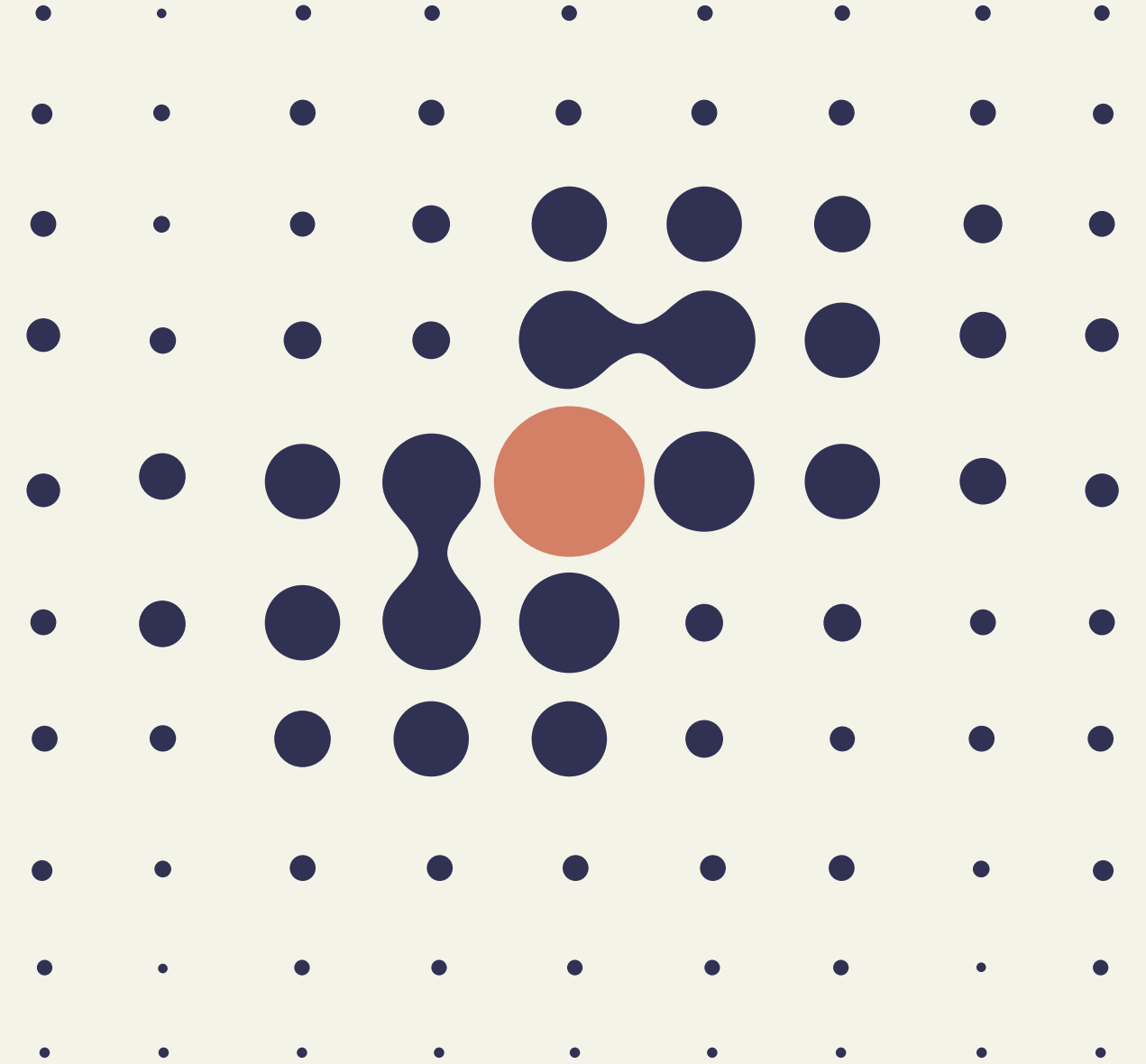


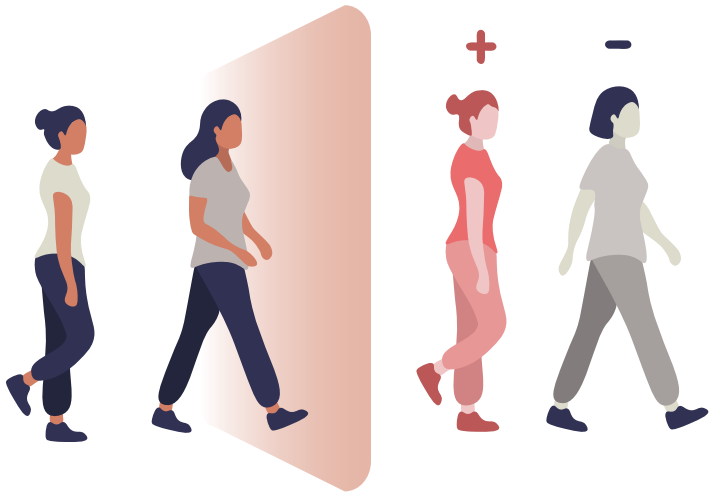
Best Practices in Cervical Screening Programmes:

Audit of Cancers, Legal and Ethical Frameworks, Communication, and Workforce Competencies

International Agency for Research on Cancer

World Health Organization

Introduction



> Screening is a pathway, not just a single test.

Cervical cancer is a significant public health challenge globally, and cervical screening plays a crucial role in the prevention and early detection of this disease.

What is cervical screening?

The purpose of cervical screening is to detect precancer or early-stage cancer of the cervix in asymptomatic individuals so that timely treatment can be offered. Treatment of precancers significantly reduces the risk of developing cervical cancer in the future. Treatment of cervical cancer at an early stage is less aggressive and has a higher possibility of cure.

A well-organized cervical screening programme that offers all age-eligible women a screening test at a regular interval is expected to reduce the incidence of cervical cancer significantly (but never to zero) by detecting and treating the disease at a precancerous stage. Cervical screening also reduces mortality from cervical cancer by detecting early-stage cancers before they are symptomatic and therefore when treatment is likely to be effective.

Cervical screening is not just a single test but a process and a pathway. It starts by identifying the women who are eligible for screening, referred to as the target population. Women with positive screening test results need to undergo further evaluation to confirm a diagnosis of cervical cancer. The screening pathway includes diagnosis and treatment of the women who test positive on the screening test.

A screening programme operates as a cycle. People who have a normal screening test result are invited to come back after a certain interval to be screened again.

The final step in the pathway is reporting outcomes and evaluating the screening programme.

How is a screening test different from a diagnostic test?

Screening test

- Targets apparently healthy population
- Has potential to detect cancer earlier, at a precancerous stage for cervical cancer
- Has to be simple, acceptable, and inexpensive for mass testing
- Positive results indicate suspicion of disease that warrants a diagnostic test for confirmation and/or close follow-up

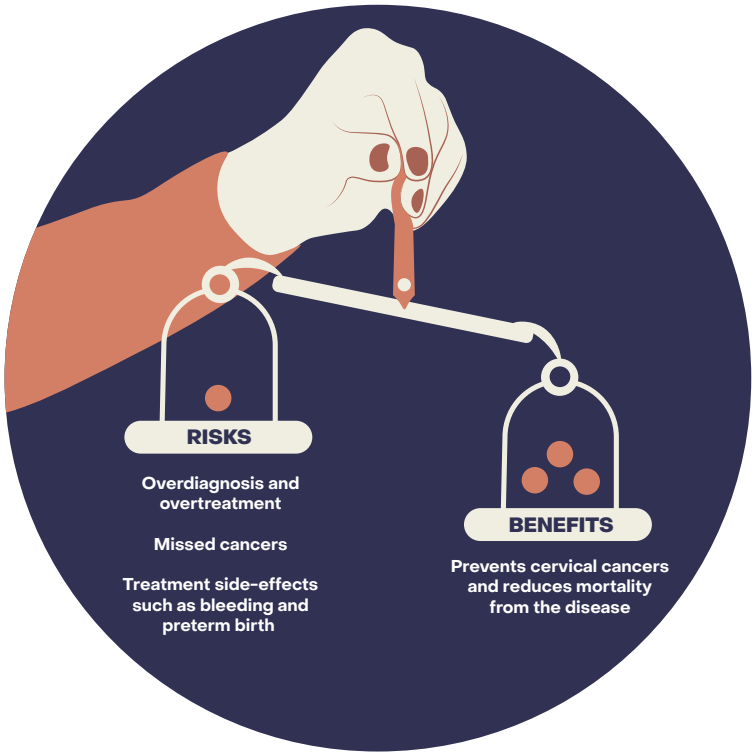
Diagnostic test

- Targets individuals with symptoms of cancer or those positive on a screening test
- Usually more complex and time-consuming than a screening test
- Results provide a definite diagnosis
- Diagnostic accuracy is significantly higher than that of screening tests

What are the challenges of cervical screening?

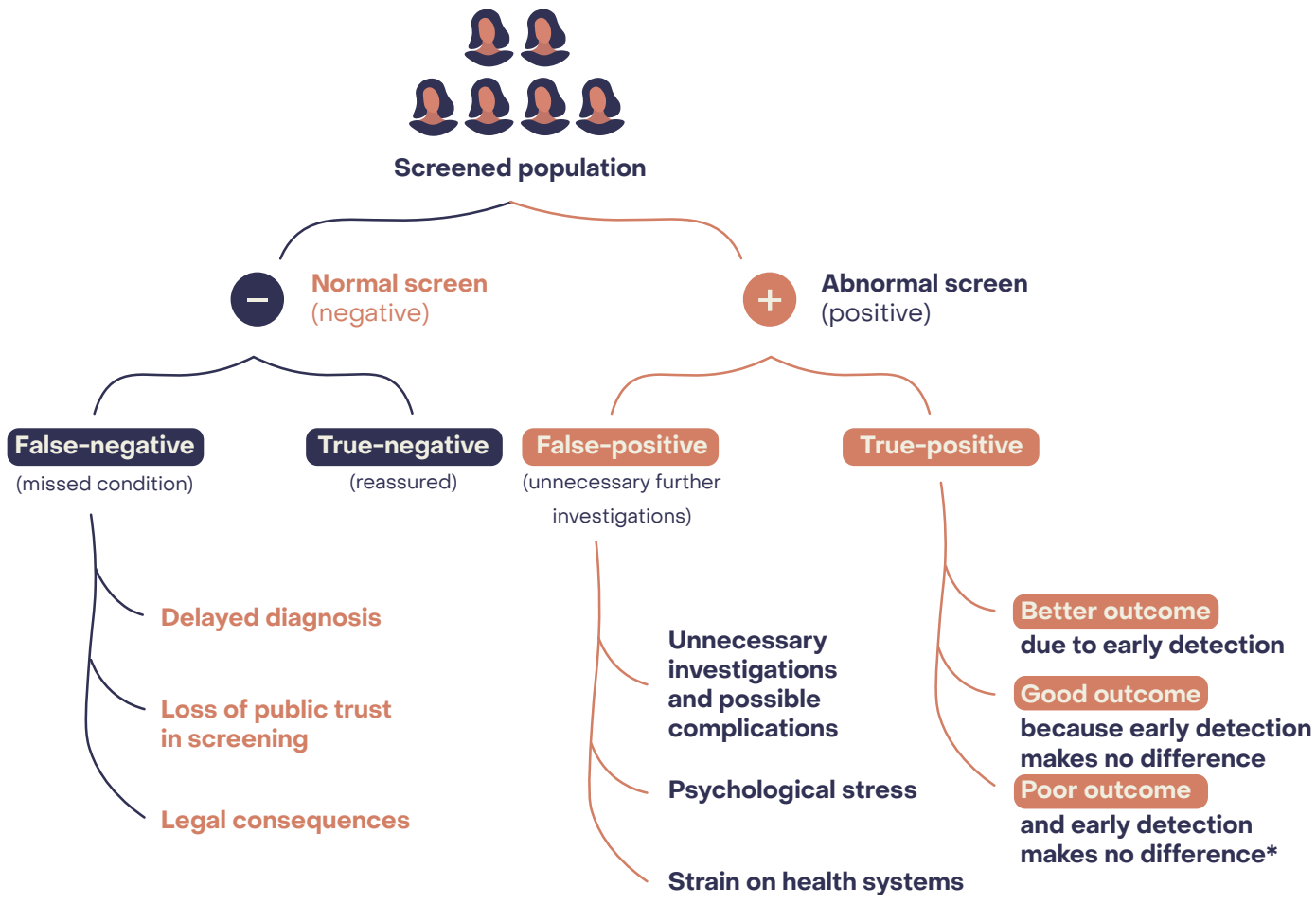
Screening programmes target very large numbers of people who are apparently well and are not seeking advice about the condition being screened for until they are informed by the programme or by their health professionals. This makes screening different from other usual medical encounters, which are initiated by patients with at least some symptoms.

Screening may lead to risks (also called harms) as well as to benefits, although in cervical screening the benefits far outweigh the risks. This means that there is a moral imperative for the screening programme or health professionals to provide complete information that enables people to make the right decision for themselves. This is informed decision-making or personal informed choice.



What are the possible outcomes of screening?

While informing women, it is important to consider all the potential consequences of screening. In cervical screening, a false-negative test result (missed precancers or cancers) provides false reassurance and can lead to delayed diagnosis of cancers, whereas false-positive test results may lead to unnecessary further investigations, psychological stress, and strain on health systems. Cervical screening can also lead to detection of precancers that would never have progressed or caused any harm in the woman's lifetime. Such overdiagnosis will lead to unnecessary treatment and possible complications. Not providing this information in a balanced way may cause loss of public trust in screening and may have legal consequences for the screening programme.



*due to unnecessary treatment with risks of complications (overdiagnosis and overtreatment)

What information is it important to communicate to women who are offered screening?

Invitation and information

- The benefits and risks of screening
- That participation is voluntary and screening is a personal choice
- What they will be consenting to when they participate
- Where information can be obtained
- Making an informed decision about whether to be screened

Screening

- The screening process, benefits and risks, and possible outcomes of screening
- The quality assurance process
- Facilitation of shared decision-making
- That cervical screening prevents most cervical cancers, but it cannot prevent all of them

Reporting of outcomes of screening tests

For both positive and negative test results:

- Established process to inform the women and offer next steps

For screen-negative women:

- That developing cervical cancer is not common, and it is even more unusual to develop cervical cancer with negative test results, but it does sometimes happen

Follow-up

For screen-positive women:

- What will happen next
- Correct information on where they can seek assistance if needed

How to design a communication strategy for improved cervical screening uptake

The use of a stage-based behaviour change model is valuable when considering ways to support informed decision-making about cervical screening. An informed counselling process aims to move women across the following stages:

The stage-based precaution adoption process model (PAPM) for cervical screening uptake

Unaware of cervical screening → **Unengaged** with cervical screening → **Undecided** about undergoing cervical screening → **Decided to** to undergo cervical screening → **Underwent** cervical screening

Screening information needs to:

- clearly highlight that screening is a personal choice and that the health authorities are offering the tests because the benefits of undergoing the tests far outweigh the risks and limitations;
- include clear statements on the benefits, risks, and limitations of screening, supplemented by visual aids; and
- provide a clear statement on the estimates of probabilities of the condition and potential positive and negative outcomes from screening.

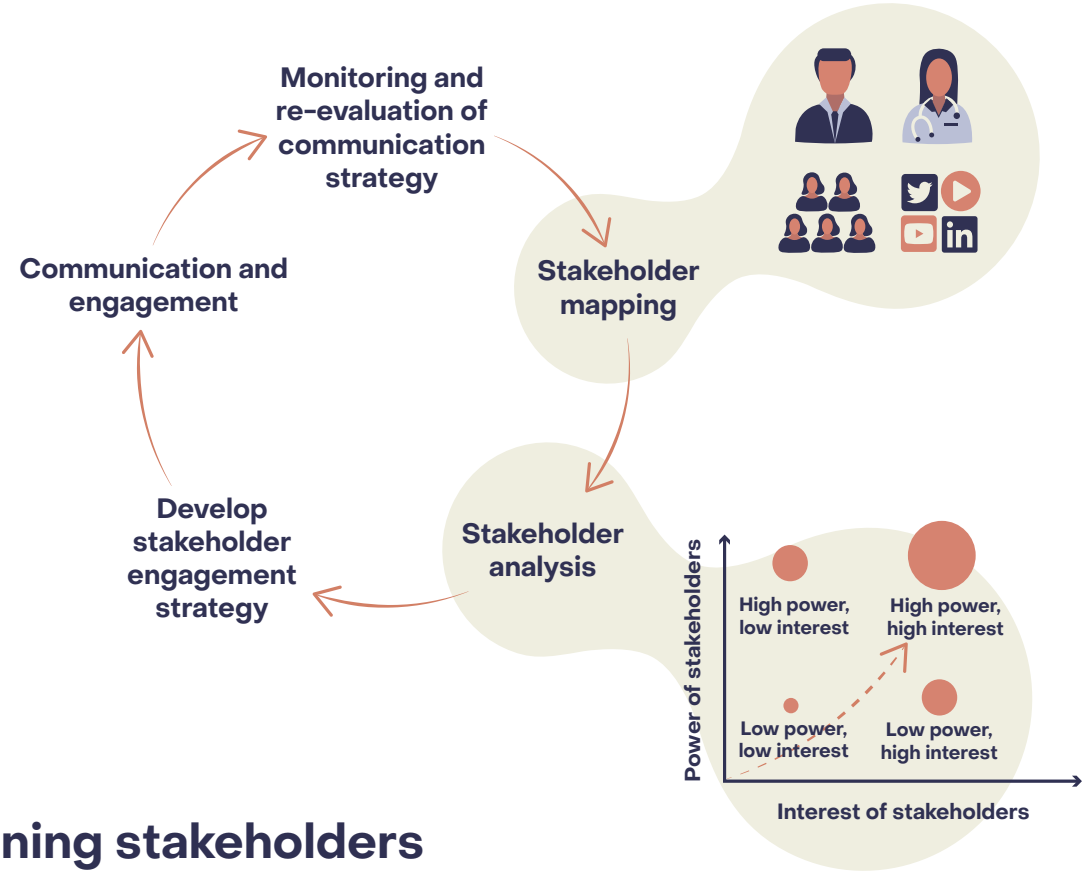
When developing screening information materials:

- use easy-to-read and simple language, supported by visual aids to help understanding;
- make the information materials simple to understand by individuals of all literacy levels;
- provide information using a tiered approach, starting with basic concepts and building up to more complex information; and
- seek behavioural science support to develop a decision-making approach (e.g. the use of interactive worksheets) for decision-making about participation in screening.

The delivery strategy needs to be multipronged and should be capable of:

- using digital media and online tools, depending on the local setting;
- ensuring the availability of a printed version for people who are unable to access online materials;
- delivering information to the women who are offered screening either by letter (in invitation-based screening programmes) or at the time of clinical interactions;
- using a campaign approach (e.g. observation of Cervical Cancer Awareness Month) when appropriate, and using mass media (both print and digital) to support the campaign;
- adopting innovative strategies (e.g. identifying a brand ambassador or adopting health branding) appropriate to the local context;
- obtaining feedback on the appropriateness of the content and the acceptability of the delivery modes; and
- encouraging frank and fair discussions between potential participants and health-care professionals to support informed decision-making.

Identifying the stakeholders in a cervical screening programme and how to communicate with them



Defining stakeholders

For a cervical screening programme, stakeholders may be a variety of organizations or individuals in addition to the target population and their family members. Stakeholders include policy-makers from the ministries of health and finance, other politicians, health insurance agencies, other funding agencies, programme managers, service providers, professional bodies representing relevant medical disciplines, civil society organizations and patient groups, journalists and other media representatives, and health-care industry representatives.

> “A communication strategy needs to target a variety of stakeholders in addition to the women who are offered screening.”

Identifying stakeholders through a mapping exercise

This mapping exercise should consider stakeholders' knowledge and experience, their levels of interest and influence, and their power to facilitate effective engagement. It should also define the roles that a particular stakeholder will play in a screening programme and the resources that the stakeholder will contribute (expertise, information, knowledge, funding, alliances, and/or advocacy).

Stakeholder engagement

High power, low interest (e.g. a politician): **Inform or educate** in one-way communication without expecting a response. Receiving feedback will be useful.

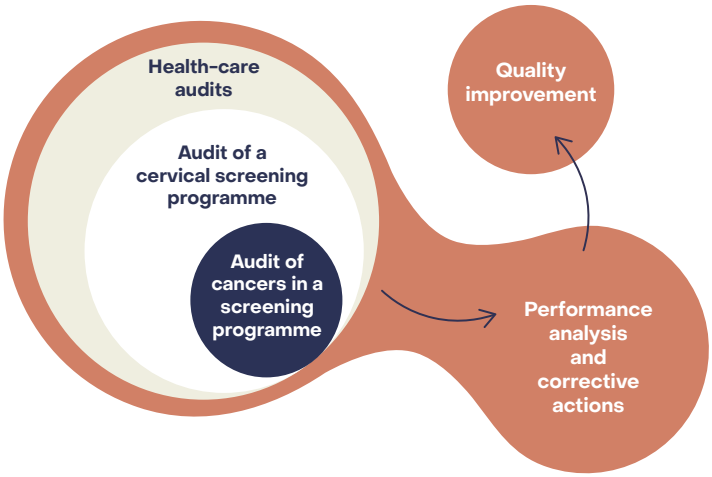
Low power, low interest (e.g. general population): **Consult** to obtain information and feedback to inform decisions. Get them **involved** by working directly with them throughout the process to ensure that issues and concerns are understood and considered.

High power, high interest (e.g. civil society organization): **Collaborate** with them to develop mutually agreed solutions and a joint plan of action. Learning, negotiation, and decision-making take place through two-way or multiway communication.

Low power, high interest (e.g. women offered screening): **Empower** them by delegating decision-making on a particular issue to them. Stakeholders are enabled or equipped to actively contribute to the achievement of outcomes.

Programmatic audit in a cervical screening programme

What is audit?



The overarching aim of a programmatic audit of cancers in cervical screening is to evaluate the effectiveness of the programme in reducing the incidence of cervical cancer and minimizing the risks associated with screening. The purpose is to discover discrepancies between actual practice and recommended standards in order to identify any changes needed in the process or the system to improve the quality of care.

Findings from the programmatic audit of cancers in a cervical screening programme are expected to direct further investigations of screening practice that target improvement rather than blaming an individual professional or an organizational entity for perceived lapses.

Any cervical cancer that occurs in a population targeted by a screening programme needs to be audited as part of programmatic audit, to understand whether it could be prevented or detected even earlier through improved quality of services.

Programmatic audit produces aggregate (i.e. system-level) results and does not pinpoint what has happened to a specific patient.

On the basis of the programmatic audit outcomes, rational decisions can be made about modifications in several areas of service delivery, such as the training of health professionals, the introduction of an improved screening test, the strengthening of fail-safe mechanisms, the improvement of capacity to reduce delays, and the reduction of inequalities.

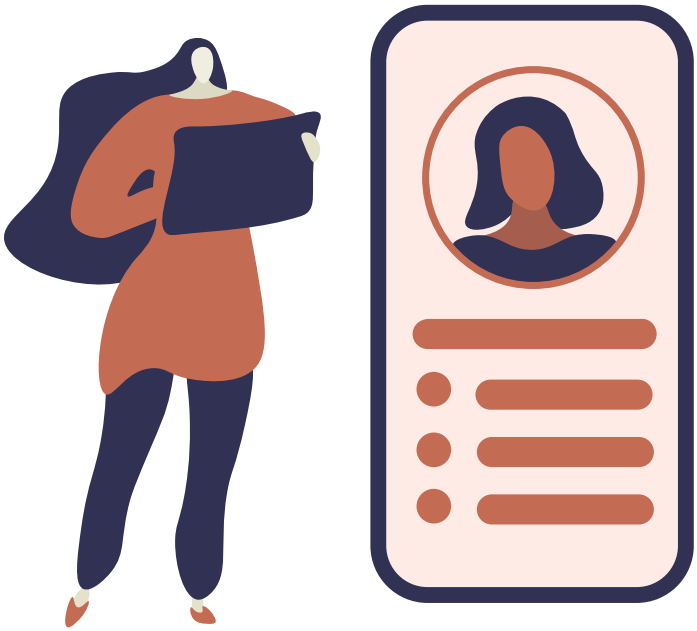
What is the difference between a programmatic audit and an individual case review?

An individual case review of cervical cancer occurring in a woman participating in screening should be distinguished from a programmatic audit and should be planned and implemented differently, because the two processes have different objectives.

An individual case review is not based on quality assurance principles of improving the programme. Instead, it is an attempt to determine how or why a specific individual developed cancer despite participating in screening.

A programme may offer an individual case review to any woman who develops cancer and requests such a review. As in audit, the process involves a review of the patient's clinical records, test results, pathology specimens, and care received before the diagnosis.

In contrast to a cancer audit, in an individual case review (i) the process is usually initiated by a patient or her relatives, (ii) the patient's consent is needed, and (ii) the results must be disclosed to the patient. Neither a cancer audit nor an individual case review changes the management of the cancer for the individual patient.



What are the key issues in the practice of cancer audits in cervical screening programmes?

How is cervical cancer audit practised in different countries?

There is wide variability in practices of cancer audit in cervical screening in different countries.

Should all cervical cancers be included in an audit?

All cervical cancers should be audited, whether detected in screened women or in unscreened women. Audit of cancers in unscreened women is relevant only for population-based programmes that have a system of sending individual invitations and follow-up. Whenever possible, screen-detected cancers should be distinguished from cancers detected in symptomatic women outside routine screening, and all interval cancers should be identified.

Is it mandatory to obtain informed consent for programmatic audit?

Analyses based only on consenting women are likely to be biased. Not obtaining individual informed consent at the time of a programmatic audit is justified. This is because the public good and the responsibility to provide a high-quality screening programme outweigh the possible risks to an individual from participating in the audit.

Is ethics approval necessary for an audit?

An audit protocol may be formally reviewed by an ethics committee, but this will be in the context of it being at most non-experimental health systems research. The use of personal data requires approval of competent authorities in most legal systems.

Interval cancers and cancer screening

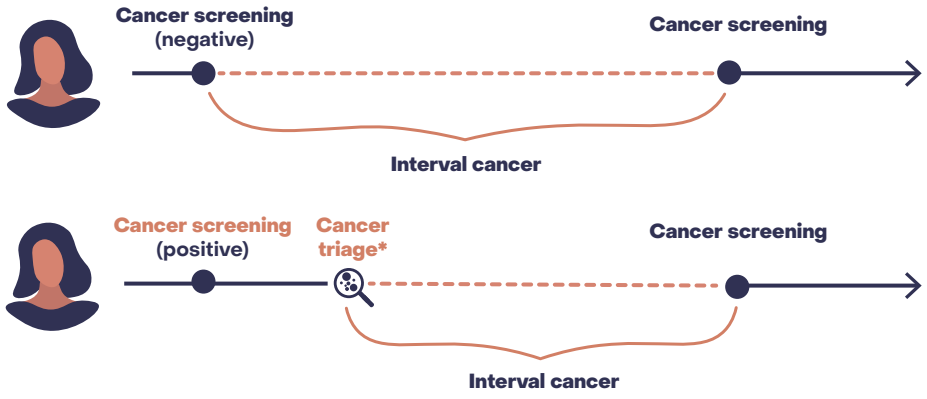
An interval cervical cancer is any cancer (including microinvasive cancer [stage IA]) diagnosed in a woman between her two screening episodes, at an interval stipulated by the programme, who had either (i) no abnormal screening test result or (ii) an abnormal screening test result but a negative triage test result or a negative diagnostic test result.

Interval cancers – cancers that are diagnosed in between routine screening episodes – are an unfortunate but inevitable part of any population screening programme.

Although interval cancers are rare in the context of the number of individuals screened and the numbers of lives saved through screening, they are nonetheless a painful and upsetting reality and a potential risk for any individual participating in any cancer screening programme.

Measuring the interval cancer rate gives a good indication of whether the screening programme in question is performing within standards and in line with its peers internationally, although no screening programme can detect all the cancers occurring in the target population.

Interval cancers



* Triage is the process of determining the priority of patients' treatment based on the severity of their condition

Causes of interval cancer

Ethical obligations and programmatic audit

Operators of cervical cancer screening programmes have an ethical obligation to carry out programmatic audits that seek to improve patient care and outcomes through systematic review of care against explicit criteria and to take action to improve care when standards are not met.

Participants in cervical screening should be informed when they consent to undergo screening that their test results will be subject to a programmatic audit. The specimens and data from a participant may be included in an audit even if the participant denies consent for the data to be included in an audit, but only after careful removal of all personal data. This is because the public good and the responsibility to provide a high-quality screening programme outweigh the possible risks to an individual from participating in the audit in an anonymized manner. However, in this situation it is essential that the audit process makes exceptionally determined efforts to ensure that data are kept safe and confidential.

Disclosure of results of a programmatic audit in cervical screening

Programmatic audit should preferably be conducted using anonymized or de-identified data, whereby consent from each screening participant is not necessary and disclosure of findings is not possible and the audit outcome does not change the management of the cancer.

The benefits of anonymization of a programmatic audit are as follows:

- Sharing of data for audit while protecting individual privacy is a measure for quality improvement.

- Anonymization enables health information to be shared when it is not mandated or practical to obtain consent from each participant.

If anonymization is not done, operators will need to rely on consent as the primary mechanism, which may lead to bias in audit findings.

Screening participants who were diagnosed with an interval cancer (or their relatives) may wish to know whether a discrepancy has been detected upon audit. Because of this, screening programmes may offer an individual case review to such participants after obtaining informed consent. The outcomes of the review need to be communicated to the women.

Consent model

Informed consent in screening

The requirement that the participant provides informed consent (written or verbal, depending on the local regulations) is a fundamental principle in cervical screening. Participation in a screening programme is always voluntary.

A screening-eligible person who is invited to participate in cervical screening should be informed about the following:

- The nature and purpose of cervical screening overall.
- The nature and purpose of an individual cervical screening test. This should expressly describe what the experience of undergoing a cervical screening test is like.
- The various possible results of the cervical screening test and the likely recommendations for further management.
- The benefits, risks, and limitations of undergoing the cervical screening test for the individual participant.
- Explanation of the limitations of cervical screening, including:
  - the possibility of missing a cancer by a screening test even if it is highly sensitive, like the HPV test;
  - the relative rate of false-positive and false-negative test results in cytology, HPV tests, or any other screening test in use in the programme;
  - the fact that the cervical screening system cannot achieve a zero error rate, because the triage tests also have limitations; and
  - information on interval cancers and the fact that screening cannot prevent every cancer.
- The right of the person to decline to undergo a cervical screening test.
- The right of the person to opt out of the cervical cancer screening programme on a long-term or permanent basis.
- Information on the consequences of opting out of the programme, such as not being re-contacted for screening and an increased risk of developing cervical cancer.
- Information about methods of withdrawing consent for participation in the screening programme, and information on how to re-enter the screening programme if the person changes their mind.

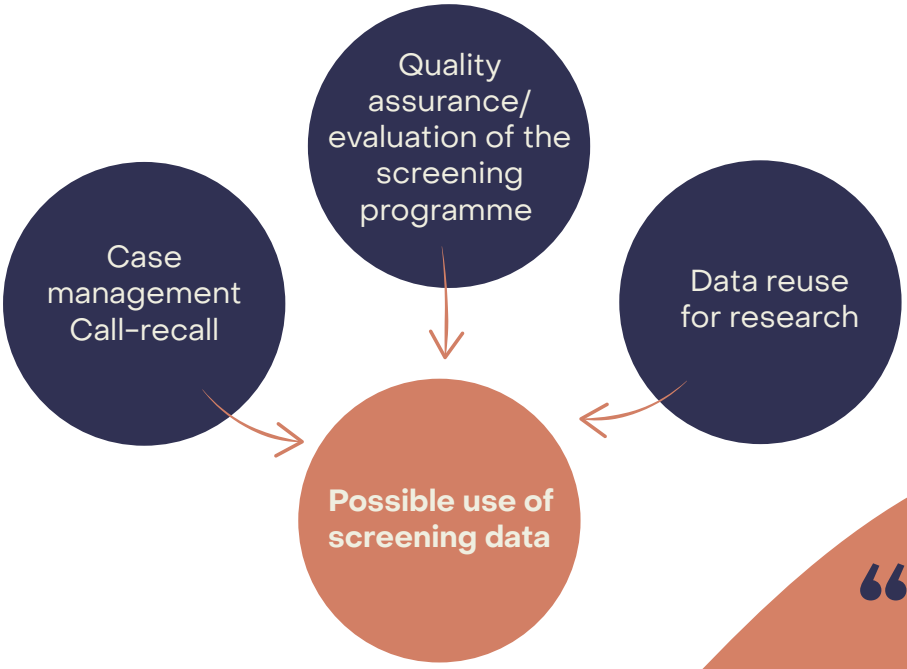
Data protection law in cervical screening

Protection of confidentiality or privacy is essential in cervical screening. Information about a cervical screening test is highly sensitive, given that it may include the results of the test and information about the participant's cancer or precancer status.

The medical records may also contain other relevant information either provided by the patient while undergoing the test or observed by the health-care professional performing the test. Therefore, there is a strong ethical imperative to ensure the confidentiality of this information. Consent to undergo a cervical screening test as a health-care intervention is not the same as consent for the processing of data related to that screening test for audit. It may be permissible to request consent for both purposes in one document, if the programme decides to obtain consent for audit.

Whether or not separate documents are used, consent for each purpose should be specifically delineated. The participant should understand the distinction between consent to undergo the cervical screening test and consent for the processing of data about that screening test. The data subject has a right to withdraw consent at any time.

How can data be used in a screening programme?



> Consent to undergo a cervical screening test is not the same as consent for the processing of data related to that screening test.

Legal liability for errors in cervical screening

The nature of cervical screening presents challenges for legal liability for negligence or malpractice. Unlike routine medical interventions, an invitation to cervical screening is initiated by the programme or health provider, and interval cancers occur despite participation in screening.

Reviews of individual interval cancer cases, although essential to maintain programme quality, are associated with hindsight bias, which is known to play a significant role in the evaluation of an antecedent event in both medical and judicial settings.

Knowing in advance that there was a poor outcome can bias the reviewer's ability to pass judgement and heighten the reviewer's perception that the outcome was preventable. Such hindsight bias might lead to an unjustified evaluation of the performance of a health professional involved in routine care.

Processes need to be in place to ensure that the determination of negligence incorporates the inherent limitations of cervical cancer screening. These include the following:

- The subjective nature of the tests should be taken into consideration.
- There is necessarily some variation in how properly qualified and trained health-care providers would read a particular slide on cytology or histopathology or interpret changes seen on colposcopy.
- There is also some variation in how a specific person would read a particular

cytology or histopathology slide in a routine (often busy) practice setting versus a review setting (with more time and knowledge of the final outcomes).
- Legal determinations of negligence in cytology, histology, or colposcopy must allow valid objective and contextual determination of the performance of the test.
- A test result is not necessarily negligent just because a different screener would have formed a different opinion.
- The standard should be tailored to the qualification level of the person performing the original screening within the particular screening programme.
- The reporting of the slide should be judged by reference to the information available to the screener at that time.
- The reporting of the slide should be judged with reference to the conditions of the original screening.
- The influence of hindsight bias in the audit outcome needs to be duly considered.
- Legal processes for assessing negligence in slide reporting must be differentiated from audit review processes.

The International Agency for Research on Cancer (IARC) is a unique organization dedicated to promoting international collaboration in cancer research and to carrying out research wherever in the world offers the best opportunity for finding the answer. IARC has a global remit, focusing in particular on cancers with a high burden in low- and middle-income countries or on cancers that cannot be easily studied within national borders.

IARC produces high-quality, independent research that is highly respected by scientists, governments, and the public. It is responsible for producing some of the most authoritative reference materials on cancer, which are made available to the international community.

Training of the next generation of cancer researchers is central to IARC's mission, through an integrated programme of fellowships and courses. IARC's research provides the evidence base for policy and guideline development by the World Health Organization (WHO) and national governments, and supports the implementation of effective national programmes for cancer prevention and control.

Despite IARC's modest size and budget, the scope, quality, and impact of its work are remarkable. The Agency's collaborative approach and its achievements over more than five decades make it a true catalyst for progress.

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International Agency for Research on Cancer

World Health Organization

International Agency for Research on Cancer
25 avenue Tony Garnier
CS 90627
69366 Lyon CEDEX 07
FRANCE
www.iarc.who.int