Cancer Control

Knowledge into Action

WHO Guide for Effective Programmes

Early Detection

World Health Organization

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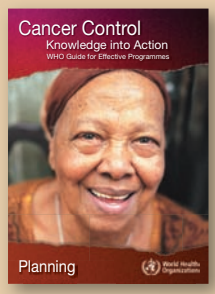
Introduction to the Cancer Control Series

Cancer is to a large extent avoidable. Many cancers can be prevented. Others can be detected early in their development, treated and cured. Even with late stage cancer, the pain can be reduced, the progression of the cancer slowed, and patients and their families helped to cope.

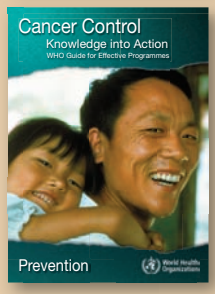
Cancer is a leading cause of death globally. The World Health Organization estimates that 7.6 million people died of cancer in 2005 and 84 million people will die in the next 10 years if action is not taken. More than 70% of all cancer deaths occur in low- and middle-income countries, where resources available for prevention, diagnosis and treatment of cancer are limited or nonexistent.

But because of the wealth of available knowledge, all countries can, at some useful level, implement the four basic components of cancer control – ***prevention, early detection, diagnosis and treatment, and palliative care*** – and thus avoid and cure many cancers, as well as palliating the suffering.

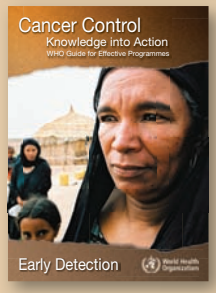
Cancer control: knowledge into action, WHO guide for effective programmes is a series of six modules that provides practical advice for programme managers and policy-makers on how to advocate, plan and implement effective cancer control programmes, particularly in low- and middle-income countries.



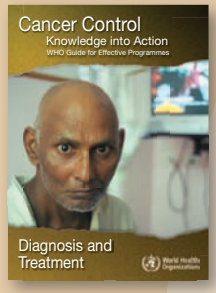
PLANNING
A practical guide for programme managers on how to plan overall cancer control effectively, according to available resources and integrating cancer control with programmes for other chronic diseases and related problems.



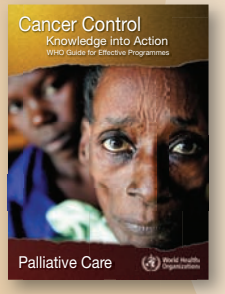
PREVENTION
A practical guide for programme managers on how to implement effective cancer prevention by controlling major avoidable cancer risk factors.



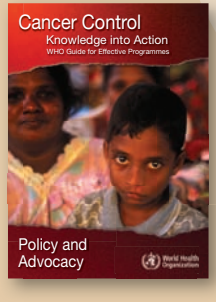
EARLY DETECTION
A practical guide for programme managers on how to implement effective early detection of major types of cancer that are amenable to early diagnosis and screening.



DIAGNOSIS AND TREATMENT
A practical guide for programme managers on how to implement effective cancer diagnosis and treatment, particularly linked to early detection programmes or curable cancers.



PALLIATIVE CARE
A practical guide for programme managers on how to implement effective palliative care for cancer, with a particular focus on community-based care.



POLICY AND ADVOCACY
A practical guide for medium level decision-makers and programme managers on how to advocate for policy development and effective programme implementation for cancer control.

The WHO guide is a response to the World Health Assembly resolution on cancer prevention and control (WHA58.22), adopted in May 2005, which calls on Member States to intensify action against cancer by developing and reinforcing cancer control programmes. It builds on *National cancer control programmes: policies and managerial guidelines* and *Preventing chronic diseases: a vital investment*, as well as on the various WHO policies that have influenced efforts to control cancer.

Cancer control aims to reduce the incidence, morbidity and mortality of cancer and to improve the quality of life of cancer patients in a defined population, through the systematic implementation of evidence-based interventions for prevention, early detection, diagnosis, treatment, and palliative care. Comprehensive cancer control addresses the whole population, while seeking to respond to the needs of the different subgroups at risk.

COMPONENTS OF CANCER CONTROL

Prevention of cancer, especially when integrated with the prevention of chronic diseases and other related problems (such as reproductive health, hepatitis B immunization, HIV/AIDS, occupational and environmental health), offers the greatest public health potential and the most cost-effective long-term method of cancer control. We now have sufficient knowledge to prevent around 40% of all cancers. Most cancers are linked to tobacco use, unhealthy diet, or infectious agents (see Prevention module).

Early detection detects (or diagnoses) the disease at an early stage, when it has a high potential for cure (e.g. cervical or breast cancer). Interventions are available which permit the early detection and effective treatment of around one third of cases (see Early Detection module).

There are two strategies for early detection:

- *early diagnosis*, often involving the patient's awareness of early signs and symptoms, leading to a consultation with a health provider – who then promptly refers the patient for confirmation of diagnosis and treatment;

- *national or regional screening* of asymptomatic and apparently healthy individuals to detect pre-cancerous lesions or an early stage of cancer, and to arrange referral for diagnosis and treatment.

Treatment aims to cure disease, prolong life, and improve the quality of remaining life after the diagnosis of cancer is confirmed by the appropriate available procedures. The most effective and efficient treatment is linked to early detection programmes and follows evidence-based standards of care. Patients can benefit either by cure or by prolonged life, in cases of cancers that although disseminated are highly responsive to treatment, including acute leukaemia and lymphoma. This component also addresses rehabilitation aimed at improving the quality of life of patients with impairments due to cancer (see Diagnosis and Treatment module).

Palliative care meets the needs of all patients requiring relief from symptoms, and the needs of patients and their families for psychosocial and supportive care. This is particularly true when patients are in advanced stages and have a very low chance of being cured, or when they are facing the terminal phase of the disease. Because of the emotional, spiritual, social and economic consequences of cancer and its management, palliative care services addressing the needs of patients and their families, from the time of diagnosis, can improve quality of life and the ability to cope effectively (see Palliative Care module).

Despite cancer being a global public health problem, many governments have not yet included cancer control in their health agendas. There are competing health problems, and interventions may be chosen in response to the demands of interest groups, rather than in response to population needs or on the basis of cost-effectiveness and affordability.

Low-income and disadvantaged groups are generally more exposed to avoidable cancer risk factors, such as environmental carcinogens, tobacco use, alcohol abuse and infectious agents. These groups have less political influence, less access to health services, and lack education that can empower them to make decisions to protect and improve their own health.

BASIC PRINCIPLES OF CANCER CONTROL

- **Leadership** to create clarity and unity of purpose, and to encourage team building, broad participation, ownership of the process, continuous learning and mutual recognition of efforts made.
- **Involvement of stakeholders** of all related sectors, and at all levels of the decision-making process, to enable active participation and commitment of key players for the benefit of the programme.
- **Creation of partnerships** to enhance effectiveness through mutually beneficial relationships, and build upon trust and complementary capacities of partners from different disciplines and sectors.
- **Responding to the needs of people** at risk of developing cancer or already presenting with the disease, in order to meet their physical, psychosocial and spiritual needs across the full continuum of care.
- **Decision-making** based on evidence, social values and efficient and cost-effective use of resources that benefit the target population in a sustainable and equitable way.
- **Application of a systemic approach** by implementing a comprehensive programme with interrelated key components sharing the same goals and integrated with other related programmes and to the health system.
- **Seeking continuous improvement,** innovation and creativity to maximize performance and to address social and cultural diversity, as well as the needs and challenges presented by a changing environment.
- **Adoption of a stepwise approach** to planning and implementing interventions, based on local considerations and needs (see next page for WHO stepwise framework for chronic diseases prevention and control, as applied to cancer control).

WHO stepwise framework

1 PLANNING STEP 1
Where are we now?

Investigate the present state of the cancer problem, and cancer control services or programmes.

2 PLANNING STEP 2
Where do we want to be?

Formulate and adopt policy. This includes defining the target population, setting goals and objectives, and deciding on priority interventions across the cancer continuum.

3 PLANNING STEP 3
How do we get there?

Identify the steps needed to implement the policy.

The planning phase is followed by the policy implementation phase.

Implementation step 1
CORE

Implement interventions in the policy that are feasible now, with existing resources.

Implementation step 2
EXPANDED

Implement interventions in the policy that are feasible in the medium term, with a realistically projected increase in, or reallocation of, resources.

Implementation step 3
DESIRABLE

Implement interventions in the policy that are beyond the reach of current resources, if and when such resources become available.

EARLY DETECTION MODULE CONTENTS

KEY MESSAGES

- Every year, millions of cancer patients could be saved from premature death and suffering if they had timely access to early detection and treatment.

- Early detection is based on the concept that the sooner in its natural history the cancer is detected, the more effective the treatment is likely to be.

- The aim of early detection is to detect the cancer when it is localized to the organ of origin and before it invades the surrounding tissues and distant organs, or for some sites, to detect a precancerous lesion.

- There are two main components of early detection programmes for cancer:
  - early diagnosis
  - screening.

key definitions

An **early detection programme** is the organized and systematic implementation of:

- early diagnosis or screening (or both)
- diagnosis
- treatment
- follow-up.

Early diagnosis is the awareness (by the public or health professionals) of early signs and symptoms of cancer in order to facilitate diagnosis before the disease becomes advanced. This enables more effective and simpler therapy. The concept of early diagnosis is sometimes called "down-staging".

Screening is the systematic application of a screening test in a presumably asymptomatic population. It aims to identify individuals with an abnormality suggestive of a specific cancer. These individuals require further investigation.

Opportunistic screening is the unsystematic application of screening tests in routine health services.

Precancerous/premalignant lesions are abnormal changes that occur in tissues in an early stage of cancer development which have the potential to progress to invasive cancer if left untreated. Screening for cervical cancer aims to detect cancer at this stage.

The preclinical phase of a cancer starts with the biological onset of disease. The disease then progresses and reaches a point at which it can be detected by a screening test; this is the beginning of the *detectable preclinical phase* of the disease. To be suitable for early detection and screening, a disease must pass through a detectable preclinical phase.

PRE-PLANNING

Worldwide, about a third of all cancers are estimated to be amenable to early detection and potential cure with treatment. If cancer is detected early, within a comprehensive cancer control plan, a significant number of cancer patients can be cured or have their lives prolonged significantly. Without early detection, treatment costs rise substantially, resources are used inefficiently and the need for palliative care services increases unnecessarily.

Early detection programmes include education of the public and of health-care professionals to increase awareness that some cancers can be detected early. The aim of raising awareness is to make sure that a high proportion of the target population participates in the programme.

Before raising awareness in the population and inviting the target group to join the programme, all the components of the early detection programme should be well organized and accessible. Early detection involves costs to the individual and the health services. False positive tests or inadequate clinical procedures may result in physical and psychological harm.

In a population where the majority of the cancers amenable to early detection are diagnosed in late stages, the establishment of an *early diagnosis* programme may be the most feasible strategy to reduce the proportion of patients presenting with late stage cancer and improve survival rates.

Several countries have introduced national cancer early detection plans that provide good models of how to proceed. For examples, see http://www.who.int/cancer/modules/en/index.html

"I DON'T WANT ANYONE TO DIE WHEN GOD HAS PROVIDED AN OPPORTUNITY FOR US TO LIVE LONGER."

Dawn, 32 years old, Kenya

her story

Dawn learned from the health worker that cervical cancer affects women over 30 years of age and is preventable if detected through a screening test and treated early.

The community worker gave Dawn a card and told her where she should go to have a screening test. After the examination, the nurses told Dawn that they had detected a lesion and that she needed to go for further analysis and treatment at the district hospital in Busia. After about a month, Dawn was able to save enough money to get to the hospital.

At the Busia Hospital, the diagnosis of a precancerous lesion of the uterine cervix was confirmed. Dawn was given a second appointment for treatment and she was asked to return for follow-up care to ensure that the treatment had worked and that the site was healing.

Now one year after her follow-up appointment, when the nurses assured her she was fine, Dawn has begun to speak publicly about her experience, wherever an opportunity arises. Her courage has had an impact; women she has spoken to have followed her advice and have been tested. "At least 10 of them have turned out to be positive, and many more are now going for check-ups." Dawn is happy to be helping others. "I don't want anyone to die when God has provided an opportunity for us to live longer," she says.

As illustrated in Dawn's story, families and communities play an important role in cervical cancer prevention. Understanding and support from family members and communities are critical to women's participation.

In Kenya, the Alliance for Cervical Cancer Prevention (ACCP) has worked with several local organizations and the Kenyan Ministry of Health on the Western Kenya Cervical Cancer Prevention Project, which among other activities, has developed and evaluated a model cervical cancer prevention programme for rural, low-resource settings in Africa that can be integrated into the existing health system.

Source: Alliance for Cervical Cancer Prevention (2004). *Women's stories, women's lives: Experiences with cervical cancer screening and treatment.* Alliance for Cervical Cancer Prevention (http://www.path.org/files/RH_womens_stories.pdf, accessed 4 October 2007).

For more information on ACCP's work and publications, visit www.alliance-cxca.org or www.rho.org.

A *screening programme* is a far more complex undertaking than an *early diagnosis* programme. In a screening programme:

- An effective test needs to be applied to over 70% of the population at risk.
- All the necessary infrastructure and resources have to be in place for offering the test periodically and adequately treating those found to have cancer or a precancerous lesion. In addition, mechanisms for systematic follow-up and the corresponding services should be available for the different population subgroups that are identified as having cancer by the screening test.
- Organized screening is much more cost-effective than unorganized or opportunistic screening.
- Organized screening causes less harm than opportunistic screening, because it avoids over-screening and over-treatment.

IS A NEW OR UPDATED EARLY DETECTION COMPONENT NEEDED?

The decision to include early detection as part of a comprehensive cancer control plan is justified if:

- cancers amenable to early detection (see Table 1) are frequent;
- high proportions of cancer patients present in advanced stages;
- cost-effective, affordable and acceptable early detection methods are available and easily accessible for the majority of the at-risk group;
- diagnosis, treatment, follow-up and quality assurance procedures can be implemented at the appropriate levels of care;
- the benefits of early detection outweigh the disadvantages, in terms of complications and harmful effects.

Figure 1 illustrates the decision tree for developing an early detection component within a cancer control plan.

Figure 1. How to decide if an early detection component is needed within a cancer control plan

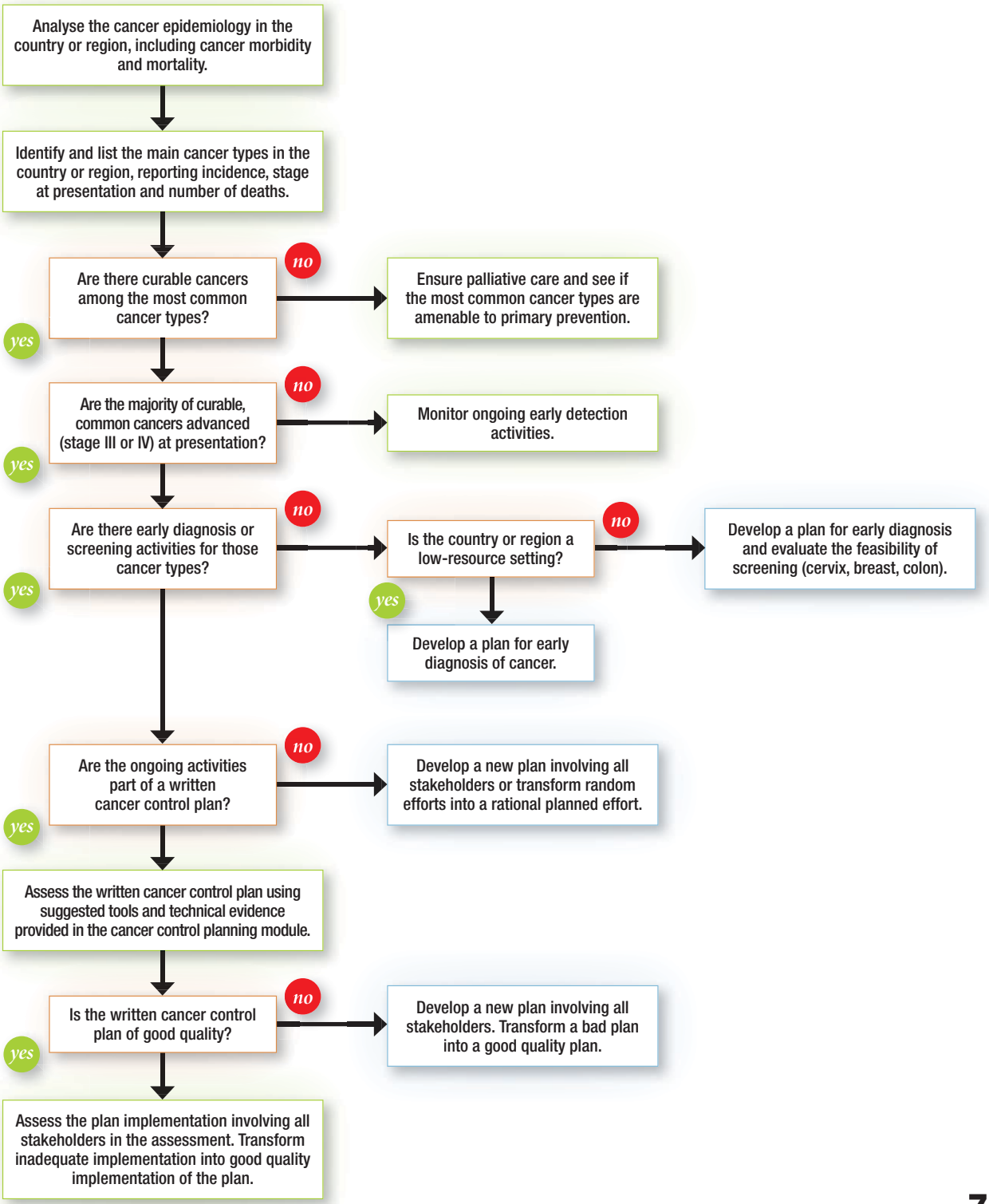


Table 1 lists the cancers for which *early diagnosis* is applicable. It also indicates those few cancers for which *screening* programmes would be appropriate, provided that resources are available to cover the costs of reaching a high proportion of the target population, the costs of the tests and the costs of diagnosis and management of the abnormalities identified. Early diagnosis is not recommended where there is currently no evidence that it will make a difference to survival rates, although patients with symptoms might benefit from early diagnosis through less morbidity after treatment. Table 2 lists the signs and symptoms associated with cancers suitable for early diagnosis.

Table 1. Recommended activities for early detection of selected cancers

Site of cancer	Activities for	
	Early diagnosis	Screening
Breast	Yes	Yes[a]
Cervix	Yes	Yes
Colon and rectum	Yes	Yes[b]
Oral cavity	Yes	Yes
Naso-pharynx	Yes	No
Larynx	Yes	No
Lung	No	No
Oesophagus	No	No
Stomach	Yes	No
Skin melanoma	Yes	No
Other skin cancers	Yes	No
Ovary	No	No
Urinary bladder	Yes	No
Prostate	Yes	No
Retinoblastoma	Yes	No
Testis	Yes	No

[a] Screening for breast cancer using mammography is recommended in high-resource settings only.
[b] In high-resource settings only.

Table 2. Signs and symptoms associated with cancers suitable for early diagnosis

Site of cancer	Common symptoms
Breast	Lump in the breast, asymmetry, skin retraction, recent nipple retraction, blood stained nipple discharge, eczematous changes in areola
Cervix	Post-coital bleeding, excessive vaginal discharge
Colon and rectum	Change in bowel habits, unexplained weight loss, anaemia, blood in the stool (rectal cancer)
Oral cavity	White lesions (leukoplakia) or red lesions (erythroplakia), growth or ulceration in mouth
Naso-pharynx	Nosebleed, permanent blocked nose, deafness, nodes in upper part of the neck
Larynx	Persistent hoarseness of voice
Stomach	Upper abdominal pain, recent onset of indigestion, weight loss
Skin melanoma	Brown lesion that is growing with irregular borders or areas of patchy colouration that may itch or bleed
Other skin cancers	Keratosis (lesion or sore on skin that does not heal)
Urinary bladder	Pain, frequent and uneasy urination, blood in urine
Prostate	Difficulty (long time) in urination, frequent nocturnal urination
Retinoblastoma	White spot in the pupil, convergent strabismus (in a child)
Testis	Swelling of one testicle (asymmetry)

PLANNING STEP 1

Where are we now?

The *Planning* module provides an overview of what to assess in relation to the overall cancer needs in the general population, and in the groups particularly at risk, and also the existing cancer control plan and services for responding to those needs. This *Early detection* module provides more detailed information on what to assess in terms of those cancers that are amenable to early detection. It also discusses how to assess the existing plan and services for early detection.

ASSESS THE CANCER BURDEN AMENABLE TO EARLY DETECTION

Assessing the cancer types amenable to early detection is in many ways equivalent to assessing the potential for curing cancer. This assessment provides responses to the following key questions:

- What proportion of all cancer cases are amenable to early detection, and therefore, are potentially curable?
- Which are the most frequent cancer types amenable to early detection?
- For each frequent cancer type amenable to early detection:
  - What are the age, sex and geographical disparities in incidence, stage distribution, mortality and survival?
  - What is the level of awareness in the population that the cancer can be detected early?

Table 3 provides a template for organizing data gathered as a result of the assessment. This can guide as to which cancer types should get prioirity and be included in the early detection plan (see pages 14–15 of the *Planning* module for possible data sources).

Table 3. The burden of cancers amenable to early detection: what to assess

Cancer amenable to early detection	Incidence	Stage and diagnosis	Survival	Mortality	Awareness
Breast					
Cervix					
Colon and rectum					
Oral cavity					
Naso-pharynx					
Larynx					
Stomach					
Skin melanoma					
Other skin cancers					
Urinary bladder					
Prostate					
Retinoblastoma					
Testis					
All cancers					

Various methods can be used to assess awareness of early detection of cancer, including surveys using semi-structured questionnaires and focus groups.

For examples of tools to assess awareness about early detection of cancer, see
http://www.who.int/cancer/modules/en/index.html

ASSESS THE EXISTING EARLY DETECTION PLAN AND CURRENT ACTIVITIES

Table 4 shows what to assess regarding an existing plan for early detection of cancer, and related activities.

Table 4. The early detection plan for cancer and related activities: what to assess

Plan and activities	What to assess
Early detection plan	○ Endorsement of the plan and scope (geographical area and cancer sites included) ○ Whether or not part of a comprehensive cancer control plan ○ Timeliness (updated/outdated) ○ Accessibility to the written plan ○ Stakeholder involvement in plan development ○ Inclusion of critical sections of the plan (assessments, goals and objectives, strategies, timetable, responsible persons, resources, monitoring and evaluation) ○ Comprehensiveness and priorities (objectives and actions related to early detection, diagnosis and treatment of frequent early detectable cancers) ○ Integration with the plan for noncommunicable diseases and other related problems ○ Utility of the plan (used to guide programme implementation)
Ongoing early detection activities and services	○ Number and type of early detection programmes and related services offered ○ Coverage of ongoing early detection activities ○ Quality of ongoing early detection activities ○ Integration of ongoing activities with those for noncommunicable diseases and other related problems ○ Evaluation of outcomes, output and process indicators, and trends
Resources of ongoing early detection activities and services	○ Information systems (cancer registries, surveillance of early detection programme) ○ Protocols, guidelines, manuals, educational materials etc. ○ Physical resources (infrastructure, technologies, medications) ○ Human resources (leaders, councils, committees, health-care networks, health-care providers, partners, traditional healers) ○ Financial resources ○ Regulations and legislation
Context of the early detection plan and activities	○ SWOT analysis: **s**trengths and **w**eaknesses of the cancer early detection programme, **o**pportunities to improve the performance of the programme, and **t**hreats to achieving the programme's objectives

An early detection programme is a complex system comprising of various components interacting at different levels (i.e. at the community, primary, secondary and tertiary health care levels). It is embedded in a specific socioeconomic and cultural context. At the same time, early detection is a subsystem of a broader cancer control programme and is interrelated with other programmes and initiatives.

As mentioned in the previous section on pre-planning, screening programmes are far more complex than early diagnosis programmes (refer Page 6). This is illustrated, in the case of cervical cancer, by comparing the systems required for the early diagnosis (Figure 2) with those for cytology screening (Figure 3).

Figure 2. Early diagnosis of cervical cancer

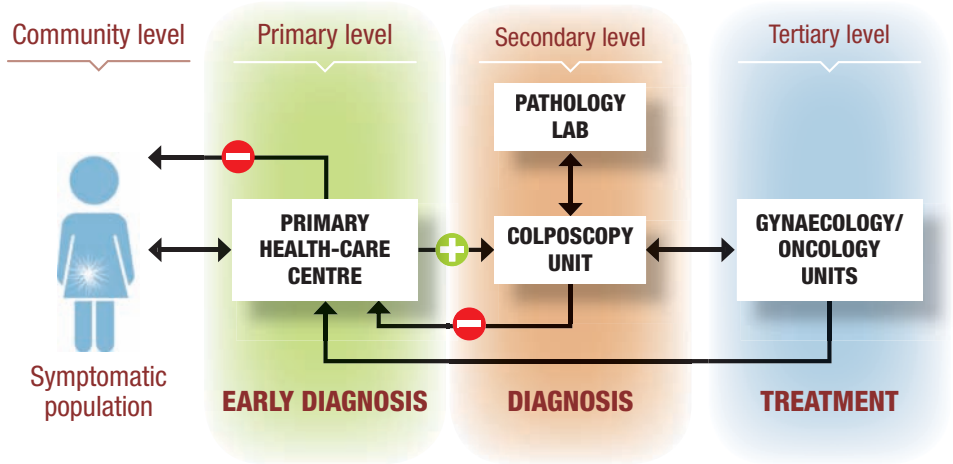
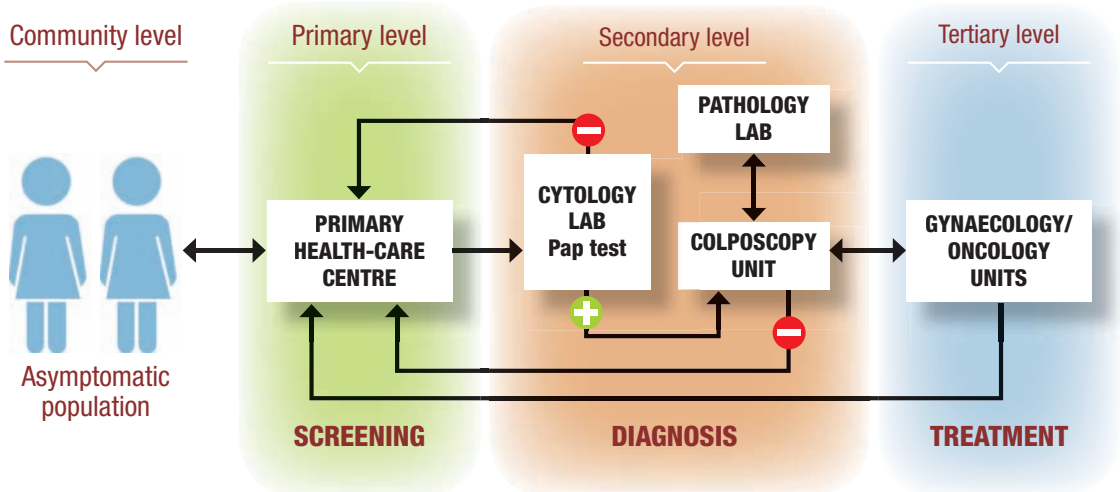


Figure 3. Cytology screening for cervical cancer



In assessing the existing early detection plan and current activities, the focus should be on the gap between what is needed and what is currently available. Start by asking the following questions:

WHAT EARLY DETECTION PROGRAMMES AND RELATED SERVICES ALREADY EXIST?

- Are there early detection programmes for one or more cancer types? How are they organized?
- What is the target population for each early detection programme? Does it correspond to the age group at risk?
- What methods are carried out for early diagnosis and screening for specific cancer types in the target population?
- How often are people tested? What proportion of the target population is covered?
- Are there education programmes to raise awareness among the public and health-care professionals about early detection of specific cancers?
- Is there a system for regular monitoring and evaluation? Does it include quality control of early detection tests, and of diagnostic, treatment and follow-up methods?

HOW WELL DO EARLY DETECTION PROGRAMMES PERFORM?

For each early detection programme, it is important to ask if measures of service delivery quality have been established and monitored. Quality can be assessed through a system model of inputs, processes, outputs and outcomes (short-, medium- and long-term). Quality can also be assessed using a continuous improvement framework based on a number of quality dimensions. These dimensions can be explored through questions such as:

- Are all the services of the early detection programme *accessible* (to ensure coverage and timeliness) to the target population?
- Are the services *acceptable* (satisfying providers and patients) and *appropriate* (based on established standards) for the target groups?
- Are the *competencies* (knowledge and skills) of providers appropriate for the services needed?
- Is there *continuity* (integration, coordination and ease of moving forward) in the activities of early detection programmes?
- Are the early detection services *safe* for providers, patients and the environment?
- Are the early detection programmes *effective* (do they improve health status) and *efficient* (do they produce best results at lowest cost)?

ASSESS THE EFFECTIVENESS OF EARLY DETECTION PROGRAMMES

In the *short term*, an effective early detection programme is expected to increase the proportion of cancer cases that are diagnosed at earlier stages.

A high proportion of the target cancers should be detected by screening. For example, for breast cancer, diagnosis at an earlier stage would imply a decrease in the mean diameter of breast cancers, say from 5 cm to 3 cm at the time of presentation. Also, if a high proportion of breast cancers are detected by screening, few cases of breast cancer would occur in the intervals between screens.

In the *medium term*, an effective early detection programme is expected to show improvement in 5-year survival of people with the targeted cancers. It should be noted that increases in survival over time may reflect the benefits of early detection or improved treatment or both, but they may also result from lead-time bias, length bias, selection bias and over-diagnosis, all of which occur as a result of screening (Miller, 1996).

In the *long term*, an effective early detection programme with extensive coverage is expected to decrease mortality from the targeted cancer sites.

If a screening programme is in place, the incidence of targeted cancer sites that have precursor lesions will be decreased. For example, in the case of cervical cancer, early diagnosis should reduce the prevalence of advanced disease and, provided that effective treatment is given, reduce mortality. If a screening programme is in place, this should be able to identify precursor lesions prior to their developing into an invasive cancer. Initially, cervical cancer screening produces a temporary increase in incidence because cancers have been diagnosed that would not otherwise have been detected clinically. Then the incidence begins to decline as a result of the removal of precursor lesions, and after some years, there is a decline in the mortality rate.

DEFINITIONS

Lead-time bias: The time by which screening brings forward diagnosis. Thus, early diagnosis of the disease falsely appears to prolong survival time, when in fact, no additional life has been gained.

Length bias: Screening is performed intermittently; therefore it tends not to detect severe disease (which progresses rapidly) and therefore over-represents less aggressive, less deadly, disease.

Selection bias: People volunteer to be screened. Those who do, tend to be health conscious, and more likely to seek early detection if they develop symptoms.

Overdiagnosis: The detection of cancers not destined to present clinically in that person's lifetime.

ASSESS THE EFFICIENCY OF EARLY DETECTION PROGRAMMES

Early detection programmes, even with the same level of resources, can achieve very different results. For this reason, it is important to examine how well a particular programme is doing, given the resources available to it. Questions that need to be asked to assess the efficiency of early detection programmes are shown in Table 5.

ASSESS PATIENT SAFETY IN EARLY DETECTION PROGRAMMES

Patient safety is achieved by avoiding, preventing or ameliorating adverse outcomes or injuries stemming from the processes of health care (WHO, 2005). In the United States of America, the National Cancer Institute has recommended common terminology criteria for adverse events, applicable to all oncology clinical trials regardless of chronicity or modality. This terminology is useful in assessing the safety of all health-care interventions (National Cancer Institute, 2003).

For more information on patient saftey issues, see
http://www.who.int/patientsafety/reporting_and_learning/en/

To assess whether an early detection programme is safe in a country or region, it is useful to answer the following questions:

HOW MANY PEOPLE EXPERIENCE MEDICAL ERRORS OR SUFFER INJURIES ASSOCIATED WITH THE DELIVERY OF HEALTH CARE RELATED TO EARLY DETECTION DURING A YEAR?

In answering this question, it is important to consider complications of tests and treatment, medication errors, side-effects of medications, critical incidents, psychosocial consequences of tests, and quality-of-life issues.

WHAT EFFORTS ARE BEING MADE TO ACHIEVE PATIENT SAFETY ASSOCIATED WITH THE DELIVERY OF HEALTH CARE RELATED TO EARLY DETECTION?

- Is there a system to identify medical errors and causes of patient injury?
- Are practices being implemented to eliminate medical errors and systems-related risks and hazards?

Table 5. Examples of questions to help assess the efficiency of the early detection component of a cancer control programme

Efficiency measure	Basic question(s)	Additional questions	Reference to best practice
Technical efficiency (using given resources to maximum advantage)	Could we produce the same outcome with fewer resources?	○ Are early detection services directed at the wrong target groups? For example, are programmes on cervical cancer directed at women less than 25 years old? ○ Do we test too frequently? For example, with cervical cytology, annual testing is not needed. ○ Are staff inadequately trained or performing poorly? ○ Is equipment inadequate for use in testing or treatment? ○ Are some facilities or supplies not being fully used? ○ Is there available information that is not being used? If the answer is yes to any of these questions, the programme is inefficient.	WHO, 2006 IARC, 2005
Productive efficiency (choosing different combinations of resources to achieve the maximum health benefit for a given cost)	Could we improve the health outcome for the same cost?	○ Do we reallocate the available resources within the early detection programme to obtain better outcomes? ○ Do we complete the diagnostic, treatment and follow up protocol in persons found to have cancer or precancerous lesions? ○ Do we develop and maintain the performance of health workers? ○ Do we maintain workload of the involved facilities between the minimum and maximum standards? ○ Do we monitor tests using quality assurance? If the answer is yes to all of these questions, the programme is efficient.	WHO, 2006
	Could we reduce costs and still achieve the same health outcome?	According to the evidence, are we using the most cost-effective: ○ screening tests? ○ diagnostic tests? ○ treatment options? ○ follow-up options? ○ health workers? ○ strategies to empower the target groups to take more responsibility for action? ○ strategies to reach the target groups? ○ strategies to reach people with abnormal results and refer them for further investigations? ○ strategies to follow up the patients who have been treated? ○ strategies to improve the performance of health workers? ○ strategies for quality control? If the answer is yes to all of these questions, the programme is efficient.	Legood et al., 2005 Rojas et al., 2005
Allocative efficiency (achieving the right mixture of health-care programmes to maximize the health of society)	Could we come closer to maximizing the health of society?	○ What are the most cost-effective health interventions for the population? ○ What is the cost-effectiveness of cancer prevention versus cancer early diagnosis? ○ What is the cost-effectiveness of cancer prevention versus cancer screening? If you can answer all of these questions, the planning of the programme has been efficient.	Jha et al., 1998

ASSESS CUSTOMER SATISFACTION WITH EARLY DETECTION PROGRAMMES

Customer satisfaction is the state of mind that customers (patients and their families) have when their expectations about health services have been met or exceeded. Customer satisfaction is subjective.

To know whether an early detection programme for cancer is producing customer satisfaction, it is useful to answer the following questions:

- Do patients comply with the diagnostic tests, treatment and follow-up?
- Is customer satisfaction improving over time?
- How many formal complaints have been received?
- What are customers' preferences, needs and requirements?
- Are the services designed to meet customers' preferences, needs and requirements?

THE PHILIPPINES

Evaluation of breast screening

In 1996, the Department of Health, in collaboration with the International Agency for Research on Cancer, initiated a large randomized trial of screening for breast cancer by physical examination among women aged 35 years or older in the Philippines. Women residents in 12 of the municipalities of metropolitan Manila were offered an examination performed by trained nurses at health centres. If detected positive, they were referred to one of the three tumour clinics that had been set up for the management of project cases. The cost of the whole diagnostic process was covered by the project.

Though screening was well received, only 40% of women who were detected as positive reported to the tumour clinics, even after a second home visit. The cost of treatment, lack of trust in the health system and fear of a disease still largely perceived as fatal, were the main reasons given for refusing clinical follow-up. The intervention that was planned to last for five annual examinations was therefore discontinued after the completion of the first round of screening.

The project nevertheless showed that a good quality programme could be provided with affordable and sustainable investments, even in the context of limited resources. It suggested that improved cancer care could affect outcome. After 2 years of follow-up, the median survival of women who were screened and in whom breast cancer was detected was 13.4 months, significantly greater than the median survival of refusers (6.0 months) and of symptomatic cases diagnosed in the control areas (3.9 months).

Source: Pisani P et al. (2006). Outcome of screening by clinical examination of the breast in a trial in the Philippines. *International Journal of Cancer*, 118:149–154.

People attend early detection services seeking reassurance. They wish to be told that they do not have cancer. They do not seek a cancer diagnosis as a reward for agreeing to have a test. Therefore, if they are informed that they have an abnormal finding, they may not necessarily consent to further investigation. This response was clearly seen in the Philippines breast-screening trial (see Box), and has also been documented in other settings. These findings suggest that at the time an abnormality is detected, major endeavours may be needed to persuade people to undergo further investigations. The difficulty of persuading people to comply with diagnostic tests, treatment and follow-up is often greatest in cultures where cancer is regarded as inevitably fatal.

Sometimes, physicians share the pessimism of their patients regarding the curability of cancer. This is one of the main reasons why programmes fail. Also, people may believe that modern medicine has no cure for cancer, so prefer to go to traditional healers, faith-based healers or practitioners of alternative medicine. It is essential, therefore, for early detection programmes to be preceded by a campaign to educate the public and professionals. As early detection programmes penetrate a population, information on their impact tends to be disseminated. Responses to invitations to be screened and acceptance of diagnostic tests tends to improve as a programme begins to demonstrate its success. This was seen, for example, in a research project on breast-screening in Cairo (Boulos et al., 2005).

SELF-ASSESSMENT BY COUNTRIES

WHO has developed a set of self-assessment tools for assessing population cancer needs and existing services in countries. The tools, which operate at different levels of complexity, are described in the *Planning* module.

Self-assessment tools, which can be adapted to country circumstances, are available at
http://www.who.int/cancer/modules/en/index.html
The WHO cancer web site also provides links to sources containing more specific tools for assessing the need and services for early detection of different cancer types.

PLANNING STEP 2
Where do we want to be?

The assessment (planning step 1) identifies existing services, as well as data and knowledge, with regard to the burden of cancers amenable to early detection and the population at risk.

The next step is to consider what *could* be done, given limited resources and capacity, in order to answer the question: Where do we want to be?

DEFINE THE TARGET POPULATION FOR EARLY DETECTION OF FREQUENT CANCERS

The selection of the target population for an early detection plan depends on the burden of cancers amenable to early detection, and the natural history of the disease.

In *early diagnosis programmes*, the target population will be all patients of a certain age group and sex, prone to developing a specific cancer, and presenting with early signs and symptoms suggesting that cancer. For example, in the case of retinoblastoma, the target population would be all children presenting with a white spot in the pupil and convergent strabismus. In the case of breast cancer, it would be women over 35 years of age presenting with a lump in the breast. Women aged 20–34 years with a strong family history of breast cancer should also be included. It is not justifiable to raise awareness in normal-risk women aged less than 35 years because breast cancer is very rare among this subgroup, and any lump in the breast will most probably be a benign tumour.

In *screening programmes*, it is rarely justifiable to screen people of all ages. For example, screening for cervical cancer is recommended for women from the age of 30 years and, when resources permit, for women aged 25 years and above. Screening is not necessary for women over 65 years, provided the last two smears were negative. (WHO, 2006). For breast cancer, sufficient evidence of efficacy is available only for mammography screening of women aged 50–69 years. However, several countries have chosen to evaluate screening for breast cancer for women using other approaches such as clinical breast examination, from the age of 35 or 40 years (see Table 7). Only for colorectal cancer, is there evidence to support screening for men, but this is recommended only for high-resource settings.

Screening that concentrates solely on "high-risk groups" is rarely justified, as a high proportion of cancer patients do not have identifiable risk factors. For example, in breast cancer, it is possible to identify known risk factors only in less than 30% of cases. However, in planning the coverage of screening programmes, measures must be introduced to ensure that all those at high risk are included. This is particularly important for cervical cancer screening.

The *frequency of screening*, that is to say, how often those who test negative should be invited to return for re-screening, is an important decision in the planning of any screening programme. In the past, it was the norm to advise annual screening. Increasingly, however, it has been recognized that the frequency of re-screening should depend upon the natural history of the disease, as well as the resources available in the country. For example, three screens in a lifetime, at ages 35, 45 and 55 years, will produce a substantial effect in the case of cervical cancer (IARC, 2005).

For further information on breast, cervical and oral cancer screening, see
http://screening.iarc.fr/

IDENTIFY GAPS IN EARLY DETECTION SERVICES

Based on the assessment, gaps in early detection services can be identified (present state versus desired state) and potential corrective interventions considered.

It is important to assess both the impact of early detection interventions previously implemented in the target population, and the effect of interventions that have been successfully applied elsewhere, particularly in similar socioeconomic and cultural settings. For example, in a country where resources are constrained and if the majority of breast cancer patients are presenting in advanced stages, the introduction of a well-organized early diagnosis programme could, in the long-term, significantly improve survival and reduce mortality from breast cancer.

SET OBJECTIVES FOR EARLY DIAGNOSIS AND SCREENING

Objectives should respond to the needs of the population and should be directly related to the gaps in services identified. For the early detection plan to be effective, all process and outcome objectives need to promote the common goal of reducing mortality from the most frequent cancers amenable to early detection.

Table 6 provides examples of short-, medium- and long-term objectives of an early detection programme according to level of resources.

Table 6. Examples of short-, medium- and long-term objectives of an early detection programme using WHO's stepwise approach

Component	Core	Expanded	Desirable
Overall goal	○ To reduce incidence of advanced cancer and mortality, and improve quality of life ○ To ensure that prioritized early detection services are provided in an integrated, equitable and sustainable way		
Short-term process and outcome objectives (within 5 years)	○ To increase to over 80% the awareness of early signs and symptoms of cervical and breast cancers among patients and health-care providers ○ To achieve, through the early detection strategy, early referral and prompt treatment in specialized clinics for over 80% of cervical and breast cancer patients ○ To reduce late presentation at diagnosis by 50% in women with cervical and breast cancers	○ To increase to over 90% the awareness of early signs and symptoms of all cancer cases amenable to early diagnosis ○ To achieve, through the early detection strategy, early referral and prompt treatment in specialized clinics for over 90% of all people with cancer ○ To achieve 80% coverage in women over 35 years old with Pap smear testing every 5 years	○ To ensure that all women with abnormal mammograms are referred and get prompt diagnosis and treatment in specialized clinics ○ To achieve over 70% coverage of women over 50 years old with mammography screening every 2 years ○ To reduce late presentation at diagnosis to less than 10% in women with cervical and breast cancers
Medium-term outcome objectives (5–10 years)	○ To increase by 30% the 5-year survival of patients with cervical and breast cancer	○ To increase by 50% the 5-year survival of patients with cervical and breast cancer	○ To reduce the proportion of patients with breast cancer presenting with advanced (stage III or IV) disease to 30%
Long-term outcome objectives (10–15 years)	○ To reduce by 20%, through early diagnosis, the mortality from cervical and breast cancers	○ To reduce by 30% the mortality of all cancer cases amenable to early diagnosis ○ To reduce by 60% the mortality from cervical cancer	○ To reduce by 30% the mortality from breast cancer

Note: The terms "core", "expanded" and "desirable" refer to the WHO's stepwise approach (see page vi for a description of the WHO stepwise framework for chronic diseases prevention and control, as applied to cancer control).

ASSESS FEASIBILITY OF EARLY DETECTION INTERVENTIONS

The feasibility of early detection for a given population depends on the skills and infrastructure available, the knowledge and attitudes of the target population, and the motivation of the government and health-care providers.

In order for an early detection programme to be effective, it should deliver good quality services (early detection, diagnosis, treatment and follow-up) equitably and indefinitely to all members of the target population.

Some resource-constrained countries with a high proportion of patients presenting with cervical cancer in advanced stages have, instead of introducing low-cost interventions, such as early diagnosis which could be offered to the whole population, opted to invest in cytology screening for cervical cancer, even though such an intervention serves only a small percentage of the population.

It is particularly important to investigate the feasibility of a cancer screening programme in view of its complexity and because its introduction requires the provision of new resources. A good screening programme might eventually reduce health-care costs related to a specific cancer, but the overall cost of health care is unlikely to be reduced because screening has to be provided to large numbers of people. Could the new resources required for screening be better spent on another aspect of cancer control, or on another aspect of health care? Any proposal for cancer screening should be assessed in conjunction with national planning for cancer control and overall planning for health care (WHO, 2002).

A disease is suitable for screening if:

- the disease is an important health problem justifying the effort of screening;
- the asymptomatic phase is a long enough for the disease to be detectable during that period;
- a significant proportion of lesions found in this asymptomatic preclinical phase will progress to become clinical lesions;
- an acceptable treatment is available which could, with earlier diagnosis, improve a patient's prognosis;
- screening tests that detect the condition in the asymptomatic period and are acceptable to patients are available at reasonable cost.

ADDRESS ETHICAL ASPECTS

Ethical issues that should be addressed in an early detection programme include the following:

- All the target population should have equal access to the early detection programme. Vulnerable and marginalized populations, who may comprise those at greatest risk, are unlikely to be included unless the programme is well organized and fully funded.
- In the case of screening, if the test is inefficiently administered, there is a risk that those who truly have the disease will be missed (false negatives), and that those who do not have the disease will be wrongly categorized as having the disease (false positives). For the false negatives, there will be a delay in diagnosis and treatment. For the false positives, there will be a risk of harm from unnecessary diagnostic tests and treatment. Efforts should be made to minimize these risks. Before introducing a screening programme, the risks should be carefully weighed against the potential benefits of the programme.
- The introduction of screening may result in the transfer of resources to the screening programme from other health services. The allocation of scarce resources to screening programmes has therefore to be planned with regard to other pressing health needs.
- Those with an abnormal screening test or examination require diagnosis and treatment. It is unethical to offer early detection services if appropriate diagnosis and treatment are unavailable.

SET PRIORITIES FOR EARLY DETECTION

It is essential to set priorities, because resources will never be able to meet all health needs. Careful priority setting is particularly important where resources are constrained, because of the need to make the best use of very limited resources. The criteria for selecting priorities will need to be discussed by the committee steering the overall cancer control planning process.

The following steps are recommended for prioritizing strategies for the early detection of cancer:

- First choose the target cancer types amenable to early detection (see Table 1), according to:
  - the burden they represent in terms of mortality and morbidity;
  - the proportion of cases in advanced stages;
  - the societal impact of the disease (e.g. whether the disease affects relatively young people).
- Then for each selected cancer site, choose the type of early detection strategy according to:
  - cost-effectiveness;
  - affordability;
  - sustainability;
  - political attractiveness.

Information on cost-effectiveness of some cancer interventions can be accessed at http://www.who.int/choice/en/

CHOOSING BETWEEN EARLY DIAGNOSIS AND SCREENING

There are far fewer individuals with symptomatic cancers than there are asymptomatic individuals who would have to be included in a cancer screening programme. Therefore, where resources are scarce, it will initially be more cost-effective to concentrate on early diagnosis of symptomatic individuals, rather than on screening of asymptomatic people. This is particularly true for populations with a high proportion of people with advanced cancers that are amenable to early diagnosis. However, given a higher level of resources, a combination of early diagnosis and low-cost screening is a reasonable approach.

At present, the only cancers for which there is good evidence that screening can reduce mortality are breast, cervix, colorectum and, possibly, oral cancer (Sankaranarayanan et al., 2005). In most low-resource countries, low-cost approaches to screening for breast and cervical cancer are the only screening activities likely to be considered (see Table 7). Because cervix screening is much more effective than breast screening, placing a higher priority on screening for breast cancer is justifiable only if breast cancer occurs at least three times more frequently than cervical cancer.

The cancers for which *prophylactic vaccines* are available are liver and uterine cervix cancer. Programmes of vaccination against hepatitis B virus will reduce liver cancer incidence, and are strongly supported by WHO. In the case of cervical cancer, even if vaccination against human papilloma virus is widely introduced for young women, prior to infection, the full effect of the vaccine will be seen only when the vaccinated population reaches the age of maximum risk for cervical cancer (50 years or more), as discussed in the *Prevention* module. Hence, for at least the next 30 years, early detection programmes for cervical cancer will continue to be required (WHO, 2006).

Table 7 provides a summary of the latest international recommendations on screening for breast and cervix cancer.

Table 7. Evidence on the efficacy of screening for breast and cervix cancers

Site of cancer	Evidence	Reference
Breast	There is *sufficient evidence* that inviting women aged 50–69 years for screening by mammography alone reduces mortality from breast cancer. In the trials in which the efficacy of screening women aged 50–69 years was established, screening was offered at least every 24 months. There is *limited evidence* that inviting women aged 40–49 years for screening by mammography alone reduces mortality from breast cancer. Generally speaking, clinical breast examination as a screening modality, administered by trained health professionals, should only be used in trials or demonstration projects. However, clinical breast examination may be of particular importance in countries where there are insufficient resources for mammography and where disease is usually at an advanced stage at the time of diagnosis. Research on this is already being conducted and further information may become available.	IARC, 2002 Boulos et al., 2005
Cervix	There is *sufficient evidence* that screening of women between the ages of 35 and 64 years for cervical cancer precursors every 3–5 years by conventional cytology reduces the incidence and mortality of cervical cancer. In women aged 25–34 years, screening at intervals of 3 years or less may have a smaller impact. There is no evidence that screening annually in either age group results in significantly greater efficacy. There is *sufficient evidence,* based on surrogate markers, that testing for human papilloma virus, using a validated system as the primary screening modality, can be expected to be at least as good as conventional cytology. To avoid the problems associated with low specificity at young ages, it is undesirable to offer such methods of screening to women under the age of 35 years. There is *limited evidence* that screening by visual inspection with application of acetic acid or Lugol's iodine can reduce cervical cancer incidence and mortality rates. Long-term information on the effectiveness of visual inspection with acetic acid application (VIA) is not yet available. It is being evaluated in several studies. It is thus recommended that VIA should be used only under circumstances where its impact can be evaluated. A significant reduction in cervical cancer incidence and mortality following a single round of VIA screening by nurses has been demonstrated in one randomized trial. Programme managers should be aware that further information on visual methods will become available in the near future.	IARC, 2005 Sankaranarayanan et al. 2007

In summary, an early detection programme for cancer should be a priority in countries or regions where:

- the target disease is a common form of cancer, with high associated morbidity or mortality;
- the common cancers are amenable to early diagnosis or, for some types, to screening (see Table 1);
- primary prevention measures are not widely accessible to the at-risk population – or will not prevent the problem for several decades (e.g. human papilloma virus vaccine);
- the early detection tests are cost-effective, affordable, acceptable, safe and accessible to the whole target population;
- diagnosis, treatment and follow-up procedures are cost-effective, affordable, acceptable, safe and accessible to everyone who tests positive;
- a quality control programme can be organized to ensure high accuracy and efficiency of testing and treatment;
- there is political will to support the programme in the long term for the whole target population.

Many countries do not have the resources to introduce breast and cervix screening in accordance with the recommendations given in Table 7. The box on Tunisia describes how this middle-income country addressed this problem.

TUNISIA

Early detection of breast and cervical cancer

Tunisia is in "epidemiological transition"; infectious diseases are decreasing sharply, while chronic diseases (cardiovascular diseases, diabetes and cancer) are becoming predominant. The predominant cancers are lung (24%) and bladder (10%) in men, and breast (27%) and cervix (6.7%) in women.

Only three public facilities (in Tunis, Sousse and Sfax) are equipped with a radiotherapy unit, and there are a further three private radiotherapy units in the country. The Salah Azaiz Institute (ISA) in Tunis, created in 1969, is the only one with complete high-level technical and surgical capacity for cancer treatment. The low number of specialized units has resulted in late diagnoses and treatment of the majority of cancer cases. For example, the mean diameter of breast cancer being treated at the ISA is still roughly 34 mm, decreasing from 50 mm in 1985, and 22.5% are diagnosed at a metastatic stage.

In these circumstances, improving early diagnosis is a key element for a successful cancer control programme. The Office National de la Famille et de la Population (ONFP) has therefore decided to organize, at national level, a *breast and cervical cancer* early detection programme (Oberti, 2004). The ONFP, which is largely responsible for reproductive health, has 43 regional centres, 622 basic health-care centres and 13 mobile clinics, with 340 educators and coordinators, 212 midwives, 30 general practitioners and 39 gynaecologists. The ONFP has set up a training centre to teach smear-taking of the cervix and palpation of the breast.

The incidence of *cervical cancer* remains relatively low, but over 30% of cases are diagnosed at stages III and IV. The survival rate at 5 years is 35%. Early detection will be aimed at women aged 35–59 years (a target of 1 980 400 women) and will initially be one smear test a lifetime. After reaching around 60% coverage, the programme will offer a test every 5 years. The smears will be prepared by the doctors and midwives of the ONFP and DSSB centres and departments of gynecology, following training. There will be 24 cytology units with one cyto-technician each. Any positive or doubtful slides will be sent to 9 pathology centres, along with 10% of the negative slides. At present 4 units are open, capable of examining 27 000 smears a year. A quality control programme will be implemented with assistance from pathology laboratories in France. Data will be collected to assess participation, the quality of tests, and the completeness of diagnostic and therapeutic follow-up.

For *breast cancer*, since 94% of currently diagnosed tumours are ≥ 20 mm, the programme will rest on palpation performed every year by trained general practitioners and midwives at ONFP centres. The programme will target women aged 30–69 years. For women under 50 years of age, without familial risk in first-degree relatives, mammography will be performed only when anomalies are detected. For women aged 50 years and over, mammography is proposed every two years, even if palpation is negative, for women with the following risk factors: obesity, no children or first child after the age of 30 years, familial risk, and use of hormone replacement therapy, Indicators of participation, quality control and follow-up will be collected.

Sources: Khemakhem A, Bouzouaia N (2007). *Cancer Control Plan in Tunisia 2006–2010.* Abstract published in the Proceedings of the IXth Seminar on Cancer Prevention, Sousse, Tunisia, 20 April 2007 (Page 10), (adapted with the permission of the authors) and Oberti J (2004). Cancer in Tunisia, inventory project – plan for cancer detection: breast, cervix, 2005–2007. National Family Planning Office.

PLANNING STEP 3

How do we get there?

What can be done with available resources? Having identified objectives for the early detection plan, the next step is to formulate an action plan to achieve them.

A template for developing a detailed action plan is provided at http://www.who.int/cancer/modules/en/index.html

Examples of priority interventions for early detection according to level of resources can be found in the *Planning* module (see Table 8, page 32).

Translating an early detection plan into action requires strong leadership and competent management. It also requires a participatory approach to identify what needs to be done, and in what order. For example, before inviting a target group to be screened, the necessary screening, diagnostic, treatment and follow-up services need to be in place and readily accessible. The aim is to implement feasible and sustainable activities in order to bridge the gaps identified during planning step 2.

BRIDGE THE GAPS

It is important to assess actions to bridge the gaps from the perspective of:

- those who support the actions;
- those who will eventually implement the actions;
- any opponents.

Next, there is a need to identify the key person (or group) with the power to decide on the plan, and see how that person (or group) can be motivated to make planned changes.

Table 8 provides examples of actions to bridge a gap in cancer control in a low-income country. The country has prioritized *early diagnosis* of breast and cervical cancers, and has chosen to implement activities gradually in terms of:

- the *target population* (i.e. the planned activities will initially target the women who present to health-care services, before widening its contact through women's organizations and eventually community outreach schemes (Salas I, 2006)), and
- the *geographical scope* (i.e. the programme will focus effort in a demonstration area before expanding into other areas and, ultimately, the whole country).

WORK AS A TEAM

It is important to make sure that the early detection programme is accessible to the large majority of the target population, and that services are delivered in an equitable manner. This requires a strong network of trained health-care practitioners, with specific roles and functions across the different levels of care. Examination of symptomatic patients or administration of screening tests should be decentralized and easily accessible to target groups. Diagnosis and treatment should take place in specialized centres, where expertise and sophisticated technology are concentrated.

Local managers and health-care providers should work in multidisciplinary teams across the health system. They need to coordinate closely with community leaders to ensure that all entities involved in the programme are working towards a common goal.

A WHO tool to assist in team building is available
http://www.who.int/cancer/modules/en/index.html

Table 8. Examples of actions to bridge identified gaps in cancer control (through early detection) in a low-income country

Health situation	Level of interventions	Key actions	Who has the power to decide on action?	How can the decision-maker be activated?
GAPS (difference between OBSERVED and DESIRED status) **OBSERVED** High mortality from breast and cervical cancer: over 80% of patients are diagnosed in very late stages because of late referral from primary health-care clinics or because women seek health-care late **DESIRED** Reduction in breast and cervical cancer mortality Not more than 20% of cases diagnosed in late stages **STRENGTHS** Existence of specialized diagnostic and treatment facilities, strong primary health-care network and community health initiatives in geographical areas X and Z Nationwide health insurance system under development	**CORE**			
	Using available resources and reorganizing the services to improve early diagnosis	In areas X and Z Elaborate and disseminate standards for early diagnosis, referral, follow-up and clinical management, including pain relief and palliative care Include early detection, diagnostic, treatment and palliative care packages in the health insurance scheme Identify the specific target group, estimate the demand for services and reorient referral mechanisms and diagnostic, treatment and palliative care services to ensure timeliness and quality of actions Train health-care professionals on early signs and symptoms of cancer and introduce adequate referral mechanisms Train health-care professionals to initially reach and educate all women over 35 years old who seek health-care at primary health-care clinics or hospitals (involve men if culturally relevant) Create a basic information system to monitor and evaluate actions at the different levels of care	Local health authorities in areas X and Z, together with leading health-care professionals of relevant sectors supported by national authorities	By providing information on the problem and on possible solutions through personal interactions and meetings with the relevant stakeholders By presenting testimonies of patients and health-care providers
	EXPANDED			
	With some additional resources	Identify partners in the community and develop joint educational strategies for reaching the target women in community areas where they tend to congregate (e.g. schools, community-based organizations, textile factories) Adjust the primary health-care services and the specialized clinical services to meet the estimated increase in demand for services and correct weaknesses identified through the monitoring and evaluation system	Local political and health authorities, health-care and community leaders, and traditional healers, supported by the national authorities	By disseminating the results of the evaluation of previous activities (core) and by advocating for the need to reach more women in the target age group within community organizations
	DESIRABLE			
	With more additional resources	Develop educational strategies and low-cost media campaigns for broad community outreach Monitor the activities and evaluate the results If the evaluation in the target areas is satisfactory, start mobilizing resources to expand activities to the rest of the country	National and local political or health authorities, health-care and community associations and leaders	By disseminating the results of the evaluation of the previous activities (core and expanded) By campaigning to reach all women in the target age group in the whole community By campaigning to expand activities to the rest of the country

CHILE

Example of an effective and innovative reorganization of a cervical cancer programme

The cytology screening programme for cervical cancer was reorganized in Chile in 1987, as part of the WHO Cancer Control Demonstration Project. A key element of the reorganization was the active involvement of health-care leaders and their teams throughout the health-care system. This was done using the "spiral of problem solving" method. This method gives ownership of the process to managers and health professionals through their active participation in planning, implementation, monitoring and evaluation. This innovative approach clearly improved the technical and managerial skills of staff, as well as overall programme management. Staff became more motivated, and felt that they had a role to play in the country in preventing premature deaths and unnecessary suffering.

A few months after the programme was reorganized, the head technician at the central cytology laboratory commented: "Now, whenever I am looking at Pap smears through a microscope, I not only see cells but I also see all the women behind the cells, whom I can help by detecting their cancer early". This type of attitude, along with involvement in the process, has enabled health-care workers to contribute to improving the efficiency and the effectiveness of the cervical cancer screening programme in Chile.

Sources: Sepúlveda C, Prado R (2005). Effective cervical cytology screening programmes in middle income countries: the Chilean experience. *Cancer Detection and Prevention*, 29: 405–411 and Salas I (2006). Methodology for reorganization of the cervical cancer programme in Chile. *Cancer Detection and Prevention*, 30:38–43.

RAISE THE NECESSARY RESOURCES

An early detection plan needs to be accompanied by a resource plan. The resource plan should outline:

- existing resources;
- possible strategies for acquiring the needed resources, from both governmental and nongovernmental sources.

Because of the complexity of undertaking early detection programmes, particularly screening programmes, initially a demonstration project should be introduced in just one area. When experience has been gained and the organizational requirements worked out, the project can be expanded. An informed decision then needs to be taken to initiate or reorganize early diagnosis or screening in the context of a national cancer control programme. In other words, there needs to be the political will to proceed. Support and funding from the ministry of health is essential. A successful programme requires an adequate health-care infrastructure and support from all potential stakeholders. Also, the activities of health-care providers, both in the public and private sectors, have to be coordinated.

To make sure that the necessary human and financial resources are available to implement the early detection plan, the following questions need to be answered:

- What resources are currently dedicated to cancer control?
- What resources are specifically allocated to early detection?
- Besides resources currently being expended on early detection, what else is needed to achieve the objectives of the early detection plan?
- What potential sources (internal and external) of funding or other resources are available to meet these needs?
- How can partners work together to raise funds from government or the private sector?
- How can resources be reallocated or shared to achieve the planned outcomes?

In low-income countries, a large share of scarce resources is often dedicated to ineffective treatment of advanced cancers. Many of these cancers are, however, amenable to early detection. A more effective approach is, therefore, to provide advanced cancer patients with good quality and low-cost palliative care, and to allocate a significant amount of the resources to an early diagnosis programme. This approach will eventually reduce the number of advanced cancers.

For examples of templates for estimating resources needed for early detection programmes, see http://www.who.int/cancer/modules/en/index.html

IMPLEMENT THE ACTIVITIES REQUIRED FOR EARLY DIAGNOSIS AND SCREENING

As previously explained, *early diagnosis* focuses on symptomatic patients, while *screening* focuses on asymptomatic at-risk populations. Early diagnosis programmes can in general be organized in any country. Screening programmes are only possible in settings that can provide an adequate level of resources not only for diagnosis and treatment, but also for the systematic follow-up of those who test positive?

Both early diagnosis and screening require prompt referral for the detected cases, confirmation of diagnosis, and timely treatment. The main difference between the programmes, in relation to resources and activities, derives from the difference in the size of the target population and the need, in case of screening, of a special test (see Figure 3).

EDUCATION

The target population and health-care providers should be continuously educated to understand that cancer, when diagnosed early, is far more likely to respond to effective treatment. This information can be provided within or outside the health facility, by a variety of health workers, community leaders and traditional healers who need to be appropriately trained. In programmes for early detection of cancer in women, it may be necessary for cultural reasons to involve and educate women's partners to ensure that women attend for examination.

Substantial efforts may be needed to dispel the myths, fears and gloom that tend to accompany any consideration of cancer. Health education involves communicating up-to-date general information and messages about changing behaviour to individuals or groups. Although messages have to be based on national guidelines, they need to be adapted locally addressing common social barriers. Messages should be developed in collaboration with the community, and should use simple, understandable language.

The specific educational activities needed will depend on the type of early detection programme chosen, but broadly are as follows:

EARLY DIAGNOSIS

- *Create awareness of early signs and symptoms.* The target population and health-care providers should learn the possible significance of certain signs and symptoms, such as lumps, sores, persistent indigestion or cough, and bleeding from the body's orifices. Table 2 provides a list of curable cancers and the principal warning signs and symptoms.
- *Refer for medical attention, if necessary.* The target population should learn the importance of seeking prompt medical attention, if necessary, at well identified and accessible health-care centres. Health-care providers, particularly primary health care workers and traditional healers, are at the forefront of the initial contact between possible cancer patients and the medical care system. They must be alerted to the signs and symptoms of early cancer, educated to provide counselling and refer the patient to a specialized centre when necessary.

MALAYSIA

A pilot study of early diagnosis in Sarawak

In 1995, an early cancer surveillance programme was started with the intention of promoting the early diagnosis of the three most common cancers in Sarawak: breast, cervix and nasopharyngeal carcinoma. The programme consisted of training health staff in departmental and rural clinics to improve their skills in early cancer diagnosis, and raising public awareness through pamphlets, posters and sensitization by health staff. Community nurses from 154 rural clinics of Sarawak and the health staff from 18 district hospitals were trained for 2 days in the theoretical and practical aspects of nasopharyngeal carcinoma, breast and cervical cancer. Public awareness was achieved by the distribution of pamphlets and posters in various local languages. The aim was to motivate patients to go to the nearest rural clinic if specific symptoms were present. In addition, as part of their routine duties, the community nurses working at rural clinics were instructed to hold health education talks and discussions on the subject during one of their monthly visits to the villages under their jurisdiction. During a four-year follow-up period, the proportion of breast cancers diagnosed in stage III and IV was reduced from 60% (1994) to 35% (1998) [$p<0.0001$]. In the case of cervical cancer, the reduction in late stage diagnosis (in stage III and IV) was greater still, from 60% (1994) to 26% (1998) [$p<0.0001$]. No reduction was observed for nasopharyngeal carcinoma, the corresponding percentages being 88% (1994) and 91% (1998).

Source: Devi BCR, Tang TS, Corbex M (2007). Reducing by half the percentage of late stage presentation for breast and cervix cancer over 4 years: a pilot study of clinical downstaging in Sarawak, Malaysia. *Annals of Oncology,* 18:1172–1176.

SCREENING

- *Create awareness in target groups about the importance of being screened for certain cancers.* Target groups should be informed where, how and when to request screening services. Health-care workers (physicians, nurses, midwives) must be trained on how to administer the screening test adequately, communicate effectively with people who are being screened, and provide appropriate counselling and psychosocial support when needed.

EARLY DETECTION SERVICES AND REFERRAL

People need access to trained health workers who are competent to perform the necessary examinations (including female health workers for women) or screening tests at primary health centres, outpatient clinics or mobile clinics. Health-care providers should be able to communicate appropriately to patients the results of a positive test or examination, and use referral mechanisms that ensure timely further investigation. Activities, and associated resources, will vary according to the type of early detection programme, as follows:

EARLY DIAGNOSIS

- *Examine patients presenting with early signs and symptoms.* A basic examination room, with an examining couch and changing corner, should be available at every primary health-care centre or outpatient clinic.
- *Provide the result of the clinical examination and, if necessary, refer the patient for further investigation.* If the result of the clinical examination suggests a possible cancer, the patient should be referred immediately for further investigation.

SCREENING

- *Invite the target group for screening, and advise them to come again for re-screening, as necessary*. Community leaders, those already screened, health-care providers and family members can help to ensure that the target population comes for screening or re-screening.
- *Administer the screening test to the target group*. The facilities and equipment required will depend on the type of test employed. For example, physical examination of the breasts requires a basic examination room, but the facilities and equipment required for mammography are substantial.
- *Process the screening test*. If necessary, call on specialized laboratories (e.g. for cytology screening).
- *Provide the result of the screening test and refer cases with abnormal results*. In general, the results of the screening test are not available on the spot. The patient can only be informed several days after his or her visit. Normal tests can be reported by mail, with the appointment for the next screening test. In the case of an abnormal test, the health-care provider needs to inform the patient in person, and refer the patient to a specialized clinic.

DIAGNOSIS AND TREATMENT

Every person with a suspected cancer or precancerous lesion must be promptly referred for appropriate diagnosis and treatment. The staff and facilities necessary to provide effective treatment must be accessible to patients. Psychosocial and financial barriers need to be taken into account, and mechanisms to overcome them should be identified during the planning and monitoring processes.

The facilities, equipment and expertise needed for diagnosis and treatment will vary depending on the cancer type. For example, for the diagnosis of breast cancer, fine needle aspiration cytology, core biopsy or open (excisional) biopsy may be required, which will require as a minimum an experienced surgeon and an experienced pathologist or cytopathologist. For further information, see the *Diagnosis and treatment* module.

Treatment is not always possible for people diagnosed with advanced cancer. It is therefore important to ensure that these patients have access to appropriate palliative care services (see the *Palliative care* module).

FOLLOW-UP

The purpose of follow-up is to ensure that the patient, having been referred for diagnosis, reaches the facility, receives the diagnostic tests, and receives the treatment required. For those treated, follow-up ensures that there are no complications of treatment and determines whether or not further treatment or rehabilitation is required.

In the case of *screening programmes*, follow-up should ensure that people in the target population who have never been screened are invited to join the programme. After the screening test, there should be follow-up for:

- those with a positive or suspicious result for cancer, to ensure that they are promptly referred to the specialized services;
- those with a doubtful result, to ensure that the screening test is repeated soon;
- those with a negative result, to ensure that they are re-screened according to the screening schedule.

QUALITY CONTROL

For a public health programme to be effective, the programme has to be managed and services have to be provided in accordance with quality standards. Key elements in a quality control system are:

- education of target groups;
- continuous training of health-care providers;
- monitoring of management processes and results;
- provision of clinical services.

Quality assurance is of particular importance in *screening* programmes, which involve testing of a large asymptomatic population. In such programmes, too many false negative (low sensitivity) or false positive (low specificity) results of the test can cause unnecessary harm to the targeted individuals. Quality control is difficult to implement when tests such as **v**isual **i**nspection with **a**cetic acid (VIA) and cytology are used, which are essentially subjective. Close monitoring of test-positivity and disease-detection rates, as well as periodic retraining, are essential to maintain good standards of visual testing (Sankaranarayanan et al., 2005).

If cytology is used for cervical screening, it is very important to ensure that cytology laboratories are highly efficient, right from inception. Efficient laboratories are vital to the operation of successful screening programmes. Keep in mind that the operational cost of cytology laboratories is high (about 50% of the total cost of the screening programme). Inefficient laboratories cost just as much as efficient ones; and inefficient laboratories only waste resources.

REGISTRATION AND COORDINATION SYSTEMS

Registration and coordination systems are essential to ensuring adequate follow-up of all the individuals in the target group. They are also important for quality control, monitoring and evaluation purposes. For example, adequate coordination between the centres at the different levels of care means that the delay between detection and referral to a specialized clinic is kept to a minimum.

For a *screening programme*, the ideal is to have population-based comprehensive cancer registries which include the whole target population. These can be used to invite the target group to be screened, to check that the expected proportion of the population has attended and to evaluate the impact of the programme on the incidence of cancer. In the absence of an existing population-based registry, other means should be sought to identify the target population. Establishing a population-based registry for the purposes of the programme may be very costly and difficult to implement. It is sometimes possible to use lists of voters, or lists of attendees at primary health-care centres, for this purpose.

Those initiating the screening programme are responsible for evaluating the available means of identifying the target population. It is not possible to demonstrate achievement of the planned coverage levels unless there is some register of the target population.

An initial option could be to register all individuals who join the programme at the primary health-care centre, and gradually include case registries at every level of the health system (Sepúlveda and Prado, 2005). Over a year, most members of a target group will generally visit a primary health-care centre for some purpose. These visits should be used to bring potential participants into the programme.

Alternatively, a registry for a specific disease (for example cancer of the breast or cervix) could be established. This could be built up as the need arises and the programme expands.

MONITORING AND EVALUATION

Both the development and the implementation of a cancer early detection plan need to be monitored and evaluated periodically in order to ensure that the objectives of the programme are achieved. Evaluation needs to be carefully designed and planned. The design and planning for monitoring and evaluation should therefore start early in the process of programming the implementation of activities.

This module describes how the performance of early detection programmes can be evaluated using the quality improvement framework (see pages 14–16 and Table 5). *National cancer control programmes: policies and managerial guidelines* (WHO, 2002) provides further guidance on monitoring and evaluating cancer control programmes, including early detection programmes, using the quality improvement and the system model frameworks.

No matter which framework is used, the evaluation plan needs to define:

- who will evaluate the implementation of early detection activities;
- what will be evaluated;
- what will be the core indicators (measures) and their respective standards (values set by stakeholders);
- how the evaluation will be designed and carried out to ensure credibility;
- how the results of the evaluation will be used to improve programme performance.

Table 9 provides examples of structure, process and outcome indicators, and their related standards, that could be used to evaluate a cervical cancer screening programme.

Table 9. Examples of structure, process and outcome indicators, and their related standards, for evaluation of a cervical cytology screening programme

Core indicators	Standards
STRUCTURE	
○ Organized cervical cancer screening programme included in the national cancer control policy	Official documents and guidelines published, updated and available
○ Early detection, diagnosis and treatment services for cervical cancer screening included in the health insurance package	
○ Network of health-care providers across the different levels of care	Guidelines, meeting or workshop reports
○ Network of community leaders trained and motivated to provide good quality services	
PROCESS	
○ Number of women in the target group (35–64 years of age)	
○ Proportion of women in the target group that have been screened in last 3 years (coverage)	>70%
○ Proportion of screening tests done in the target population as specified under the programme	>80%
○ Proportion of screening tests that needed to be repeated because they were inadequate	<5%
○ Proportion of primary health-care providers monitored for adequate administration of the test	100%
○ Proportion of test-positive women in the screened group	1–5%
○ Proportion of test-positive women who receive their screening test result within 3 weeks	>90%
○ Proportion of test-positive women who are referred and reach a specialized clinic for diagnosis	>80%
○ Proportion of test-positive women who receive confirmation of diagnosis within 1 month	>80%
○ Proportion of test-positive women diagnosed with precancerous lesions or cancer	~30%
○ Proportion of women diagnosed with precancerous lesions or cancer who receive appropriate treatment within 2 months of diagnosis	>80%
OUTCOME	
Short-term outcomes	
○ Ratio between the number of early cancer cases (cancer in situ, stage I) detected by screening and the number of cancers diagnosed during the screening intervals (false negatives missed during screening and fast growing tumours that developed during the screening intervals)	>5
○ Proportion of cases diagnosed in early stages	>70%
Medium-term outcomes (5 years)	
○ Overall 5-year survival rate for cervical cancer	>80%
Long-term outcomes (10 years)	
○ Invasive cervical cancer incidence rates	Decrease by >60%
○ Invasive cervical cancer mortality rates	Decrease by >60%

CONCLUSION

A plan for early detection of cancer is a key component within an overall cancer control plan. It enables cases to be detected at an earlier stage, when treatment is more effective and there are greater chances of cure.

A cancer screening programme is a far more costly and complex undertaking than an early diagnosis programme. Therefore, where resources are limited, and where the majority of cases are diagnosed in late stages, early diagnosis of the most frequent cancers, linked to appropriate treatment, is likely to be the best option to reduce premature deaths and suffering due to cancer.

Where the necessary resources are available, screening for cancers of the breast and cervix could be advocated, especially if there is high morbidity and mortality from such cancers. In high-resource settings, screening for colorectal cancer could similarly be justified. However, screening for other cancer sites must be regarded as experimental, and cannot be recommended at present as public health policy. Such screening should be implemented only as a research project, within a cancer control programme, and there should be mechanisms to evaluate the effectiveness of the screening. Research projects might include screening for cancers of the oesophagus, stomach, liver, lung, ovary, bladder, or prostate.

Early detection programmes need to be linked to the provision of palliative care services. As an early diagnosis or screening programme evolves, fewer patients will be diagnosed in advanced stages. This is particularly true for a screening programme. However, even with the best screening programmes, some patients will present with late stage cancer because of a lack of adherence to the programme or failure of the screening method. All of these patients will require palliative care.

Cervical cancer has now a great potential for being prevented through vaccination against human papilloma virus (HPV). However, even if a nationwide vaccination programme is introduced targeting young women, it will take up to 40 years to have a major impact on incidence. Hence, it will be necessary for several decades to develop or reinforce early diagnosis and screening programmes to reach the older population of women who already have acquired persistent HPV infection.

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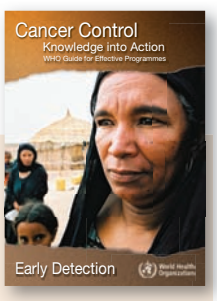


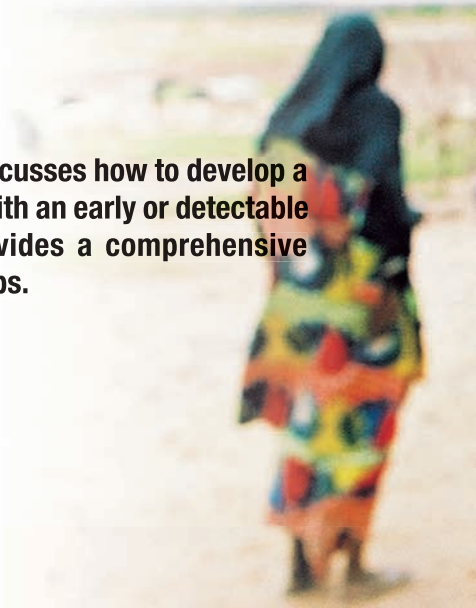
This module on early detection is intended to evolve in response to national needs and experience. WHO welcomes input from countries wishing to share their successes in early detection. WHO also welcomes requests from countries for information relevant to their specific needs. Evidence on the barriers to early detection in country contexts – and the lessons learned in overcoming them – would be especially welcome (contact at http://www.who.int/cancer).

The World Health Organization estimates that 7.6 million people died of cancer in 2005 and 84 million people will die in the next 10 years if action is not taken.

More than 70% of all cancer deaths occur in low and middle income countries, where resources available for prevention, diagnosis and treatment of cancer are limited or nonexistent.

Yet cancer is to a large extent avoidable. Over 40% of all cancers can be prevented. Some of the most common cancers are curable if detected early and treated. Even with late cancer, the suffering of patients can be relieved with good palliative care.

Cancer control: knowledge into action: WHO guide for effective programmes **is a series of six modules offering guidance on all important aspects of effective cancer control planning and implementation.**



This module addresses specific aspects of cancer early detection. It discusses how to develop a plan and programme that effectively respond to the needs of patients with an early or detectable cancer. This module is based on the *Planning* module, which provides a comprehensive understanding of the cancer control planning process and its main steps.

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