



COURSE: Evidence-Based Approaches to HPV Screening implementation

Module 8. Implementation of screening programmes

Authors

Josep Alfons Espinàs, MD PhD

Coordinator of the Office of Cancer Screening, Cancer Plan for the Catalan Department of Health, Spain.

Raquel Ibáñez, PhD


Senior Investigator, Cancer Epidemiology Research Programme, Catalan Institute of Oncology (ICO), Spain.

Valentina Rangel-Sarmiento, MD

Predoctoral Researcher, Cancer Epidemiology Research Programme, Catalan Institute of Oncology (ICO), Spain.

Esther Roura, PhD

Biostatistician, Cancer Epidemiology Research Programme, Catalan Institute of Oncology (ICO), Spain.



Reviewers

Kate Cuschieri, PhD

Director, Scottish HPV Reference Laboratory, NHS Lothian Lead HPV Research Group, Centre for Reproductive Health, University of Edinburgh, Scotland, United Kingdom.

Paula Peremiquel-Trillas, MD, MPH

Preventive medicine specialist, Cancer Epidemiology Research Programme, Catalan Institute of Oncology (ICO), Spain. Cervical cancer screening programme coordinator.

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INTRODUCTION AND LEARNING OBJECTIVES


The successful implementation of a screening programme whose suitability has been considered appropriate requires thorough planning as well as human and financial resources.

Some of the main aspects to be considered include:

- Establishing a governance framework tailored to the country's legal and regulatory context.
- Effective leadership and coordination across healthcare sectors.
- Sustainable funding of all programme components to prevent disruptions
- Detailed mapping of the screening pathway—from initial testing to diagnosis and treatment—based on evidence-based protocols.
- Adequate health system capacity to prevent resource strain on other services.
- Clear and transparent communication strategies to help individuals make informed decisions about screening.
- A robust health information system, such as a cancer screening registry, to invite and track individuals and ensure quality standards.
- Continuous training for healthcare professionals.

Once implemented, monitoring is essential to ensure the quality assurance, performance and effectiveness of the screening programme.

This module addresses these key components, providing participants with the necessary knowledge to design, implement, and sustain effective screening programs.



At the end of this module, participants will be able to:

- Acquire the knowledge to design, implement, and sustain evidence-based screening programs.
- Identify the phases and activities involved in a screening programme.
- Recognize the importance of identifying the target population for screening and strategies to achieve high participation rates.
- Identify the key topics in effective communication to the target population to make informed decisions regarding screening participation and follow-up care.
- Recognize the importance of continuous personnel training to achieve and maintain high-quality service delivery.
- Understand the role of health information systems in collecting data to evaluate cervical cancer screening programs effectively.
- Recognize the important role of quality control in ensuring all aspects of the screening services are performed to the highest standards.
- Discern the quality assurance measures needed at different stages of the screening process (e.g. HPV testing, cervical cytology, colposcopy, biopsy, and treatment).
- Identify key performance indicators for monitoring and evaluating the effectiveness of a cervical screening programme.



UNIT 1. BUILDING THE FOUNDATIONS OF A SCREENING PROGRAMME

1.1 Legal framework

The first step towards the implementation of a screening programme is ensuring that the target disease is suitable for screening. This assessment can be done through the Wilson and Jungner principles ([Wilson et al., 1968](#)), which provide a framework to assess whether screening is appropriate for a specific disease.

NOTE: For more information on how these principles are fulfilled by cervical cancer screening, please refer to **MODULE 2**.

Once screening is considered suitable for implementation, a legal framework and a government mandate are essential to support its implementation. This framework should outline responsibilities for the key aspects of the screening programme:

- Clinical guidelines
- Performance monitoring
- Service delivery
- Financing and payment systems
- Data access
- Quality assurance

Screening programs are complex interventions that go beyond the processing of a single test. They involve multiple phases—screening, follow-up/work-up and treatment, if necessary—which require effective coordination of multiple activities carried out by different professionals at different levels of care (**Figure 1**).

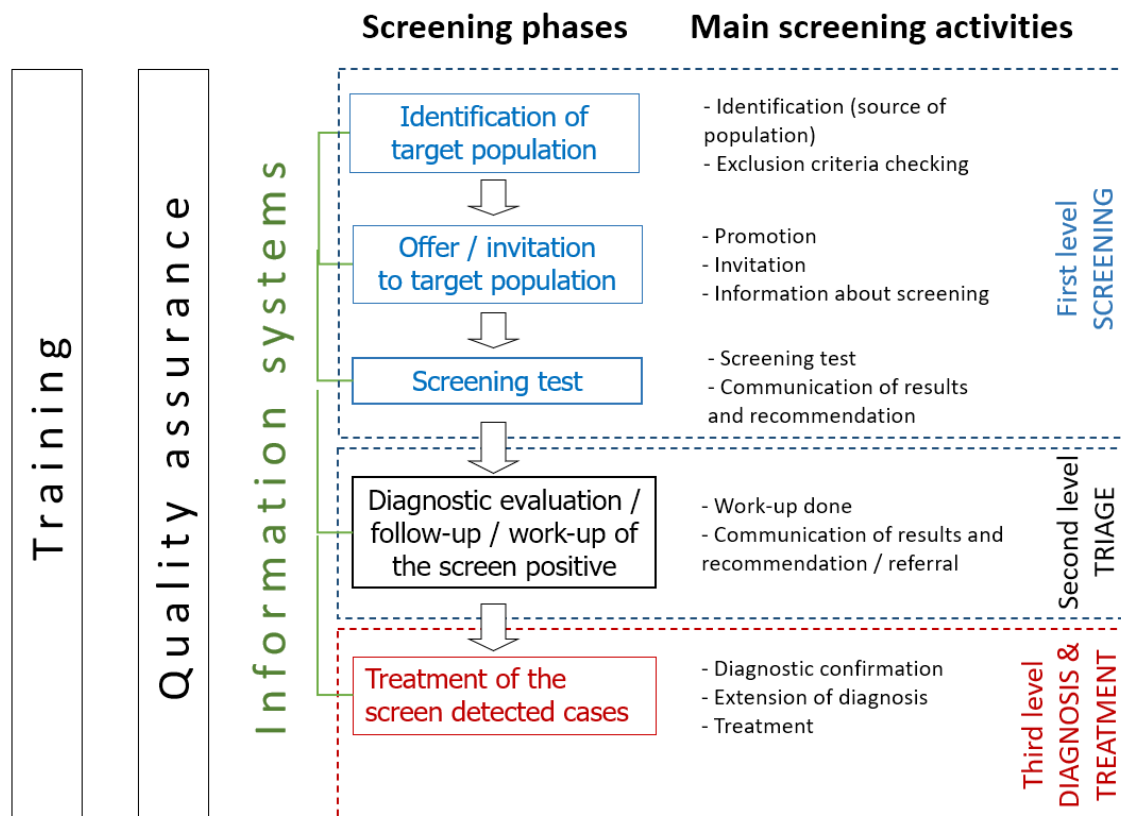


Figure 1. Phases and activities of a screening programme. Created by Josep Alfons Espinàs

Therefore, the effectiveness of a screening programme depends on several key factors, including the flow of participants and data across phases, the coordination among professionals at different levels, and the overall quality of all the screening activities. To ensure these aspects, the minimum structure of the government body would include a person in charge (or coordinator), a steering committee and a multidisciplinary advisory committee.

In accordance with [Lyngge et al. \(2012\)](#), successful implementation should encompass the following four phases:

- Comprehensive planning
- Preparation of all screening components
- Scaling-up from pilot to service screening
- Running a full-scale screening programme



1.2. Comprehensive planning for screening programs.

Planning screening programs requires a multidisciplinary approach engaging all key stakeholders and defining all essential processes within the programme (identification of the target population, invitation systems, screening test performance, follow-up of positive cases, referral for treatment, etc.). This process must consider the necessary human resources, specialized training, organisational needs and financial resources/funding, as well as the definition of protocols and quality standards.


Effective screening programs rely on strong leadership, coordination, and management at all levels. This includes establishing dedicated teams to oversee the programme at the national or regional level, as well as teams responsible for managing service delivery at hospitals and screening centres. Intersectoral collaboration is essential, with all stakeholders working closely to ensure throughout the screening process. Therefore, getting the support and acceptance from all involved parties and professionals involved in screening is crucial for success.

Did you know?

Discrete event simulation models are valuable tools to support resource and operational planning for cervical cancer screening programmes. They help optimize resource use and streamline processes, such as managing patients' flow and sample handling through resource-constrained steps. Please refer to [Gravitt et al., \(2020\)](#) for more information.

Computerised information systems and accessible registries are also needed to support effective and efficient screening services, including call/re-call systems, fail-safe procedures for follow-up of participants with abnormal test results, and monitoring and evaluation programme performance and outcomes.

The organisation and delivery of the screening programme must be aligned with the country healthcare system structure, whether centralised, decentralised or involving multiple public healthcare providers.



The screening programme should be standardized throughout the territory, with consistent definitions of the target population, clinical guidelines as well as quality and training requirements.


Likewise, securing sufficient, sustainable and reliable funding is essential for the successful delivery of a screening programme as inconsistent financial support would disrupt its functionality. Adequate resources must be allocated to all phases and activities, from screening to diagnosis and follow-up care, including also information systems, data collection, and quality assurance at all levels.

All care along the screening pathway should be at no cost to participants. Funding only the screening test without covering subsequent procedures compromises the programme's effectiveness and accessibility.

1.3. Preparation of all screening components, including piloting

After planning and operationally defining all programme components and processes, a small-scale pilot programme adapted to the territory characteristics should be conducted. This piloting may help identify aspects previously overlooked during the planning phase and help refine the planned programme.

The pilot programme should enable and assess whether the organisational aspects are functioning as intended while providing preliminary results for the specific setting, such as participation, positivity test rates, referral rates for diagnostic and follow-up tests, etc. In this pilot phase, communication materials should also be tested in a routine real-world context.



A pilot programme provides a unique opportunity to adjust organisational aspects and to accurately estimate the resources needed for full-scale implementation.

1.4. Scaling up from pilot to full-service screening

Building on the pilot's experience, the next step is a progressive expansion of the programme to the full territory. Each region must work with its providers to define and implement the program.

This expansion should occur gradually within a reasonable timeframe to allow for necessary and feasible increases in funding and resource acquisition.

1.5. Full-scale screening programme and intensive monitoring

Once the programme is scaled up across the entire population or territory, it requires systematic and regular monitoring and evaluation to ensure effective outcomes. Therefore, it is important to evaluate the performance and quality at every phase of the programme, from invitation of the target population to follow-up and treatment of the detected lesions. This includes, among others, assessing the screening test itself and the management of the detected abnormalities.

After full implementation, the governing bodies must continuously:

- Identify and propose corrective measures to address underperformance and other potential identified issues.
- Recommend organisational and/or technical improvements based on results or technological advancements.
- Ensure the programme's financial sustainability beyond the initial phase.



ACTIVITY

Read the following statements and decide if they are TRUE or FALSE.

1. A screening programme is considered effective if it only includes a high-quality test and does not require coordination between different levels of care.
2. A legal framework is a prerequisite for implementing a screening programme, outlining responsibilities such as financing, quality assurance, and data access.
3. Piloting a screening programme before full-scale implementation helps identify unforeseen issues and allows for adjustments in resources and organization.

The correct answers are:

1 False, 2 True, 3 True.



UNIT 2. ENGAGING AND RETAINING WOMEN IN SCREENING

Designing a screening pathway aligned with a country's healthcare system is essential for guiding participants from being identified as eligible target population to diagnosis and treatment, if needed. Each step must be guided by evidence-based standards and protocols. This screening pathway also informs the design and development of information systems, training plans, and estimates how many people will require screening, diagnosis, and treatment.

The success of any screening programme depends on:

- Invitation coverage: the proportion of the target population invited to participate.
- Screening uptake or participation rate: how many of the invited women are screened.
- Follow-up adherence: the proportion of screen-positive individuals who comply with subsequent follow-up testing, diagnostic procedures and/or treatment recommendations.

2.1. Invitation of eligible women

Participation rate is one of the most critical factors influencing the impact of any screening programme, particularly in cervical cancer screening, where reaching high-risk population is crucial.

In a population-based screening programme, all eligible individuals within the target population are identified and personally invited to participate, regardless of their use of health services. Different studies indicate that organised, population-based programmes with personal invitations have a positive impact on both coverage (proportion of the target population invited) and participation (proportion who actually attend), leading to better outcomes compared to non-organised, opportunistic programmes.



EXAMPLE


The analysis of the screening history of cervical cancer cases in the target population of the screening programme in the USA (Leyden et al., 2005) highlights the importance of effective programme organisation. Out of 833 cervical cancer cases:

- 56% of cases resulted from no cytology screening in the last three years, emphasizing the need to improve identification of the target population and the invitation system.
- 32% were due to non-detection by the screening test which was cytology, underscoring the importance of adequate quality control and quality assurance.
- 12% were due to the lack of adherence to follow-up procedures, highlighting the need to ensure proper follow-up.

An effective recruitment system for a population-based screening programme has two basic components:

- **Identification of the target population:** This step requires the creation and the maintenance of a detailed database for the entire target population, including full name, age, sex, contact information and healthcare identification number, as well as useful additional information about exclusion criteria (i.e, hysterectomy), other disease conditions (i.e, immunosuppression), vaccination status or primary healthcare provider, among others.
- **Call/recall systems:** An automated system should send personalized invitations to eligible individuals due for screening in the target population. This requires a tailored, secure, comprehensive, and computerised information system with reliable back-ups.

The programme should remove or mitigate barriers to participation by ensuring the procedures are free and convenient. Measures aimed at facilitating access – such as mailing the self-sampling device – may increase screening participation, although at the expense of higher costs and/or reduced cost-effectiveness.



Tailored efforts are essential to engage hard-to-reach populations, facing socioeconomic, physical, mental, ethnic, geographic or linguistic challenges, ensuring equitable access to screening services.

An effective invitation system is crucial for achieving high participation and reducing inequities in access to screening.

In a screening programme, asymptomatic people are invited to undergo a test in a population-level programme to detect a disease before symptoms occur, allowing for earlier, less invasive, and more effective treatment if needed. However, since screening has both potential benefits and risks, those invited to take part in any screening programme must be provided with clear, balanced and accurate information to help them make an informed choice about whether to participate.

This information needs to be sensitive to the individual needs for information so that basic information is to be provided to the entire eligible population together with the details on how to access more information for those willing to get it.

The invitation is usually the first direct contact with eligible women, inviting them to participate in the screening programme. It can be sent by postal letter or electronically and it is usually accompanied by a leaflet and/or a landing webpage. Invitation letters and leaflets/landing webpages are usually designed to complement each other, and some information not contained in the former may be found in the latter to avoid too long invitation letters.

In case of clinician-collected samples, the invitation can be:

- An open invitation asking the individual to schedule an appointment.
- An invitation with a pre-booked appointment that can be modified if needed.



In case of HPV self-sampling, invitations can be:


- An invitation to collect the self-sampling device in a convenient facility.
- An invitation to request/order the delivery of the self-sampling device.
- Direct mailing of the self-sampling device to the individual's home, together with the invitation letter.
- Personally offered by a healthcare professional when opportunistically visiting a healthcare setting.
- Personally offered by a community healthcare worker in awareness events, at home or work.

NOTE: For more information on the potential strategies to invite women to self-collected vaginal samples, please refer to **MODULE 5**.

Contents of the invitation letter

The invitation should ideally address the following:

- Purpose of the screening and target population (e.g. age group)
- Type of screening test and screening interval
- Cost (whether the test is free of charge or not)
- Test delivery (how to schedule or modify an appointment for clinician-collected samples or how to collect, order and/or send a self-sampling device)
- Expected timeframe and method for result delivery
- Possibility of being recalled for additional tests
- Where to find further information (e.g. information services, helplines, and websites)
- Data protection and confidentiality information.



Below you can find, as an example, the invitation letter from the Dutch cervical cancer screening programme:

<https://www.rivm.nl/en/documenten/invitation-letter-for-cervical-cancer-screening-30-year>

Contents of the invitation letter (paper leaflet or other media)

The invitation leaflet, whether in print or another format, should ideally address the following:

- Information about the disease: what is HPV, how it is transmitted, natural history of the disease, cervical cancer incidence and risk factors.
- Definition of the target population for screening.
- Nature, purpose and validity of the test.
- Test procedure: how is the sample taken and how long it takes, lab processing overview, and turn-around time until the result will be available. ,
- Screening interval.
- Meaning and importance of early detection.
- Benefits and disadvantages of cervical cancer screening (include information on side effects i.e. pain, discomfort, anxiety).
- Procedure for delivery of results and their interpretation (negative, positive, inconclusive).
- Further management and follow-up: possibility and need of further tests after screen-positive including the possibility of false positives and uncertainties of the test results.
- The possibility of false negative results and the recommendation to consult a health care professional if symptoms appear, even after a negative test.
- Quality control measures: information about safety, reliability, and accuracy of the screening process.
- References or links for further information and contact details for support services.

- Dates and sources of the information provided.

Please check the following link to check the invitation letters and leaflet used in the cervical cancer screening programme from the Netherlands:

<https://www.bevolkingsonderzoeknederland.nl/en/cervical-cancer/the-invitation/>

For examples from the UK in different languages, including a video on sign language:

<https://www.gov.uk/government/publications/cervical-screening-invitations>

A screening test is a marker of risk, not of disease—that requires a diagnostic test. Screening reduces risk but does not remove it entirely, so clear communication is essential to avoid false expectations


2.2 Ensuring work-up and follow-up

The effectiveness of any screening programme depends on the proper functioning of all phases of the screening process: invitation/participation, performance of the screening test, results evaluation, management of screen-positive cases, treatment of detected lesions and follow-up care according to clinical guidelines.

Did you know?

[Sasieni et al. \(1996\)](#) estimated that 21% of cervical cancer cases in the UK among women with an inadequate screening history were due to incomplete follow-up of abnormalities detected during screening.

Organised screening helps address the issue of loss to follow-up, as one of its key strengths over opportunistic screening lies in having structured systems that ensure participants move through each phase of the programme. In that sense, the main components of effective work-up and follow-up are:


- 
- Evidence-based clinical protocols for management of screening results and treatment of lesions, ensuring optimal and uniform care for all participants (i.e, avoiding over- and undertreatment).
 - A communication and an appointment system ensuring timely completion of additional examinations and tests following a positive screening result, tailored to the level of risk.

Regarding the communication of screening results, most programmes communicate negative screening test results either by letter or SMS. Positive results communication varies among countries, they could be communicated face-to-face in a recall visit, by phone or, less frequently, by letter or electronically, especially in case of less severe lesions that do not need work-up procedures. The content should be adapted to the media used.

Contents of the screen results communication

The screening result communication should ideally contain the following information:

- Name of the patient and explanation of the screening result in plain, non-technical language.
- If the result is normal (negative), its meaning should be explained in terms of the likelihood of having a future lesion and the possibility of false negatives. The screening interval should be specified.
- If the test is positive, its meaning should be explained in terms of the risk of having a lesion and the possibility of false positives. Women should be informed of any additional tests/exploration needed (colposcopy, further cytology/HPV test) and how the arrangements for this follow-up management will be made.
- For those with abnormal results that require an immediate work-up visit (recall) direct communication by phone or in the recall consultation can help ensure patient understanding and adherence.
- For those with abnormal results that do not require immediate work-up visit according to the programme protocol, the rationale behind not requiring immediate follow-up should be clearly stated.

- 
- Regardless of the test result, information addressing common doubts or concerns that the woman may have should be included, as well as how to get further information and contact support services.


Below you can find, two examples of communication of results:

- Ontario (Canada) Cervical Screening Program Normal Result Letter - <https://www.cancercareontario.ca/en/get-checked-cancer/letters-to-public/ocsp-normal-result-letter>
- Netherlands Cervical Screening Program Normal Result Letter - https://www.rivm.nl/sites/default/files/2023-07/76261_014811_23403132_RIVM_A5_BR_BMHK%20Uitslag%20jun%2023_EN_T_G_PDF.pdf

ACTIVITY

Read the following statements and decide if they are TRUE or FALSE.

1. A well-designed screening pathway not only guides participants through the screening process but also helps define information systems and training plans.
2. Opportunistic screening programmes, where individuals are invited to screening when they visit health facilities or screened when they actively request it, consistently achieve higher participation and coverage rates than organised, population-based programmes.
3. Ensuring timely follow-up and treatment after a positive screening result is as important as being screened in reducing cervical cancer cases. Women who have cleared a naturally acquired HPV infection are still at risk of reinfection with other HPV types.



The correct answers are:

1 True, 2 False, 3 True.



UNIT 3. HEALTH INFORMATION SYSTEMS


Health Information Systems (HIS) are systems designed to collect, store, manage, and communicate information related to the health of individuals or the activities of healthcare organizations. It supports decision-making at all levels of healthcare by providing accurate, timely, and relevant data.

The systems are crucial for the successful operation of screening programs, with cancer screening registries serving as a central component. These registries integrate all steps of a screening process and play a key role in programme implementation and quality assurance monitoring.

Inviting transgender men and non-binary individuals with a cervix to screening can be challenging when sex assigned at birth is not available in HIS and/or when the health identifier which previously identified a screen-eligible individual has been modified through or after a transition process

3.1. Healthcare levels

Throughout the screening programme, individuals progress through three main levels of care in which different activities are done. Consequently, each level collects and/ or generates different data (**Figure 2**).



	Centers	Activity	Available data
First level SCREENING	<ul style="list-style-type: none"> • Primary care centres • Specialised screening units 	Target individuals are screened	<ul style="list-style-type: none"> • Sociodemographic information • Medical history • Past screening and HPV vaccination history • Screening tests performed (cytology, HPV) and results
Second level TRIAGE	<ul style="list-style-type: none"> • Referral centres 	Referred individuals receive follow-up assessment	<ul style="list-style-type: none"> • Follow-up tests performed (triage test, cytology/HPV test post-treatment) and results • Procedures (colposcopy, biopsy) and results • Treatments (cryotherapy, LEEP, cold coagulation, surgery) and results
Third level DIAGNOSIS AND TREATMENT	<ul style="list-style-type: none"> • Oncology centres 	Individuals with cervical cancer receive clinical management	<ul style="list-style-type: none"> • Clinical information on cancer cases (stage, classification) distribution of cancer cases • Treatment provided (surgery, chemotherapy, radiotherapy) and results • Palliative care and complications • Registration of deaths

Figure 2. Data collection based on healthcare level

The above-mentioned data is stored in different HIS. Therefore, effective monitoring requires these three levels to be interconnected.

These records must be capable of linking individual patient data across healthcare levels together with population data, screening programmes and cancer registries. In fact, the ideal HIS should enable standardised data collection, avoid duplication of information and records, and promote bidirectional communication between levels.

It is crucial to maintain comprehensive, preferably computerised records.

3.2. Cancer screening registries

A **cancer screening registry** is an information system designed to collect, manage, and store data related to cancer screening for programme management and reporting. It can be implemented as a computerized system and/or a paper-based system, although the latter is preferred.





Its primary functions include:

- Maintaining a comprehensive database of screening records of individuals along the screening pathway
- Inviting eligible individuals and ensuring that each participant has consistent screening records
- Tracking individuals with positive screening results to evaluate outcomes
- Recording diagnostic and treatment data, including pre-cancer and cancer cases
- Sending reminders to participants due or overdue for screening
- Activating failsafe mechanisms for individuals with positive screening results who have not attended follow-up procedures

To maximize its effectiveness, the registry should ideally integrate with other HIS, enabling quality assurance, monitoring, and programme evaluation. This requires a robust legal framework to manage individual data securely and ensure smooth linking between population databases, screening files, and cancer and mortality registries. Integrated and well-structured HIS are critical to ensuring the efficiency, reliability, and success of cancer screening programs.

Implementing permanent unique individual identifiers can help prevent data mismatches, duplication of records and support the development of specialized HIS.

Cancer screening registries can be either provider-based or population-based.

A) Provider-based registries:

In this type of registry, data is only collected for individuals who access screening or diagnostic services at specific healthcare facilities since each of them keeps and maintains its own records.



Databases or registers for facility-level HIS should comprise:

- A screening registry with details of the screened women
- A referral registry for tracking screen-positive women
- A follow-up registry to document clinical information for women attending follow-up visits after treatment
- A colposcopy and treatment registry
- A laboratory registry for recording laboratory-based test results (HPV test, cytology, histopathology).

Main disadvantages of this type of registry are the multiple reporting format, as each facility may report differently and the difficult linkage between different databases.

Facilities providing screening, diagnostic tests and treatment services should have a computerized data system to collect and store individual data, provided adequate resources are available.

In limited resource settings where a computerised system is not available, the process of recording information mostly relies on paper forms and registries which is far from ideal.

B) Population-based registries:

A population-based registry is a centralized, computerised system—ideally using a server-linked infrastructure—that collects individual (preferably) or aggregated data from all the health facilities serving all the individuals in the target population within a defined geographic area. To ensure consistency, data collection at each facility adheres to standardized reporting formats.

A centralised system supports efficient data processing and automated report generation for calculating programme indicators at the district, regional, sub-national and national levels.



To qualify as a population-based registry, the screening registry must be linked with population databases (census data, electoral rolls or insurance records) to identify the target population for invitation purposes. Additionally, it should be integrated with healthcare provider records as the collection of individual-level data allows to track screen-positive women requiring diagnostic and/or treatment services and enabling follow-up of treated women. The system may also be linked to cancer registries for monitoring of cervical cancer incidence and mortality.

Cancer screening registries and cancer registries should function collaboratively to enhance programme effectiveness.

3.3. Cancer registries

Cancer registries systematically collect information on cancer cases, including the type of cancer, stage at diagnosis and treatments received.

There are three types of cancer registries (

Table 1):

Table 1. Types of cancer registries.

Population-based cancer registries	Hospital-based cancer registries	Pathology-based cancer registries
Collect data on all cancer cases within a defined geographic area. Provide insights into cancer incidence, prevalence, survival rates, and trends in the population that	Collect detailed information about cancer patients diagnosed or treated at a specific hospital or healthcare facility. Primarily used for improving patient care, clinical research, and evaluating	Collect data directly from pathology laboratories on cancers confirmed through microscopic examination. Essential for identifying cancer cases that may not be captured by other



support public health planning and evaluation of cancer control programs.	treatment outcomes within the institution.	registry systems and for tracking pathological trends.
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Population-based cancer registries are essential to evaluate cervical screening impact; pathology, hospital, or mortality registry data can complement it if well linked to other HIS.

The effectiveness of screening programmes can be monitored by linking a cancer registry to a cancer screening registry. The linked data can be used to:

- Assess disease development in screen-negative individuals
- Measure cervical cancer incidence and mortality rates in the screened population
- Compare cancer stage distribution in screen-detected cancers compared to those detected in unscreened or false-negative populations
- Analyse trends in cervical cancer incidence and mortality over time following the programme's introduction.

To accurately measure cervical cancer mortality rates in the screened population, **mortality data** for individual cases should feed into the registry. Efficient data linkage, ideally using unique identification numbers is fundamental for a reliable analysis.



ACTIVITY

Which of the following statements is FALSE for a population-based cancer registry?

- a) Involves collection of information on new cancer cases occurring in a well-defined population.
- b) Describes the cancer burden and determines cancer patterns in different populations.
- c) Helps improve patient care in oncology centres.
- d) Helps in planning, monitoring and evaluating cancer control programmes.

The correct answer is C

The information recorded in population-based cancer registries has no direct impact in patients' care although it can inform on policies aimed to improve cancer care.



UNIT 4. TRAINING OF PROFESSIONALS

Before the implementation of a new screening strategy on a routine basis, in addition to verifying its feasibility, cost-effectiveness, quality assurance and monitoring, it is crucial to ensure training of the professionals involved to support the success of the entire programme.

All healthcare professionals participating in the screening process should have a clear understanding of the programme's overall purpose, strategy, benefits and safety. If changes occur, they should also be promptly informed.

Lack of training and communication, can lead to resistance and hinder the successful implementation of new protocols.

Many countries are undergoing or have undergone significant changes in their cervical cancer screening strategies to replace cytology with HPV testing as the primary test. This involves not only a transition from a morphological test to a molecular test but also extending the screening interval from every three years to every five years or more. It is crucial that professionals understand the rationale behind these changes, the associated benefits this new screening strategy entails and the updated clinical management algorithms. A well-trained professional will understand these changes, conduct their work with greater confidence, and inform women more accurately, improving the programme effectiveness and public trust.

EXAMPLE


The impact of training for cervical cancer screening professionals was evaluated in a study carried out in the city of Goiânia (Brazil). Following training, there was a significant improvement in completion of the application form, adherence to Ministry of Health recommendations on frequency and age range, and sample adequacy ([Amaral et al., 2014](#)).

4.1. Professional training needs

The training content for each category of professionals involved in the different screening activities must be defined (**Table 2**).

Table 2. Identification of relevant professionals and training topics based on the screening component. Adapted from [Arbyn et al., 2008](#) and [Asia, 2017](#).

Component of screening	Professionals	Training topic
Community awareness and education on the cervical cancer screening programme	Community health workers, general practitioners and health volunteers	General information on cervical cancer prevention, importance of screening, screening tests performance, counselling, recall and management and follow-up tests for those with abnormal screening results.
Primary screening	Midwives, nurses, gynaecologists, physicians, other healthcare professionals (depending on the country)	Screening protocol, anatomy and physiology of the female genital tract, natural history of cervical cancer, counselling, infection prevention practices, screening tests performance, sample collection, interpretation of cervical test reports, quality assurance for screening test, communicating results and need of adherence to follow-up strategies.
Diagnosis	Gynaecologists, physicians	Management of positive/abnormal screening test results, screening and triage tests performance, colposcopy quality assurance and report, communicating results and need of adherence to follow-up strategies.
Treatment of cervical precancers	Gynaecologists, physicians, midwives, nurses (depending on the country)	Treatment options for cervical precancers, colposcopy report, biopsy report interpretation and treatment, quality assurance for colposcopy and treatment, communicating results and need of adherence to follow-up strategies.
Implementation, monitoring and evaluation	Public health specialists, screening programme	Concept of screening and screening programme, models of screening programs and strategies, quality



Component of screening	Professionals	Training topic
	managers, information systems managers	assurance, programme monitoring including key indicators, population-based data management, population-based health information systems.
Laboratory procedures	Biologists, microbiologists, pathologists, cytotechnologists, laboratory technicians	HPV testing and cervical cytology test delivery and performance assessment, pre- and processing of all samples, biopsy samples, conisation pieces, results reporting guidelines, laboratory quality assurance, self-sample management, coding of diagnosis

When shifting from cytology-based screening to HPV primary screening, cytology may become a triage test within the screening and diagnostic process. This transition changes both the type and volume of cytology work, e.g. less overall amount of cytology but a much greater proportion of abnormal results due to the pre-selection of HPV-positive women. Thus, to maintain accuracy, cytopathologists and pathologists interpreting slides from HPV-positive women will require special training, appropriate quality control measures, and monitoring of the predictive value of cytology in the triage setting. Reduced cytology workload can present a challenge in that sufficient levels of abnormalities and “rare” cases must be observed to help maintain competency. The set up of a reference, cytology “training school” which maintains a repository of training slides and acts as a hub for best practice can mitigate this risk and help ensure ongoing quality.

The transition to HPV testing could also involve a shift to liquid-based cytology as sample media, which also requires of proper training for sample collectors to ensure the collection of high-quality specimens using appropriate sampling equipment as sample quality directly impacts the performance of the screening test. Training of laboratory personnel to cover receipt, processing, storage, testing and resulting of samples is also needed, whether these are clinician-collected or self-collected.



4.2. Training strategies for healthcare professionals

Whenever a screening programme is implemented or modified, effective training of involved professionals is essential. There are several ways to carry out and facilitate training for the professionals involved:

a) Online training

Online training offers flexible self-paced learning and is ideal for both, training new staff as well as updating those already involved in the screening programme. This approach standardises training, ensures its sustainability over time and is the fastest way of scaling knowledge in a specific area. However, it requires investment in developing, maintaining and updating the training platform.

b) Cascade training or train-the-trainer approach


In a cascade approach, training is imparted via several layers of trainers until it reaches the final target group. For example, a select group of facilitators are identified and trained as master facilitators by an external facilitator (regional or national). These master facilitators train other service providers (local) and also identify potential master facilitators from their trainees. This approach builds a large pool of trained providers and facilitators, thus ensuring the sustainability of training. In this approach, a suitable training site must be selected and equipped with the necessary resources for each round of training.

c) A specific trainer or group of trainers

Trainers for a particular region/district train service providers for the whole area by a single trainer or group of trainers using existing training materials to ensure consistency. While this approach ensures quality, it takes longer to build capacity in a defined area as it is slower to scale. Also, a suitable training site must be selected and equipped with the necessary sources for training.

d) External training

Outsourcing training to specialised external organisations guarantees standardised, professional delivery. However, this approach does not help developing training capacity within the programme itself and requires adequate funding to sustain training.



4.3. Communicating changes in cervical cancer screening to the general public

When screening strategies change, it is critical to effectively inform the general population, particularly those targeted for screening.


Did you know?

In most EU countries, general practitioners, gynaecologists and screening providers play a key role in providing information about cervical cancer screening. Their long-term personal, ongoing relationships with patients make them trusted sources of information. Providers are usually trusted by their patients in the decision-making process. Research indicates that their involvement is an important factor influencing screening coverage. Likewise, providers are central to optimising women's experience, satisfaction and continued acceptance of screening. If they receive women in a calm, relaxed and friendly atmosphere, answering questions and carefully explaining the procedures, they can generate confidence in women and increase their co-operation while minimizing their anxiety (Giordano et al., 2008). Health professionals should therefore receive appropriate training in communication skills.

Thus, the patient-provider relationship can contribute to:

- Reduce anxiety and fear about the screening process and the test itself
- Improve understanding of procedures
- Provide relevant and personalized information
- Encourage informed participation
- Increase satisfaction and long-term engagement with the programme.

Health professionals need a comprehensive understanding of the screening programme, including its benefits, limitations, and procedures, to accurately communicate key information to the population.



Educating, training and motivating health professionals to enable and empower women to make informed decisions about participation in cervical screening is a significant part of a well-run screening programme.

Moreover, accuracy of information depends not only on the content but on how health professionals deliver the message. Health professionals must:


- Be sensitive to educational, cultural, linguistic and religious differences among women
- Use plain, jargon-free language
- Avoid complex mathematical or statistical concepts and explanations when explaining risk that may confuse rather than clarify.
- Create a safe space where women feel comfortable asking questions.

Replacing cytology with HPV testing or any other change in screening may raise new concerns that should be addressed openly, honestly, respectfully and transparently with women.

ACTIVITY

Read the following statements and decide if they are TRUE or FALSE.

1. Without proper training and communication, professionals may resist adopting new screening protocols.
2. Only gynaecologists need training when changes are made to the screening programme.
3. Online training is a fast and scalable way to educate new and current screening staff.
4. Health professionals must have a thorough understanding of the screening programme to effectively communicate with the population. Women who have cleared a naturally acquired HPV infection are still at risk of reinfection with other HPV types.



The correct answers are:

1 True, 2 False, 3 True, 4 True.



UNIT 5. QUALITY ASSURANCE


Quality assurance (also known as quality management, quality assessment or quality control) involves systematic monitoring and evaluation of the services to ensure they meet established quality standards. Ensuring a high-quality cancer screening programme is essential to maximize benefits and minimize harms of screening.

Quality assurance in a screening programme should include four key activities:

- Monitoring providers: regularly assess individual screening service providers, focusing on screening processes, positive screening reports, and referral times to diagnostic services.
- Annual performance monitoring: track key performance indicators such as coverage and participation rates.
- Outcome evaluation: periodically review outcomes, such as invasive cancer detection rates or interval cancer rates, to ensure the programme meets its goals.
- Reviewing new evidence: regularly update the programme according to new research or population changes to maintain effectiveness and cost-efficiency, especially when new prevention strategies, tests, or treatments are introduced.

Quality control in a screening programme requires robust management and coordination to ensure all aspects of the screening process are performed adequately. The programme's expected benefits – such as reducing cervical cancer morbidity and mortality – depend on maintaining high quality at every step, from identifying the target population to follow-up and proper treatment of individuals with abnormal screening results.

Key indicators may be identified to systematically collect data for quality evaluation.



A team of experts should analyse this information periodically (every 6 or 12 months, at least) and implement the necessary changes if the required standards are not met. Comparing results with reference standards and conducting blind reviews across teams can help identify errors and improve the programme. Structured data collection through HIS can facilitate this process.

5.1 Quality control of screening techniques and diagnostic tests

Quality control for screening techniques and diagnostic tests, including laboratory processing and interpretation the results is essential.

Laboratories and screening units should obtain ISO 15189 accreditation ([International Organization for Standardization \(ISO\), 2012](#)). This standard provides independent and objective certification of the laboratory's commitment to quality as well as its technical competence as it addresses:

- the need for a management system.
- covers all fundamental elements of clinical laboratory service including personnel, procedures, facilities and equipment at all stages of the process (pre-analytical, analytical, and post-analytical).
- emphasizes the final use of laboratory reports to support clinical management and patient care.

a) Quality control of the HPV test

Effective quality control of HPV tests begins with choosing the most reliable and suitable HPV detection technology for screening.



HPV tests used in screening must be clinically validated based on their ability to detect HSIL/CIN2+.

Cervical cancer screening programmes should only use high-risk clinically validated HPV tests that have consistently shown high sensitivity for detecting HSIL/CIN2+ and HSIL/CIN3+ lesions, and only minimal detection of clinically irrelevant, transient HPV infections.

Programme organisers should also consider whether the assay has obtained regulatory certifications, such as CE marking and/or Food and Drug Administration (FDA) approval, WHO IVD prequalification, or validated through independent initiatives such as VALGENT (Arbyn et al., 2016) or VALHUDES (Arbyn et al., 2018) to confirm their performance standards following the International validation criteria. The highest possible degree of automation in the testing process should also be prioritized.

[NOTE] For more information concerning the choice of screening tests and validation criteria for HPV screening tests, please refer to **MODULES 1 and 3**, respectively.

For HPV testing, there are different types of quality measures:

Internal quality control

It refers to the daily use of controls other than those provided by the manufacturer such as cell line material or those provided by external agencies, including both positive and negative samples. They are included alongside clinical samples in each test run (routine laboratory component) and generally, if the control result falls outside the expected range, the entire run is deemed invalid. It is useful to assess each run, kit batch and process over time.

Internal quality assessment

It refers to the retesting of samples to assess the laboratory's ability to obtain reproducible results. Although not mandated for accreditation purposes, it can be helpful. Potential discrepancies should be recorded considering factors that could affect the result, such as sample degradation over time.



External quality assessment (or proficiency testing)


It refers to the independent assessment of the analytical performance of the test either by processing blinded samples provided by an external organization (external quality assurance) or through interlaboratory exchange schemes, which allow to compare the laboratory performance to expected standards or results from other laboratories.

The optimal components of an external quality assessment for molecular HPV testing should ideally include:

- Representation of all 12–14 high-risk HPV types, whether individually or in pools, at some point within the scheme cycle. It should also include negative high-risk HPV samples to evaluate specificity.
- Reflect the sample-collection media used (e.g. liquid-based cytology or self-collection).
- Be suitable for use in different nucleic acid amplification technologies (real-time conventional polymerase chain reaction (PCR), DNA array, transcription-mediated amplification and isothermal amplification).
- Have the ability to assess the analytical performance of the assay
- Have at least an annual distribution.
- Assess the end-to-end process of the assay including pre-analytics, extraction (if applicable), HPV detection and result reporting.
- These assessments are typically conducted annually or at regular intervals depending on program guidelines and is frequently a requirement for obtaining ISO accreditation or other formal certifications.

Did you know?

Endogenous controls can also be used for quality control. These refer to built-in components of the assay such as the detection of β -globin gene to confirm the presence of human DNA in HPV tests although it does not confirm that the detected human cells are from cervical origin.



An annual quality assurance review serves to update and comprehensively evaluate the entire HPV molecular testing process. This review should include a thorough analysis of the following areas:

- Quality control measures in place
- Performance and compliance of supplier
- Relevant issues/findings from internal and external audits
- Feedback from users about the services provided
- Documented deviations from procedures
- Suggestions for Improvement from the technical staff, together with an evaluation of current needs and improvement of laboratory infrastructure
- Quality indicators such as the turnaround time (time interval between processing steps)
- The impact of work processes and the implications of their disruption/failure on patient safety


For more information on quality control assurance of HPV testing, please refer to Cuschieri et al. (2019, 2023) and Arroyo Mühr et al. (2023).

b) Quality control of cervical cytology

Key components of internal and external quality control for cytology are detailed in **Table 3**.

Table 3. Key components of internal and external quality control for cytology Adapted from Arbyn et al., 2008 and Tresserra Casas, 2019.

Internal quality assessment	External quality assessment
<p>Review of the results:</p> <p>A) Review of pathological cases: 100% prospective review by a pathologist. For HSIL cases, infiltrating squamous carcinoma or adenocarcinoma, it is recommended to review previous negative cytologies or with severe discrepancy from the past 3–5 years.</p> <p>B) Review of negative cases: recognized methods for reviewing negative cases include:</p> <ul style="list-style-type: none"> ▪ Rapid peer-review of 100% of the cases by cytotechnologist, spending 30 to 120 seconds per slide. ▪ Random review by a supervising cytotechnologist or by a pathologist of 10% of the cases, including those of high-risk patients, examining the entire slide. ▪ Target re-screening: focused re-screening of samples from a certain group of patients most susceptible to have a lesion, based on clinical history, pathological history, and /or previous positive cytologies. 	<p>External intercomparisons: involve the review of cytologies by professionals outside the originating service:</p> <p>A) Random review of both negative and positive cytologies sent from the Pathology services to accredited scientific centres or societies. Various exchange programs are available, such as those of the European Federation of Cytology Societies and the College of American Pathologists, among others.</p> <p>B) Competition tests between different hospitals with subsequent sharing and evaluation of the results. Each hospital selects a number of cases that are reviewed by professionals from other centres. Results are shared and evaluated collaboratively, fostering learning and consistency in cytological diagnosis, serving also as a valuable tool for ongoing professional training.</p>



C) Internal intercomparisons: procedures in which the same cytology is reviewed by more than one professional from the same service include:

- A peer-review of pathological cases by cytopathologist or an experienced pathologist.
- Re-screening of previous negative samples by pathologist-cytotechnologist and cytotechnologist-cytotechnologist.
- Random re-screening of 1% of selected negative or positive cases by pathologists.

Diagnoses should follow international coding/reporting standards like the Bethesda System for cervico-vaginal cytology to ensure consistent and accurate reporting.

Did you know?

A discrepancy occurs when there are two diagnostic conflicting opinions for a cytology or between cytology and histological studies. Discrepancies should be graded based on their impact on diagnosis and patient management. They should be communicated to the involved professionals, who will decide whether to inform the patient, if clinical management changes. In the event of an initial diagnosis being escalated to moderate or severe, a complementary report should be issued.

5.2 Quality control of colposcopy

The European Federation for Colposcopy (EFC) promotes high-quality colposcopy practices and has established a set of quality indicators with specific reference performance targets (**Table 4**).

Table 4. Performance indicators for the practice of colposcopy (European Federation For Colposcopy (EFC), n.d.)

Indicators	Target
Documentation of the type of transformation zone (TZ) (1,2 or 3)	100%
Proportion of cases undergoing a colposcopic examination prior to treatment for abnormal cervical cytology	100%
Proportion of excisional treatments/conisations with a definitive histology of HSIL/CIN2+ (based on the highest-grade lesion identified from any diagnostic or therapeutic biopsies).	85%
Proportion of clear margins in excisional treatment biopsies	80%
Number of colposcopies personally performed each year for a low-grade/minor abnormality on cervical cytology	>50
Number of colposcopies personally performed each year for a high-grade/major abnormality on cervical cytology	>50


These indicators are standardized and can be used in most countries, though countries can adapt them to their specific contexts or develop new ones tailored to their own needs.

Colposcopy quality control requires detailed data collection on healthcare activities. A systematic data collection system is essential for evaluating and ensuring quality.

5.3 Quality control of histology and treatment

The final diagnosis of premalignant and malignant cervical lesions relies on the histopathological study of targeted biopsies and excisional specimens.

The accuracy of histopathological diagnosis depends on:

- 
- Obtaining adequate samples via colposcopically-directed punch biopsies, with endocervical curettage (if necessary), or excision of the transformation zone or conisation.
 - Proper macroscopic description, technical processing, microscopic interpretation, and quality management, including correlation with cytological and histological diagnoses.

Histopathology standards must be monitored, and internationally accepted terminology should be used, such as CIN.

Did you know?


Histological diagnosis is the gold standard (reference point) for quality control of cytology, HPV molecular assays and colposcopy. It also provides diagnostic data for cancer registries, which is critical for evaluating screening programmes.

Good quality control of cytology, HPV testing, and colposcopy, relies on well-maintained electronic records. These records enable comparisons and correlation of histological results with cytology, HPV testing, colposcopy, and conisation outcomes.

5.4 Quality control of personnel

The qualifications and expertise of personnel are critical to maintaining quality. For more information on training of healthcare professionals, please check Unit 4 of this module.

Cytology and HPV laboratories, along with colposcopy or cervical pathology units, must process enough tests to ensure their staff maintain their skills. Professionals must have the necessary qualifications to perform their roles safely and accurately. Quality control measures should evaluate ongoing training, workloads and competency for each role.



Colposcopy should only be performed by trained and experienced colposcopists. The EFC offers a high-quality training programme with common goals and structure for all federated societies. Ideally, all colposcopy unit members should be accredited and undergo regular training. In addition, colposcopists should audit their work to ensure their assessment and colposcopically-directed treatment aligns with internationally established standards.

ACTIVITY

Read the following statements and decide if they are TRUE or FALSE.

1. Internal quality assessment includes verifying the reproducibility of test results by retesting selected specimens.
2. Discrepancies in cytology results should be ignored if they do not change clinical management.
3. Clinically validated HPV tests must demonstrate high sensitivity for detecting HSIL/CIN2+ lesions.
4. Quality assurance in screening only involves evaluating the final treatment outcomes.
5. Colposcopy quality can be ensured without any standardized indicators.

The correct answers are:

1 True, 2 False, 3 True, 4 False, 5 False.



UNIT 6. PROGRAMME EVALUATION AND MONITORING

A cancer screening programme should be designed to demonstrate its quality and effectiveness, enabling thorough and continuous evaluation.

To determine the **quality assurance** of a screening programme, continuous and ongoing evaluations are needed. Performance against screening indicators is crucial for monitoring the screening process and identifying and reacting to potential problems at an early stage.

Long-term evaluation of the **effectiveness** of the screening programme is also essential to impacting the burden of disease in the population, i.e. reduction of cervical cancer incidence and mortality.

Publishing regular performance assessments and evaluations ensures that decision-makers and staff stay informed about the programme's performance and outcomes.

Standardised performance indicators, like those recommended in the European guidelines (Arbyn et al., 2008), are essential for quality management. These indicators:

- Help identify successful programmes and approaches.
- Improve data comparability.
- Promote international collaboration and knowledge-sharing, supporting continuous quality improvement.

To properly evaluate and interpret a screening programme, it is crucial to consider biases that may influence outcomes.

NOTE: For more information on biases in screening, please check **MODULE 1**.



There are two main requirements for monitoring the performance and evaluating the impact of a screening programme:

- A detailed, mandatory screening protocol that includes the recommended screening interval, target population, and specific age groups.
- A robust HIS to support the screening programme and monitor and evaluate each step of the screening process.

HIS requirements detailed in Unit 3 must be met. Otherwise, performance against some indicators cannot be estimated.

Performance should be evaluated using **key performance indicators**, including:

- Screening intensity.
- Screening test performance.
- Diagnostic assessment and treatment.

The number of indicators that can be evaluated will largely depend on the design of the system, the structured information available and the feasibility of data linkage between registries.

Did you know?

In 2025, a panel of European screening experts defined a core set of performance and outcome indicators to assess the quality of cancer screening programmes ([Sheridan et al., 2025](#)).

6.1. Screening intensity

Key indicators of screening intensity include coverage of the target population by invitation and screening tests, compliance with the invitation, test consumption, and the incidence of invasive cervical cancer in unscreened and under-screened women at a given interval.

Coverage is the proportion of eligible women in the target population who are either invited or screened at least once during the standard recommended screening interval (usually 3 or 5 years).

Coverage should be computed for the entire target age group as defined by the national or regional screening policy. This is the most widely calculated indicator and is therefore used to compare screening programmes. **Figure 3** illustrates coverage in the specific age range of screening programme in the European Union, excluding opportunistic screening and including only those women invited and screened.

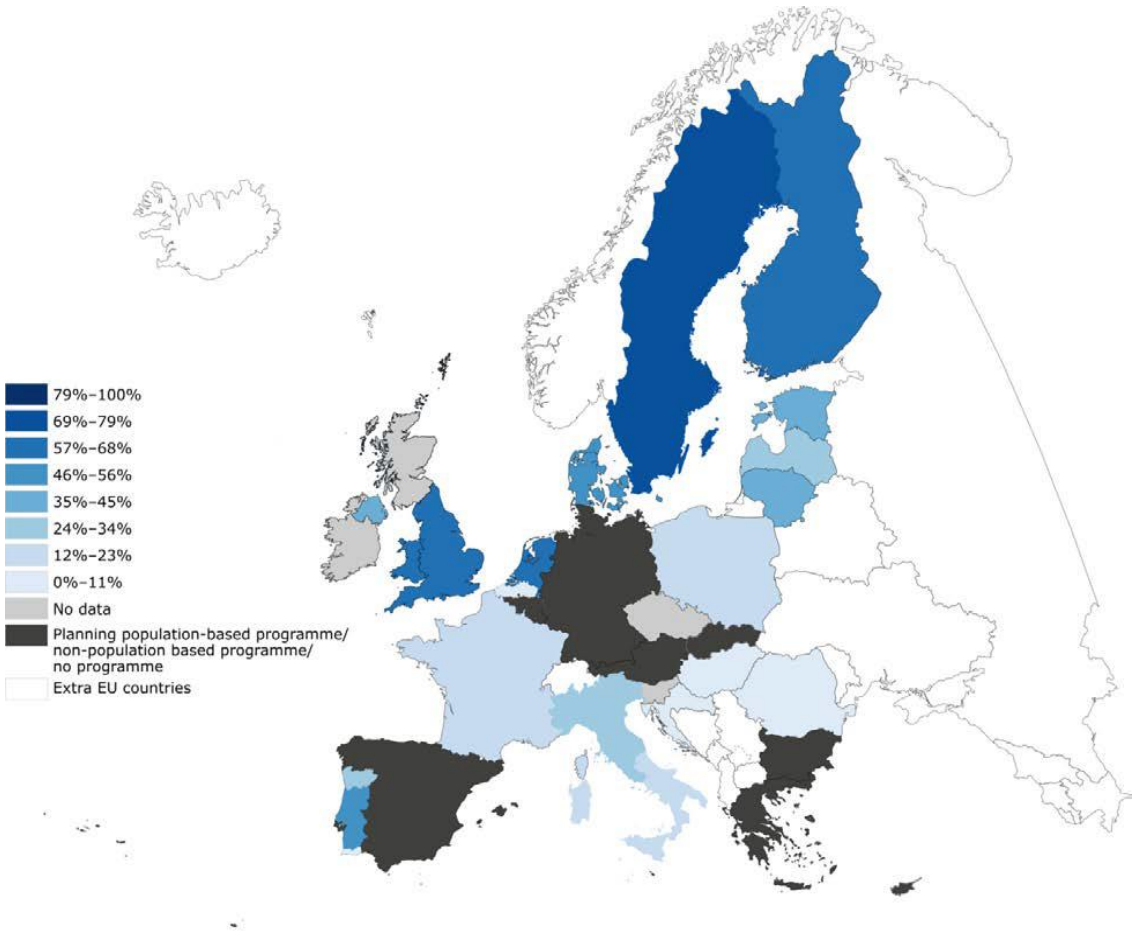


Figure 3. Cervical cancer screening programmes in the European Union: coverage in specific age range (Ponti et al., 2017).




ACTIVITY

To achieve high screening coverage, the programme must reach the entire target population. Within the recommended five-year interval in a population-level screening programme, this means that invitations must be sent to:

- a) about one fifth of the target population each year. - **CORRECT**
- b) about one fifth of the screened population each year.
- c) about one fifth of the target population over 5 years.
- d) about one fifth of the screened population over 5 years.

The correct answer is C

If a fifth of the target population is invited each year, over five years all eligible women would have been invited. Those invited in the first year will be invited again in the sixth year if the screening test was negative, in compliance with the five-year interval.



Compliance with invitation is the proportion of invited women who were screened in a given period. This indicator is relevant in organised screening programmes and provides a measure of the effectiveness of sending invitations.

Test consumption is the number of performed screening tests in a given period in the target population (does not include necessary repeated tests, such as those following an unsatisfactory smear or as follow-up). An excess of screening tests per screened woman increases the financial and human costs with only a marginal reduction in incidence and mortality.


Incidence of invasive cervical cancer in underscreened women (including women never screened and women who were screened at longer intervals) in a given period by number of person-years of women not screened provides a direct measure of the burden of disease resulting from non-optimal coverage.

6.2. Screening test performance

Distribution of screened women by screening test result reflects the proportion of women screened with each specific outcome. For example, in a programme with partial HPV genotyping, it could provide the proportion of women with a negative, HPV 16/18 positive or non HPV16/18 positive result.

Referral rate for colposcopy is the proportion of screened women who are referred for colposcopy. This metric highlights the programme's economic cost and the burden/impact on women (i.e. anxiety, use of time), and should ideally be as low as possible.

Referral rates for colposcopy depend on screening test results test accuracy, and disease prevalence in the target population.



The **positive predictive value (PPV) of referral for colposcopy** is calculated as the proportion of screened women referred to colposcopy who have histologically confirmed CIN2+ lesions. This indicator evaluates the effectiveness of the referral process in identifying significant lesions.

Test specificity is estimated as the proportion of women with a negative screening test result among those who did not have histologically confirmed CIN2+ lesions. This indicator measures the test's ability to correctly identify women without significant disease.

The **detection rate of CIN2+** is the proportion of screened women with histologically confirmed CIN2+ lesions. This rate depends on the prevalence of lesions in screened population (disease prevalence) and the ability of the test to correctly identify these lesions (sensitivity).


6.3. Diagnostic assessment and treatment

A critical factor for the success of a screening programme is ensuring that diagnostic assessments are performed when needed (i.e, compliance or adherence).

Compliance with referral for colposcopy is the proportion of screened women referred to colposcopy who undergo colposcopy. It should be computed for each screening result leading to colposcopy referral.

Proportion of women hysterectomised for CIN2+ is calculated for screened women with histologically confirmed CIN2+ who undergo hysterectomy. It serves as an indicator for identifying extreme overtreatment.

Incidence of cervical cancer following abnormal cytology represents the number of invasive cancers detected in screened women following an abnormal test result, expressed per person-years of screened women after a abnormal test. The



incidence of cervical cancer in women not detected by screening, even with abnormal screening results, serves as a summary indicator of failure associated with diagnostic assessment and treatment.

NOTE: For more information on how to estimate these performance indicators, please see the *European Guidelines on Quality Assurance* (Arbyn et al., 2008)

Indicators based on the incidence of invasive cervical cancers for direct evaluation of the impact of screening require long-term follow-up data and integration with cancer registry data.


Did you know?

The costs of individual procedures, tests, etc. should be combined with data on the actual number of procedures and tests conducted to calculate the cost of running the programme and successfully assess the cost-effectiveness of different screening strategies.

ACTIVITY

Read the following statements and decide if they are TRUE or FALSE.

1. There is no need to assess the effectiveness of a programme if other countries have already established it.
2. Screening coverage refers to the proportion of eligible women invited or screened at least once during the recommended screening interval.
3. Compliance with invitation is irrelevant in organised screening programmes.
4. Indicators are only useful to assess the quality of the procedures.




The correct answers are:

1 False, 2 True, 3 False, 4 False.




SUMMARY


- Screening programmes are complex interventions requiring effective coordination across multiple phases, activities, and levels of care.
- Comprehensive planning, involving a multidisciplinary approach and engagement of all key stakeholders, is crucial for defining processes and allocating resources. Conducting a small-scale pilot programme can help identify unforeseen issues, refine organisational aspects, and accurately estimate resource needs.
- Standardisation of the programme across the territory, including target population definitions, clinical guidelines, quality, and training requirements, is important for consistency.
- Effective Health Information Systems (HIS) and cancer screening registries are fundamental for programme management and evaluation, quality assurance, identifying the target population, and tracking participants through all phases. All HIS components must be interconnected using a unique personal identifier enabling end-to-end evaluation of the screening process.
- Achieving high participation rates and ensuring adherence to follow-up procedures (diagnostic assessment and treatment) are critical factors for the success and effectiveness of any screening programme.
- All eligible participants must receive clear, balanced, and accurate information to support informed decision-making about participation in screening and attendance to follow-up visits after a positive or abnormal result.
- Comprehensive and ongoing training for all healthcare professionals involved is essential to support the programme's success, ensure understanding of new strategies, and facilitate accurate communication with the public.
- Systematic quality assurance, involving continuous monitoring, evaluation of performance indicators, and regular review of outcomes and new evidence, is necessary to maximise benefits and minimise harms as well as to identify and address potential problems early.

- 
- Rigorous quality control measures for screening techniques, diagnostic tests (e.g., ISO accreditation, validated HPV tests), and the qualifications of personnel are mandatory.
 - Continuous monitoring and evaluation of the programme's performance and long-term impact on disease burden, often relying on integrated data from screening and cancer registries, are essential for demonstrating effectiveness.

BIBLIOGRAPHY

- Amaral, A. F., Araújo, E. S., Magalhães, J. C., Silveira, E. A., Tavares, S. B. do N., & Amaral, R. G. (2014). Impact of training about cervical cancer screening on health professionals working in basic health care units. *Revista Brasileira De Ginecologia E Obstetricia: Revista Da Federacao Brasileira Das Sociedades De Ginecologia E Obstetricia*, 36(4), 182–187. <https://doi.org/10.1590/s0100-7203201400040004>
- Arbyn, M., Anttila, A., Jordan, J., Ronco, G., Schenck, U., Segnan, N., Wiener, H., Herbert, A., Daniel, J., & von Karsa, L. (2008). *European guidelines for quality assurance in cervical cancer screening. Second edition*. International Agency for Research on Cancer (IARC). https://screening.iarc.fr/doc/ND7007117ENC_002.pdf
- Arbyn, M., Depuydt, C., Benoy, I., Bogers, J., Cuschieri, K., Schmitt, M., Pawlita, M., Geraets, D., Heard, I., Gheit, T., Tommasino, M., Poljak, M., Bonde, J., & Quint, W. (2016). VALGENT: A protocol for clinical validation of human papillomavirus assays. *Journal of Clinical Virology: The Official Publication of the Pan American Society for Clinical Virology*, 76 Suppl 1, S14–S21. <https://doi.org/10.1016/j.jcv.2015.09.014>
- Arbyn, M., Peeters, E., Benoy, I., Vanden Broeck, D., Bogers, J., De Sutter, P., Donders, G., Tjalma, W., Weyers, S., Cuschieri, K., Poljak, M., Bonde, J., Cocuzza, C., Zhao, F. H., Van Keer, S., & Vorsters, A. (2018). VALHUDES: A protocol for validation of human papillomavirus assays and collection devices for HPV testing on self-samples and urine samples. *Journal of Clinical Virology*, 107, 52–56. <https://doi.org/10.1016/j.jcv.2018.08.006>
- Arroyo Mühr, L. S., Lagheden, C., Hassan, S. S., Eklund, C., & Dillner, J. (2023). The International Human Papillomavirus Reference Center: Standardization, collaboration, and quality assurance in HPV research and diagnostics. *Journal of Medical Virology*, 95(12), e29332. <https://doi.org/10.1002/jmv.29332>
- Asia, W. H. O. R. O. for S.-E. (2017). *Cervical cancer screening and management of cervical pre-cancers: Trainee's handbook and facilitator's guide - Programme manager's manual*. World Health Organization. Regional Office for South-East Asia. <https://apps.who.int/iris/handle/10665/258745>
- Cuschieri, K., Fellner, M. D., Arroyo Mühr, L. S., Padalko, E., Correa, R. M., Dillner, J., Gultekin, M., & Picconi, M. A. (2023). Quality assurance in human papillomavirus testing

- 
- for primary cervical screening. *International Journal of Gynecologic Cancer*, 33(5), 802–811. <https://doi.org/10.1136/ijgc-2022-004197>
- Cuschieri, K., Schuurman, R., & Coughlan, S. (2019). Ensuring quality in cervical screening programmes based on molecular human papillomavirus testing. *Cytopathology: Official Journal of the British Society for Clinical Cytology*, 30(3), 273–280. <https://doi.org/10.1111/cyt.12679>
- European Federation For Colposcopy (EFC). (n.d.). European Federation For Colposcopy. <https://efcolposcopy.eu/>
- Giordano, L., Webster, P., Anthony, C., Szarewski, A., Davies, P., Arbyn, M., Segnan, N., & Austoker, J. (2008). Improving the quality of communication in organised cervical cancer screening programmes. *Patient Education and Counseling*, 72(1), 130–136. <https://doi.org/10.1016/j.pec.2008.02.010>
- Gravitt, P. E., Rositch, A. F., Jurczuk, M., Meza, G., Carillo, L., Jeronimo, J., Adsul, P., Nervi, L., Kosek, M., Tracy, J. K., Paz-Soldan, V. A., & Proyecto PreCancer Study Group. (2020). Integrative Systems Praxis for Implementation Research (INSPIRE): An Implementation Methodology to Facilitate the Global Elimination of Cervical Cancer. *Cancer Epidemiology, Biomarkers & Prevention: A Publication of the American Association for Cancer Research, Cosponsored by the American Society of Preventive Oncology*, 29(9), 1710–1719. <https://doi.org/10.1158/1055-9965.EPI-20-0501>
- International Organization for Standardization (ISO). (2012). *ISO 15189:2012 Medical laboratories—Requirements for quality and competence*. ISO. <https://www.iso.org/cms/render/live/en/sites/isoorg/contents/data/standard/05/61/56115.html>
- Leyden, W. A., Manos, M. M., Geiger, A. M., Weinmann, S., Mouchawar, J., Bischoff, K., Yood, M. U., Gilbert, J., & Taplin, S. H. (2005). Cervical cancer in women with comprehensive health care access: Attributable factors in the screening process. *Journal of the National Cancer Institute*, 97(9), 675–683. <https://doi.org/10.1093/jnci/dji115>
- Lynge, E., Törnberg, S., von Karsa, L., Segnan, N., & van Delden, J. J. M. (2012). Determinants of successful implementation of population-based cancer



screening programmes. *European Journal of Cancer (Oxford, England: 1990)*, 48(5), 743–748. <https://doi.org/10.1016/j.ejca.2011.06.051>

Sasieni, P. D., Cuzick, J., & Lynch-Farmery, E. (1996). Estimating the efficacy of screening by auditing smear histories of women with and without cervical cancer. The National Co-ordinating Network for Cervical Screening Working Group. *British Journal of Cancer*, 73(8), 1001–1005. <https://doi.org/10.1038/bjc.1996.196>


Sheridan, B., Irzaldy, A., Heijnsdijk, E. A. M., Dimitrova, N., Senore, C., Basu, P., & de Koning, H. J. (2025). Prioritizing performance and outcome indicators for quality assessment of cancer screening programs in the EU. *Public Health*, 239, 185–192. <https://doi.org/10.1016/j.puhe.2024.12.010>

Tresserra Casas, F. (2019). *Guía de calidad en citopatología*. Societat Catalana de Citopatologia.

Wilson, J. M. G., Jungner, G., & Organization, W. H. (1968). *Principles and practice of screening for disease*. World Health Organization. <http://www.who.int/iris/handle/10665/37650>

ADDITIONAL MATERIAL

- Arbyn M, Haelens A, Desomer A, Verdoodt F, Thiry N, Francart J, Hanquet G, Robays J. Cervical cancer screening programme and Human Papillomavirus (HPV) testing, part II: Update on HPV primary screening. Health Technology Assessment (HTA) Brussels: Belgian Health Care Knowledge Centre (KCE). 2015. KCE Reports 238. D/2015/10.273/17.
- Cancer Prevention and Screening: Concepts, Principles and Controversies. Editor(s): Rosalind A. Eeles, Christine D. Berg, Jeffrey S. Tobias. First published:14 August 2018. Print ISBN:9781118990872 |Online ISBN:9781118990957 |DOI:10.1002/9781118990957
- Elfström KM, Arnheim-Dahlström L, von Karsa L, Dillner J. Cervical cancer screening in Europe: Quality assurance and organisation of programmes. *Eur J Cancer*. 2015 May;51(8):950–68.

- 
- Improving data for decision-making: a toolkit for cervical cancer prevention and control programmes. Geneva: World Health Organization; 2018. Licence: CC BY-NC-SA 3.0 IGO.
 - von Karsa L, Arbyn M, De Vuyst H, Dillner J, Dillner L, Franceschi S, Patnick J, Ronco G, Segnan N, Suonio E, Törnberg S, Anttila A. European guidelines for quality assurance in cervical cancer screening. Summary of the supplements on HPV screening and vaccination. *Papillomavirus Res.* 2015 Dec; 1: 22–31.