IARC WORKING GROUP REPORTS

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AUDIT OF CANCERS, LEGAL AND ETHICAL FRAMEWORKS, COMMUNICATION, AND WORKFORCE COMPETENCIES

IARC WORKING GROUP REPORT NO. 11

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Gender language disclaimer

This publication uses the word "woman" (and the pronouns "she" and "her") to describe individuals whose sex assigned at birth was female, whatever their gender identity.

Foreword

The International Agency for Research on Cancer (IARC) is pleased to publish these Technical Working Group recommendations on best practices in various aspects of a cervical screening programme. Cervical cancer is a significant public health challenge globally, and cervical screening programmes play a crucial role in the prevention and early detection of this disease. The development of best practices for cervical screening programmes is critical to ensure that these programmes are effective, efficient, and safe for all participants.

This document emphasizes the importance of conducting regular audits of cervical cancers to ensure the quality of screening programmes. It also highlights the critical role of ethical and legal frameworks in obtaining consent, conducting cancer audits, and communicating the audit outcomes to patients and health-care workers.

Effective communication to all women is another crucial element of cervical screening programmes. This document provides recommendations to ensure that communication is transparent, understandable, and culturally appropriate. It also recognizes the need to build workforce competencies in communication to ensure that all women receive the information and support they need to make informed decisions about their health.

The development of these recommendations was prompted by events in Ireland after an audit of interval cancers in the cervical screening programme in 2018. This document contains the outcomes of the deliberations of three Technical Working Groups of global experts. The IARC Secretariat conducted a review of the work undertaken by professional bodies and government agencies in several countries, including Ireland. The members of the Technical Working Groups thoroughly examined the evidence and consulted with all relevant stakeholders to develop practical and actionable recommendations. I would like to extend my gratitude to Dr Anne Mackie, Dr Peter Sasieni, and Dr Marc Arbyn for leading their respective Technical Working Groups and providing excellent guidance to colleagues at IARC. This document is a testament to the value of collaboration between researchers, practitioners, policy-makers, and cancer advocates in advancing cancer prevention and control efforts.

Despite the variation between countries in screening programme organization, legal practice, and communication strategies, I hope that this document will serve as a guide for existing and planned cervical screening programmes as they evolve. The members of the Technical Working Groups acknowledge that the recommendations provided in this document are not definitive, given the paucity of high-level evidence in this area. However, I believe that this document will provide a valuable resource for practitioners and researchers working in cervical screening programmes and will help to ensure that these programmes operate in a safe and effective manner.

Dr Elisabete Weiderpass
Director, International Agency for Research on Cancer

Executive summary

Well-organized cervical screening programmes have been shown to reduce the incidence of and mortality from cervical cancer at the population level. This document describes current best practices in the following aspects of a cervical screening programme:

- conducting an audit of cervical cancers;
- establishing legal and ethical frameworks to safeguard the interests of screening participants, health professionals, and programme managers associated with cervical screening;
- developing a strategy for effective and transparent communication with target populations and other stakeholders about the benefits, risks, and limitations of cervical screening; and
- establishing a framework for developing workforce competencies in communication.

This document is based on a review of the scientific literature and on the opinions of technical experts who were convened through three Technical Working Groups. A summary of the current best practices as noted by the members of the Technical Working Groups is given below.

Audit of cervical cancers in a screening programme

- The purpose of programmatic audit of cancers in a cervical screening programme 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. Audit findings 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.
- There is variation between countries with regard to the need for, the implementation of, and the communication of audit of cervical cancers. No legal or ethical consensus prevails internationally.
- It is not possible to achieve zero-error screening in standard practice, no matter how high the quality of cancer screening is.
- Audit planning and the engagement of stakeholders are key to the success of the entire audit process.
- An individual case review should be distinguished from a programmatic audit and should be planned and implemented differently, because the two processes have different objectives.
- 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. Thus, not obtaining individual informed consent at the time of

a programmatic audit is justified. However, this means that the women who undergo screening must be informed at the time of the screening of the possibility of an audit.

- The European guidelines recommend that all cervical cancers should be investigated, whether detected in screened women or in unscreened women.
- An interval cervical cancer is defined as any cancer (including microinvasive cancer [stage IA]) diagnosed in a woman between her most recent screening episode and her next screening round, 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. It is important to distinguish between these two different types of interval cancers.

Legal and ethical frameworks associated with cervical screening programmes

- A screening-eligible woman who is invited to participate in cervical cancer screening should be informed about the nature and purpose of cervical screening and of the tests, the possible results, and the benefits, risks, and limitations. The woman's right to decline to undergo a test and the possible consequences of opting out should also be explained.
- 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.
- Confidentiality and the protection of privacy are 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.
- 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.
- 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. Even where consent is not relied upon as the basis for data processing, the data controller should ensure that privacy notices are prominently displayed that inform the screening participants about how their data will be processed.
- Screening programmes may offer an individual case review to participants after obtaining informed consent. When consent is obtained for an individual case review, participants should be asked whether they wish to be informed of a discrepancy if one is detected in the future.
- Regarding legal liability for errors in screening, it should be possible to make a claim for negligence with respect to cervical screening, but the standards applied by courts in assessing such claims should accommodate and reflect the reality of cervical screening, including hindsight bias in an audit of cancers. The determination of whether the particular screening error was serious enough to be categorized as negligent and/or serious enough to entitle the participant to compensation needs to consider the inherent limitations of cervical screening.

Effective and transparent communication about cervical screening

- Because of the heterogeneity of the target population for screening, the approaches to screening and downstream management are variable across settings, and so are the access barriers encountered. These differences need to be considered when developing messages and designing communication strategies to promote uptake of cervical screening.
- The screening information conveyed should highlight that screening is a personal choice and should include clear statements on the benefits, risks, and limitations of screening. The information needs to provide a clear statement on the estimates of probabilities of the condition and potential positive and negative outcomes from screening. It also needs to highlight that the programmeprovides screening because of the significant burden of disease and because the benefits of undergoing the tests outweigh their risks and limitations.
- Acknowledging that screening has risks and describing the benefit-to-risk balance through a pragmatic communication strategy is likely to build long- lasting trust in the programme and ensure autonomy in decision-making by every potential screening participant.
- When developing screening information materials, the information should be provided using a tiered approach, starting from basic concepts and building up to more complex information, supported by visual aids and using behavioural science support.
- A multipronged delivery strategy and obtaining feedback from all relevant stakeholders on the appropriateness of the content and the acceptability of the delivery modes are important.

- Communication with all other stakeholders is essential to build relationships of trust that will facilitate the implementation and operation of the screening programme. Stakeholder analysis helps to define various audiences, their level of sophistication, and their willingness to hear the messages that are communicated. The content and delivery mode of the messages must be tailored to the intended audience and must consider cultural norms and sensitivities.
- Once the stakeholder analysis is complete, a documented stakeholder engagement strategy needs to be developed. Such a strategy improves trust in the screening policies, increases buy-in, and may help to mitigate any short- and long-term issues with the programme.
- Screening programmes should be prepared by having a communication strategy in place for events that may evolve into a crisis. Such incidents may be related to risks of screening, a change in the screening criteria or the interval of screening, or any occurrences after screening, which may not be directly related to the screening programme itself.

Workforce competencies in communication about cervical screening

- Health professionals involved in the screening pathways need to acquire appropriate knowledge and should be able to demonstrate skills that include:
  - being able to foster a relationship of mutual trust, understanding, and commitment;
  - being able to exchange information that recognizes the individual's information needs and overcomes any barriers related to low health literacy and poor understanding of statistical information and considers cultural contexts;
  - being able to manage uncertainty by acknowledging it and providing further information, support, and cognitive strategies;
  - supporting shared decision-making through active involvement of the potential participants and their family members in the information-exchange and deliberation stages of the decision-making process; and
  - enabling people to navigate the health system by providing appropriate guidance on seeking appropriate care and finding further information.

Abbreviations

CIN	cervical intraepithelial neoplasia
GDPR	General Data Protection Regulation
HPV	human papillomavirus
IARC	International Agency for Research on Cancer
LBC	liquid-based cytology
LLETZ	large loop excision of the transformation zone
PAPM	precaution adoption process model
TWGs	Technical Working Groups
WHO	World Health Organization

Introduction

Well-organized cervical screening programmes have been shown to reduce the incidence of and mortality from cervical cancer at the population level. In such screening programmes, important quality assurance measures need to be ensured. These include:

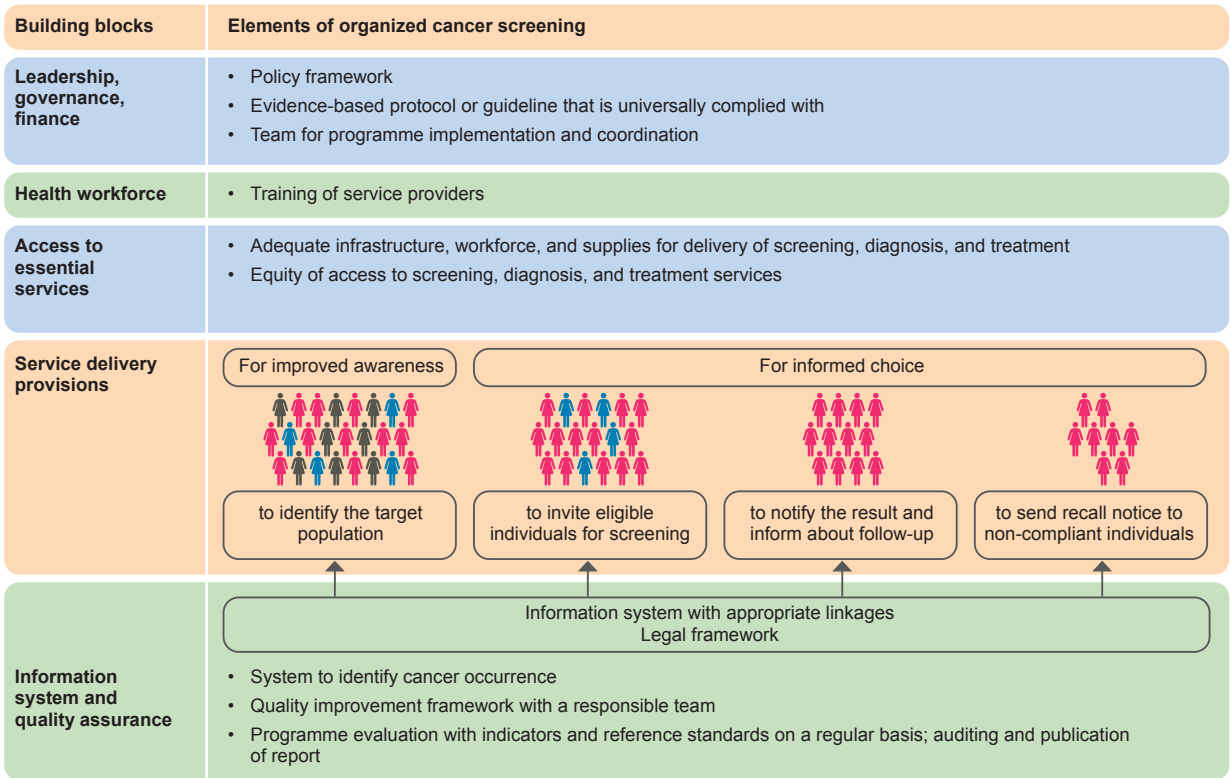
- high coverage of the target population with minimal inequalities;
- a strong linkage between screening and management of screen-positive women, to ensure timely and appropriate treatment of precancers and cancers; and
- high quality of services across the screening continuum.

On the basis of expert consensus, the International Agency for Research on Cancer/World Health Organization (IARC/WHO), France, identified 16 essential criteria that a screening programme needs to fulfil in order to be considered an organized programme (Fig. 1). Audit of cancers, as an integral part of a quality improvement exercise, is included in these essential criteria. Despite the pivotal role of an audit of cancers in the quality improvement process, there is a lack of consensus on its definition, role, and methodology. Interpretation of the audit outcomes in the context of individuals whose records or specimens were audited in relation to the larger programmatic context has sometimes been a source of contention.

Recent incidents in Ireland have demonstrated that gaps in communicating audit outcomes in a timely, efficient, and transparent manner may lead to confusion, psychological trauma, litigation, and loss of trust in the programme (Box 1). In Ireland, this was to some extent due to the lack of a clear legal framework on how to conduct such audits of cancer, and to lapses in communicating the outcomes in a transparent manner to the women whose review test results have been found to be discrepant. In fact, effective communication at all levels of the screening process through a workforce that is adequately competent in health communication may be a key determinant of the success of an audit.

In the context of health care, a best practice is defined by WHO as "a technique or methodology that, through experience and research, has proven to reliably lead to a desired outcome" [1]. Best practice is not about perfection or setting the gold standard. It is about learning from others and avoiding similar mistakes in order to develop and implement solutions adapted to similar health problems in different situations. Best practices are time-sensitive because they may change with new evidence and experience. For this reason, this document uses the term "current best practices", which are described in subsequent sections.

Fig. 1. Elements of organized cancer screening, categorized across the five building blocks of health systems. Source: [2]. From Zhang et al. (2022). Published under https://creativecommons.org/licenses/by/4.0/.



Box 1. Experience with audit of cancers in the cervical screening programme in Ireland

As part of a quality assurance exercise in the cervical screening programme in Ireland, an audit of all cervical cancers detected in a cohort of 1.1 million eligible women screened in 2008–2014 was undertaken in 2018 by the national screening service (CervicalCheck). On average, the programme screens about 300 000 women per year. The audit identified 221 cancer cases where, on review, the screening cytology result was upgraded to one that would usually lead to referral for colposcopy or repeat testing.

Although the programme management aimed to communicate the audit outcomes to patients with cancer, there was hesitancy and delay in communicating the results, and this led to a public outcry. The perception grew that the non-disclosure of the audit result had led to delayed treatment for women. Many people were convinced that finding discordant cytology results on review meant that the cervical screening programme in Ireland had performed poorly and had tried to cover up inadequacies.

An independent review by the Royal College of Obstetricians and Gynaecologists, United Kingdom, found discordance between a retrospective expert smear review and the original CervicalCheck result in 30% (308 of 1034) of cancer cases, which included microinvasive cancers. In nearly half of these discordant cases, the expert panel considered that the original CervicalCheck result had an adverse effect on the woman's outcome because it led to a delay in diagnosis. Crucially, the report also found that the discordance rate was similar to that observed in the cervical screening programme in England. Despite this, the view that the Irish cervical screening programme had not served women well or honestly prevailed in Ireland.

A scoping inquiry was also conducted, and the recommendations of this have been implemented by the Irish cervical screening service. Although the Irish cervical screening service has consistently met the highest international performance standards, since the audit incidents there has been an exponential increase in the number of legal cases in Ireland arising from participation in screening programmes. As of August 2022, the estimated potential liability of legal claims is up to €300 million against a 2019 operating budget of €34 million; this could render screening financially unsustainable.

Key learnings from the incidents in Ireland

- Screening tests for cervical cancer and precancer are very different from diagnostic tests, and they will both miss and overcall abnormalities routinely, even in a programme that is performing well.
- Screening services and the professionals involved need to take responsibility for comprehensive, timely, and transparent communication to women who opt for screening.
- Audit of cancers is crucial to improving the quality of screening programmes, and an appropriate legal framework is needed to conduct such audits.
- Screening staff and clinicians need to have indemnity from non-negligent inadequacies of screening.

Objectives and scope of this document

This document is based on a review of the scientific literature and on the opinions of technical experts. It aims to describe current best practices in the following aspects of a cervical screening programme, which are infrequently discussed in the scientific literature:

1. Audit of cervical cancers in a screening programme.
2. Legal and ethical frameworks to safeguard the interests of screening participants, health professionals, and programme managers associated with cervical screening and related services.
3. Effective and transparent communication with target populations and other stakeholders about the benefits, risks, and limitations of cervical screening.
4. Establishing a framework for developing workforce competencies in communication.

Three Technical Working Groups (TWGs) made up of global experts were convened by IARC to address the above-mentioned subjects. The current best practice recommendations aim to assist policy-makers, programme managers, and other health professionals associated with cervical screening and downstream management. Participants in cervical screening, patients with cervical cancer, civil society organizations, and legal professionals may also benefit from understanding these best practices. The document is accompanied by infographics targeting these audiences.

Initially, the members of the TWGs (Annex 1) identified the key questions related to three areas (cancer audit, legal and ethical frameworks of cervical screening, and effective and transparent communication) to be addressed by this best practice document. The IARC Secretariat conducted a review of the published literature, national guidelines, and protocols to prepare responses to the questions for each TWG. Unpublished information was also collated from several ongoing surveys within Europe. The responses were reviewed by the members of the TWGs and deliberated upon at the TWG meetings to arrive at a consensus.

A stakeholders' advisory group on the same issues was organized in Ireland (as a country in which the document will be highly relevant) (Fig. 2). It was made up of relevant local stakeholders, which were identified through a mapping exercise, and the group included those from the micro, meso, and macro levels. The views and preferences of the stakeholders were presented to the chairpersons of the TWGs and were

Fig. 2. The stakeholders' advisory group in Ireland. © IARC.

considered when this best practice document was finalized.

The contents of this best practice document are applicable to cervical screening programmes with a reasonable degree of organization and resources. Countries with well-organized population-based screening programmes (i.e. those that have a system of identifying eligible women, inviting them to screening, and recalling them) should perform audit of cancers following the principles and methods described in this document. The applicability of this document to cervical screening programmes in low- and middle-income countries will depend on the resources, process, and organization of screening in those countries. A recent IARC journal publication on screening programmes globally reveals that most low- and middle-income countries have opportunistic screening, and that audit of cancers is seldom undertaken in these settings [2].

Quality assurance including audit of cancers should be an integral part of a screening programme, irrespective of whether there is a system for inviting the screening-eligible women. Obtaining the screening history of every woman who presents with cervical cancer at a tertiary care centre and collating the information periodically can give some idea of the proportion of cancers detected through the screening pathways and the proportion of cancers diagnosed despite a previous negative screening or triage test result.

The basic principles of communication remain the same irrespective of the setting. However, the communication strategies, the delivery mode and the content of the messages, and capacity-building of health professionals in communication should be tailored to the needs and organization of the programme, cultural issues and the local ethos, and the average level of knowledge of the target population about cervical cancer and its prevention.

CHAPTER 1.

Audit of cervical cancers in a screening programme

1.1 Definition of audit in general and audit in the context of cervical screening

A **health-care audit** is defined as a quality improvement cycle or process to measure the effectiveness of health-care services against agreed, proven, evidence-based, and recognized standards to improve quality of care and outcomes [3–6]. Audit of any health-care service is considered by WHO to be a critical function of an organization, to provide objective assurance on its integrity and credibility [7].

Specifically, a cervical screening programme benefits from being audited. **Audit of a cervical screening programme** is defined as a programmatic set of measurements of quality and effectiveness of screening services using structural, process, and outcome indicators against evidence-based and realistic standards agreed upon by relevant stakeholders.

Audit of cancers in a cervical screening programme is part of the programmatic audit process and is a component of the overall evaluation of screening effectiveness. It involves an in-depth review of the screening pathway for women diagnosed with cervical cancer [8]. An audit of cancers may include any of the following categories of cancer:

- cancers that occur in women with irregular participation or non-participation in screening;
- cancers that are detected in women with abnormal screening test results; and
- cancers that are detected in women with normal screening test results.

The terms audit, quality assurance, and quality improvement are often used interchangeably, although they are not synonymous. **Quality assurance** has been defined as a systematic process that describes the achievable and the desirable levels of quality and assesses the extent to which these levels are achieved. The aim of quality assurance is to enable a level of quality to be reached [9]. Whereas quality assurance focuses on measuring compliance against quality standards, **quality improvement** is a more proactive approach that aims to improve systems and outcomes based on a systematic analysis of current performance. **Audit** is the part of the quality assurance or quality improvement process that focuses on specific issues of health-care and clinical practice.

An audit by itself will not assure quality or lead to quality improvement unless the audit outcome leads to specific recommendations to close

any quality gaps identified by the procedure and actions are taken based on those recommendations to improve quality. **Hence, audit of cancers is part of a broader quality assurance or quality improvement exercise in any cervical screening programme**.

1.2 Key objectives of an audit of cervical cancers

The overarching goal of programmatic audit in any health-care service 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 [10]. A well-organized cervical screening programme is expected to reduce the incidence of cervical cancer significantly (but never to zero) and to ensure that incidence rates remain very low by detecting and treating the disease at a precancerous stage. Cervical screening also reduces the mortality from cervical cancer by detecting early- stage cancers before they are symptomatic and therefore when treatment is likely to be effective. For this reason, any cervical cancer that occurs in a population targeted by a screening programme needs to be audited, to understand whether it could be prevented or detected even earlier through improved quality of services.

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 [8]. It is of critical importance for the audit team to ensure that the professionals involved in the screening process do not interpret audit as an inspection of their individual clinical competence, which may make them avoid participating in the audit process, either consciously or subconsciously, thus defeating the very purpose of the audit [10]. It is also important that all stakeholders – screening participants, the media, politicians, and legal teams – do not interpret audit as a process used to identify error or negligence. Rather than finding fault, an audit may identify best local practice and innovation that should be promoted and disseminated in the programme and elsewhere.

1.3 The cancer audit process – guiding principles

An audit of cervical cancers in a screening programme, like any other health-care audit, should have a documented policy and process framework. An audit process involves a cycle (Fig. 3), which consists primarily of the following phases [4, 6, 11, 12]:

1. The audit process starts with a **planning phase** to select a suitable clinical condition to be investigated (e.g. cancers detected in a cervical screening programme), to identify indicators to be used to determine performance (e.g. interval cancer rate, percentage of cytology slides reviewed that contain missed abnormalities, or percentage of cases not managed according to national guidelines), and to agree on standards of performance relevant to the selected clinical condition.
2. The next phase is systematic data collection to **measure performance against the agreed standards,** which will lead to identification of the gaps in service or some of the best practices.
3. **All stakeholders then need to review** the audit outcomes and formulate strategies to address the gaps identified, to disseminate the best practices, and to improve quality.
4. The **process needs to be continued** as a cyclical exercise.

Audit planning is key to the success of the entire exercise. It starts with the selection of an appropriate theme [10], which ensures that:

- the problem to be audited has an important impact in terms of costs, resources, or risk;
- there is strong scientific evidence available (guidelines and systematic reviews), which has been used to determine the acceptable and desirable standards; and
- the improvements to be recommended on the selected theme have important clinical or organizational consequences and can be easily measured.

Occurrence of cervical cancers in a screening programme fulfils all the above-mentioned criteria and is a suitable clinical condition to be audited.

The **objectives of the audit** should be clearly delineated in the plan. For example, the core objective of an audit of cervical cancers in a screening programme is to maximize the benefits of screening without increasing the risks to the women who are offered screening. The aims of an audit in the NHS England Cervical Screening Programme are shown in Box 2.

An **audit team** should be customized to the selected topic and should include representatives from multiple disciplines with appropriate skills (e.g. cytopathologist, colposcopist, histopathologist, and statistician for an audit of cervical cancers). The responsibility for initiating the audit process regularly according to the programme's published policy and framework lies with the managers of the organization that provides the screening services.

The indicators to measure performance and their standards (often categorized as acceptable

Fig. 3. Stages of a health-care audit. © IARC.

Box 2. Aims of an audit of cervical cancers in the NHS England Cervical Screening Programme

The aims of an audit of cervical cancers as stipulated in the NHS England Cervical Screening Programme are to:

- support the **continuous learning and development** of health professionals involved in the programme;
- **monitor the effectiveness** of the cervical screening programme by comparing the screening histories of individuals who develop cervical cancer with those who do not;
- identify **areas of good practice** and indicate where **improvements** might be made to support evidence-based policy and practice; and
- ensure that participants are given **information** about their screening history review (if they wish to receive it).

and desirable) should be listed and derived from international guidelines, the scientific literature, expert consensus, and data obtained from other health-care facilities or case studies. The threshold of acceptability for each standard (as desirable and acceptable, or as satisfactory and unsatisfactory) needs to be defined. Defining the indicators and standards requires active engagement with all stakeholders. Before proceeding with data collection, it is necessary to plan carefully how the variables will be recorded and the type of analysis to be conducted.

Data collection (from case records, review of specimens, etc.) requires an appropriate legal and ethical framework (see Chapter 2). Reviewing the results and developing action plans for quality improvement should be a multidisciplinary process that involves various levels of stakeholders. The audit process should be repeated periodically in order to document that the implementation of the suggested action plan has resulted in improvement [11].

An appropriate strategy for communication of the programmatic audit outcomes and the recommended improvements should be incorporated into audit planning. After the data have been collected and analysed, the results of the programmatic audit and the action plan should be communicated to all the stakeholders. The members of the TWGs concurred that a programmatic audit is not the same as **an individual case review** (for more details, see Section 1.4). Programmatic audit should produce aggregate (i.e. system-level) results and not pinpoint what has happened to a specific screening participant.

The audit plan needs to make provision for adequate resources (financial and logistic) to support audit planning, team building, data collection, training of health professionals (including education on audit techniques), facilitation, and data management and dissemination. The strategy for effective audits is shown in Box 3.

1.4 Audit of cancers versus individual case review in a cervical screening programme

The overarching aim of programmatic audit of cancers in cervical screening is to evaluate the effectiveness of a screening programme in reducing the incidence of cervical cancer and minimizing the risks associated with screening [13]. 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 [13–16].

As mentioned earlier, audit of cervical cancers aims to evaluate the programme (i.e. the system) and not individual health professionals or what happened to an individual participant. In any programme, some cancers will be missed. Some interval cancers are due to fast-growing tumours that could not be detected through screening at the specified interval. Also, cervical cytology was not designed to assess endocervical disease and will miss many such cases. Missing such cancers is not a deficiency of the programme. The audit looks at the extent to which cervical cancer could be further prevented in the population by avoiding human or systematic errors, and not at whether the failure to detect a cancer in a particular woman was a result of human error. This distinction is key to an understanding of the programmatic value of audit of cervical cancers. The results of a cancer audit should not appear in the medical records of an individual patient, because the results have no bearing on the patient's management or treatment outcomes.

Box 3. How to make audits work effectively

1. Engage all health-care professionals involved to use the shared commitment of the entire team working together and sharing common protocols and practice. Follow the local bottom-up approach through discussion with professionals to recognize issues of interest from their own discipline.
2. Involve relevant stakeholders (including screening participants, patients, and public advocates) in the design and communication of the audit.
3. Focus on knowledge-sharing. Make it clear to the health-care professionals that the audit is a learning opportunity. Dedicate time and attention to sharing knowledge with colleagues about the quality of care as it relates to the design of the care pathway.
4. Identify a local champion (or champions) as the driving force behind the audit. This is more likely to encourage health-care professionals to take ownership and see the audit process as worth the effort. The champion will motivate colleagues and work with them to implement changes in practice.
5. Educate all stakeholders in advance about the interpretation of results and likely actions.
6. Create an enabling environment to receive feedback. Encourage health-care professionals and other stakeholders at all levels to provide feedback on the audit process and outcomes.

It is also important to remember that no matter how high the quality of cancer screening is, it is **not possible to achieve zero-error screening** in standard practice [17]. A well-organized population-based screening programme with high quality and good coverage will significantly reduce the number of cervical cancers but will never eradicate the disease. Many of the diagnostic investigations used in cervical screening, such as cervical cytology, colposcopy, and histopathology, are subjective tests and are susceptible to interpretation errors. Although the practice standards have not been well defined in cytology, a systematic review reported that even in countries with organized screening programmes, 20–55% of women who developed cervical cancer had had false-negative smear test results within 6 years before the diagnosis [18].

The same subjectivity also applies to colposcopy and histology. Although a well-organized cervical screening programme is expected to detect and treat most disease when the risk of progression to cancer is high, and thus to be very efficient in preventing progression to invasive cancer, the **incidence of cervical cancer cannot be reduced to zero**, even in the best of circumstances. Combined data from the four randomized controlled trials in Europe demonstrated that even in such highly controlled research settings the cumulative incidence of invasive cervical carcinoma in women with negative results from human papillomavirus (HPV) testing (which is currently considered to be the most accurate test available) was 4.6 per 100 000 at 3.5 years and 8.7 per 100 000 at 5.5 years. All of these cancers were detected in subsequent rounds of screening. The corresponding values for women with negative cytology results (not screened with HPV testing) were 15.4 per 100 000 at 3.5 years and 36.0 per 100 000 at 5.5 years, which shows the inherent low sensitivity of cytology, even in a research setting [19].

An **individual case review** 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 medical records, test results, pathology specimens, and care received before the diagnosis. However, in an individual case review, (i) the patient's consent is needed, and (ii) the results must be disclosed to the patient, which is not mandatory in programmatic audit of cancers. When discussing an individual case review with the patient, every attempt should be made to explain the process before the review is done. The patient should be told about:

- the likely outcomes of a review, and that such a review is very unlikely to modify the course of treatment;
- the relevance of retrospective (or hindsight) bias and how a finding of discordance between the original result and the review result is not always a proof of negligence; and
- the possible psychological impact of finding out on review that abnormal cells were present but were not reported.

An introductory meeting is key, so that the patient who is requesting such a review can outline her main areas of concern. It also gives the clinical team an opportunity to explain what the comprehensive review entails and to discuss the issues mentioned above. This helps the team to plan the schedule for delivering the review results and to plan any support to the patient that may be required.

If the patient has died or is not in a physical or mental state to provide informed consent, an individual case review may be requested by the partner, spouse, or other close relative(s) of the patient. The principles of the restorative approach to individual case review are shown in Box 4.

1.5 Cervical cancer audit practices in different countries

There is wide variability in audit practices internationally. The IARC Secretariat reviewed publications that reported the processes used for the audit of cervical cancers in various countries. Most reports were based on regional or national population-based screening programmes in European countries, such as Denmark [20–22], England [15], Finland [23], the Netherlands [24], Poland [25, 26], and Sweden [27]. The IARC Secretariat also found a report from New Zealand [28]. Some reports were based on the routine audit of screening programmes [15, 22, 28], whereas other audits were undertaken for one-time research to inform quality assurance and practice.

Audits of cervical cancers collate data from different sources, including population-based cancer registries, screening registries, routine medical records, screening invitations, cytology and histology laboratories, and colposcopy clinics. Cytology review was the most commonly described audit process across different countries, although NHS England also includes colposcopy and histology review [15] as part of an audit of cancers. In countries where cytology

Box 4. Principles of the restorative approach to individual case review

The restorative approach aims to bring all of those affected by an adverse event together in a safe and supported environment. Key principles that must be followed are to:

- prepare the patient in advance for the potential review findings;
- ensure that a support person is available for patients during the process;
- use simple language to explain the review findings; and
- ensure that post-disclosure support is available.

The approach to individual case review should contain the following elements. There should be an introductory meeting, to provide information and set expectations for the review. The case review should be followed by a discussion meeting, which should facilitate supported discussion of the review findings and the resulting clinical impact. The meeting will give an opportunity for patients to understand how discordance happens (if such discordance has been observed), and such an explanation needs to be provided in a protected and compassionate space.

This process aims to restore screening to its place in health care as a service that benefits population health but also acknowledges its limitations.

review was performed using controls, the case-to-control ratio varied; the ratios used included 1:2 [26], 1:4 [15], 1:5 [14], and 1:10 [29]. Countries also differed in who reviewed the cytology or histopathology. In some programmes, the technicians or pathologists who reviewed the slides for the audit were those who had performed the original review, in some programmes the audit review was performed by an independent panel, and in some programmes it was a mixture of these two approaches. The degree of blinding during audit also varied. On the basis of reports from the various programmes and the opinions of the members of the TWGs, some of the best practices in the audit of cervical cancers are listed in Section 1.6.

1.6 Audit of cancers in a cervical screening programme – practice issues

1.6.1 Should all cervical cancers be included in an audit?

The European guidelines recommend that all cervical cancers should be investigated, whether detected in screened women or in unscreened women [30]. **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 (according to the definitions given Section 1.6.2). However, such comprehensive evaluation requires robust linkage between the population-based cancer registry and the screening registry (the database that maintains individual records of the women eligible for screening) and individual medical records. As much as possible, the list of cancer cases that were diagnosed during the time period under consideration and the clinical information for each case (screening invitations, cytology results, colposcopy results, histology, and mode of detection) should be obtained from the population-based cancer registry and the clinical records.

For cancers that are diagnosed in unscreened women in a population-based programme, the process of invitation and response to invitation should be examined. A systematic audit will distinguish between a situation where there was a failure to invite the woman (Was full information available in the register? Did the woman receive an invitation or a reminder as per protocol?) and a situation where a woman was invited but did not attend screening for various reasons. The proportion of women diagnosed with cervical cancer within the eligible age group who did not receive an invitation is a key indicator and is estimated either from the case records or by interviewing the patients, or both. Feedback on this issue from the women themselves – including perceived barriers to accessing screening, and perceptions of screening and how it is delivered, whether it is culturally acceptable, and resulting inequalities – is particularly valuable and may help to develop strategies to improve the programme.

1.6.2 How are interval cervical cancers defined?

Definitions of interval cervical cancer and its reported incidence vary in the literature. Most of the programmes or studies define only those cancers that occur in screen- negative women as interval cancers and do not include cancers that occur after a negative diagnostic test result (colposcopy and/or biopsy) in screen-positive women in the definition of interval cancer. Hakama et al. considered such cases to be failures of the screening episode and that this justified including such cancers within interval cancers. Some audits

exclude microinvasive cancers [31–33] in the definition, whereas other do not. On the basis of evidence from this review [15, 16, 31–36] and from the multicountry survey [37], the members of the TWGs defined an interval cervical cancer **as any cancer (including microinvasive cancer [stage IA]) diagnosed in a woman between her most recent screening episode and her next screening round, 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.**

Thus, an audit of interval cancers should consider the following:

- cancers in women with negative results from screening tests performed within an interval stipulated by the programme;
- cancers in women with positive screening test results but negative triage test results (when the protocol involves triage); and
- cancers in women with positive screening test results (and positive triage test results, depending on the protocol) but negative diagnostic test results (colposcopy and/or biopsy).

Cancers that occur during follow-up after treatment of high-grade precancers (cervical intraepithelial neoplasia grade 2 or 3 [CIN2/3]) have different follow-up protocols and risk profiles and should not be defined as interval cancers. The members of the TWGs are of the opinion that any abnormal screening tests reported within the 6-month period before diagnosis should be considered to have led to the diagnosis of cancer. Therefore, cancer cases with an abnormal screening test reported within 6 months of diagnosis should be excluded from the definition of an interval cancer.

1.6.3 Is it mandatory to obtain informed consent from the women to be included in an audit?

As Sasieni and Cuzick explain, reliable audits cannot depend on consenting women alone but must be representative of the whole population. Analyses based only on consenting women are likely to be biased and misleading [13]. The members of the TWGs concluded that **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. However, this means that the women who undergo screening must be informed at the time of the screening of the possibility of an audit. It also means that the auditors must make exceptionally determined efforts to ensure that the data are kept safe and confidential. Clear information about the process should be provided to women at the time of invitation to or participation in screening, so that they are adequately informed about the audit process. All personal data should be removed at the time of audit to ensure anonymization when a woman has denied consent for the use of her data. For further information on the consent requirements and process in an audit, please see Section 2.2.

1.6.4 Is ethics approval necessary for an audit?

Although an audit is designed and conducted with the sole purpose of defining or judging the quality of current service, very often an audit of cancers in cervical screening is both an audit and a research activity. However, an audit is not the same as experimental clinical research, because there is no intervention. An audit is a form of non-intervention system research. 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 in most legal systems. For more information on the use of personal data, please see Section 2.4.

1.6.5 How to measure and compare rates of interval cancers

Interval cancers are measured in different ways. As a result, the estimated rates vary widely, which makes it difficult to compare them between programmes. The members of the TWGs observed the following different ways in which interval cancer occurrence has been measured:

1. **Interval cancer incidence as person-years at risk.** This is calculated in women with an interval cancer from the date of the entry test to the date of the next (second) routine test, the date of diagnosis of cancer, the date of emigration to a foreign country, the date of death, or the end of the period of estimation, whichever occurred first.
2. **Interval cancer rate in a screening episode.** This is defined as the number of interval cervical cancer cases detected within the interval after a single screening episode with negative cervical screening results and before the next scheduled episode, per 100 000 women.
3. **Age-standardized interval cancer incidence rate.**
4. **Percentage of women with interval cancers who had a false-negative screening test result.** This is the percentage of patients with cervical cancer who had a negative cytology test result within *X* years (where *X* = the screening

interval) of cancer diagnosis and whose slides upon review were upgraded to borderline (atypical squamous cells of undetermined significance [ASC-US]) or worse cytology.

5. **Relative risk of developing cervical cancer** in women screened in time and who had only normal test results compared with unscreened women.

The measurements are often stratified by age groups. Whatever method is used to measure the occurrence of interval cancers, the programmes need to compare interval cancer occurrence over time. It is also useful to compare the rates of newly detected cervical cancers in screened women (both screen-detected and interval cancers) and unscreened women for a particular year.

1.6.6 How to decide on the standard (benchmark) for interval cervical cancer rates

The number of cancers diagnosed in the interval between screening episodes is one of the fundamental indicators of the quality of programme performance. A low interval cancer rate usually demonstrates high effectiveness of the screening programme. This review found that in population-based screening, rates of interval cervical cancer were between 1.4 and 10.2 per 100 000 women-years in screen-negative (on cytology) women. These different rates may be due to the different denominators used. The members of the TWGs concurred that a rate of < 10 interval cervical cancers per 100 000 women-years is an acceptable rate in a cytology-based programme, but the programme should aim for < 4 interval cervical cancers per 100 000 women-years, especially for screening based on HPV testing. The programme has to take into consideration the cervical cancer incidence rate and the inclusion of stage 1A disease, which can increase the number of interval cancers.

When comparing newly detected cancers in screened women (both screen-detected and interval cancers) and unscreened women, the members of the TWGs agreed that the rate of cervical cancers (stage 1B and above) in screened women should be less than 25% of the rate in unscreened women. However, the number of screen-detected cancers is expected to be high in a programme that has recently launched screening based on HPV detection, because it is more sensitive in detecting prevalent disease.

1.6.7 How to assess cancers in unscreened or inadequately screened women

Very few details are available in the literature about the audit of cancers in unscreened or inadequately screened women. The measure used in the audit of these groups of women is cervical cancer risk associated with non-participation in screening (the relative risk of invasive cervical cancer in women who were unscreened or inadequately screened in the past two screening rounds compared with women who were screened in time).

1.6.8 What is the process of review of cytology slides?

In a cytology-based programme, the European guidelines recommend a review of the negative cytology slides preceding the detection of cancer for all cervical cancer cases [30]. For patients who develop cancer despite undergoing screening, the slides for one or two screening rounds before the diagnosis of cancer need to be retrieved from the relevant cytology laboratories; for this, documented ethical and legal guidelines are essential. Smears collected within 6 months of the date of diagnosis of cancer should be disregarded because they are most likely to have led to the cancer diagnosis.

A set of control slides for women (age-matched) without cervical cancer may be included in the review. In published studies, the number of controls per case varies from 2 to 30 [2, 7, 12–14]. It is recognized that because of retrospective (or hindsight) bias, 30–50% of slides obtained from patients with interval cancer will be found to have abnormalities when a review is performed. Adding the controls and reviewing the slides in a blinded manner help to adjust for such bias by comparing the proportion of unsatisfactory misses in cases with that in controls.

If the audit of cancers decides to include controls to verify whether the reading of slides under audit conditions increases the detected abnormality rate, slides from at least 100 controls per age group (e.g. 100 controls aged 20–49 years and 100 controls aged 50–69 years) and at least one control per case are required for the review. Obtaining slides from a sample of women with false-positive cytology reports is also recommended. Both blinded and non-blinded assessments need to be performed, to enable distinction between human error in cytological interpretation and interpretation error due to factors beyond the control of the cytology reader, such as slides that contain very few abnormalities or slides that are poorly prepared or poorly stained.

More than one (preferably three) cytopathologists or technologists should review the sample slides. Usually, the cytopathologist or technologist who examined the slides originally is included in the team. The final decision should be based on consultation with the reviewers, thereby arriving at a consensus. Each slide is first assessed for suitability for review. The review result will distinguish false-negative interpretations due to human errors from the features recognized as being at risk of being missed (e.g. few or

pale abnormal cells). In England, the programmes categorize each cytology slide according to the nature of discordance between the original result and the reviewers' interpretations into satisfactory, satisfactory with learning points, or unsatisfactory [2].

1.6.9 Should histopathology slide review be a part of an audit of cancers?

Ideally, for all cancer cases included in the audit, the previous histopathology slides (if any) should be reviewed as well. The data required for such a review include the date of specimen collection, the type of specimen, the pathological diagnosis, and the excision margins (for large loop excision of the transformation zone [LLETZ] or other excisional specimens). Multiple reviewers should be involved, just as for cytology review. In England, for example, all cervical histology slides reviewed for the audit of invasive cervical cancers are categorized, as with cytology, into satisfactory, satisfactory with learning points, or unsatisfactory.

1.6.10 Should review of colposcopy be a part of an audit of cancers?

Any colposcopic examinations that predate the index referral by up to 5 years should be reviewed, because these examinations (and associated management) may have affected the development of cervical cancer. For each case under review, colposcopy data are obtained; these include the total number of colposcopy appointments and, for each, the date of the appointment, attendance at the appointment, whether the examination was satisfactory, and information on any biopsy or treatment procedure(s) performed. Additional findings include the colposcopic impression (including cervical images, if available), the pathological diagnosis, whether the woman was pregnant, the time to the next follow-up appointment, and whether the case was managed according to existing guidelines.

1.6.11 Laboratory audit for cervical screening based on HPV detection

Most cervical cancer screening programmes in higher-resource settings either have already replaced cytology with the detection of oncogenic HPV as the primary screening test or will do so in the near future. The principles of the audit of cancers in cytology-based screening may not be applicable to screening based on HPV testing, because the cervical specimens collected during a screening interval before a cancer diagnosis may not be available for retesting. The review should include the original result, valid run data either from the analyser archive viewer or downloaded and stored on laboratory digital data storage systems (where available), and external laboratory quality assessment reports. For patients who were diagnosed with an interval cervical cancer despite a positive HPV test result, the triage cytology slides (when cytology triage is used) and downstream management must be reviewed as described in this document. The experience of such audits within a screening programme based on HPV detection is still very limited.

For example, the central cervical screening laboratory in Stockholm, Sweden, identified 2033 cases of cervical cancer or CIN3 diagnosed through an organized screening programme in 2012–2017. These cases had had a previous cervical screening test (either an HPV test or liquid-based cytology [LBC]) within 3 years of cancer diagnosis [38]. The available LBC specimens taken before diagnosis of invasive cancer and a random selection of the specimens taken before diagnosis of CIN3 were selected for auditing (a total of 1054 specimens). The histopathology slides of patients who originally had an HPV-negative test result were reviewed to confirm the diagnosis. The LBC samples from patients who were either HPV-negative on screening or did not have an HPV test were tested or retested with a validated HPV test. The LBC samples that tested negative on the HPV test were subjected to a highly sensitive HPV genotyping test and whole-genome sequencing (if the genotyping was negative). The cytology slides were also reviewed.

The key observations were as follows:

- The validated HPV test had an average sensitivity of 97.0% to detect CIN3 or worse (CIN3+).
- Cytology had an average sensitivity of 91.6% to detect CIN3+.
- The proportion of CIN3+ cases that were HPV-positive but false-negative on reflex cytology was very low.
- When the few apparently HPV-negative samples were retested with the same method, about 17% showed HPV positivity, thus proving that no detection method is 100% reproducible or 100% accurate.
- Only 0.4% of the samples had no evidence of presence of HPV by any of the tests.

Screening programmes based on HPV detection often rely on a centralized laboratory where a quality control protocol similar to the one described above may be followed. A standard operating procedure is required for archiving the samples collected for HPV detection. Audit of cytology would be required if the test is used for triage, and the principles and procedures described earlier would need to be followed.

1.7 Next steps after analysis of data from an audit of cervical cancers

Outcomes of the audit must be discussed in a multidisciplinary forum so that factors that resulted in cancers not being prevented can be put in the context of other factors, such as the stage and pathology of the cancer and whether the cancer was detected through the screening programme (screen-detected cancers also include those detected during follow-up processes). Feedback of the audit results to the health professionals concerned requires appropriate planning. Communication of an interpretation error to an individual professional in a manner suggesting blame can be counterproductive and is not the objective of an audit of cancers. The performance of all staff needs to be monitored as part of routine programme quality assurance, and any issue that is identified through an audit should not be considered as reflecting an individual's skills or abilities. A contingency plan based on the audit outcomes must be prepared to improve the quality of services (e.g. reorientation training or improving coverage in vulnerable women) and should be included in the communication.

For the principles of disclosure of audit outcomes to the screening participants, please see Section 2.6.

CHAPTER 2.

Legal and ethical frameworks to safeguard the interests of cervical screening participants, health professionals, and programme managers associated with cervical screening and related services

2.1 Law and ethics in the context of cervical cancer screening

Many of the legal and ethical complexities in cervical cancer screening arise from the fact that the screening process is not diagnostic. Most legal and ethical frameworks in the health-care sphere were developed in the context of diagnosis and treatment. Screening tests do not naturally fit into this approach.

Furthermore, although patients will often understand and accept complications that occur in the investigation or treatment of a disease process, they are perhaps less forgiving of a complication that arises from an intervention when they are apparently healthy, especially because the interaction is initiated by a screening programme or a health professional.

Although cervical screening is not treatment or diagnosis, it is a medical intervention and an intervention that involves an interference with bodily integrity. Accordingly, core principles in health-care law and ethics must be upheld in screening, albeit in a different context. The fundamental rights of the individual screening participant must be protected, while ensuring the efficacy of the screening system as a whole.

Cancer screening is directed at achieving an aggregate benefit within a population, but it achieves that benefit by accepting that most of the population will benefit at the cost of harm to a small proportion. This presents an ethical challenge. Some people will undergo investigations and treatments for precancers that would never progress to cancer, or even for cancers that would not have become symptomatic in their lifetime, and thus the intervention turns out to have been unnecessary. The experience of undergoing the intervention may also have caused the person unnecessary psychological

trauma and inconvenience. Routine medical interventions usually occur in the presence of symptoms or signs of possible disease, which the patient–clinician team seek to understand, thus increasing the threshold for tolerance of any adverse impacts of what are seen as necessary investigations or treatments. Non-maleficence – the requirement not to do harm – is a fundamental principle of medical ethics. Cancer screening poses a challenge because the potential for harm is an anticipated outcome of the intervention in an apparently healthy person.

A separate challenge arises from the fact that it is not possible to achieve a zero error rate in screening. Cytology is highly subjective, and even in a quality-assured screening programme there are a significant number of false-negative test results. Even the highly objective laboratory-based HPV detection tests are not 100% sensitive [39]. Again, this distinguishes cervical cancer screening from routine medical interventions. Such errors that are inherent in all subjective tests pose ethical and legal questions in the context of screening, especially with regard to informed consent and legal redress. As discussed below, a major challenge is ensuring that those few cases where negligence has occurred are distinguished from the inevitable cases of non-negligence where an abnormality is not found but actually exists. The difference between clinical negligence and errors in screening is shown in Box 5.

Box 5. Clinical negligence versus errors in screening

In a clinical negligence claim, the true test for establishing negligence in diagnosis or treatment on the part of a medical practitioner is either:

- whether he or she has been proved to be guilty of such failure as no medical practitioner of equal specialist or general status and skill would be guilty of if acting with ordinary care

or

- whether, if he or she deviated from a general and approved practice, it is proved that the course he or she did take was one which no medical practitioner of like specialization and skill would have followed, had he or she been taking the ordinary care required from a person of his or her qualifications.

However, the clinical circumstances in which a slide is being read by a screening technician as part of a national screening programme are very different from the above-mentioned principles of negligence and causation, considering the different circumstances under which the initial examination of the slide is performed, compared with any later examination of the same slide under very different conditions and by people with a different and higher qualification and level of experience, especially when the reviewer knows that an abnormality has been missed.

This document is intended to be applicable globally and does not have a particular jurisdictional focus. Rather, it attempts to set out some general principles that may be of use across a range of legal systems. However, in some instances this document refers to pieces of legislation or legal rules that originate in a particular jurisdiction (e.g. the General Data Protection Regulation [**GDPR**] in the European Union) where these are of special relevance. It is important to recognize that the legal context and framework for cancer screening varies widely across jurisdictions, and it has been observed that the lack of a legal framework for screening causes problems in many regions or jurisdictions. Variation across legal systems will affect the implementation of some of the best practice principles discussed in this document. Best practice should be implemented to the extent possible within the domestic legal system.

The legal issues addressed in this document are primarily ones that arise between the individual screening participant and the screening system. The focus is not on broader regulatory issues with respect to cervical screening or oversight and quality assurance in the screening system. These issues engage various complex legal concerns that span a multiplicity of legal fields, such as regulatory law, administrative law, public procurement law, and constitutional law. However, the members of the TWGs consider that the best approach is to establish a bespoke legal framework for cervical screening through legislation. Such a framework would help countries to address the legal and ethical issues that arise, because it would enable effective standardization of practice across the system. In the absence of a specific legal framework for screening, it is difficult for countries to put in place legal mechanisms to achieve the aims discussed in this document.

2.2 Consent and information

The requirement that the participant provides informed consent (written or verbal, depending on the local regulations) is a fundamental principle in cervical screening. Although issues about consent also arise in the context of data protection or privacy, it must be recognized that informed consent is a stand-alone ethical principle in medical practice [40] and in clinical research [41]. In most jurisdictions, the principle of informed consent is also a legal requirement [42]. Informed consent in the healthcare context requires that the participant should be fully informed about the nature of the intervention, and the projected benefits and risks of that intervention, compared with alternative interventions, and with the benefits and risks of taking no action. A proper informed consent considers the particular characteristics of the person undergoing the intervention and their particular needs and preferences. Typically, the requirement to disclose information is more onerous in the context of elective medical interventions.

The general principles that govern informed consent must be adapted for implementation in the context of cervical screening, which, as discussed above, differs from routine medical treatment in several important respects. Participation in a screening programme is always voluntary. Screening is directed at population-wide outcomes, and a screening programme with poor uptake cannot deliver population-wide results. A well-organized screening programme requires a built-in mechanism to improve coverage (e.g. sending invitations to all screening-eligible women). Nonetheless, every individual participant has an absolute right to decline to participate in screening, whatever the reason. Thus, screening will always fall into the category of elective medical intervention. Where a woman is advised to undergo a cervical screening test on the basis of a specific clinical indication, this is properly considered a diagnostic test and is not technically part of the screening system. Accordingly, asymptomatic people have a right to decline to undergo a cervical screening test and should also be afforded the right to withdraw entirely from the screening programme into the future.

The members of the TWGs noted that it may not be advisable to allow people to opt out of the screening programme on a permanent basis. A person may in time wish to reconsider their decision, but if they are entirely outside the programme then they will never receive a reminder about future cervical screening tests and therefore may be denied the chance to opt back in, even if they have changed their mind. The members of the TWGs recommend that the managers of individual screening programmes should consider whether to allow people to opt out on a permanent basis. This issue is not applicable in a programme that does not have a system for inviting individual women.

Taking these factors into account, a screening-eligible woman who is invited to participate in cervical cancer 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 fact that a cervical screening test is not a diagnostic test.
- Explanation of the limitations of cervical cancer screening, including:
  - the subjective nature of cytology and its inevitable inherent error rate;
  - the relative rate of false-positive and false-negative test results in cytology, oncogenic 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; 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.

These basic information requirements should be supplemented as appropriate with information about data protection or privacy and audit, as discussed below.

Receiving comprehensive information about the benefits, risks, and limitations of screening will enable prospective participants to make an informed decision about whether to participate in the programme (see Chapter 3). Without good and timely information, they cannot make an informed and autonomous decision. A person who is offered screening should also be offered the opportunity to ask questions about undergoing a cervical screening test. This opportunity might be provided by

the individual health-care provider who will administer the test, who needs to be appropriately trained. The above-mentioned information should also be made available to the participant immediately before they undergo the screening test, for example via a leaflet provided by the health-care provider or, more properly, by the screening programme.

2.3 Legal liability for errors in cervical screening

There have been examples of people receiving compensation for errors in cervical cancer screening across many jurisdictions [43–45]. The nature of cervical screening presents challenges for legal liability for negligence or malpractice. Unlike routine medical interventions, cervical screening tests, especially cytology, have a well-recognized false-positive and false-negative rate. Both false-positive and false-negative results may cause risk, for which participants may seek redress. As noted in Section 1.4, one systematic review found the false-negative rate of cytology to be between 20% and 55% [18]. Clearly, if every participant with such a result were to be entitled to compensation, screening programmes would quickly become unsustainable. Uncontrolled and unjustified litigation poses a serious threat to current screening programmes and to the establishment of new screening programmes.

Reviews of individual interval cancer cases (which are known to trigger a claim for compensation) are associated with hindsight bias, which is known to play a significant role in the evaluation of an antecedent event and has been demonstrated in both medical and judicial settings. The knowledge that the participant went on to develop cancer can bias the reviewer's ability to pass judgement and heighten the reviewer's perception that the cancer was preventable. This might lead to an unjustified evaluation based disproportionately on a poor outcome, and not because care was poor. No matter how closely any review panel tries to reproduce the original screening conditions, the conditions of the review are different, and the fact that a review includes the records of a patient who is known to have a serious condition, such as cancer, will inevitably heighten a reviewer's vigilance and will increase reports of abnormality. Although it may be intuitively difficult to understand, finding discrepancies on review (e.g. up to 40% in cytology reviews) does not imply that the same diagnoses should have been made under routine screening programme conditions.

Of course, if negligence occurs at any of the screening or management stages, complete immunity cannot be afforded. This would conflict with the fundamental principles of most national legal systems. It would also fail to appreciate that claims for negligence are often a mechanism for vindication of the human rights of the person injured through medical error [46]. Instead, the members of the TWGs recommend that it should be possible to make a claim for negligence with respect to cervical screening, but that the standards applied by courts in assessing such claims should accommodate and reflect the reality of cervical cancer screening, including hindsight bias in an audit of cancers. Successful claims for negligence should concern errors that are not merely inevitable consequences of the limitations of the screening process.

The particular mechanism for achieving this end will vary depending on the type of legal system in question and the precise form of negligence proceedings. Some systems will require people to go to court to secure compensation, and some will not. All systems will involve some determination of whether the particular screening error was serious enough to be categorized as negligent and/or serious enough to entitle the participant to compensation. The members of the TWGs consider that the processes in place to make this determination should be designed to reflect the inherent limitations of cervical cancer screening. These include the following:

- Tests involved in cervical screening (cytology, visual inspection with acetic acid [VIA], colposcopy, histopathology, and immunohistochemistry) are subjective. 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 on different occasions (e.g. during routine practice versus during an audit) [47]. 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. If the slide was originally reported by a cytologist, the report should be judged by reference to the skill of the reasonably competent cytologist. The report should not be judged by reference to the skill of a differently skilled professional, such as a cytopathologist or histopathologist. If the expert witness works at a different qualification level than the original screener, this should be declared as part of the evidence.

- The reporting of the slide should be judged by reference to the information available to the screener at that time. The original screener would not have been aware that the participant would go on to develop cancer. The expert witness should also comment on the influence of hindsight bias on the preparation of their report.
- The reporting of the slide should be judged with reference to the conditions of the original screening. For example, if the original screener had to review the slide briefly alongside many other slides, this should be reflected in the standard to which the screener is held.
- Judging the cytology or histology slide for the purposes of assessing legal liability is a very different exercise to reviewing the reporting of a slide or performance in the context of audit. In an audit, hindsight is an actively helpful and important factor because it enables the audit to assess the original report in the context of what actually occurred for the participant. Legal processes for assessing negligence in slide reporting must be differentiated from audit review processes.

In audits of cytology slides from patients with interval cancers, abnormalities have been seen on up to 40% of the slides originally reported to be normal. Although most of these missed abnormalities will be a result of pitfalls of cytology, there are likely to be about 5% of cases where the screening is considered unsatisfactory because there are abnormalities present that most screeners would be expected to detect. This is scientifically unavoidable, because the proficiency test for screeners is that they are expected to detect 95% of high-grade changes when presented with a slide pack where the outcomes are known. Because of the complexities of negligence assessment, the judge may request a specific adviser to the court who can help to adjudicate over clinical evidence by the plaintiff and defence expert witnesses.

Concerns may arise with regard to the personal liability of individuals within a screening programme for errors. This should be governed in line with general rules of liability in a legal system. Operators of cervical screening programmes should take steps to ensure that individual health-care providers involved in screening are not at risk of individual legal liability unless special circumstances arise where personal liability is justified. This may be achieved by the provision of an indemnity by the operator of the screening programme in favour of individuals. Similarly, where screening activities are allocated between different organizations, legal liability may be governed by indemnities with regard to negligence claims.

2.4 Data protection and privacy in cervical cancer screening

Confidentiality is a founding principle of medical ethics [48]. In many jurisdictions, it has long been supplemented by legal protection of the patient's right to confidentiality. In the 20th century, the duty of medical confidentiality came to be characterized as a fundamental right of the patient [49]. Protection of confidentiality or privacy is essential in cervical screening. Information about a cervical screening test is highly sensitive. It may include the results of the test and information about the participant's cancer or precancer status. It 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. Notably, the ethical principle of medical confidentiality persists after the death of the patient. This is an important distinction from the position under data protection law.

2.4.1 Data protection law

In recent decades, many jurisdictions have enacted data protection law regimes, which usually supplement older forms of privacy or confidentiality law [50]. These regimes have important implications in the health-care context [51]. One of the most significant and far-reaching data protection regimes is contained in the European Union GDPR [52]. Because of the extensive influence of the GDPR in countries with organized cervical screening programmes, this document specifically considers some key issues in the application of the GDPR in the context of cervical cancer screening. However, it should be noted that this document does not provide formal legal advice. Individuals and organizations that are subject to the GDPR should seek specific legal advice tailored to their domestic context and, if necessary, should seek guidance from the national supervisory authority.

2.4.2 The GDPR and cervical screening programmes: general principles

The GDPR applies only to personal data, which is defined as "any information relating to an identified or identifiable natural person" (Article 4(1)). Information that is anonymous is not personal data. However, information is only anonymous if it is irreversibly anonymized. If it is possible – albeit difficult – to trace the data back to an identifiable person, the data will be considered pseudonymized data and will be subject to the GDPR. The definition of natural persons does not include deceased persons. Operators of screening programmes should be very clear

about whether the various categories of data that they are dealing with are anonymous or not.

The GDPR regulates all "processing" of personal data (Article 4(2)). This is defined as "any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction". In effect, all actions that may be taken with regard to data – including storage of that data – are governed by the GDPR.

The GDPR attaches an enhanced level of protection to "special categories of personal data", and one of those is health data. Accordingly, almost all data processed in the context of screening will constitute special category data.

The GDPR establishes fundamental principles relating to the processing of data (Article 5). The first of those is that data must be processed lawfully, fairly, and in a transparent manner. This means that there must be a clear legal basis for all processing of personal data. Thus, operators of screening programmes must clearly identify the legal basis for the processing of data. The GDPR provides for several different legal bases for processing (Article 6(1)), and the processing of health data must also satisfy one of the exceptional bases provided for in Article 9(2).

The provision of consent is one of the potential legal bases for processing of data [53]. However, it must be noted that Article 9(2) states that for the processing of special category data, only explicit consent (as opposed to implied or assumed consent) constitutes an adequate legal basis. Furthermore, the nature and quality of consent are strictly controlled by the GDPR. For consent to be valid under the GDPR, it must adhere to the following requirements (Article 7):

- Consent must be specific and granular.
- If the consent is provided alongside consent for other matters or purposes, the consent for processing of data must be clearly delineated.
- The request for consent must be presented in an intelligible and easily accessible form.
- The data subject must have a genuinely free choice with respect to giving consent. Where consent is sought for the provision of a service, it is not permissible to make that service conditional on the provision of consent to something that is not necessary for the provision of that service.

These principles raise some issues of particular note in the context of cervical screening and audit:

- The request for consent must specifically describe how the participant's data will be processed in the context of cervical screening, including an audit of cancers, if applicable.
- Consent for the processing of data related to undergoing cervical screening must be distinguished from consent for the processing of data for other purposes, such as audit.
- It is not necessary to include a woman's personal data in an audit. Therefore, a woman who denies consent to include her data in an audit process must have all her personal data removed irreversibly before her slide is included in the audit.
- It would not be permissible to make participation in screening conditional on the participant consenting to the processing of data for other purposes, such as audit.

It is essential to appreciate that 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. The members of the TWGs recommend that, 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 (Article 7(3)).

Even where consent is not relied upon as the basis for data processing, the data controller should ensure that privacy notices are prominently displayed that inform the screening participants about how their data will be processed.

Other potential legal bases under Article 6(1) for processing data in cervical screening are the following:

- Article 6(1)(c) – processing is necessary for compliance with a legal obligation to which the controller is subject; and
- Article 6(1)(e) – processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller.

Article 6 (1)(c) will apply only if there is a legal obligation to process the data within the domestic legal system. Article 9(2) contains several legal bases that may apply as an alternative to relying on consent. These include where processing is necessary for substantial reasons of public interest in the area of public health (Article 9(1)(2)(i)). However, many of these alternative bases require that the processing should be carried out on the basis of European Union or domestic law, or pursuant to a contact with a health-care professional, and therefore they cannot be relied upon in the absence of that. Furthermore, some of these legal bases operate only if there are "suitable and specific safeguards" in

place to safeguard the fundamental rights and interests of data subjects.

The GDPR also provides for several ongoing rights on the part of the data subject that are relevant to the context of cervical screening. Data subjects have a right of access to their data (Article 15), a right to rectification (Article 16), a right to erasure (Article 17, often known as the "right to be forgotten"), a right to restriction of processing (Article 18), and a right to data portability (Article 20). Mechanisms to facilitate the exercise of these rights, where applicable, should be built into the screening programme.

2.5 Audit of cervical cancers – ethics and data protection issues

2.5.1 Ethical obligations and audit

As discussed in Section 1.1, audit of any health-care service is considered by WHO to be a critical function of an organization and to provide objective assurance on its integrity and credibility. 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. Retrospective audit of invasive cancer is part of this quality improvement process and includes audits in many other programmatic aspects, such as the detection rates of low-grade and high-grade precancers, positive predictive values of screening tests and colposcopy, laboratory turnaround times, and waiting times to receive test results and colposcopy appointments.

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 the information that their screening test missed a probable or imminent cancer may be painful to an individual woman.

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 slides and data from a participant may be included in an audit even if the participant denies consent 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.

2.5.2 The GDPR and audit

Undertaking a clinical audit raises a range of additional issues under the GDPR. Overall, all the general principles discussed earlier will apply. Operators of a screening programme must first consider whether the data involved in the audit are identifiable. If so, the data are subject to the GDPR. Audit of clinical data is by definition the processing of data. It must therefore be justified by a legal basis. It is possible to rely on consent as a legal basis for the processing of data for clinical audit. However, the right to consent can be withdrawn at any time. This can constitute a logistic challenge. Furthermore, participants are entitled to provide consent to undergo the screening test but to refuse consent for the audit. If consent is the only available legal basis, then the audit would not include the data of these participants and would therefore not be able to provide a full clinical picture of the screening programme. For this reason, it is sometimes recommended that consent is not used as the legal basis for clinical audit [54].

Furthermore, screening programmes that are currently operational may hold data for the purposes of audit but may not have obtained consent for the use of that data for audit. Thus, they are precluded from relying on consent unless they contact each individual data subject and obtain fresh consent.

A potential alternative legal basis for audit is found in Article 9(2)(i), which governs processing in the public interest for reasons of public health, including to ensure "high standards of quality and safety of health care". Article 9(2)(h) is potentially also applicable, because it addresses "the provision of health or social care or treatment or the management of health or social care systems". Both bases require suitable and specific safeguards. Article 9(2)(i) requires a basis in Member State or European Union law, whereas Article 9(2)(h) requires either a basis in Member State or European Union law or a contract with a health-care professional.

It is also of relevance to note that regardless of which legal basis applies, data subjects have a right to object to processing of their data, subject to certain limited exceptions (Article 21).

Those designing audit systems may wonder whether pseudonymization of data within an audit might relieve the data controller of the obligation to ensure the rights of data subjects under Articles 15–20, particularly the right of data subjects to access their data. As a general principle, pseudonymization does not mean

that the rights of the data subject are compromised. Rather, the GDPR conceives of pseudonymization primarily as a mechanism to safeguard data from third-party risks [55]. Therefore, it has to be assumed that even pseudonymized data will be subject to the ongoing rights of the data subject, including the right of access. Article 11 provides for a limited exception to this principle. The rights of data subjects under Articles 15–20 will not apply where the controller can demonstrate that it cannot identify the data subject by reference to the data that it holds. However, if the data subject can provide additional information that enables the subject to be identified, then the rights under Article 15–20 will apply as normal.

2.6 Disclosure of audit results

It is important to distinguish between population-based programmatic audit, which is performed as a quality assurance exercise, and an individual case review, which is performed to help a single individual understand their particular case history.

A question that has arisen in many screening programmes is whether a participant should be informed if an audit detects a discrepancy between an original test result and a test result on review. Typically, this situation will arise where the original result was negative but the review detected an abnormality. As discussed earlier, the review result is usually arrived at with the benefit of hindsight – the knowledge that the participant went on to develop cancer. It is important to prepare women in advance about the likely results of an individual case review and to explain that a finding of discordance is not proof of poor performance of the programme.

There is a wide divergence in practice across screening programmes with respect to the disclosure of audit results [56]. The members of the TWGs also noted that the inconsistent approach to disclosure of audit discrepancies proved very problematic in Ireland and generated a great deal of public criticism of the cervical screening programme, with some people characterizing the non-disclosure as a "cover-up" [57]. The independent report into the CervicalCheck Screening Programme was also extremely critical of failures to inform women of the outcome of audits and was adamant in recommending that open disclosure and a duty of candour must be enshrined within the system in the future [58]. Despite this diversity of practices, the members of the TWGs believe that 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.

The benefits of anonymization of a programmatic audit (hence, not being able to disclose results) are that:

- it protects individual privacy;
- it enables health information to be shared when it is not mandated or practical to obtain consent from each participant;
- operators do not need to rely on consent as the primary mechanism, which may lead to bias in audit findings; and
- it will gain support from health-care providers, who will be keen to get involved in programmatic audit.

The members of the TWGs acknowledge that some screening participants who were diagnosed with an interval cancer will 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. At the time when consent is obtained for an individual case review, participants should be asked whether they wish to be informed of a discrepancy if one is detected in the future. If they say they do not wish to be informed, they should not be contacted in the future for this purpose. If they say they do wish to be informed, they should be contacted if a discrepancy is detected. If a discrepancy is detected, the participant should be informed of the simple fact of a discrepancy and asked whether they wish to have more information about it. If they indicate that they do wish to be further informed, further information should be provided. This information should be delivered by a trained senior clinician who can answer questions about all aspects of the screening process. Support should be made available to patients before, during, and after meetings where discordant results are discussed, because this situation can be traumatic for patients.

In addition to the ethical justifications for open disclosure of findings of an individual case review, it should be noted that many participants will have a legal right of access to audit and review results pursuant to the GDPR or analogous legislation. It is preferable to actively disclose this information in a sensitive and constructive manner, rather than for participants to access it via a data subject access request.

2.7 Research and the GDPR

Many screening programmes will generate data that can be a useful resource for further research. Research is entirely distinct from audit and raises different issues under the GDPR. For example, it is more likely that data used for research will be entirely anonymized. If so, they are outside the scope of the GDPR. If not, the GDPR applies. Importantly, the GDPR provides a specific legal basis for the processing of data for research purposes (Article 9(2)(j)). This applies only where processing is based on Member State or European Union law and there are suitable and specific safeguards in place.

CHAPTER 3.

Effective and transparent communication with target populations and other stakeholders

3.1 Challenges in communication in the context 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 [35]. This means that there is a moral imperative to provide complete information that enables people to make the right decision for themselves. This is informed decision-making or personal informed choice.

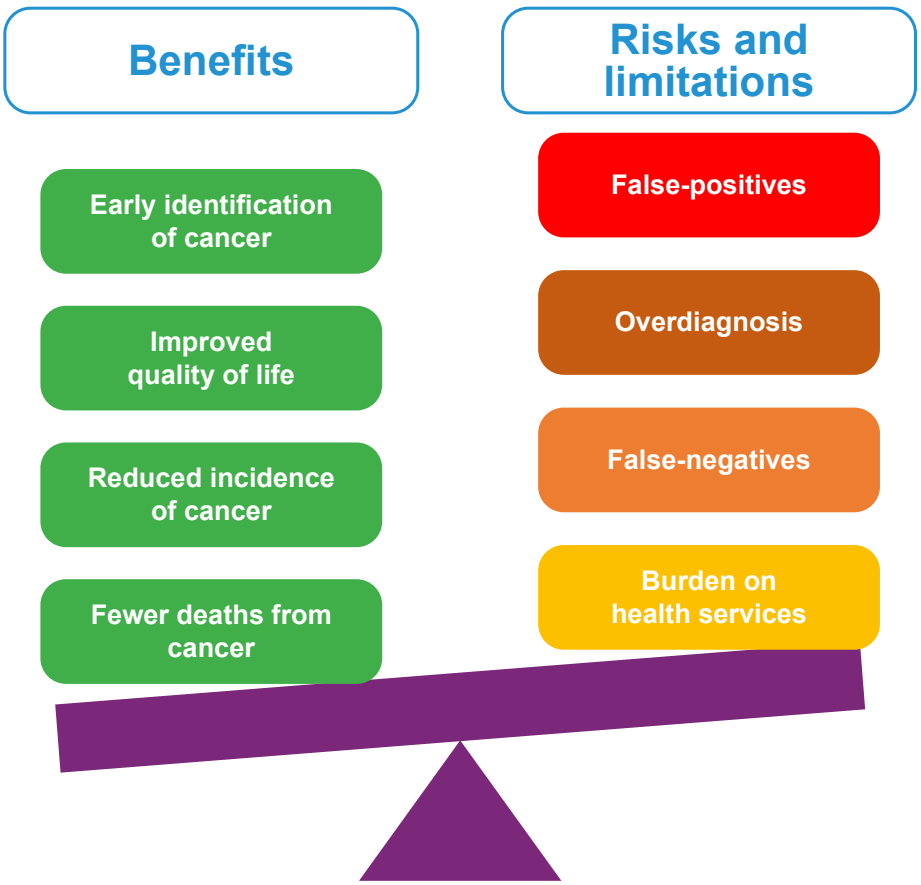
Informed decision-making encompasses a process that enables an individual to make a health-care decision for themselves after having learned about the intervention and its likely consequences and having considered their preferences. A communication strategy that is designed to describe the limitations and possible risks of screening as well as the benefits in a balanced and transparent manner can promote informed decision-making. The right balance in communication is essential to avoid raising expectations too high (by overemphasizing the benefits) or demotivating women from undergoing screening (by overemphasizing the risks). The content (i.e. what to communicate) and the methodologies (i.e. how to communicate) of communication about cancer screening should be context-specific and are greatly influenced by the knowledge, attitudes, culture, and perceptions of the target population.

The health messages, such as the benefits, risks, and limitations of screening (Fig. 4), and the communication techniques need to be tailored to the audience and the context. It should be borne in mind that the communication skills of health professionals are highly variable.

There are two main ways to conduct screening:

- via a whole-population approach, which requires invitations that are received as letters or digital communications or through community

Fig. 4. Benefits, risks, and limitations of screening. © IARC.



health workers (usually in limited-resource settings); or

- opportunistically, whereby an individual attends for a health-care consultation for another issue and is offered a screening test as part of that conversation.

Clearly, the one-to-one discussion in opportunistic screening will be different from that in a whole-population approach. Uptake of opportunistic screening is often facilitated by mass media campaigns that highlight the benefits of screening. Irrespective of the context, health messages in cervical screening need to present the benefits, risks, and limitations of cervical screening in a balanced way based on evidence. Communicating with honesty about how much an individual stands to benefit and including a description of the potential risks in a manner that is appropriate to the knowledge, beliefs, and attitudes of the target population helps to retain trust and makes the programme more effective in the long run. However, this is not an easy task.

Many aspects of screening are not intuitive or easy to discuss, for example population and individual risk, false-positive and false-negative test results, and the benefit versus risk of treatment of precancers. Therefore, programmes need to keep critical stakeholders and the relevant workforce up to date so that they can understand the benefits, risks, and limitations of screening (Box 6). This will enable them to communicate more confidently with the public, with those who are offered screening, with the media, with legal professionals, and with the government.

Box 6. Benefits, risks, and limitations of cervical screening

Benefits of cervical screening

- Studies nested in population-based cervical screening programmes in Europe reported a cervical cancer **mortality reduction** of 41% to 92% for women who attended screening compared with non-attenders [59].
- Women in whom cervical precancers are detected and treated appropriately are **saved from having a cancer** diagnosis, thus avoiding cancer treatment and associated side-effects and saving the direct and indirect costs likely to be incurred for cancer treatment.
- Women in whom cancer is **detected at an early stage** undergo less-aggressive treatment (which is also cost-saving), survive longer, and have improved quality of life.
- Cervical screening is a **highly cost-effective** public health strategy. It has been estimated that for every US$ 1 invested in a cervical screening programme at least US$ 3.20 is returned to the economy [60].

Risks and limitations of cervical screening

- The result of a screening test (or downstream investigations) may be falsely negative in some women. A **false-negative** result provides false reassurance, which may lead to late detection of cancer and resultant consequences *(limitation)*.
- Every screening test may have results that are **falsely positive**, leading to possible adverse physical impacts (because of unnecessary investigations and interventions), psychological trauma, and inconvenience *(risk)*.
- For some women, undergoing screening may be an **unpleasant emotional experience**, because of fear and anxiety associated with undergoing the test and apprehension about being diagnosed with cancer, being stigmatized, or losing fertility *(risk)*.
- A screening programme that is implemented inefficiently will not have the desired benefit and will **drain healthcare resources** *(societal risk)*.

3.2 Communications targeting women eligible for cervical screening – underlying principles of designing communication messages and strategies

Designing effective communication messages (i.e. what to communicate) and strategies (i.e. how to communicate) requires a thorough understanding of the target audience's perception of cervical screening. This can vary widely, from a belief that the test is essential to a total denial of its value in saving lives. Other factors also influence an individual's decision-making process.

3.2.1 Women's perceptions of cervical screening

Studies have evaluated women's knowledge about and attitudes to cervical screening. Although the results are highly heterogeneous, they indicate that a negative attitude to screening is strongly linked with a low level of knowledge about cervical cancer or the screening procedures. A pooled estimate from eight studies conducted in different countries in Africa reported that 57% of women living with HIV did not have any knowledge of cervical cancer screening and that only 38% had a positive attitude to cervical cancer screening [61]. A recent systematic review of studies on attitudes and perceptions of women to breast cancer screening reported a strong association between negative perceptions of screening and the following factors: low literacy level, negative attitude to a cancer diagnosis (i.e. cancer will invariably be fatal, will affect the relationship with their partner, is shameful to have), and denial (i.e. "normal women cannot have cancer") [62]. Interestingly, "partners having a good knowledge of breast cancer" has been shown to be associated with a positive attitude to breast cancer screening in women [63]. The same factors are likely to influence perceptions of cervical screening.

Studies also show that women and men who undergo screening in higher-resource settings and where screening services are easily available generally have a positive attitude to screening. However, the participants and the clinicians often tend to overestimate the benefits of screening, believing that more is better when it comes to medical tests. Two large surveys, one in Great Britain and one in the USA, indicated that women and men were so committed to frequent screening that 58% of women would overrule a physician who suggested less-frequent cervical screening and 77%

of men would continue with prostate screening even if their physician recommended against it [64, 65]. This strong motivation to undergo frequent screening may be explained by an eagerness to be in control of their own health, a feeling of social obligation to follow peer groups, or a need for reassurance of protection against cancer. These attitudes may be based on unrealistic expectations arising from overestimation of the benefits of screening and underestimation of the risks. Such perceptions of the infallibility of the cervical screening process in preventing cervical cancer, which may be propagated through miscommunication, may lead to discontent in those screening participants who are subsequently diagnosed with cancer. This results in a loss of trust in the programme [56]. It is rarely explained to the patients in whom cervical precancer was detected through screening and who underwent treatment that they may still develop cancer, sometimes as long as 20 years after treatment [66].

3.2.2 Factors that influence decision-making by individuals

An individual woman's decision about whether to undergo screening is influenced by two major considerations: the perceived relevance of screening to the woman herself, and the perceived value of screening. A systematic review that synthesized the qualitative literature on women's perceptions and experiences of cervical screening included 39 studies, mainly in Australia, the Republic of Korea, Sweden, and the United Kingdom [67]. A substantial proportion of the studies involved immigrants, socioeconomically deprived populations, and other vulnerable populations. The review observed that the perceived **relevance of cervical screening to an individual woman** ("Do I need the test?") appeared to fluctuate during a person's lifetime and was influenced largely by four factors: beliefs related to the cause of cancer, life stage, current health status, and family history. Women perceived their risk of cervical cancer to be low (and hence that screening was not required) if they were in a stable marriage or belonged to certain ethnic and religious groups. Some women reported feeling more vulnerable during menopause; others reported that being postmenopausal meant that screening was no longer important for them. For many women, a lack of gynaecological symptoms was a reason for non-attendance. Family history was often identified as a risk factor for cervical cancer, and women interpreted the absence of a family history as an indication that screening was less important for them [67].

The same systematic review also highlighted the finding that many women tend to question the **value of cervical screening** ("What is the point of having the test?"). Some women believed that screening was not important, either because they felt that they would know if they were ill or because they felt that if there was something wrong, it would resolve by itself. Some described a lack of trust in the test results, potentially based on an experience of false-positive results in earlier screening rounds. Other women expressed a general cynicism about the motives of cervical screening programmes; some suggested that they were being "used to fulfil quotas" [67]. Other studies have reported **fatalistic attitudes** to cancer ("I will die of the disease in any case") and screening being of low priority compared with other health issues as common reasons for women not finding any value in cervical screening, especially in low- and middle-income countries [68].

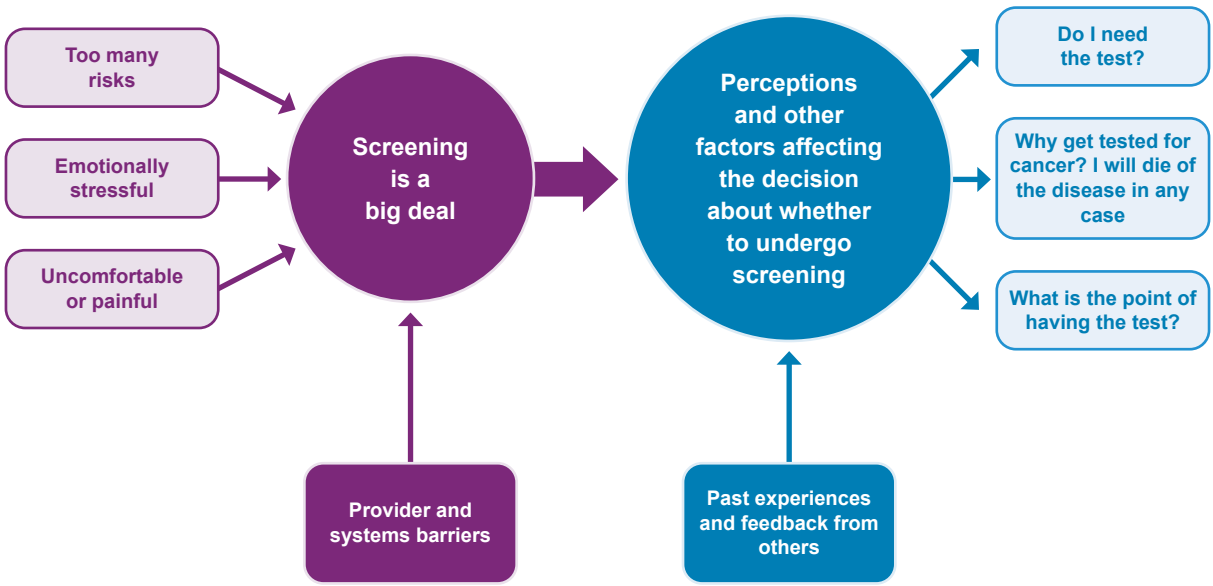
In the same systematic review, women who believed that screening had value said that it enabled cancer to be detected early, which was beneficial, and that they appreciated the reassurance provided by a negative screening result. However, it was observed that some of these women did not understand the limitations of screening; some felt that a negative result provided a "certificate of health", indicating that there was "nothing untoward happening" and that they were "free of cancer". Many women had misperceptions about the purpose of cervical screening; some saw it as a general cancer test, a test for genital infections, or a reproductive check-up. This highlights the knowledge gaps that may exist even in well-organized screening programmes [67].

Decision-making by an individual woman about screening participation is also heavily influenced by the barriers to accessing screening services that she has to face, at an individual level (e.g. lack of transportation, long distance from home to health-care facility, absence of family support), at the provider level (e.g. provider too busy, poor communication skills), and at the system level (e.g. poor quality of services, long waiting times). These barriers also influence the woman's perception of screening (Fig. 5).

3.2.3 Designing communication strategies

From the earlier review of perceptions of screening, the members of the TWGs noted that the target population for screening is a highly heterogeneous group in any country. Thus, the approaches to screening and downstream management are variable across settings, and so are the access barriers encountered by potential participants. These differences need to be considered when developing messages and designing communication strategies to promote uptake of cervical screening.

Fig. 5. Women's experiences of cervical screening and barriers to participation. Source: [67]. Adapted from Chorley et al. (2017). © 2016 Chorley AJ et al. Psycho-Oncology. Published by John Wiley & Sons Ltd.



To enable people to make individual decisions about participation in screening, both the advantages and the disadvantages of screening need to be communicated. This requires a range of approaches. Such approaches need to take into consideration the sociodemographic profile of the target population (especially the average literacy level), cultural issues and the local ethos, levels of trust between the service provider and the service users, levels of organization of cancer screening, the medium being used for such communication, and whether communication is one-to-one or population-based (one-to-many).

The use of a stage-based behaviour change model such as the precaution adoption process model (PAPM) has been found to be of value when considering ways to support informed decision-making about cervical screening. The PAPM can be used to develop targeted interventions for behaviour change communication in cervical screening; it categorizes people into the following stages (Fig. 6):

1. those who are unaware of cervical screening *(unaware)*;
2. those who have learned about cervical cancer and screening but have not considered whether they need to do anything about it *(unengaged)*;
3. those who have learned about cervical cancer and screening but have not decided to act because they do not find any relevance *(undecided)*; and
4. those who have decided to undergo cervical screening *(decided to act)*.

For individuals to progress from one PAPM stage to the next, they need to take deliberate actions. Such actions are influenced by the person's health beliefs, such as perceived susceptibility, severity, barriers, benefits, and self-efficacy. The primary aim of a communication strategy is to inform a person's health beliefs appropriately and to help them to progress through the stages.

The local context plays a substantial role in determining the PAPM stage at which most individuals are. For example, in low- and middle-income countries with scarce availability of screening, most women will be at stage 1 (unaware) and a few will be at stage 2 (unengaged). The communication programmes and materials designed to change informed behaviour related to cervical screening need to consider this qualitative difference in eligible women. It is also important to consider this during one-to-one communications between a potential participant and a health professional.

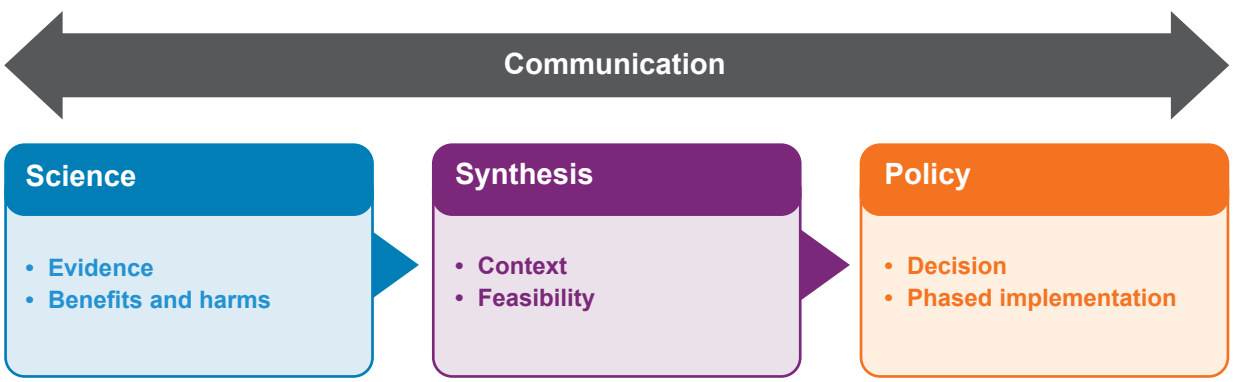
Fig. 6. The stage-based precaution adoption process model (PAPM) for cervical screening uptake. © IARC.

The members of the TWGs noted other evidence relating to participants' perspectives about the uptake of, follow-up of, and adherence to the cervical screening programme that are relevant in the design of communication messages and strategies. These are summarized as follows:

- When communicating the risks and limitations, it may be useful to inform people that the government or health authorities have carefully evaluated the benefits and risks and have decided to offer screening to all eligible women because the benefits outweigh the risks.
- Communication should emphasize the value of any changes in testing methods (this is highly relevant for programmes adopting screening based on HPV detection), citing appropriate recommendations from recognized international or national expert groups, because people may view changes in practice as "less care" or cost-cutting measures [69].
- The communication strategy needs to consider the competing priorities of the participants (e.g. parental duties or occupation) and existing barriers (e.g. transportation to the health-care facility and opportunity costs, including time missed from work) [70].
- Use of a contact point that women are more familiar with (e.g. community health workers) improves acceptance of the messages [71].
- In countries where different languages are spoken in different regions, use of the screening participant's language is important for a culturally competent encounter. Lack of understanding of the importance of language and sociocultural needs has been shown to result in dissatisfaction and inadequate participation [72].

Communication materials and strategies should be designed based on the evidence of the benefits and risks and with a clear objective (e.g. to move people across the PAPM stages). The final product and strategies will be heavily influenced by the local context in terms of the target population and the feasibility and organization of the screening programme. The tools and strategies will need to be fine-tuned based on feedback obtained through pilot testing in the target population before they are fully implemented (Fig. 7).

Fig. 7. The context of communication. © IARC.



3.3 Developing screening information materials and communication strategies

3.3.1 Key principles and strategies

The members of the TWGs reviewed evidence from Al-Khudairy et al. [73], who used mixed-methods research involving systematic rapid evidence synthesis, primary research, and a consensus principles workshop with international representation to prepare a set of principles to support the development of screening information materials for breast cancer and fetal anomaly screening for Public Health England. The members of the TWGs suggest the following strategic guidance for the development of cervical screening information materials.

Screening information materials need 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 outweigh their risks and limitations;
- include clear statements on the benefits, risks, and limitations* of screening, supplemented by visual aids (infographics); and
- provide a clear statement on the estimates of probabilities of the condition and potential positive and negative outcomes from screening using prevalence estimates, event rates, or treatment success rates (for precancers).

* Benefits include detection of disease at a premalignant stage that requires simple treatment, prevention of cancer and cancer death, greater chances of survival from the cancer (if the disease has already occurred), less-invasive treatment because of earlier diagnosis of cancer, and improved knowledge. Risks include anxiety, false-positive test results, and overtreatment, and the consequences that flow from these. False-negative test results are a limitation of screening.

When developing screening information materials:

- use easy-to-read and simple language, supported by visual aids to improve 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.

A multipronged delivery strategy will be capable of:

- using digital media and online tools, depending on the local setting, to make information widely accessible and interactive;
- ensuring the availability of a printed version for people who are unable to access online materials;
- delivering information to those 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 [74];
- 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.

When communicating with individuals about their informed choice, it is also important to highlight that the health authorities have decided to implement the screening programme after careful evaluation of the benefits and risks and that this exercise has been done in consultation with all relevant stakeholders. In many higher-resource settings, communication about cancer screening involves sending a letter of invitation from the health authority (which may be seen as a recommendation in itself) and a leaflet that provides more information about benefits and risks. The content of the leaflet should encourage people to assess the offer of screening, rather than simply encourage them to undergo screening, and should make it clear that they can choose to decline the offer.

The development of information material and the development of communication strategies are highly context-specific and will vary with the stakeholders' expectations. The methodology used in England to develop new information about breast cancer screening provides a useful example (Box 7) [75].

3.3.2 Communicating risks and limitations

There is no reference standard on how to communicate risks and limitations effectively. The programmes should use evidence and pilot test the information to assess the comprehensibility and acceptability of the information by the target audience. Studies have shown that even clinicians find it difficult to interpret information about numerical risk [76]. Information materials need to take this barrier into account and should be consistent with the following guidance:

1. Use natural frequencies (absolute numbers) and absolute risk reductions instead of conditional

Box 7. Steps used in England to develop new information about breast cancer screening (2014) [75]

1. Form an advisory committee

An advisory committee was constituted to support the editorial team. The committee included academic and professional experts in screening, experts in informed choice and public communications, third-sector stakeholders, and representative members of the public eligible for screening.

2. Obtain initial input from women through a citizens' jury

A sample of the target population for breast cancer screening with adequate representation from various occupational and ethnic groups deliberated together about how the benefits and risks should be communicated. They were supported by the experts and the service providers. The citizens' jury made a set of recommendations supported by appropriate rationale. One of the key recommendations was that risks should be described using the word "risks" rather than "harms".

3. Obtain input from professional experts in screening, public engagement, informed choice, and communicating risk

The experts developed the draft information leaflet after debating about the scientific precision and adequacy of the content, the mode of presentation, the typography and imagery included, and the general appearance.

4. Obtain further input from women on the draft information, through cognitive testing

Drafts of the new breast cancer screening invitation letter and information leaflet were tested in women in the age group offered breast screening to check how well these were understood and whether they would be useful in helping the women to make a choice. This involved two rounds of one-to-one, face-to-face cognitive interviews with 20 women, half of whom had accepted the offer of screening and half of whom had not.

5. Integrate the input from the women and the professional experts

The content was finalized, ensuring that the messages were simple, that appropriate images were included, and that the views of the women who participated in the cognitive tests were respected. A link to an online source of information was included in the leaflet to enable interested women to receive further information.

probabilities and relative risk reductions [77, 78].

2. Avoid presenting estimates of risk reduction in relative terms (e.g. "screening reduces the risk of developing cervical cancer by 75%") and using verbal qualifiers without numbers (e.g. "women who have abnormal cells removed from the cervix are slightly more likely to have their baby early") [78].
3. Use a common denominator to support the use of natural frequencies. Because readers tend to focus on the size of the numerator without considering the denominator, the denominators used for the presentation of risks and the presentation of benefits should be the same [79].
4. Use visual presentations, such as pictographs or diagrams, to help people understand the information about numerical risk [77, 80]. This will be especially useful for people with low literacy levels and low numeracy skills. However, bear in mind that not everyone intuitively understands visual presentation, and thus these images should be pilot tested for comprehension [80].

3.3.3 How much information on benefits, risks, and limitations should be included?

When communicating the benefits, risks, and limitations of screening, it is always challenging to achieve the right balance of adequate information with appropriate messaging without overloading the contents. In a study of subgroups of Dutch women eligible for cervical screening, van der Meij et al. ranked the benefits, risks, and limitations according to how important the women considered them to be for decision-making about participation in screening

based on HPV detection [80]. The results are summarized in Table 1. These benefits and risks need to be appropriately highlighted in the screening information materials.

3.3.4 Framing of messages

Traditionally, public communications about cancer screening have the primary aim of maximizing the number of people who undergo screening and the number who complete the downstream management. Often, persuasive techniques are used, which largely reflect the positive views of screening held by clinicians, academicians, public health organizations, and patient advocacy groups. These persuasive communication strategies usually highlight the positive aspects of screening and downplay the risks and limitations. Framing of messages may have a strong influence on women's understanding of the implications of screening.

The persuasive communication approach usually induces a feeling of vulnerability to the cancer and then offers hope by framing screening as a simple method of protection, emphasizing the benefits and downplaying the risks [81]. Such communications have successfully created positive community views of screening and have propagated the normative expectations that screening is the right thing to do. These positive community views have led to high participation in cancer screening, especially in countries that have been able to deliver quality-assured cancer screening services. However, transparent communication about the possible risks, rather than framing that promotes screening as a foolproof intervention for cervical cancer prevention, may reduce discontent in women who are affected by the limitations of screening (e.g. diagnosed with an interval cancer). Acknowledging that screening has risks and describing the benefit-to-risk balance through a pragmatic communication strategy is likely to build long-lasting trust in the programme and ensure autonomy in decision-making by every potential screening participant.

The information materials and decision-making aids for the screening participants need to consider the framing effect when communicating risks (e.g. whether to explain that only 2 out of every 100 women who undergo a LLETZ procedure may have serious bleeding or that 98 out of every 100 women treated by the LLETZ procedure will have no serious complications) to assist with personal informed choice based on reliable information.

Table 1. Ranking of benefits, risks, and limitations according to their importance in women's decision-making about participation in cervical screening based on HPV testing

Benefits, risks, and limitations	Ranking
Benefits	
Reduced risk of developing cervical cancer	1
Reduced risk of dying from cervical cancer	2
Knowing where you stand and being reassured	3
Initial test is free	5
Risks and limitations	
Abnormal result, but turns out later that nothing was wrong	4
Follow-up test is not free	5
Falsely reassuring result	6
Unnecessary treatment	7
Having a positive HPV test result can lead to questions and worry	8
Having a smear taken can be unpleasant	9

Source: [80]. Adapted from van der Meij et al. (2019). © 2019 van der Meij et al.

An example of framing a message about the benefits and risks of screening in simple, straightforward language is given in Box 8 [82].

Box 8. Independent UK Panel on Breast Cancer Screening estimates

Among **10 000** women invited to screening in the United Kingdom from age 50 years for 20 years, about **681** breast cancers will be detected and **43** deaths from breast cancer will be prevented. Prevention of one death from breast cancer will be associated with diagnosis of approximately three patients with breast cancer that would not have caused any symptoms in the woman's lifetime (overdiagnosis), and these women would be treated unnecessarily [82].

3.4 Stakeholder engagement and communication with stakeholders

Stakeholders are actors (people or organizations) with a vested interest in the health policy and/or programme that is being promoted. Effective communication with stakeholders is essential for the success and sustainability of any health programme, and cervical screening is no exception [83]. Stakeholders can be either primary or secondary. **Primary stakeholders** are people or organizations whose continuing participation in the policy or programme is essential to its success. For example, in cervical screening, women in the target age group are primary stakeholders. **Secondary stakeholders** are people or organizations who have some influence on the policy or programme or are somewhat affected by it. However, their engagement is not essential for the policy or programme to succeed or the issue to be addressed. For example, in cervical cancer screening, public health researchers might be secondary stakeholders.

Effective engagement with stakeholders (both primary and secondary) is an indicator of good governance and increases accountability to the clients of a screening programme. It also enables the programme managers to assess support for and opposition to a policy, gives the programme visibility and legitimacy, empowers the stakeholders, increases collaboration, improves use of resources, and ensures the sustainability of the programme.

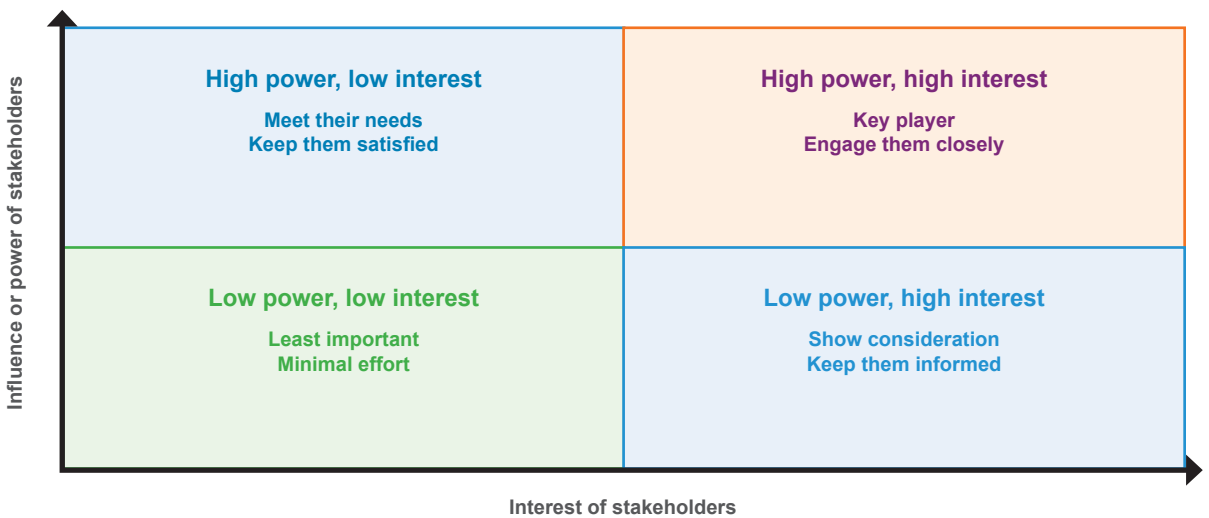
3.4.1 Identifying the stakeholders

For a cervical cancer screening programme, stakeholders (other than the target population and their partners) include the programme managers, service providers, professional bodies, patients, policy-makers from the ministries of health and finance, other politicians, health insurance agencies, other funding agencies, civil society organizations and patient groups, journalists and other media representatives, and health-care industry representatives.

Screening policy planners need to conduct a stakeholder mapping and analysis to ensure that the correct individuals and organizations are listed. This mapping exercise should consider factors such as stakeholders' knowledge and experience, their levels of interest and influence, and their power to facilitate effective engagement. It is also helpful to define the roles that a particular stakeholder will play in the screening programme and the resources that the stakeholder will contribute (expertise, information, knowledge, funding, alliances, and/or advocacy). The policy of engagement with a particular stakeholder will depend on their position in the influence versus interest matrix (Fig. 8):

- **High power, low interest group:** Provide sufficient and accurate information to ensure that they are kept up to date but are not overwhelmed with data.
- **Low power, high interest group:** Keep them adequately informed, and gather feedback to ensure that no major issues arise. The greatest communication efforts should be made during special situations (e.g. a policy launch).
- **Low power, low interest group:** Provide information only when relevant. Monitor whether this group moves to another profile.
- **High power, high interest group:** This group requires full engagement and the highest efforts to satisfy them.

Fig. 8. Stakeholder influence versus interest matrix.



3.4.2 Engaging with the stakeholders

Stakeholder engagement aims to raise awareness of the programme and to accelerate action by stakeholders by:

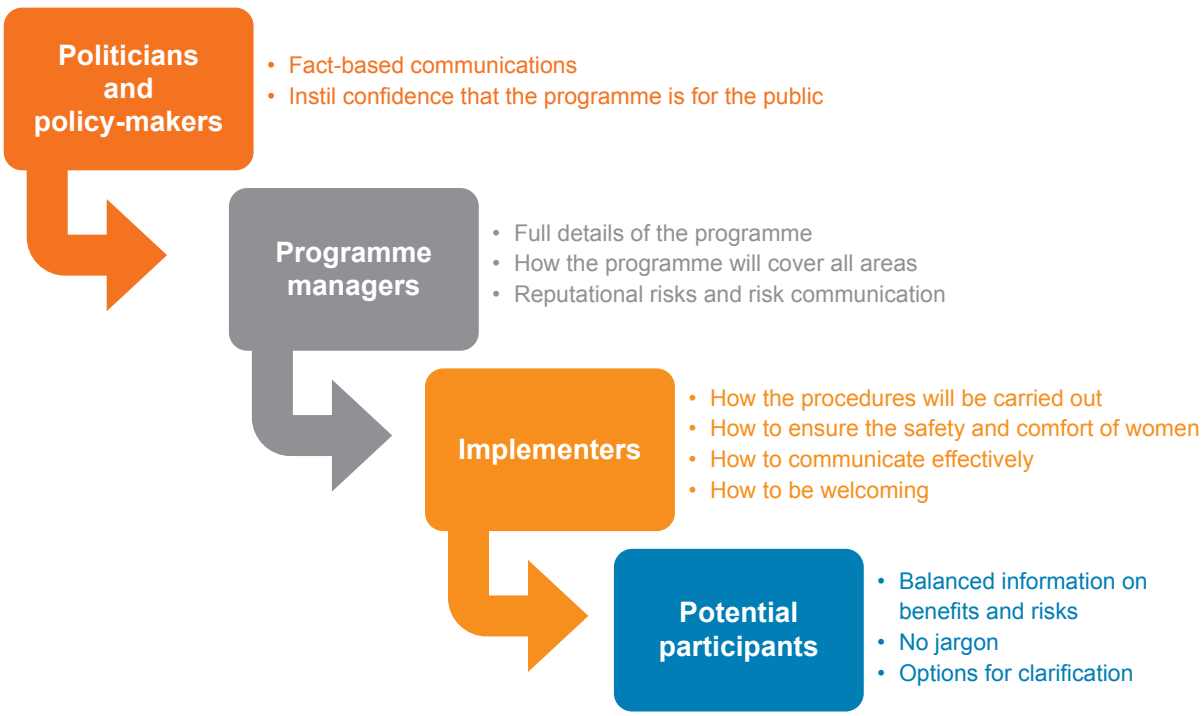
- developing an understanding of the underlying objectives and core values of the programme;
- increasing stakeholder commitment to the programme;
- calling for investments in resources (workforce, infrastructure, information systems, effective regulations, and accountability) to support the programme; and
- building trust in the programme and between the stakeholders.

Once the stakeholder analysis is complete, a documented **stakeholder engagement strategy** needs to be developed. Given the value of and the reputational risk to cervical cancer screening programmes, such a strategy, if implemented correctly, improves trust in the screening policies, increases buy-in, and may help to mitigate any short- and long-term issues with the programme.

Communication and engagement activities must have a clear objective and should be planned based on the positions of the stakeholders in the influence versus interest matrix and their preferred information sources and channels. An example of such a plan is given in Fig. 9. Stakeholder engagement can be implemented at different stages. However, it is more likely to be effective when it is developed in the early stages of the programme. The level of engagement with the stakeholders can be categorized as informing, consulting, involving, collaborating, or empowering. These levels are defined as follows:

- ***Inform:*** Stakeholders are informed or educated in one-way communication without expecting a response. It will be useful to receive feedback.
- ***Consult:*** Information and feedback are obtained from stakeholders to inform decisions. Two-way communication may be limited.
- ***Involve:*** Stakeholders are involved by working directly with stakeholders throughout the process to ensure that issues and concerns are understood and considered. Communication is two-way or multiway, and learning takes place on both sides.
- ***Collaborate:*** Partnerships are formed with the stakeholders and/or groups to develop mutually agreed solutions and a joint plan of action. Communication is two-way or multiway, and learning, negotiation, and decision-making take place on both sides. Stakeholders work together to take action.

Fig. 9. Engagement with different stakeholders in cancer screening programmes. © IARC.



- ***Empower:*** Decision-making on a particular issue is delegated to the stakeholders. Stakeholders are enabled or equipped to actively contribute to the achievement of outcomes.

Any stakeholder may be involved in multiple levels of engagement depending on their position in the influence versus interest matrix. Table 2 provides examples of engagement with various stakeholders in a cervical screening programme. However, this list is not meant to be exhaustive, and the levels of engagement may change in certain circumstances (e.g. policy-makers may get involved when a new policy is being planned.

Additional levels of engagement also exist, such as:

- ***Monitoring:*** There is no active relationship with this group of stakeholders. An example of individuals and organizations who would potentially be in this group is those who have protested or expressed views against continuation of the programme.
- ***Transaction:*** This group includes those who have a contractual relationship whereby one partner directs the objectives and provides funding.

Building relationships of trust between the stakeholders will facilitate the cooperation needed to implement and operate a screening programme. Stakeholder analysis helps to define various audiences, their level of sophistication, and their willingness to hear the messages that are communicated. The content and delivery mode of the messages must be tailored to the intended audience and must consider cultural norms and sensitivities [84].

Table 2. Examples of engagement with various stakeholders in a cervical screening programme

Stakeholders	Level of engagement				
	Inform	**Consult**	**Involve**	**Collaborate**	**Empower**
Politicians	Share policy briefs, programme reports, updates	Consult via existing advisory groups, bilateral meetings			Provide categorical information to enable decision-making on policies, priorities, and finances through regular meetings or sharing reports
Programme managers	Share policies, programme guidelines, training plans	Consult on perceived barriers to programme implementation	Involve through technical committees, implementation, quality assurance teams		Provide categorical information to enable decision-making on policies, priorities and finances and also to advocate for the programme through regular meetings or sharing reports
Civil society	Share policies, fact sheets, programme guidelines	Consult via public and bilateral meetings	Involve through participatory decision-making via consultative committees, workshops	Collaborate through joint programmes and partnership initiatives to implement a screening programme	Empower through integration of civil society in the governance structure of screening committees
People eligible for screening and their partners or spouses	Share fact sheets, websites, bulletins, community events, media releases	Consult via surveys, focus groups, public meetings	Involve through participatory decision-making via consultative committees, workshops, citizens' juries	Collaborate through joint programmes and partnership initiatives to implement a screening programme	Empower through integration of participants in the governance structure of screening committees
Media	Provide media guides, policy updates	Consult via media sessions on the latest information about burden, prevention, actions taken			

3.4.3 Communication with political stakeholders

Communication with political stakeholders should aim to educate them about the structure and operation of the cervical screening programme and the potential benefits and possible risks to those participating in the programme. The political stakeholders should have confidence in the organization and effectiveness of the programme but understand its unavoidable limitations (and that no screening programme is perfect). Political stakeholders should have key experts to contact when they have a question or concern or when communication with the media is a possibility. Technical advisory groups may be created to provide regular feedback not only on the benefits of implementation in a local context but also on the challenges faced in the local health system. Whenever a major change is planned in the protocol and/or the organization of a screening programme or there is a crisis situation, communication with political stakeholders should be established early; appropriate facts and action plans should be provided, and the need for support should also be emphasized [85].

3.4.4 Communication with professional societies

Maintaining the public's trust in their health-care workers is important. Efforts are needed to keep the professional societies up to date, confident about what the programme does, and aware of what its benefits and unavoidable limitations are. Members of these professional bodies are often skilled and trusted public communicators, and their support should be sought in times of difficulty. Commitment from the top leadership of such societies can help to garner support for the programme from the members. Communication with professional societies can be carried out through stakeholder workshops, dissemination of scientific evidence, inclusion of these societies in advisory groups or technical groups, and effective use of cancer and screening data and research.

3.4.5 Communication with civil society organizations

Civil society organizations have a multifaceted role to play and can make important contributions to building stakeholder confidence. Obtaining buy-in from the top management of such organizations can help to garner support from the members.

The following guidelines are useful when engaging with civil society organizations:

- Discussion should focus on how to ensure that the client is at the centre of the programme and how the design of the screening programme can reflect this.
- Conversations should include how best to engage underserved target groups (e.g. people living in rural and remote regions; culturally and linguistically diverse people; Indigenous people; refugees and asylum seekers; people with disability; people who are lesbian, gay, bisexual, trans, or queer; intersex people; and people from socially or economically disadvantaged backgrounds).
- The organizations should be kept informed about the measures taken to improve the quality of services across the programme.

Communication with civil society organizations can be carried out through bilateral meetings, stakeholder workshops, mass media, dissemination of programme policies and reports, and inclusion of these organizations in advisory groups or technical groups to represent the public and the programme participants.

3.4.6 Communication with health professionals

Health-care providers play key roles in ensuring the success of a prevention programme. Effective communication with health professionals is essential to disseminate the correct messages to front-line staff and to support their buy-in and confidence in the programme. Thus, regular communication should be maintained with the implementers at all levels of the health system. The communication should answer their scientific questions, inform them about policy changes for implementation and training opportunities, and provide pragmatic implementation solutions.

3.4.7 Communication with journalists and other members of the media

Communications with journalists and other members of the media should focus on raising their awareness of cervical cancer prevention through screening, of the public health value of the programme, and of any policy updates. Such communication should encompass the following:

- Messages should provide a comprehensive view of various aspects of cervical screening based on themes such as [86]:
  - readers' interest in screening tests;
  - the ingredients of a good news story (e.g. adoption of a new policy, data showing the impact of the programme);
  - knowledge of the potential risks and the limitations of screening tests;
  - factors that influence the framing of media coverage of screening tests; and
  - barriers to and enablers of critical media coverage of screening tests.
- Messages should be:
  - clear, consistent, and credible;
  - honest and transparent, providing information on all aspects of the screening programme, including benefits and risks; and
  - tailored to the various target audiences and types of media.

- An updated list of media contacts in various media (scientific, mainstream, medical, etc.) should be maintained, and a relationship of trust should be developed with some key media contacts so that they can be briefed when necessary.
- A wide range of materials should be produced that are tailored to different media channels, including articles, opinion pieces, interviews, news items, press releases, maps, videos, photographs, infographics, talking points, questions and answers, and briefing notes.
- Efforts should be made to proactive liaise with the media whenever possible by organizing press briefings and proposing opinion pieces or articles to editors.
- Opportunities to communicate with potential media interest should be identified, planned, and/or created (e.g. events, conferences, specific days, launches of reports or results).
- Risks of misrepresentations should be mitigated. Although it is not possible to fully counter all distortions, the communication strategy should help to mitigate the risk of misrepresentations by:
  - ensuring that results and activities are understood by the media;
  - developing clear messages and avoiding jargon and technical terms;
  - responding to the media or to questions or allegations when necessary or possible;
  - identifying, briefing, and training spokespersons (e.g. programme managers) in communication and interview techniques when necessary;
  - supporting spokespersons and helping them to identify, prepare, and deliver media-friendly messages for journalists;
  - preparing reactive lines when faced with sensitive questions, to be ready to respond to the media and address misconceptions quickly;
  - when relevant, preparing communication materials (e.g. questions and answers, fact sheets, flyers, infographics, briefing notes, and talking points) that provide information to various audiences and target audiences (scientific or mainstream media); and
  - monitoring criticisms in the public domain (blogs, press releases, articles, media, and social media).

Another important type of communication in a screening programme is crisis communication (Box 9).

Box 9. Crisis communication in a screening programme

Any screening programme is likely to face incidents that have the potential to threaten both trust in screening and the continuity of the programme itself. Such incidents may be related to risks of screening, a change in the screening criteria or the interval of screening, or any occurrence after screening, which may not be directly related to the screening programme itself. It is vital that the programme is well prepared and has a communication strategy in place for events that may evolve into a crisis. Each crisis will be different and will require a response that is tailored to the sociocultural context.

The WHO communication plan for a vaccine crisis may be adapted to the screening context (Fig. 10). Communication during a public health crisis must be consistent, clear, timely, and based on credible evidence. The designation of a spokesperson is a critical early step in controlling the messaging that goes out to the public and the media. Crisis communication needs to be tailored and should anticipate a diverse group of stakeholders, including the media, who may best be informed through an official statement that provides facts and credible information.

Fig. 10. How to communicate in a crisis situation. Source: [87]. Adapted from WHO Regional Office for Europe (2022). © World Health Organization 2022. Licence: CC BY-NCSA 3.0 IGO.

CHAPTER 4.

Development of workforce competencies in communication about cervical screening

4.1 Value of competencies in communication

Appropriate communication from the health professional who performs any medical procedure may shape how individuals interpret new information. Clinicians and other healthcare providers tend to be respected as credible sources of advice and can influence public perceptions of cancer screening. The need to improve the competencies of health professionals in communication is highlighted by the following observations from various studies:

1. Women's experiences of cervical screening are often shaped by the quality of their interaction with the health professional who performs the procedure.
2. Women report much more satisfactory experiences when clear information about the procedure is provided.
3. Women often cite poor communication as the reason for a negative experience during the screening procedure.
4. Women report a negative experience when their desire for explanation about the procedure as it is carried out is not met or when they are not given enough opportunity to ask questions.
5. Poor communication seems to exacerbate the sense of loss of control that some women associate with screening.
6. Women largely dislike efforts by health professionals to reduce or deny the emotional significance of the screening procedure by emphasizing its routine nature.
7. Specialized training of health professionals improves their communication skills and their sensitivity in dealing with the special needs of groups such as ethnic minority women and differently abled women.

Two different models of communication are illustrated in Box 10.

A person may receive initial information about screening through an invitation letter or email, mass media, or other campaigns before a clinical encounter. Population-based programmes invite eligible people to undergo screening and, of necessity, do so using written information. Thus, the first time a person discusses the screening offer with a

Box 10. Transmission model versus transactional model of communication

In the transmission model, communication is viewed as a linear process in which a sender transmits a message to a receiver. The focus is on the sender and the message; this supports an uneven balance of power [88].

In the transactional model, communication is seen as a dynamic and interpersonal process in which intrinsic and extrinsic factors play key roles. In this model, feedback and validation are recognized as fundamental for effective communication. The transactional nature of this model lies in its recognition of communication as a reciprocal process in which communication is simultaneous and shared between people as communicators, rather than as a sender and a receiver [89]. The transactional model recognizes that environmental, social, and personal factors influence how messages are interpreted. This perspective reminds health professionals to be attentive to both verbal and nonverbal cues about how a participant is interpreting a transaction [88, 90].

Nonverbal communication is mostly about body language and can be used to supplement spoken communication, to reinforce or substitute for a spoken message, or to undermine communication, for example when nonverbal cues contradict a spoken message. Nonverbal messages can be more powerful than words. Therefore, it is important for health professionals in screening to understand body language and use it appropriately to aid communication, to avoid unconscious messages, and to decode and react appropriately to a participant's visual cues [91].

health professional would be either if they ask to discuss the offer with a trusted professional (e.g. primary care worker) or when they attend for the screening test. The person may make an informed choice based on that information or may seek further advice from a one-to-one discussion with a health professional.

In opportunistic screening settings, the first offer of screening will be made face-to-face, so a more complex shared decision-making conversation is possible [92]. **In either type of screening system, the professional who first sees the potential participant needs to understand the screening programme and feel confident in providing the person with information that can be used to make a personal informed choice.**

In addition to having access to information, people who are offered screening must also be able to discuss their screening options with an appropriately trained member of the screening team. A personal informed choice is a decision that is made to accept or decline a screening test based on access to accessible, accurate, and evidence-based information covering:

- the condition being screened for;
- the testing process;
- the benefits, risks, limitations, and uncertainties; and
- the potential outcomes and ensuing decisions.

The person should also be given the opportunity to reflect on what the test and its results might mean to them. Support should be available to potential participants to help them make a decision based on their individual circumstances. This may include discussion of any aspects of the information that are relevant to that person.

A continuing professional development programme for health professionals will ensure that the messages conveyed are consistent, are up to date, and have the desired impact, while maintaining the full autonomy of the potential participant in decision-making. An important goal of any cervical screening programme is to develop ways to support the health professionals in communicating more effectively with potential participants about cervical screening and management, its benefits and risks, audit of cancers, and other challenging topics, through competency-based training. In a cervical screening programme, the focus of workforce competencies should be on the early stage of care, up to the management of precancers. Information on the more advanced, specialized, and detailed aspects of care of patients with cancer could be provided by specialized oncology and/or multidisciplinary teams. Although the present competency framework focuses on communication between health professionals and people who are offered screening, the health professionals (especially those in a managerial position) may also need to communicate with other stakeholders, for which appropriate competencies need to be built.

4.2 Communication competency framework

Having an accurate knowledge and understanding of a woman's perspective, including her concerns, feelings, preferences, beliefs, and values, enables a health professional to provide more personalized communication by using language she can understand, providing clear explanations, and validating or addressing her emotional states (Box 11). Effective communication with the women who are offered cervical screening and their accompanying family members requires five key competencies for health professionals [93].

Box 11. Fundamental competencies for effective communication in cervical screening

Throughout the screening pathway, health professionals must be able to demonstrate competence in communicating effectively with participants. This includes:

- using appropriate language;
- avoiding jargon;
- active listening;
- asking open questions;
- checking understanding;
- correcting misunderstanding;
- seeking clarification;
- using appropriate body language;
- correcting understanding; and
- responding appropriately to other people's body language.

Source: [93]. Adapted from Epstein and Street (2007).

For each of the competencies described below, the health professionals involved in the screening pathways need to acquire appropriate knowledge and to be able to demonstrate certain skills.

Competency 1: Being able to foster a relationship of mutual trust, understanding, and commitment

Knowledge to be gained:

- Building rapport with individuals.
- Effective communication through verbal and nonverbal techniques.
- Participants' knowledge, attitude, and perceptions related to cervical cancer and its prevention through screening.

Skills to be demonstrated:

- Being deliberate about showing respect in every interaction with participants.
- Eliciting, understanding, and validating the perspective (e.g. concerns, feelings, and expectations) of the person who is offered screening.
- Active listening and being patient.
- Encouraging the person to participate in the conversation.
- Using appropriate nonverbal behaviour during the conversation, such as maintaining eye contact.
- Offering concrete feedback.
- Engaging with participants, demonstrating empathy, and answering their questions without being judgemental.
- Actively assessing the person's satisfaction with the interaction.

Competency 2: Being able to exchange information that recognizes the individual's information needs and overcomes any barriers related to low health literacy and poor understanding of statistical information

Knowledge to be gained:

- Information about the existing screening policies and protocols.
- The implications of the various test results at screening, diagnosis, and follow-up.
- The benefits and risks of screening.
- Framing of messages.
- Social determinants of health and how they affect access to screening and downstream management.
- The laws governing privacy, confidentiality, and compensation.

Skills to be demonstrated:

- Gathering information about the context of the clinical interaction; the principles and practice of screening as a public health offer; the aim, potential benefits, possible risks, and limitations of cervical screening, and how to explain these to the potential participant; the etiology and course of progression of cervical cancer; and the relevant national and/or local cervical screening programme guidelines, policies, procedures, and protocols, including training requirements.
- Understanding the communication methods and approaches best suited to the situation that:
  - promote equality and diversity;
  - promote the rights of people to communicate using their preferred method, media, and language; and
  - avoid medical jargon, acronyms, or technical terminology.
- Adapting communication styles in ways that are appropriate to the needs of the individual.
- Using different approaches, methods, and techniques that support individuals when handling complex and sensitive issues, and understanding the importance of:
  - focusing on the individual;
  - space and positioning when communicating;
  - body language and eye contact when communicating;
  - giving individuals sufficient time to communicate;
  - checking that the health professionals and the individuals understand each other; and
  - active listening.
- Understanding when to recognize silence as an effective aid during verbal communication.
- Using verbal or written communication that:
  - facilitates positive outcomes;
  - is constructive;
  - is relevant and sufficiently comprehensive to be understood by the recipient; and
  - uses language that is appropriate to the context, the audience, and the information being exchanged.
- Using the appropriate decision aids.
- Understanding their own values, beliefs, and attitudes and how these could affect their work.
- Knowing the importance of working within their role and sphere of competence, and seeking advice when faced with situations outside their sphere of competence.
- Understanding the principles of confidentiality, security, and information sharing for their work environment.

Competency 3: Being able to manage uncertainty by acknowledging it and providing further information, support, and cognitive strategies

Knowledge to be gained:

- The uncertainties that exist in the screening process (e.g. whether HPV-positive participants will develop cervical cancer, or whether participants in whom cervical precancer was detected will develop cervical cancer if the precancer is not treated).
- How to handle uncertainties.

Skills to be demonstrated:

- Acknowledging that uncertainties exist and that they cannot be eliminated.
- Being able to explain why the particular issue is uncertain.
- Framing information in terms of what is known and what is unknown.
- Offering additional information to support decision-making by the person.

Competency 4. Supporting shared decision-making through active involvement of the potential participants and their family members in the information-exchange and deliberation stages of the decision-making process

Knowledge to be gained:

- How decision-making is influenced by the person's knowledge, values, needs, and preferences.
- The concept and art of shared decision-making.

Skills to be demonstrated:

- Supporting the person to make a decision through a stepwise process of information exchange, deliberation, and final decision-making.
- Being able to build partnership with the person through facilitative communication to elicit their perspective.
- Being able to offer multiple options to achieve the same goal, and giving the person enough time to consider choices.
- Supporting the decision with current clinical evidence.
- Reconciling any differences of opinion, and accommodating the person's preference.

Competency 5: Enabling people to navigate the health system by providing appropriate guidance on seeking appropriate care and finding further information

Knowledge to be gained:

- The challenges that people usually face in navigating the health-care system and accessing services.
- The roles and responsibilities of a navigator.

Skills to be demonstrated:

- Providing adequate information about what the person may encounter if they decide to undergo screening.
- Providing clear explanations about ways the person can manage possible scheduling for further investigations or treatment or follow-up and can manage possible side-effects.
- Providing access to adequate resources.

4.3 Implementation of the competency framework

The competency framework described above can be used as a reference tool when planning to build capacities in communication. It should be applied locally, according to the local context and needs. Some competencies outlined in this document may not be relevant for some work environments, depending on factors such as the programme organization, capacity, and resources. Additional competencies may be added as required.

Using the framework, the programme can create a self-assessment tool that individual professionals can use to assess their level of competence as well as an assessment tool that organizations can use to assess the competencies of the staff currently employed by the organization. On the basis of assessment of the competencies, the professionals may be categorized as competent, proficient, or expert. These levels are defined as follows:

Competent:

- Has undergone basic training in health communication.
- Has trained in communication related to cervical screening.
- Is capable of routine and non-routine conversations with participants and their families.

Proficient:

- Has all the competencies mentioned earlier.
- Is capable of complex conversations via intuition and analytical thinking.
- Assumes leadership roles.
- Has supervisory responsibilities.

Expert:

- Has all the competencies mentioned earlier.
- Is capable of assessing the quality of communication and areas for improvement in the organization.
- Is capable of developing strategies and assigning leadership responsibilities to others.
- Is capable of supervising multiple tiers of staff.

The competency framework needs to be evaluated periodically to review the implementation and to reflect on lessons learned in the continuing practice of health communication in the context of cervical screening programmes. The framework may be adapted for use in communication with other stakeholders, such as policy-makers and members of the media.

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ANNEX 1.

Members of the Technical Working Groups

Technical Working Group 1

Chairperson: Peter Sasieni (Academic Director of the Clinical Trials Unit and Professor of Cancer Prevention, King's College London, United Kingdom)

Members:

- **Caroline Mason Mohan** (Director of Public Health, National Screening Service, Ireland)
- **Christine Bergeron** (President, CerbaPath; President, French Society of Colposcopy and Cervicovaginal Pathology, France)
- **Gráinne Gleeson** (Programme Manager, CervicalCheck, National Screening Service, Ireland)
- **Joakim Dillner** (Scientific Director, Medical Diagnostics Karolinska, Karolinska University Hospital and Head of Unit, Center for Cervical Cancer Prevention, Sweden)
- **Julia Brotherton** (Medical Director, Population Health, Australian Centre for the Prevention of Cervical Cancer, Australia)
- **Kirsten McCaffery** (National Health and Medical Research Council Principal Research Fellow; Director, Sydney Health Literacy Lab, Sydney School of Public Health, Faculty of Medicine and Health; Director of Research, School of Public Health, The University of Sydney, Australia)
- **Rachel Kitonyo Devotsu** (Regional Manager Africa, McCabe Centre for Law and Cancer, based in Nairobi, Kenya)
- **Silvina Arrossi** (Coordinator, Cancer Screening Programme and Researcher, Argentina)

Technical Working Group 2

Chairperson: Anne Mackie
(Director of Programmes for the UK National Screening Committee, United Kingdom)

Members:

- **Cherian Varghese** (Cross-Cutting Lead for Noncommunicable Diseases and Special Initiatives, Department of Noncommunicable Diseases, World Health Organization, Switzerland)
- **David Ritchie** (Cancer Prevention Manager, Association of European Cancer Leagues, Belgium)
- **Dearbhail McDonald** (Eisenhower Fellow; Author of *Bust: How the Courts Have Exposed the Rotten Heart of the Irish Economy* [Penguin, 2010])
- **Fiona Ness** (Communications Manager, National Screening Service, Ireland)
- **Mame-Yaa Bosomtwi** (Stakeholder Management Officer, World Health Organization, Switzerland)
- **Nóirín Russell** (Clinical Director, CervicalCheck, National Screening Service, Ireland)
- **Raúl Murillo** (Director, Javeriana Oncology Center, San Ignacio University, Colombia)
- **Robert Smith** (Senior Vice President, Cancer Screening, American Cancer Society, USA)
- **Sarah Fitzgibbon** (Primary Care Clinical Advisor, CervicalCheck, National Screening Service, Ireland)

Technical Working Group 3

Chairperson: Marc Arbyn
(Unit of Cancer Epidemiology, Belgian Cancer Centre, Belgium)

Members:

- **David Keegan** (National Clinical Lead for Diabetic Retinopathy, National Screening Service, Ireland)
- **Groesbeck Parham** (Director of the CIDRZ Cervical Cancer Prevention Program; Professor of Gynecologic Oncology, Department of Obstetrics and Gynecology, University of North Carolina, USA)
- **Linda Rabeneck** (Professor of Medicine and Professor, Dalla Lana School of Public Health, University of Toronto, and Senior Scientist, ICES, Canada)
- **Mary Donnelly** (Law School, University College Cork; Director of Law School Staff Development and Welfare; Associate Editor of *International Journal of Law and Psychiatry,* Ireland)
- **Ondřej Májek** (Head of Department of International Affairs, Scientific Lead of National Screening Centre, Institute of Health Information and Statistics of the Czech Republic, Czechia)
- **Philippa Pearmain** (Regional Head of Screening Quality Assurance (Midlands and East)/National Cervical Quality Assurance Lead, Screening Quality Assurance Service, NHS England and NHS Improvement, United Kingdom)
- **Vasco Rosa Dias** (Data Protection Officer, Instituto de Saúde Pública da Universidade do Porto, Portugal)

Disclosures of interests

Christine Bergeron reports being employed by Cerba Path, which is a diagnostic laboratory specialized in anatomo-cytopathology.

Ondřej Májek reports that his unit at the Institute of Health Information and Statistics of the Czech Republic benefited from research funding from GSK and Roche.

Peter Sasieni reports having received personal consultancy fees from Roche and being an advisory board member for NSV Ltd.

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