National Guidelines for Diabetes Care

Support for governance and management
Preface

These guidelines contain the National Board of Health and Welfare's recommendations concerning the care of adults with diabetes. They are a revised version of the National Guidelines for Diabetes Care from 2010 and hereby replace these.

These guidelines aim both to encourage the use of scientifically evaluated and effective interventions and to be a basis on which to conduct transparent and systematic prioritisation within the health services. The objective is to contribute to patients receiving a high standard of care, regardless of their geographical location or group affiliation.

These guidelines are directed at politicians, senior civil servants and senior administrators, as well as others working in health and social care. The National Board of Health and Welfare expects that its recommendations will have an impact on the allocation of health and social care resources resulting in a relative increase in the resources allocated to high-priority conditions and interventions, compared to those that have a low priority.

The healthcare regions, trade and professional organisations, private-sector health and social care providers as well as other stakeholders have all provided valuable feedback on the version of these guidelines that was circulated for consideration and comment. The National Board of Health and Welfare has processed all of this feedback before adopting the positions stated in the current guidelines.

One important aspect of these guidelines is the National Board of Health and Welfare's indicators of good care, based on the key recommendations in these guidelines. Some of the indicators also have target levels that state how great a proportion of a patient group should receive a certain intervention or which results the care should achieve.

The National Board of Health and Welfare would like to extend a thank you to all those who gave their great commitment and expert knowledge in the preparation of these guidelines.

Lars-Erik Holm
Director-General
Summary

These guidelines provide recommendations concerning the care of adults with diabetes. They are a revised version of the National Guidelines for Diabetes Care from 2010 and thus replace these. The recommendations concern targeted screening, prevention and lifestyle, glycaemic control, cardiovascular disease, nursing, diabetic complications and diabetes in pregnancy.

These guidelines contain a total of 140 recommendations, over fifty of which are of particular significance to the finances and organisation of the health service and to ensuring that people with diabetes receive a consistently high standard of care. These key recommendation are presented in this document – Support for governance and management.

The conclusions of these guidelines have been made on the group level. These guidelines also contain assessments of the recommendations’ financial and organisational consequences, as well as monitoring indicators.

Some key recommendations

Preventing type 2 diabetes

The risk of developing type 2 diabetes can be reduced by interventions relating to diet and exercise, and interventions that lead to weight loss. The health service is therefore able to offer structured programmes that impact on lifestyle (diet and physical activity).

Women who have had gestational diabetes (reduced glucose tolerance that has appeared or been diagnosed during pregnancy) are at a greater risk of also developing diabetes later in life. The health service should therefore offer support in order to help women who have suffered from gestational diabetes change any unhealthy habits. The health service should also systematically monitor these women’s weight, blood glucose and cardiovascular disease risk factors.

Preventing diabetic complications

Diabetic complications can be delayed or prevented by tackling the risk factors that are most strongly associated with the emergence of changes in the blood vessels. Consequently, the health service should invest in effective treatment for hypertension and treatment for hyperlipidaemia using statins. In addition, the health service should help those with diabetes to stop smoking and, if necessary, become more physically active.

The health service should also provide intensive blood glucose-lowering treatment in type 1 diabetes and newly diagnosed type 2 diabetes without known cardiovascular disease in order to achieve the best possible glycaemic control.

Losing weight has an effect on elevated blood glucose, hypertension and hyperlipidaemia. Non-surgical treatment for those who are overweight or
obese reduces their weight by about five per cent over the course of one to two years, but does not usually lead to any permanent weight loss. Obesity surgery results in the loss of a large amount of weight over a long period of time, and in improved glycaemic control. Consequently, following careful clinical assessment, the health service should offer obesity surgery with structured follow-up to people with type 2 diabetes and severe obesity (BMI over 40 kg/m²). Surgery can also be considered for those with a BMI of 35–40 kg/m² in cases where there is a difficulty controlling blood sugars and risk factors.

**Patient education**

Educating patients in self-care has a key role in the care of people with diabetes. The health service should offer group-based patient education led by people who have expertise in the subject as well as the teaching skills needed to achieve the best possible results from treatment.

It is also important that self-care is adapted to the individual and takes into account any differences in their view of health and disease. Accordingly, the health service should also offer culturally adapted education in groups.

**Glycaemic control**

When improved dietary and exercise habits are not sufficiently effective in cases of type 2 diabetes, drugs are used to reduce the blood glucose level. The objective of treatment is to reduce the patient's symptoms and prevent complications such as damage to blood vessels and nerves. Metformin is the first-line drug of choice for treating type 2 diabetes. If the blood glucose level target is not achieved with metformin alone, the health service should offer other drugs in tablet form (repaglinide or sulphonylureas) and insulin – as monotherapy or as a complement to metformin.

Type 2 diabetes has a progressive course, which means that many patients end up requiring insulin therapy. Several types of treatment may then be appropriate. What is most common is a combination of tablets and intermediate-acting basal insulin (NPH insulin) at bedtime. Long-acting insulin analogues should only be offered when NPH insulin or biphasic insulin have been tried and when the patient has problems with repeated episodes of hypoglycaemia (blood glucose level too low).

Insulin pump therapy is an established form of treatment for type 1 diabetes and should be offered to people with type 1 diabetes who have recurrent episodes of hyper- or hypoglycaemia.

Inflammatory diseases of the tissues surrounding the teeth and dental implants (periodontitis) and deep root cavities are more common and often more serious among those with diabetes, which in turn can have a negative impact on their blood glucose level. Accordingly, it is important that the health service recognises that poor oral health is linked to glycaemic control, and that treatment for periodontitis and preventative interventions can have an impact on blood glucose levels comparable to that of some drugs.
Multidisciplinary foot teams
Multidisciplinary foot teams (i.e. foot teams consisting of several different professionals) have proved successful in dealing with serious foot problems and can, for example, result in fewer amputations. The objective of the care and treatment provided in cases of serious foot ulcers is to accelerate and achieve healing. This is dependent on the health service developing procedures for collaboration involving the members of the multidisciplinary foot team and primary care or home care services.

The consequences of these recommendations
The recommendations involve a general increase in the cost incurred the health service in the short term, but in some cases the interventions may also free up resources in the long term. Meanwhile the long-term costs are expected to increase as a result of the general increase in population, and because people are living increasingly long lives with disease thanks to improved control of risk factors. This assessments reflects the national level and the consequences may thus differ at the local and regional level.

Monitoring indicators
While drawing up these guidelines, the National Board of Health and Welfare has also revised and supplemented the existing indicators in the guidelines from 2010. The intention is for the indicators to reflect the most important recommendations in the guidelines and various aspects of consistent, high-quality care.

A selection of the indicators also have target levels, which state how great a proportion of a patient group should be considered for a certain investigation or achieve a target for a certain treatment. The target levels are used to support monitoring of the results at the local, regional and national level.
Introduction

These guidelines provide recommendations concerning the care of adults with diabetes. The guidelines cover the following areas:

- targeted screening, prevention and lifestyle
- glycaemic control
- cardiovascular disease
- nursing
- diabetic complications
- diabetes in pregnancy

These guidelines contain a total of 140 recommendations and are a revised and delimited version of the National Guidelines for Diabetes Care from 2010, which contained 185 recommendations.

Since the previous version, we have updated the evidence base of about half of the 140 recommendations. In the case of other recommendations, it has been assessed that the evidence base is stable and that no update has been required. In cases where condition-intervention pairs have been removed, this may be due to the matter now being covered by another guideline or it having been judged that guidance is no longer required. Some fifteen new recommendations have also been added on the basis of new information.

In some cases, the order of precedence of the recommendation in the revised guidelines has been changed from that of the guidelines from 2010, even if the evidence base remains unchanged. This is due to the research basis and the priority of alternative treatments having been adjusted or the circumstances of the health economic assessment having been changed.

Content of this document

This document – Support for governance and management – contains the following parts:

- Key recommendations from the National Guidelines for Diabetes Care. Key recommendations are those that are of the greatest significance to the finances and organisation of the health service and to ensuring that people with diabetes receive a consistently high standard of care.
- An analysis of the key recommendations' financial and organisational consequences.
- A list of conditions and interventions for all 140 recommendations.
- Indicators for monitoring results and processes within diabetes care.

Support for governance and management is only one part of the complete guidelines. The other parts include a complete list of conditions and interventions and the evidence base for each of the 140 recommendations. The com-
The National Board of Health and Welfare's guidelines mandate

The National Board of Health and Welfare has an open-ended mandate to draw up national guidelines for high-quality health and social care in those areas where the health and social care services utilise a great deal of resources. The guidelines are to contribute to ensuring that health and social service resources are used effectively, allocated on the basis of the population's needs and directed by systematic and transparent prioritisation.

The guidelines can contribute to improving the quality of the health and social services by ensuring that the right intervention is used for the right group of patients. This also increases the chances for patients and service users to receive high-quality health and social care.

The guidelines focus primarily on issues where the need for guidance is particularly high.

The guidelines take their cue from the Government Bill *Prioritisation in the Health Service* (Govt. Bill 1996/97:60). This bill states that healthcare priorities should be set on the basis of three ethical principles: human dignity, need and solidarity, and cost-effectiveness.

The mandate also involves keeping the content of the guidelines up to date through frequent updates and revisions.

Use and recipients

The recommendations in the guidelines are to provide guidance for decision-making at the group level in management and governance issues. They can be used as the basis for allocating resources or deciding when the health service has to change a working method or organisation format. They can also be used as the basis for drawing up regional and local care programmes within the health service.

The primary audience for the guidelines are decision-makers in the health service, for example politicians, senior civil servants and senior administrators.

The recommendation can also provide healthcare professionals with guidance when making decisions affecting individuals. However, healthcare professionals must also take into account laws and regulations, the patient's specific circumstances and wishes, and their own professional expertise.

Focus on certain interventions

The National Board of Health and Welfare's national guidelines primarily encompass interventions where the health service is in particular need of guidance. This may be because the interventions are controversial, because there are differences in practice within the health service regarding these
interventions or because there is a great need for quality improvements in a certain area.

The National Board of Health and Welfare expects interventions not encompassed by the guidelines to be included in national and regional care programmes in order to cover the entire healthcare system.

**Collaboration with other bodies**

While drawing up these guidelines, the National Board of Health and Welfare has worked together with SBU, the Dental and Pharmaceutical Benefits Agency (TLV) and the Medical Products Agency. SBU has provided an evidence base concerning equipment for continuous blood glucose monitoring and insulin pumps and (since the previous guidelines) concerning patient education, intensive glucose-lowering treatment and systematic self-monitoring of blood glucose. The TLV has provided health economic analyses for many of the issues relating to drug treatment. There has also been collaboration with the Medical Products Agency, which has drawn up drug recommendations concerning preventative treatment of cardiovascular disease.

Aside from these government agencies, representatives of health authorities, specialist associations and other interest groups and medical experts have also contributed. Through the National Coordination Group for Evidence-based Governance (NSK), the health authorities have nominated experts to take part in the work to select priorities. The National Board of Health and Welfare has worked together with the National Programme Council for Diabetes on the national seminar that was arranged following the publication of the draft version. The National Programme Council for Diabetes is the programme council of the county councils and regions led by the NSK’s regional group and supported by the Swedish Association of Local Authorities and Regions (SALAR).

**Diabetes care today**

Diabetes is a serious disease that causes premature death, primarily through cardiovascular disease. The most common forms of diabetes are type 1 and type 2 diabetes. Type 1 and type 2 diabetes both lead to elevated blood glucose levels and an increased risk of complications, which continues to increase the longer the person affected has had the disease and the higher their blood glucose has been over time. Examples of common complications are nerve damage, kidney damage and changes in the fundus oculi. People with type 1 diabetes, despite relatively good glycaemic control (HbA1c of around 52 mmol/mol), can have an increased risk of premature death, compared with people of the same gender and the same age who do not have diabetes. The risk increases further if glycaemic control is poorer [1].

About four to six per cent of the Swedish population aged 16–84 have diabetes [2, 3]. In addition, there are many people with diabetes who have yet to
be diagnosed. These are presumed to constitute one third of all people with diabetes.

The majority of patients with type 1 diabetes have check-ups and are cared for at medical or endocrine clinics in hospitals. This is also the case for more complicated cases of type 2 diabetes or for patients who require specialist care for some reason. However, the majority of patients with type 2 diabetes are looked after within primary care.

A long tradition of quality monitoring

An important success factor in diabetes care is for patients to have access to the care they require, and for this care to be provided by staff with the necessary expertise.

Diabetes care in Sweden has a long tradition of quality monitoring thanks to the National Diabetes Register (NDR), which contains results for adults with diabetes from 1996–2013. As of 2013, there were reports from 100 per cent of medical clinics and over 90 per cent of primary care units. It is estimated that about four per cent of the Swedish population has diabetes, which means that 92 per cent of those with diabetes were registered in the NDR in 2013.

Both the degree of participation and the incidence of diabetes vary from county council to county council. It is therefore important for the health authorities to set requirements for participation in the register and to monitor compliance, with respect to both public and private care providers.

Multidisciplinary teams are common

Diabetes care in Sweden largely has the ambition to make use of multidisciplinary teams. The diabetes nurse and the diabetes consultant have central roles in the team, which also includes other professionals such as dieticians, podiatrists, counsellors and physiotherapists.

The diabetes team work together with the patient to set targets for the treatment. The targets are based on an assessment of the patient's quality of life and risk of complications. They also take into account the patient's ability to cope with a certain treatment. If the treatment is to have the best possible results, the patient has to be well-informed about and take significant personal responsibility for their own care.

Evaluations of compliance with the guidelines

The National Board of Health and Welfare conducts evaluations in those areas of health and social care covered by the national guidelines in order to monitor how they are applied. The aim is to evaluate the extent to which the recommendations in the guidelines are complied with and also to shed light on the quality and effectiveness of health and social care.

One further aim is to take what is learned from the evaluations and integrate this into the revision of existing guidelines. This can relate to results that show care is not distributed equally or that the quality of the care provid-
ed is not the same based on varying socioeconomic aspects. By shining light on these deficiencies, the evaluations can be a driving force towards care being provide on the basis of the recommendations in the guidelines. However, the evaluations can also shed light on what needs to be addressed when the guidelines are next updates or revised.

The evaluations are based on the indicators worked out within the scope of the work to draw up the guidelines. The indicators are intended to reflect the most important recommendations in the guidelines, as well as different aspects of high-quality care.

**Evaluating the diabetes care's compliance with the guidelines**

The National Board of Health and Welfare has undertaken an evaluation [4] of compliance with the recommendations in the *National Guidelines for Diabetes Care* from 2010. The evaluation has also been based on the new indicators for diabetes care drawn up during the process of reviewing the guidelines.

The evaluations indicates that decision-makers in the county councils and regions viewed the National Guidelines for Diabetes Care as a good support. Several of the recommendations in the guidelines have also had an impact in practice.

Meanwhile, the evaluation also indicates that there are a number of areas for improvement within the county councils and regions as well as the municipalities. These are areas where the health service needs to make more of an effort to improve compliance with the guidelines and achieve the National Board of Health and Welfare's proposed targets in future [5].

In most cases, diabetes care has positive results and the trends point to steady improvement, in terms of both the processes involved in healthcare and their results. The results are worse in those areas where more specialised, frequent and enduring contact is required between the health service and the patient. Examples of this are deficient compliance with the targets for HbA1c care and blood pressure. Another is insufficient initiatives from the health service to help patients stop smoking and take more physical activity. To quit smoking is one of the most common preventative interventions to reduce the risk of diabetic complications and premature death.

Other examples identified in the evaluation are that more people with diabetes should undergo examinations of their feet and fundus oculi. In addition, more people with diabetes should be offered preventative interventions to tackle dental caries and periodontitis. The health service also needs to increase the extent to which it offers group education and culturally adapted education.

When it comes to diabetes care provided by the municipalities, this can be improved using staff training. They also need to ensure that people with diabetes have their feet examined regularly and that they receive preventative foot care as required.
The National Board of Health and Welfare has used the results of the evaluations from both 2011 and 2015 when choosing the key recommendations and reporting on the financial and organisational consequences.

Complementary evidence-based support

National Guidelines for Methods of Preventing Disease

The National Board of Health and Welfare's National Guidelines for Methods of Preventing Disease [6] contains recommendations concerning methods for helping patients to change unhealthy lifestyles (i.e. risky drinking, tobacco consumption, inadequate physical activity and unhealthy eating habits).

According to the National Guidelines for Methods of Preventing Disease people with diabetes and unhealthy eating habits should initially be offered qualified counselling in order to change their eating habits. Simpler forms of counselling such as advice with or without specific follow-up have a lower priority.

The National Guidelines for Methods of Preventing Disease are an important complement to the National Guidelines for Diabetes Care.

Dietary advice for diabetics

Along with other treatment, an adapted energy intake and improved eating habits are important interventions in cases of diabetes from a health perspective. Good dietary choices and possible weight loss can stabilise blood glucose and provide poor metabolic control. If the beneficial effects endure, they can reduce the risk of diabetic complications, including cardiovascular disease.


Limit values for gestational diabetes

Pregnant women with hyperglycaemia are currently treated differently depending on where in the country they live. One reason for this is that the limit values for a diagnosis of gestational diabetes differ in different parts of the country. There is a lack of both scientific evidence and consensus about the level of hyperglycaemia at which pregnant women should be offered some form of treatment to reduce their blood glucose [10].

The National Board of Health and Welfare is now working on national recommendations for the blood glucose values that justify treatment, the aim being to make the care of pregnant women more evidence-based and con-
sistent. A draft version of the recommendations is being published in spring 2015.

Guidance from others
The Swedish Association of Local Authorities and Regions (SALAR), through the National Programme Council for Diabetes, has published a care programme on treatment strategies for patients with high blood glucose values and the care of older people with diabetes in care homes and using home care services. The care programme complements the national guidelines. SALAR have also produced an instructors manual for nursing staff who deliver group education for people with type 2 diabetes.

The Medical Products Agency has drawn up drug recommendations for the prevention of cardiovascular disease [11]. The Medical Products Agency's recommendations also include a detailed description of how to estimate the cardiovascular risk of people with diabetes.

There is guidance concerning the treatment of children with diabetes in the national care programme for children and young people with diabetes [12]. The results are monitored in the national quality registry Swediabkids, which has almost complete coverage.
Key recommendations

This chapter contains a presentation of the key recommendations the National Board of Health and Welfare has assessed to be of particular important to the health service from a governance and management perspective. These recommendations can also be used by the health service as the basis of a more detailed care programme, drug lists or similar and can provide healthcare professionals with guidance when choosing treatments.

All of the recommendation are reported in a list of conditions and interventions in Appendix 1. A complete list of conditions and interventions and the evidence base for the guidelines is also available to download from the National Board of Health and Welfare’s website www.socialstyrelsen.se/nationellariktlinjer. It is also possible to search for individual recommendation using the website's search function, Search in the Guidelines.

About the recommendations

Three types of recommendations

In order to be able to recommend a certain intervention, the National Board of Health and Welfare arranges different conditions-intervention pairs into an order of precedence. In total, we provide three different types of recommendation: recommendation with priority 1–10, the recommendation R&D and the recommendation avoid. Tabell 1 Table 1 provides an overview of the different types of recommendation.

Table 1. The different types of the National Board of Health and Welfare recommendation

<table>
<thead>
<tr>
<th>Type of recommendation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Priority 1–10</td>
<td>Interventions the health service should or can offer. The interventions arranged in order of precedence are reported according to the prioritisation scale 1–10; interventions with a priority of 1 have the highest order of precedence and those with a priority of 10 the lowest.</td>
</tr>
<tr>
<td>R&amp;D</td>
<td>Interventions that the health service should not routinely carry out, only within the context of clinical studies. The National Board of Health and Welfare wants to use the recommendations to help the health service carefully evaluate new interventions before they are put into use.</td>
</tr>
<tr>
<td>Avoid</td>
<td>Interventions that the health service should not carry out at all. The National Board of Health and Welfare wants to use the recommendations to help the health service stop using ineffective interventions.</td>
</tr>
</tbody>
</table>
The method used for prioritisation and the scientific evidence for all the recommendations are included in the appendices Method and Scientific Evidence, respectively. The appendices are available to download from the National Board of Health and Welfare's website http://www.socialstyrelsen.se/nationalguidelines.

The priority is based on the national model

The National Board of Health and Welfare's prioritisation of different condition-intervention combinations is based on the national prioritisation model [13]. This model is in turn based on the ethical platform in the Government Bill Prioritisation in the Health Service (Govt. Bill 1996/97:60).

According to the national model, the order of precedence is to be based on an overall assessment of

- the condition's severity (determined on the basis of the risk of illness, reduced quality of life and premature death resulting from a certain condition)
- the effect of the intervention
- the cost-effectiveness.

The National Board of Health and Welfare also takes into account evidence of effectiveness, i.e. how strong the evidence base is.

Adaptation to the most ailing older people

The most ailing older people are those who have the most severe comorbidity and are most frail. These people's particular circumstances can affect the applicability of the National Board of Health and Welfare's national guidelines. Complying with individual recommendations in the guidelines can in some cases lead to the risk of giving these people the wrong treatment.

In these guidelines, this applies to several recommendations, for example the recommendations concerning intensive blood glucose-lowering treatment and drug treatment for hypertension. The recommendations affected are listed in the National Board of Health and Welfare's justification for the key recommendation in this document and in the complete list of conditions and interventions in Appendix 1.

The risk of inappropriate treatment, both overtreatment and undertreatment, is particularly high when a person is simultaneously suffering from multiple diseases, and when the health service is applying recommendations from several different guidelines in parallel. Providing the most ailing older people with high-quality care is dependent on the adaptation of the recommendations in the national guidelines to their specific circumstances. Guidance on this issue is provided in the appendix The Most Ailing Older People and National Guidelines, which can be downloaded from the National Board of Health and Welfare's website www.socialstyrelsen.se/nationellariktlinjer.
Preventing type 2 diabetes

Altered and unhealthy lifestyles and insufficient physical activity have contributed to the population becoming increasingly overweight and obese. This also increases the risk of type 2 diabetes. At the same times, this increase in prevalence has probably been relatively small in Sweden in recent years when compared with many other countries. However, the total incidence of type 2 diabetes continues to be relatively high, due mainly to people living longer.

Preventative interventions can reduce the risk of developing type 2 diabetes and with that the need for healthcare. In order to detect those who are at a high risk of developing diabetes, there may be justification for screening targeted at high-risk groups.

The National Board of Health and Welfare's National Guidelines for Methods of Preventing Disease contains recommendations concerning methods that can be used to help patients change unhealthy lifestyles (i.e. risky drinking, tobacco consumption, inadequate physical activity and unhealthy eating habits) [6]. The methods recommended in the guidelines can differ, depending on whether they are being used for healthy individuals or those with a disease. The guidelines for methods of preventing disease are an important complement to the recommendations concerning preventative interventions in the diabetes care guidelines.

Structured lifestyle programmes for those with an increased risk of type 2 diabetes

(Guidance in the list of conditions and interventions: A2)

Several studies have shown that the risk of developing type 2 diabetes from impaired glucose tolerance (a pre-diabetic state) can be reduced with the help of interventions affecting eating habits and physical activity and that lead to weight loss.

Changes to unhealthy eating habits may involve a reduced energy intake, either through limiting fat content or a Mediterranean diet with a low carbohydrate content. This refers, for example, to exercise of an average intensity for at least 30 minutes per day or at least 150 minutes per week.

Justification for the recommendation

According to the National Board of Health and Welfare's recommendation, the health service can offer structured programmes that have an intensive impact on unhealthy lifestyles to people who are at an increased risk of developing type 2 diabetes. Decisive to this recommendation is that the intervention can reduce the risk of developing type 2 diabetes among those with an increased risk and is thought to have a positive impact on cardiovascular disease and premature death. The intervention has a positive impact on health and results in cost savings or has a low cost per quality-adjusted life year (QALY) gained compared with no structured programme. Meanwhile, the condition has a low degree of severity.
Help with lifestyle changes and systematic monitoring following gestational diabetes

(Guidance in the list of conditions and interventions: F8)

Women who have suffered from gestational diabetes are at an increased risk of developing diabetes later in life and of developing risk factors for diabetes and cardiovascular disease (overweight and obesity, hypertension and blood lipid disorders).

There are no studies evaluating general advice about lifestyle following gestational diabetes. However there is strong evidence that interventions that aim to alter unhealthy lifestyles can prevent the emergence of diabetes in those with a high risk of impaired glucose tolerance. Women with gestational diabetes have also been included in such studies.


Justification for the recommendation

According to the National Board of Health and Welfare's recommendation, the health service should offer women who have suffered from gestational diabetes help to change unhealthy lifestyles and systematically monitor their weight, blood glucose and risk factors for cardiovascular disease (priority 3).

Recommendation

The health service can

- offer structured programmes that have an intensive impact on unhealthy lifestyles to people who are at an increased risk of developing type 2 diabetes (priority 5).

Prevent diabetic complications

Diabetes is very costly for society as a whole, primarily due to the complications associated with the disease such as nerve damage, kidney damage, changes in the fundus oculi and cardiovascular disease. These can lead to
suffering and absence from work due to illness, and may involve an increased requirement for health and social care.

There is now strong evidence to indicate that diabetic complications can be delayed or prevented by tackling the risk factors that have a great impact on the emergence of complications in the small and large blood vessels.

The small blood vessels (capillaries) are damaged when they are exposed over a long period to excessive blood glucose levels. This changes can affect vision, result in kidney damage that necessitates dialysis or kidney transplantation and nerve damage leading to, for example, slow-healing foot ulcers that may result in amputations. The large blood vessels are affected by arteriosclerosis, which develops at a faster pace in diabetes and leads to double the risk of stroke, myocardial infarction and impaired circulation in the legs. The increased risk of cardiovascular disease is the chief contributing factor to the mortality rate of people with diabetes being higher than that of the general population.

Hypertension, blood lipid disorders (high cholesterol) and smoking also have an impact on the risk of cardiovascular disease. The difference in the case of diabetes is that the risk is even higher due to the disease itself already involving a greater risk. Smoking and hypertension also aggravate diabetic changes in the kidneys and fundus oculi.

Maintaining a good long-term control of blood glucose, hypertension and hyperlipidaemia, and stopping smoking markedly reduces the risk of these diabetic complications. In cases of both hypertension and hyperlipidaemia it is important to change unhealthy lifestyles, for example by stopping smoking, increasing physical activity and eating healthier food. Drug treatment may be considered if this is not sufficiently effective. However, continued good lifestyle is also important in order to reduce the risk of myocardial infarction and stroke.

The surest way to prevent complications is to prevent the development of diabetes. There is currently no way to prevent type 1 diabetes. However, it is possible to influence the risk of developing type 2 diabetes in those who have a high risk by changing their unhealthy lifestyles.

Estimating the risk of cardiovascular disease in diabetes

When diabetes first appears, the risks of cardiovascular disease is not elevated due to the diabetes itself, rather this risk is dependent on the same risk factors as for people who do not have diabetes. The risk only increases markedly after some time. The most important factors contributing to increased risk are age, long disease duration, smoking, hypertension and high cholesterol, as well as being male and showing signs of kidney damage. Having hyperglycaemia for long periods also contributes, but less so in type 2 diabetes.

In order to assess the risk of falling ill or dying prematurely of cardiovascular disease in cases of diabetes, the health service can use what are known as risk estimation models. The risk estimate takes into account different risk factors and provides an understanding of the probability that a person with
diabetes will become ill or die as a result of a myocardial infarction or stroke. The estimate can also provide an understanding of how large a proportion of an increased risk is due to factors that can be influences by the patient and the health service, for example by stopping smoking or improving blood pressure or cholesterol. This creates the conditions under which it can be determined which interventions, drugs or lifestyle changes will be of the greatest benefit to the patient.

Diabetes can be divided into different levels based on the risk of becoming ill or dying from cardiovascular disease: moderate, high or very high risk. Tabell 2 Table 2 shows how great the risk is (in per cent) at each of the risk levels. The information in the table is based on data from the NDR.

Table 2. Distribution of risk levels based on the risk of cardiovascular disease

<table>
<thead>
<tr>
<th>Risk level</th>
<th>Risk of cardiovascular events over 5 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderate</td>
<td>2–8 per cent</td>
</tr>
<tr>
<td>High</td>
<td>8–20 per cent</td>
</tr>
<tr>
<td>Very high</td>
<td>Over 20 per cent</td>
</tr>
</tbody>
</table>

It is important to use models that are specific to people with diabetes and are based on current data from this country in order to make reliable risk estimates. The National Diabetes Register's (NDR) risk estimation models are based on Swedish data from 2002–2007. The models assess the risk over the subsequent 5 years and are valid for people without previous myocardial infarction or stroke between the ages of 30 and 65 who have type 1 diabetes, and for people aged 30–74 who have type 2 diabetes. For younger people with type 1 diabetes, risk estimation should also be carried out based on the assumption that they are, for example, 60 year old. Otherwise the lifetime risk can be underestimated.

For people who do not have diabetes, the Medical Products Agency is, as of 2014, recommending a risk level estimation according to the European SCORE algorithm [11]. For people with diabetes, the limits for the risk levels are set in such a way that, for example, moderate risk is the same level of risk as moderate risk for people who do not have diabetes. Thus the Medical Products Agency's recommendations can also be applied to people with diabetes.

Continued development of these methods, improved educational instruments and validation in new groups can provide diabetes care with better data to use in the assessment of risk factors for cardiovascular disease.

Treatment with lipid-lowering drugs

(B) (Guidance in the list of conditions and interventions: C10a–c and C13a–c) Blood lipid disorders are one of the most common causes of myocardial infarction, but they also contribute to increasing the risk of stroke and impaired circulation in the legs. Drug treatment with statins for those at an increased risk of cardiovascular disease markedly reduces the increased risk and also has few side-effects. However, any decision concerning drug treatment for
the prevention of cardiovascular disease and diabetic complications should always be made on the basis of an assessment of overall risk, not just the individual risk factors such as HbA1c, blood pressure or blood lipids.

Those who are at the greatest risk of becoming ill with cardiovascular disease also have the most to gain from treatment with statins. Consequently, statin treatment is very important for people with diabetes who have a high to very high risk of becoming ill from cardiovascular disease. Lifestyle changes may also be an alternative to statins for people with a moderate risk. Detailed information about dosages can be found in the Medical Products Agency's recommendations concerning drug treatment for the prevention of cardiovascular disease [11]; an overview of these is provided in Table 3.

### Table 3. Drug treatment for the prevention of atherosclerotic cardiovascular disease

<table>
<thead>
<tr>
<th>Risk level</th>
<th>Treatment model</th>
<th>Recommended preparation and dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderate</td>
<td>Lifestyle changes or standardised statin treatment</td>
<td>Simvastatin 20–40 mg Atorvastatin 10–20 mg</td>
</tr>
<tr>
<td>High</td>
<td>Standardised statin treatment</td>
<td>Simvastatin 20–40 mg Atorvastatin 10–20 mg</td>
</tr>
<tr>
<td>Very high</td>
<td>Intensive statin treatment</td>
<td>Atorvastatin 40–80 mg Rosuvastatin 20–40 mg</td>
</tr>
</tbody>
</table>

Rather than stating target values for LDL cholesterol as the treatment goal, the health service's goal should be to use statins to treat the majority of diabetic patients whose risk level is high or very high. The goal of drug treatment should be based on an individual assessment of benefit and risk, with measurement of LDL cholesterol primarily being used as a basis for discussing treatment compliance with patients. A target value for LDL cholesterol of less than 2.5 mmol/l can be used for individual patients with a very high risk.

More information about the treatment of blood lipid disorders can be found in the Medical Products Agency's recommendations [11].

### Justification for the recommendations

According to the National Board of Health and Welfare's recommendation, the health service should offer statin treatment to people with a high to very high risk of cardiovascular disease. Decisive to this recommendation is that the condition has a high degree of severity and the intervention has an impact on premature death and cardiovascular disease. The treatment carries a low cost per QALY gained, compared to lifestyle changes without drugs.

According to the National Board of Health and Welfare's recommendation, the health service can offer statin treatment to people with a moderate risk of cardiovascular disease. Decisive to this recommendation is that the condition has a moderate degree of severity and that the intervention has an impact on premature death and cardiovascular disease.
For the group ‘most ailing older people’ it can be particularly important to decide whether the recommendation needs to be adapted with respect to age and expected patient benefit. The use of many drugs at the same time also increases the risk of side-effects.

**Recommendations**

*The health service should*

- offer intensive treatment with statins to people with diabetes and a very high risk of cardiovascular disease (*priority 1*).
- offer standardised treatment with statins to people with diabetes and a high risk of cardiovascular disease (*priority 2*).

*The health service can*

- offer standardised treatment with statins to people with diabetes and a moderate of cardiovascular disease (*priority 5*).

**Treatment of hypertension**

*(Guidance in the list of conditions and interventions: C1)*

Hypertension is the most common cause of stroke and makes a significant contribution to the increased risk of myocardial infarction, impaired circulation in the legs and renal failure and thus to the increased risk of premature death among those with diabetes. The variation between different county councils in achieving blood pressure targets is relatively large [4].

A target value as the treatment goal for hypertension is blood pressure under 14/85 mm Hg. It is important that the goal is based on an individual assessment of benefit and risk. Lower blood pressure targets can be considered for young patients and those with elevated albumin secretion in the urine (macroalbuminuria) or if the treatment can be administered without side-effects. There is a greater risk of side-effects among patients who are older and more frail and they are also more likely to have complicating diseases and relative contraindications. It may be reasonable to set a higher target for these patients. It is also particularly important for this group to weigh up the benefit of a strong focus on achieving the target against the risk of the treatment being too intensive.

The treatment goal is based on consensus. There are only a few studies in which the results of morbidity and mortality outcomes have been evaluated at different target levels. This means that new scientific analyses of the evidence for blood pressure targets, as well as new treatment possibilities, may result in the target levels being re-evaluated in future.

**Justification for the recommendation**

According to the National Board of Health and Welfare’s recommendation, the health service should offer treatment with blood pressure-lowering drugs to people with diabetes and hypertension. Decisive to this recommendation is
that the intervention has a good effect on both premature death and cardiovascular disease and that the condition has a high degree of severity. Strict control of blood pressure also has a low cost per QALY gained, compared with less strict control. The scientific evidence of this effect is based primarily on data concerning patients with type 2 diabetes, but the benefit to patients can be presumed to be similar in patients with type 1 diabetes.

For the group consisting of the most ailing older people it may be particularly important to decide whether the recommendation needs to be adapted with respect to age and expected patient benefit. The use of many drugs at the same time also increases the risk of side-effects.

**Recommendation**

The health service should

- offer treatment with blood pressure-lowering drugs to people with diabetes and hypertension (priority 1).

### Smoking cessation

*(Guidance in the list of conditions and interventions: A18)*

A high proportion of younger people with type 2 diabetes are smokers [4]. Smoking is one of the most common causes of premature death, myocardial infarction, angina, stroke, impaired circulation and renal failure. Stopping smoking results in a guaranteed reduction in morbidity and mortality among people without diabetes after as little as 5–10 years. This has not been studied in diabetes specifically, but it is probable that the benefit of stopping smoking is just as great for those with type 1 and type 2 diabetes as for those without diabetes.


**Justification for the recommendation**

According to the National Board of Health and Welfare's recommendation, the health service should offer people with diabetes help to stop smoking. Decisive to this recommendation is that the condition has a high degree of severity. There is limited scientific evidence for the effect on cardiovascular events specifically for people with diabetes, but points in the same beneficial direction as the effect on the general population.

**Recommendation**

The health service should

- offer people with diabetes help to stop smoking (priority 1).
Physical activity

(Guidance in the list of conditions and interventions: A23 and A24)

Physical activity has many beneficial effects from a population perspective. Regular physical activity has a clear association with a decreased risk of cardiovascular disease, type 2 diabetes and overweight. One condition when giving advice to people with type 2 diabetes is that recommendations concerning physical activity, in addition to daily walks, be preceded by a thorough examination and adapted to their increased risk of cardiovascular disease.

Physical activity is a resource that is underused in diabetes care, despite such aids as physical activity on prescription (FaR®). There are also big differences between county councils when it comes to the proportion of people with diabetes who are physically active regularly and at least three times per week. The differences are seen both in primary care and medical clinics [4].

National Guidelines for Methods of Preventing Disease contains recommendations concerning various methods of helping people to become more physically active.

Justification for the recommendations

According to the National Board of Health and Welfare's recommendation, the health service should offer people with type 1 or type 2 diabetes help to become more physically active. Decisive to this recommendation is that the intervention has an impact on premature death and cardiovascular disease in type 2 diabetes and that physical activity in combination with dietary advice has a lower cost per QALY gained, compared with conventional care. There is a lack of scientific evidence of the interventions effect in type 1 diabetes, but it is supported by proven experience. It is probable that the benefit of regular physical activity for people with type 1 diabetes is the same as for those without diabetes.

For the group ‘most ailing older people’ it can be particularly important to decide whether the recommendation needs to be adapted with respect to the patient's individual circumstances. The exercise needs to be adapted to the older person's circumstances and any cardiovascular disease, musculoskeletal disease and other diseases common among this group.

Recommendations

The health service should

- offer people with type 2 diabetes help to become more physically active (priority 1).
- offer people with type 1 diabetes help to become more physically active (priority 3).
Intensive blood glucose-lowering treatment

(Guidance in the list of conditions and interventions: B1–B3)

The risk of diabetic complications increased with increasing blood glucose levels (HbA1c) and the number of years the patient has had the disease. Complications in the eyes, kidneys and nerves are a significant problem contributing to worsening the state of health and quality of life of people with diabetes. Excessively high blood glucose levels can lead to the need for dialysis or kidney transplantation, as well as to foot ulcers and the risk of amputation.

There are studies showing that diabetic complications and cardiovascular disease decrease in both type 1 and type 2 diabetes when intensive treatment is used to reduce blood glucose. In diabetes care it is therefore vital to achieve the best possible glycaemic control while maintaining a high quality of life, without side-effects such as serious hypoglycaemia (i.e. excessively low blood glucose).

There is a high proportion of people with diabetes who have an HbA1c over 70 mmol/mol. These people may have specific needs and require extra help in the form of more frequent visits to the diabetes nurse and doctor or other professionals on the diabetes team, when necessary. Long periods between visits can have a devastating impact on the chances of achieving improved glycaemic control [4]. However, intensive treatment to reduce the HbA1c is very demanding for the patient in terms of lifestyle changes and checking their own blood glucose several times per day. In type 1 diabetes, there is also a requirement for several insulin injections per day or a continuous supply via an insulin pump. The treatment is also very demanding for the health service in terms of additional visits, more education and support for the patient.

The National Board of Health and Welfare proposes a treatment target for HbA1c of under 52 mmol/mol. However, the relationship between risk and benefit of a course of intensive treatment is different for different people in both type 1 and type 2 diabetes. An upper target value for HbA1c can be 70 mmol/mol as values around and above this seriously increase the risk of diabetic complications.

The treatment decision is always based on the individual patient's situation and should be made on the basis of an individual assessment of the benefit and potential risks of the treatment. Newly diagnosed diabetes, first appearing at an early age and with a low risk of undetected cardiovascular disease may justify aiming to achieve an HbA1c value close to that of people without diabetes. More intensive treatment is appropriate for people who have the ability to take in the information required in order to achieve good glycaemic control. Frequent severe hypoglycaemia, serious microvascular and macrovascular complications, including cardiovascular disease, other disease and limited remaining lifespan due to disease or advanced age may justify a higher level.

The treatment targets are consensus-based as there are only a few studies in which the results of outcomes such as morbidity and mortality have been evaluated against different target levels. New scientific analyses of the evidence for HbA1c targets, as well as new treatment possibilities, may result in
the target levels being re-evaluated in future. There is more background information on the proposed target levels in the appendix *Scientific Evidence*, which can be downloaded from the National Board of Health and Welfare's website www.socialstyrelsen.se/nationellarktlinjer.

**Justification for the recommendations**

According to the National Board of Health and Welfare's recommendations, the health service should offer intensive blood glucose-lowering treatment to people with type 1 diabetes and from the initial appearance of type 2 diabetes without cardiovascular disease. Decisive to these recommendations is that the intervention has a big impact on cardiovascular disease and other complications and that the intervention is associated with a low to moderate cost per QALY gained, compared with the standard treatment.

According to the National Board of Health and Welfare's recommendations, the health service can offer intensive blood glucose-lowering treatment to people with type 2 diabetes of a longer duration or with known cardiovascular disease. Decisive to this recommendation is that the scientific evidence of the beneficial effect is weaker when the disease is of a longer duration or there is known cardiovascular disease than in newly diagnosed type 2 diabetes without known cardiovascular disease.

When treating the group ‘most ailing older people’ it may be particularly important to decide whether the recommendation needs to be adapted with respect to age and expected patient benefit. There is a risk of overtreatment when the insulin requirement decreases with increasing age. The use of many drugs at the same time also increases the risk of side-effects.
Annual urine test for albumin

(Guidance in the list of conditions and interventions: E3)

Failing renal function is a common and potentially serious complication of diabetes. Kidney damage in diabetes is most often characterised by increasingly high levels of albumin leaking into the urine. Consequently, early detection of and continuous test for albumin in the urine are important in enabling timely action to prevent the development of kidney damage.

Albumin in the urine is also an important factor for predicting which patients have a substantially increased risk of dying of cardiovascular disease.

The proportion of people with diabetes whose urine is tested annually for albumin decreased up to 2010, only to increase in recent years and is now thought to have stabilised at a higher level. [4, 14].

Justification for the recommendation

According to the National Board of Health and Welfare's recommendation, the health service should test for the presence of albumin in the urine of people with diabetes annually. Decisive to this recommendation is that albumin in the urine is a very strong indicator of the risk for severe kidney damage, myocardial infarction, stroke and premature death and that the condition has a moderate degree of severity.
Fundus oculi examination in type 2 diabetes

Regular examination and, if necessary, treatment of the fundus oculi of people with diabetes has reduced the prevalence of various types of visual impairment. This applies particularly to the number of new cases of blindness in those with type 1 diabetes.

It is an established and functional practice for patients with type 1 diabetes who do not have retinopathy to undergo fundus oculi examinations every other year.

For those with type 2 diabetes who do not have retinopathy, studies have shown that an examination every three years is sufficient. In specific cases, more frequent fundus oculi examinations may be justified by the presence of other risk factors such as hypertension and suboptimal glycaemic control. However, it is certain that fundus oculi examinations are not currently carried out to a sufficient extent in cases of type 2 diabetes.

Justification for the recommendation
According to the National Board of Health and Welfare's recommendation, the health service should offer people with type 2 diabetes who do not have fundus oculi disease fundus oculi imaging every three years. Decisive to this recommendation is that the risk of developing visual impairment is reduced by regular examination and treatment as required, and that the condition has a moderate degree of severity.

Recommendation
The health service should

• offer fundus oculi imaging every three years in type 2 diabetes without fundus oculi disease (priority 1).

Obesity surgery with structured follow-up

Overweight and obesity are common causes of type 2 diabetes. When type 2 diabetes is first diagnosed, the average BMI (body mass index) is 30.7 kg/m² [3]. However, the average BMI has not increased among those newly diagnosed with type 2 diabetes in recent years. Around 47 per cent of the women
and 40 per cent of the men included in the National Diabetes Register (NDR) are obese [3].

Weight tends to increase rather than decrease when the patient is receiving blood glucose-lowering treatment. In addition, weight loss takes place more slowly and is not as successful among people with type 2 diabetes and overweight or obesity, compared with others. Furthermore, many drugs (sulphonylureas, repaglinide, glitazones and insulin) often contribute to weight gain. Because weight loss in has, to a varying extent, an impact on hyperglycaemia, hypertension and hyperlipidaemia, this is a major challenge for diabetes care.

Non-surgical treatment of overweight and obesity involves various interventions such as group weight-loss treatment and increased physical activity or drug treatment. These interventions can lead to weight loss of about five per cent over 1–2 years, but do not usually lead to permanent weight loss.

Obesity surgery reduces weight by about 25 per cent in for up to five years after the operation. After ten years, there is a remaining weight loss of about 16–25 per cent. With experienced surgeons and large volumes of surgery, the risk of surgical complications is low (1–2 per cent).

There is however an uncertainty about the long-term effects of surgical treatment for obesity. For example, there is a lack of complete results from long-term follow-up studies of the surgical method that is currently the most common (gastric bypass).

Obesity surgery is also an extensive procedure that places demands on preparation. Those who have undergone surgery have a life-long requirement for vitamin supplements and testing. Many also need corrective surgery or other surgical procedures. Accordingly, all decisions to undertake obesity surgery need to be made on the basis of the patient's own wishes and a clinical assessment of the benefit and risk in comparison with other treatment options.

The need for structured follow-up is substantial as the majority of those who undergo obesity surgery have various complications resulting from their obesity. This means that the health service needs to offer continued check-ups following the surgery and also needs to support necessary changes to unhealthy lifestyles.

The access to long-term follow-up probably varies between county councils. According to the national quality register the Scandinavian Obesity Surgery Register (SOReg), the majority of participating units monitor their patients for 1–2 years following surgery. The follow-ups are primarily undertaken by a specialist nurse who takes blood samples and records the patient's weight. After two years, the patient is normally referred on to primary care, but there is a lack of consensus about how the life-long monitoring that is required subsequently will take place. The health service thus needs to develop a procedure for the regular monitoring of patients in the long-term, as well as for monitoring whether the treatment also has the intended effect in the long-term.
Justification for the recommendations
According to the National Board of Health and Welfare's recommendation, the health service should offer obesity surgery with structured follow-up to those with type 2 diabetes and severe obesity (BMI over 40 kg/m²). Decisive to this recommendation is that the condition has an impact on several crucial and significant endpoints (myocardial infarction, remission of diabetes illness, weight loss and HbA1c reduction) and that the intervention has a low to moderate cost per QALY gained, compared with conventional non-surgical treatment. At the same time, there is some uncertainty concerning future side-effects and the long-term effects and impact on quality of life, as well as on how the patients' need for life-long monitoring will be met.

According to the National Board of Health and Welfare's recommendation, the health service can offer obesity surgery to those with type 2 diabetes and obesity (BMI 35–40 kg/m²) and concurrent difficulty achieving glycaemic and risk factor control. Decisive to this recommendation is that the condition has a moderate degree of severity, that the intervention has an impact on several crucial and significant endpoints (remission of diabetes, weight loss and HbA1c) and finally that the intervention has a low to moderate cost per QALY gained, compared with the conventional non-surgical treatment. The scientific evidence supporting the effect on remission of diabetes (i.e. normalisation of blood glucose for a shorter or longer period) is weaker than in cases where the BMI is higher. There is also a lack of support for the effectiveness of the intervention on the risk of myocardial infarction for those with a lower BMI. There are also uncertainties about the intervention's effectiveness in the long-term for those with a lower BMI.

Recommendations
The health service should
• offer obesity surgery with structured follow-up to those with type 2 diabetes and severe obesity (BMI over 40 kg/m²) (priority 4).

The health service can
• offer obesity surgery with structured follow-up to those with type 2 diabetes and obesity (BMI 35–40 kg/m²) and difficulty achieving glycaemic and risk factor control (priority 6).

Patient education
Educating patients in self-care has a key role in the care of people with diabetes. Every day, people with diabetes make many important decisions about the management of their disease. Accordingly, the goal of patient education is to improve patients' chances of caring for themselves effectively, while maintaining good control of risk factors for ill health and a good quality of
life. One requirement is that the effectiveness of education programmes is continuously evaluated and monitored.

**Patient education in groups**  
*(Guidance in the list of conditions and interventions: D3–D4)*

Patient education can be delivered individually or in groups. It is important that the educators have both expertise in the subject and teaching skills. This probably applies to both type 1 and type 2 diabetes.

Expertise in the subject means a good knowledge of diabetes and its treatment. Teaching skills mean being very familiar with the educational methods and theories (approaches) used in the educational programme in question. Furthermore, there is a requirement for knowledge of adult learning.

Despite patient education programmes often being a requirement for effective self-care, there are several hospital diabetes clinics for adults and primary care clinics that do not offer group-based education. The picture is similar in 2015 to how it was in the evaluation from 2011 [4, 14].

**Justification for the recommendations**

According to the National Board of Health and Welfare's recommendation, the health service should offer group-based education programmes to people with diabetes. Decisive to this recommendation is the intervention's impact on HbA$_{1c}$ and that the intervention has a low cost per QALY, compared with individual education programmes. In addition, patient education is a prerequisite for good results from other treatments.

**Recommendations**

*The health service should*

- offer group-based education programmes to people with type 2 diabetes with support from people who have both expertise in the subject and teaching skills (*priority 3*).
- offer group-based education programmes to people with type 1 diabetes with support from people who have both expertise in the subject and teaching skills (*priority 4*).

**Patient education that takes into account cultural background**  
*(Guidance in the list of conditions and interventions: D8)*

When providing diabetes care to people with another cultural background, the health service needs to take into account the person's own cultural patterns. Knowledge about the characteristic features of different cultures is important if care is to be adapted to people with different cultural backgrounds. This adaptation applies to language (with or without an interpreter), but also largely to diet and other lifestyle factors. Patient information and
accompanying illustrations that are translated into the patient's own language make care and education easier. The participation of family members can be an important factor in successfully providing care to patients from cultures in which the family bond is particularly strong.

Only a few hospital diabetes clinics and primary care units currently offer culturally adapted patient education [4, 14].

Justification for the recommendation
According to the National Board of Health and Welfare's recommendation, the health service should offer people with diabetes patient education in groups that takes into account their cultural background. Decisive to this recommendation is that the condition has a moderate degree of severity and that the intervention has an impact on HbA1c. In addition, patient education is a prerequisite for good results from other treatments.

**Recommendation**
The health service should
- offer people with diabetes patient education in groups that takes into account cultural background (priority 4).

Monitoring and controlling blood glucose levels

Self-monitoring of blood glucose
*(Guidance in the list of conditions and interventions: B10–B12)*
There are many different ways to check and monitor blood glucose levels. The most commonly used and studied methods are self-monitoring of blood glucose with test strips and measurement of HbA1c. Self-monitoring involves the patient reading the test themselves with the help of a monitoring device (self-monitoring of blood glucose, SMBG) that shows the blood glucose level at the point the sample is taken. HbA1c is a reflection of the average glucose level over the course of 6–10 weeks.

Self-monitoring of blood glucose has several aims. It can be used systematically or sporadically in specific situations (known as targeted self-monitoring) such as when altering treatment, when there are sudden fluctuations in blood glucose or for educational purposes.

For type 2 diabetics, systematic monitoring consist most often of measurements prior to and two hours after meals over the course of a day (6–7 times), twice per week in order to see variations in blood glucose levels over a 24 hour period. In type 2 diabetes, measurements take place every day. However, there is no generally accepted definition of systematic self-
monitoring of blood glucose, which means that different studies often differ with respect to the intensity of glucose measurements per day or per week.

**Justification for the recommendations**

According to the National Board of Health and Welfare's recommendations, the health service should offer systematic self-monitoring of blood glucose to people with diabetes who are treated with insulin. Decisive to this recommendation is that the intervention is a necessary requirement for the treatment and constitutes a safety measure for avoiding serious hypoglycaemia.

According to the National Board of Health and Welfare's recommendations, the health service should offer targeted self-monitoring of blood glucose to people with type 2 diabetes who are not treated with insulin. Decisive to this recommendation is that the intervention is supported by proven experience and has an educational purpose. The intervention may then be regarded as one aspect of patient education, which in turn is a requirement for achieving good results from other treatments. Furthermore, the intervention makes it possible to monitor blood glucose levels over short periods of time when it may be expected to fluctuate such as in acute illness, cortisone treatment or when changing medication.

According to the National Board of Health and Welfare's recommendations, the health service can offer systematic self-monitoring of blood glucose to people with type 2 diabetes who are not treated with insulin. Decisive to this recommendation is the intervention's impact on HbA1c and that the cost-effectiveness has been improved over time due to the cost of the intervention having decreased.

**Recommendations**

*The health service should*

- offer systematic self-monitoring of blood glucose to people with type 1 diabetes or type 2 diabetes treated with insulin (*priority 1*)
- offer targeted self-monitoring of blood glucose to people with type 2 diabetes not treated with insulin in specific situations such as when altering treatment, acute fluctuations in blood glucose or for educational purposes (*priority 3*).

*The health service can*

- offer systematic self-monitoring of blood glucose to people with type 2 diabetes not treated with insulin (*priority 8*)
Continuous subcutaneous glucose monitoring in type 1 diabetes

(Guidance in the list of conditions and interventions: B63a–d)

Continuous glucose monitoring in the subcutaneous fat (known as subcutaneous glucose monitoring) is a method that is increasingly being used. This method is used for people with type 1 diabetes with recurring hypo- or hyperglycaemia or when there may be a suspicion that there are blood glucose variations that do not allow themselves to be captured by frequent self-monitoring of blood glucose.

The most common method is sensors that provide a result that can be read directly and have an alarm that sounds when there are high and low glucose values. Even sensors that do not provide a result that can be read directly are used. With these, the glucose curves are analysed retrospectively using a computer (known as retrospective continuous glucose monitoring).

Continuous glucose monitoring is used together with insulin pumps (see the subsequent section on insulin pumps in this chapter) or together with multiple injections of mealtime and basal insulin. This can take place over a long period of time and then has a better impact on glycaemic control than traditional self-monitoring in combination with injections. Continuous glucose monitoring can also be used for diagnostic purposes over the course of short periods (1–3 weeks at a time) in order to find previously undetected glucose fluctuations and adjust the dosage and timing of insulin injections accordingly.

However, the intervention carries a relatively high cost and there is variation in the extent to which the method is used. In addition, there is a lack of scientific evidence of the method’s effect on crucial and significant endpoints.

Justification for the recommendations

According to the National Board of Health and Welfare’s recommendations, the health service can offer subcutaneous glucose monitoring the results of which can be read directly – either continuously or for a shorter period for diagnostic purposes – to people with type 1 diabetes and problems with recurrent hyper- or hypoglycaemia. Decisive to these recommendations is that the condition has a high degree of severity concurrent with inadequate scientific evidence of their effectiveness for several important endpoints. However, continuous subcutaneous glucose monitoring does have an impact on HbA1c and short-term measurement for diagnostic purposes is supported by proven experience.

According to the National Board of Health and Welfare’s recommendations, the health service can, in exceptional cases, offer subcutaneous glucose monitoring with results that can be read directly – either continuously or for a shorter period for diagnostic purposes – to people with type 1 diabetes who do not have problems with recurrent hyper- or hypoglycaemia. Decisive to the weaker recommendations is that this condition has a lower degree of severity, compared with the group of patients who have problems with sharply fluctuating blood glucose.
Glucose-lowering drugs in type 2 diabetes

There is currently a variation in procedures between county councils with respect to drug treatment for type 2 diabetes. New drugs have also appeared in the past 5–10 years, which is why there is a need for guidance concerning drug treatment.

Metformin increases insulin sensitivity and has been used in diabetes care for more than 50 years. This drug has a documented effect on diabetic complications, including cardiovascular disease. Both sulphonylureas, which stimulate the release of insulin, and insulin treatment have a proven effect on diabetic complications.

Repaglinide – which acts in a similar way to sulphonylureas – is short-acting and taken at mealtimes. Acarbose (not commonly used in Sweden) obstructs the breakdown of carbohydrates in the intestines and thus limits the rise in blood glucose that follows meals.

Pioglitazone increases insulin sensitivity and thus decreases the blood glucose level, mainly by its effect on adipose tissue. The effect of treatment is of the same magnitude as that of metformin, but also has some side-effects.

GLP-1 receptor agonists and DPP-4 inhibitors have been approved from 2007 and onwards, which is why the level of experience in terms of their long-term effects and safety has increased since 2010. They primarily act by stimulating the secretion of insulin. They also have some effect on satiation.

Recommendations

The health service can

- offer continuous subcutaneous glucose monitoring with results that can be read directly to people with type 1 diabetes and problems with recurrent hyper- or hypoglycaemia (priority 5)
- offer short-term continuous subcutaneous glucose monitoring with results that can be read directly for diagnostic purposes to people with type 1 diabetes and problems with recurrent hyper- or hypoglycaemia (priority 6).

The health service can, in exceptional cases,

- offer continuous subcutaneous glucose monitoring with results that can be read directly to people with type 1 diabetes who do not have problems with recurrent hyper- or hypoglycaemia (priority 9)
- offer short-term continuous subcutaneous glucose monitoring with results that can be read directly for diagnostic purposes to people with type 1 diabetes who do not have problems with recurrent hyper- or hypoglycaemia (priority 9).
and can by slowing the emptying of the stomach reduce the increase in blood glucose following meals, but can also have side-effects such as nausea, particularly when starting treatment. The addition of GLP-1 receptor agonists leads to an average reduction in weight of around 2 kg, compared with placebos.

The SGLT2 inhibitors dapagliflozin and canagliflozin came onto the Swedish market in 2013 and 2014, respectively, and act by increasing glucose secretion in the urine and hence can decrease the blood glucose level.

Justification for the recommendations
According to the National Board of Health and Welfare's recommendation, the health service should offer metformin monotherapy as the first choice drug treatment for type 2 diabetes. Decisive to this recommendation is that the intervention has a demonstrable effect on premature death, complications and HbA1c.

The health service should also offer insulin, repaglinide and sulphonylureas as monotherapy or in combination with metformin. Decisive to this recommendation is that insulin, repaglinide and sulphonylureas monotherapy lead to a reduction in HbA1c comparable to that of metformin, and that there is a long experience using these drugs. However, insulin, repaglinide and sulphonylureas carry an increased risk of hypoglycaemia and weight gain, compared with metformin alone. Combining insulin, repaglinide and sulphonylureas with metformin has a lower treatment cost in the short-term than other potential combination treatments.

According to the National Board of Health and Welfare's recommendation, the health service can offer GLP-1 receptor agonists in combination with metformin. Decisive to this recommendation is that GLP-1 receptor agonists have a complementary effect on HbA1c and weight loss. The risk of hypoglycaemia is thought to be very small. The cost per QALY of GLP-1 receptor agonists in combination with metformin is also relatively low, compares with sulphonylureas or insulin in combination with metformin. There is now less uncertainty regarding the long-term effects of treatment using GLP-1 receptor agonists than when the previous version of the guidelines was compiled, which has had an impact on its priority.

According to the National Board of Health and Welfare's recommendation, the health service can offer DPP-4 inhibitors as blood glucose-lowering drugs in type 2 diabetes. DPP-4 inhibitors can be used as monotherapy or in combination with metformin. Decisive to this recommendation is that DPP-4 inhibitor monotherapy has less of an effect on HbA1c than monotherapy using metformin, repaglinide and sulphonylureas. DPP-4 inhibitors in combination with metformin also have less a lowering effect HbA1c than other preparations in combination. Combination therapy with DPP-4 inhibitors has a moderate cost per QALY gained, compared with combination therapy with sulphonylureas or insulin. However, DPP-4 inhibitors do not lead to any weight loss, which has affected their priority in relation to GLP-1 receptor agonists. There is now less uncertainty regarding the long-term effects of treatment
using DPP-4 inhibitors than when the previous version of the guidelines was compiled, which has had an impact on its priority.

According to the National Board of Health and Welfare's recommendation, the health service can, in exceptional cases, prescribe acarbose as monotherapy or in combination with metformin. Decisive to this recommendation is that acarbose has less of an effect on HbA1c than alternative treatments and carries a high risk of gastrointestinal side-effects.

According to the National Board of Health and Welfare's recommendation, the health service can, in exceptional cases, offer pioglitazone as monotherapy or in combination with metformin. Decisive to this recommendation is that treatment with pioglitazone entails a risk of heart failure, oedema, fractures and other side-effects such as a small increase in the risk of bladder cancer.

According to the National Board of Health and Welfare's recommendation, the health service can, in exceptional cases, offer SGLT2 inhibitors in combination with metformin. Decisive to this recommendation is that the intervention has less of a supplementary effect on HbA1c than other drugs and that there is uncertainty concerning effectiveness and side-effects in the long-term.

For the group ‘most ailing older people’ it can be particularly important to decide whether the recommendation needs to be adapted with respect to the patient's individual circumstances. Impaired renal function and other forms of organ failure can constitute grounds for caution when using metformin in this group. Difficulties perceiving the symptoms of hypoglycaemia can constitute grounds for caution when using sulphonylureas and repaglinide. For newer drugs, there is limited experience of using these in the treatment of older people.
Recommendations
The health service should

- offer metformin monotherapy to people with type 2 diabetes if they are not intolerant and there are no contraindications (priority 1)
- offer insulin in combination with metformin to people with type 2 diabetes (priority 3)
- offer insulin, repaglinide or sulphonylureas as monotherapy to people with type 2 diabetes (priority 4)
- offer repaglinide or sulphonylureas in combination with metformin to people with type 2 diabetes (priority 4).

The health service can

- offer GLP-1 receptor agonists in combination with metformin to people with type 2 diabetes (priority 6)
- offer DPP-4 inhibitors as monotherapy or in combination with metformin to people with type 2 diabetes (priority 7).

The health service can, in exceptional cases,

- offer acarbose as monotherapy or in combination with metformin to people with type 2 diabetes (priority 9)
- offer pioglitazone as monotherapy or in combination with metformin to people with type 2 diabetes (priority 10)
- offer SGLT2 inhibitors in combination with metformin to people with type 2 diabetes (priority 10).
Insulin therapy in type 2 diabetes

(Guidance in the list of conditions and interventions: B46, B47a–c, B48 a–b and B61)

Type 2 diabetes is a progressive disease, which means that the treatment used to achieve glycaemic control must be gradually intensified. Ten years after becoming ill, almost half of all patients are being treated with insulin. There is currently variation in procedures across the country in terms of the time at which treatment is started and the type of insulin therapy used. There is also a need for guidance with respect to the new drug insulin degludec.

Several types of treatment may be appropriate. What is most common is a combination of tablets and intermediate-acting basal insulin (NPH insulin) at bedtime. Long-acting insulin analogues can be used when the patient has problems with nocturnal hypoglycaemia or by the home care service in order to reduce the number of home visits required to administer insulin. Injections with biphasic insulin (a fixed combination of fast-acting mealtime insulin and intermediate-acting insulin) are also frequently used, either alone or in combination with tablets. Some patients use short-acting mealtime insulin in combination with basal insulin, as in type 1 diabetes.

**Justification for the recommendations**

According to the National Board of Health and Welfare's recommendation, the health service should offer NPH insulin, combination insulin or mealtime insulin (with or without NPH insulin) in cases of type 2 diabetes where oral therapy provides inadequate glycaemic control and there are no problems with nocturnal hypoglycaemia. Decisive to this recommendation is that the interventions have an effect on HbA1c equivalent to alternative types of insulin (long-acting insulin analogues) and that the cost per effect for this condition is high for detemir and glargine compared to NPH insulin.

According to the National Board of Health and Welfare's recommendation, the health service should offer long-acting insulin analogues (detemir or glargine) in cases of type 2 diabetes if treatment with NPH insulin repeatedly results in nocturnal hypoglycaemia. Decisive to this recommendation is that the interventions are thought to result in fewer episodes of nocturnal hypoglycaemia than NPH insulin, and that the cost per QALY gained is low to moderate compared with NPH insulin in the same condition.

According to the National Board of Health and Welfare's recommendation, the health service can offer the long-acting insulin analogue degludec in cases of type 2 diabetes where there is inadequate glycaemic control and using insulin glargine as the basal insulin has repeatedly resulted in nocturnal hypoglycaemia. Decisive to this recommendation is that the intervention is thought to reduce the risk of nocturnal hypoglycaemia, compared with insulin glargine. At the same time, the absolute reduction in risk is small and there is uncertainty concerning effectiveness and side-effects in the long-term. In addition, the intervention has a moderate cost per QALY gained, compared to insulin glargine.
According to the National Board of Health and Welfare's recommendation, the health service can offer long-acting insulin analogues (detemir or glargine) in cases of type 2 diabetes where oral therapy provides inadequate glycaemic control and there are no problems with nocturnal hypoglycaemia. Decisive to this recommendation is that the interventions have a high cost per QALY gained compared with NPH insulin for the same condition while also having an equivalent effect on HbA$_{1c}$.

According to the National Board of Health and Welfare's recommendation, the health service can, in exceptional cases, offer insulin (degludec) in cases of type 2 diabetes where oral therapy provides inadequate glycaemic control and there are no problems with nocturnal hypoglycaemia. Decisive to this recommendation is that the intervention has a moderate cost per QALY gained compared with glargine, and a high cost per QALY gained compared with NPH insulin while also having an effect on HbA$_{1c}$ deemed to be equivalent to that of the alternatives.

**Recommendations**

**The health service should**

- offer NPH insulin, combination insulin or mealtime insulin (with or without NPH insulin) to people with type 2 diabetes for whom oral treatment provides inadequate glycaemic control and who do not have problems with nocturnal hypoglycaemia (*priority 3*).
- offer insulin detemir or insulin glargine to people with type 2 diabetes if treatment with NPH insulin results in recurrent nocturnal hypoglycaemia (*priority 3*).

**The health service can**

- offer insulin degludec to people with type 2 diabetes and inadequate glycaemic control and for whom insulin glargine as a basal insulin causes recurrent episodes of nocturnal hypoglycaemia (*priority 8*).

**The health service can, in exceptional cases,**

- offer insulin detemir or insulin glargine to people with type 2 diabetes for whom oral treatment provides inadequate glycaemic control and who do not have problems with nocturnal hypoglycaemia (*priority 9*).
- offer insulin degludec to people with type 2 diabetes for whom oral treatment provides inadequate glycaemic control and who do not have problems with nocturnal hypoglycaemia (*priority 10*).
Insulin pump with or without combined continuous glucose monitoring in type 1 diabetes

(Guidance in the list of conditions and interventions: B64a–b, B65a–b)

Insulin pumps are an established form of treatment and have been in use for over 20 years. An insulin pump supplies the basal insulin requirement via a needle in the subcutaneous fat, as well as providing mealtime doses at the press of a button. More than 7,000 adults and 3,000 children with type 1 diabetes are treated using insulin pumps in Sweden. For adults, difficulty achieving stable glycaemic control is the main reason why insulin pumps are used.

An insulin pump combined with continuous subcutaneous glucose monitoring has begun to be used increasingly by patients who have problems with recurrent episodes of hypoglycaemia and hyperglycaemia. In these cases, the patients use a sensor that can sound an alarm when the blood glucose value reaches predetermined low and high values.

Justification for the recommendations

According to the National Board of Health and Welfare's recommendations, the health service should offer insulin pumps to people with type 1 diabetes who suffer recurrent episodes of hypo- or hyperglycaemia. Decisive to this recommendation is that the condition has a high degree of severity. At the same time, there is limited scientific evidence of the intervention's effectiveness. There is also uncertainty concerning the intervention's cost-effectiveness.

According to the National Board of Health and Welfare's recommendation, the health service can offer insulin pumps in combination with continuous glucose monitoring to the same patient group. Decisive to this recommendation is that the condition has a high degree of severity. At the same time, there is limited scientific evidence of the intervention's effectiveness. There is also uncertainty concerning the intervention's cost-effectiveness. However, the intervention is more costly than an insulin pump alone, which has had an impact on its priority.

According to the National Board of Health and Welfare's recommendation, the health service can, in exceptional cases, offer insulin pumps as a standalone intervention or in combination with continuous glucose monitoring to people with type 1 diabetes who do not have recurrent episodes of hypo- or hyperglycaemia. Decisive to this recommendation is that the condition has a lower degree of severity than if the patient also has problems with recurrent episodes of hypo or hyperglycaemia.
Oral health

(Guidance in the list of conditions and interventions: A25)
People with diabetes often have more tooth decay than those who do not have diabetes, this is due to factors such as reduced flow of saliva and high blood glucose leading to the saliva having a high glucose content. It is also more common for them to have inflammatory diseases of the tissues surrounding the teeth and dental implants (periodontitis) and deep root cavities. In addition, these conditions are often more serious among people with diabetes, which in turn has an impact on glycaemic control.

Treatment of periodontitis has been shown to have a beneficial impact on glycaemic control by reducing HbA1c by about 4.4–7.0 mmol/mol over the course of a monitoring period of 3–9 months. Accordingly, it is important that the health service recognises that poor oral health is linked to glycaemic control and that preventative interventions can have an impact on HbA1c comparable to that of some drugs. The National Board of Health and Welfare’s National Guidelines for Adult Dental Care contains recommendations concerning preventative interventions in cases of oral disease or increased disease risk where deficient oral hygiene is a risk factor [15].

Justification for the recommendation
According to the National Board of Health and Welfare's recommendation, the health service should refer people with diabetes and an increased risk of impaired oral health or an ongoing periodontal disease to the dental service for an opinion concerning preventative interventions or treatment of decay and periodontitis. Decisive to this recommendation is that the intervention has an impact on HbA1c and results in a lower cost to the economy as a
whole. The studies reviewed largely encompass people with type 2 diabetes, but it should be possible to apply the results to those with type 1 diabetes as well.

For the group ‘most ailing older people’, it may be particularly important to attend to impaired oral health.

**Recommendation**

_The health service should_

- refer people with diabetes who have an increased risk of impaired oral health or ongoing periodontal disease to the dental service for an opinion concerning preventative interventions or treatment for decay and periodontitis (priority 3).

---

### Serious foot problems

Long-standing diabetes can lead to serious foot problems such as slow-healing foot ulcers, infections and foot deformities. For the patient, this can involve an acute risk of serious injury, much suffering and a reduction in quality of life.

The successful treatment of serious foot problems is dependent on careful examination of the foot, inspection of the wound, microbiological test, examination of the veins, optimal glycaemic control and patient education concerning self-care.

The purpose of the interventions is to achieve improved circulation (vascular surgery and endovascular interventions), the treatment and prevention of infection, reduced leg swelling, effective pain relief, orthopaedic treatment (shoes, insoles, orthoses or splints), local wound treatment, improved nutritional condition and glycaemic control with the goal of optimising the patient's general condition.

### Multidisciplinary foot team

_(Guidance in the list of conditions and interventions: E27)_

Multidisciplinary foot teams have proved successful in cases of serious foot problems. A team in which specialists from different areas participate and collaborate (particularly with respect to ulcers and deformities) reduces the patient's suffering and leads to fewer amputations. There continues to be large differences in the incidence of amputations between county councils and regions [4, 14].

A multidisciplinary foot team can consist, for example, of the following specialists: diabetologist, diabetes nurse, vascular surgeon, orthopaedic surgeon, chiropodist, orthopaedic engineer, radiologist and clinical physiologist.
The objective of the treatment of serious foot ulcers is to accelerate and achieve healing. This is achieved using a systematic treatment strategy with individualised care and a coordinated way of working within the team.

**Justification for the recommendations**

According to the National Board of Health and Welfare's recommendation, the health service should offer treatment and diagnosis through a multidisciplinary foot team to people with diabetes and serious complications in their feet. Decisive to this recommendation is that the condition has a high degree of severity and that the intervention reduces the risk of amputation.

### Recommendation

**The health service should**

- offer treatment and diagnosis through a multidisciplinary foot team in which specialist care, primary care and home care services work together to people with serious complications in their feet such as slow-healing foot ulcers, infections and foot deformities (*priority 1*).

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**Negative pressure therapy**

*(Guidance in the list of conditions and interventions: E33)*

Slow-healing foot ulcers without signs of impaired blood circulation (known as ischaemia) among people with diabetes are a serious condition that usually requires a great effort on the part of the health service.

Negative pressure therapy for foot ulcers creates a continuous or temporary negative pressure in the ulcer, which contributes to the removal of dead tissue and pus. Negative pressure is also thought to have the ability to increase blood flow around the ulcer, reduce local tissue oedema and contribute to improved healing.

There are several different methods of negative pressure therapy, but not all of them have been studied in the context of diabetic foot ulcers and nor are they all guaranteed to have the same effect.

**Justification for the recommendation**

According to the National Board of Health and Welfare's recommendation, the health service can offer negative pressure therapy to people with diabetes and ischaemic foot ulcers. Decisive to this recommendation is that the condition has a high degree of severity and that the intervention has an impact on the need for amputation and on healing. There is also a need for several different treatment alternatives for people with slow-healing foot ulcers. However, there is limited scientific evidence to support this, at the same time as there is uncertainty regarding the cost-effectiveness of the intervention.
Recommendation

The health service can

- offer negative pressure therapy to people with diabetes and slow-healing non-ischaemic foot ulcers (priority 6).
Financial and organisational consequences

The National Board of Health and Welfare has undertaken an assessment of the impact of introducing the recommendations in the national guidelines on organisational structure, human resources, other resources and healthcare costs. The assessment is based on a picture of how care is generally delivered at the national level today. The intention is to provide support and evidence to the health authorities so that they can offer the best possible care to patients.

This chapter contains a presentation of the National Board of Health and Welfare's calculations for those recommendations that may be expected to involve the most significant consequences for the health service. This chapter also contains an account of the financial and organisational consequences the county councils and regions have highlighted in their gap and consequence analyses. These analyses were presented at the national seminar arranged in conjunction with the publication of the draft version of these guidelines.

The National Board of Health and Welfare expects that the recommendations will affect practice and the allocation of resources so that there is a relative increase in the resources allocated to interventions with a higher priority, compared to those with a lower priority. Furthermore, the National Board of Health and Welfare would like the health service to scrap interventions that have been given the recommendation avoid. In addition, interventions that have been given the recommendation R&D should not be used routinely given that the evidence base is incomplete.

Each decision concerning resource allocation based on these guidelines should be preceded by a careful analysis. An intervention that has been given priority 5 (for example due to low effectiveness or a small amount of evidence) may be the best option or even the only option for that specific condition. In such cases, reducing the resources may involve more harm than benefit.

Health economic data for the recommendations for which health economic assessments have been performed are presented in the appendix Health Economic Data, which can be downloaded from the National Board of Health and Welfare's website, www.socialstyrelsen.se/nationellriktlinjer.

Summary of the consequences

The financial consequences of the recommendations are a general increase in the cost to the health service in the short-term, but in some cases the interventions may also free up resources in the long-term.

The costs to the health service is expected to increase in the long-term due to the general population increase and because people with diabetes are living longer thanks to improved control of risk factors. This assessments re-
ffects the national level and the consequences may thus differ at the local and regional level.

Tabell 4 summarises the assessments of changes to county councils' costs in the short and long-term for some of the key recommendations. The short-term refers to the expected change in costs over the course of the first two years after the guidelines come into force. The long-term refers to the estimated subsequent change in costs from the third year onwards.

For example, the recommendations concerning obesity surgery are judged to result in increased costs of up to SEK 50 million over the course of the first year, only to then stabilise at the increased level over the course of the period in which there is still a pent-up requirement to offer obesity surgery to people who meet the criteria and want to undergo the procedure. In the longer-term, the need for these extra resources may decrease and with that the costs when there is no longer the same need or if the development leads to shorter operations and other improvements in the methods used in surgical procedures.

**Table 4. Financial consequences of key recommendations in the short and long-term**

Reference to paragraph in Appendix 1. List of conditions and interventions

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Prevent type 2 diabetes

Structured programmes that aim to have an impact on unhealthy lifestyles for those with an increased risk of type 2 diabetes

The National Board of Health and Welfare's assessment is that the recommendation concerning structured programmes that aim to have an intensive impact on unhealthy lifestyles among those with an increased risk of type 2 diabetes will affect resource allocation and organisational structure in the health service. The change is due to the recommendation involving the requirement for changes to practice in the county councils that do not currently offer this intervention. Three factors have a role to play in determining how large these costs will be: how many people who have an increased risk of type 2 diabetes, what the health service does currently and how extensive the interventions implemented are.

There are various ways to estimate the number of people who have an increased risk of type 2 diabetes. A conservative estimate is that this number would be equivalent to the number of people who are registered as having been newly diagnosed with type 2 diabetes in the National Diabetes Register (NDR). The number of people newly diagnosed with type 2 diabetes who have been registered in the NDR has varied over the past five years from 12,000 to 16,000. However, information from Stockholm County Council and Region Skåne indicates that this may be an underestimate of the actual number of those newly diagnosed [16]. Given the results of two Swedish studies that investigated the incidence of the preliminary stages of type 2 diabetes in the population, this figure may be significantly higher. Estimates for the entire country based on one of these studies indicate that there may be 370,000 people with impaired glucose tolerance [17]. The other study indicated that there are 250,000 people with risk factors and abnormal glucose tolerance [18].

There is insufficient data to estimate the extent to which primary care currently offers structured programmes that aim to have an intensive impact on unhealthy lifestyles among people with an increased risk of type 2 diabetes. The National Board of Health and Welfare uses as a basis a crude assumption that an additional 20,000 people will need to be offered the intervention each year.

Structured programmes of the scope reported in one Swedish study are judged to carry a cost saving or have a low cost per QALY gained, when looked at in the long-term [19]. The estimated total cost per participant for the three-year structured programme (known as the Björknäs programme) was SEK 3,300 [20]. The cost was divided approximately equally between the health service and the patient. At the national level, the total annual cost to the health service would rise by around SEK 33 million if an additional 20,000 people received the same intervention as the participants in the study.

Stockholm County Council, in its response to the preliminary version of these guidelines, called for all primary care clinics to take control of and
have the ability to work with unhealthy lifestyles within the scope of their standard activities. Its assessment is thus that specific lifestyle clinics do not need to be established, but, nevertheless, that there is a requirement for resources for the necessary training regarding methods of preventing disease.

Prevent diabetic complications

Physical activity

The National Board of Health and Welfare assesses that the recommendation concerning help to increase physical activity will affect resource allocation and organisational structure in the health service because it requires changes to practice in the county councils that do not currently offer the intervention regularly to people with type 1 and type 2 diabetes. According to the National Board of Health and Welfare's national evaluation of diabetes care, about 70 per cent of hospital diabetes clinics offer simple advice concerning physical activity [4].

According to the NDR, 16 per cent of people with type 2 diabetes (about 50,000) reported in 2012 that they never undertake any physical activity. The proportion varied somewhat with age: 16 per cent of those aged 60 and younger, 15 per cent of those aged 60–69, 15 per cent of those aged 70–79 and 23 per cent of those aged 80 or older. In addition to the group who never undertake any physical activity, there is a group almost as large who are physically active less than once per week.

If half of the group who never undertake any physical activity were to be offered structured help to improve their lifestyles, including physical activity equivalent to the intervention indicated within the scope of the Swedish Björknäs study, this would equate to an increased in costs for the health service of SEK 41 million [20]. Furthermore, the Björknäs study also indicates that the patient's own additional costs are about the same as the health service's per patient cost.

The NDR also reports statistics for people with type 1 diabetes. In this group there was 10 per cent who never undertake any physical activity, which is the equivalent of about 4,000 people. The proportion varied with age (8 per cent of those aged 60 and younger, 10 per cent of those aged 60–69, 14 per cent of those aged 70–79 and 30 per cent of those aged 80 and over). If the intervention to help increase physical activity among people with type 1 diabetes were to encompass the same measures are in the Björknäs study and 2,000 underwent the programme, this would equate to a cost increase for medical clinics of just under SEK 3.3 million.

In its response to the draft guidelines, Västra Götaland noted that there needs to be a review of the availability of physiotherapists and healthcare scientists are there are differences in organisational structure and whether there are developed structures for physical activity. One result of such a review may be to indicate the need for additional staff.
Intensive treatment to reduce HbA$_{1c}$ in type 1 and type 2 diabetes

The National Board of Health and Welfare assesses that the recommendations concerning intensive treatment to reduce HbA$_{1c}$ will have an impact on the resource allocation and organisational structure of the health service because up to half of those with type 1 and type 2 diabetes are not currently achieving their HbA$_{1c}$ treatment targets. There probably needs to be investments in several interventions if these improvements are to be achieved.

These guidelines encompass recommendations for a range of different specific interventions that aim to improve glycaemic control, for example patient education, self-monitoring of blood glucose, insulin pumps, alternative types of insulin and improved dental health.

An high HbA$_{1c}$ carries an increased risk of cardiovascular disease and other complications. The NDR reports that in 2013 18 per cent of adults (18 and older) with type 1 diabetes achieved the target of an HbA$_{1c}$ lower than 52 mmol/mol and that 21 per cent had an HbA$_{1c}$ higher than 73 mmol/mol. Accordingly, a specific challenge for the health service is the development and improvement of the blood glucose-lowering treatment with insulin for a significant proportion of those with type 1 diabetes, primarily the 9,600 people who had an HbA$_{1c}$ higher than 73 mmol/mol in 2013.

The National Board of Health and Welfare recommends that intensive treatment with the goal of reducing the HbA$_{1c}$ of people with type 2 diabetes is primarily targeted at those with newly diagnosed diabetes and no known cardiovascular disease. In 2013, half of the 300,000 people registered in the NDR had an HbA$_{1c}$ lower than 52 mmol/mol and thus good glycaemic control. At the same time, more than 27,000 people had an HbA$_{1c}$ higher than 73 mmol/mol. Around 17,000 of these people were under the age of 70 and 90 per cent of these were treated in primary care. Fifteen per cent of this group were treated with insulin, 40 per cent were on a combination of tablets and insulin and 35 per cent were on tablets alone. Only five per cent were treated using diet. In total, this means that at least 15,000 people need to receive better blood glucose-lowering treatment than they are currently.

In addition to the extra resources and improved drug treatment and other interventions for improving glycaemic control, the health service will need to increase the availability of diabetes nurses and district medical officers in primary care and diabetes teams in medical clinics. One extra appointment per year with a doctor and the diabetes team for people with type 1 diabetes and HbA$_{1c}$ higher than 73 mmol/mol equates to about SEK 44 million. One extra visit per year in primary care with a district medical officer and diabetes nurse equates to around SEK 30 million.

The National Programme Council for Diabetes has drawn up three national treatment strategies: two for type 1 diabetes (one for children and young people and one for others) and one for type 2 diabetes [21]. The treatment strategies highlight the need for improved glycaemic control for people with high HbA$_{1c}$ (higher than 70 mmol/mol). This example of using national coordination to draw up treatment programmes is welcomed in the responses to...
the draft version of the guidelines from the healthcare regions and is also called for as support for investments in culturally adapted diabetes education programmes.

In their responses, several healthcare regions noted that there needs to be more personnel resources if intensive treatment is to be offered systematically as one method of improving the fulfilment of target levels for indicators for blood pressure and blood glucose values. In its response, the Uppsala-Örebro region highlighted the role of dieticians in diabetes care and their collaboration with the municipalities. Stockholm County Council noted that there is no generally accepted definition of what intensive treatment involves. For type 1 diabetes, its response used the example of interventions that involve more staff time (more frequent appointments, consultations with the dietician and psychologist) and interventions that also include expenses for medical devices (continuous glucose monitoring with or without integrated insulin pumps). For type 2 diabetes, it was argued that intensive treatment should involve more than pharmacological glucose-lowering treatment, for example the opportunity to receive additional appointments and investments in group education. As one aspect of offering intensive treatment, the Västra Götaland region has implemented a specific intervention for children and adults with type 1 diabetes who have HbA1c values over 70 mmol/mol within the scope of a project at the Swedish Association of Local Authorities and Regions (SALAR) concerned with improved treatment strategies for diabetes.

Regular tests for albumin in the urine

The National Board of Health and Welfare assesses that the recommendation concerning regular tests for albumin in the urine will have an impact on the resource allocation and organisational structure of the health service. According to the NDR, in 2013 there was no information concerning the presence of albumin in the urine for 27 per cent of people with type 1 diabetes (about 7,000 people) and 15 per cent of people with type 2 diabetes (about 82,000 people). Albumin was present in the urine of 20 and 26 per cent, respectively, of those for whom the information was registered. Because this test improves the chances of adapting treatment, it is important to ensure early detection. In the National Board of Health and Welfare's evaluation of diabetes care, 80 per cent of hospital clinics and primary care units stated that they checked for the presence of microalbuminuria once per year [4].

If the under-reporting in the NDR is due to tests for albumin not being performed on half of the people who for whom there was no data, this means that a further 45,000 samples need to be taken and any subsequent follow-up of positive tests will need to be performed annually. This would involve SEK 1–2 million in extra costs for samples and analysis. The south-eastern healthcare region's response to the draft of the guidelines indicates that these tests are currently being performed in diabetes care, but that they could be elevated to the status of a priority quality target for the care units with the aim of increasing the achievement of targets.
Fundus oculi examination

The National Board of Health and Welfare assesses that the recommendation concerning fundus oculi examination every two years in type 1 diabetes and every three years in type 2 diabetes will have an impact on the resource allocation and organisational structure of the health service. This is because far too many people with diabetes do not currently receive fundus oculi examinations.

The rate of reporting in the NDR for fundus oculi examination has increased since 2010, when the previous national guidelines for diabetes care were published. Reporting increase by 5 percentage points for type 1 diabetes and 11 percentage points for type 2 diabetes. According to the National Board of Health and Welfare, the target level for fundus oculi examination should be at least 98 per cent of type 1 diabetes and at least 96 per cent for type 2 diabetes [4, 5]. According to an assessment based on around 11,000 people with type 1 diabetes and around 152,000 people with type 2 diabetes registered in the NDR, around 9,000 additional fundus oculi examinations would need to be performed per year. This would result in a requirement for additional resources for ophthalmic care of around SEK 7 million for these interventions.

Obesity surgery with structured follow-up

The National Board of Health and Welfare assesses that the recommendation concerning offering obesity surgery to people with type 2 diabetes who are severely obese (BMI over 40 kg/m²) or obesity (BMI 35–40 kg/m²) and difficulties achieving glycaemic and risk factor control will have an impact on the resource allocation and organisational structure of the health service. This impact is due the fact that to the number of procedures may increase and the routines for long-term follow-up may need to be improved in order to ensure enough is known about adequate treatment effectiveness in the long-term.

The National Board of Health and Welfare assesses that the health service can offer obesity surgery to an additional 250–500 people with type 2 diabetes per year. This assessment is based on a complete appraisal of the estimated number of people for whom obesity surgery may be appropriate, current capacity and ongoing clinical improvement efforts, as well as a lack of long-term data concerning patient-centred outcome measures such as quality of life and the need for life-long follow-up data.

In the short-term, the cost per person and procedure, as well as the subsequent healthcare requirement is estimated to equate to around SEK 100,000. In the longer-term, the costs to the health service may decrease as a result of less morbidity and less requirement for drugs and hospital care, according to the results of a Swedish register study [22]. The National Board of Health and Welfare's calculations state that additional cost for obesity surgery over that of conventional care is SEK 78,000 over the course of 20 years. If an additional 250–500 procedures are performed per year, this would involve an additional cost to the health service of SEK 25–50 million per year at the national level. However, the requirement for increased resources to enable
obesity surgery to be offered varies between county councils (tabell 10 in Appendix 2 Regional Statistics contains more information).

The requirement for increased resources is temporary as an increase in the current rate of surgery will lead to a reduction in waiting lists and any queues in the long-term. The development over the last five year period indicates that the duration of operations and the time spent in hospital following the procedure have been decreasing; these will probably decrease further [23].

The National Board of Health and Welfare has compiled statistics from the national quality registries for diabetes and obesity surgery (NDR and SOReg) for people under 70 years of age (tabell 10 in Appendix 2 – Regional Statistics contains more information). Established practice in the majority of county councils is based on indicators for obesity surgery that were drawn up in 2011 by a working group commissioned by the county council directors. The indicators are used in reference to people under 60 years of age and with a BMI of over 35 kg/m², but also cover people over 60 years of age if this is done in order to facilitate elective arthroplasty.

In 2013, around 8,600 people under 70 years of age with a BMI over 40 kg/m² were registered in the NDR. A total of 18,000 people had a BMI of 35–40 kg/m², 18 per cent of whom were estimated to have an HbA₁c of over 70 mmol/mol, which is the equivalent of about 3,400 people. Between 6,000 and 10,000 of these approximately 12,000 people (8,600 + 3,400) were judged to be appropriate for obesity surgery (based on the patients’ own wishes and the clinical assessment of the prerequisites for obesity surgery). At the current rate of surgery (1,500 people per year, according to the SOReg), everyone in this group could be offered obesity surgery within 4–7 years or somewhat longer given that this group has new members each year.

Obesity surgery is currently offered at a total of 46 clinics, well-spread throughout the whole of Sweden [23]. The intervention is offered by both public and private care providers. The requirement for increased resources to enable obesity surgery to be offered varies between county councils. County councils such as Dalarna, Norrbotten, Stockholm and Uppsala have a relatively small resource requirement, while there are a relatively large number of people covered by this recommendation in Kalmar, Gotland, Södermanland, Jönköping and Blekinge (tabell 10 in Appendix 2 – Regional Statistics contains more information).

Stockholm County Council’s response to the draft guidelines stated that there are routines for the postoperative follow-up of obesity surgery within the scope of the SOReg, but that these routines do not encompass information about diabetes. Follow-up reporting is currently deficient, which justifies the health service developing new routines that involves active outreach to people who have undergone obesity surgery. Patients who subsequently return to primary care also need to be picked up. Consequently, the health service can implement educational initiatives in order to ensure that the follow-up of treatment effectiveness and patient benefit in SOReg continues.
Patient education

The National Board of Health and Welfare assesses that the recommendation concerning patient education will have an impact on the resource allocation and organisational structure of the health service. This impact is due to all primary care centres and diabetes clinics not offering group education with the support of people who have both expertise in the subject and teaching skills.

Sixty-six per cent of hospital diabetes clinics responded to the National Board of Health and Welfare's national evaluation from 2014 that they offered a group-based education programme to people with type 1 diabetes, and 33 per cent offered this to people with type 2 diabetes. Eighteen per cent of the primary care units that responded offered this form of education with the support of people who have both expertise in the subject and teaching skills to people with type 2 diabetes. Only four per cent of diabetes clinics offered culturally adapted education in groups. The evaluation also indicated that insufficient resources, as well as inadequate patient participation and limited patient data, resulted in poor attendance in group education programmes [4].

In their responses to the draft guidelines, the healthcare regions welcomed the fact that SALAR had produced educational materials and called for similar national efforts to develop culturally adapted education programmes that are of an equivalent standard throughout the country. It was also noted that the organisation of patient education requires improvement to take into account models that suit current patient groups.

The south and south-west healthcare regions also highlighted that there is a large educational requirement in order to meet the needs of diabetes clinics and primary care units for more diabetes nurses with teaching skills. Stockholm County Council expressed concern that there were significant variations between care units within the county council and that many people have not undergone group education. In its response to the draft guidelines, it singled out the current payment system as a potential barrier to units working together to collectively arrange group education.

It is the National Board of Health and Welfare's assessment that the health service can offer patient education and patient education that takes into account cultural background to a further 20,000 people with type 1 and type 2 diabetes. This would involve an additional cost to the health service of between SEK 12 and 19 million per year, nationally.

Monitoring and controlling blood glucose levels

Glucose-lowering drugs in type 2 diabetes

The overall financial and organisational consequences of the National Board of Health and Welfare's recommendations for different types of glucose-lowering drugs are described here. Initially, the change in usage of glucose-
lowering drugs 2006–2013 is presented, along with a forecast showing how costs are expected to change. Following that is the National Board of Health and Welfare's assessment of the financial consequences of the recommendation for combination therapy in the event that metformin monotherapy does not provide sufficient glycaemic control. Finally, there is a presentation of the organisational consequences of the National Board of Health and Welfare's recommendations concerning choice of insulin type in the treatment of type 2 diabetes.

The proportion of people with type 2 diabetes on glucose-lowering drug treatment in the NDR varies between 73 per cent (Stockholm and Kronoberg) and 88 per cent (Jämtland) in the countries 21 county councils and regions (see also Diagram 1 in Appendix 2 – Regional Statistics). There are also differences in the type of drug treatment; the proportion on insulin therapy alone was 7 per cent in Uppsala, while it was 19 per cent in Kalmar and Västernorrland.

The use of glucose-lowering drugs changed significantly between 2006 and 2013 (see also Diagrams 2 and 3 in Appendix 2 – Regional Statistics). The number of people who were prescribed an old glucose-lowering drug (metformin) had increased by 95,000 people and the number who were prescribed DPP-4 inhibitors and GLP-1 receptor agonists (two newer types of glucose-lowering drug used to treat type 2 diabetes) had increased by 24,000 and 12,000. At the same time, the number who were prescribed an older drug (sulphonylureas) decreased by 27,000 and two newer drugs (repaglinide - 2,000 people and pioglitazone -8,000). The use of NPH insulin has increased significantly since 2010, while the increase in the use of long-acting insulin analogues has slowed down. The use of biphasic insulin has changed marginally (see Diagram 3 in Appendix 2 – Regional Statistics).

According to the National Board of Health and Welfare's proposal, the target level for the indicator HbA1c over 70 mmol/mol in type 1 diabetes should be fewer than 20 per cent [5]. This indicator underlines the need for the health service to focus on improved strategies for people who are far from having good glycaemic control on their current treatment. The group with type 1 diabetes is estimated to be 9 per cent (around 3,100 people) in the account of the target levels. An altered insulin regime is one of several strategies for the health service to use in this work. This focus is also expected to require additional and more frequent appointments and that the choice of intervention be largely based on the needs of the individual patient.

The cost to the health service for blood glucose-lowering drugs will continue to increase. When treating patients with type 2 diabetes, there are several factors that contribute to this: diabetes care initiates early treatment with first-line drugs (normally metformin), the general increase in population continues and more and more people have diabetes for longer. If the trend that an increasing number of people with type 2 diabetes are given drug treatment continues, the National Board of Health and Welfare's assessment is that the number of people who begin new drug treatment as a result of inadequate glycaemic control will increase by at least 12,000 per year. This would involve an increased cost to the health service of at least SEK 23 million, pro-
vided the recommended drugs with the highest priority are used as both monotherapy and combination therapy.

The National Board of Health and Welfare has proposed a target level of fewer than 10 per cent for an HbA1c level over 70 mmol/mol in type 2 diabetes. This assessment also underlines how important it is for the health service to focus specifically on people with newly diagnosed type 2 diabetes; around 5,000 people, according to estimates (based on the NDR). Several healthcare regions' responses to the draft of these guidelines highlighted the opportunities to test different combinations of drugs with the aim of achieving satisfactory glycaemic control, as well as the value of analysis and follow-up when new treatments are introduced in diabetes care.

The total nationwide cost of diabetes drugs increased by 16 per cent between 2010 and 2013, i.e. from SEK 1.1 billion to 1.3 billion. The volume of drugs used also increased by 10 per cent over the course of the same period as did the number of people being treated with drugs. Given the change in costs in previous years, it is not possible to predict future drug costs without making further assumptions about how the health service will be working to achieve further improvements to meeting targets and about the methods used to choose between different interventions.

**Alternative glucose-lowering drugs as combination therapy in type 2 diabetes**

It is the National Board of Health and Welfare's assessment that the recommendation concerning insulin in combination with metformin in cases of inadequate glycaemic control with metformin monotherapy will have an impact on the resource allocation and organisational structure of the health service to varying degrees, dependant on current patterns of prescribing.

There are several different alternative drugs that can be combined with the existing treatment for people with type 2 diabetes who do not achieve adequate glycaemic control with metformin or other oral monotherapy regimes (e.g. insulin, sulphonylureas, repaglinide, acarbose, pioglitazone, GLP-1 receptor agonists, DPP-4 inhibitors and SGLT2 inhibitors). The estimates here refer to the drug types prescribed at least once to at least 1,000 people over the course of 2013. Analysis of the National Board of Health and Welfare's drug register shows that, in several cases, there are significant variations in the use of specific drug types in relation to the prevalence of type 2 diabetes.

To a certain extent, there is a pattern in which the county councils that prescribe insulin relatively rarely in relation to the proportion of patients with type 2 diabetes instead relatively frequently prescribe more oral diabetes drugs and GLP-1 receptor agonists (see Diagrams 4 and 5 in Appendix 2 – Regional Statistics). For example, there was a relatively high usage of insulin in Östergötland and Västernorrland, compared with other county councils. Instead, these two county councils had used relatively small amounts of other glucose-lowering drugs. However, the use of insulin in Södermanland, Västmanland and Dalarna was at the national average, while the use of oral diabetes drugs and GLP-1 receptor agonists was significantly higher than average. Relatively high total use of all types of blood glucose-lowering
drugs may be due to the active and early establishment of drug treatment for people with type 2 diabetes.

It is the National Board of Health and Welfare's assessment that the recommendations concerning other glucose-lowering drugs in combination with metformin in cases of type 2 diabetes will have an impact on the resource allocation and organisational structure of the health service as there are currently regional variations in the use of different drug types. A redistribution between the different alternatives may result in a change in costs.

In general, there is a large degree of consistency between the county councils with regard to the use of metformin in relation to the proportion with type 2 diabetes. However, it is thought that there is no connection between this proportion and the use of sulphonylureas (see Diagram 6 in Appendix 2 – Regional Statistics). At the national level, the trend in the use of sulphonylureas shows a steady decline (see also Diagram 2 in Appendix 2 – Regional Statistics). However, there is insufficient data to determine the level at which the use of different glucose lowering drugs should be in order to be in line with the National Board of Health and Welfare's recommendations.

In the same way, it is thought that there is no clear connection between the proportion of people with type 2 diabetes and the use of the newer drugs repaglinide, pioglitazone, DPP-4 inhibitors and GLP-1 receptor agonists (see Diagrams 8–11 in Appendix 2 – Regional Statistics). Among these newer drug types, the use of DPP-4 inhibitors was on the whole highest, while GLP-1 receptor agonists, repaglinide and pioglitazone were used somewhat less recurrently.

**Insulin therapy in type 2 diabetes**

It is the National Board of Health and Welfare's assessment that the recommendations concerning alternative types of insulin in cases of type 2 diabetes will have an impact on the resource allocation and organisational structure of the health service as there are currently regional variations in the use of different drug types. The National Board of Health and Welfare's national evaluation of diabetes care 2014 describes these regional variations in more detail [4].

It is the National Board of Health and Welfare's assessment that the health service may need additional resources in order to systematically monitor the incidence of episodes of hypoglycaemia among people with type 2 diabetes who are treated with insulin. This monitoring encompasses both the best treatment for the individual patient and systematic monitoring at the group level. Such monitoring may free up resources to the extent long-acting analogues are currently prescribed to people who would not suffer episodes of hypoglycaemia if they were treated using NPH insulin as a basal insulin. Monitoring could also identify people who are not being treated optimally with NPH insulin. Systematic monitoring of people with type 2 diabetes who are being treated with insulin could thus involve a redistribution of the health service's resources. The National Board of Health and Welfare does not have the evidence on which to base an assessment of the extent to which the total costs would need to increase.
Furthermore, there are significant regional variations in the use of NPH insulin and long-acting insulin analogues. Nevertheless, there is a high degree of consistency among the county councils in terms of the use of biphasic insulin in relation to the prevalence of type 2 diabetes, which is also shown by the National Board of Health and Welfare's national evaluation of diabetes care from 2014 [4].

**Insulin pump with or without combined continuous glucose monitoring in type 1 diabetes**

It is the National Board of Health and Welfare's assessment that the recommendation concerning insulin pumps with or without continuous glucose monitoring for people with type 1 diabetes and problems with recurrent episodes of hyper- or hypoglycaemia will have an impact on the resource allocation and organisational structure of the health service. This impact is due to the health service being required to offer interventions to more people than at the present time and because the interventions cost more than normal multi-dose treatment.

It is the National Board of Health and Welfare's assessment that the health service can offer insulin pumps to approximately a further 500 people and insulin pumps with built-in continuous glucose monitoring to approximately a further 500 (in total, about 2 per cent of people with type 1 diabetes). This would involve an additional cost to the health service of around SEK 26 million per year at the national level, compared with a situation in which the same people continue with multi-dose treatment [24].

Several healthcare regions indicated that an increased use of insulin pumps, with or without continuous glucose monitoring, would initially involve an increase in the county council's costs. An expert group for diabetes in Region Skåne has drawn up a care programme with recommendations for the use of continuous glucose monitoring. It is noted that it may be pertinent to establish a system for the monitoring and evaluation of these devices. The south-east healthcare region has had a more restrictive attitude to continuous glucose monitoring and thus makes the assessment that its cost will increase as a result of the National Board of Health and Welfare's recommendation.

Stockholm County Council stated that it will require additional financial and human resources if it is to offer more people the opportunity to use insulin pumps.

**Oral health**

It is the National Board of Health and Welfare's assessment that the recommendation concerning referring people with diabetes to the dental service for preventative interventions relating to or treatment for decay and periodontitis will have a short-term impact on the resource allocation and organisational structure of the health service. In the short-term, the health service may see some reduction in its costs associated with blood glucose-lowering drug treatment as a result of a reduction in the negative effects of poor oral health. In the longer-term, the cost may also decrease as a result of fewer diabetic complications or the slower development of diabetic complications.
The National Board of Health and Welfare's analysis shows that improved glycaemic control as a result of improved dental care is cost-effective from the perspective of society as a whole. However, the current regulations governing the funding of dental charges will mean that the cost of additional appointments with dentists and dental hygienists will fall largely on the individual.

The National Board of Health and Welfare's model analysis showed that, over the course of 20 years, the preventative interventions against decay and periodontitis will lead to reduced costs of up to SEK 8,000 per patient, compared with conventional dental care, while the intervention also has a positive impact on the patients' health. This saving is primarily due to the reduced costs of treating microvascular complications, followed by reduced costs for the treatment of macrovascular complications.

A decisive factor for the consequences of this intervention is the extent to which the patients themselves can be expected to fund the additional dental care. If, for various reasons, they decline the intervention, this will mean that the positive impact on their health and the cost savings for society will not be forthcoming. Consequently, finding a way to induce patients to invest in preventative interventions against decay and periodontitis may be vital. Furthermore, county councils and regions may need to support those who do not have the financial means to make this investment.

In accordance with the National Dental Care Support Ordinance (2008:193), people with difficult-to-treat diabetes have the right to receive Special Subsidised Dental Care (STB). According to Section 17 of the National Board of Health and Welfare's Regulations Concerning Special Subsidised Dental Care (SOSFS 2012:16), difficult-to-treat diabetes is listed as: "The patient's blood sugar level will have had an average of three sequential HbA1c values over 73 mmol/mol over the course of a six month period; meanwhile, the patient's compliance with adequate treatment has been good". The limit value for HbA1c means that only 11 per cent of all those with diabetes have the opportunity to be granted the subsidy, according to the HbA1c values recorded in the NDR. The value of STB is currently SEK 600 per half year and may be used for examinations and preventative dental care. In order to receive the subsidy, the patient must get a doctor to certify that they have difficult-to-treat diabetes.

The majority of responses to the draft of these guidelines from the healthcare regions contained comments about the recommendation concerning oral health. The county councils considered the translation of the National Board of Health and Welfare's recommendation into interventions in the health service to be a challenge, as was how the collaboration with the dental service would take place. From the perspective of patients, it is important that the health service, the dental service and the Swedish Social Insurance Agency organise this collaboration and inform people with diabetes in a clear way about the benefit of preventative dental care.
Indicators of high-quality health and social care

The National Board of Health and Welfare is tasked with periodically reporting on the situation in the health service (including the dental service) and social services. The National Board of Health and Welfare is also tasked with monitoring how the national guidelines are used and their impact on practice in these organisations. Consequently, the Board develops indicators within the scope of its work on national guidelines.

The indicators are measures whose intention is to reflect high-quality health and social care. High-quality health and social care is care that is evidence-based, safe, adapted to the individual, effective, consistent and accessible.

It has to be possible for the indicators to be used as the basis for monitoring and developing activities, as well as for transparent reporting concerning the health service's processes, results and costs.

The goal is for it to be possible for various interested parties to use the indicators in order to

- enable the monitoring of the health service's development of processes, results and costs over time
- form the basis on which to compare the health service's processes, results and costs over time
- instigate improvements to the quality and effectiveness of the health service.

With the help of the indicators, it has to be possible to monitor, compare and improve at the local, regional and national level. International comparisons also have to be made easier.

The National Board of Health and Welfare's work on the development of indicators is conducted in accordance with a model that indicators being developed in cooperation with medical experts and other interested parties, using relevant evidence as a basis [25]. According to the model, an indicator of high-quality health and social care has to have a reasonable evidence base, be relevant and also be possible to measure and interpret. It also has to be possible to continuously record the data that constitutes the basis of the indicators in information systems such as computerised records, registers and other data sources.

One starting point for all indicators is to present data distributed by women and men when possible. In some cases, indicators may also be reported distributed by socioeconomic level or country of birth, in order to reflect consistent care.
Indicators for diabetes care

The National Board of Health and Welfare has drawn up 21 national indicators for the National Guidelines for Diabetes Care. It is currently possible to measure the majority of these with the help of existing data sources.

Two of the indicators are what is known as structural indicators, reflecting whether the health service has the correct prerequisites for the delivery for high-quality diabetes care. There is currently no national data source for these indicators, but it is possible to monitor them with the help of surveys sent to the health service. In this way, structural indicators can, in many cases at least be monitored at the local or regional level.

Two of the indicators are what is known as development indicators. This means that there needs to be further development work in order to make it possible to monitor the indicators at the national level. Indicators of patients' perceptions of the quality of care and health-related quality of life are important in the monitoring and evaluation of care. There is currently an ongoing effort within the national diabetes register (NDR) that is using a patient survey to help draw up measures of how people with diabetes feel and perceive their situation and their diabetes care. An initial pilot version of this has been presented in previous annual reports from the NDR and in the National Board of Health and Welfare’s evaluation of diabetes care 2011 and the national guidelines for diabetes care from 2010.

It may of course become pertinent to have further indicators in order for it to be possible to monitor the organisations’ content, quality and results. The National Board of Health and Welfare has, however, focused on indicators that will reflect the most important aspects of high-quality care and the recommendations in the guidelines.

The work to draw up national indicators is to be regarded as a continual process in which the pre-existing indicators may come to be changed or removed or in which new indicators will be added. For example, ongoing national and international development efforts may end up providing useful evidence on which to base updates to the indicators.

Goals for the indicators

The National Board of Health and Welfare has been tasked by the Government with drawing up target levels for the indicators in the National Guidelines for Diabetes Care. The target levels are used to support monitoring of the results at the local, regional and national level. The target levels state how great a proportion of a patient group should be considered for a certain investigation or achieve a target for a certain treatment. Target levels can be used as the basis of improvement efforts or to help in the governance and management of the health service.

The target levels are set on the basis of a tried-and-tested model which takes into account both statistical data and consensus processes [26]. The National Board of Health and Welfare has set the target levels for a selection of the indicators; these are presented in Target Levels for Diabetes Care [5].
Evaluating diabetes care's compliance with the guidelines

In 2011, the National Board of Health and Welfare published an evaluation of diabetes care based on the previous guidelines. Over the course of 2014, the National Board of Health and Welfare has undertaken a follow-up evaluation with the aim of investigating whether the county council's compliance with the recommendations has improved. The evaluation has been based on the indicators for which the county councils demonstrated poor results in 2011, but it also covers the new indicators drawn up as part of the work to revise the guidelines. Light has also been shed on other aspects of diabetes care that are connected to the guidelines.

Reporting of indicators

All the indicators are reported in the appendix Indicators, which can be downloaded from the National Board of Health and Welfare's website www.socialstyrelsen.se/nationellriktlinjer. All the indicators that are developed within the scope of the national guidelines are also available in the National Board of Health and Welfare's indicator library www.socialstyrelsen.se/indikatorer.
Table 5. Examples of indicators
All indicators are reported in accordance with this example

<table>
<thead>
<tr>
<th>Measure</th>
<th>The proportion of people with diabetes who have an HbA1c &gt; 70 mmol/mol, in per cent.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aim</td>
<td>The indicator shows the proportion of people with diabetes who have an HbA1c &gt;70 mmol/mol. Good glycaemic control is vital in order to reduce the risk of diabetic complications. High HbA1c carries a strongly increased risk of diabetic complications. The indicator is interesting both from a professional perspective and from a governance and management perspective.</td>
</tr>
<tr>
<td>Focus</td>
<td>A low proportion is desired.</td>
</tr>
<tr>
<td>Target level</td>
<td>The national target level for type 1 diabetes is &lt; 20% and &lt; 10% for type 2 diabetes.</td>
</tr>
<tr>
<td>Type of indicator</td>
<td>Result measure.</td>
</tr>
<tr>
<td>Status of the indicator</td>
<td>There is a national data source, continuous data gathering.</td>
</tr>
<tr>
<td>Technical description</td>
<td>Numerator: The number of people with diabetes registered in the National Diabetes Register (NDR) with an HbA1c &gt; 70 mmol/mol over the course of the past year.</td>
</tr>
<tr>
<td></td>
<td>Denominator: The number of people in the NDR with an HbA1c value registered over the course of the past year.</td>
</tr>
<tr>
<td>Data sources</td>
<td>The National Diabetes Register (NDR).</td>
</tr>
<tr>
<td>Sources of error</td>
<td>The quality of HbA1c measurements in Sweden is overwhelmingly good thanks to EQUALIS systematic quality control. However, there may still be methodological variations specifically for the increasing common patient-centred methods.</td>
</tr>
<tr>
<td>Reporting levels</td>
<td>Nationwide, county council, hospital, form of care, educational level, country of birth.</td>
</tr>
<tr>
<td>Reporting groups</td>
<td>Gender, age.</td>
</tr>
<tr>
<td>Quality area</td>
<td>Evidence-based care.</td>
</tr>
</tbody>
</table>
List of indicators for diabetes care

The tables in this section show the indicators the National Board of Health and Welfare has drawn up for diabetes care.

### Table 6. General indicators for diabetes care

<table>
<thead>
<tr>
<th>Number</th>
<th>Name</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indicator A1</td>
<td>Mortality from cardiovascular disease</td>
<td>–</td>
</tr>
<tr>
<td>Indicator A2</td>
<td>Amputation above the ankle</td>
<td>–</td>
</tr>
<tr>
<td>Indicator A3</td>
<td>Patients with diabetic nephropathy who began active uraemia care</td>
<td>–</td>
</tr>
<tr>
<td>Indicator A4</td>
<td>Still births and neonatal mortality among singletons</td>
<td>–</td>
</tr>
<tr>
<td>Indicator A5</td>
<td>Serious foetal injuries</td>
<td>–</td>
</tr>
<tr>
<td>Indicator A6</td>
<td>Incidence of proliferative diabetic retinopathy</td>
<td>–</td>
</tr>
<tr>
<td>Indicator A7</td>
<td>Lactic acidosis when treated with metformin</td>
<td>–</td>
</tr>
</tbody>
</table>

### Table 7. Guideline-specific indicators for diabetes care

<table>
<thead>
<tr>
<th>Number</th>
<th>Name</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indicator B1</td>
<td>HbA1c &lt; 52 mmol/mol</td>
<td>–</td>
</tr>
<tr>
<td>Indicator B2</td>
<td>HbA1c &gt; 70 mmol/mol</td>
<td>Type 1: &lt; 20 %. Type 2: &lt; 10 %</td>
</tr>
<tr>
<td>Indicator B3</td>
<td>Blood pressure &lt; 140/85 mm Hg</td>
<td>Type 1: ≥ 90 %. Type 2: ≥ 65 %</td>
</tr>
<tr>
<td>Indicator B4</td>
<td>Statin treatment in cases of diabetes following the degree of risk of cardiovascular disease</td>
<td>–</td>
</tr>
<tr>
<td>Indicator B5</td>
<td>Measured macroalbuminuria</td>
<td>–</td>
</tr>
<tr>
<td>Indicator C1</td>
<td>Foot examination</td>
<td>Type 1: ≥ 99 %. Type 2: ≥ 99 %</td>
</tr>
<tr>
<td>Indicator C2</td>
<td>Fundus oculi examination</td>
<td>Type 1: ≥ 98 %. Type 2: ≥ 96 %</td>
</tr>
<tr>
<td>Indicator C3</td>
<td>Measurement of albumin secretion in the urine</td>
<td>–</td>
</tr>
<tr>
<td>Indicator D1</td>
<td>Performance of physical activity</td>
<td>–</td>
</tr>
<tr>
<td>Indicator D2</td>
<td>Non-smokers among people with diabetes</td>
<td>Type 1: ≥ 95 %. Type 2: ≥ 95 %</td>
</tr>
</tbody>
</table>

### Table 8. Structural indicators for diabetes care

<table>
<thead>
<tr>
<th>Number</th>
<th>Name</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indicator E1</td>
<td>Nurses trained in diabetes</td>
<td>–</td>
</tr>
<tr>
<td>Indicator E2</td>
<td>Group-based education programmes delivered with the support of staff with expertise in the subject and teaching skills</td>
<td>–</td>
</tr>
</tbody>
</table>

### Table 9. Patient-reported outcomes

<table>
<thead>
<tr>
<th>Number</th>
<th>Name</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indicator F1*</td>
<td>How I feel, manage my diabetes and how diabetes affects me and my life</td>
<td>–</td>
</tr>
<tr>
<td>Indicator F2*</td>
<td>Access to and experience of help and support from diabetes care services.</td>
<td>–</td>
</tr>
</tbody>
</table>

* Development indicator
Consistent care, information, participation and ethics

Promoting equal care

Consistent healthcare is one of six dimensions defined by the National Board of Health and Welfare as important prerequisites for achieving high-quality care. Section 2 of the Health and Medical Services Act (1982:763) stipulates that care is to be offered on equal terms and that priority is to be given to those who have the greatest need. The Patient Act (2014:821) came into force on 1 January 2014. The goal of the Patient Act is to strengthen and clarify the patient's status and promote their integrity, self-determination and involvement. But health and social care in Sweden is currently unequal in several respects [27, 28].

Equal care means that care and treatment are offered on the same terms to everyone, regardless of personal attributes, place of residence, chronological age, gender, disability, education, social standing, ethnic or religious affiliation or sexual orientation [29]. Because health is not equally distributed, a health service that strives to achieve a good standard for health and care on equal terms for the entire population should prioritise those with the greatest need and should also be focused on health and promote health.

Equal care also has a direct link to the three principles of prioritisation included in the ethical platform in the Government Bill Prioritisation in the Health Service (Govt. Bill 1996/97:60); the principles of human dignity, needs and solidarity and cost-effectiveness. A primary focus of equal care is that all decision-making levels share the responsibility for maintaining the three principles of prioritisation.

However, the health service's staff have a specific responsibility for maintaining the principle of human dignity. This means that the individual is approached and cared for with respect and consideration. The National Board of Health and Welfare's educational material The approach to patients in the health service [30] is directed at care staff and deals with the approach to patients and delivering care on equal terms.

Providing information and making patients involved

The National Board of Health and Welfare sees the health service's communication with patients and patients' involvement in their care and treatment as key issues.

The Health and Medical Services Act (1982:763) and the Patient Safety Act (2010:659) state that the health service has to provide every patient with
individually adapted information and the opportunity to choose between different treatment options.

The individually adapted information has to contain details of the patient's condition and the investigation, care and treatment methods on offer. This is how care staff create the conditions in which the patient is able to safeguard their own interests and adopt an attitude to and become involved in their treatment.

The information needs to be adapted to the person's condition, maturity and experience, cognitive ability, any disability they may have and their cultural and linguistic background.

The National Board of Health and Welfare's handbook *Your liability to provide the patient with information and get them involved* [31] contains an overall description of the regulations that apply to the patient's status and right to self-determination, information, involvement and continuity. The handbook is intended for caregivers, managers and staff in the health service.

The National Board of Health and Welfare's *My guide to safe care* [32] is intended for patients and provides guidance and concrete advice regarding how they can become involved in their own care and treatment and thus contribute to safer care.

Both the handbook and the guide can be downloaded or ordered from the National Board of Health and Welfare's website www.socialstyrelsen.se.

### Involvement in and support for diabetes self-care

People with diabetes play a key role in their own treatment. Consequently, it is important that the patient and the health service staff responsible are involved in a dialogue concerning treatment. The patient is able to contribute to this by providing information about their self-care and the health service staff contribute with their knowledge of medicine and care. This makes it more likely that realistic goals will be set for the patient's self-care and that the health service staff will provide the patient with the support they need to achieve these. Patient education can, in this context, be an important means of support.

For people with another cultural background, who perhaps have a different view of health and disease, the support for self-care and the patient education needs to be adapted to these circumstances. Culturally adapted patient education thus requires that health service staff are knowledgeable about the potential cultural differences that exist.

One aspect of diabetes care that is often very difficult is changing previous eating habits. In this case, it is also important that the dietary advice provided is culturally adapted.

### Ethical considerations in diabetes care

When a person is suffering from a lifelong disease that requires advanced treatment, this can be received with mixed feelings and sometimes give rise
to a perceived crisis. The patient's autonomy may be threatened in such situations. It is important for the health service to provide individually adapted information about the disease and its treatment in order to help the patient regain control over their situation. Autonomy must, however, always be balanced against other ethical principles such as doing no harm.

The ethical attitude of doing good may sometimes be complicates if a treatment may be associated with various risks to the patient. In addition, the situations may be complicated further if the treatment is financially costly or if the patient is opposed to treatment. Health service staff are then faced with difficult ethical judgements; they must choose between doing good against not causing harm, at the same time as the patient's self-determination and integrity have to be respected [33, 34]. One example of this is when health service staff state that a treatment would be good for the patient's health or quality of life, but the patient does not want to be involved in this treatment.

In the field of diabetes care, this can be exemplified with a patient with type 2 diabetes who, despite being on the maximum dose of diabetes drugs, still has worsening glycaemic control. From the perspective of the health service, the establishment of insulin therapy is the most adequate choice. If the patient then does not want to accept insulin therapy, the health service staff are faced with an ethical dilemma, based on the knowledge that poor glycaemic control hastens the development of late diabetic complications. But consideration for the patient's self-determination and integrity means that the health service cannot force the patient to accept insulin therapy.

The only ethical means that are then available are to provide objective and well-founded information so that the patient is able to make a decision based on evidence and an awareness of the risks.
## Project Organisation

### Project management

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<tr>
<th>Name</th>
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<tbody>
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<td>medical advisor</td>
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<td>Mats Eliasson</td>
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<td>professor, Umeå University, consultant physician, Sunderby Hospital, Luleå</td>
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</table>
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**Work on the health economic evidence**

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25. Socialstyrelsen., SKL. Modell för utveckling av kvalitetsindikatorer 2005:


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*Socialstyrelsens föreskrifter om informationshantering och journalföring i hälso- och sjukvården*(The National Board of Health and Welfare's Regulations Concerning Information Management and Record-keeping in the Health Service) (SOSFS 2008:14)

*Socialstyrelsens föreskrifter om särskilt tandvårdsbidrag*(The National Board of Health and Welfare's Regulations Concerning Special Subsidised Dental Care) (SOSFS 2012:16)
Appendix 1 List of Conditions and Interventions

The list of conditions and interventions contains 140 recommendations for diabetes care. A more detailed list of conditions and interventions can be downloaded from the National Board of Health and Welfare's website, www.socialstyrelsen.se/nationella riktlinjer. It is also possible to read the collected information about all recommendation in the appendix Scientific Evidence.

<table>
<thead>
<tr>
<th>Row</th>
<th>Condition and intervention</th>
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</table>
| A01 | Diabetes and hypertension without microalbuminuria  
Combined lifestyle interventions (diet, exercise and potentially other interventions such as behaviour modification) | Decisive to this recommendation is that the condition has a high degree of severity and has an effect on important endpoints at a low cost per quality adjusted life year (QALY) gained, compared with conventional care. Adaptation to the group “most ailing older people”: Take into account the risk of undernourishment and the relationship macronutrients/vitamins. Exercise is adapted to older people’s circumstances. | 1               |
| A02 | Increased risk of type 2 diabetes, based on impaired glucose tolerance.  
Structured programmes that have an intensive impact on unhealthy lifestyles (diet and physical activity) | Decisive to this recommendation is that the intervention can reduce the onset of type 2 diabetes in a high-risk population, and that the intervention is a predominant strategy or has a low cost per QALY gained compared with conventional care. At the same time, the condition has a low degree of severity. | 5               |
| A06 | Newly diagnosed diabetes in adults  
Diagnosis using GAD65Ak | Decisive to this recommendation is that the condition has a low degree of severity and there is a lack of scientific evidence that the intervention is of benefit to patients.  
Comments: The intervention is supported by proven experience.  
Adaptation to the group most ailing older people: Take into account the fact that type 1 diabetes can also début at an advanced age. | 8               |
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| A07 | Newly diagnosed diabetes prior to 65 years of age  
Differential diagnosis using C-peptide | Decisive to this recommendation is that the condition has a low degree of severity and there is a lack of scientific evidence that the intervention is of benefit to patients.  
Comments: The intervention is supported by proven experience. | 10 |
| A08 | Type 1 diabetes  
Measurement of thyroid-stimulating hormone (TSH) to detect any hypothyroidism | Decisive to this recommendation is the expected benefit to patients of this intervention.  
Comments: The condition is asymptomatic for a long time and there is a danger of it affecting general condition and glycaemic control. The test is cheap and the treatment simple and effective. The intervention is supported by proven experience. | 4 |
| A09 | In advance of or during pregnancy in those with type 1 diabetes  
Measurement of thyroid-stimulating hormone (TSH) to detect any hypothyroidism | Decisive to this recommendation is the expected benefit to patients of this intervention and that the condition has a moderate degree of severity  
Comments: The risk of becoming ill is significantly higher during pregnancy. There is a danger of the foetus developing permanent cognitive impairment in cases of untreated hypothyroidism. The test and treatment are cheap and simple. The intervention is supported by proven experience. | 2 |
| A10 | Type 2 diabetes and treatment with metformin  
Measurement of vitamin B12 in order to detect any deficiency. | Decisive to this recommendation is the expected benefit to patients of this intervention.  
Comments: Metformin increases the risk of vitamin B12 deficiency, which can worsen the patient’s general condition and particularly diabetic nerve injuries. The test and treatment are cheap and simple. The intervention is supported by proven experience.  
Adaptation to the group most ailing older people: Take into account the fact that B12 deficiencies are possibly more common among older people. | 4 |
| A13 | Increased risk of type 2 diabetes  
Targeted screening for diabetes | Decisive to this recommendation is that there is no effect on crucial endpoints [mortality]. At the same time, there is not thought to be any negative impact on quality of life.  
Comments: Does not refer to population-based screening. | 5 |
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| A26a | Type 2 diabetes and overweight or obesity  
      Intensive combined lifestyle interventions (diet, exercise and potentially other interventions) under the auspices of the health service | Decisive to this recommendation is that the condition has a low degree of severity and that there is no impact on crucial endpoints (mortality, cardiovascular events). At the same time, the intervention has some impact on important endpoints (HbA1c, weight) and is a dominant strategy or has a low cost per QALY gained compared with no structured programme.  
      Comments: The intervention is defined in accordance with the Look Ahead study. | 8 |
| A14 | Type 2 diabetes with overweight or obesity (BMI over or equal to 28 kg/m²)  
      Orlistat in addition to lifestyle treatment | Decisive to this recommendation is that the condition has a low degree of severity, that there is insufficient scientific evidence for crucial endpoints (mortality, cardiovascular disease), and that the effect on important endpoints (weight, HbA1c) is minor. The intervention can have gastrointestinal side-effects.  
      Comments: The surgical alternative is supported more now than in 2010. | 8 |
| A16 | Type 2 diabetes with obesity (BMI over 40 kg/m²)  
      Obesity surgery | Decisive to this recommendation is that the condition has a moderate degree of severity, that there is an impact on several crucial and important endpoints and that the intervention has a low to moderate cost per QALY gained, compared with the normal treatment.  
      Comments: Inadequate follow-up means there is some uncertainty regarding safety, effects and quality of life in the long-term. | 4 |
| A17 | Type 2 diabetes with obesity (BMI 35–40 kg/m²) and difficulty achieving glycaemic and risk factor control  
      Obesity surgery | Decisive to this recommendation is that the condition has a moderate degree of severity, that there is an impact on several crucial and important endpoints and that the intervention has a low to moderate cost per QALY gained, compared with the normal treatment. The scientific evidence for the impact on remission of diabetes is weaker, compared with in cases where the BMI is higher. There is also a lack of support for the effect on the risk of myocardial infarction for those with a lower BMI.  
      Comments: Inadequate follow-up means there is some uncertainty regarding safety, effects, quality of life and cost-effectiveness in the long-term. | 6 |
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<tr>
<td>A18</td>
<td>Type 2 diabetes and smoking</td>
<td>Decisive to this recommendation is that the condition has a high degree of severity. There is limited scientific evidence for the effect on cardiovascular events specifically for people with diabetes, but points in the same beneficial direction as the effect on the general population. Comments: For the best methods refer to the National Guidelines for Methods of Preventing Disease.</td>
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<tr>
<td>A22a</td>
<td>Type 1 diabetes with very inadequate glycaemic control (HbA1c over 70 mmol/mol) Education in advanced carbohydrate counting</td>
<td>Decisive to this recommendation is that the condition has a moderate degree of severity and that the intervention has an impact on HbA1c in this specific condition.</td>
<td>4</td>
</tr>
<tr>
<td>A22b</td>
<td>Type 1 diabetes with inadequate glycaemic control (HbA1c around 62 mmol/mol) Education in advanced carbohydrate counting</td>
<td>Decisive to this recommendation is that there is insufficient scientific evidence. Comments: The expectation that there is some effect is extrapolated from the group with very inadequate glycaemic control.</td>
<td>7</td>
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<tr>
<td>A23</td>
<td>Type 2 diabetes Help to increase physical activity</td>
<td>Decisive to this recommendation is that the intervention has an impact on crucial endpoints (reduced mortality and cardiovascular morbidity) and that the cost per QALY gained for physical activity combined with dietary advice is low in comparison with conventional care. Comments: For the best methods refer to the National Guidelines for Methods of Preventing Disease. Adaptation to the group ‘most ailing older people’: Take into account the fact that exercise must be adapted to the circumstances of older people.</td>
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<tr>
<td>A24</td>
<td>Type 1 diabetes &lt;br&gt; <em>Help to increase physical activity</em></td>
<td>Decisive to this recommendation is that the benefit of the intervention is probably the same for people with type 1 diabetes as for people who do not have diabetes. &lt;br&gt; Comments: For the best methods refer to the National Guidelines for Methods of Preventing Disease. The intervention is supported by proven experience. &lt;br&gt; Adaptation to the group ‘most ailing older people’: Take into account the fact that exercise must be adapted to the circumstances of older people.</td>
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<tr>
<td>A25</td>
<td>Diabetes with an increased risk of worsened oral health or ongoing inflammatory disease of the tissues surrounding the teeth and dental implants. &lt;br&gt; <em>Referral to the dental service for an opinion concerning preventative interventions or treatment for decay and periodontitis.</em></td>
<td>Decisive to this recommendation is that the intervention has an impact on HbA1c comparable to some drugs and that the intervention results in a lower cost to the economy as a whole. &lt;br&gt; Adaptation to the group ‘most ailing older people’: Take into account the fact that this can be particularly important to pay attention to in this group.</td>
<td>3</td>
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<tr>
<td>B01</td>
<td>Type 1 diabetes &lt;br&gt; <em>Intensive insulin therapy with the goal of reducing HbA1c.</em></td>
<td>Decisive to these recommendations is that the intervention has a big impact on crucial endpoints (complication and cardiovascular disease) and a low to moderate cost per QALY gained, compared with the standard treatment. &lt;br&gt; Adaptation to the most ailing older people: The intervention should be adapted to individual circumstances. The benefit of preventing complication may be small when considering the short remaining lifespan. Potential reductions in insulin requirements with advancing age should also be taken into account.</td>
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<tr>
<td>B02</td>
<td>Type 2 diabetes (newly diagnosed and without known cardiovascular disease)</td>
<td>Intensive treatment with the goal of reducing HbA1c Decisive to these recommendations is that the intervention has a big impact on crucial endpoints (complication and cardiovascular disease) and a low to moderate cost per QALY gained, compared with the standard treatment. Adaptation to the most ailing older people: The intervention should be adapted to individual circumstances. The benefit of preventing complication may be small when considering the short remaining lifespan. Potential reductions in insulin requirements with advancing age should also be taken into account.</td>
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<tr>
<td>B03</td>
<td>Type 2 diabetes of long duration or with known cardiovascular disease</td>
<td>Intensive treatment with the goal of reducing HbA1c Decisive to this recommendation is that the scientific evidence of the beneficial effect is weaker when the disease is of a longer duration or there is known cardiovascular disease (compared with newly diagnosed type 2 diabetes without known cardiovascular disease). Comments: The cost per QALY for intensive treatment is relative to age at the time of disease onset and gets higher the older the patient is. There is a lack of studies of the cost-effectiveness of the treatment of patients with type 2 diabetes who have had the disease for a longer period and a lack of clear medical evidence makes health economic studies more difficult. Adaptation to the most ailing older people: The intervention should be adapted to individual circumstances. There is a risk of overtreatment in this group. Potential reductions in insulin requirements with advancing age should also be taken into account.</td>
<td>6</td>
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<tr>
<td>B06</td>
<td>Diabetes with increased risk of diabetic ketoacidosis (DKA) Self-monitoring of blood ketones (targeted monitoring)</td>
<td>Decisive to this recommendation is the expected benefit to patients of this intervention and that the condition has a moderate degree of severity Comments: The condition can develop quickly and is potentially life-threatening. Targeted self-monitoring provides the opportunity for quick and curative intervention. The intervention is supported by proven experience.</td>
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| B10 | Type 2 diabetes without insulin therapy  
Systematic self-monitoring of blood glucose | Decisive to this recommendation is that the condition has a low degree of severity and the intervention’s impact on HbA1c. Low to moderate cost per QALY gained for self-monitoring as a complement to normal care.  
Comments: Refers to monitoring prior to and 2 hours after meals, two days per week (6–7 pricks per day). Stronger evidence for effectiveness and better cost-effectiveness than the previous guidelines. | 8 |
| B11 | Type 2 diabetes with lifestyle treatment (including diet) and/or oral treatment  
Targeted blood glucose monitoring in special situations | Decisive to this recommendation is that the intervention, when used for educational purposes, may be regarded as one aspect of patient education, which is a prerequisite for good results from other treatments.  
Comments: The intervention is supported by proven experience. | 3 |
| B12 | Diabetes treated with insulin  
Systematic self-monitoring of blood glucose | Decisive to this recommendation is that the intervention is a necessary requirement for the treatment of the condition and constitutes a safety measure for avoiding hypoglycaemia.  
Comments: Applies to both type 1 and type 2 diabetes. The intervention is supported by proven experience. | 1 |
| B15 | Type 2 diabetes with lifestyle treatment and inadequate glycaemic control  
Metformin monotherapy | Decisive to this recommendation is the intervention’s impact on crucial endpoints (complication and mortality) and its impact on HbA1c.  
Adaptation to the group ‘most ailing older people’: Take into account progressive impairment of renal function and other forms of organ failure in those of advanced age. | 1 |
| B17 | Type 2 diabetes with lifestyle treatment and inadequate glycaemic control  
Sulphonylureas used as monotherapy | Decisive to this recommendation is the intervention’s impact on HbA1c, combined with the extensive experience there is of using this treatment. The risk of weight gain and episodes of hypoglycaemia is greater than with metformin.  
Adaptation to the group ‘most ailing older people’: Take into account symptoms of hypoglycaemia. | 4 |
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<th>Justification for the recommendation</th>
<th>Recommendation</th>
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<tbody>
<tr>
<td>B18</td>
<td>Type 2 diabetes with lifestyle treatment and inadequate glycaemic control Repaglinide monotherapy</td>
<td>Decisive to this recommendation is the intervention’s impact on HbA1c, combined with the extensive experience there is of using this treatment. The risk of weight gain and episodes of hypoglycaemia is greater than with metformin. Adaptation to the group ‘most ailing older people’: Take into account symptoms of hypoglycaemia.</td>
<td>4</td>
</tr>
<tr>
<td>B19</td>
<td>Type 2 diabetes with lifestyle treatment and inadequate glycaemic control Acarbose monotherapy</td>
<td>Decisive to this recommendation is that the intervention has less of an impact on HbA1c than alternative treatments and that it carries a high risk of gastrointestinal side-effects.</td>
<td>9</td>
</tr>
<tr>
<td>B20</td>
<td>Type 2 diabetes with lifestyle treatment and inadequate glycaemic control Pioglitazone monotherapy</td>
<td>Decisive to this recommendation is the risk of side-effects (e.g. fractures and oedema).</td>
<td>10</td>
</tr>
<tr>
<td>B66</td>
<td>Type 2 diabetes with lifestyle treatment and inadequate glycaemic control DPP-4 inhibitors used as monotherapy</td>
<td>Decisive to this recommendation is that the intervention has less of an impact on HbA1c than metformin, sulphonylureas and repaglinide used as monotherapy. Comments: Some uncertainty regarding the definition of episodes of hypoglycaemia. Adaptation to the group ‘most ailing older people’: Take into account that there is limited experience of treating older people with newer preparations.</td>
<td>7</td>
</tr>
<tr>
<td>B57</td>
<td>Type 2 diabetes with lifestyle treatment and inadequate glycaemic control SGLT2 inhibitors used as monotherapy</td>
<td>Decisive to this recommendation is that there is less of an impact on HbA1c than with alternative drugs. Comments: There is uncertainty regarding the effectiveness and safety in the long-term. Adaptation to the group ‘most ailing older people’: Take into account that there is limited experience of treating older people with newer preparations.</td>
<td>10</td>
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<td>Row</td>
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| B45 | Type 2 diabetes with inadequate glycaemic control on oral treatment  
**Insulin monotherapy as a second choice after metformin** | Decisive to this recommendation is that the intervention is a tried and tested alternative to oral treatment.  
Comments: Refers to biphasic insulin or a mealtime insulin-based regime. The intervention is supported by proven experience.  
Adaptation to the group ‘most ailing older people’: Take into account symptoms of hypoglycaemia. | 4 |
| B22 | Type 2 diabetes with inadequate glycaemic control using metformin monotherapy  
**Sulphonylureas in combination with metformin** | Decisive to this recommendation is the intervention’s impact on HbA1c, combined with the extensive experience there is of using this treatment. Combining sulphonylureas with metformin has a lower cost and less patient benefit than combining dapagliflozin, DPP-4 inhibitors or GLP-1 receptor agonists with metformin or other forms of oral therapy.  
Adaptation to the group ‘most ailing older people’: Take into account symptoms of hypoglycaemia. | 4 |
| B23 | Type 2 diabetes with inadequate glycaemic control using metformin monotherapy  
**Repaglinide in combination with metformin** | Decisive to this recommendation is the intervention has an impact on HbA1c, combined with the extensive experience there is of using this treatment.  
Adaptation to the group ‘most ailing older people’: Take into account symptoms of hypoglycaemia. | 4 |
| B36 | Type 2 diabetes with inadequate glycaemic control using metformin monotherapy  
**Insulin in combination with metformin** | Decisive to this recommendation is the intervention’s impact on HbA1c, combined with the extensive experience there is of using this treatment. Combining insulin with metformin results in a lower cost and lower quality of life than combining DPP-4 inhibitors or GLP-1 receptor agonists with metformin or other forms of oral therapy.  
Comments: Refers to NPH at night, biphasic insulin or bolus-basal regime.  
Adaptation to the group ‘most ailing older people’: Take into account symptoms of hypoglycaemia. | 3 |
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| B24 | Type 2 diabetes with inadequate glycaemic control using metformin monotherapy  
Acarbose in combination with metformin | Decisive to this recommendation is that the intervention has less of an impact on HbA1c than alternative treatments and that it carries a high risk of gastrointestinal side-effects. | 9 |
| B25 | Type 2 diabetes with inadequate glycaemic control using metformin monotherapy  
Pioglitazone in combination with metformin | Decisive to this recommendation is the risk of side-effects (e.g., fractures and oedema). | 10 |
| B58 | Type 2 diabetes with inadequate glycaemic control using metformin monotherapy  
SGLT2 inhibitors in combination with metformin | Decisive to this recommendation is the intervention’s poorer complementary impact on HbA1c than combinations using other drugs.  
Comments: There is uncertainty regarding effectiveness and side-effects in the long-term.  
Adaptation to the group ‘most ailing older people’: Take into account that there is limited experience of treating older people with newer preparations. | 10 |
| B33 | Type 2 diabetes with inadequate glycaemic control using metformin monotherapy  
GLP-1 receptor agonists (exenatide or liraglutide) in combination with metformin | Decisive to the recommendation is the intervention’s impact on HbA1c and weight. The risk of hypoglycaemia is thought to be very small.  
At the same time, the intervention has a moderate cost per QALY gained compared with sulphonylureas or insulin in combination with metformin.  
Comments: There is now less uncertainty regarding the long-term effects of treatment using GLP-1 receptor agonists than when the previous version of the guidelines was published.  
Adaptation to the group ‘most ailing older people’: Take into account that there is limited experience of treating older people with newer preparations. | 6 |
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<tr>
<td>B67</td>
<td>Type 2 diabetes with inadequate glycaemic control using metformin monotherapy</td>
<td>Decisive to this recommendation is the intervention’s poorer complementary impact on HbA1c than combinations using other drugs. Combining DPP-4 inhibitors with metformin or other oral therapy has a moderate cost per QALY gained, compared with sulphonylureas or insulin in combination with metformin or another oral therapy. As opposed to GLP-1 receptor agonists, combinations using DPP-4 inhibitors do not result in weight loss. Comments: There is now less uncertainty regarding the long-term effects of treatment using DPP-4 inhibitors than when the previous version of the guidelines was published. Adaptation to the group ‘most ailing older people’: Take into account that there is limited experience of treating older people with newer preparations.</td>
<td>7</td>
</tr>
<tr>
<td>B46</td>
<td>Type 2 diabetes with inadequate glycaemic control using oral treatment and without problems involving episodes of nocturnal hypoglycaemia</td>
<td>Decisive to this recommendation is that the intervention has an impact on HbA1c comparable to alternative types of insulin (long-acting insulin analogues), and that the cost per QALY gained is lower compared with long-acting insulin analogues in this condition. Adaptation to the group ‘most ailing older people’: Take into account symptoms of hypoglycaemia.</td>
<td>3</td>
</tr>
<tr>
<td>B48a</td>
<td>Type 2 diabetes with inadequate glycaemic control using oral treatment and without problems involving episodes of nocturnal hypoglycaemia</td>
<td>Decisive to this recommendation is that the cost per QALY gained is high for insulin detemir or insulin glargine, compared with NPH insulin in this conditions, while having an equivalent impact on HbA1c. Adaptation to the group ‘most ailing older people’: Take into account symptoms of hypoglycaemia.</td>
<td>9</td>
</tr>
<tr>
<td>B48b</td>
<td>Type 2 diabetes with inadequate glycaemic control using oral treatment and without problems involving episodes of nocturnal hypoglycaemia</td>
<td>Decisive to this recommendation is that the cost per QALY gained is high for insulin detemir or insulin glargine, compared with NPH insulin in this conditions, while having an equivalent impact on HbA1c. Adaptation to the group ‘most ailing older people’: Take into account symptoms of hypoglycaemia.</td>
<td>9</td>
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| B61 | Type 2 diabetes with inadequate glycaemic control using oral treatment and without problems involving episodes of nocturnal hypoglycaemia  
Long-acting insulin analogue: degludec | Decisive to this recommendation is that treatment using insulin degludec has a moderate cost per QALY gained, compared with glargine, and a high cost per QALY gained, compared with NPH insulin, while having an effect on HbA<sub>1c</sub> deemed to be equivalent to that of the alternatives.  
Comments: There is uncertainty regarding effectiveness and side-effects in the long-term.  
Adaptation to the group ‘most ailing older people’: Take into account symptoms of hypoglycaemia. | 10 |
| B47a | Type 2 diabetes with inadequate glycaemic control and where NPH insulin as basal insulin results in recurrent episodes of nocturnal hypoglycaemia  
Long-acting insulin analogue: detemir | Decisive to this recommendation is that the long-acting insulin analogues are thought to result in fewer episodes of nocturnal hypoglycaemia than NPH insulin and that the cost per QALY gained is low to moderate for treatment with insulin detemir or glargine, compared with NPH insulin, in this condition.  
Adaptation to the group ‘most ailing older people’: Take into account symptoms of hypoglycaemia. | 3 |
| B47b | Type 2 diabetes with inadequate glycaemic control and where NPH insulin as basal insulin results in recurrent episodes of nocturnal hypoglycaemia  
Long-acting insulin analogue: glargine | Decisive to this recommendation is that the intervention is thought to decrease the risk of nocturnal hypoglycaemia, compared with insulin glargine, at the same time as the absolute reduction in risk is small, there is uncertainty regarding the effectiveness and side-effects in the long-term and the intervention has a moderate cost per QALY gained, compared with insulin glargine.  
Adaptation to the group ‘most ailing older people’: Take into account symptoms of hypoglycaemia. | 3 |
| B47c | Type 2 diabetes with inadequate glycaemic control and where insulin glargine as basal insulin results in recurrent episodes of nocturnal hypoglycaemia  
Long-acting insulin analogue: degludec | Decisive to this recommendation is that the intervention is thought to decrease the risk of nocturnal hypoglycaemia, compared with insulin glargine, at the same time as the absolute reduction in risk is small, there is uncertainty regarding the effectiveness and side-effects in the long-term and the intervention has a moderate cost per QALY gained, compared with insulin glargine.  
Adaptation to the group ‘most ailing older people’: Take into account symptoms of hypoglycaemia. | 8 |
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<tbody>
<tr>
<td>B40</td>
<td>Type 1 diabetes, Rapid-acting insulin analogues</td>
<td>Decisive to this recommendation is that the condition has a very high degree of severity and that the intervention is &quot;life-saving&quot;. The intervention results in a lower HbA₁c, fewer episodes of hypoglycaemia and has a lower treatment cost than human insulin. Adaptation to the group ‘most ailing older people’: Take into account symptoms of hypoglycaemia.</td>
<td>1</td>
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<tr>
<td>B41</td>
<td>Type 1 diabetes, Rapid-acting human insulin</td>
<td>Decisive to this recommendation is that the condition has a very high degree of severity and that the intervention is &quot;life-saving&quot; and results in more recurrent episodes of hypoglycaemia than the analogues. Adaptation to the group ‘most ailing older people’: Take into account symptoms of hypoglycaemia.</td>
<td>2</td>
</tr>
<tr>
<td>B42</td>
<td>Type 1 diabetes, Intermediate-acting NPH insulin</td>
<td>Decisive to this recommendation is that the condition has a very high degree of severity and that the intervention is &quot;life-saving&quot;. The differences in impact on HbA₁c and episodes of hypoglycaemia, respectively, are so small that the intervention in rows B42, B43a and B43b cannot be differentiated in terms of their priority. Adaptation to the group ‘most ailing older people’: Take into account weaker symptoms of hypoglycaemia.</td>
<td>1</td>
</tr>
<tr>
<td>B43a</td>
<td>Type 1 diabetes, Long-acting insulin analogue: detemir</td>
<td>Decisive to this recommendation is that the condition has a very high degree of severity and that the intervention is &quot;life-saving&quot;. The differences in impact on HbA₁c and episodes of hypoglycaemia, respectively, are so small that the intervention in rows B42, B43a and B43b cannot be differentiated in terms of their priority. Adaptation to the group ‘most ailing older people’: Take into account weaker symptoms of hypoglycaemia.</td>
<td>1</td>
</tr>
<tr>
<td>B43b</td>
<td>Type 1 diabetes, Long-acting insulin analogue: glargine</td>
<td>Decisive to this recommendation is that the condition has a very high degree of severity and that the intervention is &quot;life-saving&quot;. The differences in impact on HbA₁c and episodes of hypoglycaemia, respectively, are so small that the intervention in rows B42, B43a and B43b cannot be differentiated in terms of their priority.</td>
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<td></td>
<td></td>
<td>Adaptation to the group ‘most ailing older people’: Take into account weaker symptoms of hypoglycaemia.</td>
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<tr>
<td>B59</td>
<td>Type 1 diabetes</td>
<td>Decisive to this recommendation is uncertainty about effectiveness and safety in the long-term and that the intervention has a moderate cost per QALY gained, compared with treatment using insulin glargine.</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>Long-acting insulin analogue: degludec</td>
<td>Adaptation to the group ‘most ailing older people’: Take into account weaker symptoms of hypoglycaemia.</td>
<td></td>
</tr>
<tr>
<td>B60</td>
<td>Type 1 diabetes where treatment with insulin glargine results in recurrent episodes of nocturnal hypoglycaemia</td>
<td>Decisive to this recommendation is that the intervention is thought to decrease the risk of nocturnal hypoglycaemia, compared with insulin glargine, at the same time as the absolute reduction in risk is small, there is uncertainty regarding the effectiveness and side-effects in the long-term and the intervention has a moderate cost per QALY gained, compared with insulin glargine.</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Long-acting insulin analogue: degludec</td>
<td>Adaptation to the group ‘most ailing older people’: Take into account weaker symptoms of hypoglycaemia.</td>
<td></td>
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<tr>
<td>B56</td>
<td>Latent autoimmune diabetes of adults (LADA) and inadequate glycaemic control with or without metformin</td>
<td>Decisive to this recommendation is that the intervention has an impact on HbA1c. Comments: As opposed to the previous version of the guidelines, there is now scientific evidence of an improved impact on glycaemic control, compared with oral treatment.</td>
<td>3</td>
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<tr>
<td></td>
<td>Early insulin treatment</td>
<td></td>
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<tr>
<td>B62</td>
<td>Type 1 diabetes without problems involving recurrent episodes of hyper- or hypoglycaemia</td>
<td>Decisive to this recommendation is that there is insufficient scientific evidence. Comments: May be pertinent to use in certain cases for diagnostic purposes or as blind monitoring.</td>
<td>10</td>
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<td></td>
<td>Retrospective continuous glucose monitoring</td>
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<tr>
<td>B63a</td>
<td>Type 1 diabetes without problems involving recurrent episodes of hyper- or hypogly-</td>
<td>Decisive to this recommendation is that the condition has a lower degree of severity, compared with the group of patients who have problems with sharply fluctuating blood</td>
<td>9</td>
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<td>caemia</td>
<td>Continuous subcutaneous glucose monitoring with results that can be read directly (real-time CGM)</td>
<td>Glucose. The scientific evidence is insufficient to judge the impact on crucial and important endpoints such as complications, mortality, hypoglycaemia and quality of life, but the intervention as some impact on HbA1c.</td>
<td></td>
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<tr>
<td>B63b</td>
<td>Type 1 diabetes with problems involving recurrent episodes of hyper- or hypoglycaemia</td>
<td>Decisive to this recommendation is that the condition has a higher degree of severity than in cases of fluctuating blood glucose levels and that the intervention has some impact on HbA1c. The scientific evidence is insufficient to judge the impact on crucial and important endpoints such as complications, mortality, hypoglycaemia and quality of life.</td>
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<td>Comments: There is uncertainty concerning cost-effectiveness.</td>
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<tr>
<td>B63c</td>
<td>Type 1 diabetes without problems involving recurrent episodes of hyper- or hypoglycaemia</td>
<td>Decisive to this recommendation is that the condition has a lower degree of severity than in cases of fluctuating blood glucose levels. There is a lack of scientific evidence of its effectiveness.</td>
<td>9</td>
</tr>
<tr>
<td>Short-term real-time continuous subcutaneous glucose monitoring for diagnostic purposes</td>
<td>Comments: There is uncertainty concerning cost-effectiveness. The intervention is supported by proven experience.</td>
<td></td>
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<tr>
<td>B63d</td>
<td>Type 1 diabetes with problems involving recurrent episodes of hyper- or hypoglycaemia</td>
<td>Decisive to this recommendation is that the condition has a high degree of severity. There is a lack of scientific evidence of its effectiveness.</td>
<td>6</td>
</tr>
<tr>
<td>Short-term real-time continuous subcutaneous glucose monitoring for diagnostic purposes</td>
<td>Comments: There is uncertainty concerning cost-effectiveness. The intervention is supported by proven experience.</td>
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<tr>
<td>B64a</td>
<td>Type 1 diabetes without problems with recurrent episodes of hyper- and hypoglycaemia</td>
<td>Continuous glucose monitoring integrated with an insulin pump [SAP, sensor augmented pump therapy] Decisive to this recommendation is the lower degree of severity in comparison with the group of patients who have problems with sharply fluctuating blood glucose. There is insufficient scientific evidence to judge the impact on crucial and important endpoints such as complications, mortality, ketoacidosis and treatment satisfaction. Some impact on HbA1c. Comments: The cost is probably lower than the combination of monitor and pump. However, there is uncertainty about the cost-effectiveness.</td>
<td>10</td>
</tr>
<tr>
<td>B64b</td>
<td>Type 1 diabetes with problems with recurrent episodes of hyper- and hypoglycaemia</td>
<td>Continuous glucose monitoring integrated with an insulin pump [SAP, sensor augmented pump therapy] Decisive to this recommendation is that the condition has a high degree of severity. At the same time, there is insufficient scientific evidence for crucial and important endpoints (severe hypoglycaemia, ketoacidosis and quality of life). The intervention has some impact on HbA1c and treatment satisfaction. Comments: Higher degree of severity than for patients with fluctuating blood glucose levels. The intervention has more effective that a pump alone, but it is not possible to determine if the sensor or the pump is the decisive factor. There is uncertainty concerning cost-effectiveness.</td>
<td>6</td>
</tr>
<tr>
<td>B65a</td>
<td>Type 1 diabetes without problems involving recurrent episodes of hyper- or hypoglycaemia</td>
<td>Insulin pump (continuous subcutaneous insulin infusion, CSII) Decisive to this recommendation is the lower degree of severity in comparison with the group of patients who have problems with sharply fluctuating blood glucose. There is insufficient or no scientific evidence for crucial and important endpoints (complications, mortality, ketoacidosis and treatment satisfaction). Some impact on HbA1c. Comments: The cost is probably lower than the combination of monitor and pump. However, there is uncertainty about the cost-effectiveness.</td>
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<tr>
<td>B65b</td>
<td>Type 1 diabetes with problems involving recurrent episodes of hyper- or hypoglycaemia&lt;br&gt;Insulin pump (continuous subcutaneous insulin infusion, CSII)</td>
<td>Decisive to this recommendation is that the condition has a high degree of severity. At the same time, there is insufficient scientific evidence for crucial and important endpoints (complications, mortality, ketoacidosis and treatment satisfaction). The intervention has an impact on HbA1c. Comments: Higher degree of severity than for patients with fluctuating blood glucose levels. The cost is probably lower than the combination of monitor and pump. However, there is uncertainty about the cost-effectiveness.</td>
<td>4</td>
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<tr>
<td>C01</td>
<td>Type 2 diabetes with hypertension&lt;br&gt;Primary prevention of cardiovascular disease by reducing blood pressure</td>
<td>Decisive to this recommendation is the intervention’s impact on crucial endpoints (stroke, myocardial infarction and death). The cost per QALY gained is also low for strict blood pressure control, compared with less strict blood pressure control, and the condition has a high degree of severity. Adaptation to the group ‘most ailing older people’: Take into account the increased risk of orthostatic reactions (too low blood pressure) and expected patient benefit. There are risks involved when treating patients with many different drugs.</td>
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<tr>
<td>C02</td>
<td>Diabetes with suspected hypertension&lt;br&gt;Ambulatory blood pressure monitoring for an opinion regarding treatment</td>
<td>Decisive to this recommendation is that the condition has a moderate degree of severity, concurrent with a lack of scientific evidence of the intervention’s effectiveness. Comments: The intervention is supported by proven experience.</td>
<td>4</td>
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<tr>
<td>C03</td>
<td>Type 1 diabetes with hypertension and without microalbuminuria&lt;br&gt;Treatment with ACE inhibitors, angiotensin receptor blockers (ARB), beta blockers, diuretics or calcium blockers</td>
<td>Decisive to this recommendation is that the condition has a high degree of severity, at the same time as there is a lack of scientific evidence of its effectiveness. Comments: The intervention is supported by proven experience. Adaptation to the group ‘most ailing older people’: Take into account the risk of orthostatic reactions (excessively low blood pressure) and less expected patient benefit. There are risks involved when treating patients with many different drugs at the same time.</td>
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| C06 | Diabetes and hypertension with microalbuminuria  
Treatment with ACE inhibitors or angiotensin receptor blockers (ARB) | Decisive to this recommendation is that the condition has a high degree of severity and that the intervention has an impact on crucial endpoints (death, cardiovascular disease and other complications). Treatment with ACE inhibitors has a low cost per QALY gained, compared with no treatment.  
Comments: ACE inhibitors, ARBs, thiazide diuretics and calcium channel blockers have the equivalent lowest price per comparative dose according to the TLV.  
Adaptation to the group ‘most ailing older people’: Take into account the risk of impaired renal function and the risk of hypercalcaemia (excess calcium in the blood). There are risks involved when treating patients with many different drugs. | 1 |
| C07 | Type 1 diabetes with microalbuminuria, without hypertension  
Treatment with ACE inhibitors or angiotensin receptor blockers (ARB) | Decisive to this recommendation is that there is insufficient scientific evidence for crucial endpoints (death, cardiovascular morbidity and renal impact). At the same time, there is some impact on the excretion of albumin in the urine, which is a strong indicator of the risk of a potentially serious complication. Treatment with ACE inhibitors has a low cost per QALY gained, compared with no treatment.  
Comments: ACE inhibitors, ARBs, thiazide diuretics and calcium channel blockers have the equivalent lowest price per comparative dose according to the TLV.  
Adaptation to the group ‘most ailing older people’: Take into account the risk of impaired renal function and the risk of hypercalcaemia (excess calcium in the blood). There are risks involved when treating patients with many different drugs. | 6 |
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<tr>
<td>C10a</td>
<td>Type 2 diabetes with a very high risk of cardiovascular disease (equivalent to &gt; 20 per cent risk of cardiac events over 5 years)</td>
<td>Decisive to this recommendation is that the condition has a high degree of severity and that the intervention has an impact on crucial endpoints (coronary artery disease, stroke and revascularisation). The treatment also has a low cost per QALY gained, compared to lifestyle changes without drugs.</td>
<td>1</td>
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<tr>
<td></td>
<td>Intensive treatment with statins for primary prevention of cardiovascular disease</td>
<td>Comments: Estimation of risk in accordance with the Medical Products Agency’s drug recommendation.</td>
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<td></td>
<td>Adaptation to the group ‘most ailing older people’: Take into account that the balance between expected patient benefit and side-effects may be different in those of advanced age. There are risks involved when treating patients with many different drugs.</td>
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<tr>
<td>C10b</td>
<td>Type 2 diabetes with a high risk of cardiovascular disease (equivalent to &gt; 8 per cent risk of cardiac events over 5 years)</td>
<td>Decisive to this recommendation is that the condition has a high degree of severity and that the intervention has an impact on crucial endpoints (coronary artery disease, stroke and revascularisation). The treatment also has a low cost per QALY gained, compared to lifestyle changes without drugs.</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Standardised treatment with statins for primary prevention of cardiovascular disease</td>
<td>Comments: Estimation of risk in accordance with the Medical Products Agency’s drug recommendation.</td>
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<td></td>
<td></td>
<td>Adaptation to the group ‘most ailing older people’: Take into account that the balance between expected patient benefit and side-effects may be different in those of advanced age. There are risks involved when treating patients with many different drugs.</td>
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<tr>
<td>C10c</td>
<td>Type 2 diabetes with a moderate risk of cardiovascular disease (equivalent to 2–8 per cent risk of cardiac events over 5 years)</td>
<td>Decisive to this recommendation is that the condition has a moderate degree of severity and that the intervention has an impact on crucial endpoints (coronary artery disease, stroke and revascularisation). The treatment also has a low cost per QALY gained, compared to lifestyle changes without drugs.</td>
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<td>Standardised treatment with statins for primary prevention of cardiovascular disease</td>
<td>Comments: Estimation of risk in accordance with the Medical Products Agency’s drug recommendation.</td>
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<td>Adaptation to the group ‘most ailing older people’: Take into account that the balance between expected patient benefit and side-effects may be different in those of advanced age. There are risks involved when treating patients with many different drugs.</td>
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<td>effects may be different in those of advanced age. There are risks involved when treating patients with many different drugs.</td>
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</table>
| C12 | Type 2 diabetes and low HDL cholesterol  
Fibrate treatment for primary prevention of cardiovascular disease | Decisive to this recommendation is that the condition has a low degree of severity and there is limited evidence of its effectiveness. Adaptation to the group ‘most ailing older people’: Take into account age and expected patient benefit and side-effects. | 10 |
| C13a| Type 1 diabetes with a very high risk of cardiovascular disease (equivalent to > 20 per cent risk of cardiac events over 5 years)  
Intensive treatment with statins for primary prevention of cardiovascular disease | Decisive to this recommendation is that the condition has a high degree of severity and that the intervention has an impact on crucial endpoints (major cardiovascular events). Comments: Estimation of risk in accordance with the Medical Products Agency’s drug recommendation. Adaptation to the group ‘most ailing older people’: Take into account that the balance between expected patient benefit and side-effects may be different in those of advanced age. There are risks involved when treating patients with many different drugs. | 1 |
| C13b| Type 1 diabetes with a high risk of cardiovascular disease (equivalent to 8-20 per cent risk of cardiac events over 5 years)  
Standardised treatment with statins for primary prevention of cardiovascular disease | Decisive to this recommendation is that the condition has a high degree of severity and that the intervention has an impact on crucial endpoints (major cardiovascular events). Comments: Estimation of risk in accordance with the Medical Products Agency’s drug recommendation. Adaptation to the group ‘most ailing older people’: Take into account that the balance between expected patient benefit and side-effects may be different in those of advanced age. There are risks involved when treating patients with many different drugs. | 2 |
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<tr>
<td>C13c</td>
<td>Type 1 diabetes with a moderate risk of cardiovascular disease (equivalent to 2–8 per cent risk of cardiac events over 5 years) Standardised treatment with statins for primary prevention of cardiovascular disease</td>
<td>Decisive to this recommendation is that the condition has a moderate degree of severity and that the intervention has an impact on crucial endpoints (major cardiovascular events). Comments: Estimation of risk in accordance with the Medical Products Agency’s drug recommendation. Adaptation to the group ‘most ailing older people’: Take into account that the balance between expected patient benefit and side-effects may be different in those of advanced age. There are risks involved when treating patients with many different drugs.</td>
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<tr>
<td>C15</td>
<td>Diabetes Treatment with aspirin for primary prevention of cardiovascular disease</td>
<td>Decisive to this recommendation is that there is scientific evidence that the intervention does not have any impact on cardiovascular disease and death.</td>
<td>Avoid</td>
</tr>
<tr>
<td>D01</td>
<td>Diabetes Motivational conversations in accordance with the MI methods (MI, AMI and MET) with the aim of improving glycaemic control</td>
<td>Decisive to this recommendation is that there is scientific evidence that the intervention does not have any impact on HbA1c or bodyweight.</td>
<td>Avoid</td>
</tr>
<tr>
<td>D02</td>
<td>Diabetes with inadequate glycaemic control Behaviour-oriented patient education in the form of support programmes based on cognitive behavioural therapy (CBT)</td>
<td>Decisive to this recommendation is that there is insufficient scientific evidence of effectiveness, at the same time as there are other interventions for which there is scientific evidence of impact on HbA1c. Comments: Several intervention studies are ongoing.</td>
<td>R&amp;D</td>
</tr>
<tr>
<td>D03</td>
<td>Type 1 diabetes Group-based education programmes</td>
<td>Decisive to this recommendation is the intervention’s impact on HbA1c and that the condition has a moderate degree of severity Comments: Patient education is a prerequisite for good results from other treatments.</td>
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<tr>
<td>D04</td>
<td>Type 2 diabetes</td>
<td>Group-based education programmes delivered by people with teaching skills</td>
<td>Decisive to this recommendation is the intervention's impact on HbA1c and that the intervention has a low cost per QALY gained, compared with individual education programmes. Comments: Patient education is a prerequisite for good results from other treatments.</td>
</tr>
<tr>
<td>D05</td>
<td>Type 2 diabetes</td>
<td>Group-based education programmes delivered by people without teaching skills</td>
<td>Decisive to this recommendation is that the intervention has no clinically relevant impact on HbA1c.</td>
</tr>
<tr>
<td>D07</td>
<td>Type 2 diabetes</td>
<td>Individual education programmes</td>
<td>Decisive to this recommendation is that there is strong scientific support for a very small impact on HbA1c and that the alternative (group-based education programmes) has a low cost per QALY gained, compared with individual education programmes.</td>
</tr>
<tr>
<td>D08</td>
<td>Diabetes in people from other cultures</td>
<td>Culturally adapted patient education in groups</td>
<td>Decisive to this recommendation is the intervention's impact on HbA1c and that the condition has a moderate degree of severity</td>
</tr>
<tr>
<td>D09</td>
<td>Diabetes in people from other cultures</td>
<td>Culturally adapted programmes involving individual patient education</td>
<td>Decisive to this recommendation is that the intervention has an impact on HbA1c and that the condition has a moderate degree of severity</td>
</tr>
<tr>
<td>D10</td>
<td>Diabetes and culturally differing opinions on health and disease</td>
<td>Culturally adapted diabetes care with case management</td>
<td>Decisive to this recommendation is that the intervention has an impact on HbA1c and that the condition has a moderate degree of severity</td>
</tr>
<tr>
<td>D11</td>
<td>Type 2 diabetes and a need for help with self-care</td>
<td>Help from close family or friends when attending appointments</td>
<td>Decisive to this recommendation is that the intervention has an impact on HbA1c. Adaptation to the group ‘most ailing older people’: Take into account that close family or friends may be particularly important for frail patients.</td>
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| D12     | Diabetes and a lack of involvement in their own care  
                      **Interventions directed at the patient and that aim to reinforce the patient's empowerment** | Decisive to this recommendation is that the intervention has an impact on HbA₁c and that the condition has a moderate degree of severity | 3 |
| D14     | Diabetes and fear of hypoglycaemia  
                      **Cognitive behavioural therapy (CBT)** | Decisive to this recommendation is that there is insufficient scientific evidence of effectiveness.  
                      Comments: Greater knowledge is vital as alternative methods are largely lacking for this pressing condition. Studies are ongoing. | R&D |
| D16     | Diabetes and the inability to perceive warning signals for hypoglycaemia  
                      **Structured, patient-centres education programmes with biopsychological focus** | Decisive to this recommendation is that there is limited support for the impact of the intervention on important endpoints (HbA₁c and the patient's ability to assess their blood glucose level). | 7 |
| D19     | Type 2 diabetes and stress related to living with type 2 diabetes  
                      **Stress management delivered by the care unit's staff (trained in stress management)** | Decisive to this recommendation is that the intervention has an impact on HbA₁c and quality of life. | 5 |
| D20     | Diabetes with shoulder pain – adhesive capsulitis  
                      **Low-intensity physiotherapy (within pain-free movement pathways)** | Decisive to this recommendation is the expected benefit to patients of this intervention and that the condition has a moderate degree of severity There is a lack of alternative interventions.  
                      Comments: The condition can involve pain, functional impairment and absence from work. The intervention is supported by proven experience. | 4 |
| D22     | Diabetes  
                      **Chronic Disease Self-Management Program (CDSMP)** | Decisive to this recommendation is that the intervention has no impact on HbA₁c. | Avoid |
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<tr>
<td>E02</td>
<td>Type 2 diabetes without retinopathy</td>
<td>Decisive to this recommendation is that the condition has a moderate degree of severity.</td>
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<td>Fundus oculi imaging every three years</td>
<td>Comments: Regular examination and, if necessary, treatment reduces the risk of the development of visual impairment.</td>
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<tr>
<td>E03</td>
<td>Diabetes</td>
<td>Decisive to this recommendation is that the condition has a moderate degree of severity.</td>
<td>1</td>
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<td>Annual test for albumin in the urine</td>
<td>Comments: Albumin in the urine is a very strong indicator of the risk of serious renal damage, myocardial infarction, stroke and premature death. This is a simple intervention that facilitates the early identification of individuals with albumin leakage so that interventions that prevent complication can be implemented.</td>
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<tr>
<td>E04</td>
<td>Diabetic nephropathy in the pre-ureamic phase</td>
<td>Decisive to this recommendation is that the condition has a high degree of severity. The intervention has a demonstrable impact on surrogate endpoints.</td>
<td>6</td>
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<td></td>
<td>Advice on a low-protein diet</td>
<td>Comments: The intervention can delay the need for dialysis. Adaptation to the group ‘most ailing older people’: Take into account the fact that this may be less beneficial in this group.</td>
<td></td>
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<tr>
<td>E05</td>
<td>Diabetes</td>
<td>Decisive to this recommendation is that there is scientific evidence that the intervention can predict the risk of amputation.</td>
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<td></td>
<td>Examination using a monofilament or tuning fork to identify neuropathy</td>
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<tr>
<td>E07</td>
<td>Diabetes with painful neuropathy</td>
<td>Decisive to this recommendation is that there is evidence of the effect on pain relief and that the condition has a high degree of severity.</td>
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<td></td>
<td>Treatment with tricyclic antidepressants (TCA) as the first choice</td>
<td>Comments: Relatively limited absolute differences in price between amitriptyline, gabapentin, pregabalin and duloxetine at the lowest price provide the opportunity for individual adaptation of drug treatment in order to achieve maximum patient benefit. Adaptation to the group ‘most ailing older people’: Take into account the fact that there is limited experience using these drugs among older people. There are risks involved when treating patients with many different drugs.</td>
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<tr>
<td>E08</td>
<td>Diabetes with painful neuropathy</td>
<td>Decisive to this recommendation is that there is evidence of the effect on pain relief and that the condition has a high degree of severity.Comments: Relatively limited absolute differences in price between amitriptyline, gabapentin, pregabalin and duloxetine at the lowest price provide the opportunity for individual adaptation of drug treatment in order to achieve maximum patient benefit. Adaptation to the group ‘most ailing older people’: Take into account the fact that there is limited experience using these drugs among older people. There are risks involved when treating patients with many different drugs.</td>
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</tr>
<tr>
<td>E09</td>
<td>Diabetes with painful neuropathy</td>
<td>Decisive to this recommendation is that there is scientific evidence that the intervention has no impact on pain relief.</td>
<td>Avoid</td>
</tr>
<tr>
<td>E10</td>
<td>Diabetes with painful neuropathy</td>
<td>Decisive to this recommendation is that there is evidence of the effect on pain relief and quality of life and that the condition has a high degree of severity. Comments: Relatively limited absolute differences in price between amitriptyline, gabapentin, pregabalin and duloxetine at the lowest price provide the opportunity for individual adaptation of drug treatment in order to achieve maximum patient benefit. Adaptation to the group ‘most ailing older people’: Take into account the fact that there is limited experience using these drugs among older people. There are risks involved when treating patients with many different drugs.</td>
<td>2</td>
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<tr>
<td>E10</td>
<td>Diabetes with painful neuropathy</td>
<td>Decisive to this recommendation is that there is evidence of the effect on pain relief and that the condition has a high degree of severity. Comments: There is a risk of misuse Relatively limited absolute differences in price between amitriptyline, gabapentin, pregabalin and duloxetine at the lowest price provide the opportunity for individual adaptation of drug treatment in order to achieve maximum patient benefit. Adaptation to the group ‘most ailing older people’: Take into account the fact that there is limited experience using these drugs among older people. There are risks involved when treating patients with many different drugs.</td>
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| E12 | Diabetes with painful neuropathy  
Treatment with capsaicin | Decisive to this recommendation is that the treatment involves side-effects, at the same time as the impact on pain relief is small. 
Comments: There are treatment alternative that are more effective, but there is also a need for further treatment alternative for this condition. 
Adaptation to the group ‘most ailing older people’: Take into account the fact that there is limited experience using these drugs among older people. There are risks involved when treating patients with many different drugs. | 9 |
| E13 | Diabetes with painful neuropathy  
Treatment using transcutaneous electrical nerve stimulation (TENS) | Decisive to this recommendation is that there is a lack of scientific evidence of the interventions effectiveness and that there are other alternatives the effect of which is supported. 
Comments: The intervention is supported by proven experience. There is a need for further treatment alternatives for this condition. | 9 |
| E14 | Diabetes and erectile dysfunction  
Treatment with PDE5 inhibitors | Decisive to this recommendation is that the condition has a moderate degree of severity, that the intervention is effective and that the cost per QALY gained is low, compared with no treatment. 
Adaptation to the group ‘most ailing older people’: Take into account the risk of side-effects when using many different drugs and interactions with, for example, nitroglycerine. | 3 |
| E15 | Diabetes and erectile dysfunction  
Treatment with PGE1 administered via the | Decisive to this recommendation is that the condition has a moderate degree of severity and the effectiveness of the intervention. | 5 |
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<td>Diabetes and erectile dysfunction</td>
<td>Decisive to this recommendation is that the condition has a moderate degree of severity.</td>
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<tr>
<td><strong>Treatment with PGE1 administered intracavernously</strong></td>
<td>Comments: The intervention is supported by proven experience.</td>
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<tr>
<td>Diabetes with suspected carpal tunnel syndrome</td>
<td>Decisive to this recommendation is that there is a lack of scientific evidence of the intervention's patient benefit.</td>
<td>7</td>
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<tr>
<td><strong>Diagnosis using neurography</strong></td>
<td>Comments: The intervention is supported by proven experience.</td>
<td></td>
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<tr>
<td>Diabetes with symptomatic carpal tunnel syndrome</td>
<td>Decisive to this recommendation is the expected benefit to patients of this intervention. However, there is a lack of scientific evidence of patient benefit.</td>
<td>4</td>
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<tr>
<td><strong>Treatment with an orthotic device</strong></td>
<td>Comments: Simple and side-effect-free intervention that probably has a low cost. The intervention is supported by proven experience.</td>
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<tr>
<td>Diabetes with constantly symptomatic compression neuropathies</td>
<td>Decisive to this recommendation is the expected benefit to patients of this intervention. However, there is a lack of scientific evidence of patient benefit.</td>
<td>3</td>
</tr>
<tr>
<td><strong>Referral for an opinion concerning surgical treatment when treatment using an orthotic device is inadequate</strong></td>
<td>Comments: The condition may involve pain and numbness (which does not respond to simple treatment and which has an impact on sleep and daily functions). The intervention is supported by proven experience.</td>
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<td>Diabetes without known circulatory disorders</td>
<td>Decisive to this recommendation is the expected benefit to patients of this intervention.</td>
<td>3</td>
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<tr>
<td><strong>Test for circulatory disorders in the foot using palpation of the pedal pulses</strong></td>
<td>Comments: Simple examination that probably has a low cost.</td>
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<tr>
<td>Adaptation to the group “most ailing older people”: Take into account that the examination can be particularly important among older people who cannot observe the symptoms themselves. Take into account any need for assistance at the care home.</td>
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<tr>
<td>E21</td>
<td>Diabetes without known or suspected circulatory disorders</td>
<td>Decisive to this recommendation is that the condition has a low degree of severity and that there are alternative interventions that take less time (simple palpation of the pedal pulses).</td>
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<td>Test for circulatory disorders in the foot by measuring ankle pressure and toe pressure</td>
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<tr>
<td>E22</td>
<td>Diabetes with foot ulcer and suspected circulatory disorders</td>
<td>Decisive to the recommendation is that the condition has a moderate degree of severity and that the intervention that may result from the investigation (vascular surgery) has a good effect on ulcer healing and the risk of amputation.</td>
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<td></td>
<td>Measurement of ankle pressure or toe pressure</td>
<td>Adaptation to the group most ailing older people: Take into account that the examination can be particularly important among older people who cannot observe the symptoms themselves. Take into account any need for assistance at the care home.</td>
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<tr>
<td>E23</td>
<td>Diabetes</td>
<td>Decisive to this recommendation is the expected benefit to patients of this simple examination.</td>
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<td></td>
<td>Routine examination of the feet for the presence of foot deformities</td>
<td>Comments: Simple, side-effect-free intervention that probably has a low cost.</td>
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<td></td>
<td>Adaptation to the group ‘most ailing older people’: Take into account that the examination can be particularly important among older people who cannot observe the symptoms themselves. Take into account any need for assistance at the care home.</td>
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<tr>
<td>E24</td>
<td>Diabetes and high-risk feet</td>
<td>Decisive to this recommendation is the intervention’s impact on the development of foot ulcers.</td>
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<td></td>
<td>Preventive chiropody (intervention with a structured programme encompassing regular examination, foot care, staff or patient teaching and the supply of shoes)</td>
<td>Comments: Limited evidence, but the benefit to patients from preventing foot ulcers is very great.</td>
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<td>Adaptation to the group ‘most ailing older people’: Take into account that this intervention can be particularly important among older people who cannot observe the symptoms themselves. Take into account any need for assistance at the care home.</td>
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| E25 | Diabetes with foot deformities, with normal circulation and sensation  
    | Orthopaedic treatment to prevent ulcers | Decisive to this recommendation is that the condition has a low degree of severity. There is a lack of scientific evidence of the intervention’s benefit to patients.  
    | | Comments: The intervention is supported by proven experience. |
| E26 | Diabetes with foot deformities (e.g. Charcot foot), with impaired circulation and/or sensation  
    | Orthopaedic treatment to prevent ulcers | Decisive to this recommendation is that the condition has a high degree of severity.  
    | | Comments: Impaired circulation and sensation implies that this is a high-risk foot and the expected benefit of the intervention is very high in absolute figures. The intervention can prevent slow-healing ulcers and amputation. The intervention is supported by proven experience.  
    | | Adaptation to the group ‘most ailing older people’: Take into account that this intervention can be particularly important among older people who cannot observe the symptoms themselves. Take into account any need for assistance at the care home. |
| E27 | Diabetes with serious foot problems such as slow-healing foot ulcers and infections  
    | Treatment undertaken by the multidisciplinary foot team | Decisive to this recommendation is that the condition has a high degree of severity and that the intervention has an impact on crucial endpoints (incidence of amputation). |
| E28 | Diabetes with slow-healing foot ulcers  
    | Conservative wound care with growth factors, matrix modulators, cell carpets or cell cultures | Decisive to this recommendation is that there is limited scientific evidence of effectiveness. The intervention has not been shown to be better than the standard treatment.  
<pre><code>| | Comments: Refers to non-infected wounds. The intervention is associated with much higher costs than the standard treatment. In conservative wound care, the cheapest option can be used as there is no evidence of differences in effectiveness. This option can, in exceptional cases, be used when the standard treatment has not be sufficiently effective. |
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| E29 | Diabetes with slow-healing infected foot ulcers  
Conservative wound care with compresses, bandages, dressings or gels | Decisive to this recommendation is that the alternative has not been shown convincingly to be more effective that this standard treatment.  
Comments: The intervention is supported by proven experience. The intervention has a lower cost that alternative treatments. In conservative wound care, the cheapest option can be used as there is no evidence of differences in effectiveness. | 2 |
| E30 | Diabetes with slow-healing infected foot ulcers  
Conservative wound care with local antimicrobial agents or silver-impregnated bandages | Decisive to this recommendation is that there is insufficient scientific evidence of the effectiveness of the intervention.  
Comments: The intervention is associated with much higher costs than the standard treatment. In conservative wound care, the cheapest option can be used as there is no evidence of differences in effectiveness. This option can, in exceptional cases, be used when the standard treatment has not be sufficiently effective. | 10 |
| E31 | Diabetes with slow-healing infected foot ulcers  
Conservative wound care with G-CSF (granulocyte colony-stimulating factor) | Decisive to this recommendation is that there is insufficient scientific evidence of effectiveness.  
Comments: Existing methods are often inadequate and it is vital that new alternative methods are found. In conservative wound care, the cheapest option can be used as there is no evidence of differences in effectiveness. Studies are ongoing. | R&D |
| E32 | Diabetes with gangrene and serious systemic impact or severe pain as a result of intractable ischaemia  
Amputation | Decisive to this recommendation is that the condition has a very high degree of severity and that the intervention is life-saving.  
Comments: The intervention is supported by proven experience. | 1 |
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| E33 | Diabetes with non-ischaemic slow-healing foot ulcers  
Negative pressure therapy | Decisive to this recommendation is that the condition has a high degree of severity and that there is limited scientific evidence of effect on crucial endpoints (amputation) and on wound healing.  
Comments: Compiling a detailed specification of the costs is difficult as the total cost is dependent on many factors that may have an impact on the time it takes the wound to heal and the experience and expertise of the staff. According to a report from SBU, negative pressure therapy can cost SEK 3,800 per week. | 6             |
| E34 | Diabetes and chronic slow-healing foot ulcers  
Hyperbaric oxygen treatment | Decisive to this recommendation is that there is insufficient scientific evidence for crucial endpoints (amputation). The priority is justified on the basis of the intervention’s impact on wound healing and the condition’s high degree of severity.  
Comments: There is uncertainty concerning cost-effectiveness. Compiling a detailed specification of the costs is difficult as the use of resources is dependent on many factors such as the ulcer’s original state, the degree of infection and the experience and expertise of the staff. The cost of hyperbaric oxygen is judged to be around SEK 90,000 per patient in Sweden for a treatment session encompassing 40 occasions. | 9             |
| E35 | Diabetes and slow-healing foot ulcers in the forefoot  
Orthopaedic treatment with load-bearing plaster cast | Decisive to this recommendation is that the condition has a high degree of severity and that the intervention has an impact on wound healing.  
Adaptation to the group ‘most ailing older people’: Take into account the fact that this group may require specific aids or assistance. | 2             |
| E36 | Diabetes and slow-healing foot ulcers in the forefoot  
Orthopaedic treatment with shoes, insoles or removable orthotic devices | Decisive to this recommendation is that the condition has a high degree of severity and that the intervention has an impact on wound healing, however it is less effective than a load-bearing plaster cast.  
Adaptation to the group ‘most ailing older people’: Take into account the fact that this group may require specific aids or assistance. | 4             |
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<td>E37</td>
<td>Diabetes and slow-healing foot ulcers with suspected insufficient circulation</td>
<td>Decisive to this recommendation is that the condition has a high degree of severity and that the intervention has an impact on the risk of amputation.</td>
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<td>Referral for vascular surgical assessment</td>
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<td>E38</td>
<td>Compartment syndrome in the lower legs</td>
<td>Decisive to this recommendation is that there is insufficient scientific evidence of effectiveness. Comments: Existing methods are often inadequate and it is vital that new alternative methods are found. Studies are ongoing.</td>
<td>R&amp;D</td>
</tr>
<tr>
<td></td>
<td>Fasciotomy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F06</td>
<td>Gestational diabetes</td>
<td>Decisive to the recommendation is the intervention's impact on increase foetal growth and birth injuries.</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Intervention involving dietary advice, physical activity and potentially insulin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F08</td>
<td>Gestational diabetes</td>
<td>Decisive to the recommendation is that this simple intervention can reduce the risk of type 2 diabetes emerging in a high-risk population. Comments: The intervention is supported by proven experience.</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Help to change unhealthy lifestyles and systematic monitoring following pregnancy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F10</td>
<td>Diabetes, pregnancy planning</td>
<td>Decisive to this recommendation is the expected benefit to patients (particularly the child) of this simple intervention. The condition has a moderate degree of severity. Comments: The intervention is supported by proven experience.</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Information about pregnancy to women of fertile age</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F11</td>
<td>Diabetes, pregnancy planning</td>
<td>Decisive to this recommendation is the intervention's impact on diabetes-related deformities in the child.</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Multivitamins including folate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F12</td>
<td>Diabetes, pregnancy planning</td>
<td>Decisive to this recommendation is the intervention's impact on the risk of deformities and increased foetal growth.</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Improved glycaemic control</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F13</td>
<td>Diabetes, pregnancy planning</td>
<td>Decisive to this recommendation is the intervention's impact on complications in the form of pre-eclampsia, neonatal hypoglycaemia and increased foetal growth.</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Self-monitoring of blood glucose during pregnancy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Row</td>
<td>Condition and intervention</td>
<td>Justification for the recommendation</td>
<td>Recommendation</td>
</tr>
<tr>
<td>-----</td>
<td>----------------------------</td>
<td>--------------------------------------</td>
<td>----------------</td>
</tr>
<tr>
<td>F20</td>
<td>Type 1 diabetes, pregnancy</td>
<td>Continued treatment with insulin glargine</td>
<td>Decisive to this recommendation is that the safety data indicate that treatment with glargine can continue during pregnancy. Comments: Changing to human insulin in early pregnancy can put glycaemic control at risk in an important stage of the pregnancy when high blood glucose can increase the risk of foetal injuries. Comments: The intervention is supported by proven experience.</td>
</tr>
<tr>
<td>F21</td>
<td>Type 1 diabetes, pregnancy</td>
<td>Continued treatment with insulin detemir</td>
<td>Decisive to this recommendation is that the safety data indicate that treatment with detemir can continue during pregnancy. Comments: Changing to human insulin in early pregnancy can put glycaemic control at risk in an important stage of the pregnancy when high blood glucose can increase the risk of foetal injuries.</td>
</tr>
<tr>
<td>F22</td>
<td>Type 2 diabetes, pregnancy</td>
<td>Continued treatment with metformin</td>
<td>Decisive to this recommendation is that the condition has a moderate degree of severity and that there is insufficient scientific evidence for the effectiveness of the intervention. At the same time, the treatment does not appear to involve any increased risk to the child.</td>
</tr>
<tr>
<td>F26</td>
<td>Gestational diabetes</td>
<td>Initiating new treatment with metformin</td>
<td>Decisive to this recommendation is that there is no difference in several crucial or important endpoints (risk of perinatal death, birth trauma, deformities, Apgar score, birth weight or neonatal hypoglycaemia), compared with insulin treatment. At the same time, the degree of severity is low. Comments: Studies on women with PCOS (polycystic ovary syndrome) indicate that it is safe to use metformin in pregnancy.</td>
</tr>
</tbody>
</table>
Appendix 2 Regional Statistics

This appendix contains regional statistics concerning obesity surgery and the use of drugs in type 2 diabetes.

Obesity surgery

Data from the Scandinavian Obesity Surgery Registry (SOReg) shows that around 7,500 people in Sweden underwent obesity surgery every year between 2010 and 2013, of whom 1,500 had diabetes.

Tabell 10 shows statistics per county council from the National Diabetes Register (NDR) and SOReg regarding the number of people with a BMI over 35 kg/m² and the number of people per year who underwent obesity surgery in the years 2010–2013. The table shows that county councils like Dalarna, Norrbotten, Stockholm and Uppsala undertake a relatively large number of procedures in relation to the number of people who have a BMI over 35 kg/m². However, there is, for example, a relatively large proportion of people with type 2 diabetes who have a BMI over 35 kg/m² in Kalmar, Gotland, Södermanland, Jönköping and Blekinge, at the same time as relatively few procedures are undertaken in comparison with the national average.
### Table 10. People younger than 70 year of age with a BMI of 35–40 kg/m² or greater than 40 kg/m² and the number of people who underwent obesity surgery

Average number of people per county council and year, 2010–2013

<table>
<thead>
<tr>
<th>County council</th>
<th>Number of people with a BMI 35–40 kg/m²</th>
<th>Number of people with a BMI &gt; 40 kg/m²</th>
<th>Number of people who have received obesity surgery</th>
<th>Number of people with diabetes who have received obesity surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blekinge</td>
<td>306</td>
<td>103</td>
<td>126</td>
<td>15</td>
</tr>
<tr>
<td>Dalarna</td>
<td>414</td>
<td>188</td>
<td>184</td>
<td>53</td>
</tr>
<tr>
<td>Gotland</td>
<td>70</td>
<td>34</td>
<td>25</td>
<td>4</td>
</tr>
<tr>
<td>Gävleborg</td>
<td>641</td>
<td>315</td>
<td>220</td>
<td>48</td>
</tr>
<tr>
<td>Halland</td>
<td>374</td>
<td>178</td>
<td>197</td>
<td>31</td>
</tr>
<tr>
<td>Jämtland</td>
<td>246</td>
<td>127</td>
<td>76</td>
<td>18</td>
</tr>
<tr>
<td>Jönköping</td>
<td>692</td>
<td>311</td>
<td>217</td>
<td>36</td>
</tr>
<tr>
<td>Kalmar</td>
<td>550</td>
<td>266</td>
<td>191</td>
<td>27</td>
</tr>
<tr>
<td>Kronoberg</td>
<td>420</td>
<td>207</td>
<td>139</td>
<td>29</td>
</tr>
<tr>
<td>Norrbotten</td>
<td>456</td>
<td>208</td>
<td>248</td>
<td>47</td>
</tr>
<tr>
<td>Skåne</td>
<td>2,528</td>
<td>1,182</td>
<td>1,326</td>
<td>256</td>
</tr>
<tr>
<td>Stockholm</td>
<td>3,366</td>
<td>1,490</td>
<td>1,740</td>
<td>332</td>
</tr>
<tr>
<td>Södermanland</td>
<td>666</td>
<td>312</td>
<td>166</td>
<td>33</td>
</tr>
<tr>
<td>Uppsala</td>
<td>425</td>
<td>180</td>
<td>200</td>
<td>40</td>
</tr>
<tr>
<td>Värmland</td>
<td>609</td>
<td>261</td>
<td>223</td>
<td>42</td>
</tr>
<tr>
<td>Västerbotten</td>
<td>441</td>
<td>203</td>
<td>152</td>
<td>29</td>
</tr>
<tr>
<td>Västernorrland</td>
<td>666</td>
<td>332</td>
<td>206</td>
<td>51</td>
</tr>
<tr>
<td>Västmanland</td>
<td>558</td>
<td>294</td>
<td>178</td>
<td>39</td>
</tr>
<tr>
<td>Västra</td>
<td>3,634</td>
<td>1,679</td>
<td>1,092</td>
<td>229</td>
</tr>
<tr>
<td>Göteborg</td>
<td>657</td>
<td>307</td>
<td>312</td>
<td>64</td>
</tr>
<tr>
<td>Örebro</td>
<td>915</td>
<td>440</td>
<td>349</td>
<td>78</td>
</tr>
<tr>
<td>Östergötland</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nationwide</td>
<td>18,634</td>
<td>8,617</td>
<td>7,564</td>
<td>1,500</td>
</tr>
</tbody>
</table>

Source: NDR and SOReg

Control blood glucose levels

Drugs in type 2 diabetes

Diagram 1 shows that the number of people with type 2 diabetes on blood glucose-lowering drug treatment varies between the country's county councils and regions and that there are also differences in the type of drug treatment.
Diagram 2 shows that the use of blood glucose-lowering drugs changed significantly between 2006 and 2013. The number of people using metformin increased by 56 per cent over the course of the period 2006–2013, while the number who were using sulphonylureas decreased by 30 per cent. Repaglinide and pioglitazone also decreased by 12 and 70 per cent, respectively. However, the number of people using DPP-4 inhibitors and GLP-1 receptor agonists increased steadily and since 2010 by an annual average of 28 and 58 per cent, respectively. Measures such as the volume used per 1,000 inhabitants show that metformin increased by 51 per cent and sulphonylureas decreased by 37 per cent. DPP-4 inhibitors and GLP-1 receptor agonists have been included in the pharmaceutical benefits system since 2007 and in 2013 accounted for 7 per cent and 4 per cent, respectively, of the total number of defined daily doses per 1,000 inhabitants.
Diagram 3 shows changes in trends for the use of NPH insulin, biphasic insulin and long-acting insulin analogues among people age 30 and older. While the use of biphasic insulin changed marginally, the use of NPH insulin increased beginning in 2010. At the same time, the use of long-acting insulin analogues has barely increased since 2009.
The following diagram shows regional variations in the use of drugs in relation to the estimated prevalence of type 2 diabetes in the county council. Diagram 4 and Diagram 5 first show the distribution of the use of the number of defined daily doses per 1,000 inhabitants for insulin for people over the age of 50 and for the use of oral diabetes drugs and GLP-1 receptor agonists. Following that there are six diagrams showing regional distributions between county councils in the number of defined daily doses (DDD) used per 1,000 inhabitants in relation to the proportion of people with type 2 diabetes.

Diagram 4 described the use of all types of insulin. The results become clearer with the help of an example. In Östergötland, the proportion with type 2 diabetes was 4.5 per cent and the use of insulin was 17,200 DDD per 1,000 inhabitants in 2013. In Blekinge, the proportion was similar, 4.6 per cent, but the use of insulin was lower, corresponding to 10,600 DDD per 1,000 inhabitants. Use in Norrbotten was similar to that in Östergötland, but the proportion was significantly higher: 5.1 per cent. Diagram 4 shows that there are differences in the use of insulin between county councils, but also that there is a clear link between the proportion with type 2 diabetes and the use of insulin among people aged 50 years and over.

Diagrams 5–11 show the regional variation in use in relation to the proportion with type 2 diabetes (i.e. the prevalence). The diagram contains both examples of limited differences between county councils, such as that for
metformin, and clear differences in prescription patterns, such as that for sulphonylureas.

Diagram 4. Regional variation in the use of insulin
Number of defined daily doses (DDD) per 1,000 inhabitants aged 50 and over in relation to the estimated prevalence of type 2 diabetes in 2013

Source: Pharmaceuticals Registry, National Board of Health and Welfare
Diagram 5. Regional variation in the use of oral diabetes drugs and GLP-1 analogues (ATC code A10B)

Number of defined daily doses (DDD) per 1,000 inhabitants in relation to the estimated prevalence of type 2 diabetes in 2013

Source: Pharmaceuticals Registry, National
Diagram 6. Regional variation in the use of metformin (ATC code

Number of defined daily doses (DDD) per 1,000 inhabitants in relation to the estimated prevalence of type 2 diabetes in 2013

Source: Pharmaceuticals Registry, National
Diagram 7. Regional variation in the use of sulphonylureas (ATC code A10BB)

Number of defined daily doses (DDD) per 1,000 inhabitants in relation to the estimated prevalence of type 2 diabetes in 2013.

Source: Pharmaceuticals Registry, National.
Diagram 8. Regional variation in the use of repaglinide (ATC code A10BX02)

Number of defined daily doses (DDD) per 1,000 inhabitants in relation to the estimated prevalence of type 2 diabetes in 2013.

Source: Pharmaceuticals Registry, National Board of Health and Welfare.
Diagram 9. Regional variation in the use of pioglitazone (ATC code A10BG)

Number of defined daily doses (DDD) per 1,000 inhabitants in relation to the estimated prevalence of type 2 diabetes in 2013

Source: Pharmaceuticals Registry, National Board of Health and Welfare
Diagram 10. Regional variation in the use of DPP-4 inhibitors (ATC code A10BH)

Number of defined daily doses (DDD) per 1,000 inhabitants in relation to the estimated prevalence of type 2 diabetes in 2013

Source: Pharmaceuticals Registry, National Board of Health and Welfare
Diagram 11. Regional variations in the use of GLP-1 receptor agonists (ATC code A10BX04 and A10BX07)

Number of defined daily doses (DDD) per 1,000 inhabitants in relation to the estimated prevalence of type 2 diabetes in 2013

Source: Pharmaceuticals Registry, National Board of Health and Welfare
Appendix 3 List of external appendices

There are a number of external appendices associated with these guidelines:

- List of Conditions and Interventions (complete)
- Scientific Evidence
- Health Economic Evidence
- Indicators for Diabetes Care
- The Most Ailing Older People and National Guidelines
- Method

All the appendices are available for download at the National Board of Health and Welfare's website
http://www.socialstyrelsen.se/nationalguidelines.