Screening - a report

THE DANISH COUNCIL OF ETHICS
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THE DANISH COUNCIL OF ETHICS
2001
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the Danish Council of Ethics
on tel. (+45) 35 37 58 33,
fax: (+45) 35 37 57 55,
via e-mail: etiskraad@etiskraad.dk
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The Danish Council of Ethics
Ravnsborggade 2-4
DK-2200 Copenhagen N
Denmark
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Foreword

The Danish Council of Ethics is publishing its report on the use of screening programmes in the health service. The purpose of the report is to direct the focus on the ethical problems connected with screening, and it is the Council’s hope that the report can contribute to the debate on screening currently taking place among the public as well as in the political system.

The report has been dealt with at the Council of Ethics’ plenary sessions based on an outline from the Council’s working party on the use of screening programmes. The working party comprised Linda Nielsen (chairperson), Lene Koch, Sven Asger Sørensen, Sigurd Olesen, Inga Steiner Sørensen, Erling Tiedemann, Søren Holm and Frederik Christensen.

The working party has benefited greatly from a number of experts who have made their expertise available at meetings with the group. For this valuable input, thanks are extended to Dr Ole Hartling, MD, senior consultant at Vejle Hospital, Dr Birgit Petersson, MD, senior lecturer at the Panum Institute, Professor Bent Nørgaard-Pedersen, MD, senior consultant at the National Serum Institute, Dr Henning Mouridsen, MD, senior consultant at Rigshospitalet, the National University Hospital, Hans Peder Graversen, senior consultant and Head of Division at the National Board of Health, Denmark, and Dr Inga Marie Lunde, MD, a GP in Silkeborg. In addition, our thanks go to the following for reading through the factual sections of the report: Professor Mogens Blichert-Toft, MD, senior consultant at the National University Hospital, Professor Frede Olesen, MD, University of Aarhus, Dr Ole Færgeman, MD, senior consultant at Aarhus County Hospital, Svend Juul Jørgensen, medical director at Bispebjerg Hospital and Dr Torben Jørgensen, MD, senior consultant and head of the Centre for Preventive Medicine at Glostrup University Hospital.

For the sake of good order it should be mentioned that none of the above is responsible for the contents of this report.

The report has been compiled by Anna Skyggebjerg, MA, and Claus Holm, MA, of the Council of Ethics’ secretariat, based on the discussions of the working party and the Council.

April 1999

Linda Nielsen Berit Faber
Chairperson Acting Head of Secretariat
Chapter 1: Introduction
—why is the Council of Ethics reviewing screening examinations?

The Danish Council of Ethics has been urged by the Minister for Health to shed light on the ethical problems involved in the use of screening programmes. The Council has therefore decided to take screening under ethical advisement.

Screening is a term denoting the early detection of illness and the detection of signs of possible future illness by examining a large group of people. Screening always pertains to a particular disease or group of diseases. The aim of early illness detection is to increase the chances of either curing the disease or of preventing an increased risk of being sick from developing into actual sickness. A screening programme includes a lot of people who feel healthy with a view to finding a handful of sick ones.

The best known screening programmes are mammographic screening for breast cancer and screening for cervical cancer. The future will presumably present more opportunities for screening. Even today some 35 screening options exist (see Chapter 3, A screen a day keeps the doctor away). Individual screening programmes can be ethically problematic. Furthermore, the existence of an increasing number of programmes can entail new problems. The Council of Ethics sees the Minister for Health’s invitation as an opportunity to clarify the problems associated with one programme and with the existence of an increasing number of programmes.

The Council has chosen to adopt four perspectives on screening.

Firstly, one of the key questions is whether screening tests reflect a pathologization of many healthy people or whether, on the contrary, they reflect a good service offered to a few sick people, and one that can also be reassuring for the healthy subjects being examined. In this context, the Council of Ethics has discussed three topics:

1) Is it reasonable for many healthy people to be asked to take part in screening tests that benefit only a few sick people?
2) Does participation in screening tests imply pathologization and “anxietization”. Pathologization is used as a term for participants in screening programmes possibly becoming dependent on experts regularly vouching for the fact that they are not ill. The term anxietization is used to denote participants’ fear of being ill.
3) Are the many healthy people reassured by finding out that they are not ill?

Secondly, it is important to be aware that screening programmes entail false examination results. That is to say that, as a consequence of a screening test, a certain number of people will be told that they are sick or healthy—without being so. On the subject of false examination results the Council of Ethics has discussed four topics:

1) Should a screening programme be accepted because the benefit of helping sick people outweighs the drawback of inflicting false test results on people?

2) Or should a screening programme be accepted because informed consent can be used to ensure that the individual participant is familiar with the risk of receiving a false result?

3) What significance will getting a false positive test result have for the individual? A false positive result occurs when a screening test arouses suspicion that the examinee is ill but additional examinations, and possibly treatment, show that suspicion to be unfounded.

4) What significance will getting a false negative test result have for the individual? A false negative result occurs when a screening test clears the examinee because the disorder is not seen during the examination—i.e. the examinee is given a clean bill of health on a false basis.

Thirdly, the use of screening programmes is about the way the health service distributes and prioritizes its resources. Does the implementation of screening programmes represent equitable distribution and prioritization of health service resources? And what preventive impact can screening programmes be assumed to have?

In this context the Council of Ethics has discussed the following topics:

1) Who should the health service primarily spend its resources on—sick people or people who may be or become ill?

2) Should everyone in a target group be granted access to the screening programme before it is introduced?

3) How many extra years of life need to be gained?

4) What role should financial savings and considerations of efficiency play?

5) What quality requirements should be imposed on a screening programme prior to its implementation?

Fourthly, screening tests are fundamentally about the value of risk evaluations. A risk evaluation is involved when the result of a screening test does not affirm whether a person is ill but merely whether that person is at greater or lesser risk of being or becoming ill.

In this connection the Council of Ethics has discussed four topics:

1) Is there a crucial difference between a situation in which the physician informs the individual about a disease the physician knows for certain the person in question has and a situation in
which the physician informs the individual of the risk of being ill?
2) What psychological reactions are there to receiving information about possibly being ill?
3) Does the individual confuse the risk of illness with actual illness?
4) Who should provide information and advice on risks—and to whom?
Chapter 2: What is screening?

2.1. Examining a healthy population group

"Prevention is better than cure". That is one of the adages that has entered the language as a truism—and perhaps also the philosophy underlying the health authorities’ use of screening programmes?

To screen means to examine a population group that feels healthy—or at least has no inkling of being sick with the particular disease addressed by the screening programme. The screening programme can include either the whole population or a selected population group.

The purpose of a screening test is to prevent a disease from developing, or to find a disease at such an early stage in its development that it is easier to treat or is treatable with better results.

The concept of screening originally came from the word "screen", used in the sense of a "sieve". The point of screening is to sift sick people from healthy ones. Of necessity it also involves healthy individuals having to undergo the examination or pass through the screen.

As well as meaning a "sieve", the word "screen" can also be used in the sense of a monitor or cinema screen. This sense of the word captures another meaning of the concept, that screening renders visible. In screening, a disease is made visible at an earlier point than would otherwise have happened. The person being screened has hitherto invisible aspects of their state of health made visible—for example, diseases or risks of diseases.

In order to visualize a screening programme, you can imagine, in slightly popular terms, sieving a bag of peas to sort the large ones from the small ones. All the peas will have to pass down into the sieve to work out which ones pass through the holes in the sieve and which are left. The large peas left in the sieve represent the people “caught” by the examination, who are therefore either ill or at risk of becoming ill from the disease being screened for. In a way, you might call a screening programme a sorting machine that sifts the healthy from the (possibly) ill. The (possibly) ill are offered additional examinations and, where appropriate, treatment.

2.2. The health authorities are the initiative-takers

In addition to being a population survey of healthy subjects (people without symptoms of disease), a
characteristic of a screening programme is that the health authorities take the initiative for the examination. Usually, of course, the reverse is true, in that people contact the doctor on their own initiative when they themselves experience problems with their health.

Another distinguishing feature of participating in a screening test is that it is a recurring, routine event. This is familiar, for example, from examinations of elderly motorists who must undergo annual ophthalmic check-ups to assess whether their sight is good enough to allow them to function as motorists. Another example is that most people are encouraged by their dentist to have their teeth checked with some degree of regularity.

2.3. When the result is not a diagnosis but a risk evaluation

In many instances the reply received after taking part in a screening programme will not be a diagnosis, but a risk evaluation. A diagnosis states whether one is sick or healthy. A risk evaluation says something about the probability of being or having the potential to become ill. For instance, an examination can indicate a person’s increased risk of having or later contracting the disease addressed by the screening programme. Notifying a participant of increased risk will presumably intensify their motivation to have more tests done, receive treatment or attend a similar new examination—for instance, once a year for a particular number of years.

One example of an examination in which the result will nearly always be a risk evaluation is the examination for a high cholesterol value. Having a high level of cholesterol is not a disorder per se (except in rare cases), of course, but it can be an indication of an increased risk of contracting cardiovascular diseases. Exactly how elevated that risk will be typically depends on various factors concerning lifestyle and family history. Notification of raised cholesterol values can sometimes be difficult to interpret clearly, therefore.

Of course, it is also a risk evaluation (as well as a division into high-risk and low-risk groups) when the health authorities initially decide to offer participation in a screening programme to a selected group. The National Board of Health’s recommendation, for example, that women aged 50-69 be offered mammographic screening for breast cancer is naturally not just because women of that age develop breast cancer. Women outside that age range are also at risk of contracting breast cancer, but the majority of experts have evaluated—based on different considerations—that the risk for these women is not such as to warrant recommending a publicly funded mammographic screening service.

2.4. When the result is right, and when the result is wrong

Any medical examination—including a screening test—can yield results that are either not completely clear-cut, and will therefore typically
require a further examination, or results that are downright wrong.

If a woman undergoes mammographic screening for breast cancer and is given the correct result as to whether she does or does not have cancer, this is a true test result: if the woman is told she is ill, and actually is ill, the result of the examination is true positive. If the woman is told she is healthy, and actually is healthy, the result of the examination is true negative.

If a woman is screened for breast cancer and notified incorrectly on the other hand, the test result is false: if she is told she has cancer, but is actually healthy, the result of the examination is false positive. If she is told she does not have cancer, but actually is ill, the result of the examination is false negative.

<table>
<thead>
<tr>
<th>Possible result for a healthy participant</th>
<th>Possible result for a sick participant</th>
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<tbody>
<tr>
<td>HEALTHY</td>
<td>SICK</td>
</tr>
<tr>
<td>(true negative result)</td>
<td>(true positive result)</td>
</tr>
<tr>
<td>SICK</td>
<td>HEALTHY</td>
</tr>
<tr>
<td>(false positive result)</td>
<td>(false negative result)</td>
</tr>
</tbody>
</table>

Everyone agrees that it is essential to minimize the number of false results in a screening programme, but false results cannot be avoided altogether, and the question of what level of false results is acceptable depends how the purpose of the screening programme is formulated.

If—again—we compare a screening programme with sorting peas, where the peas that remain in the sieve represent sick or possibly sick people, one way of formulating the purpose of the screening programme will require a sieve with large holes, while another will require a sieve with very small holes. The concepts of large and small need to be viewed as relatives in this context.

2.5. High-specificity screening programmes
—a sieve with large holes

You may think a screening programme should be arranged so as only to find people who have the disease with the greatest degree of certainty humanly possible. In order to succeed in this aim, the screening programme needs, metaphorically speaking, to be designed like a sieve with large holes. A sieve with large holes means that the sieve captures only people at great risk of contracting the particular disease or people with a very advanced—yet still asymptomatic—stage of a disease. When this design is used, it is referred to in the jargon as a high-specificity screening programme. The implication of a high-specificity screening programme (large holes) for the distribution of misdiagnoses is as follows: relatively fewer healthy subjects are erroneously told that they are ill (false positives), while relatively more sick subjects are erroneously told that they are not ill (false negatives).
2.6. High-sensitivity screening programmes
—*a sieve with small holes*

Conversely, you may also think a screening programme should be arranged so as to find all people with the disease. In order to succeed in this aim, the screening programme needs, figuratively speaking, to be designed like a sieve with small holes. A sieve with small holes will mean that more people at even minor risk of the disease, or people at a less advanced pathological stage of the disease, will be caught in the sieve. When this design is used, it is referred to in the jargon as a high-sensitivity screening programme. The implication of a high-sensitivity screening programme (small holes in the sieve) for the distribution of misdiagnoses is as follows: relatively fewer people with the disease are told they are healthy (false negatives), while relatively more are erroneously assumed to be sick (false positives).

Of course, the actual technology used in the examinations, e.g. mammography machinery, is partly instrumental in defining whether a screening programme acts as a large or a small-holed sieve. But apart from the capabilities of the technology, other aspects of the way the screening programme is organized play a role in the distribution of false results. It can generally be said that high specificity in a screening programme is detrimental to its sensitivity and, conversely, that high sensitivity is detrimental to its specificity. It is not possible to rule out entirely erroneous results in a screening programme: there will always be peas that get caught in the sieve, even though by rights they should have gone through (because there is nothing wrong with them); and there will always be peas that pass through the sieve, even though by rights they ought to have been intercepted (because there is a disease or risk of disease).

2.7. What do we in Denmark screen for?

Visits to the dentist and children’s examinations—are they screening?

In Denmark a wide range of screening programmes exists, targeting all age groups. Screening has been defined above as a generally recurring examination of healthy people, and something for which the health authorities take the initiative. Based on this definition, as already mentioned, most Danes can be said to take part in a screening programme when the dentist sends a roughly six-monthly reminder that it is time for a dental checkup.

When pregnant women are invited for an examination with the doctor and midwife, that is also screening, in that the doctor and midwife take the initiative to examine the pregnant woman and the fetus for a number of different disorders or disease indicators. The expectant woman, for example, has her blood pressure measured, blood samples taken and is weighed, and the fetus has its weight estimated when the midwife feels the woman’s stomach with her hands and in some cases is scanned with ultrasound.
This type of screening continues immediately after the child’s birth, when the parents are given the offer of the child having a blood sample taken from its heel, which is intended to determine whether the child has a genetically conditioned disorder, Følling’s disease (PKU), in which case it can be treated for it.

During the early days after the child’s birth the parents will receive an additional offer of having a health visitor come to their home to measure and weigh the child, test its reflexes and observe how it is functioning socially. The purpose of these calls is to screen for disorders, disease indicators or failure to thrive on the part of child and parents.

Finally, the child will be invited to various paediatric examinations at the GP’s, where screening will be done for vision defects, inter alia.

The examinations mentioned above are largely examinations we are accustomed to taking advantage of and ones which (with the possible exception of ultrasound fetal scanning) are generally perceived as being unproblematic from an ethical point of view.

Nonetheless, it is true of some of the examinations mentioned, as it is true of more “serious” screening for cancer diseases, that there will be false test results, with resultant ethical problems. Perhaps these test results are just less well known, less conspicuous or have less serious consequences than with screening programmes aimed at serious cancer diseases?

Similarly, any general-level discussion on the use of screening programmes will also include these generally accepted screening programmes as a basis.

The Danish Council of Ethics has therefore chosen to mention them in this section as examples of the breadth of the screening programmes on offer to Danish citizens. Other than that, the Council will not take a more detailed stance on them.

Furthermore, the Council of Ethics will not deal until a later occasion with presymptomatic, genetic screening—that is to say, early detection of genetically conditioned disorders such as Huntington’s.

2.8. Guidelines for implementing screening programmes

Back in 1968 the World Health Organization, WHO, published a number of principles to be followed by screening programmes. Throughout this report reference will repeatedly be made to WHO’s principles—they therefore call to be set out at this early point in the report. According to the 1990 edition by the National Board of Health, Denmark, the principles are as follows:

1. The disorder must represent a significant health problem.
2. There must be an accepted treatment for patients with a recognized disorder.
3. Diagnostic and therapeutic facilities must be available.
4. The disorder must be demonstrable at a latent or early-onset symptomatic stage.

5. There must be a suitable method of testing or examination.

6. The method of testing/examination must be acceptable to the general public.

7. The course of the disorder in untreated instances—including the development from latent to manifest phase—must be sufficiently elucidated.

8. The therapeutic indications must be clearly defined.

9. The costs of screening (including those of diagnosing and treating patients) must be in reasonable proportion to the health service’s overall outlay.

10. Screening efforts must be an ongoing process, not a one-off occurrence.

In 1990 these ten points were amplified and supplemented with four points in the National Board of Health’s screening report, Screening—Why – When – How?:

11. Before making any decision on the initiation of a screening activity, the following must be evaluated:
   - validity of the testing system
   - technical efficiency
   - predictive value of test results

12. An evaluation must have been made of:
   - the ethical and psychological consequences for the examinees
   - stigmatization
   - the consequences of “false positive” and “false negative” test results

13. An economic evaluation must be performed:
   - cost-benefit, cost-effectiveness and/or cost-utility analysis
   - cash-economic evaluation
   - marginal economic evaluation
   - cost-effectiveness

14. There must be a detailed description of:
   - programme organization
   - steering committee (make-up, competence)
   - registration system
   - triage planning
   - provision of information to target group
   - staff training
   - test result dissemination.


In addition, the Council of Europe has drawn up a recommendation on screening, which has been reprinted in this report as Appendix 2.
Chapter 3: Status and examples of screening programmes

3.1. A screen a day keeps the doctor away

In 1990 the National Board of Health, Denmark, published the report just mentioned, "Screening—Why – When – How?", in order to play an instrumental part in structuring the debate already in progress at the time on the initiation of new screening programmes.¹

And there is reason to assume that screening programmes will continue to become increasingly widespread. According to Dr Inga Marie Lunde, a physician, consideration is being given in Denmark to screening for more than thirty diseases or risks of diseases. Lunde’s overview of possible and already functional screening programmes is reprinted below:

In the USA this development is further advanced. The book ‘Guide to Clinical Preventive Services’ was published in 1996 by the US Preventive Services Task Force, under the US Department of Health and Human Services. This details 53 different screening programmes, 6 different vaccination programmes, programmes for the prevention of deficiency diseases and 11 different programmes in which it is attempted to prevent health problems through counselling. All these screening programmes have been initiated at either federal, state or local level.

To further illustrate American conditions, it can be mentioned that the American College of Physicians advises 278 contacts with the health service for a healthy woman (examinations, tests and counselling) from her 20th to her 70th year. This is borne out by the organization’s official guidelines on preventive health examinations.

In the following, the Danish Council of Ethics will examine in more detail two screening programmes already implemented, i.e. mammographic breast cancer screening and cervical cancer screening.

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Of the screening programmes being discussed for implementation in Denmark among professional circles, the Council has chosen to take a closer look at two: screening for aortic aneurysm and screening for intestinal cancer.

It has been chosen to emphasize these particular (possible) programmes because of large-scale investigations having been conducted into screening for intestinal cancer and aortic aneurysm, the resulting availability of material and the existence of grounds for believing that screening in these fields may be among impending new screening initiatives. In addition, screening for both intestinal cancer and aortic aneurysm raises issues of ethical interest, for example the question of how to evaluate the ethical and psychological consequences for those examined.

Furthermore, the Council of Ethics will look in more detail at an example of grey-zone screening, i.e. widespread screening for high cholesterol values. Grey-zone screening is a term for the common use of screening conducted outside the framework of an organized screening programme.

3.2. Mammographic screening for breast cancer

The National Board of Health, Denmark, recommends that women aged 50-69 be offered mammographic screening for breast cancer every second year. In its latest report on the subject the Board of Health writes that over a ten-year period such an offer can prevent 1,100-1,200 cases of death from breast cancer. Breast cancer can be treated by an operation, sometimes followed by radiation therapy and medicine. In the case of mammography screening, breast cancer can be detected at an earlier stage, when the size of the lump is smaller. As a result, not only is the therapeutic effect greater but treatment can also be made less invasive.1

A total of about 100,000 50 to 69 year-old women in the municipalities of Copenhagen and Frederiksberg as well as Funen County are offered mammographic screening for breast cancer every other year. They make up 1/5 of all Danish women between the ages of 50 and 69. In round figures the outcome of the first screening round in the three locations was as follows: approximately 75,000 of the 100,000 invited chose to take part in the screening. For every 1,000 individuals screened, 9.3, 9.8 and 12 cases of breast cancer were discovered, respectively. The proportion of false positives was 1.8 percent, 4.6 percent and 5.5 percent. These figures fell in the subsequent screening round.

All the experts agree it is important that the proportion of false positive results in screening programmes should get smaller, but some experts regard false positive results as being a minor side-effect for those on the receiving end. Other experts regard false positive results as being far more serious and point out that the risk of being given such a result accumulates with the number of screening tests.

1 Tidlig opsporing og behandling af brystkæft. Status report, National Board of Health, Denmark, 1997:19
National Board of Health recommends mammographic screening for breast cancer
Breast cancer is currently the most frequent form of cancer among Danish women, with approx. 3,500 new cases annually and approx. 1,300 deaths annually.

The National Board of Health, Denmark, has published three reports on mammographic breast cancer screening—in 1989, 1994 and 1997, respectively. In two of these reports the Board of Health recommends—albeit with varying forcefulness—that the Danish counties establish a service of organized mammographic breast cancer screening for women aged 50-69.

In the 1989 report the recommendation of the National Board of Health’s mammmography committee is that county screening programmes should be put in place for women aged 50-69.²

In the 1994 report the recommendation is more moderate: “Overall, the National Board of Health’s opinion is that the nature of the arguments for and against mammography screening is not such as to make a positive and desirable effect in the form of a reduction in mortality from breast cancer dismissible. Therefore, the Board cannot advise those county authorities that have plans to do so against introducing the programme. Conversely, on the basis of the psychological problems and economic consequences, the Board cannot unconditionally recommend the introduction of such throughout the country.”³

The 1997 status report again sounds a very clear message. The National Board of Health concludes “that on the basis of an overall consideration it is recommended that an offer of mammography screening be introduced for all women aged 50-69.”⁴

On the positive side, this all-round consideration includes the fact that organized mammography screening can reduce mortality from breast cancer, allowing 1,100-1,200 deaths to be avoided over ten years.

On the negative side, it includes the drawbacks of mammography screening: the false test results, psychological strains in connection with the screening programme and cancer resulting from radiation. Similarly, the National Board of Health cites the derivative drawbacks associated with treating the cancerous disorder.⁵

The various recommendations in the 1994 and 1997 reports build on the same information base. The status report from 1997 shows that since 1994 there has been no change in the results from breast cancer screening.

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⁵ Ibid, page 19
⁶ Ibid, page 31
cancer screening for women in the 50-69 age group.

In both 1994 and 1997 the National Board of Health assessed that over a ten-year period nationwide mammography screening will result in 1,100-1,200 fewer women dying of breast cancer. Another way of saying the same thing is that in the screened group there will be a 29 percent drop in mortality from breast cancer or that screening can reduce the total risk of dying from breast cancer from 5 percent to 4 percent.

Organizing breast cancer screening in Funen County and the Copenhagen Hospital Corporation

Mammographic screening for breast cancer in women aged 50-69 currently takes place in organized screening programmes at three locations in Denmark, i.e. in Funen County and the municipalities of Frederiksberg and Copenhagen. Some counties are in the process of putting in place breast cancer screening, while others are still considering it; and still others, such as Vejle County, have decided they are not willing to offer mammographic breast cancer screening.

Funen County and the municipalities of Frederiksberg and Copenhagen, respectively, are home to some 48,000, 10,000 and 43,000 women aged 50-69. That means approximately one fifth of all women aged 50-69 currently receive a regular offer of mammographic screening for breast cancer. The women are invited for screening every second year, making a total of ten times each. An examination is carried out by compressing each breast between two plates, after which an X-ray is taken of each breast. During initial screening rounds, however, two images are taken. A radiologist analyses the image for early stages of breast cancer, and the woman is then informed whether or not there are grounds for additional examinations.

In the Municipality of Copenhagen mammographic screening for breast cancer was introduced as a standard service on 1 April 1991. In Funen County it was initiated in November 1993, and in Frederiksberg Municipality it was introduced on 1 June 1994.

The women are invited for screening by means of a letter from the hospitals (Bispebjerg Hospital and Odense University Hospital) where the examinations are conducted. Those who do not respond to the invitation also receive a reminder. In Funen two reminders are used; in Copenhagen and Frederiksberg municipalities, only one. These examination invitations, reminders and results from Funen are shown as examples in Appendix 1.

Mammographic breast cancer screening in figures

The National Board of Health, Denmark’s, latest status report has a statistical synopsis of the results from the first and subsequent rounds of the mammographic screening:
### Results from initial and subsequent rounds of mammography screening in Denmark

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<tbody>
<tr>
<td><strong>Proportion of invitees taking part</strong></td>
<td>71%</td>
<td>88%</td>
<td>76%</td>
</tr>
<tr>
<td><strong>Proportion of participants called in for extra examinations</strong></td>
<td>6.7%</td>
<td>2.7%</td>
<td>5.5%</td>
</tr>
<tr>
<td><strong>Proportion of participants who had a breast biopsy taken</strong></td>
<td>1.9%</td>
<td>1.3%</td>
<td>1.3%</td>
</tr>
<tr>
<td><strong>Number of breast cancer cases discovered per 1,000 screenees</strong></td>
<td>12.0</td>
<td>9.8</td>
<td>9.3</td>
</tr>
<tr>
<td><strong>Of which carcinoma in situ cases</strong></td>
<td>12%</td>
<td>16%</td>
<td>14%</td>
</tr>
<tr>
<td><strong>Proportion of those recalled presenting breast cancer</strong></td>
<td>18%</td>
<td>36%</td>
<td>13%</td>
</tr>
<tr>
<td><strong>Proportion of women with biopsy presenting cancer</strong></td>
<td>61%</td>
<td>74%</td>
<td>55%</td>
</tr>
<tr>
<td><strong>Proportion of false positives</strong></td>
<td>5.5%</td>
<td>1.8%</td>
<td>4.6%</td>
</tr>
</tbody>
</table>

**Subsequent rounds:**

<table>
<thead>
<tr>
<th></th>
<th>70.5%</th>
<th>92%</th>
<th>-</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Proportion of participants called in for extra examinations</strong></td>
<td>4.5%</td>
<td>1.3%</td>
<td>-</td>
</tr>
<tr>
<td><strong>Number of breast cancer cases discovered per 1,000 screenees</strong></td>
<td>7.3</td>
<td>4.4</td>
<td>-</td>
</tr>
<tr>
<td><strong>Proportion of false positives</strong></td>
<td>3.6%</td>
<td>0.9%</td>
<td>-</td>
</tr>
</tbody>
</table>

As an example of how to read the figures in the chart, a few comments will be appended on the first column here: In initial screening rounds in the Municipality of Copenhagen 71 percent of the 43,000 or so women called in took part in the screening test. Of these, 6.7 percent were recalled for further examination. 1.9 percent of the participants (equal to about 1/4 of those recalled) had a breast biopsy taken. 18 percent of those recalled had cancer.

That means that for every 1,000 screenees 12 women with breast cancer were found. Of these, 12 percent were cases of carcinoma in situ. That means that precursors to cancer were found in a lump in the woman’s breast but did not spread and therefore failed to develop into actual cancer in the contiguous tissue. However, it is known that between 25 and 75 percent of these cases will develop into actual cancer; often, therefore, the woman will receive an offer of having the lump removed operatively. 5.5 percent of all participants were given a false positive result.

The bottom half of the chart shows that all these figures are different in the subsequent rounds. With screening programmes, it is nearly always so that more cases of the disease being screened for are discovered in the first round than in subsequent rounds. In addition, subsequent screening rounds will usually show a fall in the proportion of participants recalled. The proportion of patients with cancer rises amongst those recalled, and consequently the false positive rate falls. In a screening context the results of initial screening rounds are not as interesting. These involve a mixture of clinical cancers (palpable) and subclinical ones (non-palpable). In the second screening round the clinical cancers are almost completely weeded out. The results from the second round onwards are the screening-related findings proper.

Technology, training and false exam results

In part, the number of false positive results is a corollary of the actual design of a screening programme. It has been attempted to illustrate this by comparing a screening programme with a sieve with holes so small that some peas are left in the sieve—i.e. caught by the screening programme—though by rights they should have gone through because they are not sick. If the holes were made larger, the opposite problem would simply be encountered: too many peas would pass through, equivalent to there being relatively more false negative results in the screening programme (people who are erroneously told they are healthy).

False positive findings can also be due to:

- Benign changes in the mammary gland tissue, which can resemble cancer.
- Projection errors, which are clarified if X-ray images are taken from a different angle. This is

7 Personal communication from Professor Mogens Blichert-Toft, MD, senior consultant at the National University Hospital.
done by recalling subjects and carrying out a clinical mammography examination using three projections.

- Substandard film or haziness of the film.
- The doctor’s insufficient experience in reading mammographic images. It is important to have a screening unit of a suitable size, so that the radiologist can maintain the technical quality of the image analysis. Similarly, it is important that part of the screening unit should involve clinical assessment of the women recalled. The largest screening unit in Denmark analyses up to about 1,000 images daily, divided between two radiologists, as duplicate reading of images may be involved.

Particularly with breast cancer screening, incidentally, it has proved that a number of the false results may be due to defects in apparatus and lack of experience in reading X-ray images of a breast.

In a survey the Danish National Institute of Radiation Hygiene has documented that 90 percent of the country’s 59 mammography units took substandard images in 1995-97 and 30–40 percent of the units produced excessive radiation. The units in the municipalities of Copenhagen and Frederiksberg as well as in Funen County were the only ones completely up to standard. Some of the other appliances have since been replaced, but not until May 2000 will a Danish executive order come into effect, stipulating that the individual examination establishments comply with different quality criteria with regard to image quality and radiation levels. It is not possible for women scheduled to have a mammographic examination to find out which units comply with these requirements.

**Costs of mammographic breast cancer screening**

It is difficult to make precise analyses of the cost involved in introducing a breast cancer screening programme. Perhaps it is particularly difficult to evaluate the results of the analysis: how much, for example, may one gained year of life cost in order to be able to say that a screening programme is a success?

The National Board of Health, Denmark’s, 1997 status report contains a table (page 149) illustrating the years of life gained through various screening programmes and their cost; that is to say, programmes with different intervals between examinations offered to different age groups. This shows that, over 36 years, the expense of mammographic breast cancer screening for women aged 50-69 (with an examination every second year) will be approximately DKK 108 million for a population the size of Funen’s. This DKK 108m represents the present value. It is estimated that this programme would give 3,232 gained years of life—and the average cost per year of gained life would thus be DKK 33,500.

The Board of Health writes that the calculation includes a number of uncertain parameters. One important determinant of costs, for example, is the
frequency of expensive tissue samples in the case of surgical interventions. Similarly, whether or not to incorporate future health expenditure in the calculation for the surviving women is key. If this is to be included, the 108 million kroner must be multiplied by a factor of 1.61—making the cost DKK 174m instead.

It goes without saying that if the same population group is screened but the interval between examinations is changed, both the expense and the number of life years gained will be altered. If the women are examined every year (instead of every second year), the price will be DKK 200m instead of 108m, and the number of life years gained will increase from 3,232 to 3,863. Under this programme, a life year gained will cost around DKK 52,000.

If, on the other hand, the women are examined every third year, the cost will naturally be less—i.e. about DKK 77m—and the number of life years gained will be an estimated 2,708. In this programme a life year gained will cost approx. DKK 28,000.

In principle, there is no ceiling on the amount of economic resources that can be spent on achieving extended lifetime. Implementing any screening programme will therefore necessarily involve setting priorities, which is to say deliberating on when costs and gains are in acceptable proportion to each other—when the screening programme is cost-effective.

It has not been possible to find analyses of mammographic breast cancer screening costs other than those of the National Board of Health, Denmark.

Problems associated with false positive test results
Everyone agrees that working to minimize the proportion of false results in screening programmes poses a great challenge. But there is no consensus among experts as to how the seriousness of such false results should otherwise be assessed.

Some experts regard the false results as an unfortunate side-effect—certainly, a side-effect on which a stance needs to be taken, but one which must otherwise be accepted as the price of helping those to whom the screening programme is of benefit. These experts typically look to the studies that show that the psychological reactions of receiving a false positive result (for example, stress, depression or anxiety) are transient and can be reduced by carefully informing the participants in a screening programme.

Other experts ascribe greater significance to the false positive findings. They typically look to the studies that put the lifetime risk of receiving a false positive result at about 25 percent, at the same time saying that the consequences of such false positive results are serious—at both individual and group level. Some studies show that around five percent of the women in a screening programme who have received a false positive result consider this to be the gravest experience of their lives. Viewed at group
level, such false positive findings result in people being overdiagnosed or pathologized; in the worst case scenario, the false negative findings may entail increased morbidity, as people with a false negative diagnosis are given a sense of false security, making them less susceptible to respond to the body’s signals that something is actually the matter.

**Questions on mammographic screening for breast cancer**

Viewed in relation to WHO’s criteria for implementing a screening programme, mammographic screening for breast cancer raises questions about the following points in particular:

*Diagnostic and therapeutic facilities must be available*
Are there sufficiently trained staff and optimally functioning equipment to ensure all women participation in a high-quality screening programme?

Viewed in relation to the National Board of Health, Denmark’s, supplementary requirements, mammographic screening for breast cancer raises questions about the following points in particular:

*There must be an evaluation of the ethical and psychological consequences for the examinees, stigmatization and consequences of “false positive” and “false negative” test results.*

Is there sufficient Danish material evaluating these conditions?

There must be a detailed description of assessment planning and provision of information to the target group.

Do such detailed descriptions exist about the way the target group for a screening programme should be informed and invited?

It should be noted that the above is mentioned merely as an illustration of some of the many questions that can be raised about implementing a screening programme.

**3.3. Screening for cervical cancer**

The National Board of Health, Denmark, recommends offering women between the ages of 23 and 59 a three-yearly examination designed to prevent cervical cancer. It is further recommended that women aged 60-74 be offered an examination for a number of years until the incidence of disease falls at these ages.

In 1996 90 percent of Danish women aged 23-59 were invited for screening. For women aged 60-74 the figure was 46 percent.¹

A woman’s risk of contracting cervical cancer is usually deemed to be reduced by 80-90 percent if she takes part in a screening programme with an examination every third year. The risk of dying from the disease is estimated to be reduced by 90-95 percent.

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There is no general overview of the number of examinations conducted every year as part of the screening programmes. There is no overview of the number of cases in which the woman examined is told that cell changes have been found in her cervix. There are no statistics on the proportion of false positive and false negative results.

There are no common guidelines on the quality of the tests.

Cervical cancer is the eighth most frequent form of cancer among Danish women. Every year some 550 women are diagnosed, and around 200 die of cervical cancer annually. It is not possible to highlight a clear reason for a woman developing cervical cancer. However, a major link has been demonstrated between cervical cancer and the presence of certain types of HPV, a virus that is transmitted sexually. The disease is more frequent if the woman or partner has had multiple sexual partners or made his/her sexual debut early on. Early first pregnancy, smoking habits and educational background also have a bearing. The disease is more frequent in lower social groups.

From the time the preliminary stages of cervical cancer are ascertainable till the full outbreak of cancer proper, it usually takes about 10-15 years. But not all preliminary stages develop into cancer—in many instances they disappear of their own accord. There are no official figures for the frequency with which cell changes develop into cervical cancer. Thus a woman who is examined every third year will typically be examined three or four times during the period when preliminary stages are present.

National Board of Health recommends screening

In 1986 the National Board of Health, Denmark, published a report entitled “Forebyggende undersøgelser mod livmoderhalskræft” [Preventive Screening against Cervical Cancer], in which it was recommended:

- that all women aged 23-59 be offered an examination with their own GP every three years to prevent cervical cancer and preliminary stages of cervical cancer. It was also recommended
- that for a period of time, women aged 60-75 should be offered the examination because many cases of illness occur at that age.

The National Board of Health’s objective in implementing such a screening programme was to trace and treat the preliminary stages of the disorder before those stages develop (if ever) into actual cancer, as preliminary stages of cervical cancer can be treated effectively, and treatment will lead to a fall in the frequency of cervical cancer and
consequently to a fall in the number of women dying of cervical cancer.

The examination consists of a pelvic examination in which the doctor removes cells from the mucous membrane of the woman’s cervix (the neck of the womb). This is also called a smear or smear test. The cell sample is subsequently analysed at the laboratory.

**Screening for cervical cancer in figures**

When the National Board of Health, Denmark, published its report in 1986, 25 percent of Danish women between 20 and 59 were covered by an organized screening programme. But a great many examinations were performed outside of the screening programmes: too many and too young women were examined far too often. The Board of Health therefore expected it to be possible to effect the recommendations without increasing the total number of examinations, with a higher rate of coverage and without increased expenditure, i.e. more cost-effectively (obtaining better value for money) than achieved with grey-zone screening—the many examinations not organized into actual screening programmes.

In 1996 90 percent of Danish women aged 23-59 and 46 percent of women aged 60-74 were covered by organized screening programmes, and the number of examinations outside of the organized screening programmes has fallen as anticipated.5

Women covered by a screening programme receive a written invitation followed by one or two reminders. Approximately 70-85 percent subsequently undergo examination. The invitations and reminders from the various counties in Denmark contain virtually the same information. The invitation and the two reminders used at the Copenhagen Hospital Corporation have been reprinted as an example, together with an invitation and a reminder from the county of South Jutland.

However, there is no total overview of the number of smears performed annually in the organized screening programmes; as a result, nor is there any inventory of the number of abnormal findings, i.e. the number of cases in which the woman examined is told that cell changes have been found in her cervix.

Figures for the false positive rate and the false negative rate are not available either. The sensitivity (ability to detect cell changes) of an individual test is usually given as about 90-95 percent, and the specificity (ability to exclude cell changes) as about 98 percent. When the test is repeated regularly every third year, the number of false negative results is reduced owing to the long period of time from the start of cell changes to actual cervical cancer. Conversely, a woman’s

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overall risk of testing false positive increases every time she is examined.\(^6\)

**No ruling out false results**

Among experts there is a consensus that false positive and false negative results cannot be eliminated entirely. The reason is primarily that preliminary stages of cervical cancer are investigated manually. Both sampling at the GP’s and the subsequent cytological analysis at a laboratory are susceptible to human “error”. For example, the doctor can take a cell sample that does not contain particularly many or particularly suitable cells, and the cell sample analysis is dependent on the laboratory technologist’s experience and undivided concentration.

Some experts feel that, given our present knowledge and skills, the ideal scenario is to have less than 5 percent false positive results and 5 percent false negative results in a screening programme. Between 5 and 10 percent error either way is acceptable, 10-15 percent error is critical, and with more than 15 percent error either way a screening programme is characterized as substandard.\(^7\) Others feel that a screening programme is not optimal until there are 2-4 percent false positive and false negative results.\(^8\)

However, it should be realized that the figures for the proportion of both false positive and false negative results are dogged by great uncertainty. The methods used to measure the false positive rate and the false negative rate in screening programmes differ greatly. The results are also very different, therefore, and not directly comparable. The false negative rate, for example, in different literature is stated as being between 2 and 33 percent.\(^9\)

**Examinations in Funen**

Funen County has published an evaluation of its screening programme for the period 1 April 1989 to 31 December 1995.\(^10\) The screening programme follows the National Board of Health, Denmark’s, guidelines and can provide an indication of the figures for which no overall statement exists.

The evaluation shows that within the framework of the Funen screening programme, between (in round figures) 22,800 and 29,600 smears were performed annually from 1990 to 1995.

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6 Personal communication from Professor Frede Olesen, MD, University of Aarhus.
7 Personal communication from Jahil Hariri, consultant at the Department of Pathology at Hvidovre Hospital, and Finn Løve Jepsen, executive consultant, Esbjerg Hospital
8 Personal communication from Professor Frede Olesen, MD, University of Aarhus
The annual number of newly diagnosed cases of cervical cancer fell during the period after the introduction of screening in Funen County. During the period 1973-84, when there was already significant uncoordinated screening, the number was about 65. Immediately following the introduction of the screening programme in April 1989 the number rose, as expected. Thus there were 100 cases in 1990, but there has since been a gradual decline to 46 cases detected in 1995.

The number of deaths caused by cervical cancer has fallen correspondingly. The figures for the years 1989 to 1994 were as follows: 29, 25, 23, 21, 19 and 17.

The evaluation contains no figures documenting how many of the women examined had cell changes detected, nor does the evaluation contain any figures for the proportion of false results.

However, in another statistical statement from Funen County the diagnostic breakdown can be seen for all smears over a 6-month period. This, then, enables a figure to be reached for the number of women who had cell changes detected.11 In the period from 1 July 1992 to 31 December 1992 a total of 18,135 smears were performed. This number also includes smears taken outside the purview of the screening programme.

Of these, 1,905 were non-negative, i.e. they were either unsuitable or showed cell changes or outright cervical cancer. This figure corresponds to 10.5 percent of all smears.

Of the 1,905, 1,018 smears were unsuitable. This is often due to the test not being up to standard or, for example, breakage of the tube containing the cell sample on arrival at the lab. Women with an unsuitable sample will be called in for fresh sampling. The remaining 887 samples, equal to 4.89 percent of the total, showed cell changes or cervical cancer. In round figures, then, 10 percent of the women will be offered another test—half of these due to cell changes in the first sample.

By way of summary, it can be said that within the screening programme in Funen County some 27,000 women will be examined every year, in round terms. Taking the figures for the second half of 1992 as a basis, some five percent (equal to approximately 1,350 women) will have cell changes ascertained. (It is important to bear in mind that the 1992 statement includes all smears, not just smears taken within the framework of the screening programme. The five percent is only an estimate, therefore.) Fewer than 50 will be diagnosed with cervical cancer, and fewer than 20 will die of cervical cancer.

An executive consultant at Esbjerg Hospital, Finn Løve Jepsen, informs the Council of Ethics that the figures for Ribe County are roughly on a level with

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the figures from Funen County. Every year some 12,000 smears are taken within the framework of the county screening programme. About 10 percent of the women have a new sample taken—half owing to cell changes and half because the original sample was not in order.

The Danish Cancer Registry states that in Ribe County 18 women were diagnosed as having cervical cancer in 1994 (the most recent figure available). This figure includes women diagnosed as a result of screening as well as women diagnosed outside the purview of the screening programme.

The Danish Mortality Registry states that in Ribe County 4, 9 and 2 women died of cervical cancer in the years 1994, 1995 and 1996, respectively (latest available figures).

In Aarhus County’s screening programme the proportion of women who have an extra sample taken, owing to cell changes or an unsuitable initial sample, is five percent. Kjeld Erbs, manager of the county’s mass survey to combat cervical cancer, informs the Council of Ethics that Aarhus County carries out some 51,000 smears annually. Approximately 14,000 are indication samples—which in this case means samples taken outside the purview of the organized screening programme. Some 37,000 are samples taken within the purview of the screening programme. He goes on to state that the number of newly diagnosed cases of cervical cancer since the start of the screening programme in 1989 has been as follows:

<table>
<thead>
<tr>
<th>Year</th>
<th>Cases Found Through Screening Programme</th>
<th>Indication Samples</th>
</tr>
</thead>
<tbody>
<tr>
<td>1989-1992</td>
<td>63</td>
<td>95</td>
</tr>
<tr>
<td>1992-1995</td>
<td>60</td>
<td>76</td>
</tr>
<tr>
<td>1996</td>
<td>12</td>
<td>18</td>
</tr>
<tr>
<td>1987</td>
<td>7</td>
<td>25</td>
</tr>
</tbody>
</table>


**The discussion among experts**

All the experts agree that screening for preliminary stages of cervical cancer saves lives, but there is no consensus as to whether the costs are in reasonable proportion to the gains.

Adherents of screening assert that preliminary stages of cervical cancer are one of the most obvious candidates for screening, because the preliminary stages are treatable, so that in theory cervical cancer can be prevented. They point to the fact that the number of cervical cancer cases has fallen greatly since the 1960s, and that the fall is greatest in those counties with the most functional

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12 Personal communication from Dr Peter Bichel, MD, executive consultant, Aarhus District General Hospital
screening programmes. With an organized screening programme, a participation rate of 75-90% is achieved, whereas without a screening programme that invites women for examination with the same number of smears only about 55-65% of the women in the relevant age groups get examined.

Those sceptical about the use of screening programmes say that although the screening programmes naturally identify preliminary stages and cervical cancer proper (and consequently save lives), many cases are “caught” outside the purview of the screening programmes, i.e. when women go to their doctor with symptoms of disease on their own initiative. Although screening does have a certain impact, part of that impact would persist, even if the initiative for examinations were left to “grey-zone screening” and the women themselves. In general terms the sceptics state that the problem with screening for cervical cancer is the same as with all other screening programmes: an unacceptably large number of healthy subjects have to be inconvenienced in order to help a few sick ones—and the price is too high in terms of pathologization and false positive and false negative results.

In addition, there is another discussion afoot among experts relating to cell-sampling standards once a screening programme has been implemented: when a smear is “suitable” for analysis, and when it is “unsuitable”. The discussion is about whether a smear should contain a special type of cell, endocervical cells, to qualify as “suitable”. The presence of endocervical cells is evidence that the smear has been taken in that part of the cervix where most preliminary stages of cervical cancer arise. But there is no documentary evidence that screening programmes that require endocervical cells in the samples save more lives. Because of this disagreement surrounding the importance ascribable to the presence of endocervical cells in a smear, there are no collective national standards. Smears accepted in one county as suitable are rejected in others. In some counties the GP who has taken an unsuitable sample is asked to take a fresh one. In other counties it is up to the GP him/herself to judge whether there are grounds for resampling.

Some experts feel that since a screening test rather than a sample is being taken as an indication of cancer, the sample need not contain endocervical cells; because if endocervical cells are required, more samples have to be taken, more women inconvenienced and the woman’s risk of receiving a false positive result increases—a result to the effect that there are cell changes, which generally disappear of their own accord anyway and therefore never develop into cancer. Others state that the gain from repeating the examination when the first sample lacked endocervical cells is undocumented or too small.13 Still others,
however, feel that there is no logic in training women to take advantage of screening programmes to combat cervical cancer and simultaneously allowing any preliminary stages of the disease to be discovered later than is actually possible.

The National Board of Health has not taken a stance on the question of uniform suitability criteria.

Questions on screening for preliminary stages of cervical cancer

Viewed in relation to WHO’s criteria for implementing a screening programme, screening for preliminary stages of cervical cancer raises questions about the following points in particular:

- **The disorder must represent a significant health problem**
  How great a proportion of the population needs to have a particular disorder before it represents a significant health problem?

- **The course of the disorder in untreated instances—including the development from latent to manifest phase**—must be sufficiently elucidated.
  Is sufficient known about how often (and if so, how) cell changes develop into cervical cancer?

- **The therapeutic indicators must be clearly defined**
  Is the point at which cell changes require operating clearly defined?

Viewed in relation to the National Board of Health, Denmark’s, supplementary requirements, screening for preliminary stages of cervical cancer raises questions about the following points in particular:

- *An evaluation must have been made of the ethical and psychological consequences for the examinees.*
  - stigmatization
  - the consequences of “false positive” and “false negative” test results
  Is there adequate knowledge in these areas? How is the gravity of these consequences evaluated in relation to the wish to prevent severe illness?

### 3.4. Screening for aortic aneurysm

When an outpouching or ballooning of the abdominal aorta (the part of the main artery located in the stomach region) occurs, it is called an abdominal aortic aneurysm (AAA). Such aortic aneurysms normally present no symptoms, yet they are a potentially fatal condition: if the aortic aneurysm ruptures, there is between a 75 and 95 percent risk of dying from it. The number of deaths due to AAA is on the increase in Denmark. In 1991 403 died of AAA, as against 226 in 1981. Related mortality increases with age and is considerably higher for men than for women. In all, AAA deaths made up 1.4 percent of all deaths in 1991 among 65 to 79 year-old men.

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1 Only little material is available describing, on the basis of Danish conditions, abdominal aortic aneurysm. The factual information in this section is based on the following:


Screening is currently not being done for AAA, but it is one of the diseases for which screening is being discussed. There are screening programmes in several places abroad, and in Denmark a trial has been conducted at Viborg Hospital in which 6,000 men aged 65-73 were offered screening for AAA. It is the results of this trial that have fuelled a discussion as to whether the initiative should be taken for an actual screening programme.

Screening for AAA consists of an ultrasound examination. The examination is painless and takes about five minutes to perform. The price is approx. DKK 85 per examination.

During an ultrasound examination of the aorta it is easy to see any aortic aneurysm. The specificity of the examination is 95 percent. That is to say that in 95 percent of cases it excludes disease in healthy subjects. The sensitivity of the examination is 99 percent. That is to say that in 99 percent of cases it finds AAA in patients who have a genuine aortic aneurysm.

If the aortic aneurysm is a certain size, there is a risk of it bursting. An operation will therefore be offered in order to prevent rupture. But in approximately 85 percent of cases in which AAA is found, the aortic aneurysm is so small that it does not require operating. Instead, the screenee will be offered regular check-ups, usually an annual examination. This happens because an aortic aneurysm can grow to a size where an operation is deemed necessary.

The Danish study estimates that if 100,000 65-year-old men are screened, aortic aneurysms larger than five centimetres are operated, and follow-up given to those who have a minor aortic aneurysm, 672 deaths from AAA can be prevented before the age of eighty. Given that the age-group in question has high mortality, however, this figure will be partly offset by other deaths, making the net gain 445 deaths avoided, corresponding to 3,400 years of life.

It should be noted that although the number of AAA operations doubled from 1979 to 1988, the number of deaths due to a ruptured aortic aneurysm has nevertheless risen. The explanation for this development is not known but is presumably a mounting incidence of AAA.

**Questions about screening for aortic aneurysm**

The most obvious problems connected with screening for AAA have to do with interpreting the ultrasound scan. There is a statistical risk that an aortic aneurysm will rupture, but there is no way of knowing what the consequences of an aortic aneurysm will be for the individual person.

It is not known whether a “large” aortic aneurysm will actually burst. The risk is 5-10 percent per annum (if the aneurysm is larger than 6 centimetres). Nor is it known whether a “small” aortic aneurysm will grow; what is more, a small aortic aneurysm can also burst, but the risk is less than 1 percent per annum.
Anyone notified after screening that they have an aortic aneurysm that requires operating is thus in a dilemma: the operation may reduce the risk of death in the longer term, but there is an inherent risk of approximately five percent of dying from the operation. The risk depends on the patient's age and state of health.

Anyone notified after screening that they have a small aortic aneurysm that should be kept under observation has now been alerted to an increased risk of developing a life-threatening disease. Or, to put it another way: the person has been notified that they are walking around with a time-bomb ticking away in their stomach and that there is no certainty of being given an early warning. In some patients there will be uncharacteristic pain for a while prior to rupture. Some of those screened will therefore have a chance to seek treatment before bursting occurs.

With reference to WHO's guidelines for implementing screening programmes, screening for AAA raises questions about the following in particular:

- **The disorder must represent a significant health problem**
  How great a proportion of the population needs to have a disorder before it represents a significant social problem? Or how great a proportion of a special risk group?

- **There must be an acceptable treatment for patients with a recognized disorder.**
  Is a safe operation an accepted treatment? Which risks of an operation are acceptable, and which are not?

- **The course of the disorder in untreated instances must be sufficiently elucidated.**
  Is enough known about the probability of an aortic aneurysm of a certain size bursting? Is sufficient known about when and how a small aortic aneurysm develops?

- **The therapeutic indicators must be clearly defined.**
  How great must an aortic aneurysm be before it calls for an operation? Does a small aortic aneurysm always need following up?

The psychological and ethical consequences of implementing screening for AAA are not known. For example, there are currently no answers to the following questions:

- How is life affected by being faced with the choice of either carrying on living with an aortic aneurysm and the risk of it rupturing, or undergoing an unsafe operation?
- How is life affected by being under surveillance for a minor aortic aneurysm?
- How is life for the healthy participants in a screening programme affected by being made aware of the risk of developing a life-threatening disease?

According to the National Board of Health, Denmark, the ethical and psychological consequences for the examinees must be evaluated before a screening programme can be initiated (see page 21 of this report). These questions have been mentioned merely to illustrate how many questions can be raised on the initiation of a screening programme and to exemplify the assessments that ought to precede the initiation of any screening programme.
3.5. Screening for intestinal cancer

Intestinal cancer is one of the types of cancer most frequent in Denmark. According to the latest figures from the National Board of Health, Denmark, 3,135 Danes were diagnosed with cancer of the rectum or colon (colorectal carcinoma) in 1995. Of these, 1,616 were women and 1,519 men. In that same year 2,085 Danes died of intestinal cancer. Of these, 1,026 were women, 1,059 men.

There is no screening for intestinal cancer in Denmark, but at Odense University Hospital a mass survey has been conducted, running over ten years, from 1985 to 1995. This survey concludes that screening every second year for blood in the stools can reduce mortality from intestinal cancer, and whether the initiative should be taken for an organized screening programme has since been the subject of discussion.

In the Funen mass survey 30,967 people between the ages of 45 and 75 were invited for colorectal cancer screening. The control group comprised 30,966 people. These controls were not informed about the mass survey. When, during the ten-year period, intestinal cancer was found in members of the control group, it was thus due to the fact that they had contacted the health service on their own initiative. The statistics for the control group as compared with the statistics for the screening group allow the effect of the mass survey to be measured.

The individuals in the screening group were sent a Haemoccult-II test. The test is performed by smearing stool samples from three successive evacuations onto a kind of blotting paper, which is then sent to the hospital, where the stools are examined for blood. For three days prior to and during samplings, certain dietary and medication rules have to be adhered to.

The invitation was followed up by two reminder letters during initial screening rounds and by one reminder during the subsequent screening rounds. 67 percent of recipients performed the test during the first round. In the subsequent screening rounds the test was carried out by more than 90 percent of the people who took part in the initial screening rounds. A total of 14,203 people completed all five screening rounds. If the test showed signs of faecal blood, the person was invited to have medical case notes recorded, and to have a clinical and colorectal examination.

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1 Only little material is available on screening for intestinal cancer in a Danish context. The factual information in this section is based on the following:


(coloscopy). Where the coloscopy was incomplete, an X-ray examination was made of the intestine.

The proportion of positive samples varied from 0.8 percent to 1.8 percent during the five screening rounds. On completion of the examination 481 cases of intestinal cancer were found in the screening group, as opposed to 483 cases in the control group. The number of people who died of intestinal cancer during the ten years, including complications of the treatment, was 205 in the screening group and 249 in the control group.

The examination thus concludes that "it is possible to reduce mortality from CRC [colorectal cancer] by 18 percent after ten years in individuals from 45 to 75 by offering screening with Haemoccult-II every second year. (...) In Denmark an 18 percent reduction in mortality would mean 1,640 instead of 2,000 deaths a year from CRC.” ("Randomized population screening....", page 4, 980).

It has not been possible to find a figure for the cost of a screening programme equivalent to the one in the survey—i.e. an examination every second year of people in the 45-75 age group. But the price per year of life gained by screening every second year for the 55-74 age group is estimated at USD 3,580, roughly equal to DKK 22,600 ("Screening for Colorectal Cancer...", page 6).

No Danish studies have been conducted into the psychological consequences of screening for intestinal cancer.

Questions about screening for intestinal cancer

Viewed in relation to WHO’s criteria for guidelines in implementing screening programmes, screening for intestinal cancer raises questions in relation to the following in particular:

- **The test/examination method must be acceptable to the general public.**
  
  Is it possible to obtain satisfactory support for a screening programme that involves the Haemoccult-II test?

- **The therapeutic indications must be clearly defined.**
  
  Has sufficient light been shed on when a precursor to intestinal cancer should be surgically removed? Is there sufficient medical expertise to ensure the quality of an anticipated increase in the number of coloscopies and operations?

Viewed in relation to the National Board of Health, Denmark’s, explanatory guidelines, screening for intestinal cancer raises questions in relation to the following requirements in particular:

- **There must be an evaluation of the ethical and psychological consequences for the examinees.**

- **There must be an evaluation of the consequences of “false positive” and “false negative” test results.**
  
  How are these consequences to be assessed? How is the seriousness of anxiety or depression in a participant in the screening programme assessed against the desire to prevent intestinal cancer? How is the gravity of false results assessed?
Again, it must be said that the above is mentioned merely as an illustration of some of the many questions that can be raised about implementing a screening programme.

3.6. An example of grey-zone screening: Screening for raised cholesterol levels

Cardiovascular diseases are the most frequent cause of death in Denmark. Every fourth death or so is due to cardiovascular disease, which is consequently regarded virtually as a national scourge.

Internationally, WHO expects that between 1990 and 2020, cardiovascular diseases will move from fifth to first position among disorders posing a burden on the world community. This is due partly to WHO’s expectations of a continued reduction in the occurrence of infectious diseases and partly to expectations of continued ageing in the populations of practically all countries and the continued spread of smoking in the developing countries.1

The disease strikes men and women alike, and both relatively young and old people.

In 1989 the Danish government formulated a prevention programme on cardiovascular diseases, a subsidiary target of which was to reduce the number of cardiac deaths among people under 65 by 15 percent by the year 2000.

One of the ways in which the number of deaths can be reduced is to identify people at increased risk of developing the disease. Cardiovascular disease is a multifactorial disorder. That is to say, a number of factors compound the risk of developing the disease. Of these factors, some are open to influence. This applies in particular to increased cholesterol levels, smoking, overweight, physical inactivity, diabetes and psychosocial stress. Other risk factors cannot be influenced. This applies, for instance, to sex, familial disposition and age.

Focus on cholesterol level

It is known from studies that reducing the amount of cholesterol in the blood lowers the risk of developing cardiovascular disease. In 1990, therefore, a set of guidelines were drawn up for deciding when serum cholesterol measurement is indicated in 20 to 60 year-olds with a view to reducing their risk of developing cardiovascular disease. The guidelines were compiled by the National Board of Health, Denmark, the Danish Heart Foundation, the Danish College of General Practitioners (DSAM) and the Danish Organization of General Practitioners (PLO), and paved the way for individuals belonging to a special risk group to be offered serum cholesterol measurement.

Offering such a service to a risk group is called a selective high-risk strategy. In the 1990 guidelines it was suggested combining this strategy with a

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1 Personal communication from Professor Ole Færgeman, MD, senior consultant at Aarhus County Hospital. The figures are based on the following source: Murray, CJL, Lopez, AD. Alternative projections of mortality and disability by cause 1990-2020: Global Burden of Disease Study. Lancet 1997; 349:1498-1504
mass strategy, in which the entire population is informed of the risk factors for heart disease.

In 1998 new guidelines were produced by the Danish College of General Practitioners. These are based on recent studies into the prevention of ischaemic heart disease (IHD) (blood clots in the heart). They are in line with new European guidelines but have been tailored to national standards. The 1998 guidelines also recommended measuring cholesterol in the blood, providing certain criteria are met—e.g. the patient has heart disease or increased risk of cardiac disease owing to high blood pressure (hypertension), diabetes or smoking. But the new guidelines contain an important amendment, namely that a ‘global’ risk evaluation must be undertaken. Neither blood pressure measurement, blood sugar measurement nor blood cholesterol measurement have any inherent interest. Conversely, the measurements must always be done in tandem, and they must be compared with information on smoking, age and sex so that together doctor and patient can form an impression of the patient’s risk of having a blood clot in the heart within the next ten years. Based on the calculated ten-year risk of blood clots in the heart, various preventive treatments are recommended: either lifestyle changes alone or lifestyle changes combined with medical treatment.

Grey-zone screening

Neither the 1990 nor the 1998 guidelines recommend screening for increased serum cholesterol with a view to preventing cardiovascular disease. The new guidelines expressly mention that screening is advised against for increased serum cholesterol, as it will direct the focus onto serum cholesterol rather than onto what is quintessential, “i.e. counting risk factors and evaluating the absolute risk of IHD (blood clots in the heart)”.

Indeed, nor have any Danish counties introduced such organized screening—either of the population in general or of individuals falling into a risk group.

Nevertheless, cholesterol measurements are very widespread. Serum cholesterol measurement enjoys the attention of the authorities precisely because of its correlation with disease prevention. The measurement has lodged fast in the health system, too, becoming a service in demand with users, and one which health staff are generally happy to accommodate. In other words, there is faith in cholesterol measurement as a beacon of a person’s state of health, and it may therefore be felt that we actually have grey-zone screening for increased serum cholesterol—i.e. screening that is simply not organized into a proper screening programme.

It is only natural to think that the sharp focus on cholesterol measurement is one of the things that has occasioned the Danish College of General Practitioners to pose the question of screening for increased cholesterol in its new guidelines. As yet it

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2 Forebyggelse af iskæmisk hjertesygdom i almen praksis—med særligt henblik på dyslipidemier. Danish College of General Practitioners, 1998:14
is too early to judge whether the new guidelines will alter the practice for measuring cholesterol.

As mentioned in the section on screening for cervical cancer, it was precisely widespread grey-zone screening that lay behind the National Board of Health, Denmark, taking the initiative to orchestrate an array of examinations for cervical cancer into a screening programme, resulting as it did in better utilization of resources—when forces were marshalled into examining women in a specially defined age group with a specific time interval between examinations.

With the new European and Danish guidelines for the prevention of cardiovascular disease, it is certainly unlikely that grey-zone screening for increased serum cholesterol will result, in the same way, in an organized screening programme—as is the case in the USA, for instance. However, it is likely that serum cholesterol measurement will continue to be a very widespread practice. Either measurement will be part of a global evaluation of a person’s risk of cardiovascular disease (compare the new guidelines) or it will be more freestanding, as often seems to have been practised to date. Grey-zone screening for increased serum cholesterol will still be in practice, therefore—how long depends whether and at what pace the new guidelines will be implemented.

**Screening for a risk factor**

Screening for increased serum cholesterol (whether it involves organized or unorganized screening) differs from the aforementioned established and possible screening programmes by not providing an answer to whether there is anything wrong—for example, a lump in the breast, cell changes in the cervix uteri, aortic aneurysm or cell changes in the intestine. Instead, serum cholesterol measurement provides the answer that the examinee has an “acceptable cholesterol level”, is in the “grey zone”, has “moderate hypercholesterolaemia” or “severe hypercholesterolaemia”. The result may also be that the person is at “low”, “moderate”, “increased” or “high” risk of cardiovascular disease. According to the new guidelines for the prevention of blood clots in the heart, the reply given will be that the person has a ten-year risk of blood clots in the heart of, say, 30 percent.

At any rate, the result is nearly always a risk evaluation instead of a diagnosis proper. That raises ethical problems, in particular; this in turn prompts the Danish Council of Ethics to attach some comments on screening for serum cholesterol.

In Chapter 5 of the report the Council will develop the discussion of the ethically problematic issues associated with risk evaluations. At this point, therefore, only some of the problems particularly linked with screening for serum cholesterol will be outlined.

**What do we know about cardiovascular disease and cholesterol?**

There is consensus among experts that a reduction in serum cholesterol can lower the incidence of
cardiovascular disease and reduce total mortality, particularly for people at very increased risk of contracting cardiovascular disease. There is also consensus that serum cholesterol cannot be viewed in isolation, but a person’s overall risk profile must be taken into account: sex, age, familial disposition and the other modifiable risk factors. And there is consensus on recommending serum cholesterol measurement only when other risk factors are present, but not recommending screening of a general population group.3

Questions about screening for serum cholesterol
The most obvious problems in connection with screening for serum cholesterol are linked to the actual fact that the test result is a risk evaluation rather than a diagnosis proper.

A minority of individuals who are in a risk group will contract cardiovascular disease. A risk evaluation gives the individual no information as to whether he or she in particular will become ill and will therefore benefit from a change in lifestyle—possibly combined with medical treatment. The majority of those screened will be infused with a fear of illness and advised to make lifestyle changes that are unnecessary. Apart from the overall problems associated with the use of risk evaluations, the quality of the databases on which the risk evaluation rests is specifically debatable. The question is how precisely the people to be treated for serum cholesterol can be singled out.

The psychological consequences of being identified through screening as an at-risk individual, a person at increased risk of disease, are not known. A number of studies have been done, though these do not draw a clear-cut picture of the consequences. However, a consensus does exist that there is a genuine risk that screening for disease risk factors may bring about a deterioration in mental well-being and increased absenteeism due to illness.4

In addition, cholesterol level measurement will naturally be subject to error. Screening for serum cholesterol will entail false positive and false negative test results—precisely as is the case, for example, with mammographic screening for breast cancer and screening for cervical cancer. A study from 1990 indicates that 13 percent of those examined were erroneously classified using the most common measuring method, Reflotron measurement. The low measures were measured too low—with a risk of false negative results. The high values were measured too high—with a risk of false positive results.5

3 Christensen, Bo. 1995. Forebyggelse af iskæmisk hjertesygdom i almen praksis. University of Aarhus: Department of General Medical Practice: 10-13
4 Same source: 28
With reference to WHO’s and the National Board of Health, Denmark’s, guidelines for implementing screening programmes, screening for serum cholesterol raises questions in relation to the following in particular:

- **There must be an accepted treatment for patients with a recognized disorder.**
  Is it an accepted treatment to have to restyle one’s life on account of a relative risk of disease?
  Only between 10 and 30 percent of patients follow their doctor’s advice on lifestyle change.\(^6\)
  It is worth mentioning that a change of lifestyle is not the only treatment for increased serum cholesterol, since it can be supplemented with medical treatment, as pointed out. But the medical treatment will never stand in isolation: it will always be given in the context of a call for lifestyle change.

- **The course of the disorder in untreated instances— including the development from latent to manifest phase—must be sufficiently elucidated.**
  Is enough known about the interaction of the various risk factors to be able to decide what significance not treating, say, a moderate increase in cholesterol level will have for the development, if any, of cardiovascular disease?

- **An evaluation must have been made of the ethical and psychological consequences for the examinees.**
  Is there sufficient knowledge about the future significance of risk evaluations for the examinees’ quality of life? Is there sufficient knowledge about the significance of accumulated risk evaluations?

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6 Bo Christensen. 1995: 25
Chapter 4: Social and psychological effects of screening programmes

Participants in a screening programme can react very differently to either false or true information about their state of health. Participants’ actual social and psychological response to taking part in screening programmes is hard to characterize precisely, however. The conclusions from the studies available on participants’ social and psychological reactions are not necessarily transferable between different countries, and there is very little Danish research in the field. The National Board of Health, Denmark’s, requirement from 1990 that an evaluation of social and psychological reactions must have been made before taking any decision to implement a screening activity is thus not a requirement generally met today.

4.1. Overview of possible social and psychological effects of screening programmes

Since actual knowledge of the social and psychological effects of screening programmes is limited, a more systematic overview is given below of the possible social and psychological consequences of screening programmes. The main aim of formulating this overview is to provide a basis for arguing for both the advantages and the disadvantages of screening programmes. The division into advantages and disadvantages is not altogether distinct. In some instances, what is presented as a disadvantage may be an advantage, and vice versa.

The invitation to a screening test

What psychological and social reactions can there be to being invited to take part in a screening programme anyway?

Disadvantages
- It does not feel voluntary: The invitation presents a possible disease which it can be difficult to decline being screened for. This may have to do with the fear of being reproached for not having been screened, should one subsequently fall ill. In connection with

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The formulation was inspired by Schikle, D & Chadwick, R. (1994): The ethics of screening is ‘screeningitis’ an incurable disease, in Journal of Medical Ethics 1994; 20: 12-18
mammo-graphic screening for breast cancer, for example, one participant stated the following about the invitation, “If I hadn’t come, there would always be a little part of me wondering if I was wrong. Just supposing... I’ve always thought it’s a service to take part in because it’s a service being offered to me; I’m the one being helped. I don’t think people should say no. But many people are scared, even though there’s really nothing wrong with them. I think that’s wrong in a way... I think they should pull themselves together and attend instead. You get a number of people at that place with a letter like that. If they weren’t invited, there are probably lots who wouldn’t come until they noticed something themselves. And then it’s too late.” (Lunde, 1997, page 5)

Advantages
- There is a feel-good factor to receiving the offer, i.e. it gives you a feeling of reassurance: in connection with mammographic screening for breast cancer, one participant stated the following about the repeat invitation for breast cancer examination, “It was lovely to receive the letter again... It’s two years since I last went, after all. I feel it’s a safety measure. And if it comes down to it, they’ve managed to get hold of you: and if there is anything, well we have it under control. I think it’s reassuring to go there every now and then... It’s a double-check.” (Lunde, 1997, page 9)

1) Should people always be allowed to decline an offer of screening?
2) How should invitations to screening tests be formulated?

True positive test results
This is the group of people who learn, as a result of taking part in the screening programme, that they are ill, and indeed actually are ill, or are at a certain increased risk of becoming ill.

Disadvantages
- If the ensuing treatment has no effect, it does not increase the person’s hopes of life. On the contrary, the person must live with the disease for longer because it has been found earlier on.
- The person becomes sick with worry. This may be partly due to people thinking they are healthy and suddenly being called ill. This turn of events can increase the psychological problems, particularly if they are not given time to get used to the idea.
- The person may experience reduced quality of life on account of stressful treatment.
- Negative reactions from the surroundings (stigmatization): Family and friends can become overprotective, overwatchful or disassociative. There is the possibility of experiencing a similar response in work-related contexts.
**Advantages**
- The earlier investigative and therapeutic course may be tantamount to the treatment being cheaper, less uncomfortable for the patient and offer a greater chance of cure.
- The sick person has symptoms explained. It may diminish their worries that the causes of their symptoms are known and that endeavours are in progress to cure or alleviate them.
- An early knowledge on the part of the individual of some increase in risk may provide time and opportunity for a healthier way of life and increased personal fortitude, and hence possibly diminish the risk of the illness becoming full-blown.
- Positive reactions from the surroundings: A diagnosis gives the person the right to certain social benefits, as long as that person reports sick. The surroundings may become increasingly sympathetic to the individual's situation as a sick person or a person at increased risk of such.

1) Should the health service offer screening tests where no effectively curative or palliative treatment exists?
2) Can risk evaluations or diagnoses be made too early on?

**True negative test results**
This is the group of people who are correctly told that there is nothing the matter. What possible advantages and disadvantages are there of having undergone the screening test and having been presented with the possible problem?

**Disadvantages**
- Undue concern while the person awaits the results of the screening test.
- As a consequence of the screening test, some people may possibly become more concerned about developing the disease in question after the event.
- The regular examinations may mean, however, that people become less aware or sure of their own perception of the body's signals.
- The examination may legitimate an unhealthy lifestyle. For example, it is conceivable that a person may think, “If my examination for breast cancer didn't show anything, surely my smoking isn't doing me any harm”.

**Advantages**
- People are assured that there is nothing wrong with them, which may make the individual less concerned about having something the matter with them.
- In connection with the examination, people are informed how to maintain or improve their way of life, so that they will be able to prevent the disease(s) in question in future too.

1) Can healthy people justifiably be presented with possible problems of illness they themselves have not asked to be presented with?
2) Can healthy people justifiably not be presented with (severe) problems of illness that are preventable by pointing them out early on?

False positive test results
This is the group of people called in for an additional examination who are told they may be sick. The new examination, however, shows that there is nothing wrong with them after all.

Disadvantages
- Unnecessary worry and possible social branding until the correct diagnosis has been made.
- Unnecessary examinations and treatment. Amongst other things, unnecessary time-wasting, unnecessary discomfort or pain during examinations, and unnecessary expense. By way of example, a positive finding for mammographic screening for breast cancer will result in renewed, extended mammographic examination.
- Protracted fear of contracting the disease in question. This may be partly due to the person having been put in two minds as to what and whom to believe, "I wonder if they know what they're doing? They did get it wrong the first time. Can they have got it wrong again?"
- The worry of contracting the disease can be so great that some people suppress the possibility of contracting it. This may be reflected in their disregard for the body's signals.

Advantages
- The actual examination procedure provides an opportunity to receive more counselling and guidance as to what style of life increases the risk of contracting the relevant disease. It is thus possible to be instrumental in preventing the next round of examinations from actually showing that the person has the disease.

False negative test results
This is the group of people who, despite having been to a screening test that showed they were not ill, nevertheless become ill. They start off, then, by undergoing a process in which they are told that they do not have the disease in question. It later transpires that they actually do have the disease.

Disadvantages
- A false sense of security that there is nothing wrong as the disease develops unheeded. If the person then contracts the disease—possibly
between two screening tests—the person may foreseeably react with disappointment, anger, bitterness and perhaps a feeling of injustice, “Now that I’ve done everything they told me to do, I get sick anyway”. (Bonde, 1997, page 50).

- That may lend credence to an unhealthy lifestyle: the false negative examination result can have the effect of falsely calming the person, thus making them less attentive to the signals from their body. This can result in the person concerned failing to seek medical contact when symptoms present, delaying normal diagnosis (and treatment, where appropriate) in the process.

- Commencing treatment later may result in treatment becoming more uncomfortable or onerous for the individual. The chances of curing the person may be reduced, and finally the financial cost may be greater for the individual and/or society.

**Advantages**

- It may be that a person is “spared” certain worries in instances where there is no curative treatment for the disease in question.

1) Should political exigencies stipulate how great a risk of false negative findings is allowable before giving permission to implement specific screening programmes?

2) Is it up to individuals to choose to expose themselves to the risk of a false negative finding, provided that they are informed to that effect beforehand?
As stated in Chapter 1, the Danish Council of Ethics has collected its deliberations and discussions into four main topics, which can be summarized under four headings:

First topic: Being scared or reassured
This topic deals with the risk of pathologization and anxietization versus the hope of being cured of disease—or of avoiding falling sick altogether.

Second topic: False results
This topic involves how to relate to the fact that some of the participants in a screening programme will be given false results.

Third topic: Fair priority-setting
This topic is about the degree to which the health service should deploy resources on the ill or the possibly ill. In addition, it is about regard for the group as opposed to regard for the individual, and about regard for the process as opposed to regard for the result of a screening programme.

Fourth topic: Unsolicited approaches and precise information
This topic is about the way an unsolicited approach from the health authorities is perceived and how much information should be given at the time of the approach.

5.1. Social and psychological effects—being scared or reassured

Screening tests can be regarded as a good service for both the many healthy and the few ill. The healthy are additionally reassured by being told that they are not ill, and the ill increase their chances of being cured as a result of early discovery and treatment of the disease. But it may also be felt that many healthy people risk being pathologized and anxietized to increase the odds of curing a few sick people.

Pathologization and anxietization
One key viewpoint is that society should be very careful about offering screening tests, as singling out and classifying people into risk groups may be a general factor in making many healthy people morbid and anxious.

Pathologization: The offer of a screening test singles out the individual as a person at risk of becoming ill. The offer, therefore, rests not on an absolute distinction between healthy and sick
people; on the contrary, the offer of screening tests rests on a knowledge of groups at greater or lesser risk of having or contracting a particular disease, without it being directly visible to themselves. As a consequence, the guarantee of not being ill can be dependent on experts, and this is precisely the sort of dependency that can be characterized as pathologization. For the individual, for example, it means that the person in question feels healthy only if he or she is regularly given the doctor’s guarantee of not being ill. A woman who took part in breast cancer screening put it like this, “…That’s what’s so damned annoying, the fact that there’s something you yourself don’t notice…”. (Lunde, 1997, page 16)

Extensive use of screening tests, then, may mean firstly that the health service creates in the individual screening participant a dependency on its experts. That is to say that the individual person’s well-being becomes dependent on the regular offer of expert health-professional assistance and monitoring: “It was lovely to receive the letter again... It’s two years since I last went, after all. I feel it’s a safety measure. And if it comes to it, they’ve managed to get hold of you; and if there is anything, well we have it under control. I think it’s reassuring to go there every now and then... It’s a double-check.” (Lunde, 1997, page 9)

So in that sense, participants in screening tests are people—you might call them a kind of pre-patient—who run the risk of becoming dependent on a doctor satisfying them at regular intervals that they are not ill. Secondly, extensive participation in screening tests can create an expectation that ‘preserving one’s good health’ is not something one can or should attend to oneself. A participant might therefore think as follows, “As long as the last screening test gave me a clean bill of health, there’s no reason to change my unhealthy lifestyle”; or “As long as I’m involved in the screening programme, I don’t need to be so attentive myself”. As sickness surveillance is left to the doctors, therefore, the individual arguably becomes more helpless and irresponsible in relation to potential illness. Conversely, it can be said that if an individual learns of the illness personally, it is also that individual who takes the responsibility and initiative to do something about it.

Anxietization of healthy people: The offer of a screening test alone can bring on great anxiety. For example, receiving an unsolicited letter from the health service saying that you are in an age group with an increased risk of contracting a particular type of cancer may be a frightening experience: “The actual act of being called in for mammography examination means you’re alerted to the problem. It’s brought home to you for a short while, then it all falls back into place...That can have a short-term impact... But I think you can take that in your stride.” (Lunde, 1997, page 10) Furthermore, as is generally borne out, the more times a person is examined, the greater risk there may be of becoming uncertain about, preoccupied with and frightened of becoming ill.

Reproaches from self and others
A letter offering a screening test may result in recipients not daring to decline the offer, but
feeling pressurized by themselves or their surroundings to accept the offer.

The offer of screening tests may give rise to the individual person *him/herself* anticipating the possible illness. Such self-reproach is exemplified by the following statement: ‘If I hadn’t come, there would always be a little part of me wondering if I was wrong. Just supposing.... I’ve always thought it’s a service to take part in because it’s a service being offered to me; I’m the one being helped.’ (Lunde, 1997, page 5) Or one participant’s answer to the question of how she would have felt, had she declined: ‘I think I would have felt bad about it. Let’s say you discovered something after a couple of years had passed; surely I’d reproach myself for not having done it. Then it would be down to my own stupidity.’ (Lunde, 1997, p. 20) The individual participant’s self-reproach may thus find a voice if the person contracts the disease but, having previously turned down a screening test, does not feel that he or she is entitled to put a strain on the public health service.

But the offer of screening tests may also lead to others reproaching an individual who opts not to take part in the examination. For example, the spouse of a woman invited for mammographic screening for breast cancer might be envisaged saying the following. ‘I don’t think she should say no—although she’s afraid, and even though there will turn out to be nothing wrong with her. In a way, I think it’s wrong to say no; I think she should pull herself together and attend instead. If she’s not invited, she won’t go there until she notices something herself. And then it’ll be too late.’ The reproaches of family and friends can therefore engender a lack of sympathy for anyone opting not to take part.

The health service, too, can reproach the ‘rejectionist’. In specific terms, the health service may be thought to be doing this indirectly already, having made the success of a screening programme dependent on a group of a certain magnitude taking part, given that this is the prerequisite for upholding calculations of the number of years of life gained, financial savings and efficient utilization of resources. Furthermore, some may feel quite specifically that the use of reminders is a reflection of the health service reproaching a potential participant who does not report for participation immediately.

Finally, it is possible to envisage the very down-to-earth reproach that would be forthcoming if the health service made tax-financed treatment of the disorder in question conditional on taking part in screening. That is to say that anyone choosing not to take part in screening tests would have to pay for the treatment and care of the disease themselves, should it eventuate. In a welfare society the feeling may be that it should be the duty of the individual citizen to support and, where appropriate, take part in screening tests so as to enable the disease to be identified and a minority of sick people to be provided with optimum help.
Hope, cure and security

Another main viewpoint stresses that screening tests are not only beneficial for the few sick, but also benefit the many healthy and the health service at large.

Advantages for the sick person

The sick person increases his or her chances of being cured of the disease. For example, a woman with preliminary stages of cervical cancer can markedly increase her chance of not contracting cervical cancer. Another advantage is linked to avoiding the disease entirely. If, for example, it was envisaged screening a group of men for increased serum cholesterol as a risk factor for cardiovascular disease, then men diagnosed with an elevated cholesterol level could increase their chances of avoiding the disease by, say, altering their dietary habits and exercising somewhat more. These men, in other words, could make themselves less vulnerable to cardiovascular disease.

One advantage for the sick participant is associated with the increased chances of being cured. Another ties in with the course of the disease—the investigative and therapeutic procedure—which may be less stressful and risky when the disease is in its early stages. For example, the woman with early-stage breast cancer may—after the shock of actually having breast cancer—nevertheless have a greater and more justified hope of a cure, as well as perhaps making do with a less operative intervention. Precisely because of these factors, perhaps, the woman’s level of worry and stress may be less. However, this calls for alertness to the fact that there are screening programmes in which any treatment required may help, on the one hand, but is simultaneously risky on the other. This dilemma may well be very taxing in mental terms. Screening for aortic aneurysm is one case in point: On the one hand, participants may be informed that there is a five percent risk or so of dying during an operation for aortic aneurysm (the risk depends on age and state of health). On the other hand, participants can lower the risk of death in the longer term with an operation. Moreover, a participant with aortic aneurysm knows that there is between 75 and 95 percent risk of dying if the aortic aneurysm ruptures. (Cf. Chapter 3, section 3.4.)

The support afforded the sick is still an advantage of screening tests. For one thing, there is reason to believe that in the vast majority of cases the immediate surroundings—family and friends—will provide support and care for the sick person or a person at a high risk of falling ill. That might mean, for example, that a man at increased risk of cardiovascular disease will enjoy the support of his wife, so that they rearrange their joint life by following a low-fat diet and exercising together. Or conversely, that the woman diagnosed with breast cancer at an early stage in its pathological development will enjoy the understanding of her family and friends in realizing that she is ill and needs their help.

Advantages for the healthy

By far the majority of participants receive a screening result that assures them they are just as
healthy as they felt prior to the offer—a true negative result. So there is no reason to believe that people given an offer of a screening test will be made morbid or anxious. Rather, in the vast majority of cases screening tests will assure people that they are fit and healthy. You might even say that participants are given extra reassurance by receiving the regular offer of an examination that enhances their positive feeling of being in control of their own health. At the same time, the examination affords an opportunity to get good advice on how to maintain good health and perhaps even be able to lead a healthier life, thus reducing the risk of becoming ill. In this way, screening tests will prevent people becoming dependent on the health service like an actual patient.

Advantages for society

Why should society institute screening programmes that take in many people, only a handful of whom will prove to be ill, treatable and enjoy any resultant health benefits? One argument in favour of this is that, by initiating a screening programme, society will sometimes be able to save money. In many cases it will also be possible to argue in favour of both the target group—the few sick—and society enjoying the advantages of screening. The sick gain years of life and society saves money.

Finding defects or promoting health

- prevention by screening?

"Prevention is better than cure". Prevention can take a number of different shapes, however. Screening is one of them. A question central to the Council’s discussions has been what role screening programmes should play in relation to prevention.

In screening tests, doctors look for possible disease. Prevention by screening usually means two things, therefore: partly preventing an increased risk of becoming ill from developing into actual disease, and partly preventing a disease from becoming so fatal that someone dies of it, for example.

One point of view is that the use of screening programmes should be seen as a positive contribution to helping people discover disease at an early stage, improving the odds of a cure, for instance. Screening programmes should be seen in the context of other types of prevention. But just as screening programmes should not represent the only mode of prevention, nor should one succumb to the idea that other types of prevention allow screening programmes to be dispensed with—or for that matter that other types of prevention involve fewer problems than using screening programmes.

Another point of view is that using the concept of prevention about screening is censurable, since for most people it will probably be the case that prevention is tightly bound up with the possibility of avoiding disease entirely, not ‘just’ discovering it early on. Use of the concept of prevention or the adage “prevention is better than cure” about screening must therefore be considered misleading to most people. If screening programmes are used,
therefore, particular care should be taken to explain to possible participants in a screening programme that the purpose of screening tests is to find potential disease in order better to help participants obtain a cure, assuming cure is an option.

A third point of view is that the use of an increasing number of screening programmes can help make a lot of healthy people highly preoccupied and afraid that there may be something wrong with them, and that they may be sick. Great caution should therefore be exercised about promoting the widespread use of screening programmes. Using screening programmes, then, is not the way to prevent. Instead, there needs also to be a constant commitment to promoting healthier and better conditions of life. The risk of making people afraid of being ill is presumably smaller if endeavours are made to inform them how to keep fit and healthy. Moreover, it should be realized that prevention need not be geared to the actual individual having to make the effort by taking part in a screening test or changing over to a healthier lifestyle. The possibility of a healthy life is also about the general social and living conditions—housing, work environment etc.—under which people are more or less compelled to live.

**Conclusion—lack of knowledge**

The Danish Council of Ethics recommends raising the standard of knowledge about the social and psychological effects of taking part in screening programmes.

There is currently a lack of knowledge and documentation of the extent to which participation in screening programmes results in pathologization and anxietization, and the extent to which it represents a reassuring measure for healthy people and a conservative form of treatment, and possible cure, for sick people. We do not know sufficient about the participants’ own evaluations of the relationship between anxiety and reassurance. How, for example, do the participants in a screening programme perceive the long-term effect of anxiety? How do they evaluate the waiting time in connection with additional examinations? And what importance do they attribute to this in relation to the advantages of the screening programmes?

The Council of Ethics’ recommendation of more knowledge about the social and psychological effects of the use of screening tests is in line with the National Board of Health, Denmark’s, recommendations from 1990, but the Board of Health’s recommendations do not seem to have had any appreciable impact.

The Council of Ethics recommends that, in evaluating a new screening programme, consideration be given to the importance of partly or wholly including in the programme people already covered by other screening programmes. Such considerations will foreseeably become increasingly relevant in pace with the introduction of ever more screening programmes.
Some women, for example, will be participants in both screening for cervical cancer (23-59 year-old women) and mammographic screening for breast cancer (50-69 year-old women). An assessment should be made of participation in a single programme as opposed to multiple programmes, in order to gain some impression of whether the overall effect of screening programmes can be pathologizing or anxietizing for particular groups.

5.2. False test results

The purpose of screening programmes is to pinpoint the few sick among the many healthy. The individual screening test does not provide a definitive, cast-iron diagnosis, however. More often it offers a risk evaluation, so that as a participant in a screening test—in contrast to an ordinary visit to the GP on the patient’s own initiative—there is a risk, for instance, of being treated as if one were sick, without being so.

The difference between an ordinary visit to the GP and a screening test may illustrate why it can be an ethical problem.

A person goes to the doctor’s because he or she feels ill. The doctor carries out an examination, makes a diagnosis and offers the patient treatment. At the same time, however, there can be certain drawbacks to being treated. The patient may decide to accept the treatment, thinking that the prospect of a cure outweighs the disadvantages of actual treatment. For the patient, the disadvantages take the form of acceptable side-effects. The same person is therefore affected by cure and side-effects.

Given this overlap, it may be felt that there are no ethical problems involved in society offering this treatment.

In the case of screening tests, the advantages and disadvantages of examination and treatment do not affect the same person. This is because, primarily, screening tests do not set out to furnish a definitive diagnosis. On the contrary, screening tests primarily single out individuals at increased risk of having a particular disease. Additional examinations and possible treatment will show that some participants have been falsely suspected. Overdiagnosis and overtreatment, for example, are an already familiar possible consequence of any screening test, making screening tests essentially different from examining a single patient.

During a diagnostic examination of one patient the doctor may well make the wrong diagnosis and offer the wrong treatment, but the doctor does not anticipate this happening. When initiating a screening programme that targets a population group, the doctors often know beforehand that a certain number of errors of judgement will occur—false positive and false negative test results—as a consequence of the introductory examination. Consequently, in order to increase the chances of helping some people suffering from disease, the health service uses a screening test that creates other problems.
False positive test results are problematic because they are a contributory factor in some people feeling ill without being ill.

First and foremost, the health service should cure sick people, not make many healthy people unduly afraid of being ill. Additional examinations are required to ascertain that the initial result was false. These examinations are indicative of overdiagnosis and overtreatment, and participants may perceive these examinations as both physically and mentally stressful and painful.

For example, a false positive examination result in connection with mammographic screening for breast cancer can give rise to a woman being subjected to a fine-needle (aspiration) biopsy, in which a cell sample is taken from the suspected cancerous tumour. Some women may find this painful. Similarly, they will usually perceive the period pending the final 'verdict' as severely stressful in psychological terms. Finally, even after the immediate relief at a mistake having been made, those subjected to a false positive result can experience increased uncertainty and fear of having the disease. A woman had this experience in connection with mammographic screening for breast cancer, where she was recalled but subsequently turned out to be healthy. Her reaction was "Then it was like plunging down into a hole of relief. Still, it was an odd experience, and it gives you food for thought. There’s no taking anything for granted any longer...it has created fear...Since then, I’ve been thinking 'Is what they say really true?'. I’m not over that dilemma yet.... I don’t feel confident." (Lunde, 1997, page 11)

False negative test results are problematic because they are instrumental in reassuring people falsely. Screening tests therefore risk helping to make some people feel healthier than they actually are. If, for example, a woman suddenly discovers breast cancer between two screening programmes—interval cancer—she may foreseeably react with disappointment, anger, bitterness and possibly a feeling of injustice, "Now that I’ve done everything they told me to do, I get sick anyway".

False positive and false negative test results are also problematic because they can distract the screenee’s attention from the body’s danger signals. For example, examinations of participants in mammographic screening for breast cancer have shown the following. "We know from examinations that women’s concerns about contracting the disease are crucial to whether they examine their own breasts. The women who are least and most concerned about becoming ill are known to be the ones who self-examine least of all. That is to say that patients who have been through a false positive experience could later end up in a group who are least in touch with their bodies. The same applies to women reassured by mammography screening. Perhaps something of the gain from screening is lost in this way." (Bonde, 1997, p. 50.)

How many false results should be accepted?
Everyone agrees that the most suitable test or
examination is the one that precisely and exclusively reveals those who are actually ill, sidestepping false test results in the process. As a rule, however, this is not altogether possible, partly for reasons of technical expertise, which is to say the quality of the examination apparatus.

Given this fact, the question is often how stringently the examination should be required to be precisely capable of “catching” the ill, i.e. catching neither too few nor too many.

In this connection it is important to stipulate requirements of the test’s ability to identify disease (test sensitivity), as this ensures that the provisional diagnosis of “susicion of disease” often holds good. Conversely, the outcome of inadequate sensitivity requirements will be that the health service not only makes these participants unduly scared of being ill, but treats them as if they were so. The reason it is not possible to rely on the individual him/herself being able to decide, on the basis of the information, whether the test is up to standard is that many participants will probably not have the physical wherewithal to consider it, but on the contrary will often be so worried that they dare not decline further examinations and any treatment proposed.

**Conclusion—lack of knowledge and information**

*The Danish Council of Ethics recommends,* in particular, stepping up efforts to generate a knowledge of the consequences for participants given false test results. This consolidated initiative should be put in place in relation to both ongoing and future screening programmes.

There are few studies of the consequence for individual participants of receiving a false test result, and amazingly little knowledge exists about Danish conditions.

The Council of Ethics’ recommendation is in line with the National Board of Health, Denmark’s, 1990 recommendation that, prior to making any decision to initiate a screening programme, an evaluation must have been made of the consequences of “false positive” and “false negative” test results. The Board of Health’s recommendation does not seem to have had any appreciable impact.

*The Council of Ethics recommends* making it a requirement that, prior to any participation, people have been informed about the risk of a false result. Information must be provided about:

1. the risk of receiving a false examination result associated with the individual examination
2. the risk of receiving a false result associated with taking part in the entire screening programme (lifetime risk). For instance, participation in ten screening rounds for breast cancer will yield a total risk of receiving a false positive result of approximately 25 percent (cf. section 3.2).
3. the increased risk of receiving a false result if taking part in a number of independent screening programmes.
There is currently no independent requirement in force to inform people prior to any participation in a screening programme about the risk of receiving a false test result.

The Council of Ethics’ recommendation on providing information about the risk of false results is related to the National Board of Health’s general requirement from 1990 that the target group must be given detailed information prior to examination.

The Council of Ethics recommends stating how great a proportion of participants in screening programmes can be expected to be called in for a follow-up examination.

The Council of Ethics recommends that the waiting time pending the results of examinations, including recalls for additional examinations, be made as short as possible. The waiting time should not exceed seven days.

When performing screening tests, it is very important to organize examinations in such a way that people can be called in for follow-up examinations with a minimum of waiting time, so as not to place undue strain on the individual participant. It should be possible to manage this by purely organizational restructuring, i.e. making an appointment in some way other than is the case today.

5.3. Prioritizing screening tests

The question of fair prioritization of screening tests involves:
- which patient groups to prioritize first: the sick or the possibly sick?
- whether the health service should be capable of giving everyone equal scope for examination before the screening programme is initiated?
- what social benefit a screening programme must yield?

Help the sick first

“The healthy don’t need a doctor; the sick do.” One viewpoint is that, first off, health service resources should be spent on patients who have a severe disorder here and now. This view may translate into screening tests not being offered for severe disorders that a group of people may have or may get. The fundamental principle that those who are actually ill should be helped first is rooted in a dedicated duty to help and care above all for those whose lives are under greatest threat from their illness at this very moment. If priority starts being assigned to the possibly sick on a par with the actually sick, there is a risk of what might be called a reverse Robin Hood effect, whereby resources are taken from the sick and given to the possibly sick.

“The possibly sick also need a doctor.” Another viewpoint is that the health service should also tend to the possibly sick who do not have a disorder but are at a substantiated high risk of having or contracting a severe, life-threatening disorder.
argument in favour of this view is the importance of offering these people examinations and possibly treatment at a point in the development of the disease when it is possible to provide treatment that gives the patient a greater chance of surviving the disease. Expressed in reverse, it may be termed a failure to care if the patient is not offered examination and treatment until the disease has progressed so far that the possibility of effective, curative treatment is diminished. In other words, health service initiatives are more likely to offer patients alleviation or a short-term improvement in their state of ill health.

A fundamental principle that the possibly sick should also be helped is that the dedicated duty to primarily help people in greatest need of help should not merely involve instances where people are in acute distress but should also include people who may eventually find themselves in acute distress.

The principle of equality and its constraints
A majority on the National Board of Health’s monitoring group on mammographic screening for breast cancer recommended in November 1997 that 50 to 69 year-old women throughout Denmark be covered by the offer of organized mammography screening. In January 1999 the 50 to 69 year-old women in Funen County, the Municipality of Frederiksberg and the City of Copenhagen received an offer of mammographic screening for breast cancer. But the other counties offer no organized mammography screening service.

Is this an example of unreasonable discrimination of women with the same needs, or are the differences acceptable?

It may be felt that any difference in access to screening programmes that depends on the county of residence is tantamount to failing groups of people in counties without a specific screening programme. After all, in principle, this group benefits just as much from taking part in such a programme. Based on a principle of equality, then, criticism can be levelled on the basis that people are not receiving the help which there are, say, medical and financial grounds for receiving.

Conversely, it may be thought that differences between counties represent a given that cannot be altered—certainly not in a situation where there is disagreement as to the value of a screening programme; and certainly not along the lines that no one at all should get it unless everyone gets it. Furthermore, differences between local bodies can be regarded as reflecting the value in which a principle of decentralized control is held—a principle of subsidiarity, which on the face of it is incompatible with the principle of equality. At any rate, a principle of equality should not pose an obstacle to deciding to help people in some places, using a screening programme deemed not to have the same value in other places.

Screening for the benefit of society
- public health and national economy
Instead of the sick or possibly sick person’s need for
help, it is possible to talk of the need to organize screening programmes so that they yield the greatest possible benefit for society.

**Benefit to society of screening programmes**
The benefit to society of screening programmes can be calculated in two different ways, two ways that are often coterminous.

One consists of evaluating their importance for public health, which often means the health of a population group. One public health target is the total number of years gained, which will be the result of a population group regularly attending screening tests. For instance, mammographic screening every other year for breast cancer in women between 50 and 69 will mean a total gain over a 36-year period of 3,232 years of life (present value) as compared with a situation in which no mammographic screening for breast cancer is carried out. (National Board of Health, Denmark, 1997a, page 18)

The other way of calculating the benefit to society consists of evaluating whether the screening programme is worthwhile. For example, economic calculations have shown that the cost of detecting and treating a small, curable cancerous lump in the breast is less than the cost would be if such patients were later struck by chronic cancer disease, with all the therapeutic and nursing costs entailed. (Bjurstam, 1996, page 117) These financial calculations are also factored in when scheduling the frequency of examinations. If, for example, breast cancer screening was done every year instead of every other year, the number of years of life gained would increase from 3,232 to 3,863, but the price per year of life gained would increase from DKK 33,500 to approx. DKK 52,000 per year of life. (National Board of Health, Denmark, 1997a, page 149) One of the reasons for screening every other year rather than every year is that the cost of gaining more than 3,232 years of life increases disproportionately in relation to the gain in the number of years of life. This is also expressed by saying that mammographic screening of women between 50 and 69 every second year is the most cost-effective way of organizing the screening programme. (Cf. section 3.2)

A first criticism of the effect of screening tests on cure is that there is sometimes a tendency to overestimate this effect because, for example, no account is taken of the importance of other historical factors for the decline in mortality from the disease in question. Screening programmes for cervical cancer and tuberculosis can be criticized for overestimating the impact of efforts on health. Whether the decline in the number of women dying from cervical cancer is due to the use of screening tests alone is questionable, since a fall in mortality was evident even before examinations were introduced. The same doubt is raised with the screening programme for tuberculosis, where there was also a fall both in the spread of the disease and in mortality before screening and antibiotic treatment were introduced. Incidentally, screening for tuberculosis was halted in 1972, when the occurrence of tuberculosis cases had been very small for a number of years.
A second criticism is that the calculations performed often depend on all county authorities introducing an organized screening programme. Yet that cannot always be counted on. Screening for breast cancer is one example of such an organized screening programme not being introduced by all counties.

A third criticism: Benefit calculations also depend on a certain quality of diagnosis and treatment facilities being present. In connection with mammographic screening for breast cancer, criticism of the quality of a number of X-ray machines (mammography appliances) and criticism of the lack of trained staff highlight the probable impossibility of matching the computed benefit owing to poor diagnostic and therapeutic conditions.

Duty to take part in screening tests?
The computed benefit of an organized screening programme depends on a group of people participating regularly and systematically in screening tests. But the question is whether to make it an out-and-out duty to take part in screening programmes and thus contribute to achieving the computed benefit.

One argument in favour of a duty to participate may be the threat to public health when faced with a crisis situation. Another argument in favour of the duty to participate may be that, just as people have a duty to drive with safety belts, for instance, there should be a duty to take part in screening tests. The purpose of both is to safeguard against the risk of developing poor health, and often the purpose is also to save society the expense of treating sick people.

One argument against such a duty to take part in screening programmes is that as a general rule society should not commit citizens to screening programmes that are not unequivocally beneficial to the individual, but conversely may also be highly taxing in psychological terms. For example, it may be felt that making participation in a screening programme obligatory is vastly different from making the use of safety belts for motorists obligatory. The former is presumably associated with a much greater risk of pathologization and anxietization than the latter.

Finally, one may ask whether people who choose not to take part in a screening programme and later contract the disease for which they could have been examined should have the same treatment as those who chose to take part and were diagnosed with the disease? Or should opting out of participation have consequences, with non-participants receiving inferior treatment to participants in the screening programme?

In its report "Priority-setting in the Health Service" (Danish Council of Ethics, 1996, section 6.4) the Council of Ethics warned against making use of a priority-setting criterion based on the actual individual taking responsibility for his or her own suffering if the person has been informed about the risk of falling ill but has chosen not to make use of
facilities, like screening programmes, that could have helped earlier on and possibly made treatment better and cheaper.

The financial argument in favour of obligating citizens to take part in screening tests is that it enables society to save money. Society, in other words, will be able to claim that the citizen is behaving asocially, i.e. imposing a risk of unnecessary care expenditure on society, if the person in question refuses to take part in an examination and any treatment required. If society allows the individual citizen not to take part, however, society can simultaneously choose to reduce its obligation of care vis-à-vis that citizen, were he or she to contract the disorder concerned. A crucial objection to this point of view is that a welfare society ought to be based on an obligation to help the sick—irrespective of whether they have previously acted egoistically and inconsiderately.

**Requirements for a decision-making basis for introducing a screening programme?**

What information needs to be available to decide whether a screening programme is good enough to warrant being introduced? Straight off, one might say that it is enough to know that introducing a screening programme will enable the disorder to be detected earlier on and at the same time allow better treatment options to be provided than if the disorder were not discovered until the sick person spotted the symptoms him/herself. But it may also be felt that these formulations create far too vague a foundation on which to base a stance, and that much more precise and systematic demands should be made of the basis for taking a stance on a screening programme. For instance, it may be felt that the purpose of the programme should be formulated so clearly that calculations are made available detailing the numbers needed to take part in order to save one life as well as calculations detailing the social and psychological stresses involved, if any, for the individual taking part in one or more programmes.

**What is the purpose of screening programme?**

The purpose of a screening programme may be to save lives. That is the case with screening for breast cancer. But it can also be to prevent people falling ill. For example, neonatal screening—sampling blood by pricking the heel of newborns (phenylketonuria or PKU testing)—must evidence a hereditary disorder early enough to allow treatment to be initiated and thus avoid the child becoming mentally retarded. One question is whether it can also be envisaged accepting screening programmes whose main aim is to be able to undertake less invasive treatment or make provision to identify the sick so that they do not infect the healthy.

How many people need to take part in a screening programme in order for one person to receive the help outlined by the purpose of the screening programmes? A figure for this is not very often available as part of the decision-making basis for introducing a screening programme. However, it may be felt that the advantages—the help planned for one person—of a specific screening programme
should be articulated so precisely that it is possible to formulate the average number of individuals needing to be screened in order for one person to secure the advantages on balance. How many people, for example, need to be screened for breast cancer in order to save one human life? In order to evaluate the reliability of such a figure, a so-called safety interval of e.g. 95 percent may need to be given together with the figure, meaning that there is a 95 percent probability of the number falling within this range, which is to say that the figure also holds good in practice. The reason for needing to have such a figure available as part of the decision-making basis for introducing or rejecting a screening programme is that it provides a clearer and more distinct possibility of gauging whether the advantages for the individual are considered great enough to outweigh any conceivable disadvantages there may be for the many.

How great is the benefit derived from initiating a screening programme—in relation to not doing so?
If the intention of a possible screening programme is to save human lives, it is essential to work out how great a fall in total mortality can be expected by introducing the programme. Thus it is not enough that the screening programme reduces mortality for certain groups of the population (for example, those diagnosed with the disorder). The rationale behind this point of view is best illustrated by an example:

Lung cancer is the cancerous disorder that claims most deaths in Denmark. Lung cancer is due to smoking, and about five percent of the Danish population die of lung cancer. Five-year survival is low for lung cancer (about five percent), and there are several large-scale studies in which it has been attempted to screen smokers with regular X-ray exams of the lungs—once a year, for example—with a view to detecting and treating lung cancer early on and thus saving human lives. The studies have typically been conducted so as to X-ray the lungs of a large population base and then divide it into two equal-size groups, a screening group and a control group. Members of the screening group underwent an annual X-ray of the lungs while members of the control group were merely monitored with an eye to registering those who developed lung cancer. If, say, there were 10,000 people in each of the two groups, a typical finding was 100 cases of lung cancer in the control group and 30 percent more, i.e. 130 cases, in the screened group. The number of deaths due to lung cancer in the two groups was typically the same, e.g. 90 in each group. Since 90 deaths make up a smaller percentage of 130 cases of lung cancer in the screened group than of 100 cases in the control group, it might look as if people with lung cancer fared better in the screening group than in the control group; but that is of no import, as long as the total number of deaths in the two groups is equally large. The conclusion has therefore been that screening for lung cancer by conventional X-ray examination of the lungs cannot be recommended. Cf. figure by way of illustration.
Table 1: Example: screening for lung cancer

A total of 20,000 people underwent X-ray examination of the lungs

<table>
<thead>
<tr>
<th>10,000 were screened</th>
<th>10,000 were not screened</th>
</tr>
</thead>
<tbody>
<tr>
<td>130 found on examination</td>
<td>100 develop symptoms</td>
</tr>
<tr>
<td>90 have died after five years</td>
<td>90 have died after five years</td>
</tr>
</tbody>
</table>

Discussion has been devoted to why more people with disease are often found by screening than by non-screening. There may be a number of explanations:

1) Methods of detecting disease always involve some uncertainty, so a number of those found by screening will not be sick at all.

2) Some of those with the disease amongst the non-screenees will die of other causes (traffic accidents, for example) before the disease reveals itself through symptoms.

3) Some of those with the disease amongst the non-screenees will die of the disease without it ever having been detected. Theoretically, the last point may cause the impact of screening to be underrated. However, most people consider dying of, say, lung cancer in Denmark rather improbable without a diagnosis having been made.

How reliable is the screening test?

Similarly, it may be felt that it is important to obtain a very exact knowledge of the screening test’s ability to detect only people with the disorder. The lack of such precision means that apparently relevant information can be misleading in reality. For example, it is often put forward as an argument for screening that those diagnosed with a disorder by means of screening fare better than those who are not screened and therefore have the disease ascertained from the symptoms only. If screening does result in more people having a disorder diagnosed, the argument may be misleading, however. The reason more people with a disorder are found by screening may be, as mentioned, that the method of detecting disease is not reliable, and that individuals who neither have nor will develop the disorder also run the risk of having ‘disease’ detected during screening. Screening can thus result in treatment being given to people who are not in the slightest bit sick. As a rule, these people do better than those who have the disease. This can give the erroneous impression that treatment results are better in the screened group than in a group that was not screened, and in reality that erroneous impression may reflect the fact that the method of examination is so unreliable that it forces additional examinations and treatment to be conducted, often involving great mental stress, pain and new risks.

Consequences of taking part in screening programmes— for the group or the individual?

In addition, it may be felt that introducing or not introducing a screening programme should be based both on a description of whether the screening programme addresses a group of people already covered by screening programmes and on evaluations of the advantages or disadvantages this group gains by taking part in an additional screening programme. Does it make them more...
afraid or more reassured about their state of health?

Finally, it may be felt that some assessment of these factors should be made by an interdisciplinary authority, on which independent experts and laypersons are represented. This is partly due to the very great difference that may exist in the factors ascribed importance. For instance, is the emphasis on advantages or disadvantages for the group or for the individual participant? One example of various types of calculations of the reduction in risk achieved by taking part in screening programmes may illustrate the difference between emphasizing the advantages for the group and emphasizing the benefit for the individual. If a figure is given for so-called relative risk reduction, it says something about the average reduction in the risk of the group dying from the disease. If a figure is given for so-called absolute risk reduction, it says something about the average risk reduction achieved by one member of the group as a result of participating. The figure for the group as a whole (relative risk reduction) is generally always higher than the figure for one person in the group (absolute risk reduction). According to a Norwegian survey, doctors usually set greatest store by a knowledge of the risk reduction for the group (relative risk reduction) as the main objective of a screening programme’s impact, and for the same reason many doctors will interpret information about group risk reduction far more positively than they would have done if they were dealing more with the risk reduction for one person in the group (absolute risk reduction). (Hetlevik & Holmen, 1994, page 1710)

Conclusion—more and better reasons for prioritization

The Danish Council of Ethics recommends that screening programmes not be initiated before clarity has been achieved as to the availability of financial resources and before mapping out where financial resources for the screening programme are coming from—what other tasks will be downgraded or not carried out at all if the screening programme is implemented?

The Council of Ethics recommends that the health service not implement a screening programme before diagnostic and therapeutic facilities are available matching the quality standards that can be regarded as professionally defensible and before there are adequately trained staff to operate the machinery and interpret the results.

If the proper diagnostic and therapeutic facilities are not present, it will firstly not be possible to meet the calculated gain in health terms, and secondly not to meet the economic targets. Furthermore, the lack of proper facilities will probably also expose participants to a greater risk of false test results. Thus there can be said to be a greater risk of participating under a false notion of the safety and benefit of the examination.

This recommendation is in keeping with the Council of Europe’s recommendation, WHO’s
recommendations and the National Board of Health, Denmark's, recommendations from 1990. However, the recommendations of the Council of Europe, WHO and the National Board of Health seem not to have had any appreciable impact on the drafting of screening programmes—not in the context of mammographic screening for breast cancer, for instance.

The Danish Council of Ethics recommends that screening programmes be evaluated regularly in order to ensure that they are still relevant.

From screening for tuberculosis, for instance, it is known that an ongoing screening programme can eventually run for longer than is medically justified unless a regular review of its relevance is stipulated right from programme start-up.

The Council of Ethics recommends intensifying and qualifying the requirements governing the decision-making basis for the possible introduction of a screening programme. The policy-makers involved in the decision whether to initiate a screening programme should base that decision on the following information:

1) The purpose of the screening programme should be set out quite clearly. Is it, for instance, to save lives? Or is it to be able to provide more conservative treatment?

2) It should be made clear what participation rate is required to achieve the calculated health gains. In this connection a figure should be put on the number needing to participate in a screening programme in order for one person to receive the help outlined by the objective of the screening programme. (Cf. section 5.3.)

3) Similarly, a statement ought to be available quantifying the benefit of initiating a screening programme as compared to not doing so. One question that should be answered, for example, is how great a drop in mortality (both in absolute figures and as a percentage) is achieved as a consequence of the screening programme, compared with the same scenario without a screening programme.

4) The reliability of the examination methods for detecting only the sick should also be stated precisely.

This recommendation is in accordance with the Council of Europe's recommendation, "Screening followed by diagnosis and intervention in an early stage of the disease should provide a better prognosis than intervention after spontaneously sought treatment." (Council of Europe's recommendation, 3.4.)

The Council of Ethics recommends that independent elucidation and evaluation be provided by experts—not directly involved in the relevant screening programme—and laypersons. This should be done before the relevant political body takes a stance on whether to conduct the screening programme.
The appointment of an interdisciplinary body can also be claimed to be in line with WHO’s recommendation to ensure that the examination is acceptable to the population.

5.4. Unsolicited approaches and information

—about the risk of illness and the chances of cure

Should the health service make unsolicited approaches to the individual? The question can be expanded on: Does the community violate the individual’s self-determination or personal integrity by offering screening tests? Or is an offer of a screening test a reinforcement of the individual’s self-determination?

Initially, an approach from the health service offering a screening test not only provides the knowledge that the individual—as indeed the population at large, or a section thereof—is at a particular risk of having or developing a particular disease. If the individual chooses to take part in the examination the second time round, it may lead to the knowledge that there is nothing wrong. If there is something wrong, on the other hand, a man, for example, can risk being informed that he has an increased cholesterol level and is thus at risk of contracting cardiovascular disease. Or it can result, for instance, in a woman being told she has cervical cancer.

It is the value of such knowledge opportunities that can be crucial to the way the individual feels about whether the health service should be given leave to make unsolicited approaches to offer screening tests. If the individual would rather be spared these approaches, the individual can be said to be taking advantage of the right not to know. If, on the other hand, the individual welcomes such approaches, he or she can be said to have the right to know.

The “Danish Act on the Legal Status of Patients’ embodies a desire to protect both the right not to know and the right to know. This law also covers participants in a screening programme. The intent of the law is to safeguard patients’ dignity, integrity and autonomy as well as to be instrumental in protecting the relationship of trust and confidentiality between patient and health-care worker.

The right not to know

Approaches from the health service offering a screening test can be perceived as a violation of personal integrity. The direct and personal invitation per se risks changing the individual’s self-image: from the feeling of being healthy to the fear of being ill. For example, inviting women to mammographic screening for breast cancer reflects the accent on the woman invited belonging to the group that the health service feels to be at increased risk of getting breast cancer. That may arouse concerns in some women—concerns the individual woman might prefer to do without. Perhaps the woman’s conviction—in the particular context—is that the information will not give her a more secure and happier life but, on the contrary, make her insecure and even afraid. More generally, the popular mantra
about the right not to know may either live on in the expression ‘ignorance is bliss’ or in the expression ‘what you don’t know can’t hurt you’.

Freedom and the right not to know

The individual may also perceive the actual approach as compelling, as “an offer you can’t refuse”. If that is the case, the screening test will not be a genuine offer, but rather an examination which the individual undergoes as an order, “I think it’s hard to say no to an offer from the health service. If I said no, I think I’d feel ‘that was daft of you, when you were given an offer’”. (Lunde, 1997, p. 20) In order to understand that the offer of a screening test can actually be perceived as an order, perhaps it also needs to be realized that the health service’s information and offer of screening tests is probably harder to reject than the local supermarket’s regular special offer on shampoo.

A hands-on example of exercising the right not to know is familiar from stickers on people’s letterboxes or doors, saying “No advertising please!” The question is whether it would also be possible or desirable for the individual to opt out, once and for all, of the health service’s letters containing information and offers of screening tests?

Though maybe a “sticker solution” is far from being “just what the doctor ordered” when it comes to screening tests?

One of the reasons for this may be that people have well-differentiated views as to which screening tests they would like and which they would not. Some people may only be interested in finding out something about severe disorders. Other people may only want to find out something about less severe disorders which they feel they can do something about without having to go through what they consider to be very onerous treatment. Others again may only want to receive offers of screening tests involving examinations that ascertain whether they do or do not have the disorder, whereas they do not want to be examined if the outcome is purely a risk evaluation.

Another reason why it can be difficult to opt out of screening tests once and for all is that, many times, a person cannot make up their mind over time whether they want one kind of knowledge but not another. In other words, most people are familiar with the dilemma between, on the one hand, the expression, “What you don’t know can’t hurt you” and, on the other hand, the expression, “I can’t miss out on that”.

A completely different way of preventing the individual from receiving unwanted knowledge—enforced information—may consist of society deciding not to permit this type of examination. However, it may be felt that such a decision is a violation of the individual’s right to know.

The right to know

There is also the option of viewing an approach with an offer of screening as an out-and-out welfare benefit for the individual. A person with
this outlook will view the approach and offer of participation in the programme as a benefit, since it provides an opportunity to keep their autonomy intact. The offer of a screening test gives the individual an opportunity to prevent a specific disease from developing, and the individual as a sick person from losing the autonomy of the healthy person. More generally, the popular motto for the right to receive this information may live on in the expression, "I can't miss out on that" or in the words of the vexed person, "if only I'd known a little earlier...I would have ....".

The consequence of this view, on the one hand, is that the individual cannot be completely ignorant of the health service’s belief that specific knowledge exists which he or she will probably benefit from knowing about. On the other hand, it does not need to mean that the individual’s autonomy is compromised.

The right to know—and the freedom to opt out
Offer, not compulsion. One viewpoint is that a screening test should depend solely on the individual’s free choice. That is to say that the individual should have received sufficient information to be able to make a considered decision to opt in or out. The purpose of the health service’s invitations for screening tests, then, should not be to have the individual make the decision the health service considers right—that would be compulsion. Conversely, the invitation to a screening test should always be formulated in a way that enables the individual to arrive at the decision he or she considers best. By the same token, reminders and additional information should be arranged so that the recipient does not feel pressurized into taking part in the screening programme and possibly even feel at risk of being penalized for not taking part, should he or she subsequently need treatment for the disorder addressed by the screening programme.

Overall, then, the health service’s offer of screening should be based on two considerations: Firstly, it is fair to assume that the health service only offers examinations to people at such high risk of having or contracting particular treatable disorders as to warrant sending them an invitation to a screening test. It may be felt that a welfare society has an obligation to give certain risk groups such an offer; otherwise members of those risk groups may rightly feel disappointment and anger at society not having given them the chance to avoid certain diseases and disorders. Secondly, it is fair to assume that the health service is obliged to inform risk groups. Just as they are entitled to know what they are taking part in, so too they have a right to know what they are declining to take part in. But the crucial thing is that the individual should not feel obligated or pressured into taking part in these examinations. It should be a free choice, an offer. Participants are not always left with this impression by the health service’s unsolicited invitations and the use of reminders.
Information with respect for self-determination?
How should information be provided about the risk of disease and the chances of cure, so as to enable the individual to make up his or her mind about taking part in a screening test and any treatment required?

Risk of disease does not mean a person is ill
One view is that, before any examination is undergone, it should be endeavoured to impress upon participants that the risk of disease does not mean the person concerned will contract the disease if he or she does not take part in the examination. So it should be ensured that the potential participant does not confuse a risk of disease with actual disease. How is that done? One contribution is to explain to the potential participant that "membership" of a risk group merely means having a particular statistical likelihood of having or developing a given disorder. That is to say that no one knows in advance who in the risk group has or will get the disease. As a starting point, the sick are anonymous. The potential participant should therefore be told that it is not certain he or she will miss out on early treatment and increased odds of being cured of the disease. Similarly, the potential participant should be told that there is a risk of the examination possibly "clearing" or incorrectly suspecting someone—i.e. the test result proving to be wrong. Not everyone knows this. For example, on being recalled for breast cancer screening, a woman said she expected the mammography examinations to be perfectly reliable, going on to say, "I've always believed that, I have to admit ... I know full well there may be something they can't see ... But certainly 99 percent—that's my view. I dare say I'm a bit orthodox ... But I have some sort of belief that of course there's nothing wrong with me; so when they even tell you that into the bargain, there probably isn't." (Lunde, 1997, page 17)

Improved chances of a cure not synonymous with getting better
Correspondingly, another viewpoint is that, prior to any examination, it should be endeavoured to impress upon participants that a screening test which clears participants of suspicion of the disease does not eliminate the risk of the disease. More particularly, though, efforts should be made to point out to participants that any early discovery of disease, on the one hand, provides a better chance of being cured, but on the other hand is no guarantee of being cured. So it should be ensured that the possible participant does not confuse the chance of a cure with a cure. How is that done? Again, the participant has to be told that early discovery of the disease is known to mean increasing the chance of a cure, measuring the odds at group level. Yet, at the same time, it should be made clear that it is not known who the cured—"the winners"—will be. The cured are basically just as anonymous as those participants who, for example, will die of the disease concerned. Not everyone knows there is no guarantee of a cure. A woman who took part in mammographic screening for breast cancer, for example, said, "I find it reassuring to know they're going to examine you,
and if there is anything, it won’t be so advanced as to be incurable.” (Lunde, 1997, p. 10)

The main reason for telling people about the uncertainty, i.e. stressing the risk of being sick, the risk of getting a false positive result and the chance of a cure, is that the individual may otherwise be thought to be taking part on a false premiss.

Precise presentation of information

The main problem with having to give the individual participant a precise explanation about the risk of disease, the risk of false results and the chances of a cure is that the relevant figures reflect probabilities that exist at group level, not individual level. However, this knowledge can be presented in different ways and at different levels.

One point of view is that the individual participant, prior to any decision whether or not to take part in an examination, should have a knowledge of the total risk reduction—i.e. information about reducing the risk of dying for the individual in the group, not just the relative risk reduction, information on reduction for the group. The difference can be illustrated with figures taken from mammographic screening for breast cancer.

On the one hand, the potential participant can be told that there will be a 29 percent reduction in mortality for women between the ages of 50 and 69 from participating in a screening programme. The 29 percent is the relative risk reduction, i.e. the relative difference between the number of women in the group of screenees who died and the number of women who died in the group of non-screened subjects. On the other hand, the potential participant can be told that she can reduce her overall risk of dying of breast cancer by 1 percent, from 5 to 4 percent, by taking part in mammographic screening at the age of 50-69. (National Board of Health, Denmark, 1997a, page 156—excerpt from minority statement.) Based on this difference, then, it may be felt that the potential participant is not being given a genuinely informative basis by telling her solely about a 29 percent reduction in mortality. On the contrary, one may say this is giving the individual woman a wrong impression of the risk reduction she can achieve by taking part in the screening programme. A 30 percent reduction in mortality probably seems more alluring than an overall reduction of 1 percent in the risk of dying of breast cancer. Unless the objective is to get as many as possible to take part, the woman’s autonomy will be tendentiously violated by informing her of a 29 percent reduction rather than the 1 percent reduction.

Another example of certain ways of presenting knowledge that may violate the individual’s autonomy stems from the Danish book “Risiko og forebyggelse—Urealistiske forventninger” [Risk and Prevention—Unrealistic Expectations] (1998) by Susanne Reventlow and Torsten Lauritzen. This (pp. 48-49) gives an example of mammographic screening for breast cancer involving two different ways of presenting information, one of which can be considered a violation of the individual’s scope for self-determination.
The results show (...) that seven years after 10,000 50 to 70 year-old women were offered mammography screening, there are:

- 1,500 who have had a demonstrable finding necessitating further examinations,
- 137 who have had breast cancer diagnosed,
- 11 who have died of breast cancer among the 10,000 women screened, while in the control group of 10,000 non-screened women 15 have died of breast cancer.

All in all, a difference of four people—or a risk reduction of 30 percent (4/15). For the individual that means four fewer deaths from breast cancer per 10,000 women examined, representing an individual chance of gain of 0.04%.

Again, it is presumably the case that a number of people will feel more tempted by the offer of a screening test, given a risk reduction of 30 percent, than if the individual chance of gain is 0.04 percent. Choosing to present knowledge in one way rather than another is fundamentally about whom it is felt the information should be precisely honed to—the group or the individual.

With regard to the risk of false results, the problem is the same. However, there is an additional aspect. One can tell a person about the risk of a false result associated with an individual examination in a single programme and leave it at that; conversely, however, one may also feel that the full or most accurate picture of the risk of false results is not present unless the individual participant is given information on the overall risk of false results from participation in the screening programme as a whole. Dr Inga Marie Lunde, MD, a general practitioner, has just highlighted this in connection with mammographic screening for breast cancer. ‘The lifetime risk of healthy women getting at least one false positive result in 10 screenings is about 25 percent. The incidence of interval cancers is about 24 percent, which means that not all women affected by cancer are found by screening. These are given false reassurances.’. (National Board of Health, Denmark, 1997a, page 156, excerpt from minority statement)

As an extension of this, someone offered the chance to take part in several examinations may feel that they should be given information on the way it increases the risk of false test results.

Another viewpoint is that there is no need to detail or precisely describe these differences, certainly not in a written invitation to an examination.

Part of the rationale underlying this view relates to the calculated social impact of a screening programme being dependent on a high rate of participation, for which reason information should not be given that may jeopardize the objective of a high participation rate.

Another reason for the point of view is that a more detailed description would only make participants more confused and insecure than they have reason to be. One participant in mammographic screening for breast cancer, for
example, said the following about the uncertainty and the possibility of false results, "I don't think too much detail should be given about it. I think they should just say it isn't 100 percent reliable, so that people don't go thinking everything in the garden is lovely ...". (Lunde, 1997, page 18) Another example illustrates the same consideration, "I know perfectly well that all those examinations aren't reliable. But when things are more or less right, I feel comfortable with it." (Lunde, 1997, page 17)

Further to this, it is possible to take the view that the health service is not only responsible for offering increasingly more screening tests, on which the individual has to take a stance, but is also responsible for ensuring that the individual does not suddenly land in a situation where the risk of pathologization, anxietization and false test results become disproportionately high.

**Conclusion—better information and greater voluntariness**

*The Danish Council of Ethics recommends* generally enhancing the precision with which invitations to participate in a screening programme provide potential participants with information about possible advantages and disadvantages, the main aim being to give the recipients an opportunity to make their decision on an informed basis. Precisely because the approaches involved are unsolicited, the health authorities are especially obliged to provide thorough and well-graduated information on the screening programme.

The invitation should explain what the purpose of the screening programme is.

The advantages of a specific screening should be articulated with sufficient precision that it is possible to formulate the average number of people needing to be screened in order for one person to secure the advantages on balance. How many women, for instance, need to undergo mammographic screening for breast cancer in order to save one life? Similarly, the participation rate necessary to obtain the calculated gains in terms of health and economy using the screening programme should be made clear.

The drawbacks of a specific screening should emerge clearly. How great is the risk of a screening test being unable to provide a correct result with certainty, calling for additional examinations (with renewed risks) to be performed in order to clarify whether a participant in the screening programme is sick or healthy? Similarly, it should be clear that there is a risk of a false result from the examination. Information must be given on the risk of a false result associated with the individual examination, the risk of false results from participation in all screening rounds of the programme (lifetime risk), and the increased risk of a false result when taking part in several independent programmes.

If data are provided on the statistical results of the screening programme, in as far as possible
these should be conveyed in such a way as to relate to the effect of screening for the individual participant. On mammographic screening for breast cancer, for instance, it is not sufficient to provide the information that there will be a 29 percent fall in mortality from breast cancer (relative risk reduction) in the screened group. Above all, it needs to be communicated that screening can reduce the individual woman’s overall risk of dying from breast cancer from 5 to 4 percent (absolute risk reduction). (Cf. section 3.2)

Precise and thorough information should be given on the risks—pain, mental strain, risk of death and so on—entailed by the actual treatment for the disease being screened for. This includes information on other medically justifiable treatment options and on the implications of not initiating treatment.

*The Danish Council of Ethics recommends* stressing carefully in any invitation to take part in a screening programme that participation is voluntary.

The invitation should show clearly that the service is an offer, not an obligation, and that declining to take part will in no way have consequences with regard to any subsequent need for treatment for the disorder addressed by the screening programme.

Reminders and other information should also be conveyed in such a way that the individual is not indirectly pressured into taking part in the screening programme.

The above recommendations are in keeping with the National Board of Health, Denmark’s, recommendation that, prior to a screening programme being initiated, there must be a detailed description of the information available to the target group. However, in a number of the written invitations to potential participants in a screening programme, this has not resulted in the precision of information recommended by the Council of Ethics.

The recommendations are also in line with the Council of Europe’s recommendation on screening, which characterizes a failure to draw attention to the known positive and negative aspects of a screening programme as unethical and in violation of the individual’s autonomy.
Chapter 6: Resumé of the Council of Ethics’ recommendations

The Danish Council of Ethics takes a concerned view of the current situation, in which most screening programmes are initiated on an inadequate basis with too great a degree of haphazardness in the decision-making process. The National Board of Health, Denmark’s, guidelines—and WHO’s recommendations—are not being followed on a number of central points, and there is a lack of knowledge and clarity surrounding important factors relating to social and psychological effects, false negative and false positive test results, priority-setting bases and information. The debate on the possible introduction or expansion of screening programmes is often characterized by that same inadequacy.

Against this background the Council of Ethics recommends introducing a politico-ethical procedure. This should ensure that policy-makers are given a qualified basis on which to take a stance on possible screening programmes. In addition, it should ensure that invitations to potential participants in a screening programme are formulated so that the decision whether or not to participate in the programme is made on an informed and voluntary basis. Finally, as a minimum objective, screening programmes should comply with the guidelines of WHO and the National Board of Health, Denmark.

6.1. Social and psychological effects—we lack knowledge

The Danish Council of Ethics recommends raising the level of knowledge about the social and psychological effects of taking part in screening programmes.

There is currently a lack of knowledge and documentation of the degree to which participation in screening programmes leads to pathologization and anxietization, and the degree to which it constitutes a reassuring measure for healthy people and a conservative mode of treatment and a possible cure for sick people.

The Council of Ethics’ recommendation for greater knowledge about the social and psychological effects of the use of screening tests is in line with the National Board of Health, Denmark’s, recommendations from 1990, but the National Board of Health’s
recommendations seem not to have had any appreciable impact.

*The Council of Ethics recommends* that in evaluating a new screening programme, consideration be given to the importance of the programme wholly or partly including people already covered by other screening programmes. There is a foreseeable likelihood of such considerations becoming increasingly relevant in pace with the introduction of ever more screening programmes.

Some women, for example, will be participants in both screening for cervical cancer (23-59 year-old women) and screening for breast cancer (50-69 year-old women). There should be an evaluation of participation in a single programme as opposed to multiple programmes, in order to gain some impression of whether the overall effect of screening programmes can be pathologizing or anxietizing for particular groups.

### 6.2. False test results—lack of knowledge and information

*The Danish Council of Ethics recommends*, in particular, that efforts be intensified to generate a knowledge of the consequences for participants given false test results. Such consolidative action should be put in place for both ongoing and future screening programmes.

There are few studies of the consequences for individual participants of receiving a false test result, and amazingly little knowledge exists about Danish conditions.

The Council of Ethics’ recommendation is in line with the National Board of Health, Denmark’s, 1990 recommendation that, prior to making any decision on the initiation of a screening programme, an evaluation must be made of the consequences of ‘false positive’ and ‘false negative’ test results. The National Board of Health’s recommendation does not seem to have had any appreciable impact.

*The Council of Ethics recommends* making it a requirement that, prior to any participation, people have been informed of the risk of a false result. Information must be provided about:

1) the risk associated with the individual examination of receiving a false examination result;
2) the risk of receiving a false result associated with taking part in the entire screening programme (lifetime risk). For instance, participation in ten screening rounds for breast cancer will yield an overall risk of receiving a false positive result of approximately 25 percent (cf. section 3.2);
3) the increased risk of receiving a false result associated with taking part in a number of independent screening programmes.

There is currently no independent requirement in effect to inform people prior to any
participation in a screening programme about the risk of receiving a false test result.

The Council of Ethics’ recommendation concerning information about the risk of false results is related to the National Board of Health’s general requirement from 1990 that the target group be given detailed information before the examination.

The Council of Ethics recommends stating how great a proportion of the participants in screening programmes can be expected to be called in for a follow-up examination.

The Council of Ethics recommends that the waiting time pending the results of examinations, including recalls for additional examinations, be made as short as possible. The waiting time should not exceed seven days.

When performing screening tests, it is very important to organize examinations in such a way that people can be called in for follow-up examinations with a minimum of waiting time, so as not to place undue strain on the individual participant. It should be possible to manage this by purely organizational restructuring, i.e. making an appointment in some way other than is the case today.

6.3. Prioritization and control—more and better reasons

The Danish Council of Ethics recommends that screening programmes not be initiated before clarity has been achieved as to the availability of financial resources and before mapping out where financial resources for the screening programme are coming from—what other tasks will be downgraded or not carried out at all if the screening programme is implemented?

The Council of Ethics recommends that the health service not implement a screening programme before diagnostic and therapeutic facilities are available matching quality standards that can be regarded as professionally defensible and before there are adequately trained staff to operate the machinery and interpret the results.

If the proper diagnostic and therapeutic facilities are not present, it will firstly not be possible to meet the calculated gain in health terms, and secondly not to meet the economic targets. Furthermore, the lack of proper facilities will probably also expose participants to a greater risk of false test results. Thus there can be said to be a greater risk of participating under a false notion of the safety and benefit of the examination.

This recommendation is in keeping with the Council of Europe’s recommendation, WHO’s recommendations and the National Board of Health’s recommendations.
Health, Denmark’s, recommendations from 1990. The recommendations of the Council of Europe, WHO and the National Board of Health, however, seem not to have had any appreciable impact on the drafting of screening programmes—not in the context of mammographic screening for breast cancer, for instance.

The Council of Ethics recommends that screening programmes be evaluated regularly in order to ensure they are still relevant.

From screening for tuberculosis, for instance, it is known that an ongoing screening programme can eventually run for longer than is medically justified unless a regular review of its relevance is stipulated even from programme start-up.

The Council of Ethics recommends intensifying and qualifying more precisely the requirements governing the decision-making basis for the possible introduction of a screening programme. The policy-makers involved in the decision whether to initiate a screening programme should base that decision on the following information:

1) The purpose of the screening programme should be set out quite clearly. Is it, for instance, to save lives? Or is it to be able to provide more conservative treatment?

2) It should be made clear what participation rate is required to achieve the calculated health gains. In this connection a figure should be put on the number needing to participate in a screening programme in order for one person to receive the help outlined by the objective of the screening programme. (Cf. section 5.3.)

3) Similarly, a statement ought to be available quantifying the benefit of initiating a screening programme as compared to not doing so. One question that should be answered, for example, is how great a drop in mortality (both in absolute figures and as a percentage) is achieved as a consequence of the screening programme, compared with the same scenario without a screening programme.

4) The reliability of the examination methods for detecting only the sick should also be stated precisely.

This recommendation is in accordance with the Council of Europe’s recommendation, “Screening followed by diagnosis and intervention in an early stage of the disease should provide a better prognosis than intervention after spontaneously sought treatment.” (Council of Europe’s recommendation, 3.4.)

The Council of Ethics recommends that independent elucidation and evaluation be provided by experts—not directly involved in the relevant screening programme—and laypersons. This should be done before the relevant political body takes a stance on whether to conduct the screening programme.
The appointment of an interdisciplinary body can also be claimed to be in line with WHO’s recommendation to ensure that the examination is acceptable to the population.

6.4. Information and unsolicited approaches—better information and greater voluntariness

The Danish Council of Ethics recommends generally enhancing the precision with which invitations to participate in a screening programme provide potential participants with information about possible advantages and disadvantages, the main aim being to give the recipients an opportunity to make their decision on an informed basis. Precisely because the approaches involved are unsolicited, the health authorities are especially obliged to provide thorough and well-gradated information on the screening programme.

The invitation should explain what the purpose of the screening programme is.

The advantages of a specific screening should be articulated with sufficient precision that it is possible to formulate the average number of people needing to be screened in order for one person to secure the advantages on balance. How many women, for instance, need to undergo mammographic screening for breast cancer in order to save one life? Similarly, the participation rate necessary to obtain the calculated gains in terms of health and economy using the screening programme should be made clear.

The drawbacks of a specific screening should emerge clearly. How great is the risk of a screening test being unable to provide a correct result with certainty, calling for additional examinations (with renewed risks) to be performed in order to clarify whether a participant in the screening programme is sick or healthy? Similarly, it should be clear that there is a risk of a false result from the examination. Information must be given on the risk of a false result associated with the individual examination, the risk of false results from participation in all screening rounds of the programme (lifetime risk), and the increased risk of a false result if taking part in several independent programmes.

If data are provided on the statistical results of the screening programme, in as far as possible these should be conveyed in such a way as to relate to the effect of screening for the individual participant. On mammographic screening for breast cancer, for instance, it is not sufficient to provide the information that there will be a 29 percent fall in mortality from breast cancer (relative risk reduction) in the screened group. Above all, it needs to be communicated that screening can reduce the individual woman’s overall risk of dying from breast cancer from 5 to 4 percent (absolute risk reduction). (Cf. section 3.2)
Precise and thorough information should be given on the risks—pain, mental strain, risk of death and so on—entailed by the actual treatment for the disease being screened for. This includes information on other medically justifiable treatment options and on the implications of not initiating treatment.

The Council of Ethics recommends stressing carefully in any invitation to take part in a screening programme that participation is voluntary.

The invitation should show clearly that the service is an offer, not an obligation, and that declining to take part will in no way have consequences with regard to any subsequent need for treatment for the disorder addressed by the screening programme.

Reminders and other information should also be conveyed in such a way that the individual is not indirectly pressured into taking part in the screening programme.

The above recommendations are in keeping with the National Board of Health, Denmark’s, recommendation that, prior to a screening programme being initiated, there must be a detailed description of the information available to the target group. However, in a number of the written invitations to potential participants in a screening programme, this has not resulted in the precision of information recommended by the Council of Ethics.

The recommendations are also in line with the Council of Europe’s recommendation on screening, which characterizes a failure to draw attention to the known positive and negative aspects of a screening programme as unethical and in violation of the individual’s autonomy.
Appendices

Appendix 1:
Examples of invitations and reminders to attend screening programmes.

Mammographic screening for breast cancer
- Funen County (pages 117-125)
- The Copenhagen Hospital Corporation (pages 127-133)

Screening for cervical cancer
- The Copenhagen Hospital Corporation (pages 135-140)
- County of South Jutland (pages 141-143)
Mass screening for early detection of breast cancer

FUNEN COUNTY is offering all women between the ages of 50 and 69 an X-ray examination of the breasts for early detection of breast cancer. An examination of this kind is called mammographic screening.

Mammography enables us to detect breast cancer so early in the course of the disease that a cancerous lump cannot yet be felt. The smaller the lump when discovered, the greater the possibility of a cure and of an operation to conserve the breast.

During the examination, the breast is compressed between two plates. Other than that, it entails no discomfort. The examination is recommended every second year, and the total time spent on the examination will not exceed 15 minutes.

Invitation

We have booked a time at:

Place:

If the time is very inconvenient, you can contact FUNEN COUNTY’s Mammographic Screening Centre on the telephone numbers below.

Results of the mammogram

You will receive a written reply within seven working days of the examination.

If you have any questions or queries about anything connected with the examination, you are welcome to contact us on tel. (+45) 6541 1602 or 6541 1603 between 9–11 am and 1-2 pm.

Your own doctor will also be able to answer any questions you may have.

Remember to bring your medical card with you.

With best wishes

[signed]

Walter Schwartz, consultant
FUNEN COUNTY
Mammographic Screening Centre
Kloeverøenget 10, 1st floor
Mass screening for early detection of breast cancer

FUNEN COUNTY is offering all women between the ages of 50 and 69 an X-ray examination for breast cancer. Some time ago, therefore, we sent you a letter with an invitation to have the examination. As we have not heard from you, we should like to offer you this service again.

Mammography enables us to detect breast cancer long before you yourself can feel any lump. That means that the chances of a cure are greater. We therefore recommend that you accept the offer of a mammogram.

Invitation

We have booked a time at:

Place:

If the time is very inconvenient, you can contact FUNEN COUNTY’s Mammographic Screening Centre on the telephone numbers below.

Results of the mammogram

You will receive a written reply within seven working days of the examination.

If you have any questions, you are welcome to contact us on tel. (+45) 6541 1602 or 6541 1603. Your own doctor will also be able to answer any questions you may have.
Remember to bring your medical card with you.

With best wishes

[signed]

Walter Schwartz, consultant
FUNEN COUNTY
Mammographic Screening Centre
Kløvervägen 10, 1st floor
Mass screening for early detection of breast cancer

You have previously received a letter from us offering an X-ray examination for breast cancer. If you have been prevented from attending for any reason, it is still not too late.

We have booked a time at:

Place:

Remember that the chances of a cure are greatest if breast cancer is discovered early on; we therefore recommend that you accept the offer of mammographic screening. The possibility of a breast-conserving operation is also greatest while a cancerous lump is small.

If you do not wish to be examined

You yourself decide whether you want to be examined, of course. If you do not wish to have an examination, please tick the boxes below and send the whole letter back in the stamped addressed envelope provided (no postage required).

With best wishes

[signed]

Walter Schwartz, consultant
FUNEN COUNTY
Mammographic Screening Centre
Kløvervænget 10, 1st floor

☐ I would like the examination postponed to another time.

When? ________________________________

☐ I do not wish to take part in the examination for the following reason(s):

____________________________________

☐ I have had the examination done through other channels:

Where? ________________________________

When? ________________________________

Other ________________________________
Mass screening for early detection of breast cancer

Unfortunately, the X-rays of your breast were not sufficient.

The changes in the first X-rays need not mean that you have breast cancer. The images may be technically poor, or the changes seen on the X-rays may prove to be benign once we have carried out a supplementary examination.

We would therefore ask you to attend for a new examination:

at Odense Hospital, Kløvervænget 10, 1st floor.

Supplementary examinations may take more than two hours, so we recommend that you park in the hospital’s long-stay car park – see map on reverse.

If the time is inconvenient for you, you can contact us on tel. (+45) 6541 1602 or 6541 1603 between 9–11 am and 1-2 pm.

With best wishes

[signed]

Walter Schwartz, consultant
FUNEN COUNTY
Mammographic Screening Centre
Kløvervænget 10, 1st floor
Mass screening for early detection of breast cancer

The X-ray of your breast showed normal conditions and no signs of cancer.

You will be called in again for an examination in two years’ time.

If you suspect anything abnormal in your breast before the next examination, you should contact your doctor.

With best wishes

[signed]

Walter Schwartz, consultant
FUNEN COUNTY
Mammographic Screening Centre
Kloværvænget 10, 1st floor
Offer to participate in mass screening for breast cancer

Offer to all women aged between 50 and 69 in the City of Copenhagen and the Municipality of Frederiksberg. The examination is offered every other year.

An X-ray examination of the breasts—a mammogram—enables breast cancer to be detected before the cancerous lump can be felt. The smaller the lump when discovered, the better the possibility of a cure and of an operation to conserve the breast.

During the examination you will be asked to complete a short questionnaire, including details of any hormone supplements and previous operations on the breast. The total stay at the clinic will last about 20 minutes.

If you have had an X-ray examination of the breasts performed at a private clinic, please bring the images with you.

The examination will take place at:
The Mammography Clinic, Bispebjerg Hospital, 23 Bispebjerg Bakke, Staircase 63, 1st floor – see map on reverse of this letter.

If you wish to change the time or cancel the appointment, please ring tel. (+45) 3531 2965, Monday, Tuesday or Thursday, 10 am to 2 pm, Wednesday 12 to 4 pm or Friday 10 am to 1 pm.

Specialists at the Mammography Clinic at Rigshospitalet/Tagensvej will assess the images, after which you will receive written notification of the results about one week after the examination.

NB!
If you have a cosmetic breast implant, which may pose a technical obstacle to the examination, please contact us on the telephone number above.

With best wishes

[signed] [signed]

Lis Bording and Hanne Thamsen
Heads of Department
People with difficulty walking can access the clinic via the lobby, entrance 60.

The Mammography Clinic, X-Ray Ward II – staircase 63
Offer to participate in mass screening for breast cancer

Offer to all women aged between 50 and 69 in the City of Copenhagen and the Municipality of Frederiksberg. The examination is offered every other year.

About two months ago, we sent you an invitation for an X-ray examination of the breasts.

There may be several reasons why you have not responded, but we would very much like to repeat the offer.

You can ring the MAMMOGRAPHY CLINIC at Bispebjerg Hospital, 23 Bispebjerg Bakke, Staircase 63, 1st floor, tel. (+45) 3531 2965 Monday, Tuesday or Thursday, 10 am to 2 pm, Wednesday 12 to 4 pm or Friday 10 am to 1 pm.

If you do not wish to take part in the mass screening, please inform us.

If you have had an X-ray examination of the breasts at a private clinic, please bring the images with you.

Specialists at the Mammography Clinic at Rigshospitalet/Tagensvej will assess the images, after which you will be sent written notification of the results about one week after the examination.

NB!
If you have a cosmetic breast implant, which may pose a technical obstacle to the examination, please contact us on the telephone number above.

With best wishes

[signed]  [signed]

Lis Bording and Hanne Thamsen
Heads of Department
The Mammography Clinic, X-Ray Ward II – staircase 63

People with difficulty walking can access the clinic via the lobby, entrance 60.
Your X-rays have now been assessed by medical specialists at Rigshospitalet's Mammography Clinic.

The X-ray examination of your breasts showed no signs of cancer.

As long as you are aged 50 to 59, you will be offered a new examination every other year.

It is a good idea to examine the breast yourself once a month in order to detect any irregularities. If you spot anything abnormal or different about your breast before the next examination, you should seek medical advice immediately.

The folder containing instructions for breast self-examination is obtainable from the chemist’s, the library or your own GP.

With best wishes

[signed]  [signed]

Lis Bording and Hanne Thamsen
Heads of Department
H/S
Rigshospitalet, the National University Hospital
Date:
The Copenhagen Hospital Corporation
Centre: Diagnostic Imaging & Clinical Engineering
Ward: MAMMOGRAPHY CLINIC
Section: 76-5-1
Direct telephone: (+45) 3545 7876
Local fax: (+45) 3545 7842

Dear Ms _____________________ ,

Unfortunately, the X-rays of your breasts are not sufficient. However, this should not give rise to undue concern, as the cause may be due to a number of factors, e.g. very dense breast tissue or a technically inadequate X-ray image.

Please contact us, therefore, on tel. (+45) 3545 7876—preferably between 11 am and 2 pm—to arrange an appointment for a new examination.

Please note that the examination will now be conducted at:

The MAMMOGRAPHY CLINIC, Rigshospitalet, 20 Tagensvej, staircase 76, 5th floor.
- Remember your medical card as well.

With best wishes

[signed] [signed]

Lis Bording and Hanne Thamsen
Heads of department

How to find the MAMMOGRAPHY CLINIC:
3-hour parking
75 Staircase 76
Entrance: 20 Tagensvej
Tagensvej 20
DK-2200 Copenhagen N
Telephone (+45) 3545 3545
Offer of preventive examination for cervical cancer

Every third year, all women between 23 and 59 years of age resident in the City of Copenhagen and the Municipality of Frederiksberg are offered an examination for cervical cancer and precursors to the disease unless a similar examination has been undertaken in the interim.

Precursors to cervical cancer are usually symptomless, but treatment can prevent the development of a cancerous disease proper. You should therefore undergo the examination, even if you feel healthy.

The actual examination includes a general examination of the pelvic region by your own doctor, who will take a cell sample from the cervix at the same time. The examination is free of charge for Group 1 patients. You can read more about the examination overleaf.

Whenever possible, the sample should be taken midway between two menstrual cycles. If you are no longer menstruating, the sample can be taken at any time.

If you have had your uterus removed, you can discuss with your own GP whether it is necessary to have the examination performed. If you are pregnant, contact your own doctor with a view to arranging an appointment for the examination.

The cell sample will be examined at the Department of Pathology at Hvidovre Hospital. The result of the examination will be sent to your own doctor.

Whatever happens, therefore, please arrange an appointment with your own GP. Bring this invitation and your medical card with you.

With best wishes

[signed]

Jette Junge
Consultant

PS! If you do not wish to take part in the examination, please tick and sign the slip on the reverse of the letter and send it to the Dept. of Pathology, 134, Hvidovre Hospital, DK-2650 Hvidovre, Denmark.

................................................................. cut out and return........................................
What are precursors to cervical cancer?
Precursors mean cell changes in the mucous membrane which, if left untreated, have the potential to develop into cancer.

Precursors are usually without symptoms and far from all precursors develop into cancer; but it is important that the precursors are discovered, evaluated and, where necessary, treated early on so that they cannot develop into cervical cancer.

If the cell sample is normal, the only reason for you to be examined in the intervening period before the next mass screening is if you discover contact bleeding or develop other symptoms.

How the examination is conducted
The cervix is the bottom of the uterus or womb. It can be seen and felt at the top of the vagina. Using a cotton bud or similar device, the doctor takes a sample from the mouth of the cervix. It does not hurt.

The cell sample is smeared onto a glass plate so that it can be examined at the Department of Pathology at Hvidovre Hospital. Under the microscope it will be possible to find any abnormal cells among the normal ones.

I do not wish to receive offers of examination for cervical cancer:
This time: (insert x) In future: (insert x)
National ID number and name:
Date: / 19
Signature
Offer of preventive examination for cervical cancer

New offer of preventive examination for cervical cancer.

You have previously received an offer of preventive examination for cervical cancer.

There may be several reasons why you have not responded. However, we should very much like to make you the offer yet again.

Precursors to cervical cancer are usually symptomless, but treatment can prevent the development of a cancerous disease proper. You should therefore undergo examination, even if you feel healthy.

Whatever happens, therefore, please arrange an appointment with your own GP. Take this invitation and your medical card with you.

With best wishes

[signed]

Jette Junge
Consultant

PS! If you have already had the test done within the past month, please ignore this request.

Cytological examination requisition

Name and address: National ID number:

Last menstruation:
Examination performed on:
Hysterectomized:
Hormones:

GP's name and provider no. PTO
**What are precursors to cervical cancer?**
Precursors mean cell changes in the mucous membrane which, if left untreated, have the potential to develop into cancer.

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---

**I do not wish to receive offers of examination for cervical cancer:**

This time: (insert x)  
In future: (insert x)

National ID number and name:

Date: / 19
Signature
Offer of preventive examination for cervical cancer

New offer of preventive examination for cervical cancer.
You can still make it.

We are taking the liberty of writing yet again, as it appears that you have still not responded to previous mailings.

If, for some reason or other, you have been prevented from attending, it is still not too late.

Surveys have shown that women taking part in preventive examinations have less risk of developing cervical cancer than those not taking part. We would therefore encourage you yet again to take up the offer.

Whatever happens, therefore, please arrange an appointment with your own GP.
Take this invitation and your medical card with you.

With best wishes

[signed]

Jette Junge
Consultant

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I do not wish to receive offers of examination for cervical cancer:

This time: In future:
(insert x) (insert x)

National ID number and name:

Date: / 19

Signature
INVITATION TO PREVENTIVE EXAMINATION FOR CERVICAL AND BREAST CANCER

The County of South Jutland invites you to a preventive examination for cancer of the cervix and breast. You can read about the background to this offer of examination at the bottom of the page.

The examination takes place with your usual GP. If you wish to take advantage of the offer, please contact your doctor. The GP should preferably be approached within one month of your receiving this letter. The offer also applies even if you have been examined recently.

With regard to possible menstruation, the examination is best done midway between two menstrual cycles. Your doctor will ask about the last menstruation date when examining you.

If you do not wish to have the examination or if you are prevented from attending within the next two months, please notify Marie Thomsen or Sonja Jeppesen on one of the telephone numbers above.

The County of South Jutland's health services will send you two reminders at approximately one-monthly intervals unless we have heard from you or you have made an appointment with your doctor.

With best wishes,
South Jutland County Council and General Practitioners in South Jutland

IMPORTANT INFORMATION:

Cancerous diseases display no symptoms initially. This applies particularly to cervical cancer, where precursors can be present for many years without being noticeable. They can be detected by an examination, however.

These precursors, as well as attacks of cancer, can be cured if discovered in time, so it is important to be examined periodically.

The country's offer of preventive examinations for cervical and breast cancer applies to women aged 23-59. All women are invited for an examination every third year.

Experience shows that, for healthy women, being examined every third year acts as such a good safeguard against cervical cancer that additional examinations are not necessary.
INVITATION TO PREVENTIVE EXAMINATION FOR CERVICAL AND BREAST CANCER

Some time ago, the County of South Jutland sent you an invitation to a preventive examination for cancer of the cervix and breast.

We are writing to give you a courteous reminder of that invitation.

- If you wish to take advantage of the offer, please contact your doctor

- If you do not wish to, or are prevented from taking up the offer, please notify Marie Thomsen or Sonja Jeppesen on one of the above telephone numbers.

With best wishes
South Jutland County Council and General Practitioners in South Jutland

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Cancerous diseases display no symptoms initially. This applies particularly to cervical cancer, where precursors can be present for many years without being noticeable. They can be detected by an examination, however.

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Appendix 2

COUNCIL OF EUROPE
COMMITTEE OF MINISTERS

RECOMMENDATION No. R (94) 11

OF THE COMMITTEE OF MINISTERS TO
MEMBER STATES
ON SCREENING AS A TOOL OF
PREVENTIVE MEDICINE

(Adopted by the Committee of Ministers on 10 October
1994 at the 518th meeting of the Ministers’ Deputies)

The Committee of Ministers,
Considering that the aim of the Council of Europe is
to achieve a greater unity between its members and
that this aim may be pursued, inter alia, by the
adoption of common action in the public health field;

Noting that chronic diseases are the major causes of
death and a high social and economic burden in
developed countries;

Considering that screening for the early detection
of some of these diseases, could in principle provide
a method for their control;

Considering that, as yet, there is no absolute proof
of the value of screening and early treatment in
most diseases;

Considering that few, if any, diseases can at the
present time be regarded as fulfilling all the
desirable criteria for screening, and that the
recommended evaluative procedures are not often
carried out in full;

Recognising that the implementation of
widespread screening programmes raises major
ethical, legal, social, medical, organisational and
economic problems which require initial and
ongoing evaluation;

Taking into account the provisions of the Convention
of Human Rights and of the European Social Charter;

Bearing in mind the Convention for the protection
of individuals with regard to automatic processing
of personal data of 28 January 1981, as well as the
provisions of Recommendation No. R (81) 1 on
regulations for automated medical banks and
Recommendation No. R (83) 10 on the protection
of personal data used for purposes of scientific
research and statistics,
Recommends to governments of member states that they take account in their national health planning regulations and legislation of the conclusions and recommendations set out in the appendix to this recommendation.

Appendix to Recommendation No. R (94) 11

1. Introduction

1.1. For the purposes of this recommendation, screening means applying a test to a defined group of persons in order to identify an early stage, a preliminary stage, a risk factor or a combination of risk factors of a disease. In any case it is a question of detecting phenomena, which can be identified prior to the outbreak of the disease.

1.2. The object of screening as a service is to identify a certain disease or risk factor for a disease before the affected person spontaneously seeks treatment, in order to cure the disease or prevent or delay its progression or onset by (early) intervention.

1.3. The value of existing forms of screening for infectious diseases is fully acknowledged but these established methods are not considered in detail in this recommendation. Emphasis is made on screening for chronic degenerative non-communicable disorders.

1.4. Screening is only one method of controlling disease. It should be viewed in the whole context of reducing the burden of ill health to the individual and the community by, for example, socio-economic, environmental measures, health education and improvement of existing health care and disease prevention systems.

1.5. Environmental factors are recognized as important contributors to disease, but inherited factors may also play an important role. With the advent of new genetic knowledge, an increasing number of genetic diseases and genetic risk factors for disease will be identified and offer the possibility for new screening procedures. As the procedures for genetic screening are not fully established nor fully evaluated, they have not been included in this recommendation.

1.6. The present position is that the implementation of screening in European countries is fragmentary, with few national screening programmes for the total population but many screening schemes restricted to population groups.

1.7. Because there are differences in health needs and health services, as well as in ethical values and in legal norms and rules between countries, the decision to implement a particular screening programme should be taken in co-operation with the medical profession by each country. Nevertheless there are common
1.8. Screening is a tool which is potentially capable of improving the health of the population but it also has adverse effects. Constant care should be taken to ensure that in any screening programme the advantages prevail over the disadvantages.

1.9. The general benefits of screening are often described. It is, however, also important to be aware of the adverse effects which can be:
- stigmatisation and/or discrimination of (non) participants;
- social pressure to participate in the screening and undergo the intended treatment/intervention;
- psychological distress where there is no cure for the disease or where the treatment and/or intervention is morally unacceptable to the individual concerned;
- exposure to physical and psychological risks with limited health gains;
- creation of expectations which probably cannot be fulfilled;
- individuals who are positively screened might experience difficulties such as access to insurance, employment, etc.;
- severe side effects of invasive clinical diagnosis of false positives;
- delay in diagnosing false negatives;
- unfavourable cost-benefit relationship of a screening programme.

1.10. The various problems which are encountered in the introduction and provision of screening services are interrelated. Nevertheless a distinction may be made between those concerned with:
1. ethical and legal issues;
2. selection of diseases (medically) suitable for screening;
3. economic aspects and evaluation of screening;
4. quality assurance;
5. organisation of a screening programme;
6. scientific research.

2. Ethical and legal values

2.1. Effectiveness is a necessary prerequisite for the screening to be ethical. It should nonetheless be kept in mind that screening can be effective and still unethical.

2.2. Advantages and disadvantages of screening for the target population and the individual must be well balanced, taking into account social and economic costs, equity as well as individual rights and freedoms.

2.3. Failure to make known information on the positive and negative aspects of the screening is unethical and infringes the autonomy of the individual.

2.4. The decision to participate in a screening programme should be taken freely. The diagnoses and treatments which may follow...
the screening should also require a free and separate consent. No pressure should be used to lead somebody to undergo any of these procedures.

2.5. The right to privacy requires that the results of the tests as a general rule are not communicated to those who do not wish to be informed, are collected, stored, and handled confidentially, and adequately protected. It is preferable not to screen individuals who do not wish to be informed of the results of the screening.

2.6. Neonatal screening can only be justified if the intervention is of direct health benefit to the child. Otherwise screening should be postponed until the child can decide for itself.

2.7. No personal data derived from the screening should be communicated to third parties unless the data subject has given consent to it or in accordance with national law.

2.8. When a screening programme is provided as a service and conducted also for research purposes, the decision to make available personal medical data stemming from the screening programme for research purposes should be taken freely, without undue pressure.

The decision not to take part in the research should not in any way prevent the individual from participating in the screening programme.

3. Criteria for selecting diseases suitable for screening

3.1. The disease should be an obvious burden for the individual and/or the community in terms of death, suffering, economic or social costs.

3.2. The natural course of the disease should be well-known and the disease should go through an initial latent stage or be determined by risk factors, which can be detected by appropriate tests. An appropriate test is highly sensitive and specific for the disease as well as being acceptable to the person screened.

3.3. Adequate treatment or other intervention possibilities are indispensable. Adequacy is determined both by proven medical effect and ethical and legal acceptability.

3.4. Screening followed by diagnosis and intervention in an early stage of the disease should provide a better prognosis than intervention after spontaneously sought treatment.

4. Economic aspects

4.1. The increasing financial burden of health care makes it necessary to assess the economic aspects of screening. However these aspects should not be the overriding consideration. In all screening programmes
human consideration regarding the value and quality of life, life expectancy as well as respect for individual rights are of prime importance.

4.2. Economic assessments are necessary to enable rational decisions to be made on the priority to be given to alternative ways of using health resources.

4.3. Measurement of the economic aspects of screening is not fully mastered. Early detection and treatment may be less expensive than late treatment. However, available studies relate only to present screening costs and further work is necessary to determine possible cost control in the long term.

4.4. Non systematic screening or spontaneous screening results in high marginal costs. Only systematic screening is able to provide means for controlling cost. Therefore, constant care should be taken to ensure that in any screening programme the allocated resources are used in an optimal way.

5. Quality assurance
5.1. Screening should aim at the highest possible standards of quality from the medical and organisational point of view.

5.2. Because of the expectations that screening creates as well as its adverse effects, screening should meet the highest quality assurance standards in all its aspects.

5.3. An assessment of the scientific evidence of the effectiveness of screening in the control of a disease should be made by experimental studies before introducing a screening programme as a service. The practical arrangements for a mass screening, which are directly linked to the health structures and systems, should obtain the same effectiveness as that obtained in the randomised trial.

5.4. Having implemented a screening programme, it should be subjected to continuous independent evaluation. Evaluation will facilitate adaptation of the programme, correction of deficiencies noted and verification of achievement of objectives. The adverse effects of the screening programme should not be ignored in the evaluation which should be carried out by independent public health experts.

5.5. If quality assurance standards are not met in the long term it should be possible for the screening programme to be corrected, and, if this is not possible, stopped.

5.6. The programme must evaluate participation, and the percentage of people screened in the target population, the technical quality of testing and the quality
of diagnosis and treatment provided as a follow-up for persons with a positive test result.

Severe side effects of false positives should be revealed and evaluated.

5.7. There is a need for more teaching of medical students in epidemiology and its application to measuring the effects of screening. Similarly post-graduate education in this field is also needed to enable practising doctors to understand the principles and evaluation of screening.

5.8. Provision of screening programmes requires that training in techniques and interpretation of screening tests is included in undergraduate and post-graduate medical teaching programmes.

5.9. A screening programme requires resources in both staff and technical facilities for carrying out the screening tests. In many instances tests can be performed by non medical staff. Provision should be made for initial and further training of the medical and technical staff who will be involved in performing the screening tests and interpreting their results. Technical methods, including automated techniques, are useful in screening for some diseases. Quality of screening methods should be monitored.

6. Organisation

6.1. The organising body of a screening programme should be held responsible throughout the programme. The organisation of a screening programme should comply with what is described in national guidelines and protocols.

6.2. Within the organisational framework the target population should be defined (by age or otherwise) as well as the frequency of screening tests and the general and specific objectives and quality assurance guidelines.

6.3. It must be stressed that screening cannot succeed without co-operation between preventive and curative systems. Organisation must be tailored to the structures of the health system. If appropriate structures in the curative health care system are lacking, screening should not be implemented until they are developed (pilot programmes, for example). There are various degrees to which screening services may be integrated with curative services or develop as a separate speciality. The advantages and disadvantages of these should be assessed separately in different health care systems.

6.4. Provisions should be made for the financing of the programme, the cost of organising and evaluating the structure, the cost of testing, the cost of quality assessment and
monitoring, and the cost of the follow-up care of those people who screen positively.

6.5. Process and outcome indicators should be constantly evaluated.

6.6. Systematic collection of data is required in screening programmes to serve the needs of the individual and of the health service. To that end, data should be collected on the target population, on persons screened (with dates and the results of the test carried out), and on the results of eventual diagnostic examinations. Access to a morbidity register considerably facilitates evaluation.

6.7. Adequate protection of all data collected by means of a screening programme should be guaranteed.

6.8. Participation of the public in screening programmes is determined by personal factors (for example attitudes, motivation and anxiety) and by situational factors (waiting time and efficient organisation, for example). These can be influenced for instance by health education and by good organisation of the screening procedure.

6.9. In order to ensure optimal participation by the target population, the best possible information should be widely provided and awareness-raising and education programmes should be organised for both the target population and the health professionals.

6.10. Invitations should be accompanied by written information on the purposes and effectiveness of the programme, on the test, on potential advantages and disadvantages, on the voluntary nature of participation and on how data will be protected. An address should be provided for those who require further information.

6.11. Participants should be informed on how, when and where their test results will be available or will be communicated to them.

6.12. The positive results found at screening should always be confirmed by subsequent diagnostic tests before commencing a treatment/intervention, unless the screening test is a diagnostic test. It is absolutely essential that adequate diagnostic facilities are available to confirm or reject the screening finding as soon as possible. Similarly, treatment facilities must be available and easily accessible to the confirmed cases. The work load placed on the health services by screening can be very large, especially since most screening programmes also lead to incidental pathological findings unrelated to the disease at which the programme is aimed.
6.13. Combining screening for several diseases into a multiple screening procedure may seem to be convenient to the individual and economic to the programme, but such a "package deal" may negatively influence the extent to which most of the criteria for screening including age limit and frequency would be met.

7. Research

7.1. Research into new, more effective, screening tests must be encouraged and the long-term effects of the various methods of treatment and provision for positive subjects studied. Research must be further developed to answer the numerous social, ethical, legal, medical, organisational and economic questions as well as psychological problems raised by screening, on which evidence is incomplete.

7.2. Quality assurance concerning research programmes should be conducted into the effectiveness of the various screening tests, the practical arrangements for screening, the measures to increase participation, the means of improving test efficiency, follow-up to and provisions for screened positive assessment process and all the economic aspects.

7.3. Information gathered during screening should be available for the purpose of scientific research, for the improvement of health services, and for the benefit of future screening, taking into account full respect of autonomy and confidentiality and the protection of personal privacy.

8. General remarks

8.1. It is particularly important that political decision-makers and target groups should be kept informed of the current state of knowledge about the value of screening for particular diseases. Improved communication should be encouraged.

8.2. Governments should promote the research and evaluation necessary for assessing the value of both new and existing programmes. This form of research necessarily means large-scale research which, in some instances, may be designed as international collaborative studies. Scientific evaluation is the only way in which the positive and negative effects of screening can be assessed in order that a rational decision can be taken on whether a screening programme should be implemented and what resources should be allocated.

Quality assurance (as defined by World Health Organisation):

"All those planned and systematic actions necessary to provide adequate confidence that a structure, system or component will perform..."
satisfactorily in service (ISO 6215-1980). Satisfactory performance in service implies the optimum quality of the entire diagnostic process i.e., the consistent production of adequate diagnostic information with minimum exposure of both patients and personnel."

Quality control (as defined by World Health Organisation):

"The set of operations (programming, co-ordinating, carrying out) intended to maintain or to improve [...] (ISO 3534-1977). As applied to a diagnostic procedure, it covers monitoring, evaluation and maintenance at optimum levels of all characteristics of performance that can be defined, measured, and controlled."
Appendix 3
Excerpt from the
Danish Act on the Legal Status of Patients

Part 1
Purpose, scope, definitions etc.

§ 1. The Act shall be instrumental in ensuring that the dignity, integrity and autonomy of patients are respected. The Act shall further be instrumental in safeguarding the relationship of trust and confidentiality between patient and health-care worker.

§ 2. The Act shall apply to patients who, within the health service or anywhere else where health-professional operations are conducted, receive or have received treatment from health-care workers, unless specifically stipulated to the contrary in the legislation.

§ 3. In this Act, treatment shall mean examination, diagnosis, treatment of disease, rehabilitation, health-professional care and health-professional preventive measures vis-à-vis the individual patient etc.

§ 4. In this Act, health-care workers shall mean persons authorized in accordance with special legislation to perform health-professional tasks and persons acting on behalf of the same.

§ 5. For a patient incapable of safeguarding his or her own interests, the person or persons authorized under the legislation to do so shall be subrogated into the patient’s rights in accordance with the Act, to whatever extent is necessary to protect the patient’s interests in the relevant situation.

Part 2
Autonomy
Informed consent

§ 6. No treatment may be initiated or continued without the informed consent of the patient unless otherwise inferred in law or provisions laid down in pursuance of the law or by Sections 8-10.

Subs. 2. The patient may revoke his or her consent at any time in accordance with subs. 1.
Subs. 3. In this Act, informed consent shall mean consent given on the basis of complete and authoritative information provided by the health-care worker, cf. Section 7.
Subs. 4. Informed consent in accordance with this Part may be written, verbal or, depending on the circumstances, tacit.
Subs. 5. The Danish Minister for Health shall stipulate further rules governing the form and content of the consent.
§ 7. The patient shall be entitled to receive information about his or her state of health and about the treatment options available, including information about risks, complications and side-effects.

Subs. 2. The patient shall be entitled to decline information in accordance with subs. 1.

Subs. 3. The information shall be given on a continual basis and give a comprehensible representation of the disease, the examination and the intended treatment. The information shall be given in a considerate manner, tailored to the individual conditions of the recipient in respect of age, maturity, experience and so on.

Subs. 4. The information shall include particulars of relevant preventive, therapeutic and care options, including information about other, medically justifiable treatment options, as well as information about the consequences of instigating no treatment. Such information shall be more extensive where treatment entails an obvious risk of serious complications and side-effects.

Subs. 5. Any patient otherwise deemed ignorant of matters of significance to the patient’s decision, cf. Section 6, shall be informed about such matters by the health-worker, unless the patient has declined to receive information, cf. subs. 2.

Subs. 6. The Danish Minister for Health shall stipulate further rules governing the form and content of the information.
Select bibliography


Bonde Jensen, Anders (1997), Hvad ved vi om de psykosociale virkninger [What Do We Know about the Psychosocial Effects?]. Conference on Mammographic Screening held by the Danish Cancer Society on Monday, 3 November 1997.


Christensen, Bo (1995): Forebyggelse af iskæmisk hjertesygdom i almen praksis [Prevention of Ischaemic Heart Disease in General Practice], University of Aarhus: Department of General Medical Practice.

Conference on Mammographic Screening. Monday, 3 November 1997, Danish Cancer Society.


Forebygelse af iskæmisk hjertesygdom i almen praksis—med særligt henblik på dyslipidæmi [Prevention of Ischaemic Heart Disease in General Practice—with Special Reference to Dyslipidaemia], Danish College of General Practitioners, 1998.


Kronborg, Ole: Screening for Colorectal Cancer with Haemoccult-II in the Average Risk Population. Paper given at a conference, kindly lent by the author.


Lunde, Inga Marie: Screening—med omtanke [Screening—with Care]. Ugeskrift for Læger 160/5, 26 January 1998: 702-704


