

# Bioethical aspects of screening programs for secondary prevention of cervical cancer

Milena Di Lanno (Naples), Monica Pinto (Naples), Benedetto Brancaccio (Caserta), Elena Esposito (Caserta), Clemente Santonostaso (Naples), Davide De Giovanni (Naples)

## ABSTRACT

*Cervical cancer is one of the most frequent oncological diseases in the female sex, with an incidence of 13.3% worldwide, but thanks to treatment and screening programs in Italy, survival at 5 years after diagnosis is 68% (Italian Cancer Registry data). The use of screening of the general population as a public health tool, in order to treat the disease early, has increased the chances of successful treatment and reduced mortality from this specific cause in the population in question. In the present article, a review of studies related to the ethical aspects of screening tests for carcinoma of the uterine cervix was conducted. This review showed how crucial the role of the Biomedical Laboratory Health Technician (BST) is in the phase of communication with the patient as well as in the preparation of biological specimens and the conduct of HPV-DNA and Pap Test. In addition, it showed that the bioethical implications of screening programs also involve the figure of the TSLB who must operate not only in a technically correct but also morally unimpeachable manner.*

## INTRODUCTION

Cervical cancer is a major cause of morbidity and mortality among women worldwide. However, thanks to screening examinations, such as the Pap test and human papillomavirus (HPV) viral genome test, precancerous lesions and early-stage cancers can be detected early, thereby increasing the chances of effective treatment and survival. While the efficacy of such screening tests is undisputed, ethical issues arise that require careful consideration, ensuring that women's health is preserved without violating basic bioethical principles:

1. **Autonomy:** One of the fundamental principles of bioethics is autonomy, the right of people to make informed decisions about their own health. In the context of cervical cancer screening tests, it is important to ensure that women are fully informed about the benefits, risks, and limitations of such tests. Understandable information should also be provided about possible consequences, such as false positives or false negatives, as well as available treatment options. In addition, women should be able to freely choose whether or not to undergo screening tests, without any coercion or external pressure.
2. **Privacy and confidentiality:** Privacy and confidentiality of medical information are essential elements in cervical cancer screening examinations. Women must be assured that their personal information and test results are treated confidentially and that only authorized health care personnel have access to the information. It is important to ensure that information collected during screening examinations is not misused or used for inappropriate purposes in order to protect the dignity and privacy rights of the women involved.
3. **Justice:** The principle of justice emphasizes the need to ensure equitable access to cervical cancer screening examinations. Economic, geographic, or cultural barriers should not prevent women

from benefiting from these services. It is critical that measures are taken to reduce inequalities in access to screening examinations, such as through free screening programs, targeted information campaigns, and health services that are accessible to all.

4. **Beneficence and nonmaleficence:** Cervical cancer screening examinations are intended to benefit women by identifying precancerous lesions or early stage cancers early. However, it is also important to consider the principle of nonmaleficence, that is, avoiding causing harm. For example, false-positive results may cause anxiety and stress to women, requiring additional tests and invasive procedures that may not be unnecessary. Therefore, a balance between the expected benefit and the potential risks associated with screening examinations is necessary to minimize negative effects and maximize positive outcomes for women's health.

## CANCER PREVENTION

Prevention is an area of great importance in medicine, it includes a set of actions and interventions to promote health in individuals and communities, and in particular it plays a very important role in the prevention of neoplastic diseases. Four types of prevention are distinguished:

- **Primary prevention,** which aims to prevent the development of disease in healthy individuals by intervening on risk factors. Two types of risk factors for cancer occurrence are distinguished: those that are non-modifiable, such as sex, a particular genetic makeup, and age, and those that are modifiable, related to lifestyle;
- **secondary prevention,** which aims at early detection of disease in clinically healthy individuals who already have biological damage, with the goal of early treatment of the disease before it becomes clinically manifest. In



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- oncology, the tool for secondary prevention is screening, which allows early detection of cancer and increases therapeutic opportunities;
- tertiary prevention, is defined as all activities and interventions aimed at reducing and controlling the complex outcomes of a disease. It therefore deals with people who are already ill, with chronic or irreversible diseases, with the aim of limiting the occurrence of recurrence, complications or disability;
- quaternary prevention that aims to prevent and reduce the consequences of over- medicalization and excessive or unnecessary treatment.

So many scientific studies have demonstrated the importance of prevention and health promotion in reducing the incidence of disease and consequently the costs to the National Health Service (NHS) and society, but also in fostering the maintenance of the population's well-being and quality of life. In a modern conception of health, its promotion and disease prevention must focus on joint actions of various sectors of society, mainly on modifiable risk factors and social, economic, and environmental determinants of health, not forgetting the importance of addressing inequalities.

Generalities about the organization of cancer screening programs

General population screening is a public health tool that refers to the systematic search for a specific disease in asymptomatic people in order to treat that disease early by increasing the chances of successful treatment and reducing mortality from that specific cause in that population. Screening is a health goal identified by the Essential Levels of Care for certain diseases, including especially neoplasms.

Scientific research strives to assess whether a screening is effective, that is, whether the intervention is capable of improving the natural history of a disease. Effectiveness is measured in terms of a reduction in the incidence of the disease targeted by the intervention, or a reduction in mortality or associated morbid effects. Evaluation is done by comparing the differences, in terms of incidence of a given cancer or mortality from that cancer, between groups screened and control, unscreened groups. The comparison can be made using observational methods.

In observational studies, two types of populations are compared, one screened and one unscreened population, having different characteristics such as age. The effectiveness of screening must be balanced against the possible negative effects, which result from the inevitable presence of false negatives, i.e., the non-identification of sick individuals, and false positives, i.e., attribution of disease to healthy people resulting in subsequent diagnostic tests for people who would not have needed them. Screening must have certain requirements:

- constitutes a complex process organized into several stages where each stage is subject to quality control;
- Involves multiple disciplines and professions;
- provides a balance between positive and negative effects;
- must assess costs, and ensure maximum equity by offering the possibility of health gain to all citizens, regardless of sociocultural level and financial means.

Communication aspects are very relevant in screening. The success of a screening program is therefore related to communication and informed consent. Low adherence rates may in fact negatively affect the overall effectiveness in terms of mortality reduction. In particular, information needs to reach especially those people who are in the target groups but have never undergone a screening test. Participation in screening is the exercise of a right that requires full awareness, however. The invitation to undergo the screening test must therefore be accompanied by adequate information, not only in terms of truthfulness, but also in terms of completeness and comprehensibility. The information must clarify the benefits that everyone can expect and the possible disadvantages associated with the test, according to the characteristics of the different types of cancer. Users must be fully aware of the possibility of being called for further (sometimes invasive) investigations, of the possible occurrence of cancers between two successive screening tests (interval cases), and of the consequent need to pay attention to any disorders. Bioethical aspects of screening tests are a topic of great relevance and debate in the field of medicine. Some highlights to consider include:

1. **Autonomy and informed consent:** It is essential to respect the autonomy of people involved in screening tests. This implies that people should be fully informed about the benefits, risks, limitations, and implications of the tests, enabling them to make informed and informed decisions.
2. **Individual and collective benefit:** Screening tests can provide a relevant individual benefit in detecting a condition or disease risk early. However, it is also important to assess the collective benefit of screening, such as reducing incidence or preventing more serious consequences.
3. **Equity and access:** Ethical aspects require that screening tests be equally accessible and that there be no disparities in access based on factors such as income, ethnicity, or geographic location. This is important to ensure that everyone has the opportunity to benefit from screening tests.
4. **Privacy and confidentiality:** The collection and processing of personal data as part of the testing of screening require respecting privacy and ensuring the confidentiality of information. È



essential to take appropriate measures to protect sensitive data and ensure informed consent for its sharing, in compliance with privacy and data security regulations.

5. Psychological impact: Screening test results can have a significant emotional impact on those involved. Therefore, it is important to provide appropriate psychological support and pre-test and post-test counseling to deal with the psychological consequences of the information detected by the tests.
6. Appropriate use of resources: The implementation of screening programs requires financial resources, infrastructure, and trained personnel. It is important to ensure that resources are used effectively and efficiently, balancing expected benefit with cost and access to care for those who test positive.

The bioethical approach in screening tests focuses on the balance between individual and collective benefit, promotion of autonomy in decision-making, equity in access, protection of privacy, and management of psychological impact. It is an evolving field that requires ongoing ethical reflection and public debate to ensure that screening programs are ethically sound and respect the rights and well-being of those involved.

#### The Role of the Biomedical Laboratory Technician in Screening Programs.

Biomedical Laboratory Health Technicians are qualified health professionals who perform biomedical and biotechnological analysis, particularly in biochemistry, microbiology and virology, hematology, cytology, analyze biological specimens (blood, surgical specimens, urine, sputum, etc.) or perform scientific research experiments.

The TSLB as well as other health professionals play an active role in screening programs:

- the TSLB promotes the safety of care through the proper execution of procedures and methods and is responsible for the processes and decisions under his or her purview, just as he or she is responsible for the maintenance and quality control of various laboratory instruments, according to the dictate of the professional profile and code of ethics;
- the TSLB carries out its activities according to its specific capabilities, in the interest of the community, putting the person at the center;
- the TSLB, protects patient privacy by maximizing confidentiality and strictly complies with data protection regulations.

#### Papilloma Virus and Screening Tests Available for Cervical Cancer

Human Papillomavirus (HPV) infection is one of the most frequent sexually transmitted infections, commonly involving adolescents and younger women after the onset of sexual activity. The

carcinogenic role of HPV, identified as a necessary, though not sufficient, factor in the development of cervical cancer, is now widely recognized.

The types of HPV that infect the cervix have been divided into HPV:

- “low-risk” (6, 11, 42, 43, 44) almost never associated with invasive carcinomas of the cervix;
- “medium-risk” (35, 39, 51, 56, 59) associated, but not frequently, with cervical cancer;
- “high risk” (16, 18, 31, 33, 45, 52, 58) frequently associated with carcinomas.

In Italy, cervical cancer represents the fifth most frequent cancer in women under 50 years of age and overall 1.3% of all those diagnosed. Worldwide, 604,000 new cases and 342,000 deaths were recorded in 2020, representing the fourth highest incidence cancer in the female sex. In addition, an estimated 84% of cervical cancer cases currently occur in developing countries. (2-5)

Overall incidence and mortality rates are closely dependent on the presence of more widely available screening programs for precancerous lesions in industrialized countries. In fact, there has been a reduction in cervical cancer incidence and mortality in industrialized countries over the past 50 years due to these interventions, although there are some exceptions. Data suggest that PAP test screening in conjunction with HPV vaccination can significantly reduce the incidence of cervical cancer in developing countries. The maximum incidence of carcinoma in situ is in the age range of 25-35 years gradually reducing until it disappears in the age group above 65 years.

Screening for HPV consists of taking both the molecular test and the Pap test. However, the Pap test will be read only if the HPV molecular test is positive. If the HPV molecular test is negative, screening will be invited again after 5 years. In these five years, a new Pap test will not be needed. The following is further clarification of the meaning of the tests:

1. Pap test: This examination involves the collection of cell samples from the cervix for microscopic analysis to detect cellular abnormalities indicative of precancerous or cancerous lesions. The Pap test can identify abnormal cells at an early stage, allowing early intervention to prevent progression to cancer.
2. HPV DNA testing: HPV DNA testing detects the presence of certain high-risk HPV types, which are associated with an increased risk of developing cancer. This test can be performed at the same time or in combination with the Pap test for better risk assessment. Cervical cancer screening examinations are generally recommended for women 30 years of age and older or depending on country-specific or



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health organization guidelines. The frequency of screening may vary depending on age, medical history and previous results.

In conclusion, cervical cancer screening examinations play a crucial role in prevention and early detection. They allow early detection of precancerous or cancerous lesions, enabling the implementation of timely and life-saving interventions.

#### Bioethical Issues in Developing Countries' Screening Programs.

Equity is defined as the absence of unfair, avoidable or remediable differences between groups of people, regardless of social, economic, demographic or geographic or other differences. Equity in access to care is enshrined in our Constitution (Article 32) and is achieved when everyone can reach their full potential for health and well-being. On their own, public health policies may prove insufficient to close disparities in health status for some socially disadvantaged groups, as such disparities are symptoms of problems such as poverty and social exclusion. Health policies, therefore, only work if they are characterized by multidisciplinary, that is, by the need to combine health expertise with social, political and urban planning expertise; by greater capacity in recognizing and valuing local needs; and by the ability to activate and enhance the collaboration of institutions and citizens. The health policies that have "worked" the most and therefore have been shown to affect health inequalities are: prevention policies, health promotion and health education policies that target disadvantaged social groups the most; policies to correct the system of care, aimed at redistributing health resources among geographic areas so as to eliminate improper barriers to accessing timely and appropriate care; and social and economic policies to reduce the harms of social inequalities through research and information policies to bring the issue to the public agenda. All of these issues are the subject of bioethical evaluations that affect the welfare of states but also individual professionals each of whom must engage as a category and as individuals to combat inequality of access to care. The purpose of the International Society for Equity in Health (ISEqH) is to promote

equity in health services internationally through education, research, publication and communication with the ultimate goal of:

- Promote equity in health and health services internationally;
- Facilitate scientific interchange and disseminate conceptual and methodological knowledge on issues related to equity in health and health services;
- advanced research related to health equity -maintain corresponding relationships with other relevant international and regional organizations.

Among the most significant problems plaguing the health care system in these countries is certainly the lack of a credible system for collecting epidemiological data on the most prevalent diseases and for identifying existing health care resources: without these data, the formulation of care programs and the planning of health education and preventive medicine interventions is not possible. Social unrest and poverty exacerbate the consequences of poor and poorly functioning health care.

#### Bioethical issues of false negatives and false positives of Screening Tests

As already mentioned, communication aspects are very relevant in screening; therefore, their success is linked to communication and informed consent. The invitation to undergo the screening test must therefore be accompanied by adequate information that must clarify both the benefits and possible disadvantages associated with the test. Screening programs result in an early diagnosis of disease at an asymptomatic stage; in an ideal situation, a screening test is expected to be able to detect negative patients from positive ones, but like any diagnostic test, screening tests can run into error. Giving false-negative results in individuals who have the disease causes great harm to the patient as they would receive unwarranted reassurance about their health status, delaying the actual diagnosis of the disease, which meanwhile progresses. On the other hand, screening tests can also lead to false-positive results, resulting in unnecessary interventions and, therefore, also unnecessary individual and societal concerns and costs. In addition, inherent in any early diagnosis process is the risk of detecting and treating lesions that would never have manifested clinically, leading to overdiagnosis and overtreatment. The administration of the screening test or follow-up examinations can be bothersome or even painful for those who undergo them, and also carry risks. Sometimes screening wait times are long and result in a significant burden of anxiety for people. Many of the possible negative effects of screening cannot be completely eliminated and must be made clear to the user along with the benefits. All available quality controls must be put in place to minimize these undesirable effects.

#### CONCLUSIONS

Getting cancer is a traumatic event that affects not only the physical health but especially the psychological dimension of a person. Cervical cancer still has a high incidence especially in young women, and in addition we can and should increase survival time, which compared to other cancers such as breast and thyroid cancer is still suboptimal: the possibility of subjecting the population to screening programs is the best available tool to increase the timeliness of treatment and thus survival. The role of the TSLB is important in communicating with the



patient and preparing biological specimens as well as in conducting HPV DNA and Pap tests, knowing that these tests can produce false-positive or false-negative results. The bioethical implications of

cervical cancer screening programs also involve the figure of the TSLB who in his or her professionalism must be trained not only technically but also have ethically correct behaviors.

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