MANAGEMENT IN HEALTH CARE PRACTICE A Handbook for Teachers, Researchers and Health Professionals	
Title	**SCREENINGS**
Module: 3.3	**ECTS (suggested): 0.2**
Author	**Mateja Krajc, MD, MSc** Cancer Registry, Institute of Oncology, Ljubljana, Slovenia
Address for correspondence	**Mateja Krajc**, MD, MSc Cancer Registry, Institute of Oncology, Ljubljana Zaloška 2, Ljubljana, Slovenia E-mail: mkrajc@onko-i.si
Keywords	screening, screening recommendations, cancer screening, breast cancer screening
Learning objectives	After completing this module students should: • know what screenings are, what are their benefits and disadvantages, as well as key issues in screening; • be aware of ethical problems of screenings; • be able to list most important recommended screenings in Europe in different age groups; • be familiar with breast cancer screening process.
Abstract	There have been various definitions of screening over the years, but simply what we are talking about in screening is seeking to identify a disease or pre-disease condition in apparently healthy individuals. This concept is now widely accepted in most of the developed word. Used wisely, it can be a powerful tool in the prevention of a disease. Screening has important ethical differences from clinical practice as the health service is targeting apparently healthy people, offering to help individuals to make better informed choices about their health. The module is presenting basic theoretical background necessary for understanding the usefulness of screenings, the screening process, and potential risks, as well as it provides a case study of breastt cancer screening.
Teaching methods	An introductory lecture gives the students first insight in characteristics of screenings. The theoretical knowledge is illustrated by a case study. After introductory lectures students first carefully read the recommended readings. Afterwards they discuss the characteristics of screenings, their benefits and disadvantages, as well as key issues in screening. They also discuss the basic criteria to be fulfilled before screening for any condition is introduced. In continuation, they are supposed to be more deeply engaged in breast cancer screening process.
Specific recommendations for teachers	• work under teacher supervision/individual students' work proportion: 30%/70%; • facilities: a computer room; • equipment: computers (1 computer on 2-3 students), LCD projection equipment, internet connection, access to the bibliographic data-bases; • training materials: recommended readings or other related readings; • target audience: master degree students according to Bologna scheme.
Assessment of students	Multiple choice questionnaires.

SCREENING

Mateja Krajc

THEORETICAL BACKGROUND

Basic definitions and explanations of terms

Screening

According to the National Screening Committee of the United Kingdom Health Departments Second Report (1, 2), screening is a public health service in which members of a defined population, who do not necessarily perceive they are at risk of, or are already affected by a disease or its complications, are asked a question or offered a test, to identify those individuals who are more likely to be helped than harmed by further tests or treatment to reduce the risk of a disease or its complications.

There have been various definitions of screening over the years (1,3-5) but put simply what we are talking about in screening is seeking to identify a disease or pre-disease condition in apparently healthy individuals. This concept is now widely accepted in most of the developed word. When used wisely, it can be a powerful tool in the prevention of a disease.

Screening has important ethical differences from clinical practice. The health service is targeting apparently healthy people, offering to help individuals to make better informed decisions about their health. Irrespective that screening has the potential to save lives or improve quality of life through early diagnosis of serious conditions it is not a fool-proof process. Screening can reduce the risk of developing a condition or its complications but it cannot offer a guarantee of protection. In any screening programme, there is an irreducible minimum of false positive results (wrongly reported as having the condition) and false negative results (wrongly reported as not having the condition).

Screening programmes

Screening programmes are public health services that are organized at the level of a large population and must be effectively monitored. Programmes must use research evidence to identify that they do more good than harm at a reasonable cost. Proposed new screening programmes should be assessed against a set of internationally recognised criteria. These criteria include the epidemiology of the condition, the screening test, any treatment options, and the acceptability of the screening programme.

The benefits of screening for disease prevention were first demonstrated in the 1940s, by the use of mass miniature radiography (MMR) for the identification of individuals with tuberculosis (TB). After the end of the Second World War, when effective treatment for TB was introduced, the use of MMR became widespread in many western countries. In 1968, WHO issued monograph Principles and Practice of Screening for Disease (5), which remains a landmark contribution to the screening literature.

Types of screening

It is important to distinguish between two main types of screening, being organized screening, and opportunistic screening. Their main characteristics are as follows (1, 6-8):

- organized screening is a process in which people thought to be at risk are invited for screening inside organized screening programme, as in the national programmes for cancer of the breast and cervix for example. It takes place in a community setting .It could be checked and monitored;
- in contrast, opportunistic screening is screening offered by a medical doctor or other health professional outside an organized screening programme. Unlike an organised screening programme, opportunistic screening may not be checked or monitored.

Screening need to be distinguished from case-finding, where individuals have sought medical advice for a specific symptom or complaint and opportunity is taken to suggest various other tests, such as the measurement of blood pressure or cholesterol, appropriate to their age and sex (3, 8). It takes place in a clinical setting.

Criteria for screening

Before screening for any condition is introduced, the basic criteria have to be fulfilled (Table 1) (5). They are fundamental to the integrity of the screening process in any country.

Table 1. Summary of criteria for screening (5).

Category	Criteria
Condition	The condition sought should be an important health problem whose natural history, including development from latent to declared disease, is adequately understood. The condition should have a detectable preclinical phase.
Target population	There should be a defined target population.
Diagnosis	There should be a suitable diagnostic test that is available, safe and acceptable to the population concerned. There should be an agreed policy, based on respectable test findings and national standards, as to whom to regard as patients, and the whole process should be a continuing one.
Treatment	There should be an accepted and established treatment or intervention for individuals identified as having the disease or pre-disease condition and facilities for treatment should be available.
Cost	The cost of case-finding (including diagnosis and treatment) should be economically balanced in relation to possible expenditure on medical care as a whole.
Screening test	Should be acceptable and safe.

The validity of screening test and the evaluation of screening

Validity

Validity of screening tests is an expression of a degree to which a test measures what it intends to measure (3). There are two measures to describe the validity of screening test – sensitivity and specificity. Both measures are conditional probabilities, and both are easy to understand using a decision matrix (Figure 1) (6).

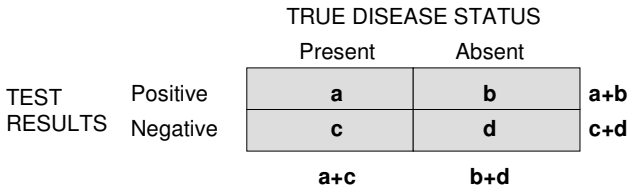

Figure 1. Decision matrix for derivation of the validity analysis of a screening test.

1. Sensitivity.
   Sensitivity (nosological) is defined as the ability of a test to detect all those with the disease in the screened population. This is expressed as the proportion of those with the disease in whom a screening test gives a positive result. Technically, it is a proportion of people with condition with positive test: a/(a+c) (Table 2).
2. Specificity.
   Specificity is defined as the ability of a test to identify correctly those free of the disease in the screened population. This is expressed as a proportion of people free of the disease in whom the screening test gives a negative result. Technically, it is a proportion of people without condition with negative test: a/(a+c) (Table 2).

But one should be aware interpreting these measures since there are two kinds of sensitivity and specificity - nozological and diagnostic (9,10). So far we were speaking of nosological conditional probabilities. Other two important conditional probabilities are positive and negative predictive values (9,11).

3. Positive predictive value.
   Positive predictive value is the probability that a person with a negative test does not have the condition under screening. Technically, it is a proportion of people with positive test who have condition: a/(a+b) (Table 2). This measure is also known as diagnostic specificity.
4. Negative predictive value.
   Negative predictive value is the probability that a person with a negative test does not have the condition under screening. Technically, it is a proportion of people with negative test who do not have condition: d/(c+d) (Table 2). This measure is also known as diagnostic sensitivity.

All screening tests should aim to have high sensitivity and high specificity.

Evaluation

Evaluation must also be an integral part of any screening procedure. In 1971, Cochrane and Holland suggested seven criteria for evaluation and these remain as valid today as they were then (12) (Table 2).

Table 2. Summary of criteria for evaluation of screening (12).

Factor	Criteria
Simplicity	The test should be simple to perform, easy to interpret and, where possible, capable of use by paramedics and other personnel.
Acceptability	Since participation in screening is voluntary, the test must be acceptable to those undergoing it.
Accuracy	The test must give a true measurement of the condition or symptom under investigation.
Cost	The expense of the test must be considered in relation to the benefits of early detection of the disease.
Repeatability	The test should give consistent results in repeated trials.
Sensitivity	The test should be capable of giving a positive finding when the individual being screened has the condition being sought.
Specificity	The test should be capable of giving a negative finding when the individual being screened does not have the condition being sought.

Benefits and disadvantages

The benefits and disadvantages of screening have been fully described over the years and have been summarized by Chamberlain (13) (Table 3).

Table 3. Benefits and disadvantages of screening (13).

Benefits	Disadvantages
Improved prognosis for cases detected	Longer morbidity in cases where prognosis is unaltered
Less radical treatment which cures some early cases	Overtreatment of questionable abnormalities
Resource savings	Resource costs
Reassurance for those with negative test results	False reassurance for those with false-negative results
	Anxiety and sometimes morbidity for those with false positive results
	Hazard of screening test itself

1. Benefits.
   The benefits are very clear. Early and accurate diagnosis and intervention will lead to an improved prognosis in some patients. At this stage treatment may need to be less invasive.
2. Disadvantages.
   The disadvantages are more complex. There will be longer periods of morbidity for patients whose prognosis is unchanged and there may be overtreatment of non-serious conditions or abnormalities identified. There are also resource costs in finding more illness both in terms of the tests themselves, the personnel costs and the subsequent management of whatever is found. There is the unpalatable certainty that some individuals with false-negative results will be given unfounded reassurance and that some with false positive results will experience, at the very least, unnecessary anxiety and, at the worst, inappropriate treatment.

Finally, there is the possibility, however remote, of hazard from the screening test itself. One point is particularly relevant here - there may be public demand (fuelled by vested interests) for the introduction of a screening test that does not meet the established criteria; an example of this is in screening for cancer of the prostate where the current screening test – prostate-specific antigen (PSA) – does not meet the criteria for accuracy or specificity.

Key issues in screening

There are a number of issues that are relevant at all stages and in every type of screening programme in any country, and are closely interrelated. There are five key issues in screening, being genetics, information, economics, ethics, and audit, evaluation and quality control (Figure 2).

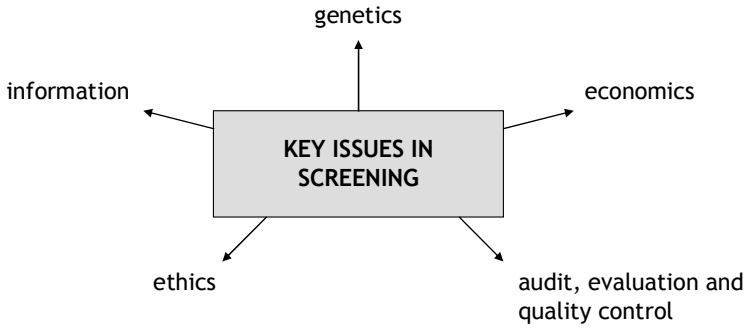

Figure 2. Five key issues of screening.

Before discussing the above mentioned key issues, one should consider components of an effectively organized screening programme. The components as described by Hakama (14) are as follows:

- the target population should be identified;
- individuals in the population who are to be screened need to be identified;
- all those eligible for screening should be encouraged to attend – for example, by issuing a personal invitation, and offering suitable timing of screening examinations to suit the needs of those involved;

- there should be adequate premises, equipment and staff to ensure that the screening examination is done under pleasant circumstances and is acceptable to those attending;
- there should be an appropriate, satisfactory method of ensuring the maintenance of the best standards of the test(s) by:
  - initial and continuing training of the personnel conducting the test(s);
  - demonstration (by appropriate records) of the maintenance standards of equipment used in the examination – for example, calibration of X-ray machines in mammography;
  - routine checks of the validity of the tests performed – for example, random duplicate measurements for biochemistry, cytology, and reading of X-rays;
- there should be adequate and appropriate facilities for the diagnosis and treatment of any individual found to require this. There should be as little delay as possible between the screening attendance, advice that the screening test was negative, advice that the screening test result required further investigation, and referral to the appropriate centre for further investigation or treatment. A timetable should be established for these different procedures and there should be continuous monitoring to ensure that the time intervals between the various stages are complied with;
- there should be regular checks to ascertain the satisfaction level of those who have undergone the screening process – those investigated, the screen-negatives and those invited who have not participated;
- finally, regular periodic checks should be made of the records of the screened individuals to ascertain their adequacy.

Genetics

In the last decade, genetic screening has developed very rapidly with the mapping of the human genome. Many see it as opening up a new era in the prevention, early diagnosis and identification of disease. However, caution is essential (4).

There are two objectives of screening for a recessive carrier state. One is to reduce the prevalence of the disorder and the other is to inform the reproductive choices of individuals and couples at risk. Information is thus regarded as worthwhile in itself, regardless of the possibility of prevention or treatment. While this type of screening can certainly help to evaluate risk and may be appropriate in certain high-risk groups. It should be carefully considered when to screen, if nothing can be done after the results of the screening test (4).

The main purpose of genetic screening at present is to prevent. In this it differs from much current screening practice and it must not be allowed to overlook the basic principles and criteria of screening (4).

Information

Information is another central concept in modern health care in general and also in screening. It must be provided in a correct way, so that possible participant may decide upon proper information, with the end-point being truly informed consent (or refusal) to participate (4).

Economics

As economic theory has entered the field, it has been recognized that screening may also do harm. All screening procedures involve the examination and testing of large numbers of individuals in order to find the few with an abnormality. There are two main consequences of this (4).

First, those who undergo screening are often understandably anxious while waiting for the result and become even more anxious if they have to undergo further investigation. Second, although most screening tests are simple, relatively cheap procedures in themselves, the actual costs are by no means trivial because of the large numbers involved (4).

Ethics

Any abnormality identified, whether in a national screening programme or in primary care, must be treatable and the investigation itself must not cause harm. Many believe that early diagnosis, particularly of cancer and heart disease, will lead to the possibility of treatment and improvement in prognosis. This is an attractive concept and can lead to a demand for a screening procedure to be introduced, irrespective of whether it has been shown that diagnosis guarantees an improved outcome (4).

Audit, evaluation and quality control

In any screening programme, as with any other service programme, adequate steps must be taken to ensure that the original objectives are being met and that the methodology meets appropriate standards (4).

The ideal method for evaluating a screening programme is the randomized controlled trial in which individuals in a population are allocated, at random, either to a group that is screened or to a group that receives only its normal medical care (4).

The components of an effectively organized screening programme have been described by Hakama (14), and have been already presented earlier in this module.

The importance of maintaining the quality of screening programmes should never be underestimated. Evaluation, audit and quality control should be an integral part of any screening programme to ensure that it is achieving what it has set out to do in a way that is acceptable to those involved.

The recommended screenings in Europe

There are several recommended screenings in Europe (4). They may be presented through different age groups, being:

- antenatal period;
- neonatal period;
- screening in childhood;
- screening in adolescence and early adulthood;
- screening in adults, and
- screening in elderly.

Recommended screenings by age groups

1. Antenatal period.
   There are many routine screenings for the total population, and some screenings for high risk groups (Table 5). There are also some screenings under research review (Table 4) (4, 14).

Table 4. Recommended screenings in antenatal period in Europe (4)

Condition under screening	Comment
	Routine
Anaemia	Blood test
Blood group and RhD status	
Hepatitis B	
HIV	
Risk factors for pre-eclampsia	
Rubella immunity	
Syphilis	
Asymptomatic bacteriuria	Urine test
Foetal anomalies: Anencephaly Spina bifida	Ultrasound, and blood test if indicated
Chromosome abnormalities: Down syndrome	Quadruple serum test, ultrasound
	High risk only
Thalassaemia/sickle cell disease	
Tay-Sachs disease	
	Under research review
Duchenne muscular dystrophy	
Chlamydia infection	
Gestational diabetes	
Fragile X syndrome	
Hepatitis C	
Genital herpes	
HTLV1	
Streptococcus B infection	

2. Neonatal period.
   There are many routine screenings, and some screenings under research review (Table 5).

3. Childhood.
   Screenings, recommended in Europe in the childhood are presented in Table 6.

Table 5. Recommended screenings in neonatal period in Europe (4)

Condition under screening	Comment
Routine	
Phenylketonuria	Bloodspot
Congenital hypothyroidism	
Cystic fibrosis	
Sickle cell disease	
Congenital heart disease	Physical examination
Congenital cataract	
Cryptorchism	
Congenital dislocation of the hip/ developmental dysplasia of the hip test	
Other congenital malformations	
Hearing impairment	
Under research review	
Biotinidase deficiency	
Congenital adrenal hyperplasia	
Duchenne muscular dystrophya	

Table 6. Recommended screenings in childhood in Europe (4)

Condition under screening	Comment
Hearing impairment	• Follow-up on neonatal programme where indicated • School entry "sweep" test to continue • Case-finding to identify late onset or progressive impairment • Investigation of any children with educational or behavioural problems
Amblyopia and impaired vision	• Orthoptist screening in 4–5-year-olds • Attention to be paid to children who miss this test for any reason
Dental disease	• School dental screening mandatory and should continue, but should be kept under research review • Early contact with dentists to be encouraged • Problems include shortage of dentists and lack of parental compliance, especially among the more deprived
Congenital hip dysplasia/ developmental dysplasia of the hip (CHD/DDH)	• Children identified by neonatal screening to be reviewed • Parental observations and concerns to be investigated
Deprived, disadvantaged or socially isolated children	• Need to identify such children and instigate screening/case-finding where relevant

4. Adolescence and early adulthood.
   Screenings, recommended in Europe in adolescence and early adulthood are presented in Table 7.

Table 7. Recommended screenings in adolescence and early adulthood in Europe (4)

Condition under screening	Comment
Chlamydia	• Opportunistic screening of those aged 25 and under who access sexual health services or primary care

5. Adults.
   In Table 8, screenings, recommended in Europe in adulthood are presented.

Table 8. Recommended screenings in adulthood in Europe (4)

Condition under screening	Comment
Breast cancer	• National programme should be continued but kept under close review with emphasis on quality control, staff training and good information
Cervical cancer	• National programme should be continued with review of alternative types of tests and of age range of those eligible and frequency of screening, • Good information to be a priority
Colorectal cancer	• National screening programme by faecal occult blood testing for adults aged 50–74 years
Abdominal aortic	• Ultrasound screening of men aged 65 and over Aneurysm seems a reasonable proposition provided the necessary resources are in place
Diabetic retinopathy	• National programme of screening for all diabetics aged over 12. It is essential to be quite clear about how, when and where screening should happen to ensure effective implementation
Risk factors for coronary heart disease (CHD)/stroke Blood pressure Cholesterol Smoking cessation	• Weight surveillance/case-finding approach in primary care

Screening in adults is potentially big business. Media interest in health is insatiable, and anyone who reads the newspapers, watches television or listens to radio can hardly fail to be aware of the various diseases that may be lying in wait for them. Of course, it is of benefit if potential health problems can be identified early and treated. But society must beware of turning health into an obsession and must resist both the increasing medicalization of life and the growing politicization of medicine.

The national programmes for breast and cervical cancer should be continued but kept under review with an emphasis on quality control and on providing balanced and

understandable information to enable women to make a truly informed choice without pressure from health professionals on whether or not to participate.

A national programme of screening for colorectal cancer by faecal occult blood testing in adults aged from 50 to 74 years has been agreed in the United Kingdom and on some other European countries but it is essential that adequate diagnostic, treatment and follow-up facilities are in place before it is introduced.

Screening for risk factors of coronary heart disease and stroke should be carried out in the primary care setting with advice, treatment and follow-up as appropriate. In the case of abdominal aortic aneurysm, it now seems clear that ultrasound screening in men aged 65 years and over would reduce mortality from this condition, although the benefit for those aged over 75 years has been questioned. As with colorectal cancer, however, national implementation should await the certainty that adequate facilities and resources are available. In the case of screening for diabetic retinopathy, close attention must be paid to audit and the need to be absolutely clear about how, when and where to screen.

6. Elderly.

Society is facing a major challenge in how best to maintain health and quality of life in populations where the proportion of people aged over 60 years now outnumbers those aged under 16 and the number of individuals aged over 85 is rising.

A system of regular surveillance and case-finding in primary care would seem to be the most appropriate form of screening, particularly in those aged 75 and over, but the resource implications of this must be confronted. Several simple tests, such as identifying difficulties with sight or hearing or problems with feet, can make a huge difference to the comfort and quality of life. Depression is another area where identification and treatment could improve well-being. Social and community support are also vital in enabling older people to enjoy as independent and contented a life as possible. The emphasis in screening at this stage of life should be on improving quality of life and preserving function and independence, rather than on providing “heroic” treatments to prevent mortality.

In Table 9, screenings, recommended in Europe in elderly people are presented.

Table 9. Recommended screenings in elderly in Europe (4)

Condition under screening	**Comment**
Hypertension	Physical assessment
Early heart failure	
Hearing loss	
Vision loss	
Incontinence	
Lack of physical activity	
Foot problems	
Review of medication	
Depression	Mental assessment
Alcohol use	T
Falls	Social assessment
Undernutrition	
Isolation	

Conclusions

Screening programmes and practices vary widely across the countries of the European Union (EU). This is inevitable given the differing structures and financing of health services, and differing demographic features of the population. There are, however, key objectives to strive for.

These include having one national body per country responsible for practice and policy, scrupulous adherence to the long-established screening criteria, accurate population registers, greater uniformity of access across different mare as of a given country and across different socioeconomic groups, and sound research evidence on which to base practice. The wide variation in practice in Europe illustrates the complexity of screening. Some lessons, however, stand out. Key points of screening in the EU are (4):

- antenatal screening programmes for Down syndrome and spina bifida are performed only in a few countries and are mainly optional. They are often only recommended to women at high risk.
- neonatal screening for phenylketonuria is systematically recommended in all countries belonging to the EU before May 2004, except Finland.
- breast cancer screening and cervical cancer screening programmes are recommended in some European countries.
- HIV screening is more common among the new Member States and three Candidate Countries and covers specific vulnerable groups, such as pregnant women and blood donors.
- TB screening is performed in a few European countries, especially central and eastern European countries, such as Hungary, Romania and Turkey.
- not all the countries follow the basic criteria for screening. A population register to allow recall and follow-up of patients is often missing. A single national body for reviewing tests and practice is rare.

CASE STUDY: BREAST CANCER SCREENING

Cancer screenings

At present the following screening tests meet requirements for organized screening programmes (Council Recommendation of 2 December 2003 on cancer screening (2003/878/EC) OJ L 327/34-38) (15):

- pap smear screening for cervical abnormalities starting at the latest by the age of 30 and definitely not before the age of 20,
- mammography screening for breast cancer in women aged 50-69 in accordance with European guidelines on quality assurance in mammography,
- faecal occult blood screening for colorectal cancer in men and women age 50-74.

Decisions on implementation of cancer screening programmes must be made as part of a general priority-setting exercise on the use of healthcare resources (16-18).

Other cancer screening tests are not yet recommended for EU-wide population-based cancer screening, although they already may be used in individual screening on demand. Such tests may provide individual benefits but at the same time may also lead to adverse effects for individuals (e.g. unfounded anxiety) and the public (e.g. additional financial burden). Recommendations for such tests cannot be made until they have shown to have benefits such as reducing disease-specific mortality or improving survival (19-21).

Potentially promising screening tests currently being evaluated in randomised controlled trials, include:

- prostate-specific antigen (PSA) testing for prostate cancer,
- mammography screening for women aged 40-49 for breast cancer,
- immunological Faecal Occult Blood Testing (FOBT) for colorectal cancer,
- flexible colonoscopy for colorectal cancer.

Once the effectiveness of a new screening test has been demonstrated, evaluation of modified testing methods may be possible using intermediate/surrogate endpoints, if the positive predictive value of such endpoints is sufficiently established. Some examples of screening methods which fall into this category are listed below:

- any novel alternative tests for faecal occult blood,
- liquid-based cervical cytology,
- testing for high risk human papilloma virus (HPV) infection,
- other novel methods for the preparation or interpretation of cervical specimens.

Any screening test which has been demonstrated to be effective should be offered on a population basis only in organised screening programmes, with quality assurance at all levels and full information about the benefits and risks (22, 23).

Breast cancer screening

Breast cancer is currently the most frequent cancer and the most frequent cause of cancer induced deaths in women in Europe. Demographic trends indicate a continuing increase in this substantial public health problem. Systematic early detection through screening, effective diagnostic pathways and optimal treatment have the ability to substantially lower current breast cancer mortality rates and reduce the burden of this disease in the population.

In order that these benefits may be obtained, high quality services are essential. These may be achieved through the underlying basic principles of training, specialisation,

volume levels, multidisciplinary team working, the use of set targets and performance indicators and audit. Ethically these principles should be regarded as applying equally to symptomatic diagnostic services and screening.

The primary aim of a breast screening programme is to reduce mortality from breast cancer through early detection. Unnecessary workup of lesions which show clearly benign features should be avoided in order to minimise anxiety and maintain a streamlined cost-effective service. Women attending a symptomatic breast service have different needs and anxieties and therefore mixing of screening and symptomatic women in clinics should be avoided.

Fundamental points and principles of the European guidelines for quality assurance of breast cancer screening programmes

Fundamental points and principles of the 4th edition of the European guidelines for quality assurance of breast cancer screening programmes are (24):

- breast cancer screening is a complex multidisciplinary undertaking, the objective of which is to reduce mortality and morbidity from the disease without adversely affecting the health status of participants. It requires trained and experienced professionals using up-to-date and specialised equipment;

- screening usually involves a healthy and asymptomatic population which requires adequate information presented in an appropriate and unbiased manner in order to allow a fully informed choice as to whether to attend. Information provided must be balanced, honest, adequate, truthful, evidence-based, accessible, respectful and tailored to individual needs where possible (24-26);
- mammography remains the cornerstone of population-based breast cancer screening. Due attention must be paid to the requisite quality required for its performance and interpretation, in order to optimise benefits, lower mortality and provide an adequate balance of sensitivity and specificity;
- physico-technical quality control must ascertain that the equipment used performs at a constant high quality level providing sufficient diagnostic information to be able to detect breast cancer using as low a radiation dose as is reasonably achievable. Routine performance of basic test procedures and dose measurements is essential for assuring high quality mammography and comparison between centres;
- full-field digital mammography can achieve high image quality and is likely to become established due to multiple advantages such as image manipulation and transmission, data display and future technological developments. Extensive clinical, comparative and logistical evaluations are underway;
- the role of the radiographer is central to producing high quality mammograms which, in turn, are crucial for the early diagnosis of breast cancer. Correct positioning of the breast on the standard lateral oblique and cranio-caudal views is necessary to allow maximum visualisation of the breast tissue, reduce recalls for technical inadequacies and maximise the cancer detection rate;
- radiologists take prime responsibility for mammographic image quality and diagnostic interpretation. They must understand the risks and benefits of breast cancer screening and the dangers of inadequately trained staff and sub-optimal equipment. For quality loop purposes the radiologist performing the screen reading should also be involved at assessment of screen detected abnormalities;
- all units carrying out screening, diagnosis or assessment must work to agreed protocols forming part of a local quality assurance (QA) manual, based on national or European documents containing accepted clinical standards and published values. They should work within a specialist framework, adhering to set performance indicators and targets. Variations of practices and healthcare environments throughout the member states must not interfere with the achievement of these;
- a robust and reliable system of accreditation is required for screening and symptomatic units, so that women, purchasers and planners of healthcare services can identify those breast clinics and units which are operating to a satisfactory standard. Any accreditation system should only recognise centres that employ sufficiently skilled and trained personnel;
- the provision of rapid diagnostic clinics where skilled multidisciplinary advice and investigation can be provided is advantageous for women with significant breast problems in order to avoid unnecessary delay in outline of management planning or to permit immediate discharge of women with normal/benign disease;
- population breast screening programmes should ideally be based within or closely associated with a specialised breast unit and share the services of trained expert personnel.

Key performance indicators for monitoring in population based breast cancer screening programme

Key performance indicators to be monitored in any population based breast cancer screening programme are presented in Table 10.

Table 10. **Summary table of key performance indicators to be monitored in any population based breast cancer screening programme.**

	Performance indicator	**Acceptable level**	**Desirable level**
1.	Target optical density	1.4 - 1.9 OD	1.4 - 1.9 OD
2.	Spatial resolution	> 12 lp/mm	> 15 lp/mm
3.	Glandular dose – PMMA thickness at 4.5 cm	< 2.5 mGy	< 2.0 mGy
4.	Threshold contrast visibility	< 1.5%	< 1.5%
5.	Proportion of women invited that attend for screening	> 70%	> 75%
6.	Proportion of eligible women reinvited within the specified screening interval	> 95%	100%
7.	Proportion of eligible women reinvited within the specified screening interval + 6 months	> 98%	100%
8.	Proportion of women with a radiographically acceptable screening examination	97%	> 97%
9.	Proportion of women informed of procedure and time scale of receiving results	100%	100%
10.	Proportion of women undergoing a technical repeat screening examination	< 3%	< 1%
11.	Proportion of women undergoing additional imaging at the time of the screening examination in order to further clarify the mammographic appearances	< 5%	< 1%
12.	Proportion of women recalled for further assessment		
	• initial screening examinations	< 7%	< 5%
	• subsequent screening examinations	< 5%	< 3%
13.	Proportion of screened women subjected to early recall following diagnostic assessment	< 1%	0%
14.	Breast cancer detection rate, expressed as a multiple of the underlying, expected, breast cancer incidence rate in the absence of screening (IR):		
	• initial screening examinations	3 x IR	> 3 x IR
	• subsequent screening examinations	1.5 x IR	> 1.5 x IR
15.	Interval cancer rate as a proportion of the underlying, expected, breast cancer incidence rate in the absence of screening:		
	• within the first year (0-11 months)	30%	< 30%
	• within the second year (12-23 months)	50%	< 50%

Table 10. **Cont**

	Performance indicator	Acceptable level	Desirable level
16.	Proportion of screen-detected cancers that are invasive	90%	80-90%
17.	Proportion of screen-detected cancers that are stage II+:		
	• initial screening examinations	NA	< 30%
	• subsequent-regular screening examinations	25%	< 25%
18.	Proportion of invasive screen-detected cancers that are node-negative:		
	• initial screening examinations	NA	> 70%
	• subsequent-regular screening examinations	75%	> 75%
19.	Proportion of invasive screen-detected cancers that are ≤ 10 mm in size		
	• initial screening examinations	NA	≥ 25%
	• subsequent-regular screening examinations	≥ 25%	≥ 30%
20.	Proportion of invasive screen-detected cancers that are < 15 mm in size	50%	> 50%
21.	Proportion of invasive screen-detected cancers < 10 mm in size for which there was no frozen section	95%	> 95%
22.	Absolute sensitivity of FNAC	> 60%	> 70%
23.	Complete sensitivity of FNAC	> 80%	> 90%
24.	Specificity of FNAC	> 55%	> 65%
25.	Absolute sensitivity of core biopsy	> 70%	> 80%
26.	Complete sensitivity of core biopsy	> 80%	> 90%
27.	Specificity of core biopsy	> 75%	> 85%
28.	Proportion of localised impalpable lesions successfully excised at the first operation	> 90%	> 95%
29.	Proportion of image-guided FNAC procedures with insufficient result	< 25%	< 15%
30.	Proportion of image-guided FNAC procedures from lesions subsequently proven to be malignant, with an insufficient result	< 10%	< 5%
31.	Proportion of patients subsequently proven to have breast cancer with a pre-operative FNAC or core biopsy at the diagnosis of cancer	90%	> 90%
32.	Proportion of patients subsequently proven to have clinically occult breast cancer with a pre-operative FNAC or core biopsy that is diagnostic for cancer	70%	> 70%
33.	Proportion of image-guided core/vacuum procedures 0o0with an insufficient result	< 20%	< 10%
34.	Benign to malignant open surgical biopsy ratio in women at initial and subsequent examinations	≤ 1:2	≤ 1:4

Table 10. **Cont.**

Performance indicator	Acceptable level	Desirable level
35. Proportion of wires placed within 1 cm of an impalpable lesion prior to excision	90%	> 90%
36. Proportion of benign diagnostic biopsies on impalpable lesions weighing less than 30 grams	90%	> 90%
37. Proportion of patients where a repeat operation is needed after incomplete excision	10%	< 10%
38. Time (in working days) between:		
• screening mammography and result	15 wd	10 wd
• symptomatic mammography and result	5 wd	
• result of screening mammography and offered assessment	5 wd	3 wd
• result of diagnostic mammography and offered assessment	5 wd	
• assessment and issuing of results	5 wd	
• decision to operate and date offered for surgery	15 wd	10 wd
39. Time (in working days) between:		
• screening mammography and result		
≤ 15 wd	95%	> 95%
≤ 10 wd	90%	> 90%
• symptomatic mammography and result		
≤ 5 wd	90%	> 90%
• result of screening mammography and offered assessment		
≤ 5 wd	90%	> 90%
≤ 3 wd	70%	> 70%
• result of symptomatic mammography and offered assessment		
≤ 5 wd	90%	> 90%
• assessment and issuing of results		
≤ 5 wd	90%	> 90%
• decision to operate and date offered for surgery		
≤ 15 wd	90%	> 90%
≤ 10 wd	70%	> 70%

LEGEND: OD=optical density, PMMA=test object material (polymethylmethacrylate), IR=incidence rate, NA=not applicable, FNAC=fine needle aspiration citology, wd= week days

EXERCISES

Task 1
Carefully read the theoretical background of this module, and recommended readings.

Task 2
Critically discuss the differences between population based and opportunistic screening.

Task 3
Name the basic criteria to be fulfilled before screening for any condition is introduced.

Task 4
How do we describe the validity of screening test? Describe an example.

Task 5
List some advantages and disadvantages of the screening.

Task 6
Which screening tests for cancer meet all requirements for organized screening programmes.

Task 7
Critically assess the advantages and disadvantages of a population based breast cancer screening programme.

REFERENCES

1. Holland WW, Stewart S. Screening in disease prevention: What works? Oxford: Radcliffe Publishing Ltd in association with the Nuffield Trust and the European Observatory on Health Systems amd Policies. 2005
2. Health Departments of the United Kingdom. Second Report of the National Screening Committee, October. London: Health Departments of the United Kingdom, 2000.
3. Last JM. A dictionary of epidemiology. Oxford, Oxford University Press, 2001.
4. Holland WW, Stewart S, Masseria C. Policy Brief. Screening in Europe. Brussels: WHO Regional Office for Europe and European Observatory on Health Systems and Policies, 2006. Available from URL: http://www.euro.who.int/document/e88698.pdf (Accessed: 24 August, 2008).
5. Wilson JMG, Jungner G. Principles and practice of screening for disease. Geneva: World Health Organization, 1968. Available from URL: http://whqlibdoc.who.int/php/WHO_PHP_34.pdf (Accessed: 24 August, 2008).
6. Detels R, McEwen J, Beaglehole R, Tanaka H, eds. Oxford textbook of public health. Oxford: Oxford University Press, 2002.
7. Dos Santos Silva I. Cancer Epidemiology: Principles and Methods. Lyon: IARC, 1999.
8. Jekel JF, Katz DL, Elmore JG. Epidemiology, biostatistics, and preventive medicine. Philadelphia: W.B. Saunders company, 2001.

9. Wulff HR. Diagnosis and principles of probability [in Croatian]. In: Wulff HR. Kliničko prosuđivanje. Zagreb: Jugoslavenska medicinska naklada, 1979. p. 73-91.
10. Adamič Š. Probability and clinical decision making [in Slovene]. In: Temelji biostatistike. Ljubljana: Medicinska fakulteta Univerze v Ljubljani, 1989. p.123-132.
11. Bradley GW. Evaluation of tests. In: Bradley GW (editor). Disease, diagnosis and decisions. Chichester: John Wiley & Sons, 1993. p. 70-90.
12. Cochrane AL, Holland WW.Validation of screening procedures. British Medical Bulletin. 1971; 27(1):3-8.
13. Chambrelain Jocelyn M. Which prospective screening programmes are worthwhile? Journal of epidemiology and Community health. 1984; 38:270-277.
14. Hakama M. Screening for cancer. Scandinavian Journal of Social Medicine Supplement. 1086; 37:17-25
15. Council Recommendation of 2 December 2003 on cancer screening (2003/878/EC) OJ L 327/34-38.
16. Grimes DA, Schulz KF. Uses and abuses of screening tests. The Lancet. 2002;359:881-884. Available from URL: http://www.hawaii.edu/cm/assets/images/Lancet-research.pdf (Accessed: 24 August, 2008).
17. Primic Žakelj M, Zadnik V, Pogačnik A, Uršič Vrščaj M. Screening for cervical cancer in Slovenia and national programme ZORA [in Slovene]. Radiol Oncol 2006;40(Suppl 1):S143-S148.
18. Štabuc B (editor). XIII. Seminar »In memoriam dr. Dušan Reja«. Early detection of cancer – challenges for the future [in Slovene]. Ljubljana: Zveza slovenskih druđtev za boj proti raku, 2005.
19. Premik M. Elements of screening programmes evaluation [in Slovene]. Slov Pediatr 1996;3:36-40.
20. Premik M. Evaluation of screening programmes [in Slovene]. Zdrav Vars 1998;37:442-446.
21. Oblak C. Early detection, early treatment and follow-up of prostatic cancer patients [in Slovene]. Radiol Oncol 2006;40(Suppl 1):S115-S120.
22. Novak Mlakar D, Maučec Zakotnik J. Screening for colon and rectum cancer in asymptomatic population aged 50-69 yeard [in Slovene]. Radiol Oncol 2006;40(Suppl 1):S95-S106.
23. U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality. U.S. Preventive Services Task Force (USPSTF). Spletna stran. Available from URL: http://www.ahrq.gov/clinic/uspstfix.htm#Recommendations(Accessed: 24 August, 2008).
24. Perry N, Broeders M, de Wolf C, Törnberg S, Holland R, von Karsa L, Puthaar E (eds) European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis. Fourth Edition. European Commission. Luxembourg, Office for Official Publications of the European Communities, 2006 (ISBN 92-79-01258-4).
25. Maučec Zakotnik J, Krajc M, Primic Žakelj M. Role and function of preventive/screening centers for breast [in Slovene]. Radiol Oncol 2006;40(Suppl 1):S31-S44.
26. Primic Žakelj M, Krajc M, Maučec Zakotnik J. Presejanje za raka dojk – kje smo danes. Radiol Oncol. 2006;40(Suppl 1):S25-S30.

RECOMMENDED READINGS

1. Grimes DA, Schulz KF. Uses and abuses of screening tests. The Lancet. 2002;359:881-884. Available from URL: http://www.hawaii.edu/cm/assets/images/Lancet-research.pdf (Accessed: 24 August, 2008).
2. Holland WW, Stewart S, Masseria C. Policy Brief. Screening in Europe. Brussels: WHO Regional Office for Europe and European Observatory on Health Systems and Policies, 2006. Available from URL: http://www.euro.who.int/document/e88698.pdf (Accessed: 24 August, 2008).
3. CINDI Slovenija. Internet site. Available from URL: http://www.cindi-slo.net (Accessed: 24 August, 2008).
4. Dos Santos Silva I. Cancer Epidemiology: Principles and Methods. Lyon: IARC, 1999.
5. U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality. U.S. Preventive Services Task Force (USPSTF). Spletna stran. Available from URL: http://www.ahrq.gov/clinic/uspstfix.htm#Recommendations (Accessed: 24 August, 2008).
6. Wilson JMG, Jungner G. Principles and practice of screening for disease. Geneva: World Health Organization, 1968. Available from URL: http://whqlibdoc.who.int/php/WHO_PHP_34.pdf (Accessed: 24 August, 2008).