

# SCREENINGS IN FINLAND 2014

## **The present state of health care screenings and future prospects**

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# SUMMARY

## SCREENINGS IN FINLAND 2014

### The present state of health care screenings and future prospects

■ The screenings to promote health have long traditions in Finland. Since 2003 the working group on screenings set up by the Ministry of Social Affairs and Health has evaluated the health care screening programmes being carried out, those proposed to be carried out and their methods.

According to the Health Care Act, local authorities must organise screenings in accordance with the national screening programme for the municipal residents. Those are listed in the Screenings Decree: screening for breast cancer for women aged 50 to 69 years at about two years' intervals, screening for cervical cancer for women aged 30 to 60 years at five years' intervals, and prenatal screenings for pregnant women. Prenatal screening comprises general ultrasound during early pregnancy, finding a risk of chromosomal abnormalities, and ultrasound for finding severe structural abnormalities.

The screenings are steered nationally by both standards and in a less binding form by information. Apart from the screenings prescribed by the Decree, the organisers of screenings can choose fairly independently both the screenings offered and how they are implemented. National steering has been increased in several countries in regard to the screening of individual diseases so as to ensure equality. A wide discussion in society about the objectives and effects of screenings provides a good basis for the steering.

Including a new screening test in the national screening programme demands a great deal of preparatory work. Public debate and an efficient support for the implementation further the acceptability of a screening and contribute to establishing uniform practices. Those also increase the participation activity of the target population. In the present report, the introduction of prenatal screenings is used as an example of preparing a new screening and embedding it in practice in Finland.

A screening should produce enough health benefits to be justified from the perspective of public health. Therefore there must be a good understanding of the benefits, costs and societal impacts of a screening until a decision is made to start a new screening programme. Many screenings have been started on the initiative of health care professionals without particular steering. In Finland the effectiveness of statutory screenings has also been assessed afterwards. Sometimes the evaluation of a screening shows that it is not useful enough to be started. The present report deals with the following screenings

evaluated by the working group on screenings: infection screening in early pregnancy, streptococci screening during pregnancy, screening for metabolic disorders in newborn infants, screening for aorta-aneurysma, and newborn hearing screening

The effectiveness of certain cancer screenings has been proved, but all cancer screenings are not necessarily useful. There must be a balance between the advantages and disadvantages of a screening. The application of a screening test that has proved effective in a research design in a population screening programme may prove less effective than was expected. The screening registers are important in view of evaluating and monitoring the implementation of the screenings, participation in them and above all their effectiveness at the population level.

Health examinations are included in the report since screenings and health examinations are not distinguished very clearly in public debate. Health examinations may include elements of screening but the aim of health examinations is not only to find diseases and precursors to them but also to support people's health, wellbeing and work ability. In health examinations of children and adolescents the focus is on monitoring and supporting their health and development, and as regards adults on promoting their health, functional capacity and work ability.

We hope that the information and experiences conveyed by the report will be of benefit when planning screenings, their steering and quality monitoring in the future.

Key words:

**cancer, effectiveness, equality, implementation, screening, steering**

# TIIVISTELMÄ

## SEULONNAT SUOMESSA 2014

### Terveydenhuollon seulontojen nykytila ja tulevaisuuden näkymät

■ Terveyden edistämiseksi tehtävillä seulunnoilla on Suomessa pitkät perinteet. Vuodesta 2003 lähtien Sosiaali- ja terveysministeriön asettama seulontatyöryhmä on arvioinut käynnissä olevia terveydenhuollon seulontaohjelmia, sellaisiksi ehdolla olevia ja niiden menetelmiä.

Terveydenhuoltolain mukaan kunnan on järjestettävä asukkailleen valtakunnallisen seulontaohjelman mukaiset seulonnat. Nämä on koottu seulontaasetukseen: rintasyöpäseulonta 50–69 -vuotiaille naisille noin kahden vuoden välein, kohdun kaulaosan syövän seulonta 30–60 -vuotiaille naisille viiden vuoden välein sekä sikiöseulonnat raskaana oleville. Sikiöseulontaan kuuluvat varhaisraskauden yleinen ultraäänitutkimus, kromosomipoikkeavuuksien riskin selvittäminen ja ultraäänitutkimus vaikeiden rakennepoikkeavuuksien selvittämiseksi.

Seulontoja ohjataan kansallisesti sekä normein että vähemmän sitovan tiedolla ohjauksen avulla. Asetuksella säädettyjen seulontojen ulkopuolella seulonnan järjestäjät voivat valita sekä tarjottavat seulonnat että niiden toteutuksen melko itsenäisesti. Useissa maissa valtakunnallista ohjausta on vähitellen lisätty yksittäisiä tauteja koskevien seulontojen osalta, jotta tasa-arvo toteutuisi. Laaja yhteiskunnallinen keskustelu seulontojen tavoitteista ja vaikutuksista on hyvä perusta ohjaukselle.

Uuden seulonnan ottaminen mukaan valtakunnalliseen seulontaohjelmaan vaatii paljon valmistelutyötä. Julkinen keskustelu ja tehokas toimeenpanon tuki edesauttavat seulonnan hyväksyttävyyttä ja luovat pohjaa yhtenäisille toimintakäytännöille. Ne myös lisäävät kohdeväestön osallistumisaktiivisuutta. Esimerkkinä uuden seulonnan valmistelusta ja juurruttamisesta käytetään tässä raportissa sikiöseulontojen aloittamista Suomessa.

Seulonnan pitää tuottaa kylliksi terveyttä, jotta sen tarjoaminen on kansanterveyden kannalta perusteltua. Niinpä seulonnan hyödyistä, kustannuksista ja yhteiskunnallisista vaikutuksista on oltava hyvä käsitys, ennen kuin uusi seulontaohjelma päätetään aloittaa. Monet seulonnat ovat käynnistyneet terveydenhuollon ammattilaisten aloitteesta ilman erityistä ohjausta. Lakisääteisten seulontojen vaikuttavuutta on arvioitu Suomessa myös jälkikäteen. Tässä raportissa käsitellään seuraavia seulontatyöryhmässä arvioituja seulontoja: alkuraskauden infektioseula, raskausajan streptokokkiseula, aineenvaihduntatautien seulonta vastasyntyneillä, aortta-aneurysman seulonta sekä kuolon seulonta vastasyntyneillä.

Toisinaan seulonnan arviointi osoittaa, ettei se ole kyllin hyödyllistä aloitettavaksi. Tiettyjen syöpäseulontojen vaikuttavuus on voitu osoittaa, mutta kaikki syöpäseulonnat eivät välttämättä ole hyödyllisiä. Seulonnan hyötyjen ja haittojen tulee olla tasapainossa. Tutkimusasetelmassa vaikuttavaksi todetun seulonnan soveltaminen väestöseulonnaksi voi osoittautua vaikutuksiltaan odotuksia pienemmäksi. Seulontarekisterit ovat tärkeitä, jotta seulontojen toteutusta, niihin osallistumista ja ennen kaikkea vaikuttavuutta väestötasolla voidaan arvioida ja seurata.

Terveystarkastukset on otettu tähän raporttiin mukaan, koska seulontojen ja terveystarkastusten välinen raja on yleisessä keskustelussa häilyvä. Terveystarkastukset voivat sisältää seulontaelementtejä, mutta terveystarkastusten tavoite ei ole pelkästään sairauksien tai niiden esiasteiden löytäminen, vaan terveyden, hyvinvoinnin ja työkyvyn tukeminen. Lasten ja nuorten terveystarkastuksissa korostuu kasvun ja kehityksen seuranta ja tukeminen, aikuisilla terveyden ja toimintakyvyn edistäminen sekä työkyvyn tuki.

Seulonnat ovat arvokas osa väestön hyvinvoinnin ja terveyden edistämistä. Sosiaali- ja terveysministeriön seulontatyöryhmä toivoo, että nyt julkaistava katsaus seulontatoiminnan historiaan ja nykytilaan antaisi hyvän pohjan suomalaisen seulontaohjelman jatkuvalla arvioinnilla ja uudistamisella myös tulevaisuuden uudessa sosiaali- ja terveydenhuollossa.

Asiasanat:

**ohjaus, seulonta, syöpä, tasa-arvo, toimeenpano, vaikuttavuus**

# SAMMANDRAG

## SCREENING I FINLAND 2014

### Nuläge för screening inom hälso- och sjukvården och framtidsutsikter

■ Screening som genomförs för att främja hälsa har långa traditioner i Finland. Från och med år 2003 har en screeningarbetsgrupp, som tillsatts av social- och hälsovårdsministeriet, bedömt pågående och föreslagna screeningprogram inom hälso- och sjukvården och deras metoder.

Enligt hälso- och sjukvårdslagen ska en kommun ordna screening för sina invånare i enlighet med det nationella screeningprogrammet. En förteckning över dessa screeningundersökningar ingår i förordningen om screening: bröstcancerscreening för kvinnor i åldern 50–69 med cirka två års intervaller, screening i syfte att förebygga cancer i livmoderhalsen hos kvinnor i åldern 30–60 med fem års intervaller samt fosterscreening under graviditetstiden. Fosterscreening omfattar allmän ultraljudsundersökning under tidig graviditet, utredning av risken för kromosomavvikelse och ultraljudsundersökning för att utreda grava anatomiska avvikelser.

Screening styrs nationellt genom både normer och mindre bindande informationsstyrning. Utanför den screening som bestäms genom förordning kan de som ordnar screening välja både den screening som ska erbjudas och hur denna genomförs förhållandevis självständigt. I flertalet länder har den riksomfattande styrningen av screening som gäller enskilda sjukdomar efter hand ökat för att likvärdigheten ska förverkligas. En omfattande samhällslig diskussion om screenings mål och effekt är en bra grund för styrning.

Att införa en ny typ av screening i det nationella screeningprogrammet kräver mycket beredningsarbete. En offentlig diskussion och effektivt stöd för genomförandet bidrar till att en screening accepteras, och de skapar en grund för enhetlig verksamhetspraxis. De ökar också målbefolkningens deltagaraktivitet. Som exempel på beredning och förankring av ny screening används i denna rapport inledandet av fosterscreening i Finland.

Screeningen måste skapa tillräckligt hälsa för att den ska vara motiverad med avseende på folkhälsa. Därmed ska det finnas en bra uppfattning om nyttan med, kostnaderna för och de samhällsliga konsekvenserna av screening innan man bestämmer sig för att inleda ett nytt screeningprogram. Flera fall av screening har inletts på initiativ av yrkesutbildade personer inom hälso- och sjukvården utan särskild styrning. Effekten av lagstadgad screening har även bedömts i efterhand i Finland. Ibland visar en bedömning av screening att den inte är tillräckligt lönsam för att inledas. Denna rapport behandlar följande typer av screening som bedömts i screeningarbetsgruppen: infektionsscreen-

ing under tidig graviditet, streptokockscreening under graviditet, screening av ämnesomsättningsjukdomar hos nyfödda, screening av aortaaneurysm och hörselscreening på nyfödda.

Effekten av en viss cancerscreening har kunnat bevisas, men all cancerscreening är inte nödvändigtvis nyttig. För- och nackdelarna med screening ska vara i balans. Tillämpning av screening, som i undersökningskonstellationen konstaterats vara effektiv, som screening av befolkningen kan i fråga om effekten visa sig vara mindre än förväntat. Screeningregistren är viktiga för att genomförandet av screening, deltagandet i screening och framför allt effekten på befolkningsnivå kan bedömas och följas upp.

Hälsoundersökningarna har inkluderats i denna rapport eftersom gränsen mellan screening och hälsoundersökningar är svävande i den allmänna diskussionen. Hälsoundersökningar kan innehålla element av screening, men målet med hälsoundersökningarna är inte enbart att hitta sjukdomar eller deras förstadier, utan att stöda hälsan, välbefinnandet och arbetsförmågan. Vid hälsoundersökningar för barn och unga betonas uppföljning och stöd av uppväxten och utvecklingen, för vuxna främjande av hälsan och funktionsförmågan samt stöd av arbetsförmågan.

Vi hoppas att den information och de erfarenheter som rapporten förmedlar är till nytta när man stakar ut riktlinjerna för screeningen, dess styrning och kvalitetskontroll i framtiden.

Nyckelord:

**cancer, effekt, genomförande, likvärdighet, screening, styrning**



# INTRODUCTION

The purpose of this publication is to describe how screening programmes are organised in Finland (the document describes the setting at the time of its completion in 2014), and how this system has been developed. Likewise, the publication examines how the provision of screening programmes is going to be steered following the social and health care reform. This publication also addresses health examinations, as these may also include screening examinations; in public debate, screening programmes and health examinations are often confused with one another.

The Ministry of Social Affairs and Health working group on screening has been responsible for drafting this publication. The Ministry appointed the working group to serve during the following terms: 16 October 2003–31 December 2006, 1 January 2007–31 December 2007, 1 September 2008–31 December 2010, and 1 January 2011–30 June 2015. The task of the working group has been to assess health care screening programmes and their methods, as well as to assess proposed screening tests to be included in a screening programme and their methods. The role of the working group was to act as a health policy adviser, rather than a specialist in matters of screening. The overall objective of the working group has been to ensure that Finland has proper screening programmes in place, taking into account morbidity and health care resources.

The working group has focused on screening programmes that have a clearly-defined objective, which is to improve the prognosis of diseases. It is also valuable to engage in a discussion of values related to screening programmes, and the criteria used in defining them. This discussion must not be limited to the working group on screening, as there may be disagreeing opinions on the justifications for the screening tests coming from outside the working group as well. Screening also inevitably poses some disadvantages – the seriousness of a certain disadvantage, and its significance for the individual and the society can vary widely. All of these factors must be taken into consideration when reaching an agreement on health care screening programmes and their content.



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# I FROM TUBERCULOSIS TO GENETIC SCREENING PROGRAMMES: THE HISTORY AND PRINCIPLES OF SCREENING IN FINLAND

Marjukka Mäkelä, Ilona Autti-Rämö

*Screening is used to examine the general population, or a group within it, with the intention of discovering a specific disease or its precursor. Screening constitutes a part of preventive health care. A screening process includes the following: specifying the target group, providing individual advice and guidance, conducting and analysing screening tests, providing feedback, making referrals for further examination, and providing the necessary health services. The national screening programme includes screening programmes specified in the Government Decree on Screenings. In some cases, one test may be used to discover several different diseases, and several different screening-type examinations are usually conducted as part of health examinations.*

In many ways, Finland has been a forerunner in population screening and in its governance. The National Board of Health used to be the one to regularly issue national guidelines on a wide variety of measures involving health and diseases. Furthermore, these guidelines are based on expert opinions. Tuberculosis was historically the first disease in Finland to become subject to screening; it was, indeed, eventually eradicated – thanks to a comprehensive national health care system, advanced medical treatment, and screening programmes.

In addition, prenatal monitoring has traditionally involved a wide variety of screening procedures for, among other things, infectious diseases. Screening pregnant women for syphilis was launched in the 1950s as a mandatory practice. HIV and Hepatitis B screening programmes tests began in 1990 without having been imposed legislatively, until a 2004 Government decree made it mandatory to screen for all three infections.

Cancer screening programmes began in the 1960s, under the supervision of the National Board of Health. During that time, cancer organisations first began screening for cervical cancer on a trial basis, and then expanded the practice nation-wide. Breast cancer screening was launched at the end of the 1980s on a trial basis, which made it possible to examine how effective the screening actually was. The health impacts of screening for breast and cervical cancer were considered significant, and the responsibility for administering these screening tests was assigned to municipalities. These screening tests were put into law at the beginning of the 1990s.

The functions previously pertaining to the National Board of Health were in 1991 transferred to the newly formed National Agency for Welfare and Health, and then to the National Research and Development Centre for Welfare and Health (STAKES). Policies in the 1990s were based on information steering, i.e. providing information to reach the planned target, as opposed to regulatory supervision, which would not be present in screening programmes for over the next ten years.

The extensive right of municipalities to independently decide on how they wish to provide their health care services led to a situation in which screening programmes varied from one municipality to another. Concerning breast cancer in particular, some municipalities began to expand their screening onto age groups that were both older and younger than the age range of 50–59 as specified in the legislation. Some municipalities also offered other types of screening programmes. The Ministry of Social Affairs and Health (MSAH) provided their input on how the provision of screening could be made equal. In 2000, the Ministry requested that the Finnish Office for Health Care Technology Assessment (Finohta), a unit within STAKES, should estimate the cost effectiveness of expanding breast cancer screening to include women between the ages of 60–69. From a societal standpoint, the impact on older age groups was found to be just as positive as on younger groups.

After an extensive public debate on Finohta's estimate, the Ministry of Social Affairs and Health decided to expand breast cancer screening tests; this decision took effect at the beginning of 2007. At the same time, there was an ongoing debate on the expansion of screening for neonatal metabolic disorders in a way which would include new disease groups. The debate also regarded guiding screening programmes for foetal structural and chromosomal abnormalities. It was considered if screening programmes could be steered in a more streamlined manner than with legislation – so that it would be possible to observe changes in the knowledge base or methods more flexibly. It was subsequently decided that screening regulations would be issued by decree.

In October 2003, the Ministry of Social Affairs and Health established a working group to assess screening programmes. Representatives from bodies such as the Association of Finnish Local and Regional Authorities, Finnish Cancer Registry, Mass Screening Registry and Radiation and Nuclear Safety Authority (STUK), as well as from the National Institute for Health and Welfare and STAKES, were invited to participate in the working group. Similar centralised steering is used in some countries, such as the Netherlands and the United States. The model for Finnish operating methods was borrowed in particular from those applied by the UK National Screening Committee (UK NSC).

The working group on screening initially agreed upon the criteria for assessing screening programmes – these are based on the ten principles of screening published by the World Health Organization (WHO) in 1968. These so called Wilson and Jungner criteria for screening were supplemented

with additional items adopted from the Danish Council of Ethics (Table 1). The criteria were tested and their order was changed so as to make the assessment more logical, at the time when the working group was deliberating over the initiation of colon cancer screening tests in 2003.

The claims made in the criteria are very different in nature. Many of the claims can be supported by reliable data based on research, while others can only be supported by second-hand data obtained, for example, through modelling. The importance of the criteria varies depending on the disease targeted by screening, and on the situation. When considering to launch a screening programme, it is important to define the health goals and to determine what kind of evidence already exists for each criterion, as well as what additional information can be obtained by, for example, a pilot study.

The working group has compiled a list of the screening tests, screening-type examinations and proposed screening tests to be carried out in Finland. The screening programmes subject to assessment have been divided into five categories: prenatal screening, screening tests for children and young people, those for persons of working age, cancer screening programmes and others. Over 60 diseases or health problems have been listed as possible screening targets, but only a few of these have been addressed in a comprehensive way. For example, no opinion has been issued on genetic screening programmes. In each category, new diseases considered to be important have been assessed in order to determine their inclusion in the screening programme. Assessments have occasionally addressed, for example, the area covered by working groups on maternity care or infectious diseases. Based on the recommendation by the working group on screening, the Ministry of Social Affairs and Health may decide that screening is not justified, or it may initiate a screening programme either under a Government decree or, at a lower level, by sending a letter of authority to municipalities. The decisions are based both on information and on an open public debate.

The assessment criteria have helped in identifying problem areas in screening programmes, and drawn attention to lack of available information. Even minor harms caused by a screening programme are taken into consideration in impact assessments, and in the provision of information to the public at large. Not all screening programmes which have gone through the assessment process have subsequently been initiated, even though their cost effectiveness, compared to other health care activities, would have been reasonable. However, not one active screening programme has yet been discontinued or downsized.

The boundary between screening programmes and health examinations is difficult to define and is often on a sliding scale. Placed at one extreme are the screening tests designed specifically for discovering a single disease, such as cancer screening programmes. On the other hand, some standard, screening-type functions, such as monitoring the height and weight of children, may be used to identify several different diseases. There are also

screening-type procedures in the Finnish health care system, but treating problems identified by these would require extensive system-wide changes. An example is screening for prenatal depression, which has been tried out in some municipalities, but discontinued when many more suspected cases were identified than could be treated with available resources.

With the working group on screening, the national steering of screening has been functioning well. Proponents of screening have waited for long time periods, sometimes years, to receive the group's comments. No "opportunistic" screening programmes have been initiated, and the screening programmes regulated by decree are fairly comprehensive. There is still a need for national guidance of screening programmes, as it is necessary to ensure equality and the appropriate implementation of limited resources. An important matter to keep in mind for the future is to organise a continuous quality control of already existing screening programmes. This is currently only done for cancer. A lack of screening registers for screening programmes other than those concerning cancer makes quality control and national overview nearly impossible.

Table 1. Assessment criteria drawn by the working group on screening. The original numbering of the WHO and Danish Council of Ethics (T) criteria are enclosed in parentheses.

1. The condition sought should be an important health problem. (WHO1)
2. There should be a recognizable latent or early symptomatic stage. (WHO4)
3. The natural history of the condition, including development from latent to declared disease, should be adequately understood. (WHO7)
4. There should be a suitable test or examination (WHO5), with an evaluated validity of the testing system (T11a), technical efficiency (T11b), and predictive value of test results (T11c).
5. The test should be acceptable to the population. (WHO6)
6. Prior to beginning screening, an evaluation must have been made of the ethical and psychological consequences for the examinees (T12a), stigmatisation (T12b), and the consequences of "false positive" and "false negative" test results (T12c).
7. There should be an agreed policy on whom to treat as patients. (WHO8)
8. There should be an accepted treatment for patients with recognized disease. (WHO2)
9. Facilities for diagnosis and treatment should be available. (WHO3)
10. The screening organisation has been explained in detail (T14), particularly the national and regional level (T14a), quality control and registration of results (T14b,c), provision of information to the target group (T14e), patient placement within the organisation (triage) (T14d), personnel training (T14f) and providing information and advice on test results. (T14g).
11. The research and treatment costs incurred by screening have been described. (WHO9)
12. The impact of screening has been assessed. (T13)
13. Case-finding should be a continuing process and not a "once and for all" project. (WHO10)
14. The cost of case-finding (including diagnosis and treatment of patients diagnosed) should be economically balanced in relation to possible expenditure on medical care as a whole. (WHO9)



## 2 STEERING AND PROVISION OF SCREENING PROGRAMMES

Marjukka Mäkelä, Päivi Koivuranta-Vaara, Ritva Bly, Kirsi Ruuhonen, Taru Haula, Neill Booth, Ulla Saalasti-Koskinen

*Screening programmes are steered at the national level both by standards and less-binding information-based guidance. Apart from screening programmes which are regulated by decree, screening providers are fairly free to choose which screening programmes they wish to offer and which screening methods to employ. In many countries, in order to ensure equality, the degree of national steering has been gradually increasing for screening of individual diseases. Extensive public discussion on the goals and impacts of screening forms a solid foundation for steering.*

### 2.1 SCREENING PROGRAMMES CARRIED OUT IN ACCORDANCE WITH THE SCREENING DECREE

As stated in the Health Care Act: “local authorities shall arrange screening within their area in such a way that complies with national screening programmes.” The following are specified in the Screening Decree: “Breast cancer screening every 20–26 months for women aged between 50 and 69”, “cervical cancer screening every five years for women aged between 30 and 60”, and prenatal screening tests for pregnant women. Prenatal screening tests include “a general early pregnancy ultrasound scan”, “detection of chromosomal abnormalities” and “an ultrasound scan for the detection of severe structural abnormalities”. Tests for chromosomal abnormalities are performed during early pregnancy – the abnormalities can be found through a combined screening (a blood screen test and neck oedema measurement during a general ultrasound scan), or through a maternal serum screening during the second trimester of the pregnancy. Tests for severe structural abnormalities are performed during a general ultrasound scan at the midway point of the pregnancy.

### 2.2 PROVISION OF SCREENING PROGRAMMES

Screening programmes are a part of promoting health and welfare, as laid down in the Health Care Act. Municipalities can also offer their residents screening programmes other than the ones mentioned in the Decree. The decision on providing screening programmes is made when municipalities

belonging to the same hospital district draft a health care provision plan, which outlines the provision of primary health care services, including screening programmes. Municipalities and joint municipal authorities can cooperate with one another, and with hospital districts, in the procurement and provision of screening services. The provision plan should focus on ensuring a uniform and comprehensive offer and quality of screening services, where screening programmes specified in the Decree and any other screening programmes are concerned.

Under the Act on Planning and Government Grants for Social Welfare and Health Care (733/1992), a municipality may provide social and health care services by itself, or by procuring services from the State, another municipality, a joint municipality or another public (e.g. hospital district) or private service provider. Today, particularly where cancer screening programmes are concerned, these services are primarily outsourced. Responsibility for screening as a whole and its quality remains with the municipality, regardless of how screening programmes are provided.

In 2013, the Ministry of Social Affairs and Health working group on screening drafted *Syöpäseulontapalvelujen hankintaopas* (Cancer Screening Services Procurement Guide), which is available on the website of the Association of Finnish Local and Regional Authorities. It contains information on the legislation concerning screening programmes and procurements, and sets out quality criteria for the provision of screening services.

## 2.3 SCREENING PROGRAMME AND SCREENING PROCESS

Under the Screening Decree currently in effect, each municipality is required to draft a screening programme in advance each year. The breast cancer screening programme is given as an example below; it is based on a precisely defined set of guidelines, which can be used as a model for other screening programmes. It should also be discussed whether it will be necessary to determine the national body which will inspect all municipal screening programmes in advance.

Breast cancer screening is governed by rules and regulations from several institutions. The Screening Decree lays down the minimum requirements for breast cancer screening. The Radiation and Nuclear Safety Authority (STUK) has issued a guideline on the quality assurance requirements concerning the radiation safety of mammography. The Decree of the Ministry of Social Affairs and Health on the medical use of radiation stipulates that a breast cancer screening programme inspected by STUK must be drafted before any screening is started. The programme must specify:

- 1) The purpose of screening and the target population groups;
- 2) The party providing the screening services and the regional scope of the screening;
- 3) The suitability of the screening method;
- 4) The radiological equipment used in the screening and its suitability;
- 5) The personnel who are to carry out procedures involving radiation exposure, and their training;
- 6) Physicians who interpret the screening results, issue statements on them, and are responsible for confirmation examinations;
- 7) Quality assurance programme;
- 8) Monitoring of the equipment's condition and performance;
- 9) Plan for implementing clinical audits;
- 10) Registering and reporting of screening data and results.

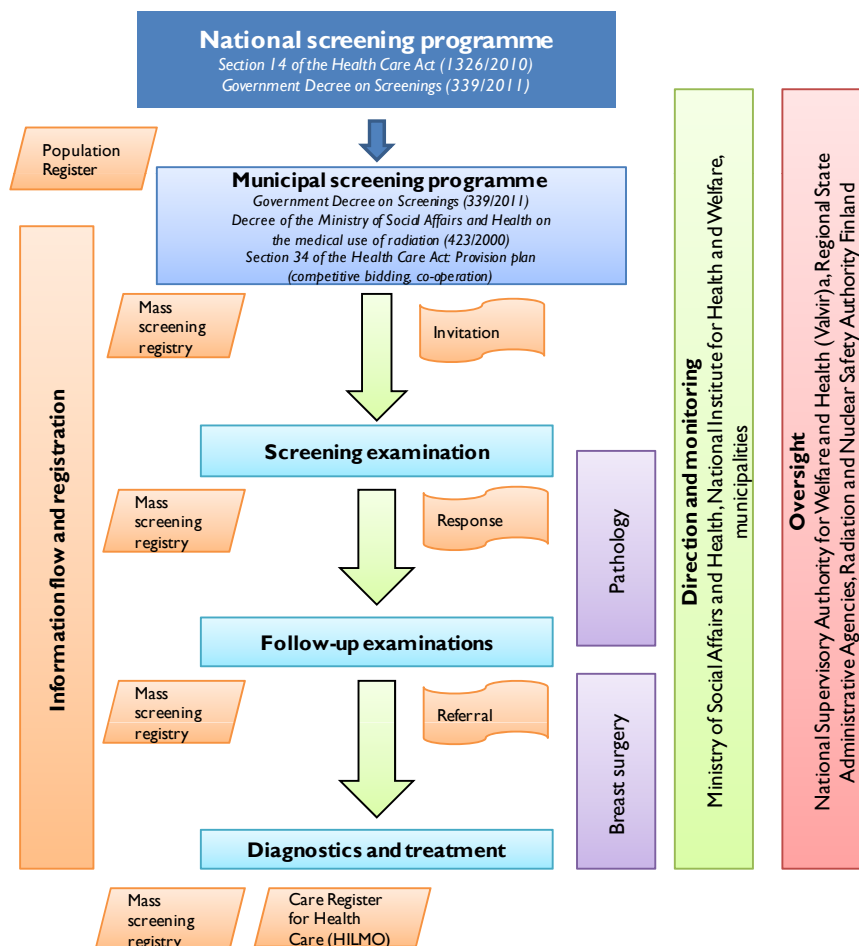


Figure 1. Cancer screening process

The screening process (Figure 1) is a chain of several functions that are jointly carried out by multiple actors. According to the Screening Decree, the screening process includes

- Specifying of the target group
- Providing individual advice and guidance
- Taking and analysing screening images or samples
- Providing information on screening results
- Referring to tertiary care examinations and providing the necessary health services.

Quality requirements apply to the entire process, from population sampling, treatment referral for a diagnosed disease, to providing results of the treatment and registering data.

The municipality is responsible for screening as a whole. The screening programme must include an appropriate quality management and quality assurance procedure, which can be used to assess the quality of the entire screening process and the reliability of screening tests, continuously and on a regular basis. The quality requirements apply to in-house functions as well as any outsourced functions. Even though high technical quality of screening and expertise of the personnel conducting it are essential, they alone are not sufficient factors to ensure the effectiveness of the screening. A supervisor in the municipality must be assigned to each screening, so as to ensure the overall quality of the screening process.

Using a register to collect screening data makes it possible to assess the impact of the screening, and this also constitutes a part of quality control. For example the Mass Screening Registry of the Finnish Cancer Registry has been collecting data since the 1960s. There is, however, no equivalent national register for prenatal screening programmes. In 2009, the Ministry of Social Affairs and Health working group on the screening of foetal abnormalities proposed a national screening register, to be established as a sub-register of the National Institute for Health and Welfare birth register. However, the necessary resources have not yet been found for creating this register. The local monitoring of prenatal screening programmes is made complicated by the fact that neonatal data cannot always be sent directly to the screening unit (maternity clinic) due to privacy protection. This, coupled with the lack of a national prenatal screening register, makes it practically impossible to ensure a process of quality assurance.

## 2.4 MONITORING AND STEERING

Regional State Administrative Agencies steer and monitor public health work within their respective areas, which also includes screening. The National Supervisory Authority for Welfare and Health (Valvira) steers the operations of the Regional State Administrative Agencies and monitors public health

work, especially in matters that are fundamentally important or far-reaching. Regional State Administrative Authorities and Valvira are also responsible for monitoring private health care. Thus, performing supervision of the municipality responsible for screening, and the private providers of screening services, is the duty of the above authorities.

The National Institute for Health and Welfare (THL) and STUK, among others, serve as institutions which provide expert opinion. Together with other actors in the field, THL monitors and assesses screening programmes currently underway and the methods the programmes employ. The THL unit Finohtha submits assessment reports to the Ministry of Social Affairs and Health so as to support the Ministry's decision-making. These reports contain assessments of, for example, the effectiveness, cost-effectiveness, and ethical and organisational factors concerning screening. In addition to this, Finohtha supports municipalities in conducting screening programmes by, for example, producing support material related to screening. STUK monitors the safety of radiation use, and issues radiation safety guidelines.

Under the Decree on National Personal Data Registers for Health Care (774/1989), health care authorities and institutions must submit all cancer screening invitation and inspection data to the THL Cancer Registry, the technical maintenance of which is the responsibility of the Cancer Society of Finland. The Mass Screening Registry, which is part of the Finnish Cancer Registry, monitors and assesses cancer screening programmes in Finland at the national level. The Mass Screening Registry collects screening data at the individual level from the level of whole Finland, compiles national screening statistics and monitors cancer screening processes and scientific studies in the field.

Assessment of the cancer screening process is ultimately based on the measure of its effectiveness (cancer mortality and incidence). For the purpose of assessment, the Mass Screening Registry also collects data on new cases of cancer and on cancer deaths in the target screening population. With the exception of cancer screening programmes, the effectiveness of screening programmes is not systematically monitored in Finland.

## 2.5 SCREENING COSTS AND FINANCIAL ASSESSMENT

According to the assessment criteria of the working group on screening, the examination and treatment costs of a new screening programme should be specified, and its total costs should be reasonable compared to other health care services (Table 1, points 11 and 14). A financial assessment compares the health and cost impacts of alternative methods. Financial profitability is affected by, for example, the extent, measurement, and assessment of cost-benefit impacts. In broad terms, screening is examined firstly from the

diagnostic and treatment process, which begins with an invitation, all the way to the final health outcomes.

Viable information on screening costs and impacts, that is suitable for Finnish conditions, is needed in decision-making. When it comes to new screening methods in particular, it is often difficult to quickly obtain information, which forces the personnel to make assumptions. Assessing the financial profitability of screening programmes involves several key factors related to, for example, the assessment perspective and the length of the period under review. These factors should be taken into consideration when interpreting the results of financial assessment and the applicability of the assessment to decision-making processes. As is to be expected, the working group on screening has also made use of expertise in health economics.

## 2.6 USE OF RADIATION IN SCREENING PROGRAMMES AND HEALTH EXAMINATIONS

X-rays and other examinations involving radiation are included in many screening programmes and health examinations. In such cases, non-symptomatic people are exposed to radiation. The benefit(s) gained from the examination must then outweigh the harm(s) or additional risk(s) it poses. The justification for radiation exposure should be assessed and explained in advance. When a health examination requires a procedure involving radiation exposure, the referring physician assesses the justification for the procedure. The referral must clearly state the examination indication. The performance of procedures which involve radiation exposure repeatedly and routinely, without assessing their need, is not in accordance with the principle for justification.

Screening tests conducted in accordance with the national screening programme are provided by invitation, not referral. At the moment, the only procedure involving exposure to radiation that is included in the national screening programme is mammography, which is used for the early detection of breast cancer. Mammography, or other x-ray examinations performed as a part of a screening programme, may not be performed during a health examination on a physician's referral.

The Screening Decree specifies which screening tests are included in the national screening programme. If the screening provider wants to expand the target group of these screening tests, or offer the public other screening tests, this must be justified separately and a plan for it must be submitted to the National Institute for Health and Welfare for assessment. Screening can be approved if it is deemed justifiable and if the public health benefit it provides outweighs the overall harm it may pose. A screening programme for screening tests which expose patients/individuals to radiation must be submitted to STUK for inspection before any screening tests are carried

out. An amendment to existing regulations has been proposed, stating that screening tests involving radiation exposure, but which are not a part of the national screening programme, would require a statement from STUK on the use of radiation. In the future, before beginning any screening programmes, the screening provider must also submit an assessment concerning the justification for screening tests which involve radiation to THL for inspection. The National Institute for Health and Welfare issues a statement to the screening provider within three months on whether the public health benefit offered by the screening outweighs the overall harm it may pose. If the screening is not deemed justifiable, it may not be initiated.

### 3 PREPARATION AND IMPLEMENTATION OF NEW SCREENING – EXAMPLE: PRENATAL SCREENING PROGRAMMES

Marjukka Mäkelä, Jaana Leipälä, Ulla Saalasti-Koskinen, Ilona Autti-Rämö

*Adding a new screening test to the national screening programme requires a great deal of preparation. Public debate and effective implementation promote the acceptability of the screening and establish a basis for common practices. They also increase the involvement of the target population.*

Each screening should meet the requirements specified in Table 1 so as to justify their use. However, screening and diagnostic methods, as well as the desired health outcomes, vary widely from one screening procedure to another. Although there is, because of these factors, a need for national steering, the steering must be specifically tailored to each screening. This chapter will use examples to describe the challenges facing the implementation of a new screening procedure.

Prior to regulatory steering, screening programmes for the detection of structural and chromosomal abnormalities in the foetus were conducted in different ways by different municipalities. The national working group on family planning and maternity care made recommendations on the subject in 1999, but the practices remained varied. However, upon further development of screening methods, more binding national steering became necessary.

Foetal abnormalities are screened for using an ultrasound and maternal blood samples. Through the obtained results, it is possible to identify some of the structural and chromosomal abnormalities in a foetus. Many of the abnormal findings require that the child be born in a unit that is well-equipped, in order to provide proper and necessary treatment. Indeed, one of the goals for prenatal screening programmes is to provide proper care during pregnancy and birth in order to ensure the health of the child.

Screening programmes can also be used to identify abnormalities that will result in a severe handicap that cannot be treated. In such cases, the information provided by the screening allows the mother to make an informed decision on whether to continue or terminate the pregnancy. However, not all abnormalities can be identified by screening - nearly all severe deformations of the brain can be identified by an ultrasound scan, but it can detect, e.g., only some of the congenital heart defects.



### 3.1 DEVELOPMENT OF PRENATAL SCREENING METHODS

In Finland, prenatal screening began in the 1970s, when it was found that an amniocentesis (taken in weeks 14–15 of the pregnancy) can be used to detect chromosomal abnormalities, such as Down's syndrome. In the 1980s, chorionic villus sampling (CVS) of the placenta during weeks 11–12 of the pregnancy accelerated the detection of chromosomal abnormalities. Both procedures involve the risk of miscarriage, which is just as high for foetuses with chromosomal abnormalities as it is for healthy foetuses. Initially, screening programmes were offered to older pregnant women, as the risk of abnormalities increases with the mother's age. The age limit was set by each municipality, ranging between the ages of 35 and 40.

Ultrasound scans were first used to determine the size and number of foetuses, and the location of the placenta, so that the delivery method and date could be determined. Methods have since become more advanced and, in the 1990s, the increased risk of chromosomal abnormalities could already be identified in the early stages of pregnancy. This meant that it was possible to limit invasive procedures only to pregnancies that exceeded this risk threshold. It also became easier to detect deformities during the pregnancy. At the beginning of the 2000s, chromosomal abnormalities were present in an average of 0.6% of newborns and major deformities in 2-3% of newborns.

At the turn of the millennium, there was an increase in the number of older women having babies, and pregnant women's access to information on various screening methods improved. The wide variety of screening practices in different municipalities led to a situation wherein the Finnish Gynecological Association requested an assessment of screening programmes for abnormalities in foetuses. Finohtha's assessment report on this topic was published in 2005, sparking extensive public debate on prenatal screening.

An early pregnancy ultrasound scan is performed in order to ensure that the foetus is alive, as well as to determine the number of foetuses and the estimated gestation period. Some severe structural abnormalities, such as the lack of a brain, can be seen at this stage, even though looking for these is not the primary objective. If parents want to screen for chromosomal abnormalities in the foetus, a neck oedema measurement is taken during the early pregnancy ultrasound. A neck oedema measurement must be discussed before it can be performed.

Chromosomal abnormalities are screened by means of a neck oedema measurement and the levels of two maternal serum markers, in relation to the mother's age and gestation period. This provides a risk classification, which indicates the likelihood of chromosomal abnormalities in the foetus. In approximately five out of every one hundred women, the result of this combination screening is abnormal, i.e. the probability of Down's syndrome is greater than 1:250. If the combination screening is not performed in time,

the likelihood of chromosomal abnormalities can be determined with a serum screening taken a few weeks later. A serum screening alone, however, is not as sensitive and precise as a combination screening.

The combination or serum screening does not provide a definite diagnosis of chromosomal abnormalities. The method can produce a false positive result as well as a false negative, failing to detect an actual abnormality. If the mother so desires, information on an elevated risk for chromosomal abnormalities will be followed by tertiary care examinations, i.e. a CVS or amniocentesis for chromosomal examination.

A structural ultrasound examination can be used mid-term to identify any severe structural abnormalities in the foetus. At this time, it is possible to provide any necessary tertiary care examinations, estimate the foetal prognosis and discuss alternatives with the mother. It is possible to terminate the pregnancy based on the condition of the foetus before the end of week 24. The mother can also choose to have a structural ultrasound later, in weeks 24–28, when termination is no longer an option. In this case, the objective of the examination is primarily to identify abnormalities which can be addressed, thus improving the prognosis of the child by means of closely monitoring the pregnancy and referring the mother to a fully-equipped hospital.

## 3.2 DIALOGUE ON INFORMATION AND VALUES

The prenatal screening assessment report provided the impetus for including screening procedures for foetal abnormalities in the Screening Decree. The report presented the effectiveness and risks of different screening methods, and addressed ethical issues concerning prenatal screening. It was possible to use new methods which detect numerous health problems, whose consequences to the foetus and mother varied widely (Table 2). Prior to the report's publication, the Ministry of Social Affairs and Health organised a public forum which addressed screening alternatives, information on them, the freedom of choice, issues concerning the termination of pregnancy due to foetal abnormalities, and a national organisation for screening programmes.

Table 2. Abnormalities detected in ultrasound examinations, risks associated with them and possible measures

<b>Abnormality</b>	<b>Risk</b>	<b>Possible measures</b>
Multiple pregnancy	Premature birth	Rest and delivery method planning
Placenta praevia	Bleeding risk, birth obstruction	Planned caesarean section
Some chromosomal abnormalities	Still birth	Frequent monitoring; abortion
Development disorder of the urethra	Kidney damage	Foetal surgery
Anencephaly	Neonatal death	Termination of pregnancy
Major heart defects	Infant death	Heart surgery immediately after birth

Based on the report and public debate on prenatal screening, as well as on subject-related expert opinions, the Ministry of Social Affairs and Health determined that there was a need to standardise screening practices. This was done by drafting the Screening Decree – onto which breast and cervical cancer screening regulations were also transferred.

The public debate on screening practices provided a wide range of views, and heard the opinions of both proponents and opponents of screening. Namely, invaluable views were offered by women who had terminated their pregnancies – both those who regretted their decision and those who were satisfied with it – and by professionals who performed screening programmes and abortions. A common denominator was the importance of having sufficient foreknowledge of the screening objectives, and the freedom of choice with regard to the screening programme. Today, it is possible to choose the time of screening so that any detected abnormality can be taken into consideration in the birth, but termination is no longer an option.

A comprehensive body of information for expecting families and screening providers was produced in accompaniment to the legislation, and numerous professionals involved in the practical aspects of screening participated in its compilation. Health care professionals also received training on how to converse with pregnant women during different screening situations. The public debate provided excellent information on how to practice screening programmes.

### 3.3 EFFECTIVE PRACTICES

The screening process begins with identifying the target group; for prenatal screening, this is done in maternity clinics. Although blood samples are generally taken at maternity clinics, an ultrasound examination is taken at a prenatal clinic or another screening unit. If necessary, tertiary care examinations are conducted at a university hospital, to which pregnant women are referred by the screening unit.

Concentrating screening programmes to sufficiently large units ensures that the employed screening methods are uniform and of a high standard. Ultrasound examinations are usually performed by a trained ultrasound nurse. A good practice would be for a nurse to be able to consult a physician immediately in the case of any suspicion of an abnormality in the ultrasound examination.

Providing unbiased and understandable information on screening is vital, so that people being called in for screening can participate in making an informed decision. The screening provider must provide information on the advantages and disadvantages of screening or of tertiary care examinations, as well as describe the various stages of the screening. Providing clear information as early as possible in the pregnancy is essential. Screening providers (maternity clinic, screening unit and tertiary care unit) must agree on a uniform provision of information.

The sharing of information between providers is also important. Computer system incompatibility and privacy practices can hinder the flow of information between providers. Information on abnormal findings should flow smoothly from the maternity clinic to the prenatal clinic, and vice versa. Information from the maternity hospital is needed at the prenatal clinic and the maternity clinic. Information flow is also a part of quality assurance, as the newborn's condition indicates the end result of prenatal screening programmes. The objective is to establish an electronic patient information system that covers all aspects of prenatal screening programmes, and supports the effective and timely provision of information. The new electronic maternity card makes it possible for pregnant women to read information from and enter it into the system.

Each municipality is responsible for providing its residents with screening programmes laid down in the Decree. According to the latest report, municipalities conduct prenatal screening programmes fairly comprehensively (Table 3). However, in 2013, screening programmes for structural abnormalities conducted after week 24 were only offered in one out of every two municipalities. The three-year transitional period specified in the Screening Decree was thus not sufficient for the full implementation of the Decree since it entered into force in 2010.

Table 3. Provision of prenatal screening programmes in municipalities in 2007, 2009 and 2013

<b>Screening for abnormalities in fetuses</b>	<b>2007</b>	<b>2009</b>	<b>2013</b>
General early pregnancy ultrasound	74%	92%	91%
Combination screening for chromosomal abnormalities	58%	87%	99%
Mid-term serum screening	10%	62%	64%
Screening for structural abnormalities in weeks 18–21	77%	88%	97%
Screening for structural abnormalities after week 24	8%	51%	51%

### 3.4 SUPPORT AND MONITORING TO ENSURE QUALITY

Legislation is not enough to implement a new national screening programme. What is needed is concrete support for screening providers, particularly in regions where screening was not offered previously. The different phases in the implementation of prenatal screening are listed in Table 4.

To support the implementation of these screening programmes, Finohta planned training and provided information in co-operation with the expert working group on screening. A general guidebook on prenatal screening programmes was produced for all pregnant women, and a separate guidebook on tertiary care examinations was produced for those referred to participate in the examinations. Training for trainers of prenatal screening professionals was arranged, and a training package was introduced for local training sessions. An interaction guidebook provided staff with advice on how prenatal screening programmes and their results should be discussed with pregnant women. Risk assessment cards for determining the risk of chromosomal abnormalities in women of different ages were also made in support to screening. All materials were compiled on the National Institute for Health and Welfare website, where they are available free of charge ([www.thl.fi/seulonnat](http://www.thl.fi/seulonnat)).

Table 4. Support phases for implementation of prenatal screening programmes

Year	Provider	Result
1999	STAKES Expert Group on Family Planning and Maternity Care	Recommendation on screening programmes and co-operation in maternity care, including structural and chromosomal abnormalities in fetuses
2003	Stadia (later Metropolia)	Initiation of a training programme for ultrasound nurses in prenatal screening
2003	Ministry of Social Affairs and Health	Establishment of the working group on screening
2003	Board of Directors of the Finnish Gynecological Association	Request for examining the effectiveness of prenatal screening
2005	Finohta/STAKES	Assessment report on the effectiveness of prenatal screening
2005	Ministry of Social Affairs and Health	Open seminar on the effects of prenatal screening and on their alternatives
2006	Ministry of Social Affairs and Health	Prenatal screening programmes made mandatory under the Screening Decree
2007–2009	National expert working group for supporting the implementation of prenatal screening programmes (co-ordinated by Finohta/STAKES)	For professionals: training and training package, interaction guidebook, risk assessment cards, website. General and tertiary care examinations guidebook for families
2008	Expert working group supporting implementation of the Screening Decree (Ministry of Social Affairs and Health)	MSAH Reports Series report, which includes prenatal screening quality requirements
2010	Assessment of the Finohta-coordinated national expert working group	Assessment report on implementation, prepared by the National Institute for Health and Welfare

The expert working group's activities and results were found to be beneficial in assessing support for the implementation of prenatal screening programmes, although there was some variation in the adoption of guidelines. Municipalities used the provided material to support their work; they did this either by adopting the material as such, or as a template for creating guidelines tailored to local conditions. Guidebooks aimed at pregnant women have been among the most ordered products issued by the National Institute for Health and Welfare for years.

The Ministry of Social Affairs and Health appointed an expert working group to promote a high quality of screening programmes for foetal abnormalities. The purpose of this action was also to promote nationally standardised prenatal screening programmes. The group outlined quality requirements for conducting screening examinations, as well as the equipment and training required for screening. For example, a person conducting structural ultrasound examinations must participate in two ultrasound training programmes and perform at least 500 examinations each year.

A new screening programme usually requires the procurement of new equipment and the training of new professionals. Clinical ultrasound nurses specialising in prenatal screening procedures are trained at Metropolia University of Applied Sciences in Helsinki. Most of the participants in the degree programme have qualifications in midwifery or public health nursing as basic training. Furthermore, screening units provide in-service training to nurses.

The Ministry of Social Affairs and Health working group has listed factors important in monitoring of quality and effectiveness, and has also presented alternatives to the process of monitoring screening quality. The working group felt that assessment of prenatal screening programmes would be most effective through the utilisation of a national screening registry. This would require the collection of tagged personal data and combined information on the mother and her child. The group proposed that a screening registry be formed as a part of the birth registry. This has not yet been realised – screening data is collected only at the regional level and in different ways. The problem is that information on the newborns cannot be transferred to the screening location due to privacy protection. This makes it difficult to provide quality assurance and determine the overall impact of screening.

### 3.5 EQUALITY AND ETHICAL ISSUES

The intention behind supporting the implementation of prenatal screening is that pregnant women can have equal access to screening services. Even though municipalities offer prenatal screening comprehensively, structural ultrasound examinations conducted after week 24 are only available in one out of every two municipalities. Before participating in a screening procedure, the pregnant woman must understand what screening is and what it might lead to. Communicating in the pregnant woman's native language is essential and, if necessary, she should have an interpreter present to explain the screening results in understandable terms. Although screening programmes are free of charge, tertiary care examinations usually involve a fee that is equal to the standard outpatient clinic fee.

Screening principles require that the procedure only looks for treatable problems, the treatment should promote health and be ethically acceptable. In prenatal screening programmes, these requirements are not always met. A single ultrasound examination can be used to identify a number of different health problems, some of which are not treatable. Screening can thus be used as the basis for terminating a pregnancy, if the expecting mother so chooses. Consequently, it is absolutely necessary for participation in the screening programme to be voluntary, so as to avoid any woman with a negative attitude toward abortion being forced into an impossible situation. Another specific ethical issue is that the pregnant woman ultimately makes the decision on

whether to terminate the pregnancy or to take another course of action on behalf of the foetus.

These issues can be addressed considering the different views and values people might have when participating in screening programmes. It is crucial to obtain sufficient information before participating in a screening. In Finland, a woman coming in for a screening procedure can state that she does not want to know about any abnormalities, but rather only the number of fetuses and gestation period. If in such a situation screening programmes reveal a significant abnormality, the screening venue should have clearly defined procedures in place for recording the result and registering information about it. The pregnant woman may also choose to schedule the structural ultrasound examination at a time when it is no longer possible to terminate the pregnancy on the basis of a severe foetal abnormality.

The possible harm of prenatal screening examinations in tertiary care (CVS and amniocentesis) is the risk of miscarriage: 1–2 pregnancies out of one hundred will end in miscarriage due to these examinations. The pregnant woman must weigh the possible risk of miscarriage and consider what the likelihood of chromosomal abnormalities would be at her age. Since most women do participate in tertiary care examinations, refraining from participation requires more information and personal deliberation on the patient's part. In this situation, the unbiased information provided by a healthcare professional is essential.

### 3.6 IMPLEMENTATION OF SCREENING CONTINUES

The need for standardising prenatal screening programmes increased significantly at the beginning of the 2000s. At that time, prenatal screening programmes were offered by municipalities in different ways, with some not offering any screening programmes at all. The assessment report on the effectiveness of prenatal screening programmes, a public debate on values, and consultation of experts formed the basis for legislation. Municipalities were given three years to implement the new screening arrangements. During this time, municipalities were given support in a variety of ways: training and guides for professionals, brochures for pregnant women and quality recommendations for screening providers. According to the assessment, the measures were successful in supporting implementation. Most of the material produced was considered useful and was adopted.

A key factor in monitoring the effectiveness and quality of screening programmes is the screening registry. There is still no national prenatal screening registry – data is collected by different means in each region. Due to the lack of a registry, it would be important to examine how screening programmes are conducted at the regional level, and how quality management is organised. In this respect there is still ongoing monitoring of the implementation.



## 4 SCREENING ASSESSMENT AND DECISION-MAKING

Marjukka Mäkelä, Ulla Saalasti-Koskinen, Taru Haula, Neill Booth, Outi Lyytikäinen, Jaana Leipälä, Ilona Autti-Rämö

*Screening programmes should provide ample health benefits, so that offering them is justifiable from a public health perspective. Therefore, there must be a clear understanding of the benefits, costs and societal impacts before a decision on launching a new screening programme is made. Many screening services have been launched without any specific guidance, on the initiative of health care professionals. The effectiveness of some mandatory screening programmes has also been assessed retroactively in Finland. In some cases, screening assessments reveal that there would be no real benefit to launching a service.*

In Finland, only a few screening programmes are regulated by law. However, rapid changes in the needs posed by healthcare and health technologies have led to the need for a more flexible approach to regulation. This is why, in 2006, regulation was moved to the purview of the Screening Decree, which sets the guidelines for cervical and breast cancer screening as well as for pre-natal screening. One of the conditions for regulation is that the State supports assigning a new mandate to municipalities through central government transfers.

A more streamlined information steering approach is used in the steering of most types of screening. For example, it would not be appropriate to include fast-changing technical methods in the Decree. In such cases, health care development should be steered and supported by other means, so that screening can be offered equally throughout the country, implemented effectively and its impacts assessed in a timely manner.

New screening programmes assessed during the years that the working group was running were quite comprehensive. Finhohta's assessment reports describe the health advantages, disadvantages and costs of screening programmes based on a systematic review of literature. Thought was also given to social and ethical aspects, and practical implementation. Although the impact of some screening programmes can already be monitored, for example, by using the Infectious Diseases or Cancer Registry, a dedicated monitoring system should be developed for some of the new screening programmes.

## 4.1 EARLY PREGNANCY INFECTION SCREENING

Maternity clinics have conducted mandatory syphilis screening since the 1950s. Hepatitis B and HIV screening programmes were gradually introduced in the 1990s without regulatory steering. These infections can be passed from the mother to the foetus, thus threatening the health of the child. Screening methods can be used to prevent the infection being passed onto the foetus, if the mother and child receive treatment early enough. In 2004, screening for all three diseases was mandated under the Decree for vaccinations and screening for infectious diseases during pregnancy.

The effectiveness and costs of screening for infectious diseases during pregnancy were assessed in a 2014 Finohta report. The current screening programme was estimated to prevent 28 neonatal infections each year: three syphilis infections, four HIV infections and twenty-one Hepatitis B infections, consequently preventing the death of one child, the disabling of two children and lifelong HIV treatment of four children. The annual cost of the early pregnancy screening programme was estimated to be approximately EUR 1 million, with the cost of an individual prevented infection being an estimated EUR 12,000–147,000.

The assessment showed that the early pregnancy screening programme and its follow-up measures are still not being implemented in a uniform way. The quality management of screening would require standardised guidelines and systematic national monitoring. Thus, regulatory steering alone has not been enough to ensure uniform implementation.

## 4.2 STREPTOCOCCUS SCREENING DURING PREGNANCY

Group B Streptococcus (GBS) causes a severe infection, which presents itself during an infant's first week of life. There are 20–40 cases in Finland each year. The bacteria are passed to the child from an asymptomatic mother during childbirth and may lead to the death of the newborn or result in a severe disability. The GBS screening is used during the final stages of pregnancy in order to identify the one out of five mothers who may be carrying the bacteria. The infection can then be prevented by effectively treating the mother during delivery.

Debate on this screening procedure began when, in 2005, an abnormally high number of newborns (57) in Finland were diagnosed with the infection. Screening also included a new method, where the GBS test is performed at the commencement of labour. However, it is difficult to ensure that the treatment is administered to the disease carrier in time. The test is also relatively expensive and providing screening during labour would have required the testing of all mothers. In the Finohta report, this was compared

to a situation where screening programmes were not conducted as well as to the identification of risky labour and late pregnancy GBS screening.

Screening done in late pregnancy produced the best results, with screening during labour having nearly as positive an impact, although with significantly greater cost. Both screening methods would have increased the use of antibiotics considerably. The annual costs of these screening methods were estimated at EUR 1.6–3 million, with the cost for one prevented infection being EUR 27,000–52,000. Lifelong treatment costs for a possible disability were not taken into consideration, nor were training costs included in the procedure of launching the screening programme.

The working group on screening did not ultimately take a stand on the initiation of a nationwide screening programme. Such a significant increase in the number of infection cases as the one that originally sparked the debate was not reported again in subsequent years. As with early pregnancy infection screening, the State was unwilling to provide funding for the screening programme. Both decisions were influenced by the fact that the steering of infection screening programmes was also in part vested to the Advisory Board on Communicable Diseases of the Ministry of Social Affairs and Health. The impact of screening for infections can be observed in the infectious disease registry and individual surveys.

### 4.3 SCREENING FOR METABOLIC DISEASES IN NEWBORNS

Although congenital metabolic diseases are rare, they can lead to serious disabilities or death if left untreated. Finland was the first country in the world to begin screening umbilical blood for hypothyreosis (hypothyroidism) at the beginning of the 1980s. Umbilical blood screening makes it possible to begin treatment before the child is discharged from the hospital. The debate on expanding the screening programme for metabolic diseases in newborns was started in the early 2000s, on the initiative of experts in the field. Screening for phenylketonuria (PKU) in newborns with both or one parent of non-Finnish descent was implemented at varying rates in different parts of the country.

Umbilical blood samples taken in order to screen for hypothyreosis cannot be used in the screening for other metabolic diseases. These diseases can be reliably screened for in children no younger than two days, when their own metabolism has begun functioning. This 'blood spot' screening can be used to identify several dozen metabolic diseases. Most of these are extremely rare and not all can be treated. In Finland, an assessment conducted in 2005 was made of the impact that screening programmes had on five diseases possible to detect by screening newborns just a few days old. The early treatment of these could prevent a severe disability or death. These five diseases were:

- Congenital adrenal hyperplasia (CAH)
- Medium chain acyl-CoA dehydrogenase deficiency (MCAD) and Long chain 3-hydroxyacyl-CoA dehydrogenase deficiency (LCHAD)
- Glutaric aciduria type I (GA I)
- Phenylketonuria (PKU)

The Finohta report estimated that screening for these diseases in Finland would make it possible to promptly treat 5–10 children each year, as well as to prevent 1–5 cases of severe disability and 1–3 deaths. The direct cost of screening was estimated at EUR 45 per newborn, i.e. EUR 2.5 million a year. Because PKU is extremely rare among Finns, but far more common in other populations, the working group on screening also requested a separate assessment of PKU screening programmes conducted on newborns whose parents were not of Finnish descent.

The Ministry of Social Affairs and Health working group on screening examined the assessment results in several meetings and heard the opinions of experts on newborn metabolic diseases. It took years for the working group on screening to render a decision, during which time the targeted PKU screening was gradually expanded as deliveries were concentrated among increasingly fewer units. Finally, the working group on screening proposed offering a screening procedure for all five diseases addressed in the Finohta report, to be applied to all newborns born in and after 2015. Together with the Association of Finnish Local and Regional Authorities, the Ministry of Social Affairs and Health sent out a letter concerning the matter to hospital districts in April of 2014. In the letter, it was proposed that university hospitals would be jointly responsible for planning and steering the screening programme at the national level. The public should be provided with information on the screening programme; furthermore, sufficient disease diagnostics, treatment and genetic counselling expertise should be ensured in all university hospitals. No specific guidelines have been drafted for assessing the impact of the screening programme, nor were there any guidelines concerning the way in which new diseases might be added to the screening programme.

According to legislative reforms, the responsibility for providing screening programmes should be localised in social welfare and health care regions. This does not, however, exclude the need for national-level steering of screening programmes. The high-quality screening programmes for metabolic diseases in newborns requires the involvement of laboratory professionals seven days a week, as well as a rapid flow of information between the screening laboratory and the hospitals responsible for the treatment of newborns. This is why there is a need to centralise laboratory functions, so as to make screening programmes cost-effective. In addition, monitoring effectiveness of the screening programme requires comprehensive collection of national data.

## 4.4 NEWBORN HEARING SCREENING

Early diagnosis of hearing impairment in children makes it possible to start rehabilitation and, if necessary, start using a cochlear implant during the infant's first year of life. The implant aids in the child's speech development. The beginning of the 2000s saw the introduction of new methods of newborn hearing screening, thus replacing the conventional horn and ratchet. Maternity hospitals requested that Finohta investigate new screening methods based on otoacoustic emissions (OAE) and auditory brainstem response (ABR).

A rapid review revealed that OAE was better in terms of sensitivity, but that ABR provided fewer false positives indicating hearing impairment. Each year in Finland, some 670 children under one year of age are given tertiary care examinations with the objective of initiating treatment for moderate to severe hearing impairment in both ears. In cases where the objective was also to detect unilateral hearing impairment, as many as 2,200 children were given tertiary care examinations. There were significant differences between the methods.

The new screening methods for hearing were assessed at a point when only less than half of the maternity hospitals in Finland had adopted one of the methods. Although Finohta assessment data was indeed used by many hospitals in choosing their preferred method, a key role in decision-making was also played by the experiences of other hospitals. A rapid review of the subject at the right time influenced the decision to change hearing screening methods without regulatory steering. Making a change was perhaps also easy because the new OAE and ABR methods were relatively inexpensive and their use did not require any changes to the organisation of screening.

## 4.5 ABDOMINAL AORTIC ANEURYSM

An abdominal aortic aneurysm (AAA) usually causes no symptoms until it ruptures. Half of all patients with a ruptured aneurysm will die before reaching the hospital, and roughly half of those who do make it to surgery will not survive either. An ultrasound examination can reveal an aneurysm while it is asymptomatic and it can be treated as prescribed. In Finland, the cost-effectiveness of this screening was compared to the present practice wherein systematic screening is not offered.

The one-off screening for AAA in Finnish men who are 65 years of age could prevent approximately 237 deaths in a single age group, and the screening of both men and women could prevent 318 deaths. An average of 10 extra days of life can be achieved for each man screened, with additional costs amounting to approximately EUR 170. This amounts to approximately EUR 6,000 per additional year of life. Cost-effectiveness can be considered reasonable compared to many procedures otherwise performed in health

care. As AAA is less common among women, any screening of women would produce fewer additional years of life and require less additional costs per person than would screening men. The implementation of screening would require additional resources for ultrasound examinations and non-emergency surgery.

The Ministry of Social Affairs and Health working group on screening has not yet recommended a screening programme for an abdominal aortic aneurysm. This type of screening would need to be organised in an entirely different way, whereas the other types of screening programmes described in this chapter can be conducted in maternity care and maternity hospitals. The small increase in lifetime achieved by being screened for an AAA would only be concentrated among the elderly population, although age as such does not serve as basis for decision-making in health care. Considering that a major risk factor for abdominal aortic aneurysm is smoking, reducing one's smoking habit can prevent the formation of an aneurysm. The cost-effectiveness of screening could therefore also be considered in relation to efforts to reduce smoking. In assessing the cost-effectiveness of screening programmes which involve lifestyle habits, it would be a good idea to more extensively assess the cost-effectiveness of preventive measures as an alternative approach.

## 4.6 CONCLUSION

Many screening programmes have been gradually introduced without regulatory steering, and screening programmes have often been promoted by professionals or organisations interested in the topic. In some cases, assessing the need for national guidance started when a screening programme already was running often due to issues of equality or quality. Today, screening programmes are also subject to comparison: What can be considered sufficiently effective and reasonable in cost? Changes in the incidence of the diseases being screened for have also sparked debate.

Regardless of the manner of steering screening programmes, decision-makers must have access to reliable information on the effects, costs and harms of screening. Information jointly accepted by the population, decision makers and health care personnel then lays the foundation for a real discussion on values.

## 5 CANCER SCREENING

Nea Malila, Tytti Sarkeala, Ahti Anttila

*The effectiveness of certain cancer screening programmes has been shown but still, all screening is not necessarily beneficial. The benefits and harms of screening must be balanced. When screening is applied as an actual public health programme, the impact is smaller than expected based on trials. Screening registries are important, so that the screening programmes, participation in them and, above all, their effectiveness can be assessed and monitored.*

Cancer screening aims to find early-stage pre-clinical (asymptomatic) cancers or their precursors, thus making it possible to prevent cancer-related deaths (or in some cases, the occurrence of cancer). Screening programmes can also offer indirect benefits, such as reducing the need for burdensome adjuvant treatments. Where society is concerned, early-stage treatment offers cost savings, as the treatment period is short and the need for expensive therapies is often eliminated. However, screening does have some disadvantages, such as anxiety and concern, false screening results (both false positive and false negative results) and overdiagnosis of early-stage cancers or precursors. In a good screening programme, the advantages and disadvantages are balanced, and there is ample research-based information available.

Screening involves a long chain of various health care functions and actors. The screening chain is a process that begins with defining the population to be screened, delivery of invitations, performing tests and interpreting them, and performing any necessary diagnostic and treatment measures. The chain ends finally at death of the subject. In a screening programme, it is precisely specified in advance when and what will be done depending on a given test result. The chain is sensitive to disturbances - failure of the weakest link can destroy the entire program. The screening chain should be assessed on a regular basis. Assessment allows for the comprehensive national registration of information produced in the various stages of screening.

## 5.1 SCREENING PROGRAMMES SPECIFIED IN THE SCREENING DECREE

Under section 14 of the Health Care Act (1326/2010), municipalities are required to offer screening that comply with the national screening programme. The Screening Decree (339/2011) prescribes the national screening programmes and the general principles by which they must abide. The Decree also prescribes the obligation to provide information: the provider must inform participants on the arrangements, objectives, effectiveness and potential risks of screening. National cancer screening programmes that are mandatory to organize include cervical cancer screening every five years for women 30–60 years of age and breast cancer screening every 20–26 months for women 50–69 years of age. The effectiveness of cancer screening programmes is evaluated in terms of cancer specific mortality. However, in some cases, various intermediate indicators, such as detection rates or stage distribution of cancer, are used. Intermediate objectives should not, however, be used in assessing the effectiveness of the screening programme and when deciding whether to launch new programs or extend current screening programs.

Participating in screening is voluntary. Those invited should be provided with sufficient information to support their decision. The information should be impartial, accessible and understandable, covering both the advantages and disadvantages of screening. The invitation to screening is a good, natural channel for providing information, as all those invited to participate in screening receive one. Still, it is important to enhance the coverage of the screening programme, as low participation rates reduce the impact of screening. As tests and imaging performed outside the screening programme are not monitored centrally, comprehensive data on their quality or effectiveness is not available.

## 5.2 CERVICAL CANCER SCREENING

The cervical cancer screening programme was launched in Finland at the beginning of the 1960s, and it was expanded into a national programme by the end of the decade. There was a clear reduction in the incidence and mortality of cervical cancer after the implementation of the screening programme (as much as a 80% reduction in the whole country). The benefit provided by screening cannot, therefore, be questioned.

The incidence of cervical cancer increased among young women in the 1990s, which is also why it has been proposed that the onset age for screening should be lowered. Research evidence, however, does not support lowering the screening age from the current 30 years, because screening of young women would increase the disadvantages of screening (self-healing HPV infections are diagnosed a great deal, particularly in young women) without improving its effectiveness. On the other hand, it might be justifiable to increase the



screening up to age 65, because cancer is more common among the elderly, and women have long lifespans.

The effectiveness of screening has also fallen following a drop in participation, particularly among women under 40 years of age. There is much to be corrected in municipal practices, which can be done through simple means, e.g., offering of a pre-reserved appointment with the screening invitation and re-inviting those who have not participated.

HPV testing has been studied as part of the normal screening programme. Even though the test can reveal a lot of precursors, its impact on invasive cancer during one screening interval is the same as that of a conventional Pap test. When girls who have received the HPV vaccination reach screening age – after approximately 15 years – the role of the screening test will have to be reassessed. At the moment, the HPV test is not recommended at all for women under 35 years of age, because HPV infections are common among young women and usually clear up on their own. Use of an HPV test can thus result in overdiagnosis, due to minor inflammatory precursory changes. Likewise, the HPV test should be administered to women 35 years of age and older systematically, so that the impacts caused by changes in the test throughout the screening process and its results can be confirmed.

### 5.3 BREAST CANCER SCREENING

In Finland, breast cancer screening programmes based on mammography are provided to women 50–69 years of age every other year. The breast cancer screening programme was launched in Finland in 1987 with a quasi-randomised research framework among women aged 50–59. The programme expanded to include women over 60 years of age beginning in 2007, thus the obligation to provide screening until 69 years of age applies to women born in 1947 or later. In the early years of screening – 1987–1991 – only women born in every other birth year were screened, thus leaving the remaining women to serve as a control group. The effectiveness of the Finnish breast cancer screening programme was assessed after the four year implementation period and again later, based on monitoring by the Finnish Cancer Registry. In Finland, breast cancer screening has achieved an approximately 20–25% reduction in mortality. We have been able to explain the justification for screening well, and the programme has not been compromised even by the heated debate on its impacts.

The adverse effects of screening, such as overdiagnosis of slow-growing cancers and localised tumours (in-situ cancers), have sparked debate. An international estimate states that the rate of overdiagnosis in screening programmes conducted among women aged 50–69 is 11–19%. According to a recent assessment published from Finland, the rate of overdiagnosis among women aged 50–69 has been 5–7% on average (range: 1–13%).

## 5.4 COLORECTAL CANCER SCREENING

Colorectal cancer screening has been proven effective (reducing the mortality from colorectal cancer) – when done either by faecal-occult blood screening or by using sigmoidoscopy as the primary screening test. Use of the faecal-occult blood tests in screening is based on the fact that colorectal growths bleed more frequently than a healthy mucous membrane. On average, screening reduces the mortality resulting from colorectal cancer by 16%, although recent estimates suggest a lower figure.

The colorectal cancer screening programme in Finland was launched within a research framework, where half of the population are invited for screening (screening group) and the other half of the target population serves as a control group. The guaiac based faecal-occult blood test is used as the primary screening test. The objective was to determine whether trial results could be applied to Finnish health care. Randomising was used to ensure a fair and balanced screening launch, a reliable and unbiased assessment of the screening programme, and the sufficiency of health care resources, such as colonoscopies.

The impact of the colorectal cancer screening programme is currently being examined, as the 10-year randomisation period set by the working group on screening came to a close at the end of 2014. Even though the programme seems to be working well – participation is approximately 70% and the provision of diagnostics and treatment has proceeded well – no final decision on screening can be made without a longer follow-up to estimate the possible mortality reduction.

## 5.5 PROSTATE CANCER SCREENING

Cancer of the prostate gland is the most common type of cancer among men, both in Finland and in many other countries with a high standard of living. An extensive multicentre trial, the European Randomized Study of Screening for Prostate Cancer (ERSPC), was launched in the early 1990s, with Finland joining in 1996. After over ten years of follow-up, it was found that PSA screening reduces the mortality rate of prostate cancer in those invited to participate in screening by 21% compared to the control group, and by 29% in participants after adjustment for non-compliance. In the Finnish part of the trial, the mortality reduction was lower – approximately 15% – and not statistically significant. A recent Cochrane review states that the impact of screening on mortality was not irrefutably proven in the meta-analysis of five randomised controlled trials. This result is due to the fact that the American Prostate, Lung, Colorectal and Ovarian (PLCO) cancer screening trial and ERSPC produced conflicting results.

An organised prostate cancer screening programme in Finland has not yet been launched, also because prostate cancer treatment has significant adverse impacts on the quality of life. Active treatment involves long-term factors that deteriorate the quality of life, such as urinary incontinence, burning sensation, erectile dysfunction and, particularly in radiation therapy, intestinal irritation. Despite this, PSA tests have largely been conducted, e.g. in occupational health care, the private sector and also in public health care. The situation is a paradox, because 'opportunistic screening' emphasises the disadvantages and reduces the number of advantages of screening: the interpretation of screening results varies, and the screening threshold value differs between units; follow-up/diagnostic examinations are not provided on a systematic basis; the access of subjects to examinations and treatment is not monitored systematically; and data is not compiled for assessment.

Screening-type PSA-testing to find prostate cancer should not be continued in the present scope, but the testing of healthy men for the sake of certainty should rather be discontinued. Alternatively, there should be a national programme which would ensure adequate availability of information on the advantages and disadvantages of screening to help subjects make an informed decision.

## 5.6 LUNG CANCER SCREENING

Lung cancer screening using conventional x-ray imaging is ineffective, i.e. it does not reduce mortality from lung cancer. Conversely, screening with a low-dose computed tomography (CT) scan reduced lung cancer mortality by 20% and overall mortality by 6.7% compared to using a conventional lung x-ray, according to the findings of an American screening trial. The target population of the trial were long-term smokers, with screening conducted once a year over a period of three years. As shown by the trial results, screening seems to reduce lung cancer mortality in a high-risk population. The challenges of lung cancer screening include issues of how it should be organised, what the disadvantages are with numerous additional examinations and how a suitable high-risk target population can be identified and invited for screening.

Because smoking is a well-known and extremely high risk factor for lung cancer, cutting down on smoking remains the primary health policy tool for prevention of lung cancer.

## 5.7 OTHER CANCER SCREENING PROGRAMMES

Screening for oral cancer by means of visual inspection has been proven to reduce mortality of high-risk persons (smokers, heavy drinkers). Screening for ovarian cancer, on the other hand, has not been shown to reduce mortality.

In Australia, there is a total-body melanoma screening trial underway. The first results of the trial are expected to be ready in 2015. Although efforts are being made to widely reduce the risk of skin cancer, particularly melanomas, by means of mole monitoring, there is no research data on its efficacy. Screening for gastric cancer was tested in Finland among men in the cities of Vantaa and Kotka in 1994–95. The trial results of gastric cancer mortality have not yet been published and, at present, gastric cancer screening does not seem to be suitable to be made into a population based screening programme.

## 5.8 SUMMARY

Because population screening programmes are focused on healthy individuals, the advantages and disadvantages must be balanced before initiating any screening programme. Minimising the disadvantages is particularly important. A functional screening programme also includes the proper guidelines for the screening interval and target age. The screening interval should be sufficiently long, so that the adverse impacts of screening can be minimised, but also frequent enough to ensure that early-stage cancers and precursor lesions are found in time. The benefits of cancer screening programmes appear at the population level as a reduction in the mortality resulting from cancer. A good screening indicator is also an improvement in the patients' quality of life which comes with less invasive, therapeutic treatments. A functional screening programme is a finely-tuned chain of activities, in which any necessary follow-up examinations are agreed upon in advance. The strength, but also a challenge, of screening programmes is the process as a whole – a screening chain which needs constant monitoring and care.

## 6 HEALTH EXAMINATIONS

Riitta Sauni, Tuovi Hakulinen-Viitanen, Marjaana Pelkonen, Marjukka Mäkelä, Erkki Vartiainen, Timo Leino Taneli Puumalainen

*Although health examinations may include elements of screening, their objective is not only to find diseases or their precursors, but also to promote health, well-being and work ability. Health examinations for children and young people place an emphasis on monitoring and supporting growth and development. For adults, the emphasis is given to promoting health and functional capacity as well as supporting work ability.*

There are many points in common between screening programmes and health examinations. According to the definition found in the Screening Decree, screening entails an examination or sampling of the population, or a certain part of the population, in order to discover a certain disease or its precursor, or in order to identify a pathogen. Health examination is a broader concept. According to the definition provided by the Ministry of Social Affairs and Health, health examinations are used to assess an individual's health condition and functional capacity by means of clinical examinations or other suitable and reliable methods. At the individual level, it is defined as a multifaceted examination of the individual's health condition and it may include elements of screening. Health examination is the general term used to describe a meeting between a health care professional and an individual coming in for an examination. It serves as a platform which can involve various examination, advisory or guidance elements, depending on the situation. The elements, such as the content of maternity or child health clinic examinations, are generally agreed upon in advance, but they are adapted and weighted in different ways in accordance with individual needs.

The purpose of health advice and health examinations is to monitor and promote public health and well-being, to promote working and functional capacity, prevent diseases, promote mental health and life skills, support choices that promote health and prevent diseases, offer nutritional and fitness advice, and support efforts to quit smoking and cut down on alcohol consumption in order to prevent chronic diseases.

The aim of health examinations is the primary and secondary prevention of diseases. Screening tests can be used as a tool in finding changes that require either tertiary care examinations and monitoring or treatment. Appendix

1 lists various types of health examinations and the associated screening examinations.

Health-promoting health examinations include those conducted in maternity clinics, child health clinics, those pertaining to school and student health care, and those provided by many occupational health care services. There are also several health examinations which an individual is required to pass in order to obtain certain permits or positions (e.g., driving licence, diving, pilot licence or military examinations as well as some occupational health care examinations). In such cases, the applicant must possess certain types of physical attributes in order to ensure their own safety and that of others. . Figure 2 shows the various general screening programmes and health examinations aimed at the public, divided by five-year age groups.

### Screenings and health examinations in Finland 2014

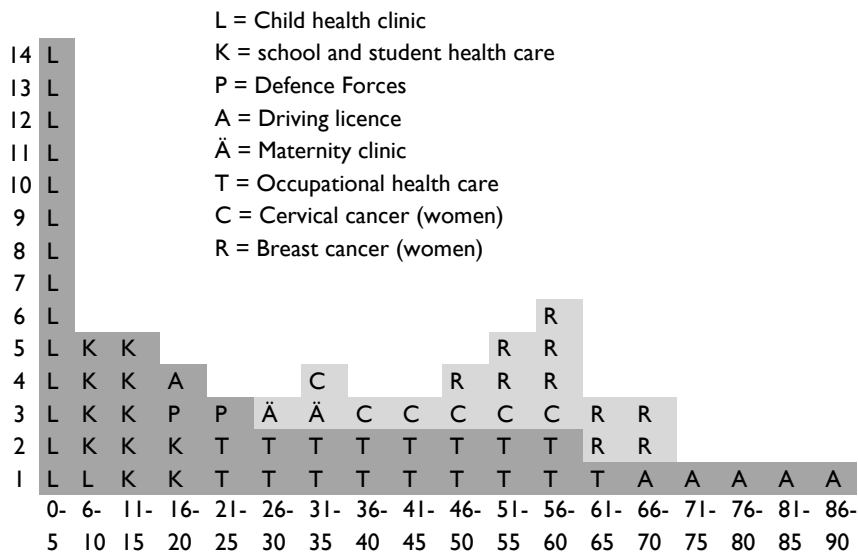


Figure 2. Screening programmes and health examinations aimed at the public, divided by five-year age groups. Screening programmes only intended for women are shown in the white field. Multiple visits are made to the maternity clinic (not specified). According to the total fertility rate (1.8), an average of two pregnancies per woman is included. 80% of the population holds a driving licence.

A health examination is based on the division of duties agreed upon between the health care nurse and physician. From a performance standpoint, it is essential that enough time be set aside for the health examination, as well as that the staff is highly skilled and can consult other professional groups. The opportunity for referral to tertiary care examinations and treatment, as well as having functional, multidisciplinary teams, is also essential.

## 6.1 WHY ARE HEALTH EXAMINATIONS FOR CHILDREN, YOUNG PEOPLE AND FAMILIES CONDUCTED?

Health examinations are conducted in order to proactively enhance factors that protect the health and well-being of children and young people. There are strong research-based justifications for health examinations' protective factors and their enhancement, with new data being produced constantly.

Furthermore, health examinations are conducted in order to detect problems or risk factors (developments, conditions, symptoms, diseases and abnormalities) that threaten the growth, development, health and well-being of children and young people as early as possible. This also involves providing advice, guidance and support, and taking the necessary measures. The above-mentioned problems may have to do with the children or young people themselves (psychosocial development and health; neurological development, interaction, speech and language; physical health, growth and development, incl. health habits, puberty; safety; vision and hearing; oral health), or with their growth and development environments (e.g. parents, home), which are dependent factors in a child's or young person's development and well-being. The measures to be taken might be, for example, support or guidance provided immediately during an examination, agreeing on a more in-depth examination of the situation, planning support measures, and referral to tertiary care examinations or treatment. If the problems are complex, it will be necessary to ask for the input of other professional groups, often involving multidisciplinary co-operation. If necessary, a personal well-being and health plan is made.

A good health examination always includes a portion that focuses on enhancing health, well-being and capabilities; problems should never be the only focus. Health examinations for children and young people are based on a positive perception of health, and on an approach which aims to enhance the examinee's capabilities.

The environment in which children and young people a growing and developing (home, day care, school/educational institution, free time) is taken into consideration in every health examination. Guidelines on health checks and scheduling related examinations can be found in various guides and manuals (Ministry of Social Affairs and Health Handbook 14/2004, Ministry of Social Affairs and Health Publication 20/2009, National Institute for Health and Welfare Guidebook 22/2012). These list the justifications for health examination subsets, and stipulate the examinations to be conducted on different age groups, including examples of diseases, disabilities and problems which are key targets for the examinations in question. Extensive health examinations, in which the health and well-being of the entire family is assessed, are more comprehensive than other types of examinations, and require a longer appointment time. Other health examinations conducted

between extensive ones can be more limited in scope and shorter in duration, as needed.

Surveys, studies, forms, interviews, etc. are used in identifying problems and need for support. Examples of methods used in maternity clinics and school health care are presented in the National Institute for Welfare and Health method manual (Handbook 14/2011) and in the appendix to the working group report on the development of student health care (MSAH 10/2014). Current Care Guidelines and nursing recommendations are also used. Assessments made by other professionals, such as day-care and school staff, are also used to increase the reliability of assessments and effectiveness of tertiary care measures.

In order to improve the quality of preventive services for children and young people, and minimise the degree of variation between municipalities, certain child health clinic and school/student health care examinations, as well as their attendant health advice, have been made statutory (Government Decree 338/2011). Health examinations are conducted most frequently during pregnancy and nursing, because growth and development are intensive at this stage, and any delay in identifying potential problems can have serious consequences. Many parents also need a great deal of guidance and support at this stage. At a later growth age, too, changes come quickly, so regular health examinations are vital to monitoring, for example, growth, puberty and posture. In recent decades, the number of health examinations has been reduced in, for example, child health clinics and, more recently, in maternity clinics. More time is now spent on targeting services (National Institute for Welfare and Health Handbook 29/2014). It is for the above-mentioned reasons that an annual school health care appointment is justified. While in secondary level education (upper secondary school/vocational school), young people are at an age where risk behaviour is common and independent health habits are being formed. In addition, many mental disorders begin at this stage of life. Providing support for the well-being of young people and identifying problems early is possible in health examinations conducted in the first and second year of secondary education. In student health care, health examinations are conducted on the basis of the results of a health survey. Student health care includes the early diagnosis, treatment and follow-up treatment of mental health and substance abuse problems.

Under the above-mentioned Decree, municipalities were made responsible for identifying children, young people and families in need of special support, and for determining the support needs of those failing to attend health examinations. The purpose is to identify need for support early, and to allocate support at the right time for those who need it, so as to reduce health disparities and prevent marginalisation and the need for child welfare. The services for children, young people and families are universal, intended for the entire age group. This is due to the fact that it is impossible to know in advance who will need support. Other national guidelines, monitoring and



supervision were enhanced in connection with strengthening of the legislation (Health Care Act/Decree). The provision of high-quality health examinations is also related to how motivated municipalities are to invest in the well-being of children and families (capabilities, management, expertise).

## 6.2 WHY ARE OCCUPATIONAL HEALTH CARE EXAMINATIONS CONDUCTED?

Health examinations are a part of occupational health care, serving a preventive purpose and promoting occupational health. Their objective is to protect employees from work-related health risks as well as to promote the employees' own capabilities and health in order to maintain their work ability. Effort is made to take preventive, corrective and rehabilitative measures for individuals and the workplace as early as possible.

An assessment of the need for a health examination is made by occupational health care professionals in co-operation with the workplace. If necessary, occupational health care experts are also used. According to Government Decree 708/2013, issued under the Occupational Health Care Act (1383/2001), occupational health care examinations shall be conducted;

- "...when so required by the age, sex or physiological state of the employee and by work-related health risks and problems;
- when abnormal work shifts or night work so require;
- when the health effects of new technologies, methods and substances being introduced so require;
- where necessary to establish the state of the employee's health and any necessary follow-up also after the end of exposure;
- on the basis of special health requirements of the work;
- as necessary when a material change occurs in the work or at different stages of the working career;
- when the employee's health and work ability at different stages of an illness so require;
- where necessary to assess and support the possibilities for coping on the job and, as necessary, to adapt the work to suit the employee's capabilities, health requirements and working and functional capacity.
- where necessary to assess the health and work ability prior to the termination of employment and determine the health requirements for employment as well as to draft a plan for the maintenance of health and work ability and referral for follow-up procedures."

During a health examination, attention is paid to the employee's health condition, work ability and functional capacity as a whole and, in particular, to the correlation between work and health. The health examination provides

a basis for assessing the need for advice and guidance, and a personal health plan is prepared in co-operation with the employee in order to promote their work ability.

### 6.3 DIFFERENT TYPES OF OCCUPATIONAL HEALTH CARE EXAMINATIONS

Occupational health care examinations can be divided into pre-employment examinations and regularly scheduled examinations. In practice, nearly every new employee is given a health examination at the beginning of employment, even though these preliminary examinations are only compulsory if the work involves health risks that may lead to illness or overexposure, or pose a threat to reproductive health.

Under currently applicable legislation, regularly scheduled examinations must be conducted "...when an employee is performing work that presents a special risk of illness or accident" (Government Decree 1485/2001). Today, a major part of Finnish occupational safety and health legislation is drafted in EU organs, at the initiative of the European Commission. One point included in many EU directives on occupational safety and health is the obligation to provide health examinations to employees exposed to occupational hazards (e.g. asbestos, noise, vibration, night work, electromagnetic fields). The objective of these health examinations is to ensure that occupational exposure does not pose a health hazard.

According to Social Insurance Institution of Finland (Kela) statistics, a total of approximately one million occupational health examinations have, for a long time already, been conducted on a yearly basis. This means that 50–60 health examinations have been conducted for every 100 employed persons. In 2011, more than 17% of health examinations were conducted for cases involving serious risk of illness and the remainder were health and work ability-based examinations. It has been possible to target health and work ability-based examinations according to a specific age group or unit; for example, every 3–5 years. As municipalities have relinquished a large percentage of adult age-group examinations, it can be said that occupational health care has also assumed responsibility for providing public health care in this respect.

Health examinations which screen persons for potential work ability risks have become more common in recent years. There is scientific evidence to support the efficacy of this practice. Risk factors related to health and work ability are identified by providing employees with online or paper form surveys. Applicants whose surveys indicate health risks that may pose a threat to work ability are then invited for a personal health examination and are provided with support. With regard to screening examinations, it has to be ensured that the entire target group will still be able to participate in health

examinations if so desired, because it is possible that the screening survey does not reach everyone in need of assistance. It must also be ensured that the surveys are valid, and that it is known who is being reached by the survey and who is not.

A multi-professional approach in occupational health care involves teamwork based on the multidisciplinary which underlies various professions. The occupational health team consists of an occupational health physician, nurse, psychologist and occupational physical therapist, but it can also include other occupational health care experts, if so required by the workplace or employee. Occupational health nurses conduct most of the examinations (58%), while physicians account for 28%, physical therapists for 10% and psychologists for 4% of the conducted examinations. The occupational health nurse is usually the one who then directs the client to a physician or other occupational health care expert. In health examinations of cases involving serious risk of work-related illness, the physician's opinion is absolutely necessary.

## 6.4 CONTENT OF OCCUPATIONAL HEALTH EXAMINATIONS

In work involving serious risk of illness or accident, an examination's content can be very specific; e.g., a hearing test or biological exposure test, in which blood and urine samples are screened for occupational exposure to certain chemicals. These examinations are compulsory for employees. The scope and content of the examinations aimed at determining health, working and functional capacity is determined through a needs assessment, which is conducted in co-operation with the workplace and the set targets. Conducting examinations requires the consent of the employee.

An occupational health examination incorporates clinical examinations and other suitable and reliable methods. If the occupational health examination includes screening, it is important to define the health targets of the screening procedure, to determine how possible it is to achieve these targets through screening, and to determine what the best screening methods are. the regulations found in the Government Decree on Screenings (339/2011) regarding screening procedures compliant with the national screening programme must also be taken into account. No screening-type examinations that fail to meet these screening criteria should be included in a health examination.

## 6.5 HEALTH EXAMINATIONS FOR IMMIGRANTS

Finland does not impose health requirements on immigration, nor does its immigration policy contain any health-related statements or take positions on the matter. Immigrants are not turned away at the border for health-related reasons, and officials who process residence permit applications are not allowed to know the results of screening tests taken during or after the entry examination. The Ministry of Social Affairs and Health recommends providing health examinations for refugees, asylum-seekers and for members of their family who arrive in Finland later, as well as for persons arriving from countries with a high incidence of tuberculosis and are planning to stay in Finland for a period longer than three months. In addition to this, some municipalities provide other immigrant groups with health examinations as part of the integration process. Participation in health examinations is voluntary.

Refugees and asylum-seekers, and the problems of preventing infections among them, is presented in the Ministry of Social Affairs and Health guideline 2009:21, which specifies the arrangement procedure, cost liabilities and medical contents of health examinations aimed at these groups. An examination in this case involves a visit to a clinic nurse or, if necessary, to a physician; a lung x-ray taken to screen for tuberculosis; and laboratory tests to screen for HIV, hepatitis B and syphilis. Children are also screened for intestinal parasites. The person's vaccination history is also examined during the clinic visit.

In 2014, the Ministry of Social Affairs and Health also issued guidelines regarding the early diagnosis of pulmonary tuberculosis during immigrant health examinations. If it is likely that their stay in Finland will be longer than three months, immigrants from countries with a high incidence of tuberculosis (List of countries to be found at: <http://www.thl.fi/attachments/Infektiaudit/Maaluettelo.pdf>) must be offered a voluntary screening for tuberculosis. This screening procedure involves a preliminary interview with a nurse or public health nurse within two weeks of arrival in Finland and, during the same clinic visit or as soon as possible after it, a lung x-ray. The objective of the screening is to protect the immigrant's own health and break the chain of infection, thus also protecting the general public from developing tuberculosis infections.

## 6.6 HEALTH EXAMINATIONS FOR THE UNEMPLOYED

As stated in section 13 of the Health Care Act, which entered into force in 2011, "[m]unicipal health counselling and health checks shall also be made available to young people and individuals of working age who are not covered by student health care or occupational health care." Based on a national health centre survey conducted in 2013, the municipalities had been responsible for

providing more health examinations for the unemployed, and related services, than they were in 2009. Of the municipalities responding to the survey, approximately half had provided health examinations for the unemployed in 2009, whereas the figure in 2013 rose to 89%. Although health examinations are conducted quite comprehensively throughout the country, there is no precise data on the number of clients. Nearly all the municipalities currently providing health examinations had agreed to continue doing so. Two factors contributing to this continuity are needs-based activities and prescribed co-operative practices.

## 6.7 OTHER HEALTH EXAMINATIONS

In order to obtain certain official permits and licences, it is required to undergo a medical examination, which also includes a health examination. This is necessary for, e.g., driver's licences, pilot's licences or a certificate of competency for a person who sets off explosives. It should also be assessed whether it is safe for a person to scuba dive before they participate in any such training programme. In the Finnish Defence Forces, health examinations are conducted whether a person is fit for military service – this is done during the call-up, when arriving for service, and at the end of service. Some municipalities provide health examinations for the elderly, which focus on assessing functional capacity and factors related to living at home. Oral health examinations are conducted in order to assess oral health, development and possible need for treatment. If necessary, a personal health plan is made. The municipality must provide these examinations to all persons belonging to a predetermined age, class year or other group, as well as based on individual need.

## 6.8 SCREENING FOR CHRONIC DISEASES IN HEALTH EXAMINATIONS

### *Risk assessment of cardiovascular diseases*

Each adult should be aware of their blood pressure and cholesterol level. According to USA recommendations, the overall risk should be assessed once every 4–6 years after the age of 20 in low-risk cases and more frequently in higher-risk cases. According to European recommendations, it would be good to assess the risk among all adults, but at least among men 40 years of age and women 50 years of age. The easiest way to measure overall risk is with the FINRISKI calculator, (<http://www.thl.fi/finriski-laskuri>) in which users enter their age, gender, total cholesterol, HDL cholesterol, systolic blood pressure, smoking habits, diabetes (if any) and whether their parents had a heart attack or stroke at a young age. The calculator expresses the probability

of contracting a cardiovascular disease, dying of atherosclerosis or a stroke, as well as the combined risk of all the aforementioned factors. The calculator also provides the risk for a man or woman of a certain age, belonging to a low-risk group, to contract a cardiovascular disease; the calculator also shows the median risk for a Finnish man or woman of a certain age possessing typical risk factors. FINRISKI is most useful for middle-aged members of the population, as the absolute risk for young adults is overall very low. However, the relative risk for a young adult can be determined by comparing their risk factors to others in the same age group, or by determining what their risk would be at the age of 60 given the continuation of the same lifestyle. Also, the predictive value of risk factors for cardiovascular diseases in older people declines. Further treatment should be planned and carried out in accordance with the Current Care Guidelines for dyslipidemia and high blood pressure (Dyslipidemia, High blood pressure).

### *Risk assessment for diabetes*

The risk of diabetes is easy to assess with an online test, which requires no laboratory testing: <http://www.diabetes.fi/files/502/eRiskitestilomake.pdf>. The test can also be taken in paper form. The two-hour glucose tolerance test should be taken at the 12-point risk limit or 15-point risk limit, depending on availability. Treatment should be given in accordance with the Current Care Guidelines for diabetes (Diabetes).

## 6.9 THOUGHTS ON THE BENEFITS AND EFFECTIVENESS OF HEALTH EXAMINATIONS

There are numerous benefits offered by health examinations. Some of these benefits can be precisely measured (diseases prevented by vaccination or other means, detected hearing impairment, etc.). Others are experiential, such as the experience of a father or mother receiving assistance and strengthening their capabilities in child-rearing. The effectiveness of a health examination therefore consists of several factors, some of which reveal their impact immediately and others only after several years. One example of delayed impact includes the early detection of learning disabilities, with treatment benefits seen through improved learning skills at the comprehensive school level. Furthermore, the early identification of behavioural problems has a major impact on the children themselves, their parents and society as a whole.

Appendix Table 2 shows research data on the benefits of operating models or work methods used in health examinations at maternity and child health clinics, and in school health care. According to the data, there are substantial potential health benefits of the operating models and work methods, influencing children, young people and parents. The benefits of health examinations and

the accompanying advice depend on in the circumstances of the examinations: How are the children and parents treated? How effectively can one support the well-being of parents, children and young people and make changes for the better? How effectively can problems or need for support be identified, and tertiary care measures taken?

Health examinations produce more benefits when the actors support protective measures more effectively, and address concerns and problems early and effectively. It is cost-effective to provide assistance to a child and its family as early as possible, before the problems have established themselves. If problems are addressed only after years of waiting, the situation is usually exacerbated, assistance is more difficult to provide, and costs multiply.

Health examination procedures should be presented in a sufficiently effective way. A single recommendation to stop smoking or to lose weight is most effective when a person frequents the same health care professional, who prescribes recommendations so as to suit the life situation of their patient. Motivational interviews have produced good results in changing health habits.

Health examinations form a continuum, which is used to regularly monitor and improve the health and well-being of every child, young person and family, and in which interventions are made when necessary. Assessing the effectiveness of only a single health examination is rarely possible or desirable. A health examination is a multi-dimensional whole, whose value and accompanying benefits depend on a variety of factors, such as management and employee skills, as well as the functionality of the service entity. It is important to treat a child and its parents as unique individuals, create a confidential relationship and develop the ability to take the needs of individuals and the population into consideration, thus facilitating participation (see also Government Decree 338/2011).

Health examinations for children and young people include various measurements, which can be used to monitor their growth and development. Other health examinations use other types of. Measurements can be studied based on how effectively they identify anomalous results. However, conducting randomised studies on health examinations as a whole is not possible. The measurements in question, and the actions taken based on them, can nevertheless be used to assess both positive and negative impacts.

For adults, health examinations usually observe either work-related health risks, risk factors for chronic diseases or, more broadly, health and functional capacity surveys. With regard to cardiovascular disease risk factors, blood pressure and cholesterol, health examinations primarily entail risk management. The risk of contracting a cardiovascular disease increases linearly as blood pressure or cholesterol level rises. Consequently, it is a good idea to make changes in one's health habits regardless of risk levels; however, medicinal intervention is recommended at certain (high) risk levels. Following a health examination, changes to one's health habits require the development

of a systematic programme, while a medicinal intervention requires a patient to be monitored and motivated.

## 6.10 RECOMMENDATIONS FOR DEVELOPMENT

Throughout one's life, health examinations are conducted due to a variety of needs and requirements placed by, for example, maternity clinics, school and student health care, the military, occupational health care and immigration authorities. The examination results are recorded in information systems, using free-form text and structure. Some data, such as vaccination history, functional capacity limitations or a personal health plan, should be attributed to person throughout their lifetime. This, however, does not happen in reality, because each health service provider keeps their own records, which are not transferred along with the person to a different service provider. There is an obvious need for cross-organisational transfer of information.

A silo mentality (when several departments or groups do not want to share information or knowledge with other individuals in the same organisation) in health care, and interruptions in the flow of information, cause a great deal of unnecessary work and compromise the ability to monitor a person's health and working and functional capacity effectively over the long term. The National Archive for Health Information (KanTa) Patient Data Repository is intended to solve the aforementioned problem. Health care providers enter patient data into the system, and the system retrieves key patient treatment data from archived records for the same or other health care providers, and for the citizens themselves to see. The structure and content of the Patient Data Repository should be developed so as to it easy to find not only key health information, but also information on conducted health examinations and personal health plan.



## 7 CLOSING REMARKS

Liisa-Maria Voipio-Pulkki

The starting point of *Screening in Finland 2014* was the unanimous view of the working group on screening that national steering of screening programmes should be strengthened. For this purpose, it was necessary to present a compact review of the history, present state and current issues of screening in Finland.

The structural reform of social welfare and health care currently underway will change the responsibilities for providing screening services. Responsibility for screening processes will be collected to a few social welfare and health care regions. The reform lays a strong foundation for a uniform, seamless, effective and cost-effective provision of screening programmes in Finland also in the future.

New screening programmes and screening-type functions are constantly becoming available. There are also changes in the core screening activities of the national screening programme – there is constant change in screening methods, population structure, epidemiology, and treatment methods of diseases being screened for. This is why the national screening programme should be critically assessed at least every decade. On the other hand, building a well-functioning screening chain takes years, as can be seen from the description of launching the prenatal screening programme in this book.

Screening programmes that have been proven effective in a carefully constructed study design might not necessarily be applicable as such, or implementable in Finnish conditions. The examples described in this publication – screening for neonatal metabolic diseases and abdominal aortic aneurysms – illustrate the difficult points which the working group on screening needs to consider when discussing a possible widening of the national screening programme. The challenging economic situation of municipalities and the current inability of the statistical authority to monitor the implementation and effectiveness of new mandatory screening programmes all have an impact on the chosen course of action. The social welfare and health care reform, and the reform of the personal data register legislation, which are currently being prepared, will aid decision-making on the national screening programme. Quality control of all screening and monitoring implementation should be co-ordinated by a single authority, in co-operation with the new social welfare and health care regions.

The criteria which a screening procedure needs to fulfil are demanding, and the threshold for gaining approval as a mandatory national screening programme is therefore high. However, there are many useful health care

activities, usually as part of health examinations, which resemble screening but do not necessarily meet all the classic criteria for screening. This is why this publication includes a description of health examinations intended for different age groups. It is important that health examinations are planned and implemented in a way that does not reduce public participation in the actual screening programmes.

People's interest in promoting their own health, as well as in health information in general, is rapidly proliferating and changing. For example, the first strategy for the use of national genomic data is currently being prepared. Combining national databases, health information produced by people themselves, and open data, can create entirely new opportunities for targeting appropriate measures and for promoting public health. In the future, the national screening programme is going to be evaluated in light of these new opportunities. The working group on screening hopes that this publication will spark debate on the future of the national screening programme, and that all people entitled to Finnish social welfare and health care services will continue to have access to uniform and effective screening programmes.

# GOVERNMENT DECREE ON SCREENINGS (339/2011)

Issued in Helsinki on 6 April 2011

## **Government Decree on Screenings**

In accordance with the Government decision made on the submission of the Ministry of Social Affairs and Health, the following is enacted by virtue of section 23 of the Health Care Act (1326/2010):

### **Section 1**

#### **Definition of screening**

For the purposes of this Decree, “screening” means examination of the population or a certain part of the population, or sampling in order to discover a certain disease or its precursor or to identify a pathogen.

Screening is part of preventive health care. Screening includes the definition of the target group, individual advice and guidance, performing and analysing the screening tests, delivery of feedback information, referral to further examinations and organization of the necessary health services.

### **Section 2**

#### **National screening programmes**

The following are screening programmes compliant with the national screening programme:

- 1) Breast cancer screening every 20–26 months for women aged between 50 and 69 who were born in 1947 or later;
- 2) Cervix cancer screening every five years for women aged between 30 and 60;
- 3) For pregnant women:
  - a) a general early pregnancy ultrasound scan during week 10+0–13+6 of the pregnancy;
  - b) detection of chromosomal abnormalities primarily through early pregnancy combined screening (serum screen test in week 9+0–11+6 of the pregnancy and the measurement of neck oedema in connection with a general ultrasound scan in week 11+0–13+6 of the pregnancy) or, alternatively, through a second trimester serum screen test in week 15+0–16+6 of the pregnancy; and
  - c) an ultrasound scan for the detection of severe structural abnormalities in week 18+0–21+6 of the pregnancy or after week 24+0 of the pregnancy.

### **Section 3**

#### **Other screening programmes**

If the municipality provides screening programmes other than those included in the national screening programme, it shall assess, before starting any screening, the requirements and impacts imposed on the health care system and how screening affects it. The assessment shall include an examination of the disease to be screened, its incidence and treatment, screening methods, effectiveness, organization and total costs of screening, as well as the ethical aspects relating to screening.

### **Section 4**

#### **Organization of screening programmes**

The screening shall be organized in accordance with a programme established by the municipality in advance, taking sufficient quality control and quality assurance procedures into account.

In order to provide appropriate screening services, the municipality shall monitor and evaluate the quality of the entire screening process and the reliability of the screen tests on a regular basis.

### **Section 5**

#### **Participation in the screening**

All of the municipality's inhabitants that belong to the screening group shall be entitled to participate in the screening on equal grounds. The participation in the screening is voluntary.

The municipality shall ensure that its inhabitants have access to sufficient information on the objectives and effectiveness of the screening, the possible risks involved with the screening, and the organization of the screening.

The health services shall be organized in such a way that there is no discrimination between the municipality's inhabitants who have participated or intend to participate and those who have not participated or do not intend to participate in the screening organized under the national screening programme or some other screening organized by the municipality.

## **Section 6**

### **Special conditions**

The health care unit participating in the collection, analysis, feedback delivery and further examination of the screening samples shall have sufficient expertise, as well as the necessary staff and equipment, at its disposal.

The municipality shall appoint a supervisor for each screening.

## **Section 7**

### **Direction and monitoring**

The National Institute for Health and Welfare shall monitor and evaluate the ongoing screening programmes and their methods in collaboration with other operators in the sector.

## **Section 8**

### **Entry into force**

This Decree enters into force on 1 May 2011.

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Radiation Act (592/1991)

Health Care Act (1326/2010)

Occupational Health Care Act (1484/2001)

Government Decree on the principles of good occupational health care practice, the content of occupational health care and the qualifications of professionals and experts (708/2013)

Government Decree on Screening programmes (339/2011)

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APPENDIX I. EXAMPLES OF VARIOUS TYPES OF HEALTH EXAMINATIONS, THEIR TARGET GROUPS, MANDATORY NATURE, COVERAGE, SCREENING ELEMENTS AND OBJECTIVES.

Health examination	Target and age group	Mandatory health examination (yes/no, reference)	Coverage (% of the target group participating, estimate?)	Screening elements included in the health examination	Objective
Maternity clinic examinations	Families expecting a child	Yes (Health Care Act 1326/2010, Gov. Decree 338/2011) Periodic health examinations (primarily 9+2, THL Guide-book) incl. 1 extensive health examination	99.8% (Birth registry, THL)	Foetal health Health of the expecting mother Health of the whole family (Äitiys-neuvola-opas THL, 29/2013, luku 7.6)	Extensive health examination *) : 1) strengthens the capabilities, health and well-being of the child, parents and entire family, 2) allows for the earlier identification of the needs for family and family member support 3) ensures the right-timing and provision of support and 4) enhances the prevention of marginalisation and reduces health disparities.
Child health clinic examinations	Children under school age (0-6 years) and their families	Yes (Health Care Act 1326/2010, Gov. Decree 338/2011) Periodic health examinations (9+6) incl. 3 extensive health examinations	99.5% (vaccination coverage data)	Psychosocial development Communication, speech and language Physical health, growth and development (physical functional capacity assessment) Vision and hearing Neurological development Oral health Health of the whole family	cf. *) Identifies problems in the child's growth, development, health and well-being (incl. diseases, disorders) as well as the needs for support as early as possible Support for the child and family as well as referral to examinations or treatment, if necessary

<b>Health examination</b>	<b>Target and age group</b>	<b>Mandatory health examination (yes/no, reference)</b>	<b>Coverage (% of the target group participating, estimate?)</b>	<b>Screening elements included in the health examination</b>	<b>Objective</b>
School health care examinations	Pupils of schools providing basic education (grades 1–9, 7–15 years of age)	Yes (Health Care Act 1326/2010, Gov. Decree 338/2011) Periodic health examinations (9) incl. 3 extensive health examinations	approx. 100%	Psychosocial development (mental health) Physical health, growth and development Vision and hearing Neurological development Oral health Health of the whole family Special examinations needed to assess the health condition	cf. *) Identifies problems in the child's growth, development, health and well-being (incl. diseases, disorders) as well as the needs for support as early as possible Support for the child and family as well as referral to examinations or treatment, if necessary
Student health care examinations	Students in upper secondary and vocational schools as well as students in institutions of higher education (16 years of age and over)	Yes (Health Care Act 1326/2010, Gov. Decree 338/2011) Periodic health examinations	? (NK-julkaisu)	Psychosocial development, Physical health, growth and development Vision and hearing Oral health	Develop an overall idea of the student's health and well-being (also in terms of coping with studies, with regard to mental health) and guide the student in making choices that promote his or her health
Driving licence examinations	When applying for a driving licence. Moped, motorcycles and passenger cars: 70–75 years of age (every 5 years). Lorry, bus: 68–70 years of age (every 2 years).	yes Act on Driving Licences 386/2011			Assessment of the fitness to drive

Health examination	Target and age group	Mandatory health examination (yes/no, reference)	Coverage (% of the target group participating, estimate?)	Screening elements included in the health examination	Objective
Military examinations Call-up examination Arrival examination Discharge examination					Assessment of fitness to serve
Occupational health care examinations for cases involving serious risk of illness due to work preliminary examination periodic health examinations  examinations for promoting health and work ability pre-employment examination targeted examinations examination at the end of employment	Employees starting work involving exposure to physical hazards and working age persons employed in such work  Employed, working age	yes  Gov. Decree 1485/2001  Gov. Decree 708/2013	>90%?  ?	According to exposure, for example, hearing, spirometry, lung x-ray, blood or urine biomonitoring tests  For example, work ability index, Audit, BBI-15, lab tests, e.g. lipids, blood glucose, liver function tests, PVK	Prevention of work-related illness and its early diagnosis  Maintaining and promoting health and work ability; referral to examinations, treatment and rehabilitation; adapting work to work ability

APPENDIX 2. EXAMPLES OF THE BENEFITS OFFERED BY WORK METHODS AND OPERATING MODELS USED IN MATERNITY AND CHILD HEALTH CLINIC AND STUDENT HEALTH CARE EXAMINATIONS (ADAPTED FROM HAKULINEN-VIITANEN & PELKONEN 2014).

<b>Operating model or work method</b>	<b>Work method/operating model benefit</b>
Growth and development monitoring, Updated growth curves and standards	Growth monitoring aids in the early diagnosis of diseases and disorders that affect growth as well as targeting treatment to those who need it. These diseases and disorders include malabsorptive disorders (e.g. coeliac disease), chronic diseases, endocrine diseases (e.g. hyperthyreosis and precocious puberty caused by excessive androgen secretion), chromosomal anomalies and deprivation. Monitoring height growth can help in making an early diagnosis and finding those who need help/ treatment. Monitoring weight accelerates the diagnosis of diseases and nutritional problems and promotes the prevention of weight gain.
Vision examination	Vision and eye examinations aid in the early identification of diseases related to visual capacity and the eyes (e.g. congenital cataracts, retinoblastoma). Vision is a child's most important channel for interaction during their first year of life, which is why any abnormalities in vision and the eyes should be noticed as soon as possible. The earlier an abnormality in vision and the eyes presents, the more likely it will have an impact on the child's development. Eye contact is part of early communication and any problems with it may indicate problems in visual capacity or the child's overall development. The benefit of examining visual acuity and correction of visual capacity is evident in the child's communication ability, functional skills and learning.
Hearing examination	Hearing examinations aid in the identification of hearing impairments and targeting of treatment. Even a minor hearing impairment can have an adverse effect on the child's speech and language development as well as success in school and the workplace later in life. The early diagnosis of hearing impairment is vital to ensuring the child's development in communication, speech, emotions, intelligence and motor skills.
Speech development examination	Examining speech development helps to find children who are delayed in their language development and require additional examination and/ or speech therapy. It is in the best interests of the child and family for speech development problems to be identified and rehabilitation begun as early as possible. Properly targeted and timed support will save on costs, because successfully rehabilitated children suffering from language development problems can attend school in normal classes.
Assessment of neurological development at preschool age and promoting development - Lene method	The Lene method helps in identifying early developmental abnormalities in children 4 years of age and initiating the necessary corrective action. Early intervention prevents the problem from deepening and building up in the area of the child's socioemotional development. Lene is also effective in assessing clear learning difficulties occurring in the first years of school (Valtonen 2006, Valtonen et al. 2007).

Operating model or work method	Work method/operating model benefit
Identifying nutritional habits and nutrition advice	Nutrition advice has been proven to be cost-effective (Kiiskinen et al. 2008). Among other things, it improves the quality of the diet by encouraging the consumption of fruits and vegetables and giving attention to the types of fat taken. Nutrition advice affects the nutritional habits of pregnant women, both in weight gain experienced during pregnancy and returning to a pre-pregnancy weight (Luoto et al. 2007, Kinnunen et al. 2008). As many as half of all gestational diabetes cases can be prevented by healthy nutritional and exercise habits (Kinnunen & Luoto 2004, Luoto et al. 2007). Nutrition during pregnancy has an impact on, for example, juvenile and adult morbidity of the child being born (Erkkola & Virtanen 2013). Nutrition advice aimed at the whole family is effective because learned nutritional habits can result in obesity both during childhood (Chen & Escarce 2010) and adulthood (Lagström et al. 2008, Singh et al. 2008).
Weight management	Nutrition advice on its own or together with exercise intervention has been proven to be cost-effective (Kiiskinen et al. 2008). The prevention of Type 2 diabetes has been shown to be cost-effective. Obesity, which is a major public health problem, causes a wide variety of diseases, which can be treated and prevented by losing weight.
Exercise habit assessment and advice	The impact that exercise has on maintaining health and well-being and preventing disease is undeniable (Sääkslahti 2005, Kiiskinen et al. 2008). Exercise protects against cardiovascular diseases, Type 2 diabetes and cerebral circulation disorders as well as lowers blood pressure. Health advice can be used to increase the amount of exercise a family gets.
Advice on the identification, prevention and reduction of smoking as well as quitting	The impacts of smoking on health are undeniable. Among other things, mothers who smoke during pregnancy have a 50% higher risk of giving birth to an underweight child than a non-smoking mother (Räisänen et al. 2013). Interventions to cut down on/quit smoking made by primary health care professionals have been proven to be cost-effective (Kiiskinen et al. 2008). A programme for quitting smoking aimed at pregnant women reduces their smoking, the number of premature births and number of underweight children born (Melvin et al. 2000). When the parents of small children quit smoking, it reduces the children's exposure to cigarette smoke. It is possible to reduce the incidence of juvenile smoking by getting their parents to quit (Kallio et al. 2006).
Identifying the consumption of alcohol and advice on reducing its consumption - Audit form	The mini-intervention implemented in primary health care is cost-effective and may save on costs (Kiiskinen et al. 2008). Of the various intoxicants available, alcohol causes the greatest amount of foetal defects (O'Leary 2004, Autti-Rämö 2011). The physical and emotional treatment of children (early interaction, attachment) has been increasingly neglected in families where the parents consume intoxicants (Pohjola et al. 2007, Pajulo & Kalland 2006). Maternal substance abuse is the most common reason for taking small children into protective care (Sarkola et al. 2007). The parents' model for alcoholic consumption influences the child's later alcohol consumption habits (Seljamo et al. 2006).
Assessment of substance abuse among young people and a health discussion for promoting sobriety; Adolescents' Substance Use Measurement (ADSUME)	ADSUME is suitable for use in health examinations for secondary school students (grades 8 and 9) (Pirskanen 2007). It helps in recognising the adverse effects of substance abuse (accidents, injury to others, conflicts, careless sexual relations), which are difficult for young people to associate with large doses of alcohol.

<b>Operating model or work method</b>	<b>Work method/operating model benefit</b>
Identification of postnatal depression and its prevention and treatment; Edinburgh Postnatal Depression Scale (EPDS)	Discussing depression and the related EPDS form are effective methods for identifying depression symptoms and targeting support for those who need it (Gibson et al. 2009, Hewitt et al. 2009). The EPDS form is, however, not suitable for making a diagnosis. A majority of depression cases are minor and can be treated by means of information and psychosocial support available at maternity clinics (Glavin 2012). The early prevention and identification of postnatal depression is crucial because its symptoms become a part of the whole family's routine (Misri & Kendrick 2008).
Identification of affective symptoms among young people and early support, Raitasalo Beck Depression Inventory (RBDI13)	The RBDI13 is suitable for identifying affective symptoms among young people and can also be used to screen for psychological symptoms requiring treatment. Although adolescence often involves a variety of emotional symptoms, these may also be accompanied by clearly distinguishable symptoms, which affect the daily routine of the young persons concerned and can cause them great suffering. Psychological symptoms can be examined and the situation can be improved with suitable treatment. Proactive treatment administered as early as possible is vital to improving the diagnosis. (Karlsson & Marttunen 2007, Raitasalo 2007)
Identification of and early intervention in interpersonal and domestic violence as well as child abuse	The entire family benefits from identification of and early intervention in interpersonal and domestic violence as well as child abuse. Violence may lead to death or permanent disability. Violence is linked to parental mental health problems, substance abuse and relationship problems. Being exposed to interpersonal and domestic violence and child abuse is a threat to the growth and balanced development of the child.
Identification of and supporting early interaction	Supporting early interaction at the maternity clinic can prevent and cure mental health problems in the child. By providing support, it is possible to improve interaction between the child and parents, thus reducing attachment problems. (Puura et al. 2011, Puura et al. 2002.) The early detection of interaction problems allows for the early identification of children whose psychological development is threatened, thus helping them at an early stage (Mäntymaa et al. 2003, Mäntymaa 2006). Providing interaction support for mothers with substance abuse problems, such as helping her to keep the baby in mind, is an effective form of treatment (Pajulo et al. 2006).
Identification and strengthening of capabilities, Resource barometer questionnaires and motivational interviews	Identifying and providing support for a family's capabilities enhances its ability to cope and reduce the level of stress (Steward-Brown & McMillan 2011). Information facilitates a proactive effort to improve family life. A motivational interview is an effective tool for improving health habits, such as by reducing stress, depression and substance abuse (Lundahl et al. 2010).
Let's Talk About the Children method	The Let's Talk About the Children method is based on opportunities for parents to support their children's development and protective factors. This treatment for interaction between the parents and child has proven to be an effective method for preventing and correcting mental health problems in children. The method reduces the child's psychosocial symptoms and promotes the support of prosocial behaviour, cognitive role-taking ability and empathy. (Solantaus et al. 2010.)
Identification of the need for peer support and its channelling to families, parental group activities	Group activities offered to all parents in a given age group has been proven to bring savings (Nilsson & Wadeskog 2008). Family coaching in small groups has been proven to expand social networks and improve the receiving of support.

<b>Operating model or work method</b>	<b>Work method/operating model benefit</b>
Making housecalls: Advice and guidance	Advice and guidance included in housecalls has been shown to have an impact on parental skills, interaction between the parents and child, the duration of nursing, identification of postnatal depression and the prevention of accidents and child abuse (Elkan et al. 2000, Bull et al. 2004, Wilson et al. 2007). The impact of housecalls is particularly evident in families needing special support. Maternity and child health clinic housecalls can have an impact on the life skills of mothers with income difficulties and relationship continuity as well as the reduction of substance abuse and child abuse (Olds et al. 2010, Barlow et al. 2007, Donelan-McCall et al. 2009).