

Evidence Report 10

Opportunistic screenings in primary care

English version 1.1 – 2010

Translated summary based on Danish version 1.1
September 2006

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Introduction

This evidence report on opportunistic screenings in primary care has been worked out as part of The Danish Community Pharmacy Evidence Database. The aim of the database is to ensure that the pharmacy sector continuously has access to an updated knowledge about the effect of medicine use and the impact of pharmacy practice.

The Danish Community Pharmacy Evidence Database consists partly of thematic summaries of studies (evidence reports), partly a database which offers a possibility of searching across the literature contained in all the thematic evidence reports.

This evidence report contains professionally analysed descriptions of studies concerning opportunistic screenings in the primary care sector. Ten evidence reports have been worked out in the following areas:

1. Drug distribution and prescription handling
2. Patient information on prescribed drugs
3. Follow-up on outcomes of drug therapy (pharmaceutical care)
4. Self-care activities
5. Health promotion and ill-health prevention
6. Promoting rational pharmacotherapy to other health professionals
7. Incidence of drug-related problems and adverse drug events in primary care
8. Patient safety and medication errors
9. Compliance and concordance
10. Opportunistic screenings in primary care.

Evidence reports 1-6 comprise intervention studies in pharmacy practice. Evidence reports 7-10 furthermore comprise descriptive studies in primary and secondary care.

The evidence report on opportunistic screenings in primary care comprises studies published in internationally acknowledged publications and relevant Danish journals from 1995 onwards. Danish and Nordic reports on studies have furthermore been included to the extent that the editors were aware of these reports.

The primary users of the database are the Association of Danish Pharmacies, Danish pharmacies and Pharmakon. Pharmakon and the Association of Danish Pharmacies jointly developed and financed the database, which Pharmakon continues to develop and maintain. All datasheets are included in the searchable, electronic version of the database on www.pharmakon.dk/dokumentationsdatabasen. The evidence reports can be downloaded from the same website as well as from the Association of Danish Pharmacies' site at www.apotekerforeningen.dk

A summarised translation of all evidence reports will be prepared and made available on www.pharmakon.com under the heading "College". The present translation is the eighth to be made available.

Specialist editor: Bente Frøkjær

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Summary

This report focuses on opportunistic screenings in primary care and is based on systematic literature search.

The report focuses on the evidence for opportunistic screening activities in relation to diseases in primary care including pharmacy practice. Studies on screening for problems with drug use are not included in the report. This type of studies is included in Evidence Report 7 (Incidence of drug-related problems and adverse drug events in primary care), Evidence Report 8 (Patient safety and medication errors) and Evidence Report 9 (Compliance and concordance).

The literature search was carried out in Medline and International Pharmaceutical Abstracts (IPA). The search was supplemented by a search in Danish literature (Ugeskrift for læger, Månedsskrift for Praktisk Lægegering) and www.bibliotek.dk. A manual search was furthermore carried out in Danish and Nordic pharmaceutical journals (Norges Apotekerforenings tidsskrift, Norsk farmaceutisk tidsskrift, Farmaceutisk revy, Svensk farmaceutisk tidsskrift, Läkemedelsvärlden, Farmaci, and Pharma). A specific search for Danish reports was undertaken at DSI (Danish Institute for Health Services Research), Sundhedsstyrelsen (National Board of Health), Sundhedsministeriet (Ministry of Interior and Health), Danish regions, AKF (Governmental research), Health Inspectors, and in WHO (World Health Organisation). Finally, reference lists in selected articles were screened for relevant literature. The literature search was carried out for 1995-2005. Search words were screening* and opportunistic* screening*.

In the report, the evidence is listed according to diseases screened for. As a result, we got four main themes: type-2 diabetes, cardiovascular diseases, hypertension and osteoporosis. The majority of the studies belong to these themes. Besides three articles on screening for nutritional conditions or Helicobacter pylori were identified. These studies are included because of their relevance to opportunistic screenings in primary care.

The report presents different types of evidence:

1. Health technology assessment on screenings based on literature review
2. Controlled, randomised studies on the effect of opportunistic screenings
3. Descriptive studies and evaluations of opportunistic screenings.

An inclusion of Danish studies in the report was prioritised. As a result, studies with strong evidence on screening methods are included, but studies with weaker evidence are, too. The purpose was to create an overview of experiences with opportunistic screenings in Denmark. The strength of the evidence will appear from the review.

When including the studies, we have prioritised a mapping of the evidence of economic analyses of opportunistic screenings on one hand, and the analyses of validity of the different screening methods on the other hand, as the public demands this particular type of evidence. Studies included in the report are referred to from following main themes: study design, screening, findings, consequences for behaviour, consequences for treatment, clinical effect, consequences for patient safety, health economic consequences and strength of the screening.

Four studies evaluating opportunistic screenings and twenty-two studies evaluating mass screenings were identified.

Based on the identified literature on screening for diabetes, mass screenings for diabetes are not recommended. Instead, a screening of patients with risk factors is recommended, if possible combined with a screening for other lifestyle diseases. An economic modulation recommends opportunistic screenings for diabetes.

A screening for cardiovascular diseases can make a clinical difference, and the risk of getting cardiovascular diseases can be reduced by a combination of screening, treatment

and counselling on cardiovascular diseases. The number of patients with a risk profile for developing cardiovascular diseases could be reduced by 50 % over a period of five years. The included studies concerning screenings for high cholesterol level were limited in numbers, which means that the clinical effect of cholesterol screenings could not be documented.

Studies on screenings for osteoporosis were practice evaluations, and the documentation for effect was weak. Studies documenting the validity of applied screenings methods were not found.

Generally, it can be concluded that nutrition data show effect, however without economic evaluation and on relatively small populations. The included studies were based on total populations and hence not opportunistic screenings.

The screening for *Helicobacter pylori* contained both mass screening and opportunistic screening, but in the end, both methods were rejected based on economic arguments.

Very few purely opportunistic screenings were identified. The identified studies lacked health economic evaluation.

Literature search

In this literature search, 1,211 articles and reports were identified. They were all screened for relevance to the present report, based on the abstracts. Out of the 1,211 articles, seventy were ordered and assessed from the inclusion criteria. Twenty-one of these articles were included in the present evidence report.

A literature search was carried out in Medline and IPA in October 2004 and May 2005, using following search words:

| | |
|--|----------|
| Opportunistic screening* and pharmacy* | 4 hits |
| Screening* and community pharmacy* | 174 hits |
| Opportunistic* screening | 192 hits |

Furthermore, a literature search was undertaken in Danish and Scandinavian literature using the same search words:

| | |
|--------------------------|----------|
| Screening | 820 hits |
| Opportunistic* screening | 1 hit |

Types of articles and study design

The studies included in the evidence report are descriptive studies, health technology assessments and controlled studies. The inclusion prioritised identifying articles where the predictive values of the screening methods were evaluated, as well as articles where an economic evaluation on the screenings method was carried out.

Contribution from the Danish Community Pharmacy Evidence Database

A search in the existing evidence database was made. This search resulted in ten hits. Nine of the ten identified articles originate in Evidence Report 5 on Health promotion and ill-health prevention, the last one in Evidence Report 6 on Promoting rational pharmacotherapy to other health professionals. Five of these ten articles are not included in this Evidence Report because they were published before 1995.

Main results and overall conclusion

Below is a summary of the studies on each of the selected diseases. An overall conclusion across all studies follows thereafter.

Main result of diabetes screening

Study design

Eleven articles on screening for diabetes are included. Four of these articles are categorised as having evidence on level A: three articles are health technology assessments, and one article is a technical review. The remaining seven articles have evidence on level D: they are descriptive studies with a number of participants of 825-1,145 individuals. This is the field where the best-documented recommendations are identified, as we are dealing with descriptive studies with high validity and quality.

Screening

The referred screening methods used in the studies are fasting blood glucose (FBG), HBA1c and oral glucose tolerance test (OGTT) as well as various questionnaires. Participants are identified by using various methods. The reviews contain mass screenings (screenings where population segments are screened) and opportunistic screenings. Three of the included studies are on opportunistic screenings, one from a Danish pharmacy, one from forty-one Irish general practices and one from an American veteran's outpatient clinic. The remaining studies are either proper mass screenings or modulations of total populations.

Findings

In most of the studies, a screening from age 45 and up is recommended, from age if risk factors are present.

The studies showed a varying number of persons in the diabetes risk group. On average 2.0 % of the screened patients were diagnosed with diabetes (varying between 0.5 % and 4.3 %).

A health technology assessment concluded that a screening for diabetic late complications could reduce the occurrence of retinopathy by 50 % as well as foot problems. No other studies concerning the relevance of screening for other diabetic late complications were identified.

Consequences for behaviour

No studies concerning screening for diabetes and consequences for behaviour were identified.

Consequences for treatment

No studies concerning the screening for diabetes and consequences for treatment were identified.

Clinical effect

Some of the studies have documented a connection between diagnosing of diabetes through screening and risk factors. The most significant risk factors among diagnosed diabetics are hypertension and overweight; furthermore, age as well as genetic factors is mentioned. No studies listing the most significant risk factors were identified.

Consequences for patient satisfaction

No studies concerning the screening for diabetes and consequences for patient satisfaction were identified.

Health economic consequences

Based on a health economic analysis it was concluded that mass screening among younger groups is most cost-effective. A screening of age group 25-34 has an additional cost of USD 13.376/Quality adjusted life year (QALY), whereas eg a screening of age group 45-49 has an additional cost of USD 44.099/QALY.

The health technology assessments show that a general screening for diabetes is not recommended because it is not cost-effective. A mass screening of age group 40-70 would cost DKK 140 million and identify 20,000-40,000 new incidents of type-2 diabetes. An opportunistic screening of the same age group would cost DKK 31-63 million and identify 16,000-65,000 persons with type-2 diabetes.

Strength of the screening

One descriptive study focuses on the strength of screening methods and concludes that a combination of fasting capillary blood glucose (n-FBG) and oral glucose tolerance test (OGTT) can increase the sensitivity and predictive value of screening for diabetes.

In one study, the strength of FBG is calculated and has a sensitivity of 64 %, a specificity of 92 % and a predictive value of 12 %.

A literature review presents an evidence-based assessment of sensitivity, specificity and predictive value for the different screening methods.

In several studies, the conclusion is that strength increases significantly when different screening methods are combined because of the internal validation of the values.

The identified literature on screenings for diabetes indicates that mass screenings are not recommended. The screening of patients with risk factors is recommended instead, possibly together with a screening for other lifestyle diseases. An economic modulation recommends opportunistic screenings.

Main results of screening for cardiovascular diseases

Study design

Six articles are included, three of which being randomised, controlled trials (level A); the remaining studies are two level C descriptive studies with comparison group, and one is a level D descriptive study without comparison group.

The number of participants was between 449 and 4,655 persons.

Screening

The studies are carried out on cardiovascular risk profiles and detailed questionnaires. Furthermore high blood pressure (BT>90 mmHg) and total serum cholesterol were used as screening methods.

Out of the included studies, one is referred to as an opportunistic screening. This study had no outcome measure. The remaining studies were localised in general practice and community pharmacy respectively, and the patients were allocated randomly.

Findings

Screenings for cardiovascular diseases were undertaken for both sexes. The screenings showed that 11.4 % were classified as having a medium to high risk of cardiovascular diseases. In a screening performed at pharmacies, 351 persons had their blood pressure measured. 121 of these were referred to general practice because of the result. 103 did not have a diagnosis for hypertension; out of these 40 % were referred to general practice, and 6 % were diagnosed with hypertension.

Consequences for behaviour

One randomised controlled study with 1,507 patients showed that self-set aims for lifestyle changes required a long-term follow-up (more than five years) in order to achieve a documented change. After five years, it turned out that the risk group for cardiovascular diseases of 11.4 % was cut down by 50 %.

Consequences for treatment

No studies concerning screenings for cardiovascular diseases and consequences for treatment were identified.

Clinical effect

The studies used the following risk factors for cardiovascular diseases: smoking, BMI>25, cholesterol, S-triglyceride and high blood pressure. It was found that the presence of several factors implied an increased risk for cardiovascular diseases.

A study showed that an effort focused on patient health status for groups of risk patients could decrease the risk for cardiovascular diseases with 13.7-53 %. BMI and high blood pressure were significantly higher for patients with high blood pressure.

Consequences for patient satisfaction

A study showed that informing patients that they have increased risk for cardiovascular diseases had no effect on their quality of life. The same study showed that an increased patient responsibility and participation in decision-making gave an increased satisfaction with self-management.

Health economic consequences

No studies concerning screenings for cardiovascular diseases and health economic consequences were identified.

Strength of the screening

No studies concerning screening for cardiovascular diseases and strength of the screening were identified.

Opportunistic screenings in this field are rarely explored.

The identified studies showed that a screening for cardiovascular diseases makes a clinical difference and that the risk for getting cardiovascular diseases can be reduced by a combination of screening, treatment and counselling on cardiovascular diseases. The group of patients with a risk profile for developing cardiovascular diseases could be reduced by 50 % over a five-year period.

Main results of screening for high cholesterol

Study design

Two studies were identified as dealing with screening for high cholesterol level. Both studies were descriptive; one study had a control group, the other not. The number of participants was 185 and 539. One should note that no studies performed later than 1996 were identified, and the included studies are both from earlier reports. It should also be concluded that both studies have a low number of participants.

Screening

Total serum cholesterol and total blood cholesterol were used as screening methods. None of the screening methods was assessed against other methods. Both screenings were mass screenings. The screenings were performed broadly in a community pharmacy setting using randomisation.

Findings

One study used a pharmacy database to identify patients at risk for high cholesterol. This resulted in 426 risk patients, eighty-eight of whom accepted to participate in the screening. Additional ninety-seven patients were identified at the pharmacy counter and participated in the screening. The other study had 539 pharmacy customers participating (65 % female, 35 % male), and 66 % of the participants were older than 65.

In a study, 78 % were measured having a high cholesterol level. The other study had risk patients as well as volunteer patients as participants. Here 68 % of the risk patients were measured having an increased cholesterol value, and 48 % of the volunteer pharmacy customers were measured having an increased cholesterol value.

Consequences for behaviour

One survey documented that 83 % of 359 screened pharmacy customers had changed their lifestyle with respect to intake of fat, weight loss or smoking cessation after counselling in connection with the screening.

A study showed that 48 % of those who were measured having a high cholesterol level in a screening for high cholesterol were subsequently in contact with their general practitioner as a follow-up on the cholesterol measurement.

Consequences for treatment

The number of prescriptions for cholesterol-lowering medicine increased by 80 % during the study period in a study on screening for high cholesterol.

Clinical effect

No studies concerning high cholesterol and clinical effect were identified.

Consequences for patient satisfaction

No studies concerning screening for high cholesterol and patient satisfaction were identified.

Health economic consequences

No studies concerning screening for high cholesterol and health economic consequences were identified.

Strength of the screening

No studies concerning screening for high cholesterol and the strength of the screening were identified.

In studies concerning screening for high cholesterol, no evaluation of opportunistic screening was identified. Studies on mass screenings had few participants, which means that the effect of the screening could not be documented. Many patients with high cholesterol were identified, but the clinical effect of the results was not mentioned in the studies.

Main results of osteoporosis screening

Study design

Four studies concerning a screening for osteoporosis are included. All of them are descriptive studies with a number of participants of 378-1,000 persons. Two of the studies are designed with a control group. The studies are characterised by being initiated in practice as the studies are relatively small, and design and method are rarely described.

Screening

The identified studies used scannings of heels and vertebrae as well as DEXA X-ray scanning. The screenings were done in community pharmacy settings or in general practices. They were all broad screenings and should be categorised as mass screenings, despite a low number of participants.

Findings

The participants in the studies were both males and females; however, primarily females in age group 30-100.

On average, the screened persons had a 42 % [33-50 %] risk for osteoporosis, and 6.5 % [4-9 %] were classified as having osteoporosis. Several studies concluded that a screening could identify persons with osteoporosis; however, the methods used were unreliable.

Consequences for behaviour

Following a community pharmacy based osteoporosis screening, 15 % of the screened persons contacted their general practitioner, and 5 % of them were referred to a specialist.

Consequences for treatment

No studies concerning screening for osteoporosis and consequences for treatment were identified.

Clinical effect

It was descriptively shown that there is a connection between incidents of osteoporosis and various risk factors: previous fracture, past or present smoking habits, low calcium intake and low oestrogen status, often related to post-menopausal females.

Consequences for patient satisfaction

Customers at community pharmacies going through a screening for osteoporosis were predominantly positive towards the screening and the counselling on osteoporosis.

Health economic consequences

No studies with general health economic analysis were identified. It was instead analysed how much pharmacy customers were willing to pay for a screening for osteoporosis. A Danish study concluded that customers were willing to pay DKK 150 [USD 27] for a scanning of the heel plus counselling on osteoporosis. In an American study, customers were on average willing to pay USD 66.18 [USD 25-300] for a screening for osteoporosis.

Generally, the quality of the studies was low, and we have not identified studies documenting the validity of the used screenings methods.

Main results of other screenings

Finally, three studies dealing with other forms of screening are included. All of these are descriptive studies. The studies are included in order to demonstrate which other forms of screenings are found relevant to perform in primary care settings. Two of the studies are mass screenings; the third is a validation of a screening questionnaire used in a nutrition screening five years earlier. The form of this screening is unknown.

Helicobacter pylori

- An English health economic analysis of observational data had the objective of examining whether a mass screening or an opportunistic screening for *Helicobacter pylori* (HP) was cost-effective.
- 4,754 persons in age group 40-49 participated in the project. The prevalence in this sample was 27.6 %. The cost for an HP test was GBP 25 per person for a breath test, and GBP 5 per person for a serology screening. Treating the persons infected would cost GBP 26.96 per person. The annual cost of dyspepsia in patients with *Helicobacter pylori* was GBP 4.44 per person, and for the sample population, the cost was GBP 0.30.
- It was concluded that the costs of opportunistic and/or mass screening and treatment in all individuals aged 40-49 were unlikely to be attractive based on cost savings alone.

State of nutrition

- A general questionnaire screening among elderly citizens in the Danish municipality of Silkeborg had the purpose of assessing the state of nutrition of elderly citizens living in their own home or in nursing homes. 628 participated in the screening. The average age was 80; 408 lived at home, and 220 in nursing homes. 42 % of the screened persons were classified as underweight. Elderly persons living in own home had previously experienced relatively higher weight loss than those living in nursing homes. Those classified as underweight were offered a "super diet". The elderly receiving a "super diet" showed an average weight increase from 57.4 to 58.6 kg when controlled. This was considered as satisfactory.
- A follow-up on a screening study from 1988 was made in 1993. The purpose of this follow-up was to investigate the predictive value of an instrument named "Mini nutritional assessment" (MNA). 115 of the originally 171 participants could be contacted for the follow-up. Of those only 13 were classified as risk patients. There were significantly more persons in the risk group who had been ill, had received assistance and lost more than 5 % in weight. There was no significant difference in the percentage that had been hospitalised or been in contact with their general practitioner or a specialist. The results indicate that MNA can be used for achieving a successful screening for risk patients.

Generally, it can be concluded that nutrition data showed effect. However, this was with no economic evaluation, and on relatively small populations. The included screenings were on total populations and are therefore not opportunistic screenings.

The screening for *Helicobacter pylori* comprised a mass screening as well as an opportunistic screening, but in the end, both methods were rejected based on economic considerations.

Overall conclusion

- Four studies on opportunistic screenings - three for diabetes and one for cardiovascular diseases - were identified. The studies lacked health economic evaluations. The study design is often badly described and has a poor validation of the screening methods. This is due to the fact that the evaluations have been performed in practice rather than in research settings.
- However, opportunistic screenings were recommended in many mass screenings, as focus should be put on risk factors in screenings for lifestyle diseases such as type-2 diabetes, cardiovascular diseases and high cholesterol.
- A documented effect of screenings for type-2 diabetes, cardiovascular diseases, high cholesterol, osteoporosis, general state of nutrition, and Helicobacter pylori has been found. The strongest study designs are found for type-2 diabetes and cardiovascular diseases, respectively.
- In several studies concerning screening for type-2 diabetes and cardiovascular diseases, screenings targeted towards risk patients and lifestyle diseases are recommended. This originates in an economic argument and in the fact that there is a large overlapping in risk factors between the two disease groups.
- The conclusion of this evidence report with respect to screening for type-2 diabetes is that screening in primary care settings allows screening patients presenting risk factors for type-2 diabetes. General population screenings are not cost-effective. Several screening methods could be combined in order to achieve results that are more precise because the validity of the joint screening hereby increases significantly.
- The conclusion of general screenings for cardiovascular diseases is that screening in primary care settings combined with an effort for improving health status allows achieving a reduced risk for cardiovascular diseases by 13.7-53 %.
- The conclusion of mass screenings for high cholesterol is that there are few studies dealing with this subject. The identified studies are not based on randomised designs and, therefore, give no background for concluding on the relevance of mass screenings for high cholesterol in primary care settings.
- The conclusion as regards screening for osteoporosis is that evidence is missing for the advantages of these screenings and that the validity of the tests is not investigated. Therefore, the screenings are subject to large variation.
- The conclusion for screening for other disorders is that additional screenings are possible in primary care settings; however, the evidence for effect is scanty.
- Only few studies including the user's perspective on screening programmes are identified.

The role of the community pharmacy in perspective

The conclusions of this report show evidence that screenings for both type-2 diabetes and cardiovascular diseases are most efficient when targeted at patients already presenting one or more risk factors for developing these diseases. However, only four studies were identified as providing evaluations of opportunistic screenings.

With regards to documenting the effect of opportunistic screenings, the findings were limited. This is due to two factors: only few studies are identified, and they are small and of a questionable quality. This could be because this field is of little interest among researchers; it has therefore not been evaluated on a wish to document the effect of opportunistic screenings.

The majority of the identified studies were mass screenings and large reviews. In several of these, opportunistic screenings were highly recommended because they are not cost-intensive and can focus more on expected risk patients.

Community pharmacies may have a task here as pharmacies have a possibility to identify patients presenting potential risk factors through their daily contact with customers. The type of screening carried out at community pharmacies is opportunistic in character because it touches a small segment of the population who is being screened for own, non-professional reasons. Furthermore, a medication review of patients would give an overview of the total disease picture. A medication review could hereby give access to an opportunistic screening, as one would thus get an overview of potential risk factors for lifestyle diseases.

In order to streamline this form of opportunistic screening, it would be relevant first to collect evidence for the risk factors that are the strongest predictors of lifestyle diseases such as cardiovascular diseases and type-2 diabetes. Secondly, it would be relevant to follow the evidence to get more valid screening results, in case more screening methods are used for identifying possible risk patients.

Knowledge is lacking on the value of opportunistic screenings offered to persons letting themselves test for an unknown reason. This self-selection could be a relevant filter together with professionals' reactions to alarm signals. This could be in community pharmacy settings with community pharmacists. Opportunistic screenings performed at community pharmacies could result in precisely risk patients' being identified.

This report has identified studies pointing at community pharmacies as possible settings for opportunistic screenings. One study evaluates a screening for cardiovascular diseases where the community pharmacist was part of an interdisciplinary team of practitioners in which the community pharmacists could contribute with counselling and medication review. Another study concerning the measurement of blood glucose documented that the community pharmacy could contribute to an early detection of diabetes as many risk patients are already visiting the pharmacy. An American study documented the same with respect to screening for risk factors for cardiovascular diseases.

With respect to screenings for osteoporosis, high cholesterol level, malnutrition and *Helicobacter pylori*, the studies included in present report show that there is no documented effect of the tests. With respect to screening for osteoporosis the conclusion of this literature search is that the validity of the screening methods is too poorly documented.

The media have criticised screenings for increasing the focus on illness in patients. In this report, the same conclusion is made in several scientific studies. When carrying out an analysis of the cost-effectiveness of screenings, the patient perspective is rarely taken into account. In health technology assessments, patient experiences are specifically looked for, and either these are not found, or they have limited focus. This part of the screenings should therefore be studied further in the future.

Screening for type-2-diabetes is well-documented and disseminated. Several health technology assessments on the evidence in this field have been carried out. The remaining screening methods would benefit from similar general analyses. It would especially be interesting to see general analyses within screening for cardiovascular diseases, as there are several randomised, controlled studies showing the effect of screening.