will be actively involved in the design, planning and implementation of the screening programme through their participation in a series of programme coordinating meetings and working groups.

#### 4.2.2.1 First Programme Coordinating Meeting

- Inform all stakeholders about the launch of a project to implement an organized cervical screening programme and explain the process by which it will be designed, planned and implemented.
- Educate all stakeholders about:
  - The structure, operation and benefits of organized cervical screening programmes.
  - The role that each of the required health services and organizations will play, and that effective coordination and cooperation between them will be essential for programme success.
- Discuss and agree cervical cancer prevention targets and the time frames for their achievement.

- Have the stakeholders:
  - Identify any barriers they see to the implementation or operation of the screening programme.
  - Identify any other organizations that should be included in the process.
- Establish working groups to collect and analyse the data needed to design, plan and implement the cervical screening programme:
  - Policy Review Working Group: evaluate existing policy documents, laws, regulations, clinical guidelines, SOPs, performance indicators, performance standards, etc. for their compatibility with the operation of an organized cervical screening programme so that areas where amendments are required or gaps where new instruments are needed can be identified.
  - Capacity Assessment Working Group: quantify the capacities of existing health services, estimate the capacities that will be needed to achieve the cervical cancer prevention targets agreed above and calculate the capacities that must be developed.
  - Knowledge, Attitudes, Beliefs and Practices Working Group: assess knowledge, attitudes, beliefs and practices regarding cervical screening among primary, secondary and tertiary health-care providers and among women of cervical-screening age to identify barriers and enablers for screening programme participation.

#### 4.2.2.2 Second Programme Coordinating Meeting

- Review and discuss the outcomes and conclusions of the three working groups;
- Review, discuss and agree the working groups' proposals for removing or overcoming barriers, building capacities, educating health-care providers and motivating public participation in the screening programme.
- Reconvene the working groups to revise and finalize their proposals based on the discussions at this meeting, and then distribute the final proposals to all stakeholders in advance of the third coordinating meeting.

#### 4.2.2.3 Third Programme Coordinating Meeting

- Review, confirm and approve the final proposals for removing or overcoming barriers, building capacities, educating health-care providers and motivating public participation in the screening programme;
- Discuss and agree the overall structure, organization and timelines for the implementation plan;
- Establish a multidisciplinary team, including representatives of the three working groups, to prepare the final implementation plan and then distribute it to all stakeholders for review and approval. If further revisions are required, then this step can be repeated.

While it is not essential to include all stakeholders in all aspects of preparing the implementation plan, it is advisable to involve all of them in each of the coordinating meetings, as these play an important role in:

- Educating stakeholders about the structure, operation and benefits of organized cervical screening programmes.
- Building relationships of trust between the stakeholders that will facilitate the co-operation needed to implement and operate the programme.

## 4.3 Policy Review Working Group

### 4.3.1 Objectives

To identify any policy barriers to the implementation or operation of an organized cervical screening programme and to prepare proposals by which these barriers can be removed or overcome.

### 4.3.2 Actions

The Policy Review Working Group (PRWG) will be established at the first coordinating meeting to evaluate existing policies, laws, regulations, clinical guidelines, SOPs, performance indicators and standards (see **Appendix 1**) for their compatibility with the operation of an organized cervical screening programme, and propose amendments or new instruments where required. A person with relevant knowledge, skills and experience will be appointed as its head. If required, international experts who understand the local context will be appointed to advise the PRWG. The PRWG will then:

- Where relevant instruments exist, review them to identify potential barriers to the operation of an organized cervical screening programme and draft amendments to be considered at the second coordinating meeting.
- Where relevant instruments do not exist, draft new ones to be considered at the second coordinating meeting.

#### 4.3.2.1 National Cancer Control Strategies

National cancer control strategies are important policy documents in that they establish the overall framework for addressing cancer prevention, help to unite stakeholders around a common strategy and prioritize the actions to be undertaken. Equally important, these documents facilitate the allocation of funding and the passing of laws that are required to implement and operate cancer prevention programmes. Finally, both the strategies and the legislation are important tools to maintain progress with the implementation of programmes when governments or their priorities change.

Among the 17 countries, territories and entities participating in the UNFPA EECARO situation analysis for the implementation of organized cervical cancer prevention programmes in the EECA region, 12 had prepared and approved national cancer control strategies.<sup>18</sup> All of these strategies made some reference to the prevention of cervical cancer and/or cancers of the female reproductive tract, and seven had separate sections or strategies focused on the prevention of cervical cancer. However, none of these specifically addressed either the implementation or the operation of *organized* cervical screening programmes, so suitable provisions should be included in the national cancer control strategies to ensure that these organized cervical screening programmes are properly integrated into overall cancer prevention strategies.

**Table 3: National Cancer Control Strategies**

1	The head of the PRWG will contact Western European countries to obtain recent examples of the provisions for cervical cancer that are contained in their national cancer control strategies and send these to the members of the PRWG for review.
2	The head of the PRWG will convene meetings of the PRWG members to prepare draft proposals for the inclusion of cervical cancer prevention within the national cancer control strategies and send these to all stakeholders for review before the second coordinating meeting.

#### 4.3.2.2 Cervical Screening Guidelines

Organized cervical screening programmes require effective coordination and cooperation among all the required health services and related organizations, together with strict QA of each. However, a lack of clarity about legal frameworks and regulations, health-care provider roles and responsibilities, QA procedures, etc. has been identified as a barrier to achieving this coordination and cooperation in some EECA countries.<sup>19-21</sup> It is therefore necessary for the structure and operation of these programmes to be fully and clearly defined in official policy documents specifying:

- The duties, responsibilities and authority of the Cervical Screening Programme Coordinator.
- The management structure of the screening programme together with clear lines of authority and responsibility.
- The target age group(s), screening interval(s), screening tests, follow-up pathways, etc.
- The responsibilities of each of the health services and related organizations, and how they will interact.
- How the component health services and related organizations will be quality-assured.
- The source(s) of funding and budget(s) for each of the required services.

**Table 4: Cervical Screening Guidelines**

1	The head of the PRWG may request support from the WHO, UNFPA, ECCA and other partner organizations to identify internationally recognized cervical screening programmes, obtain examples of their national cervical screening guidelines and send these to the members of the PRWG for review.
2	<p>The head of the PRWG will convene meetings:</p> <ul style="list-style-type: none"><li>▪ In countries that have national cervical screening guidelines:<ul style="list-style-type: none"><li>- To compare the obtained examples to the national guidelines and, if required, prepare proposals to update or amend them.</li></ul></li></ul> <p>To send proposed amendments to all stakeholders for review before the second coordinating meeting.</p> <ul style="list-style-type: none"><li>▪ In countries that do not have national cervical screening guidelines:<ul style="list-style-type: none"><li>- To review the obtained examples and evaluate their applicability to the local context.</li><li>- To use the examples (where applicable) as models to prepare draft national cervical screening guidelines.</li><li>- To Send draft cervical screening guidelines to all stakeholders for review before the second coordinating meeting.</li></ul></li></ul>

### 4.3.2.3 Conflicts between the Cervical Screening Guidelines and Existing Legislation and Regulations

While opportunistic cervical screening exists in all EECA countries, organized cervical screening programmes are rare. Therefore, existing health-sector legislation and regulations in most EECA countries will not have considered the specific requirements of these programmes and may prevent their cost-effective operation. For one example, taking cervical samples for screening is restricted to gynaecologists in some countries, although there are not enough gynaecologists to provide these services to the entire target population. For another example, even in the EECA countries that have prepared cervical screening guidelines, some have laws or regulations that prevent these guidelines from being fully applied.

It is therefore necessary to identify all existing laws and regulations that may affect the operation of an organized cervical screening programme, review them to identify potential conflicts with the national cancer control strategy and the cervical screening guidelines, and draft amended or new instruments to be submitted to the relevant authorities for review and approval.

**Table 5: Review of Laws and Regulations for Conflicts with the Cervical Screening Guidelines**

1	<p>The head of the PRWG will:</p> <ul style="list-style-type: none"> <li>▪ Contact national stakeholders to obtain copies of laws or regulations affecting the health services required to deliver an organized cervical screening programme, such as: <ul style="list-style-type: none"> <li>- Standardization and submission of data regarding cancer incidence and mortality to cancer registries.</li> <li>- Responsibilities for payments to health service providers.</li> <li>- Electronic transfer of personal medical information between health services.</li> <li>- Delivery of cervical screening services by PHC providers.</li> <li>- Designation of cervical cytology screening as a distinct laboratory speciality with a defined training curriculum, evaluation/certification procedures, CME requirements and QA policy.</li> <li>- Designation of colposcopy as a specific speciality/subspeciality with a defined training curriculum, evaluation/certification procedures, CME requirements and QA policy.</li> <li>- Mandatory use of clinical guidelines and SOPs.</li> <li>- Mandatory participation in QA programmes, including the use of performance indicators and performance standards, together with clearly defined mechanisms and lines of authority for resolving substandard performance.</li> <li>- Use of incentives or payments for achieving performance standards.</li> </ul> </li> <li>▪ Send these to the members of the PRWG for review.</li> </ul>
2	<p>The PRWG members will review the laws and regulations to identify potential conflicts or gaps relating to the implementation or operation of an organized cervical screening programme and send their comments to the head of the PRWG.</p>
3	<p>The head of the PRWG (together with international experts as required) will analyse the replies and classify the laws and regulations:</p> <ul style="list-style-type: none"> <li>▪ Those requiring no further action.</li> <li>▪ Those requiring review and amendment.</li> <li>▪ Gaps requiring new laws or regulations.</li> </ul>
4	<p>Laws or regulations requiring review and amendment together with the requirements for new instruments will be sent to the relevant clinical organizations or medical-legal experts, who will prepare proposals for amended or new instruments. These will be returned to the head of the PRWG, who will distribute them to the members of the PRWG for review.</p>

Table 5: Review of Laws and Regulations for Conflicts with the Cervical Screening Guidelines (continued)

**Table 5: Review of Laws and Regulations for Conflicts with the Cervical Screening Guidelines**

5	<p>The head of the PRWG will convene a meeting of the PRWG members, medical-legal experts, representatives of the relevant medical associations and international experts to:</p> <ul style="list-style-type: none"><li>▪ Review the conflicts/gaps identified with the laws and regulations together with the proposed amended/new instruments.</li><li>▪ Discuss and agree the final proposals for amended or new instruments, ensuring compatibility with national clinical practice, the national cancer control strategy, the cervical screening guidelines, WHO guidelines<sup>22</sup> and international best practice.</li></ul>
6	<p>Based on the outcomes of this meeting, the head of the PRWG will work with relevant clinical and legal experts to prepare draft texts for amended or new laws or regulations.</p>
7	<p>Send the proposed final texts to all stakeholders for review before the second coordinating meeting.</p>

#### 4.3.2.4 Clinical Guidelines, Standard Operating Procedures, Performance Indicators and Standards

The UNFPA EECARO situation analysis found that very few EECA countries have national clinical guidelines, SOPs, performance indicators or performance standards for any of the health services involved in cervical screening.<sup>23</sup>

It is therefore necessary to review and update the existing instruments in the few countries that do have them and to prepare new ones for the countries that do not, while ensuring compatibility with national clinical practice, the national cancer control strategy, the cervical screening guidelines, WHO recommendations and international best practice.

**Table 6: Clinical Guidelines, SOPs, Performance Indicators and Performance Standards**

1	<p>The head of the PRWG may request support from the WHO, UNFPA, ECCA or other partner organizations to identify internationally recognized organized cervical screening programmes, obtain examples of their national clinical guidelines, SOPs, performance indicators and performance standards for the health services involved in cervical screening and send these to the members of the PRWG for review.</p>
2	<p>The head of the PRWG will convene meetings:</p> <ul style="list-style-type: none"><li>▪ In countries that have national clinical guidelines, SOPs, performance indicators and performance standards:<ul style="list-style-type: none"><li>- To compare the obtained examples to the national versions and, if required, prepare proposals for amendments.</li><li>- To send proposed amendments to all stakeholders for review in advance of the second coordinating meeting.</li></ul></li><li>▪ In countries that do not have national clinical guidelines, SOPs, performance indicators and performance standards:<ul style="list-style-type: none"><li>- To review the obtained examples and evaluate their applicability to the local context.</li><li>- To use these examples (where applicable) as models to prepare proposals for national clinical guidelines, SOPs, performance indicators and performance standards.</li><li>- To send proposals to all stakeholders for review before the second coordinating meeting.</li></ul></li></ul>

## 4.4 Capacity Assessment Working Group

### 4.4.1 Objectives

To characterize the existing structural barriers to the implementation of an organized cervical screening programme and to prepare proposals by which these barriers can be removed or overcome.

### 4.4.2 Actions

In order to plan for the implementation of an organized cervical screening programme, it is necessary to:

- Quantify the current capacities of the administrative and clinical services that are required to deliver the screening programme, together with the existing national training capacities for each of these services.
- Estimate the service capacities needed to achieve the cancer prevention targets agreed at the first coordinating meeting.
- Calculate the capacity development requirements by comparing the existing capacities to the capacities needed to achieve the cancer prevention targets.
- Evaluate the proportion of capacity development that can be met by the existing national training institutions, where these national training capacities can be strengthened to meet both the short-term and the ongoing needs of the screening programme, and where external training resources are needed to fill capacity gaps in the short term.

The Capacity Assessment Working Group (CAWG) will be established at the first coordinating meeting, and a person with relevant qualifications, skills and experience will be appointed as its head. If required, international experts who understand the local context will be appointed to advise the CAWG. Cervical screening capacity assessment guides are included in **Appendix 2**, and data collection forms are included in **Appendix 3**, while the key actions to be undertaken by the CAWG are summarized in **Table 7** below.

**Table 7: Capacity Assessment of Health Services Required for Cervical Screening**

- 1 The head of the CAWG will distribute the capacity assessment data collection forms to representatives of the health services involved in cervical screening who will submit data about the existing capacities of their health services, including:
- Cervical screening programme management:
    - Number and distribution of staff with the qualifications and experience needed to manage population-based health programmes.
    - Training capacities for health service administrative staff.
    - Health information system capacities (re: the cervical screening registry).
  - PHC:
    - Number and distribution of PHC facilities stratified by number of health-care providers employed and size of the attached population.
    - Number and distribution of health-care providers stratified by qualifications (PHC gynaecologist, family physician, GP/therapist, family medicine nurse, general nurse and midwife).
    - Training capacities for nurses, family medicine nurses, general practitioners (GPs)/therapists and family physicians.
    - CME training capacities for nurses, family medicine nurses, GPs/therapists and family physicians.
  - Cytology/cytopathology:
    - Number and distribution of laboratories stratified by the maximum number of cytology samples that could be processed.
    - Number and distribution of laboratory staff stratified by qualifications (cytology technician, cytology screener, cytopathologist).
    - Training capacities for cytology technicians, cytology screeners and cytopathologists.
    - CME training capacity for cytology screeners and for pathologists to qualify as cytopathologists.
    - Inventories of relevant equipment in each laboratory.
  - Colposcopy and treatment of cervical intraepithelial neoplasia (CIN):
    - Number and distribution of colposcopy clinics stratified by the number of staff and the maximum number of patients that could be examined.
    - Number and distribution of colposcopists stratified by qualifications (gynaecology residency vs. colposcopy specialist training).
    - Training capacity for colposcopy specialists within gynaecology residency programmes.
    - CME training capacity for gynaecologists to qualify as colposcopists.
    - Inventories of relevant equipment in each clinic.
  - Gynaecological pathology:
    - Number and distribution of pathology laboratories stratified by the maximum number of samples that could be processed.
    - Number and distribution of laboratory staff stratified by qualifications (pathology technician, pathologist, gynaecological pathologist).
    - Training capacity for pathology technicians, pathologists and gynaecological pathology specialists.
    - CME training capacity from pathologists to qualify as gynaecological pathology specialists.
    - Inventories of relevant equipment in each laboratory.
  - Cancer registries:
    - Number and distribution of cancer registries.
    - Year each registry started operating.
    - Coverage of the local and/or national population, and abilities to aggregate data at the national level.
    - Affiliations with the European and/or International Association of Cancer Registries.
  - Death registries:
    - Number and distribution of death registries.
    - Year each registry started operating.
    - Coverage of the local and/or national population, and abilities to aggregate data at the national level.
    - Procedures for registration of deaths from cancer.

**Table 7: Capacity Assessment of Health Services Required for Cervical Screening (continued)**

**Table 7: Capacity Assessment of Health Services Required for Cervical Screening**

2	The head of the CAWG will collate the data received and contact stakeholders to obtain missing data or clarify outstanding issues.
3	The head of the CAWG, together with international experts if required, will: <ul style="list-style-type: none"><li>Analyse the data to produce a summary of the capacities and distribution of the existing health services.</li><li>Estimate the health service capacities needed to achieve the agreed cervical cancer prevention targets.</li><li>Calculate the capacity development requirements by comparing the existing capacities to future needs.</li></ul>
4	The head of the CAWG will convene a meeting of CAWG members, representatives of relevant medical associations and international experts to: <ul style="list-style-type: none"><li>Review the capacity gaps and capacity development requirements.</li><li>Discuss and agree proposals to develop the required capacities, ensuring compatibility with national clinical practice, the national cancer control strategy, the cervical screening guidelines, WHO recommendations and international best practice.</li></ul>
5	The head of the CAWG, together with international experts if required, will prepare a report summarizing the working group outcomes and send it to all stakeholders for review before the second coordinating meeting.

### 4.4.3 European Network of Expertise in Cervical Cancer Screening

Building capacity simultaneously across multiple health services requires access to an enormous amount of training expertise. Fortunately, a number of Western European countries have high levels of expertise and knowledge across all the required specialities, with some countries being global leaders in organized cervical screening. To facilitate access to these resources, the UNFPA EECARO and the ECCA developed the European Network of Expertise in Cervical Screening by identifying and cataloguing the training opportunities available in Western Europe to:

- Provide access to the full range of expertise needed to undertake training across multiple health services while spreading the workload among different Western European partners.
- Allow the training activities to be coordinated according to the needs set out in the implementation plan so the benefits can be maximized.
- Reduce the costs of capacity development by accessing training resources that have already been established in Western European countries.

## 4.5 Knowledge, Attitudes, Beliefs and Practices Working Group

### 4.5.1 Objectives

To characterize the systemic, cognitive and psychosocial barriers to participation in cervical screening from the perspectives of both health-care providers and women of screening age, and to prepare proposals to remove or overcome these barriers.

### 4.5.2 Actions

In the few Eastern European countries that have implemented organized cervical screening

programmes following the European Guidelines for Quality Assurance in Cervical Screening<sup>24</sup> (Estonia, Poland, Latvia, Lithuania), recruitment has remained far too low (36 per cent or less) to have a measurable impact on cancer rates.<sup>25</sup> Meanwhile, the UNFPA EECARO situation analysis found that the former Yugoslav Republic of Macedonia and Turkey have organized invitational cervical screening programmes,<sup>26</sup> although a separate review of cervical screening in the former Yugoslav Republic of Macedonia found that response to invitation was low (10-15 per cent), with most women screened opportunistically.<sup>27</sup>

These data indicate that the screening recruitment strategies currently accepted as international best practice (but that are based predominately on data from high-income countries with well-resourced, effective and accessible health systems) are not directly transferable to the countries of the EECA region. Given that screening recruitment rates of 75 per cent or more are required to maximize both effectiveness and cost-effectiveness, there is an urgent need to develop recruitment strategies that will work in the EECA region. However, doing this requires a full understanding of the barriers and enablers of screening participation from the perspectives of both the health-care providers delivering these services and the women who should use them.<sup>28</sup>

The Knowledge, Attitudes, Beliefs and Practices Working Group (KABPWG) will be established at the first coordinating meeting, and a person with relevant qualifications, skills and experience will be appointed as its head. If required, international experts who understand the local context will be appointed as advisers.

#### 4.5.2.1 Health-Care Provider Knowledge, Attitudes and Practices

Health-care providers have the power to influence cervical screening participation through the education and reassurance of women, as well as through the provision of client-oriented services that are professional, confidential, convenient and welcoming.

The role played by health-care providers in screening recruitment is well illustrated in a study that identified the five systemic barriers to screening that were most frequently classified as “important” or “very important” by women in Bulgaria and Romania (see **Table 8**).<sup>29</sup> It is therefore necessary to assess health-care providers’ knowledge, attitudes and practices relating to cervical screening in order to inform the development of policy strategies and educational modules (for primary, residency and CME programmes) that will help to remove these systemic barriers and increase screening participation.

Table 8: **Systemic Barriers to Cervical Screening in Bulgaria and Romania**

- Doctors only want to see women who are sick.
- Doctors did not recommend cervical screening.
- Gynaecological visits are unpleasant.
- Waiting times were too long.
- The costs of being screened are too high.

**Table 9: Analysis of Health-Care Provider Knowledge, Awareness and Practices**

1	The head of the KABPWG will contact national NGOs, social scientists, etc. involved in the assessment of health-care provider knowledge, awareness and practices relating to cervical screening to obtain the results of any recent studies undertaken in the country and will send these to the members of the KABPWG for review.
2	<p>If no applicable studies are found, the head of the KABPWG will facilitate the undertaking of an analysis of health-care provider knowledge, attitudes and practices relating to cervical screening by:</p> <ul style="list-style-type: none"> <li>• Identifying national or international organizations that have the required expertise.</li> <li>• Supporting these organizations to conduct focus groups, semi-structured interviews, structured interviews and/or surveys with representatives of the different health services involved in cervical screening to collect data and conduct the analyses needed to characterize the providers' views on: <ul style="list-style-type: none"> <li>- Organization and responsibilities for managing cervical screening.</li> <li>- Applicability and use of existing policies, regulations, clinical guidelines, performance indicators, performance standards, etc.</li> <li>- Financing of cervical screening.</li> <li>- Advantages and disadvantages of the existing system and suggestions for change.</li> <li>- Roles and responsibilities of health-care providers vs. those of women regarding cervical screening participation.</li> <li>- Barriers to screening participation at the level of the individual and the health system.</li> <li>- Strategies for promoting screening participation.</li> </ul> </li> </ul>
3	The head of the KABPWG will convene a meeting of the KABPWG members and the representatives of the organization(s) that conducted the study to review the outcomes of the analyses and prepare proposals for policy strategies, organizational changes and educational modules to remove or overcome the systemic barriers to screening participation that have been identified.
4	The head of the KABPWG will send these proposals to all stakeholders for review before the second coordinating meeting.

#### 4.5.2.2 Target Population Knowledge, Attitudes and Beliefs

Cervical screening targets women who are healthy and have little motivation to see a health-care provider. It is therefore necessary to understand the experiences, attitudes and beliefs of the women targeted for screening to characterize the psychological, cognitive and social factors that influence screening programme attendance. This information can then be used to design client-oriented cervical screening services that will meet women's expectations and to prepare health educational and promotional programmes to maximize participation rates.

Table 10: **Analysis of Target Population Knowledge, Attitudes and Beliefs**

1	The head of the KABPWG will contact national NGOs, social scientists, etc. involved in the assessment of women's knowledge, attitudes and beliefs relating to health services generally or cervical screening specifically to obtain the results of any recent studies undertaken in the country and will send these to the members of the KABPWG for review.
2	If no applicable studies are found, the head of the KABPWG will facilitate the undertaking of an analysis of knowledge, attitudes and beliefs relating to cervical screening among women of screening age by: <ul style="list-style-type: none"><li>▪ Identifying national or international organizations that have the required expertise.</li><li>▪ Supporting these organizations to conduct focus groups, semi-structured interviews, structured interviews and/or surveys with women of screening age to collect data and conduct the analyses needed to characterize their views on:<ul style="list-style-type: none"><li>- Accessibility and acceptability of existing cervical screening services.</li><li>- Acceptability of alternatives for the delivery of cervical screening such as family physicians, nurses or midwives vs. gynaecologists.</li><li>- Women's responsibilities for maintaining their health such as an active vs. passive roles, the requirement for personal initiative and proactive behaviour, etc.</li><li>- Responsibility, choice, agency and participation in medical decision-making.</li></ul></li></ul>
3	The head of the KABPWG will convene a meeting of the KABPWG members and the representatives of the organization(s) that conducted the study to review the outcomes of the analyses and prepare proposals for policy strategies and public health education and promotion programmes that can help to remove or overcome the barriers to screening participation.
4	The head of the KABPWG will send the proposals to all stakeholders for review before the second coordinating meeting.

#### 4.6 Review and Confirm Working Group Outcomes

The Programme Coordinator will convene the second coordinating meeting at which the stakeholders will:

- Review and discuss the outcomes and conclusions of the three working groups.
- Review, discuss and agree the proposals for removing or overcoming barriers, building capacities, educating health-care providers and motivating public participation in the screening programme.
- Reconvene the working groups to revise and finalize their proposals based on the discussions at this meeting, and then distribute the final proposals to all stakeholders in advance of the third coordinating meeting.

#### 4.7 Establish a Multidisciplinary Team to Prepare the Implementation Plan

The Programme Coordinator will convene the third coordinating meeting at which the stakeholders will:

- Review, confirm and approve the final proposals for removing or overcoming barriers, building capacities, educating health-care providers and motivating public participation in the screening programme.
- Discuss and agree the overall structure, organization and timelines for the implementation plan.

- Establish a multidisciplinary team, including representatives of the three working groups, to prepare the final implementation plan and then distribute it to all stakeholders for review and approval.

#### 4.8 Submission of Implementation Plan to the Ministry of Health

Once the implementation plan has been approved by all stakeholders (which include representatives of the Ministry of Health), the Programme Coordinator will submit it to the Ministry of Health for review and approval.

## 5. Recommended Structure and Elements of the National Action Plan for the Implementation of Organized Cervical Screening Programmes

As emphasized in the preceding sections, a key principle in the development of a plan for implementing an organized cervical screening programme is the active involvement of all stakeholders to ensure the plan is well adapted to the local context and that the people who will be responsible for delivering these services have ownership of the screening programme and a personal interest in its success. Therefore, the structure and elements included in the plan will vary by country depending on the outcomes of the working groups and coordinating meetings. Nonetheless, this section proposes an overall framework structure for the implementation plan together with examples of the key elements that are likely to be required as indicated by the outcomes of the UNFPA EECARO situation analysis.<sup>30</sup> It would be beneficial if EECA countries engaged in developing an implementation plan followed this framework structure, as this would facilitate the identification of common needs and opportunities for joint capacity-building actions that could be undertaken in partnership with the UNFPA EECARO and the ECCA through the European Network of Expertise in Cervical Screening.

### 5.1 Establish an Administrative Organization to Manage the Cervical Screening Programme

As noted above, the first step in planning for the implementation of an organized cervical screening programme is the appointment of the Cervical Screening Programme Coordinator. However, the management of an organized cervical screening programme is a complex activity that cannot be undertaken by a single person, so a Screening Coordination Office (SCO) will need to be developed as the programme is expanded and screening recruitment increases (see **Table 11**).

**Table 11: Screening Coordination Office Activities**

1	Regularly review and update the cervical screening guidelines.
2	Implement, operate and maintain the cervical screening registry.
3	Send service providers the data they need to coordinate screening call and recall, patient referrals and ensure referral compliance.
4	Work with national medical education institutions to coordinate primary medical education, residency and CME programmes.
5	Design and implement public education and promotion programmes to raise awareness and motivate screening participation.
6	Identify underscreened/unscreened people and implement programmes to increase screening participation.
7	Work with the Ministry of Health, medical education institutions and professional organizations to regularly review and update training standards, certification criteria, clinical guidelines and SOPs, performance indicators and standards.

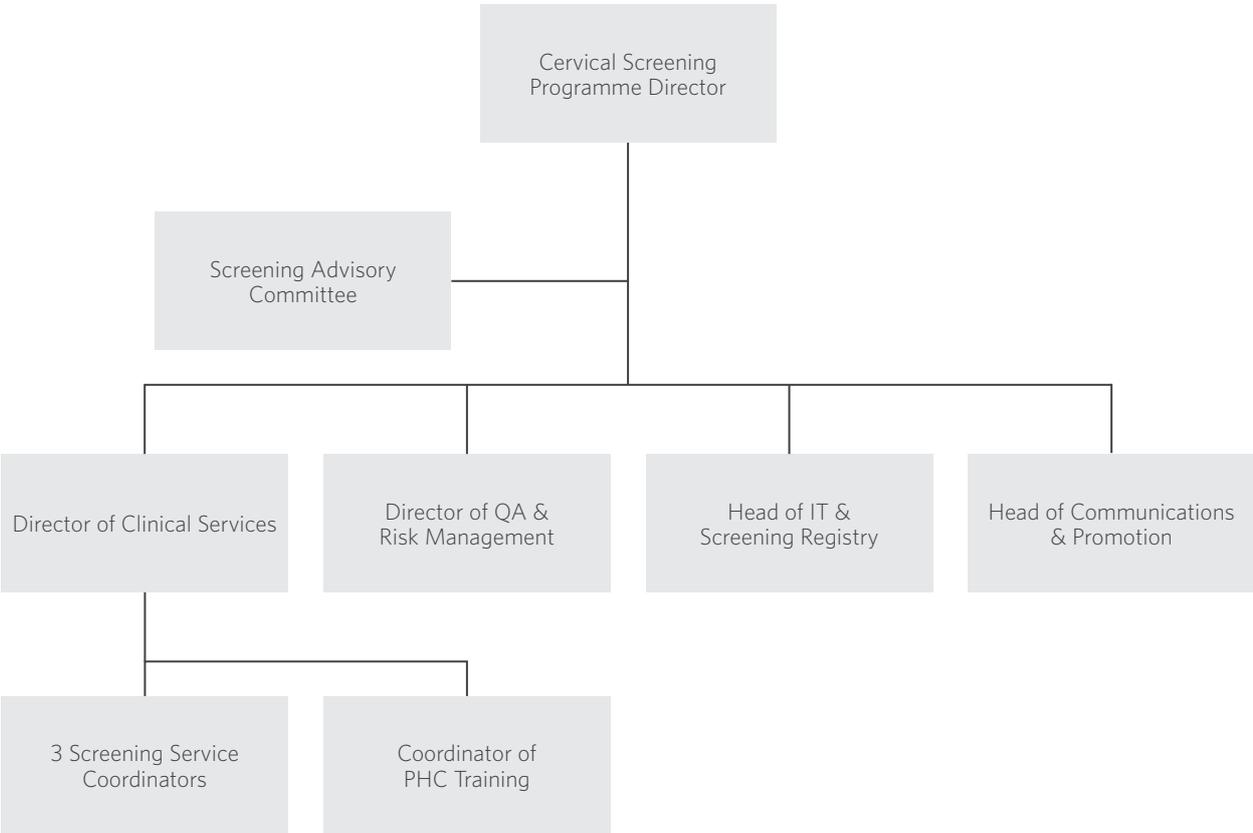
Table 11: Screening Coordination Office Activities (continued)

**Table 11: Screening Coordination Office Activities**

8	Manage the QA process by monitoring and evaluating all aspects of screening programme performance, and intervening as required.
9	Prepare and publish reports on screening programme performance for the Ministry of Health and other organizations.
10	Interact with other health services as required to ensure efficient screening programme operation (e.g. cancer registry).
11	Interact with other governmental departments and non-governmental organizations as required to ensure inter-sectoral cooperation for cancer prevention (such as the Department of Education for the inclusion of cancer prevention in secondary school health curricula).

The key SCO staff positions are noted in **Figure 3** and the roles are self-evident with the exception of the Screening Advisory Committee. This is the same multidisciplinary team set up to prepare the implementation plan but now maintained to facilitate ongoing communications between the SCO and the stakeholders so the programme can be continuously adapted to the needs of each health service and the target population. A further consideration regarding the SCO is that much of the work undertaken would be the same for all population-based screening programmes. Therefore, once the SCO has been established for cervical screening, it can be expanded in a cost-effective way to include screening programmes for breast and colorectal cancers.

**Figure 3: Key Staff for the Screening Coordination Office**



## 5.2 Prepare and Publish Cervical Screening Guidelines

This section of the implementation plan would present the PRWG's proposals for the development and approval of the Cervical Screening Guidelines specifying:

- The duties, responsibilities and authority of the Cervical Screening Programme Coordinator and SCO.
- The management structure of the screening programme, including clear lines of authority and responsibility.
- The target age group(s), screening interval(s), screening tests, follow-up pathways, etc.
- The responsibilities of each of the health services and related organizations, and how they will interact.
- How the required health services and related organizations will be quality-assured.
- The source(s) of funding and budget(s) for each of the component services.

## 5.3 Establish a Cervical Screening Registry

This section of the implementation plan would present the CAWG's proposals for the development of the cervical screening registry. Management of an effective cervical screening programme requires the timely collection and analysis of data from all the health services involved in the programme, together with prompt return of the information these services will need for patient management. The screening registry is the mechanism by which this is achieved, and the data, sources and analyses as recommended in the European Guidelines<sup>29</sup> are included in **Appendix 5**.

## 5.4 Capacity-Building for Primary Health Care

### 5.4.1 Legislative and Regulatory Changes Relating to PHC

This section of the implementation plan would present the PRWG's proposals for amendments to, or the introduction of, any laws and regulations that would affect the involvement of PHC clinics and staff in an organized cervical screening programme.

### 5.4.2 Guidelines and SOPs for PHC

This section of the implementation plan would present the PRWG's proposals for amendments to, or the introduction of, any clinical guidelines or SOPs relating to procedures undertaken by PHC staff working within an organized cervical screening programme. Evidence-based clinical guidelines and SOPs for cervical screening procedures undertaken by PHC staff are essential to ensure that each procedure will produce the expected outcomes and contribute to the effective operation of the screening programme. They are also integral to the standard training curricula, certification criteria, performance standards and QA procedures. The clinical guidelines and SOPs relevant to PHC are set out in **Table 12**.

Table 12: **Cervical Screening Clinical Guidelines and SOPs Relevant to PHC**

1	Service provider operation of the cervical screening registry.
2	Reception and registration of women for screening.
3	Pre-screening counselling of women about the benefits and drawbacks of cervical screening.
4	Assessment of cervical cancer risk and identification of women at increased risk.
5	Taking cervical samples.
6	Submitting cervical samples to the laboratory for processing.
7	Screening test results, interpretation, counselling, follow-up/referral criteria and colposcopy referral pathways.
8	Colposcopy/biopsy results, interpretation, counselling, follow-up/referral criteria and treatment referral pathways.
9	Managing the QA process.

### 5.4.3 Performance Indicators, Standards and Quality Assurance for PHC

This section would present the PRWG's proposals for amendments to, or the introduction of, any performance indicators, standards and QA procedures for PHC clinics and staff involved in an organized cervical screening programme. Performance indicators and standards have been established in a number of EECA countries. However, because organized cervical screening programmes are rare in this region, the performance indicators and standards that are required to optimize the safety, quality and cost-effectiveness of these programmes have not yet been established. It is therefore necessary for the SCO to work with the national organizations responsible for health service QA to ensure that the required performance indicators, standards and QA procedures are implemented. The relevant performance indicators and standards that are recommended in the European Guidelines are included in **Appendix 5**.

### 5.4.4 PHC Facility and Equipment Specifications

This section of the implementation plan would present the PRWG's proposals for amendments to, or the introduction of, any mandatory PHC facility and equipment specifications that are required to ensure the quality and safety of the cervical screening services. As cervical screening targets healthy women with little motivation to attend for screening, the quality of the screening facilities and equipment will have a direct impact on client satisfaction, and this will influence screening participation. It is therefore necessary for the SCO to work with the national organizations responsible for setting facility and equipment specifications to ensure that appropriate specifications, in compliance with international recommendations, are set for PHC facilities involved in the cervical screening programme. In this regard, mandatory certification with the certificates prominently displayed in the PHC clinics could be used to improve public perceptions of the screening programme and support screening participation.

#### 5.4.5 PHC Staff Numbers

The UNFPA EECARO situation analysis<sup>31</sup> found that PHC staff shortages remain a problem in all participating countries, particularly in rural and remote communities. However, all these countries already have programmes in place to increase PHC staff numbers, so this roadmap for the implementation of an organized cervical screening programme should focus on ensuring that existing and newly trained PHC staff have the skills required to effectively support the operation of the screening programme.

#### 5.4.6 PHC Staff Training

This section of the implementation plan would present the CAWG's proposals for the development of PHC staff knowledge and skills to ensure that they can work effectively within an organized cervical screening programme. As organized screening programmes are rare in the EECA region, the required knowledge and skills are not currently included in primary medical education, residency or CME programmes for either family physicians or nurses in most EECA countries. Therefore, these educational programmes should include the modules required to deliver information about organized cervical screening (see **Table 13**).

Table 13: Educational Modules for PHC staff

1	The structure, operation and benefits of organized cervical screening programmes.
2	Operating the cervical screening registry (submitting data, checking patient records, receiving results, etc.).
3	Patient reception, registration and data recording.
4	Patient counselling, communications and stress management techniques.
5	Patient confidentiality.
6	History-taking and assessment of individual cervical cancer risk.
7	Routine vs. high-risk cervical screening algorithms.
8	Anatomy, physiology and pathology of the vulva, vagina and cervix.
9	Clinical examination of the vulva, vagina and cervix.
10	Obtaining cervical samples, preparing microscope slides and laboratory submission pathways.
11	Screening test results, interpretation, counselling, follow-up/referral criteria and colposcopy referral pathways.
12	Colposcopy/biopsy results, interpretation, counselling, referral criteria and referral pathways for treatment.
13	Performance indicators, performance standards and QA procedures.
14	Fail-safe and audit procedures.

Cervical screening attendance is low in all EECA countries, and while the exact causes will be investigated as part of the implementation process, some studies have found that a lack of trust in PHC services is a barrier to the use of PHC services in the EECA region. Therefore, training and certification should be mandatory for all PHC staff involved in a cervical screening programme, not only to ensure that they have the knowledge and skills required to provide high-quality, client-oriented services, but also to improve public perceptions of the screening programme. In this regard, training certificates should also be prominently displayed in the PHC clinics participating in the cervical screening programme.

#### 5.4.7 Outreach Training for PHC Staff in Practice

As the majority of PHC staff in most EECA countries will have neither the time nor the money to travel to a distant training centre, training should be delivered through an outreach service that uses online or print materials combined with hands-on training conducted in regional centres. Here it should be noted that once established, this outreach training service could be used to deliver other training programmes to PHC providers and would thereby constitute a permanent resource for strengthening the overall health system.

### 5.5 Cervical Cytology, Cytopathology and Histopathology

#### 5.5.1 Legislative and Regulatory Changes for Cervical Cytology, Cytopathology and Histopathology

This section of the implementation plan would present the PRWG's proposals for amendments to, or the introduction of, any laws and regulations that would affect cervical cytology screening, cervical cytopathology and gynaecological-pathology laboratories and staff involved in an organized cervical screening programme.

##### 5.5.1.1 Designating cervical cytology screening as a distinct laboratory speciality

The UNFPA EECARO situation analysis found that cervical cytology screening is not classified as a distinct laboratory speciality in most EECA countries. The quality of cervical cytology will directly influence the safety and cost-effectiveness of the screening programme, so all cytology screeners must have the required knowledge and skills. Therefore, cervical cytology screening should be designated as a distinct laboratory speciality with a defined curriculum, CME requirements, certification and recertification criteria, and with certification being mandatory to work in the field.

#### 5.5.2 Guidelines and SOPs for Cervical Cytology, Cytopathology and Gynaecological Pathology

This section would present the PRWG's proposals for amendments to, or the introduction of, any cervical cytology screening, cervical cytopathology and gynaecological-pathology laboratory guidelines or SOPs. Evidence-based laboratory guidelines and SOPs for each step in the processing and analysis of cervical cytology screening tests and cervical biopsies are essential to ensure that these services produce the expected outcomes and support the effective operation of the screening programme. Laboratory guidelines and SOPs are also integral to the standard training curricula, certification criteria, performance standards and QA procedures. The laboratory guidelines and SOPs that are relevant to cervical cytology screening, cytopathology and gynaecological pathology are set out in **Table 14**.

**Table 14: Guidelines and SOPs for Cervical Cytology, Cytopathology and Gynaecological Pathology**

1	Sample receipt and laboratory processing of cervical cytology.
2	Service provider operation of the cervical screening registry.
3	Primary screening of cervical cytology.
4	Diagnosis of the cytological abnormalities identified during screening and the required reporting procedures.
5	Cervical cytology QA procedures.
6	Sample receipt and laboratory processing of cervical biopsy specimens.
7	Evaluation and diagnosis of cervical biopsy specimens and the required reporting procedures.
8	Clinico-Pathological Correlation/Multidisciplinary Team Meeting Guidelines.

### 5.5.3 Performance Indicators, Standards and QA for Cervical Cytology, Cytopathology and Gynaecological Pathology

This section would present the PRWG’s proposals for amendments to, or the introduction of, any performance indicators, standards and QA procedures for cervical cytology screening, cervical cytopathology and gynaecological-pathology laboratories and staff involved in an organized cervical screening programme. Performance indicators and standards have been established in a number of EECA countries. However, because organized cervical screening programmes are rare in this region, the performance indicators, standards and QA procedures that are required to optimize the quality, safety and cost-effectiveness of these laboratory services have not yet been established. It is therefore necessary for the SCO to work with the national organizations responsible for setting health service QA to ensure that the required performance indicators, standards and QA procedures are implemented for these laboratory services. The relevant performance indicators and standards as recommended in the European Guidelines are included in **Appendix 5**.

### 5.5.4 Facility and Equipment Specifications for Cervical Cytology, Cytopathology and Gynaecological-Pathology Laboratories

This section of the implementation plan would present the PRWG’s proposals for amendments to, or the introduction of, any mandatory laboratory facility and equipment specifications that are required to ensure the quality and safety of these laboratory services. It is therefore necessary for the SCO to work with the national organizations responsible for setting laboratory facility and equipment specifications to ensure that the required specifications are set in compliance with international guidelines.

### 5.5.5 Cervical Cytology Screening Laboratory and Staff Numbers

The UNFPA EECARO situation analysis found that all but one of the participating countries conducted cervical screening based on cytology (the Pap test), although these services needed to be expanded, improved and quality-assured in all the countries involved. This section of the implementation plan would present the proposals of the CAWG for the development of cervical cytology screening services.

In this regard, it should be noted that cervical cytology screening is a mentally tiring process with the performance of cytology screeners decreasing as fatigue sets in. Therefore, many countries limit the number of tests screened by each cytology screener per day (the number varies from 25/day to 80/day depending on the country). In addition, the European Guidelines for Quality Assurance in Cervical Cancer Screening have established working practice recommendations designed to maintain the optimal performance of cytology screeners as set out in **Table 15**.

**Table 15: Working Practice Recommendations for Cervical Cytology Screening Laboratories** <sup>32</sup>.

1	Each period of continuous screening should be $\leq 2$ hours.
2	Total time spent on primary screening/day should be $\leq 6$ hours.
3	Each laboratory should process $\geq 15,000$ Pap tests/year so cytology screeners are regularly exposed to the full range of abnormal cytology.
4	Each laboratory should have $\geq 4$ cytology screeners to enhance collaborative learning, ensure service provision during holidays, sick leave, etc.

Based on the European Guidelines, the daily limit should be 50 cytology tests per cytology screener per day and 220 working days per year; the recommended number of laboratories and cytology screeners is set out in **Table 16**. However, these staff estimates are the recommended *minimum* numbers for a programme with experienced staff, working in well-resourced laboratories. Therefore, until a country achieves a similar status, the number of staff required will be higher. Meanwhile, the estimated numbers of laboratories are *maximums*, so a smaller number of larger laboratories would still comply with the recommendations. Indeed, concentrating these services into a smaller number of larger laboratories would simplify QA and provide economies of scale that would facilitate the introduction of new technologies.

**Table 16: Estimated Number of Cytology Screeners and Laboratories**

Number of Cytology Tests/Year	Minimum Number of Cytology Screeners	Maximum Number of Laboratories
100,000	9	2
200,000	18	4
300,000	27	6
400,000	36	8
500,000	45	10

Depending on the local context and amount of work undertaken in the initial capacity assessment, the following actions could be considered as part of the implementation plan:

- Prepare an inventory of each laboratory to characterize the quantity and quality of their facilities, as well as their equipment and staffing levels relative to the number of screening samples being processed.
- Conduct an external assessment of the quality of cytology services in each laboratory.
- Restructure the laboratory network to ensure that each has the test volume and staff numbers that comply with international recommendations.<sup>33</sup> In addition, this process will allow the laboratory network to be structured to accommodate the future introduction of new technologies such as liquid-based cytology, HPV testing, etc. and thereby facilitate their implementation when found to be cost-effective in the local context.
- Design and implement targeted training programmes as required to improve the skills of the existing staff and progressively expand the workforce.
- Introduce measures to enforce compliance with the screening age range and interval recommendations to reduce the number of unnecessary screening tests and focus resources on the women who will benefit most.

### 5.5.6 Training and Certification for Cervical Cytology Screening

This section of the implementation plan would present the PRWG and the CAWG's proposals that relate to the development of cervical cytology screening staff knowledge and skills, and be coordinated with **Section 5.5.1** above. Because cervical cytology screening relies on the subjective assessments of the cytology screeners, comprehensive initial training together with CME and strict QA are essential to achieving and maintaining a safe and cost-effective service. Depending on the local context, the following actions could be included in the implementation plan:

- Preparation of a cervical cytology screening training curriculum with certification criteria.
- Implementation of a comprehensive cervical cytology QA programme.
- Establishment of a cervical cytology screening training facility that will:
  - Update the skills of the existing staff to meet international recommendations.
  - Train new cytology screeners to meet the needs of the screening programme as it is expanded together with the ongoing needs of the programme as people retire, change jobs, etc.
  - Run CME courses to update and maintain the skills of the existing workforce.
  - Support the cervical cytology QA programme with targeted training interventions.

## 5.6 Colposcopy

### 5.6.1 Legislative and Regulatory Changes Relating to Colposcopy

This section of the implementation plan would present the PRWG's proposals for amendments to, or the introduction of, any laws and regulations that would affect the colposcopy clinics and staff involved in an organized cervical screening programme.

#### 5.6.6.1 Designating colposcopy as a distinct medical speciality

This section of the implementation plan would present the PRWG's proposals regarding the designation of colposcopy as a distinct speciality or subspeciality of gynaecology. The quality of colposcopy will directly influence the quality, safety and cost-effectiveness of the screening programme, so it is essential that all colposcopists have the required training and skills. Therefore, colposcopy should be designated as a distinct medical speciality or subspeciality with a defined curriculum, CME requirements, certification and recertification criteria, and with certification being mandatory to work in this field. Doing this would not only ensure that all colposcopists have the knowledge and skills required to provide high-quality, client-oriented services, but would also help to improve public perceptions of the screening programme and support screening attendance. Therefore, training certificates should be prominently displayed in colposcopy clinics.

### 5.6.2 Guidelines and SOPs for Colposcopy

This section of the implementation plan would present the PRWG's proposals for amendments to, or the introduction of, any clinical guidelines or SOPs relating to procedures undertaken by colposcopists working for an organized cervical screening programme. Evidence-based clinical guidelines and SOPs for each step in the colposcopic evaluation and treatment of women are essential to ensuring that these services achieve the expected outcomes and are effectively integrated into the operation of the screening programme. Clinical guidelines and SOPs are also integral to the standard training curricula, certification criteria, performance standards and QA procedures. The clinical guidelines and SOPs relevant to colposcopy are set out in **Table 17**.

### 5.6.3 Performance Indicators, Standards and QA for Colposcopy

This section would present the PRWG's proposals for amendments to, or the introduction of, performance indicators, standards and QA procedures for colposcopy clinics and staff. As colposcopy is not considered a distinct medical speciality or subspeciality in most EECA countries, the evidence-based performance indicators, standards and QA procedures that are required to ensure the quality, safety and cost-effectiveness of these services have not yet been established. It is therefore necessary for the SCO to work with the national organizations responsible for health service QA to ensure that the required performance indicators, standards and QA procedures are implemented for colposcopy. The relevant performance indicators and standards recommended in the European Guidelines are included in **Appendix 5**.

**Table 17: Colposcopy Clinical Guidelines and SOPs**

1	Counselling women about abnormal Pap tests and colposcopy procedures.
2	Service provider operation of the cervical screening registry.
3	Colposcopic evaluation of the cervix.
4	Colposcopically directed cervical biopsy.
5	Treatment of CIN.
6	Treatment of recurrent CIN.
7	Colposcopy evaluation and treatment reporting procedures.
8	Follow-up after colposcopy: duration, frequency, follow-up cytology.
9	Management of glandular abnormalities.
10	Clinico-Pathological Correlation/Multidisciplinary Team Meeting Guidelines.
11	QA for colposcopy.

#### 5.6.4 Facility and Equipment Specifications for Colposcopy

This section would present the PRWG’s proposals for amendments to, or the introduction of, mandatory colposcopy facility and equipment specifications that would affect the quality and safety of the colposcopy services delivered. As colposcopy is not classified as a speciality or subspeciality in most EECA countries, the facility and equipment specifications relating to the provision of these services will not reflect the revised clinical guidelines, SOPs or performance standards noted above. It is therefore necessary for the SCO to work with the national organizations responsible for setting facility and equipment specifications to ensure that the required specifications are established for colposcopy clinics. As an example, the British Society for Colposcopy and Cervical Pathology (BSCCP) colposcopy facility recommendations are presented in **Table 18**.<sup>34</sup>

**Table 18: BSCCP Colposcopy Clinic Recommendations**

Colposcopy clinic facilities	<ul style="list-style-type: none"> <li>• A private area with changing facilities.</li> <li>• Toilet facilities specifically for the clinic.</li> <li>• A room specifically for colposcopy procedures.</li> <li>• A recovery area that is separate from the waiting room.</li> </ul>
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### 5.6.5 Colposcopy Clinic and Staff Numbers

This section of the implementation plan would present the CAWG's proposals for the development of colposcopy services.

While recognizing that these would need to be adapted to the local context, estimates of the colposcopy clinic and staff requirements for a cervical screening programme can be based on the English National Health Service and the BSCCP recommendations set out in **Table 19**.<sup>35</sup> Using these recommended timings and a mix of appointment types, each colposcopy clinic staffed by two colposcopists, two nurses and one administrator should be able to accommodate  $\leq 18$  colposcopies per day (two sessions of 3-3.5 hours per day with nine colposcopies per session) or  $\approx 3,960$  colposcopies per clinic based on 220 working days per year.

**Table 19: BSCCP Colposcopy Staff Recommendations**

Colposcopy clinic staff	<ul style="list-style-type: none"> <li>▪ A designated colposcopy clinical lead.</li> <li>▪ A second colposcopist.</li> <li>▪ 2 nurses:               <ul style="list-style-type: none"> <li>- 1 registered nurse (RN) with training in colposcopy procedures and patient counselling and who does not have other outpatient duties.</li> <li>- 1 nurse for patient support.</li> </ul> </li> <li>▪ 1 clinical assistant who is present in the colposcopy room throughout every procedure (can be the RN noted above).</li> <li>▪ Adequate clerical support for effective operation of the clinic.</li> </ul>
Minimum appointment times	<ul style="list-style-type: none"> <li>▪ New referral: 20 minutes.</li> <li>▪ New high-grade referral: 30 minutes.</li> <li>▪ Return for treatment: 20 minutes.</li> <li>▪ Follow-up examination: 10 minutes.</li> </ul>

However, colposcopy referral is based on cervical cytology results, and the distribution of results in a country is likely to change once the cytology training and QA programmes noted above have been implemented. Therefore, estimates can be based on data from the Irish National Cervical Screening Programme for 2010, as this programme was started in September 2008, so the statistics come from a population that had previously been screened opportunistically:

- A first colposcopy referral rate of 4.5 per cent.
- A 72.5 per cent uptake of colposcopy.
- Each first referral will generate an average of 2.7 follow-up colposcopy appointments.
- Each colposcopy clinic will be open for 220 days/year and conduct 3,960 colposcopies/year.
- Each colposcopy clinic will be staffed by two colposcopists, two nurses and one administrator.

**Table 20: Estimated Number of Colposcopy Clinics and Staff by Number of Women Screened**

People Screened	1st Referrals	Follow-Up Appts.	Total Appts.	Colposcopy Clinics	Colposcopists	Registered Nurses	Other Nurses	Admin Staff
100,000	3,263	8,809	12,071	3	6	3	3	3
200,000	6,525	17,618	24,143	6	12	6	6	6
300,000	9,788	26,426	36,214	9	18	9	9	9
400,000	13,050	35,235	48,285	12	24	12	12	12
500,000	16,313	44,044	60,356	16	32	16	16	16

In considering the estimates presented above, it is important to note they are based on the recommended *minimum* numbers for a programme with well-trained and experienced staff working in well-resourced clinics that have clearly defined clinical and administrative procedures. Therefore, until a country reaches a similar state, the number of colposcopies per clinic per day will be lower and the number of clinics and staff required will be higher.

### 5.6.6 Training and Certification for Colposcopy

This section of the implementation plan would present the CAWG's proposals for the development of colposcopy staff knowledge and skills to ensure that they can work effectively within an organized cervical screening programme. Most EECA countries do not recognize colposcopy as a distinct medical speciality or subspeciality, so the knowledge and skills required to meet current international standards are not included in gynaecology residency programmes. Therefore, most EECA countries will need to establish colposcopy training programmes. Substantial colposcopy expertise can be accessed through partnerships with Western European organizations such as the BSCCP, which has developed exceptional training programmes for both the practice and the teaching of colposcopy.

Colposcopy nursing staff are also essential to the smooth running of colposcopy clinics and the cost-effective use of the colposcopists' time. The BSCCP recommends that each colposcopy clinic should have two or more nurses, with one of these being a registered nurse who has also undertaken training in both colposcopy procedures and patient counselling. The shortage of colposcopy capacity across the EECA region creates a substantial barrier to the implementation of cervical screening programmes. Therefore, introducing a training programme that provides nurses with the skills to effectively support colposcopists in the clinic would help to overcome this barrier by increasing the number of patients each colposcopist could see per clinic session.

Depending on the local context, the following actions could be included in the implementation plan:

- Preparation of a colposcopy training curriculum with evaluation and certification criteria.
- Design and implementation of a comprehensive colposcopy QA system.
- Establishment of a colposcopy training facility that will:
  - Train new colposcopists to meet the needs of the screening programme as it is expanded, as well as the ongoing needs of the programme as clinicians retire, etc.
  - Run CME courses to maintain workforce skills.
  - Participate in the colposcopy QA programme by undertaking targeted training interventions to resolve quality issues that are related to staff skills.
- In parallel with the above, establish a training programme for colposcopy nurses.

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## 7. Appendices

### Appendix 1

#### Assessing Policies, Legislation, Regulations and Guidelines for Compatibility with the Operation of an Organized Cervical Screening Programme

##### 1.0 National Strategies, Entitlements and Funding Mechanisms

###### 1.1 National Strategies:

Identify and evaluate all national policy documents that include provisions for cancer prevention, screening, follow-up, diagnosis, treatment of precancer, treatment of cancer and palliative care (national cancer control strategy, reproductive health policy with provisions for cervical cancer, national health-sector development framework, cervical screening guidelines, etc.).

###### 1.2 Citizens' Legal Entitlements:

Identify and evaluate citizens' legal entitlements to cancer-related medical procedures, including cancer screening, follow-up and diagnosis, treatment of cervical precancer, treatment of cervical cancer and palliative care.

###### 1.3 Funding mechanisms:

- Identify and evaluate how the costs of cancer prevention, screening, follow-up, diagnosis, treatment of cervical precancer, treatment of cervical cancer and palliative care are paid for (e.g. the state, health insurance fund, voluntary medical insurance, patient pays part of the cost, patient pays full cost, etc.).
- If health services are paid for by the state or compulsory health insurance, are the costs paid in full or does the patient have to pay some percentage of the services?
- If health services are paid for by the state or health insurance fund, are the fees paid directly to the health-care provider or does the patient have to pay the health-care provider and subsequently obtain reimbursement?
- If private health insurance is available, what proportion of the population uses these services?
- If private health insurance is available, are cancer prevention, screening, follow-up, diagnosis, treatment of precancer, treatment of cancer and palliative care included in the coverage?

###### 1.4 Competing or complementary health-sector development programmes:

Identify and evaluate all existing or planned health capacity development programmes (such as primary health-care reform programmes, reproductive health programmes, etc.) to find areas where cooperation could be mutually beneficial. For example, programmes to develop health-sector IT systems rarely include the collection of the data needed to manage cancer prevention programmes, although these data, if considered during the planning of the IT system, could often be included with little or no additional cost.

##### 2.0 Laws and Regulations

- 2.1 Can a population database with details of the screening target population (name, sex, age, contact details) be accessed and used by the Screening Coordination Office for the screening call and recall?
- 2.2 Can clinical data (results of screening tests, colposcopy, biopsy, etc.) be accessed and used by the Screening Coordination Office to organize screening call, recall, follow-up referral and QA?
- 2.3 Can cancer registry data (name, personal identification number, etc.) be accessed and used by the Screening Coordination Office for management, QA and audit purposes?
- 2.4 Is cytology screening officially recognized as a laboratory speciality with a defined training curriculum, evaluation, certification and recertification procedures, CME requirements, etc.?
- 2.5 Is colposcopy officially recognized as a clinical speciality or subspeciality with a defined training curriculum, evaluation, certification and recertification procedures, CME requirements, etc.?
- 2.6 Under current regulations, who is legally entitled to do the following?
  - Take cervical samples for screening.
  - Process Pap smears.
  - Screen cervical cytology samples to identify abnormal cells.
  - Diagnose abnormal cytology.
  - Conduct colposcopy and take biopsies.
  - Treat preinvasive cervical disease (cervical intraepithelial neoplasia).
  - Treat cervical cancer.

### 3.0 Clinical Guidelines, SOPs, Performance Indicators and Performance Standards

- 3.1 Identify and evaluate any legally binding clinical guidelines, SOPs, performance indicators and standards for:
- Taking cervical samples for screening.
  - Colposcopy and biopsy for the follow-up of abnormal cervical cytology.
  - Treatment of cervical intraepithelial neoplasia.
  - Treatment of cervical cancer.
  - Palliative care.
- 
- 3.2 Identify and evaluate any non-legally binding clinical guidelines, recommendations, SOPs, performance indicators and standards for:
- Taking cervical samples for screening.
  - Colposcopy and biopsy for the follow-up of abnormal cervical cytology.
  - Treatment of cervical intraepithelial neoplasia.
  - Treatment of cervical cancer.
  - Palliative care.
-

## Appendix 2

### Assessing Existing Capacities of the Required Health Services

#### 1.0 Screening Programme Administration

- 
- 1.1 What agency has/would have administrative responsibility for the management and operation of a cervical screening programme?
- 
- 1.2 How much office space is/could be used by the administrative staff of a cancer screening programme?
- Number of facilities.
  - Square metres.
  - Capacity (number of people that could work in each facility).
  - Location and geographical distribution of the facilities.
  - Equipment (see **Appendix 3**).
- 
- 1.3 Screening Programme Manager (e.g. Public Health Programme Manager):
- Job classification for this position.
  - Mean salary and range for this position.
  - Minimum qualifications for this position.
  - Number of people with these qualifications currently in the country.
  - Location/geographical distribution of people with these qualifications.
  - Institutions responsible for training these people.
  - Training capacity of these institutions (people per year).
  - Prerequisites to enter training for this position (secondary school certificate, university degree, medical degree, etc.).
  - Number of people meeting these prerequisites.
- 
- 1.4 Health Systems Database Manager:
- Job classification for this position.
  - Mean salary and range for this position.
  - Minimum qualifications for this position.
  - Number of people with these qualifications.
  - Location/geographical distribution of people with these qualifications.
  - Institutions responsible for training these people.
  - Training capacity of these institutions (people per year).
  - Prerequisites to enter training for this position (secondary school certificate, university degree, medical degree, etc.).
  - Number of people meeting these prerequisites.
- 
- 1.5 Health Systems Quality Assurance Manager:
- Job classification for this position.
  - Mean salary and range for this position.
  - Minimum qualifications for this position.
  - Number of people with these qualifications.
  - Location/geographical distribution of people with these qualifications.
  - Institutions responsible for training these people.
  - Training capacity of these institutions (people per year).
  - Prerequisites to enter training for this position (secondary school certificate, university degree, medical degree, etc.).
  - Number of people meeting these prerequisites.
- 
- 1.6 Public Health Educational Specialist:
- Job classification for this position.
  - Mean salary and range for this position.
  - Minimum qualifications for this position.
  - Number of people with these qualifications.
  - Location/geographical distribution of people with these qualifications.
  - Institutions responsible for training these people.
  - Training capacity of these institutions (people per year).
  - Prerequisites to enter training for this position (secondary school certificate, university degree, medical degree, etc.).
  - Number of people meeting these prerequisites.
-

## 2.0 Cervical Screening Services

- 2.1 What organization has/would have legal responsibility for setting guidelines, SOPs, performance standards, QA procedures, etc. for the clinical services associated with cervical cancer screening (such as taking cervical samples)?
- 2.2 What organization has/would have administrative responsibility for clinical services associated with the cervical cancer screening services?
- 2.3 What facilities are/could be used for cervical cancer screening services (such as dedicated cancer screening clinics, PHC clinics, hospital clinics, mobile units, etc.)?
- Number of each type of facility.
  - Capacity of each facility (number of women screened/day).
  - Location and geographical distribution.
  - Equipment (see **Appendix 3**).
- 2.4 Which health-care providers are legally allowed to take cervical samples for screening?
- For each type of health-care provider:
    - Job classification for this position.
    - Mean salary and range for this position.
    - Minimum qualifications for this position.
    - Number of people with these qualifications.
    - Location and geographical distribution of people with these qualifications.
    - Institutions responsible for training these people.
    - Training capacity of these institutions (people per year).
    - Prerequisites to enter training for this position.
    - Number of people meeting these prerequisites.

## 3.0 Colposcopy Services

- 3.1 What organization has/would have legal responsibility for setting guidelines, SOPs, performance standards, QA procedures, etc. for the clinical services associated with the follow-up of women with a positive cervical screening test (colposcopy and biopsy)?
- 3.2 What organization has/would have administrative responsibility for clinical services associated with the follow-up of women by colposcopy?
- 3.3 What facilities are/could be used for colposcopy (gynaecology clinics, colposcopy clinics, primary-care clinics, hospital clinics)?
- For each type of facility:
    - Number of facilities.
    - Capacity of each facility (number of women/day).
    - Locations and geographical distribution.
    - Equipment (see **Appendix 3**).
- 3.4 Who is legally allowed to do colposcopies and cervical biopsies, and to provide treatment for CIN using cryotherapy, laser and loop diathermy (LEEP/LLETZ), etc.:
- Job classification for this position.
  - Mean salary and range for this position.
  - Minimum qualifications for this position.
  - Number of people with these qualifications.
  - Location and geographical distribution of people with these qualifications.
  - Institutions responsible for training these people.
  - Training capacity of these institutions (people per year).
  - Prerequisites to enter training for this position.
  - Number of people with these prerequisites.
  - How these people are paid (annual salary, per capita payment, fee for service, etc.).

## 4.0 Cytology and Pathology Services

4.1 What organization has legal responsibility for setting guidelines, SOPs, performance standards, QA procedures, etc. for cytology, cytopathology and pathology services?

4.2 What organization has administrative responsibility for cytology, cytopathology and pathology services?

4.3 Number of laboratories that can process cervical screening samples, biopsies and cervical excision samples:

Service	Number of facilities	Indicator	Capacity
Conventional Pap test		Avg. number of Pap smears/day	
Liquid-based cytology		Avg. number of LBC specimens/day	
HPV tests		Avg. number of HPV tests/day	
Gynaecological histology		Avg. number of biopsies/day	

- Location and geographical distribution of each type of facility.
- Equipment (see **Appendix 3**).

4.4 Who is legally allowed to process cervical cytology specimens to prepare them for screening:

- Job classification for this position.
- Mean salary and range for this position.
- Minimum qualifications for this position.
- Number of people with these qualifications.
- Location and geographical distribution of people with these qualifications.
- Institutions responsible for training these people.
- Training capacity of these institutions (people per year).
- Prerequisites to enter training for this position.
- Number of people with these prerequisites.

4.5 Who is legally allowed to screen cervical cytology specimens to identify cytological abnormalities:

- Job classification for this position.
- Mean salary and range for this position.
- Minimum qualifications for this position.
- Number of people with these qualifications.
- Location and geographical distribution of people with these qualifications.
- Institutions responsible for training these people.
- Training capacity of these institutions (people per year).
- Prerequisites to enter training for this position.
- Number of people with these prerequisites.

4.6 Who is legally allowed to process HPV tests:

- Job classification for this position
- Mean salary and range for this position
- Minimum qualifications for this position
- Number of people with these qualifications
- Location and geographical distribution of people with these qualifications
- Institutions responsible for training these people
- Training capacity of these institutions (people per year)
- Prerequisites to enter training for this position
- Number of people with these prerequisites

4.7 Is cytopathology a recognized clinical speciality in your country?

Who is legally allowed to diagnose cytological abnormalities that have been found in cervical cytology specimens:

- Job classification for this position.
- Mean salary and range for this position.
- Minimum qualifications for this position.
- Number of people with these qualifications.
- Location and geographical distribution of people with these qualifications.
- Institutions responsible for training these people.
- Training capacity of these institutions (people per year).
- Prerequisites to enter training for this position.
- Number of people with these prerequisites.

## 5.0 Cancer Registries

- 5.1 Number and distribution of cancer registries.
- 
- 5.2 Year each registry started operating.
- 
- 5.3 Coverage of the local and/or national target population.
- 
- 5.4 If the registries are municipal or regional, are data aggregated at the national level?
- 
- 5.5 Are there laws governing the submission of data by doctors and/or hospitals to the cancer registry?
- 
- 5.6 Are the cancer registries affiliated with the European and/or International Association of Cancer Registries?
- 

## 6.0 Death Registries

- 6.1 Number and distribution of death registries.
- 
- 6.2 Coverage of the local and/or national target population.
- 
- 6.3 If the registries are municipal or regional, are data aggregated at the national level?
- 
- 6.4 Are there laws requiring the submission of data by doctors and hospitals to the death registry?
- 
- 6.5 How are cancer deaths recorded in the death registry (e.g. on gross morphology or histopathology)?
- 

## 7.0 Population Databases

- 7.1 Is a database containing details of the target population available at the national, regional or municipal level?
- 
- Ownership/legal responsibility.
- 
- Coverage of the target population.
- 
- 7.2 Are all citizens automatically registered with a GP, family physician or other health professional?
- 
- 7.3 Can citizens change their health-care provider as they wish? If so, how are these changes registered with the payer?
- 
- 7.4 Are any population sub-groups (e.g. the unemployed, immigrants, ethnic or religious minorities, etc.) known to be missed or underrepresented in these databases or GP registration lists?
-

## Appendix 3

### Capacity Assessment Data Collection Forms

Infrastructure and Major Equipment for Cervical Screening Administration								
Facility	Number of these facilities	Geographical Location	Max. Capacity (people/facility)	Service	Equipment	Make/Model/Year	Number	Comments
				Screening recruitment (call/recall)				
<p>Responsibilities:</p> <ul style="list-style-type: none"> <li>Regularly review and update the cervical screening guidelines.</li> <li>Implement, operate and maintain the cervical screening registry.</li> <li>Send service providers the data they need to coordinate screening call and recall, patient referrals and ensure referral compliance.</li> <li>Work with national medical education institutions to coordinate primary medical education, residency and CME programmes.</li> <li>Design and implement public education and promotion programmes to raise awareness and motivate screening participation.</li> <li>Identify underscreened/unscreened people and implement programmes to increase participation.</li> <li>Work with the Ministry of Health, medical education institutions and professional organizations to regularly review and update training standards, certification criteria, clinical guidelines and SOPs, performance indicators and standards.</li> <li>Manage the QA programme by monitoring and evaluating all aspects of screening programme performance, and intervene as required.</li> <li>Prepare and publish reports on screening programme performance for the Ministry of Health and other organizations.</li> <li>Interact with other health services as required to ensure efficient screening programme operation (e.g. cancer registry).</li> <li>Interact with other governmental departments and nongovernmental organizations as required to ensure intersectoral cooperation for cancer prevention (such as the Department of Education for the inclusion of cancer prevention in secondary school health curricula).</li> </ul>				Liaison with each of the services involved in delivering the screening programme				
				Follow-up of screening-positive women as they are referred from one clinical service to the next				
				QA of all the services involved in delivering the screening programme				
				Education services for health-care providers				
				Education and promotion services for the general public				

## Infrastructure and Major Equipment for Facilities Taking Cervical Screening Samples

Facility	Number of these facilities	Geographical Location	Max. Capacity (women/day)	Service	Facility/Equipment	Make/Model/Year	Number	Comments
<p>Responsibilities:</p> <ul style="list-style-type: none"> <li>▪ Reception and registration of women for screening.</li> <li>▪ Pre-screening counselling of women about the benefits and drawback of cervical screening.</li> <li>▪ Assessment of cervical cancer risk and identification of women at increased risk.</li> <li>▪ Taking cervical samples.</li> <li>▪ Submitting cervical samples to the laboratory for processing.</li> <li>▪ Counselling women about screening test results, follow-up/referral procedures and colposcopy referral pathways.</li> <li>▪ Counselling women about colposcopy/biopsy results, follow-up/referral procedures and treatment referral pathways.</li> <li>▪ Managing the PHC QA process.</li> </ul>				Reception and registration of women for screening	Computer			
				Printer				
				Scanner				
				Internet access to screening registry				
				Pre-screening counselling for women and assessment of cervical cancer risk	Quiet and private consultation area			
				Computer with Internet access to screening registry				
				Taking cervical samples	Comfortable and private area for taking cervical samples			
					Appropriate examination couch			
					Non-disposable speculums: large, medium, small* sizes			
					Autoclave if non-disposable equipment used			
				Post-screening test counselling regarding follow-up and referral for colposcopy if required	Quiet and private consultation area			
					Computer with Internet access to screening registry			
				Post-colposcopy counselling regarding follow-up and referral for treatment if required	Quiet and private consultation area			
					Computer with Internet access to screening registry			
				Managing the QA process	Computer with Internet access to screening registry, cancer registry data and death registry data			

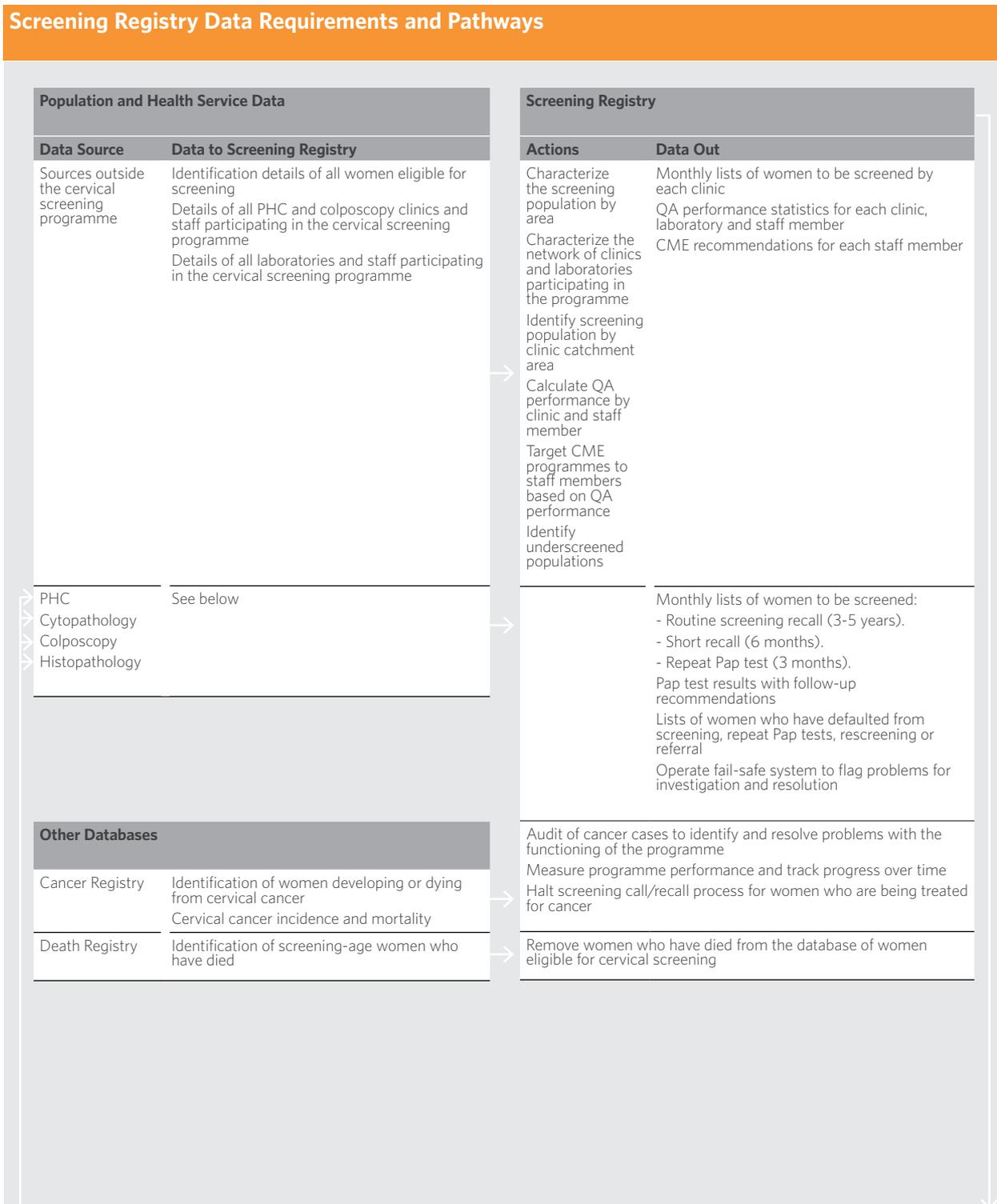
\* Disposable speculums would come under consumables.

## Infrastructure and Major Equipment for Colposcopy

Facility	Number of these facilities	Geographical Location	Max. Capacity (women/day)	Service	Facility/Equipment	Make/Model/Year	Number	Comments
<p>Responsibilities:</p> <ul style="list-style-type: none"> <li>• Reception and registration of women for colposcopy.</li> <li>• Counselling women about abnormal Pap tests and colposcopy procedures.</li> <li>• Colposcopic evaluation of the vulva, vagina and cervix.</li> <li>• Colposcopically directed biopsy.</li> <li>• Endocervical curettage.</li> <li>• Treatment of CIN.</li> <li>• Treatment of recurrent CIN.</li> <li>• Post-treatment follow-up colposcopy.</li> <li>• Management of glandular abnormalities.</li> <li>• Clinico-Pathological Correlation/Multidisciplinary Team Meeting participation.</li> <li>• QA for colposcopy.</li> </ul>				Reception and registration of women for colposcopy	Computer			
					Printer			
					Scanner			
					Internet access to screening registry			
				Pre-colposcopy counselling for women about abnormal Pap tests and colposcopy procedures	Quiet and private consultation area			
					Computer with Internet access to screening registry			
				Colposcopy	Gynaecological examination couch			
					Speculums: large, medium, small sizes			
					Endocervical speculum			
					Colposcope			
					Light source			
				Biopsy/endocervical curettage	Punch biopsy forceps			
					Endocervical curette			
					Sponge forceps			
					Long thumb forceps (toothed)			
					Long thumb forceps (non-toothed)			
					Instrument tray			
					Instrument trolley			
				Cryotherapy	Cryotherapy gun/cryo handset			
					Probe tips (shallow conical, 20 mm and/or 25 mm diameter)			
					Refrigerant gas supply (Cryogen: N2O or CO2)			
					Regulator			
				LEEP	Electrosurgical generator, cables, electrode holder, etc.			
					Grounding pad for patient			
					LEEP electrodes			
					Smoke evacuator			
					Non-conductive vaginal speculum and lateral wall retractor			
					Vaginal speculum adapted for smoke evacuator tubing			
					Long-handled needle driver			
					Thumb forceps (long)			
Infection control	Sterilization autoclave							

## Appendix 4

### Cervical Screening Registry Data Requirements and Pathways



**PHC**

<b>Data Sent to Screening Registry</b>	<b>PHC Actions</b>	<b>Data from Screening Registry</b>
Clinic identification Staff identification (for each Pap test)		
For each woman screened: - Satisfactory/unsatisfactory sampling. - Date of last menstrual period. - Type of sample: cervical or vaginal vault. - Appearance of cervix. - Additional clinical comments. Women attended but refused screening Women invited but did not attend Women known to have moved or not found	Identify and recruit eligible women to be screened	Monthly lists of women to be screened: - Routine screening recall (3 years). - Short recall (6 months). - Repeat Pap test (3 months).
	Notify women of results and remind them about 3-year recall	Pap test result – no abnormalities found, routine recall
	Counsel women about results and the need to have a repeat in 3 months	Pap test result – unsatisfactory, repeat Pap test in 3 months
	Counsel women about results and the need to be rescreened in 6 months	Pap test results requiring rescreening in 6 months
Women referred for colposcopy Women referred but who refused to go Women who moved out of the area Women who could not be found	Counsel women about Pap test results and the required follow-up procedures	Pap test results requiring referral, with referral recommendations and cytopathologist contact details for further information if required
Defaulters referred for colposcopy again Defaulters refusing to be followed up Defaulters not found	Counsel defaulters about cervical cancer risks and encourage them to comply with follow-up recommendations	Women referred for colposcopy or further tests who did not attend
	Allows PHC staff and clinic managers to understand how their performance compares to agreed standards, other clinics and programme averages to: - Identify substandard performance so targeted remedial action can be taken to resolve problems. - Introduce competition for quality of services and thereby motivate PHC staff to achieve and exceed standards.	QA reports comparing programme, clinic and staff performance: - Screening recruitment. - Screening invitation compliance. - Proportion of women recalled. - Recall invitation compliance. Time from receipt of results and: - Reporting results/referring women. - Proportion of unsatisfactory results. - Proportion of screen positives. - Distribution of cytology results. - Referral compliance.

## Cervical Screening Registry Data Requirements and Pathways

### Cytology Screening and Cytopathology

Data Sent to Screening Registry	Use	Data from Screening Registry
Laboratory identification Staff identification (for each Pap test) Specimen type Squamous cell results Endocervical cell results Other/non-cervical cell analysis Follow-up recommendations	Anticipate sample receipt and initiate tracing of Pap tests that do not arrive at lab Investigate and resolve fail-safe notices Allows laboratory staff and managers to understand how their performance compares to agreed standards, other laboratories and programme averages to: - Identify substandard performance so targeted remedial action can be taken to resolve problems. - Introduce competition for quality of services and thereby motivate laboratory staff to achieve and exceed standards.	Pap tests taken and date sent to lab Previous Pap test results Date of last menstrual period Type of sample: cervical or vaginal vault. Appearance of cervix Additional clinical comments Fail-safe notices to be investigated. QA reports comparing programme, laboratory and staff performance: - Time from receipt of Pap test to reporting of results. - Proportion of unsatisfactory results. - Proportion of positives. - Distribution of cytology results.

### Colposcopy and Cervical Surgery

Data Sent to Screening Registry	Use	Data from Screening Registry
Clinic identification Colposcopist identification Appointment attendance Extent of lesion Colposcopic opinion Biopsy taken (yes/no) Biopsy result Follow-up recommendations	Anticipate patient appointment and initiate tracing of defaulters Ensures access to referral Pap test result and related clinical information Investigate and resolve fail-safe notices Allows colposcopy staff and clinic managers to see how their performance compares to agreed standards and other clinics: - Identify substandard performance so targeted remedial action can be taken to resolve problems. - Introduce competition for quality of services and thereby motivate staff to achieve and exceed standards.	Women referred and date of referral Referring clinic/clinician identification Referral Pap test result and/or clinical indications. Pap test history Additional clinical comments QA reports for colposcopy clinic and staff performance: - Time from referral to appointment. - Biopsy rate. - Proportion of women treated after screen detected CIN1. - Proportion of women treated after screen detected $\geq$ CIN2. - Proportion of women having a hysterectomy after screen detected CIN. - Positive predictive value of colposcopy referral. - Distribution of histology results. - Cancer incidence after treatment for CIN.

### Histopathology

Data Sent to Screening Registry	Use	Data from Screening Registry
Specimen adequacy Margin status Histology result Pathologist's follow-up recommendations	Anticipate patient appointment and initiate tracing of defaulters Ensures access to required clinical information Investigate and resolve fail-safe notices Allows laboratory staff and managers to understand how their performance compares to agreed standards, other laboratories and programme averages to: - Identify substandard performance so targeted remedial action can be taken to resolve problems. - Introduce competition for quality of services and thereby motivate laboratory staff to achieve and exceed standards.	Specimen type and date of referral. Referring clinic/clinician identification Colposcopic opinion and clinical details QA reports: - Time from receipt of sample to reporting of results. - Proportion of unsatisfactory results. - Proportion of positives. - Distribution of histology results.

## Appendix 5

### Performance Indicators for Cervical Screening

Indicator		Calculation
1	<b>Programme coverage</b> <ul style="list-style-type: none"> <li>Calculate:               <ul style="list-style-type: none"> <li>regionally.</li> <li>nationally.</li> </ul> </li> </ul>	Number of targeted women in the area <b>covered by the screening programme</b> Number of women of screening age in the region or country.
2	<b>Coverage of the screening population by invitation</b> <ul style="list-style-type: none"> <li>Length of period corresponds to the routine screening interval.</li> <li>Stratification by five-year age groups is recommended.</li> </ul>	Number of women invited in <b>the screening interval.</b> Number of resident women in screening population.
3	<b>Coverage of the target population by screening test</b> Calculate separately for: invitational status: <ul style="list-style-type: none"> <li>invited/not invited/unknown.</li> </ul> programme status: <ul style="list-style-type: none"> <li>within organized programme.</li> <li>outside organized programme.</li> <li>unknown.</li> </ul>	Number of women screened at least <b>once in the specified interval.</b> Number of women in the screening target population.
4	<b>Compliance with initial invitation</b> <ul style="list-style-type: none"> <li>A cut-off date of six months after the end of the respective period is recommended for determining response to the invitation.</li> </ul>	Number of invited women <b>who were screened</b> Number of women invited in that period + six months
5	<b>Compliance to recall invitation</b> <ul style="list-style-type: none"> <li>A cut-off date of six months after the end of the respective period is recommended for determining response to the invitation.</li> </ul>	Number of recalled women who were screened. Number of women recalled in that period + six months.
6	<b>Test consumption</b> <ul style="list-style-type: none"> <li>Include only the screening test, not repeat tests, such as those conducted after unsatisfactory tests or follow-up after low-grade tests, colposcopy or treatment.</li> </ul>	Number of tests conducted within the <b>recommended screening interval.</b> Number of women screened in the same period.
7	<b>Incidence of invasive cancer in unscreened/underscreened women</b> <ul style="list-style-type: none"> <li>Include only invasive cancers and person-years of women not screened during the recommended screening interval.</li> <li>Link screening registry and cancer registry data to calculate incidence by age group.</li> <li>Analyse by cancer stage/morphology.</li> <li>Calculate separately:               <ul style="list-style-type: none"> <li>women never screened.</li> <li>women previously screened, but not within the recommended screening interval.</li> <li>women never invited.</li> </ul> </li> </ul>	Number of invasive cancers detected in <b>unscreened/underscreened women.</b> Number of person-years of unscreened/underscreened women in the same interval.
8	<b>Distribution of cytology results</b> <ul style="list-style-type: none"> <li>Calculate overall and for:               <ul style="list-style-type: none"> <li>the regular screening interval.</li> <li>shorter intervals.</li> <li>first screening event.</li> <li>second and subsequent screening events.</li> </ul> </li> </ul>	Number of each <b>cytological diagnosis.</b> Number of screening tests within the same period.
9	<b>Referral rate for repeat cytology</b> <ul style="list-style-type: none"> <li>Calculate for:               <ul style="list-style-type: none"> <li>cytology resulted &gt; repeat.</li> <li>first screening event.</li> <li>second and subsequent screening events.</li> </ul> </li> </ul>	Number of screened women invited <b>for repeat cytology.</b> Number of women screened during the same period.
10	<b>Compliance with referral for repeat cytology</b> <ul style="list-style-type: none"> <li>Calculate for:               <ul style="list-style-type: none"> <li>cytology result leading to the need for repeat testing.</li> <li>first screening event.</li> <li>second and subsequent screening events.</li> </ul> </li> </ul>	Number of women having repeat <b>cytology during the period + six months.</b> Number of women invited for repeat cytology.

Indicator	Calculation
11 <b>Referral rate for colposcopy</b> <ul style="list-style-type: none"> <li>• Calculate for:               <ul style="list-style-type: none"> <li>- cytology resulted &gt; colposcopy.</li> <li>- first screening event.</li> <li>- second and subsequent screening events.</li> </ul> </li> </ul>	Number of screened women <b>referred for colposcopy</b> Number of women screened during the same period
12 <b>Colposcopy compliance</b> <ul style="list-style-type: none"> <li>• Calculate overall and for:               <ul style="list-style-type: none"> <li>- three months after referral.</li> <li>- six months after referral.</li> <li>- Referral cytology.</li> </ul> </li> </ul>	Number of women <b>undergoing colposcopy</b> Number of women referred for colposcopy
13 <b>Positive predictive value of colposcopy referral</b> <ul style="list-style-type: none"> <li>• Calculate overall and for:               <ul style="list-style-type: none"> <li>- referral cytology.</li> <li>- histology.</li> <li>- first screening event.</li> <li>- second and subsequent screening events.</li> </ul> </li> </ul>	Number of screened <b>women with CIN+</b> Number of screened women referred for colposcopy
14 <b>Distribution of histology results</b> <ul style="list-style-type: none"> <li>• Calculate overall and for:               <ul style="list-style-type: none"> <li>- histology result.</li> <li>- the regular screening interval.</li> <li>- shorter intervals.</li> <li>- first screening event.</li> <li>- second and subsequent screening events.</li> </ul> </li> </ul>	Number of women with each <b>grade of CIN</b> Number of women biopsied
15 <b>Cancer incidence after normal cytology</b> <ul style="list-style-type: none"> <li>• Calculate overall and for:               <ul style="list-style-type: none"> <li>- interval from index cytology.</li> <li>- cancer stage/morphology.</li> </ul> </li> </ul>	Number of women with cancer detected <b>after a normal cytology result</b> Number of person-years of screened women for the same period with normal cytology
16 <b>Treatment of screening-detected high-grade CIN</b>	Number of women with CIN2/3 <b>receiving treatment</b> Number of women with screening-detected CIN2/3
17 <b>Proportion of women having a hysterectomy after screen detected CIN</b>	Number of screened women having a hysterectomy after <b>screen detected CIN</b> Number of screened women with histologically confirmed CIN
18 <b>Proportion of women treated after screen detected CIN1</b>	Number of women treated after <b>CIN1 diagnosed</b> Number of screened women with histologically confirmed CIN1
19 <b>Incidence of invasive cancer after a positive screening test:</b> <ul style="list-style-type: none"> <li>• Calculate overall and for:               <ul style="list-style-type: none"> <li>- without colposcopy carried out despite having a positive screening test.</li> <li>- with colposcopy carried out but no CIN detected.</li> <li>- with CIN detected but not treated.</li> <li>- treated for CIN.</li> <li>- cancers detected during diagnostic or post-treatment follow-up.</li> </ul> </li> <li>• Include only fully invasive cancers.</li> <li>• Exclude cases detected by the screening process.</li> </ul>	Number of cases of invasive cancer in women after <b>having a positive screening test</b> Number of person-years of screened women having a normal screening test during the same period
20 <b>Proportion of women with a negative screening test six months after treatment for CIN</b>	Number of treated women with a negative screening test <b>six months after treatment</b> Number of women treated as part of the screening process and followed up for six months

## Appendix 6

### Resources for the Implementation of Cervical Screening Programmes

1.0 Model Documents for the Preparation of National Guidelines and SOPs		Source
<b>1.1 Cervical Screening Guidelines</b>		
NHS England. Cervical Screening Programme Overview. 2015		<a href="http://www.gov.uk/guidance/cervical-screening-programme-overview">www.gov.uk/guidance/cervical-screening-programme-overview</a>
American Cancer Society, American Society for Colposcopy and Cervical Pathology, and American Society for Clinical Pathology Screening Guidelines for the Prevention and Early Detection of Cervical Cancer. 2012		<a href="http://journals.lww.com/jlgtcd/PublishingImages/ASCCP%20Guidelines.pdf#zoom=80">http://journals.lww.com/jlgtcd/PublishingImages/ASCCP%20Guidelines.pdf#zoom=80</a>
CervicalCheck Ireland. Guidelines for Quality Assurance in Cervical Screening. 2009		<a href="http://www.cancerscreening.ie/publications/QA_final_web_version.pdf">www.cancerscreening.ie/publications/QA_final_web_version.pdf</a>
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<b>1.2 Clinical Guidelines and SOPs for Staff Involved in Taking Screening Samples</b>		
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NHS England. Good Practice Guidance for Cervical Sample Takers. 2011		<a href="http://www.gov.uk/government/uploads/system/uploads/attachment_data/file/469962/CSP_GPG2_uploaded_211015.pdf">www.gov.uk/government/uploads/system/uploads/attachment_data/file/469962/CSP_GPG2_uploaded_211015.pdf</a>
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<b>1.3 Guidelines and SOPs for Cervical Cytology Screening Laboratories</b>		
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1.0 Model Documents for the Preparation of National Guidelines and SOPs		Source
<b>1.4</b>	<b>Guidelines and SOPs for Pathology Laboratories Involved in Cervical Screening</b>	
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	Royal College of Pathologists. Guidelines on staffing and workload for histopathology and cytopathology departments. 2012	<a href="http://www.rcpath.org/Resources/RCPATH/Migrated%20Resources/Documents/G/G107_GuidelinesStaffingWorkload_Apr12.pdf">www.rcpath.org/Resources/RCPATH/Migrated%20Resources/Documents/G/G107_GuidelinesStaffingWorkload_Apr12.pdf</a>
<b>1.5</b>	<b>Clinical Guidelines and SOPs for Colposcopy</b>	
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	American Society for Colposcopy and Cervical Pathology. Updated Consensus Guidelines for the Management of Abnormal Cervical Cancer Screening Tests and Cancer Precursors. 2012	<a href="http://www.asccp.org/Portals/9/docs/ASCCP%20Updated%20Guidelines%20-%202013.21.13.pdf">www.asccp.org/Portals/9/docs/ASCCP%20Updated%20Guidelines%20-%202013.21.13.pdf</a>
	NHS England. Colposcopy and programme management guidelines for the NHS cervical screening programme. 2010	<a href="http://www.gov.uk/government/uploads/system/uploads/attachment_data/file/436873/nhscsp20.pdf">www.gov.uk/government/uploads/system/uploads/attachment_data/file/436873/nhscsp20.pdf</a>
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2.0 Model Documents for the Preparation of National Training Curricula for Primary Medical Education, Residency and CME Modules		Source
<b>2.1</b>	<b>Staff Involved in Taking Screening Tests</b>	
	CervicalCheck Ireland. Smearmaker Training Prospectus 2014-2015	<a href="http://www.cervicalcheck.ie/_fileupload/Publications/CS%20PUB%20ST-2%20Rev%209%20Smearmaker%20Training%20Prospectus%202014-2015.pdf">www.cervicalcheck.ie/_fileupload/Publications/CS%20PUB%20ST-2%20Rev%209%20Smearmaker%20Training%20Prospectus%202014-2015.pdf</a>
	NHS Scotland. Standards for Education Providers: Cervical Cytology. 2013	<a href="http://www.nes.scot.nhs.uk/media/2573148/standards_for_cervical_cytology_interactive.pdf">www.nes.scot.nhs.uk/media/2573148/standards_for_cervical_cytology_interactive.pdf</a>
<b>2.2</b>	<b>Cervical Cytology Laboratory Staff Involved in Processing, Screening and Diagnosing Screening Tests</b>	
	NHS England. Cervical Screening Programme Requirements for Training in Cervical Cytopathology. 2009	<a href="http://www.cytologytraining.co.uk/pdf/nhscsp-requirements-for-training-in-cervical-cytopathology.pdf">www.cytologytraining.co.uk/pdf/nhscsp-requirements-for-training-in-cervical-cytopathology.pdf</a>

<b>3.0 Guidelines and Data Collection Forms for Undertaking Situation Analyses and Capacity Assessments for Cervical Cancer Screening</b>		<b>Source</b>
<b>3.1</b>	<b>Situation Analysis for Cervical Screening</b>	
	Situation Analysis Guide for Cervical Cancer Screening Programme Planning & Implementation. European Cervical Cancer Association, 2012	<a href="http://www.ecca.info/partners-for-prevention/capacity-building-for-cervical-cancer-prevention/guidelines/">www.ecca.info/partners-for-prevention/capacity-building-for-cervical-cancer-prevention/guidelines/</a>
<b>3.2</b>	<b>Capacity Assessment of Health Services Involved in Cervical Screening</b>	
	Capacity Assessment Guide for Cervical Cancer Screening Programme Planning & Implementation. European Cervical Cancer Association, 2012	<a href="http://www.ecca.info/partners-for-prevention/capacity-building-for-cervical-cancer-prevention/guidelines/">www.ecca.info/partners-for-prevention/capacity-building-for-cervical-cancer-prevention/guidelines/</a>
<b>3.3</b>	<b>Stakeholder Analysis</b>	
	WHO Stakeholder Analysis Guidelines	<a href="http://www.who.int/workforcealliance/knowledge/toolkit/33.pdf">www.who.int/workforcealliance/knowledge/toolkit/33.pdf</a>

<b>4.0 Organizations Providing Short-Term Capacity Development Support</b>		<b>Source/Contact Details</b>
<b>4.1</b>	<b>Planning and Implementing a National Cancer Registry</b>	
	European Network of Cancer Registries (ENCR)	<a href="http://encr.eu/">http://encr.eu/</a>
	ENCR Cancer Registry Training Courses and Workshops	<a href="http://encr.eu/index.php/activities/courses">http://encr.eu/index.php/activities/courses</a>
	ENCR Cancer Registry Software	<a href="http://encr.eu/index.php/downloads/depedit">http://encr.eu/index.php/downloads/depedit</a>
<b>4.2</b>	<b>Management of the Process to Prepare a Plan for the Implementation of a Cervical Cancer Prevention Programme</b>	
	European Cervical Cancer Association	Dr Philip Davies, Director General European Cervical Cancer Association <a href="mailto:philip.davies@ecca.info">philip.davies@ecca.info</a>
<b>4.3</b>	<b>Undertaking a Situation Analysis for Cervical Cancer Prevention</b>	
	European Cervical Cancer Association	Dr Philip Davies, Director General European Cervical Cancer Association <a href="mailto:philip.davies@ecca.info">philip.davies@ecca.info</a>
	United Kingdom. London School of Hygiene and Tropical Medicine	Dr Dina Balabanova, Senior Lecturer, Health Systems/Policy Department Global Health & Development London School of Hygiene & Tropical Medicine <a href="mailto:dina.balabanova@lshtm.ac.uk">dina.balabanova@lshtm.ac.uk</a> Health Systems Global Board Member
<b>4.4</b>	<b>Analysis of Government Policies, Laws and Strategies to Assess Compatibility with the Implementation and Operation of Organized Cervical Screening Programmes</b>	
	European Cervical Cancer Association	Dr Philip Davies, Director General European Cervical Cancer Association <a href="mailto:philip.davies@ecca.info">philip.davies@ecca.info</a>
	United Kingdom. London School of Hygiene and Tropical Medicine	Dr Dina Balabanova, Senior Lecturer, Health Systems/Policy Department Global Health & Development London School of Hygiene & Tropical Medicine <a href="mailto:dina.balabanova@lshtm.ac.uk">dina.balabanova@lshtm.ac.uk</a> Health Systems Global Board Member
<b>4.5</b>	<b>Undertaking a Capacity Assessment of Health Services Involved in Cervical Screening</b>	

4.0 Organizations Providing Short-Term Capacity Development Support		Source/Contact Details
	European Cervical Cancer Association	Dr Philip Davies, Director General European Cervical Cancer Association philip.davies@ecca.info
<b>4.6</b>	<b>Analysis of Health-Care Provider Knowledge, Awareness and Practices</b>	
	United Kingdom. London School of Hygiene and Tropical Medicine	Dr Dina Balabanova, Senior Lecturer, Health Systems/Policy Department Global Health & Development London School of Hygiene & Tropical Medicine dina.balabanova@lshtm.ac.uk Health Systems Global Board Member
	Bulgarian Health Psychology Research Center	Dr Irina Todorova, Director, Health Psychology Research Center Dalchev Street, #10 Sofia, Bulgaria 1113 ilgt1@comcast.net
	Romania. Health Psychology Research Center, Babes-Bolyai University, Cluj-Napoca	Prof. Adriana Baban, Professor of Health Psychology Health Psychology Research Center Babes-Bolyai University, Romania adrianababan@psychology.ro
<b>4.7</b>	<b>Analysis of Target Population Knowledge, Attitudes and Beliefs</b>	
	United Kingdom. London School of Hygiene and Tropical Medicine	Dr Dina Balabanova, Senior Lecturer, Health Systems/Policy Department Global Health & Development London School of Hygiene & Tropical Medicine dina.balabanova@lshtm.ac.uk Health Systems Global Board Member
	Bulgarian Health Psychology Research Center	Dr Irina Todorova, Director, Health Psychology Research Center Dalchev Street, #10 Sofia, Bulgaria 1113 ilgt1@comcast.net
	Romania. Health Psychology Research Center, Babes-Bolyai University, Cluj-Napoca	Prof. Adriana Baban, Professor of Health Psychology Health Psychology Research Center Babes-Bolyai University, Romania adrianababan@psychology.ro
<b>4.8</b>	<b>Planning and Implementing a Cervical Screening Registry</b>	
	Sweden. Swedish National Cervical Screening Registry	Prof. Joakim Dillner, Director Swedish National Cervical Screening Registry Center for Cervical Cancer Prevention Karolinska University Laboratory Huddinge, F56 S-14188 Stockholm, Sweden joakim.dillner@ki.se
<b>4.9</b>	<b>Preparing National Clinical Guidelines and SOPs</b>	
	WHO Handbook for Guideline Development. 2010	<a href="http://www.who.int/hiv/topics/mtct/grc_handbook_mar2010_1.pdf">http://www.who.int/hiv/topics/mtct/ grc_handbook_mar2010_1.pdf</a>
<b>4.10</b>	<b>Preparing National Clinical Guidelines and SOPs for Health-Care Providers Taking Cervical Screening Samples</b>	

4.0 Organizations Providing Short-Term Capacity Development Support		Source/Contact Details
	CervicalCheck, the National Cervical Screening Programme of Ireland	CervicalCheck, King's Inns House, 200 Parnell Street, Dublin 1 Ireland info@screeningservice.ie
<b>4.11</b>	<b>Preparing National Guidelines and SOPs for Cervical Cytology Screening Laboratories</b>	
	British Association of Cytopathology	British Association for Cytopathology 12 Coldbath Square London EC1R 5HL United Kingdom mail@britishcytology.org.uk
	Italian Society of Pathology and Cytopathology/Società Italiana di Anatomia Patologica e Citologia Diagnostica (SIAPEC)	Prof. Gaetano De Rosa, President SIAPEC Professore di anatomia patologica Università degli Studi di Napoli Federico II Via S. Pansini, 5 80131 Naples presidente@siapec.it
<b>4.12</b>	<b>Preparing National Clinical Guidelines and SOPs for Colposcopy</b>	
	British Society for Colposcopy and Cervical Pathology (BSCCP)	BSCCP Secretariat Birmingham Women's Hospital Mindelsohn Way, Edgbaston Birmingham, B15 2TG United Kingdom elaine.radford@bwnft.nhs.uk
	Italian Society for Colposcopy and Cervical Pathology/Società Italiana di Colposcopia e Patologia Cervico Vaginale	SICPCV Segretario Generale: Prof. Fausto Boselli, Chief Oncologic and Preventive Gynaecology Dept. of Obstetrics and Gynaecology University of Modena and Reggio Emilia Via del Pozzo, 71 41100 Modena - Italy segreteria.sicpcv@colposcopiaitaliana.it

5.0 Opportunities for Training and Knowledge/Skills Exchanges		Contact Details
<b>5.1</b>	<b>Cancer Registry Structure and Operation</b>	
	European Network of Cancer Registries (ENCR)	<a href="http://encr.eu/">http://encr.eu/</a>
	ENCR Training Courses and Workshops	<a href="http://encr.eu/index.php/activities/courses">http://encr.eu/index.php/activities/courses</a>
	ENCR Cancer Registry Software	<a href="http://encr.eu/index.php/downloads/depeditis">http://encr.eu/index.php/downloads/depeditis</a>
<b>5.2</b>	<b>Cervical Screening Programme Structure and Operation</b>	
	CervicalCheck, the National Cervical Screening Programme of Ireland	CervicalCheck, King's Inns House, 200 Parnell Street, Dublin 1 Ireland <a href="mailto:info@screeningservice.ie">info@screeningservice.ie</a>
	Cervical Screening Wales	Cervical Screening Wales Screening Division, Public Health Wales, Cardiff, Wales <a href="mailto:clare.o'hanlon@wales.nhs.uk">clare.o'hanlon@wales.nhs.uk</a>
<b>5.2</b>	<b>Cervical Screening Registry Structure and Operation</b>	
	Swedish National Cervical Screening Registry	Professor Joakim Dillner, Director Swedish National Cervical Screening Registry Center for Cervical Cancer Prevention Karolinska University Laboratory Huddinge, F56 S-14188 Stockholm, Sweden <a href="mailto:joakim.dillner@ki.se">joakim.dillner@ki.se</a>
<b>5.3</b>	<b>Development of Training Capacity for Health-Care Providers Taking Cervical Screening Samples</b>	
	CervicalCheck, the National Cervical Screening Programme of Ireland	CervicalCheck, King's Inns House, 200 Parnell Street, Dublin 1 Ireland <a href="mailto:info@screeningservice.ie">info@screeningservice.ie</a>
	Cervical Screening Wales	Cervical Screening Wales Screening Division, Public Health Wales, Cardiff, Wales <a href="mailto:clare.o'hanlon@wales.nhs.uk">clare.o'hanlon@wales.nhs.uk</a>
<b>5.4</b>	<b>Development of Cervical Cytology Screening Capacity</b>	
	British Association of Cytopathology	British Association for Cytopathology 12 Coldbath Square London EC1R 5HL United Kingdom <a href="mailto:mail@britishcytology.org.uk">mail@britishcytology.org.uk</a>
<b>5.5</b>	<b>Development of Training Capacity for Colposcopy</b>	
	International Federation for Cervical Pathology and Colposcopy	IFCPC Secretary General Prof. James Bentley 5006 Dickson Building, 5820 University Avenue Halifax, NS B3H 1V7 Canada <a href="mailto:jrbentley@me.com">jrbentley@me.com</a>
	European Federation for Colposcopy (EFC)	EFC Secretariat Ms Liz Dollery 12 Rose Road Harborne, Birmingham B17 9LJ United Kingdom <a href="mailto:liz.dollery.efc@gmail.com">liz.dollery.efc@gmail.com</a>

5.0 Opportunities for Training and Knowledge/Skills Exchanges	Contact Details
British Society for Colposcopy and Cervical Pathology (BSCCP)	BSCCP Secretariat Birmingham Women's Hospital Mindelsohn Way, Edgbaston Birmingham, B15 2TG United Kingdom <a href="mailto:elaine.radford@bwnft.nhs.uk">elaine.radford@bwnft.nhs.uk</a>
Italian Society for Colposcopy and Cervical Pathology/Società Italiana di Colposcopia e Patologia Cervico Vaginale	SICPCV Segretario Generale: Prof. Fausto Boselli, Chief Oncologic and Preventive Gynaecology Dept. of Obstetrics and Gynaecology University of Modena and Reggio Emilia Via del Pozzo, 71 41100 Modena - Italy <a href="mailto:segreteria.sicpcv@colposcopiaitaliana.it">segreteria.sicpcv@colposcopiaitaliana.it</a>



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