On the Prevention of Heart Attack in Type II Diabetes

Information and Decision Aid for Patients

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Imprint

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The authors thank Jonathan Rippin (Great Britain) and Charles Fox (Great Britain) for their great efforts to translate this decision aid from German into English.

Introduction

For whom is this decision aid intended?

This decision aid is intended for you, if you are:

- between 40 and 70 years old and have Type II diabetes,
- have already taken part in an education programme for diabetes, and
- have neither had a heart attack nor a stroke or have any signs of these.

What is it about?

It is about prevention. People with diabetes have a higher risk than other people of suffering a heart attack and of dying from heart attack.

There is a large number of recommendations for prevention of heart attack. For example: losing weight, various diets, special foods, sport, not smoking, reducing stress, improving blood sugar levels, treating high blood pressure, as well as taking medicines such as aspirin, folic acid, vitamins or drugs to reduce raised levels of fat in the blood. Most people would need to change the way they live rather a lot if they wanted to follow all of these recommendations at the same time. Some measures are however only minor or not appropriate to prevent heart attacks. For others the scientific evidence is missing. There are however very effective options to reduce the risk of heart attack.

One aim of this decision aid is to help you better understand the suggestions from your Doctor for the prevention of heart attack. If you are well informed about the advantages and disadvantages, you can decide together with your Doctor which measures suit you personally and which you might wish to carry out.

Introduction

Why participate in decision making?

Even if all people took the best possible preventive measures, not all heart attacks could be prevented. Even if you carry out preventative measures conscientiously, you could still suffer a heart attack. The risk can only be reduced if prevention is carried out consistently and over a number of years.

Some preventative measures are complicated or require a lot of effort, while others are much simpler. Simpler measures can be more successful than more complicated ones. What is perceived as complicated or a large effort can vary from person to person. Similarly, advantages over disadvantages are given different value or importance by different people.

What is a good decision?

There are usually good arguments both for and against preventative measures. To decide not to take a preventative treatment can sometimes be a good decision. “A good decision” depends on a careful weighing up of Pros and Cons. If you make your own decision about a preventative measure, you may find it easier to carry it through long term. You may also be relieved to learn that certain recommendations, which you consider to be very involved or not possible for you to carry out, are of questionable benefit anyway.

So think for yourself, which measures come into question and which ones can be incorporated into your daily life? If you decide in favour of only one or two measures, the following applies: “Prevention is more successful if it is carried out consistently over the long term”.

Introduction

How has this decision aid come about?

The decision aid was developed in the context of a research project conducted by the Unit of Health Sciences and Education at the University of Hamburg (Germany). This project was supported by a financial contribution of the Natural Sciences Department of the Allgemeine Ortskrankenkasse (AOK). The information is based on the state of scientific knowledge in the year 2008.

Choice, presentation and evaluation of scientific results need to be reproducible. You can therefore find the most important literature sources listed at the end of this document. Doctors and people with diabetes have been involved in the development and evaluation of this decision aid.

Who are the authors?

The working group of the Unit of Health Sciences and Education has many years of experience in producing information for patients and consumers. Mr. Matthias Lenz, PhD is a specialist in health sciences and education; Mrs. Professor Ingrid Mühlhauser, MD is an internationally recognized diabotologist (Dr. specializing in diabetes). You can find more detailed information about the working group on our internet pages:
www.gesundheit.uni-hamburg.de and
www.chemie.uni-hamburg.de/igtw/Gesundheit/gesundheit.htm

Hamburg, December 2008
Matthias Lenz and Ingrid Mühlhauser

Contents

The decision aid consists of six parts:

We recommend that you read the information in this decision aid carefully from beginning to end. There is space at the margin for notes ("What is Important for You?") to make a note of important pieces of information and help you to keep an overview of all the information available. Furthermore, it can be helpful to discuss the information given with your relatives or friends and to talk about unresolved questions with your doctor.

If you desire further information, you can find detailed information on the internet pages for patients of the Institute for Quality and Efficiancy in Health Care (IQWIG) …***We need to come up with an English / American website to replace this***

Heart Attack

What is a Heart Attack?

A heart attack is the consequence of the blockage of one of the coronary arteries, those blood vessels that supply the heart muscle. Any part of the heart muscle, which is cut off from its blood supply, dies off and is replaced by scar tissue. This can lead to weakness of the heart's pumping action through to severe heart failure.

Typical Symptoms are:

- Tight pain in the chest
- Shortness of breath
- Fear
- Sickness (nausea)
- Weakness

If the strength of the heart becomes too weak, a circulatory collapse and unconsciousness can follow.

The symptoms can be minor or severe and sometimes a heart attack can occur without any noticeable symptoms. In particular, the typical pain can be reduced or even absent in diabetes. Sometimes heart attacks are not noticed at all and are only discovered subsequently when a heart tracing (ECG) is carried out. The term ECG is explained on Page 56.

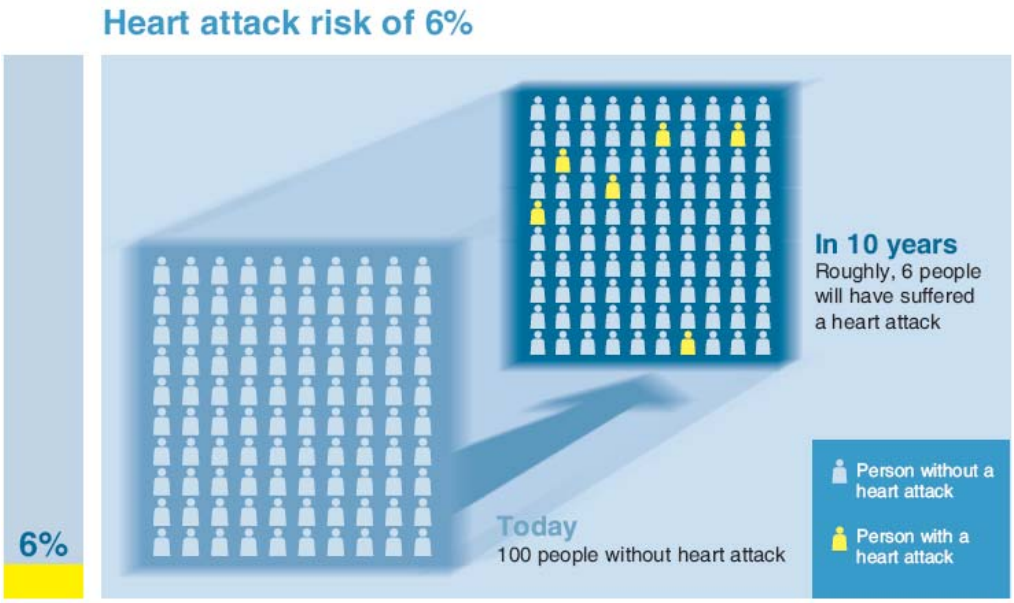
Most people survive a heart attack. A heart attack occurring between the ages of 40 and 70 leads to death in about 30/100 cases [1] (in the section "literature sources" you can look up the sources [number in the square brackets] of this information). The chance of surviving a further heart attack is lower.

Heart Attack Risk

What does heart attack mean?

Risk is a term taken from statistics. Risk means the likelihood of the occurrence of a certain event in a certain period of time. The likelihood is given in % and for a defined period of time, for example for 10 years a ten year heart risk of 6% means:

6 of 100 people will suffer a heart attack sometime in the next 10 years.



Further information which explains risk can be found in the Appendix (Page 48).

Risk Factors

What are risk factors?

Much is reported in the media about risk factors. Risk factors for heart attack are for example, smoking, raised cholesterol levels, high blood pressure and also Type II Diabetes. They increase the likelihood of a heart attack. Seen in this way, age and sex are also risk factors. With increase in age, the risk of heart attack rises.

An important risk factor is family predisposition. If parents or siblings have had a heart attack before they are 60, your own risk is then also increased.

It is also assumed, that being significantly overweight, a lack of exercise, and poor nutrition increase the risk of heart attack. What is certain is that losing weight and physical activity are helpful in the prevention and treatment of diabetes, high blood pressure and high cholesterol.

Alongside these “classical medical risk factors”, a person’s social situation is also of significance as a risk factor. People with less education, poor-employment- or poor-financial conditions or lacking social support have an increased risk of heart attack and early death.

Many risk factors are related to each other. For example, Type II diabetes occurs more frequently in older people or in people with poor social circumstances. Cholesterol levels and blood pressure are often raised in Type II diabetes.

Risk Factors, Age and Sex

Do men and women have different risks for heart attack?

Where there is no Type II Diabetes, the following holds: Women have a lower risk of heart attack than men. It is only about as half as high. This “protective factor of female sex” falls away completely in Type II diabetes so that both sexes have a roughly equal risk of heart attack in Type II diabetes.

What is the significance of age in prevention?

The risk of heart attack rises with increase of age. Thus in young people the risk is low and in old age it is high.

When is it good to start with prevention?

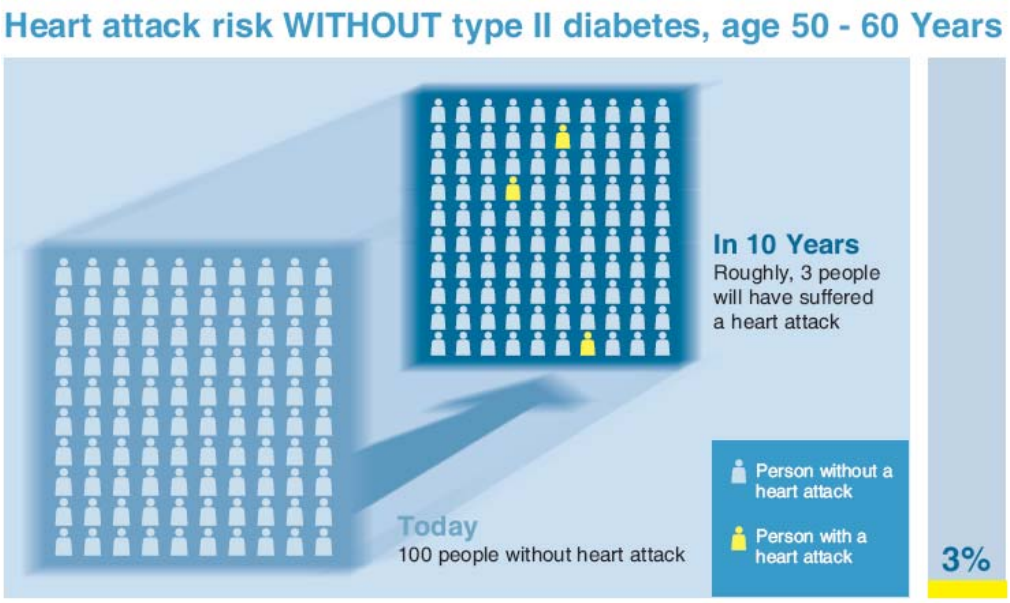
For changes in lifestyle, the explanation is very simple - the earlier prevention is started, the greater the benefit. Someone who stops smoking earlier will also have a smaller risk than someone who stops smoking later.

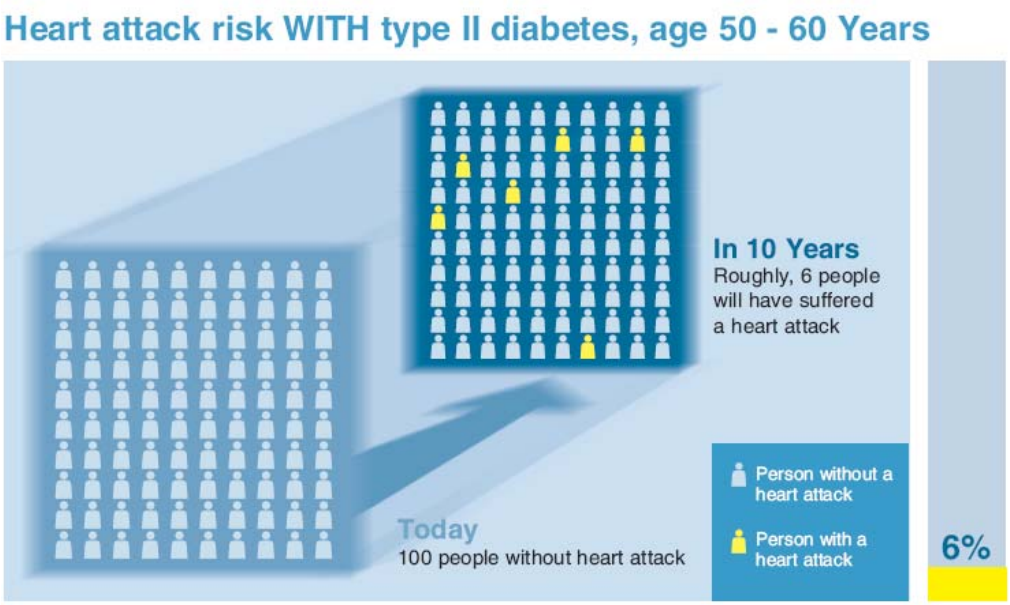
The situation is different in the case of taking medicines to lower the risk of heart attack. Assume a young healthy person were to take a medicine to prevent heart attack. He would have to take the treatment for decades, as heart attacks mostly only occur in older people. There is an unfavourable relationship between the cost and benefit. Furthermore, people between 40 and 70 years of age benefit more than younger people. Because the risk of heart attack is greater in older people, medicines are more effective and work more quickly.

From the age of 70 years, age mainly determines the risk of heart attack. Since the risk of other illnesses rises, the benefit of preventative medicines falls.

Risk Factor Type II Diabetes

Type II Diabetes is a significant risk factor. People with Type II Diabetes have approximately twice the risk of heart attack.





Risk Factor High Blood Pressure

High blood pressure (hypertension) is also a significant risk factor especially when it occurs together with Type II diabetes.

High blood pressure also means that the heart has to work more.

More effort is permanently demanded of the heart. In the long term, this can lead to weakness of the heart (cardiac insufficiency) and heart failure. In diabetes, long term poor blood sugar control puts eyes and kidneys at risk and raised blood pressure causes additional damage to these organs.

How high is your blood pressure?

My upper (systolic) value is mmHg	.....	**mm/Hg**
My lower (diastolic) value is mmHg	.....	**mm/Hg**

For the risk calculation (Page 18/19), only the upper (systolic) blood pressure value is used.

Risk Factor Cholesterol

Cholesterol is formed in the liver. It is an essential substance for the body and is involved amongst other things in the transport of fats in the circulation. A distinction is made between LDL and HDL cholesterol. LDL cholesterol is also known as “harmful cholesterol”; a **high** LDL **increases** the risk of heart attack. HDL cholesterol is called “good cholesterol”. It acts in the blood by removing fats. A **low** HDL level therefore **increases** the risk of a heart attack.

How high are your cholesterol levels?

My LDL cholesterol is	.....	**mmol/L**
My HDL cholesterol is	.....	**mmol/L**
My total-cholesterol is	.....	**mmol/L**

For the risk calculation (Page 18/19) only the LDL cholesterol level is used.

Risk Factor Smoking

People who smoke more than four cigarettes a day double their risk of heart attack [2].
Furthermore, smoking reduces life expectancy. In a British study 34,000 doctors were monitored for 50 years [3] and the life expectancy of those that had smoked was compared to those who had stopped smoking:

Those who stopped smoking at the **age of 40**, lived approximately **9 years** longer than those who continued to smoke.

Those who stopped smoking at the **age of 50**, lived approximately **6 years** longer.

Those who stopped smoking at the **age of 60**, lived approximately **3 years** longer.

The people in this study were doctors and it is not mentioned how many had diabetes. Nonetheless, there is nothing to say that this data cannot be applied to people with Type II diabetes.

Social Factors

There is a relationship between the health of a person and their social condition. This depends on income, education, work situation and social circumstances, as well as sex, family and migration history. Living in a socially disadvantaged environment increases the risk of illness, independently of how healthily the given person lives or behaves; [5;6].

Health and life expectancy are also associated with the quality of interpersonal relationships to relatives, friends and colleagues [7;9]. Social isolation counts as a risk factor for health [10]. People with low social status suffer from levels of diabetes and heart and circulatory illness that are above average [4;11;12].

Further information about the theme of social and economic factors can be found in the appendix.

How do you estimate your social circumstances?

Although it plays an important role, a person's social situation is not usually taken into consideration, when estimating the risk of heart attack.

The Risk of Heart Attack

Can and should one treat risk factors?

For a long time it was standard practice to treat individual risk factors along the lines: “If the blood pressure is too high then it is treated, if the cholesterol level is too high it is reduced”. However, because of their complex interaction, it is rarely sensible to treat individual risk factors.

The **Concept of Total Risk** has therefore been adopted. That means, the risk of heart attack is estimated taking all risk factors into account. From this estimated risk for a particular person, the need for preventative measures is derived.

There are important exceptions:

- High blood pressure can be due to kidney disease.
- Inherited abnormalities of lipid metabolism can be the cause of very high cholesterol.

In those situations the individual risk factors are always treated.

What is a low or high heart attack risk?

Whether a risk is considered low or high depends mainly on age. For older people 5% is a low risk of heart attack, while in younger people 5% is already means an increased risk.

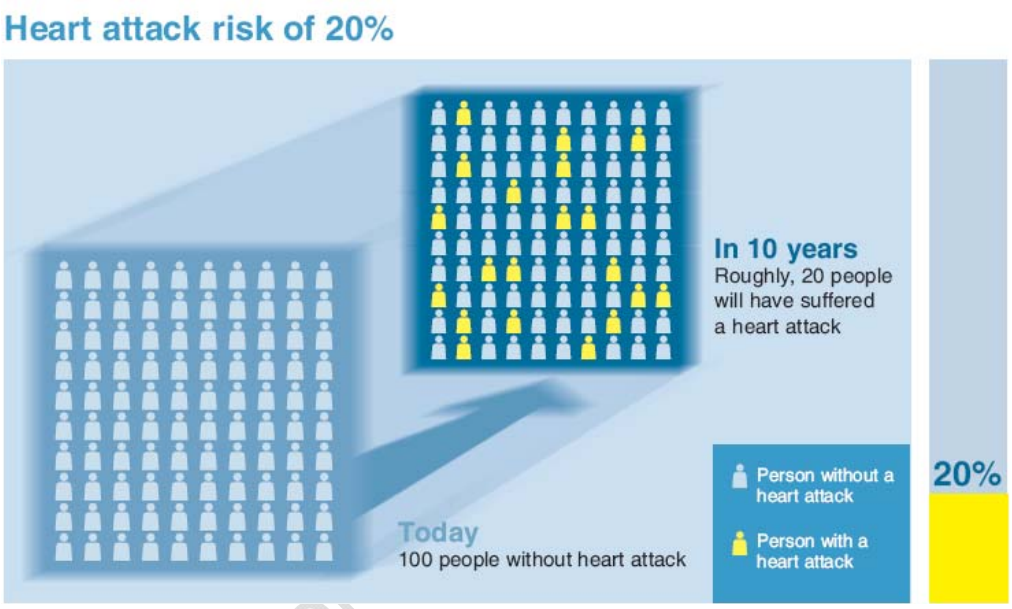
Ultimately, a low risk means that there are no risk factors present. If a risk factor such as diabetes, smoking, high blood pressure, raised LDL cholesterol level or poor social circumstances applies, the risk increases. The more risk factors that are present and the more pronounced they are, the higher the risk of heart attack. In older people with Type II diabetes it can often be greater than 30%.

The Risk of Heart Attack

In some regions of Germany, all cases of heart attack are counted and from this information, it has been estimated which particular risk factors carry the most weight.

What does this mean for one's own risk?

It is not possible to make a precise prediction for an individual person [13]. However, it is possible to give a rough estimate of the risk of a heart attack. Such an estimate is based on observational studies, i.e. the frequency of heart attack in a particular group of people.



This illustration gives an example; a person has a risk of heart attack of 20% in 10 years. This means that of 100 people with similar risk factors, approximately 20 will experience a heart attack sometime in the next 10 years (yellow figures).
80 are spared and do not experience a heart attack (light blue figure). This means a likelihood of 80% of not having a heart attack, where the person used in the example belongs to the 20% with a heart attack or the 80% without a heart attack remains uncertain. This needs rephrasing but I'm not sure how.

There is further uncertainty about risk estimation the severity of the risk factors and the frequency of heart attack vary from region to region. These regional differences are large. For the likelihood of dying due to a heart attack, the differences from one region of Germany to another are nearly 100% [12].

Risk Estimation

Is it possible to estimate the risk of heart attack?

Because of the complex interactions of individual risk factors, the **Concept of Total Risk** has been adopted. The risk of heart attack is therefore estimated by taking into account various risk factors. From this estimated risk, a person's need for preventative measures can be determined.

The following principles apply:

- The risk of heart attack rises with age.
- If there are no additional risk factors, age alone determines the risk.
- The greater the number of risk factors, the higher the risk of heart attack.

Remember that a prediction is based on study findings and relates to the frequency of heart attacks occurring in a group of people. The personal heart attack risk for an individual cannot be determined precisely. It is rather like a weather forecast.

A forecast can nonetheless help you to have a rough idea of your own risk. You can estimate your risk by entering your personal data in the risk tables on the following pages.

Risk Estimation

You require the following information to estimate your heart attack

Risk Estimation

How does the risk estimation work?

This instruction leads you in a few steps through estimation on heart attack risk on the opposite page.

1. **How old are you?**

   40-49 years
   50-59 years
   60-69 years

   Choose your age group

2. **Which of the following risk factors do you have?**

   Smoking
   Raised blood pressure (blood pressure above 140 mmHg)
   Raised LDL cholesterol (**above 3.6 mmol/L**)

3. **How many of these risk factors apply to you?**

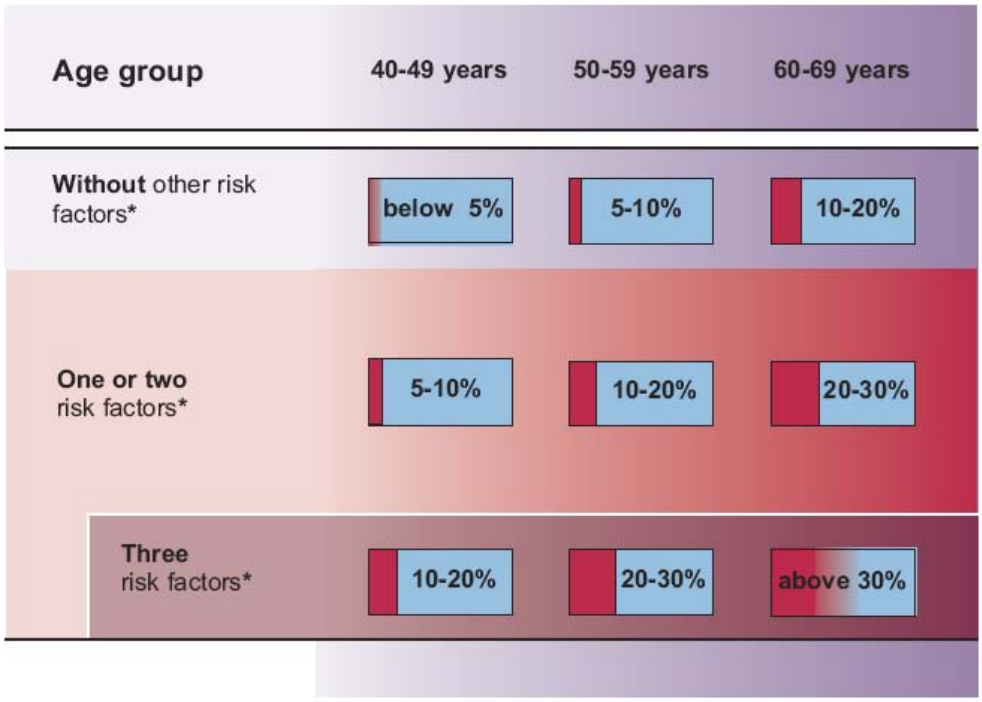
   None of these risk factors
   Two of these risk factors
   Three of these risk factors

   Look for the corresponding number of risk factors in the column on the left.

4. **How high is your heart attack risk?**

   You can find your area of risk where your age group and your risk factor number cross. It is the risk of suffering a heart attack sometimes in the next 10 years.

Risk Estimation



* As risk factors count smoking, high blood pressure, and high LDL-cholesterol

How high is your 10 year heart attack risk ? ..... %

Prevention of Heart Attack

Which preventative measures are effective?

There is a wide choice of preventative measures, but which are effective?
Which measures have been shown by scientific studies to truly reduce the risk of heart attack?

Aspirin is frequently prescribed for prevention. Taking an aspirin a day reduces the risk of heart attack in people without diabetes. However, aspirin is probably not effective in people with Type II Diabetes, who have not had a heart attack [15]. Folic Acid and other vitamin preparations have also proved ineffective at preventing heart attack.

The following measures have been proved scientifically to be of benefit:

- Stopping smoking
- Improving very poor blood sugar control
- Treating high blood pressure
- Taking a statin (a group of medicines that reduce the risk of infarction and the level of LDL cholesterol).

How is it established that preventative measures are effective?

To prove that preventative measures are effective, so called controlled studies are carried out. These investigate whether and to what extent risk can be reduced by the preventative measure in question. You can find further information in the section "How is the Benefit of a Preventative Measure Shown?" in the Appendix (Page 49) and in the section "Explanation of Terms", under "Controlled Studies".

Smoking

What effects does the end of smoking have?

The risk of heart attack falls remarkably when someone stops smoking [2;3].

It is not however known exactly how much the risk of heart attack falls when someone stops smoking. Amount and duration of smoking as well as the presence of other risk factors need to be taken into account. What is clear is that, the more and the longer one smokes, the higher the risk of heart attack.

Blood Sugar Control

Blood sugar control can be judged by the HbA1c value.

"The HbA1c Value" also gets termed the long term blood sugar value. It is established in the laboratory from a drop of blood. It reflects the average blood sugar value of approximately the last three months. A raised HbA1c level means that the blood sugar was raised during this time. The HbA1c value of a person without diabetes lies below 6%. In diabetes it is raised and can, with very poor blood sugar control, reach more than 10%.

In Type II diabetes, values below 8% are recommended [16]. This is meant to prevent damage to eyes, kidneys and nerves. Higher HbA1c levels can cause complaints such as thirst, feeling muzzy headed, fatigue, needing to pass more water, or susceptibility to infection.

Experts give varying recommendations for "good blood sugar control": HbA1c below 6%, 7% or 8%. Which recommendation should one follow? To what value should the HbA1c level be lowered? Can lowering of the HbA1c value also be harmful? What efforts are necessary and can be sustained long-term? Does it take great effort to improve the Blood Sugar Level?

What is the effort of glucose control?

Good blood sugar control can prevent late complications [16]. Blood sugar levels those are too high over several years, damage nerves, kidneys and eyes [17].

The lower the HbA1c level aimed at, the greater effort is required, such as more medications, insulin injections or more blood sugar testing.

Measures which can reduce the HbA1c are for example:

- Weight loss in overweight [16:18]
- If losing weight does not have sufficient effect, blood sugar lowering oral medications or insulin [16].
- If the pancreas produces too little insulin, insulin injections are necessary. Home blood glucose measurement then also becomes important [16].

Blood Sugar Control

Are there risks associated with blood sugar lowering treatment?

Some blood sugar lowering oral treatments or insulin can lead to hypoglycaemia (blood sugar levels that are too low). Hypoglycaemia can be life threatening.

Symptoms of Hypoglycaemia are for example:

- Restlessness
- Strong hunger
- Cold sweats
- Feeling cold
- Poor concentration
- Headaches
- Tiredness
- Unconsciousness

The symptoms can vary in severity and do not always all occur.

With which – and how many medicines are used to lower the HbA1c value does make a difference. Treatments **with medication** with the aim of achieving “at any cost” an HbA1c level that is the same as people without diabetes have (HbA1c below 6%), can be harmful. This was shown by the results of the so called ACCORD Study [19].

Approximately 10,000 patients with Type II diabetes and further risk factors were enrolled in this study and divided into two groups for comparison:

- One group was given **intensive medical treatment** with the aim of lowering the **HbA1c below 6%**.
- The other group received **less intensive treatment**.

In the group with the intensive treatment (HbA1c target below 6%) more deaths occurred. Per 1000 patients, 3 more died than in the other (controlled) group. The reasons for this are not clear.

You can find further information under “ACCORD Study” on Page 54.

Blood Sugar Control

What effect does blood sugar control have on the risk of heart attack?

The most significant scientific study that examined the relationship between blood sugar control and risk of heart attack in Type II diabetes is the so called UKPDS Study from Great Britain. It investigated the advantages and disadvantages of intensive medical treatment to lower the HbA1c level. The UK PDS took place over a period of about 10 years.

An improvement of the HbA1c level from around 8% to around 7% did not result in lowering the risk of heart attack [17]. Furthermore, the death rate was not reduced and the quality of life was not improved by intensive treatment [19].

Participants in the UKPDS had recently diagnosed Type II Diabetes. On joining the study, the average age was 50 years and only a minority were known to have coronary artery disease.

Blood Sugar Control

What effects does blood sugar control have on long term complications caused by diabetes?

In the UK PDS, improved blood sugar control did not lead to fewer heart attacks and the death rate was not improved over the10 years. However, there were fewer complications in the intensive group, who had a lower risk of “any diabetes-related event”. [17].

*The term “**any diabetes related event”** is a collective or embracing term for different complications of diabetes. It included death from hyperglycaemia (high blood sugar) or hypoglycaemia, heart attack, angina, heart failure, stroke, kidney failure, amputation, vitreous haemorrhage in the eye (bleeding from abnormal blood vessels in the eye which can lead to blindness), damage to the retina (that contains the photo receptors), blindness of one or both eyes or eye surgery for cataract.*

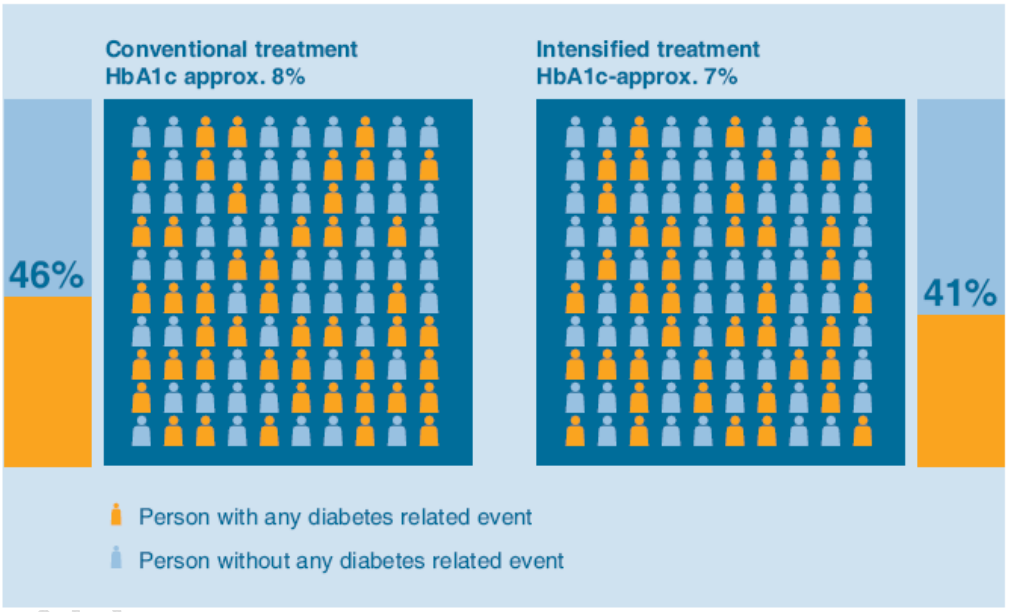
Blood sugar control and “any diabetes related event”

In the following you can read how the situation looked after 10 years of treatment of patients in the UKPDS Study [17].

Imagine two groups, each with 100 patients with Type II diabetes.

One group was treated intensively over 10 years with medication to control blood sugar levels and achieved an average HbA1c of 7%. The comparator (control group) was treated conventionally and achieved an HbA1c of 8%.

- In the group with intensive control “**any diabetes related event”** occurred in 41 of the 100 patients.
- In the group with conventional treatment “**any diabetes related event”** occurred in 46 of the 100 patients.



Therefore, intensive blood sugar control over 10 years prevented “any diabetes related event” in 5 of 100 patients. 95 of 100 people therefore had no benefit from the intensive treatment.

Blood Sugar Control

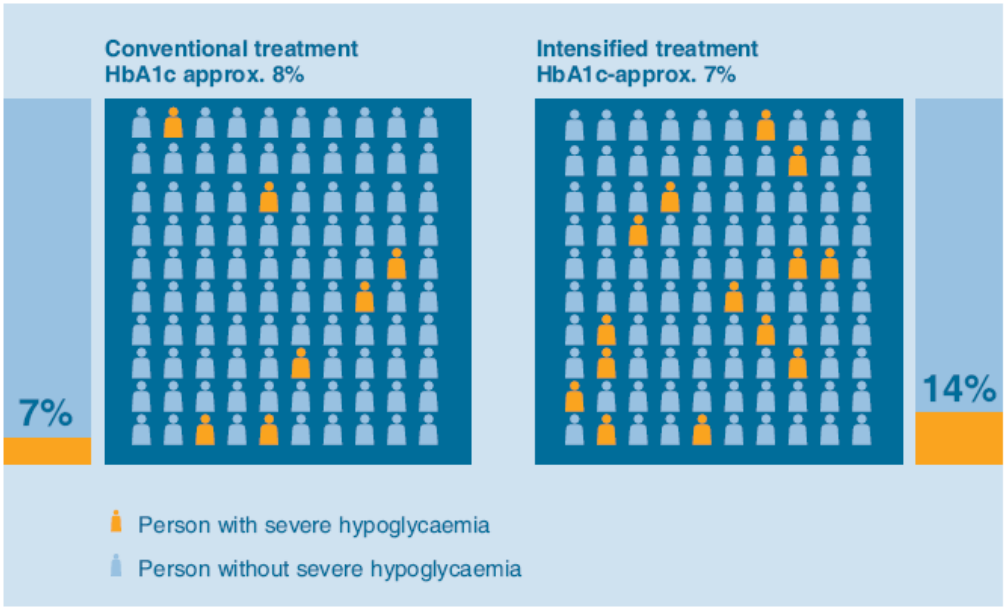
Risk of severe hypoglycaemia with intensive medical blood sugar lowering treatment

Imagine two groups each of 100 patients with Type II diabetes.

One group was treated intensively over 10 years medication to control blood sugar and achieve an average HbA1c level of about 7%. The comparator (control group) was treated in the conventional manner and achieves an HbA1c level of about 8%.

After 10 years the following picture emerges for **severe hypoglycaemia*;**

- In the group with intensive control, approximately 14 of 100 patients suffered at least one episode of severe hypoglycaemia. 86 patients therefore remained free of severe **hypoglycaemia**.
- In the group with conventional treatment, approximately 7 of 100 patients suffered at least one of episode of severe **hypoglycaemia**. 93 patients therefore remained free of severe hypoglycaemia.



Therefore, with intensive treatment over 10 years, an additional 7 out of 100 people suffered **severe hypoglycaemia.**

*an episode of severe hypoglycaemia was an episode that the patient was no longer able to manage without help from another person.

Treatment of High Blood Pressure

Do you have high blood pressure?

The risk of a heart attack is increased in people with high blood pressure [20-24]. The effect of treating blood pressure depends on how much the blood pressure is reduced [25]. Blood levels below 140/90 mmHg are aimed for [16]. For patients with high blood pressure, training programmes are offered. Patients who take part in such training programmes achieve better blood pressure levels and require fewer medicines [16;26;27]. **These all refer to German studies and it looks as if they are published as abstracts – the last 2 in English.**

What effort is required and what risks are associated with treatment for high blood pressure?

Initially an attempt is made to lower blood pressure without medication, e.g. by reducing weight or eating less salt [16]. If this is insufficient, medication can be used. If the treatment goal is not achieved with one medication, several medications can be used in combination [16].

Like all medicines, blood pressure lowering treatments (anti-hypertensives) can have undesirable effects. Side effects from medications are more likely to occur when they are taken in high doses or when too many are taken. The more intensive the treatment, the more medications are used and the higher the risk of side effects.

Complaints such as dizziness or fatigue are usually the result of blood pressure lowering that is too rapid or too profound.

Treatment of High Blood Pressure

What is the benefit of treating high blood pressure?

In the UKPDS, intensive medical treatment of high blood pressure reduced the risk of “any diabetes related event” [28].

“Any diabetes related event” *is a collective or embracing term for different complications of diabetes. It included death from hyperglycaemia (high blood sugar) or hypoglycaemia, heart attack, angina, heart failure, stroke, kidney failure, amputation, vitreous haemorrhage in the eye (bleeding from abnormal blood vessels in the eye which can lead to blindness), damage to the retina (that contains the photo receptors), blindness of one or both eyes or eye surgery for cataract.*

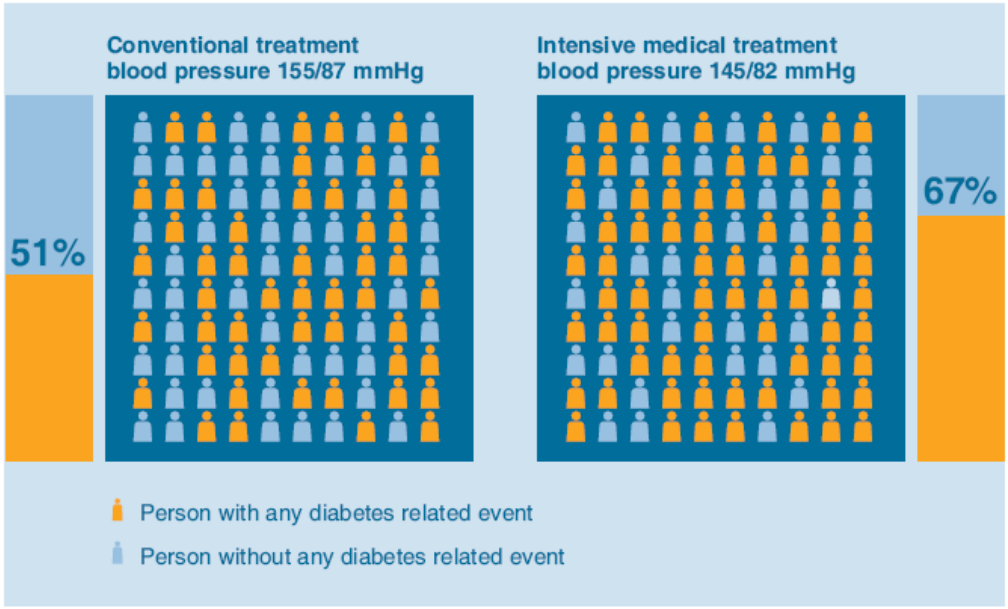
The benefit of intensive blood pressure control was greater than the benefit of intensive blood sugar control.

Treatment of High Blood Pressure

Blood pressure treatment and "any diabetes related event"

Imagine two groups, each of 100 people with Type II diabetes and high blood pressure. One group of patients was treated intensively with medications to lower blood pressure and achieved an average blood pressure level of 145/82 mmHg. A control group was treated in the conventional manner and achieved an average blood pressure level of 155/87 mmHg. After eight years of observation of the patients in the UKPDS:

- In the group with **intensive medical treatment** "any diabetes related event" occurred in 67 of 100 patients.
- In the group with **conventional medical treatment** "any diabetes related event" occurred in 51 of 100 patients.



Through intensive blood pressure lowering treatment over eight years "**any diabetes related event"** was prevented in 16 of 100 patients. 84 patients therefore had no benefit from intensive treatment.

The risk of heart attack was not reduced. However, the risk of heart failure, stroke and death caused by diabetes fell.

Statins for Heart Attack Prevention

What are Statins?

The term “Statin” is applied to a group of drugs that reduce the level of LDL cholesterol and aim to prevent heart attacks. Patients with an increased risk of heart attack are often prescribed Statins for prevention.

Different Statins are prescribed in **Germany.**

The following are the active compounds: Atorvastatin, Fluvastatin, Lovastatin, Pravastatin, Rosuvastatin and Simvastatin.

Statins are offered under various trade names. You can find the active compound on the packet the medication comes in and in the accompanying data sheet or information leaflet.

Maybe you are already taking a Statin. If you are not sure, ask your Doctor.

You can find further detailed independent information about Statins on the patient information pages of the Institute for Quality & Economy in the Health Service (IQWIG) on the internet under: heart disease and diabetes:which Statins are well studied? http:///www.gesundheitsinformation.

What risks and side effects are associated with taking Statins?

Statins are generally well tolerated. The most common side effects are muscle pains and muscle weakness.

Other complications that can occur are:

- Mild liver function disturbances (frequency 1%, i.e. 1 in 100 people who take Statins) [29]
- The most serious recognized complication is severe muscle damage (so called rhabdomyolysis, frequency less than 0.1%, so less than 1 in 1000 people who take Statins [29].

These figures are based on case reports from the USA and only give a rough indication [30].

To date the effects of long term use of Statins are unknown. The longest time period in controlled studies is only 6 years [31]. This is true both for desired and undesired effects.

Statins for Heart Attack Prevention

How is the risk of heart attack influenced by Statins?

Statins can reduce the risk of a heart attack. How much the risk of a heart attack can be reduced with Statins depends on the individual risk of a heart attack (further information relating to this can be found in the appendix on Page 50).

The higher the risk, the greater the benefit of treatment. You can find your personal information on benefit in two steps:

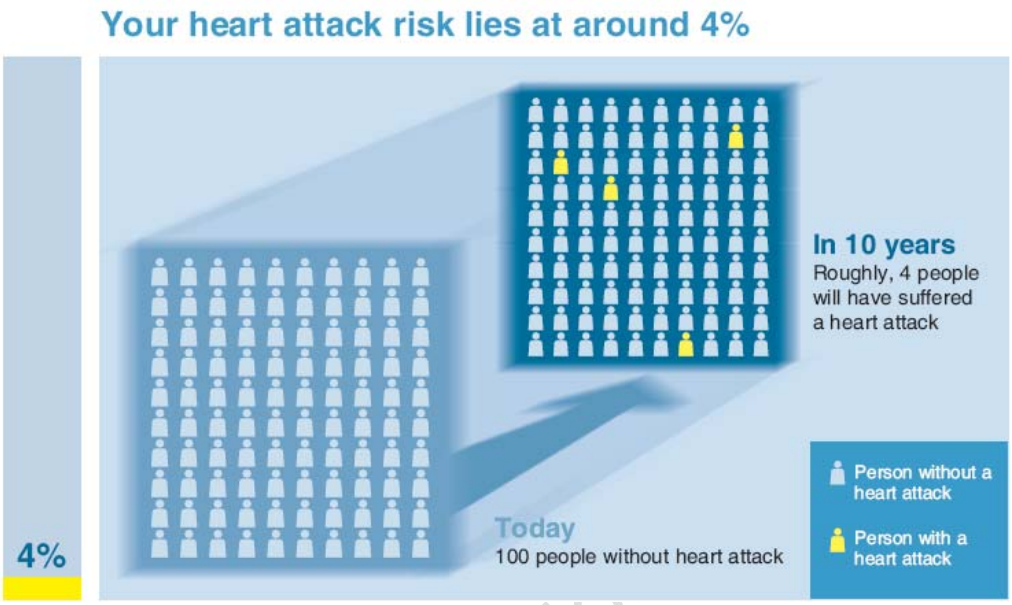
1. Go back to page18 and estimate your risk of heart attack.
2. Find the appropriate page relating to the level of your risk using the following table.

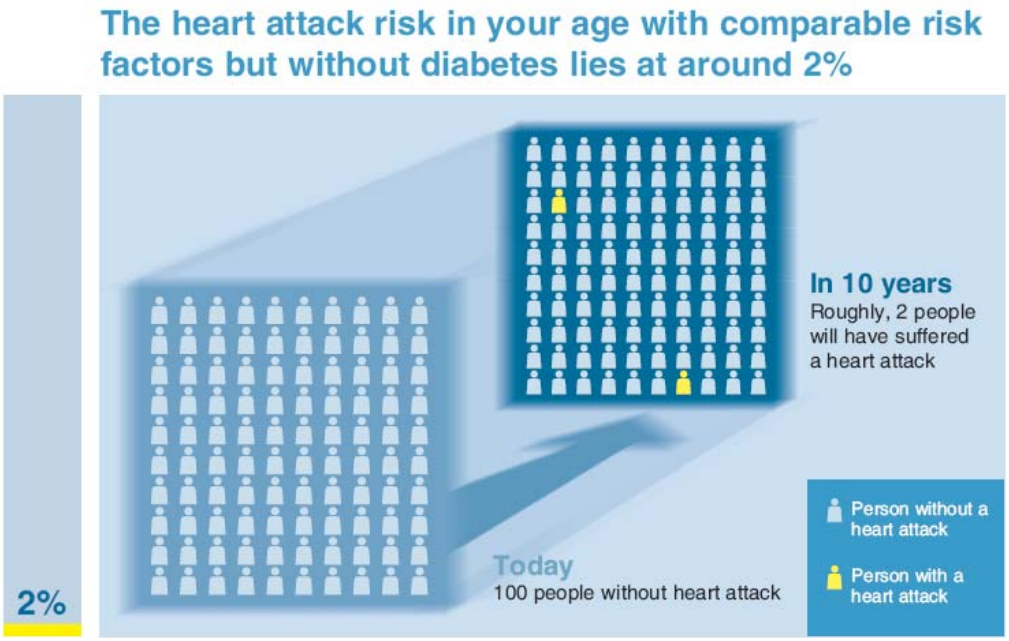
There you can find your personal information about prevention with Statins.

Under 5%	▶ Page 34
5 - 10%	▶ Page 36
10 - 20%	▶ Page 38
20 - 30 %	▶ Page 40
Over 30%	▶ Page 42

Risk of Heart Attack Below 5%

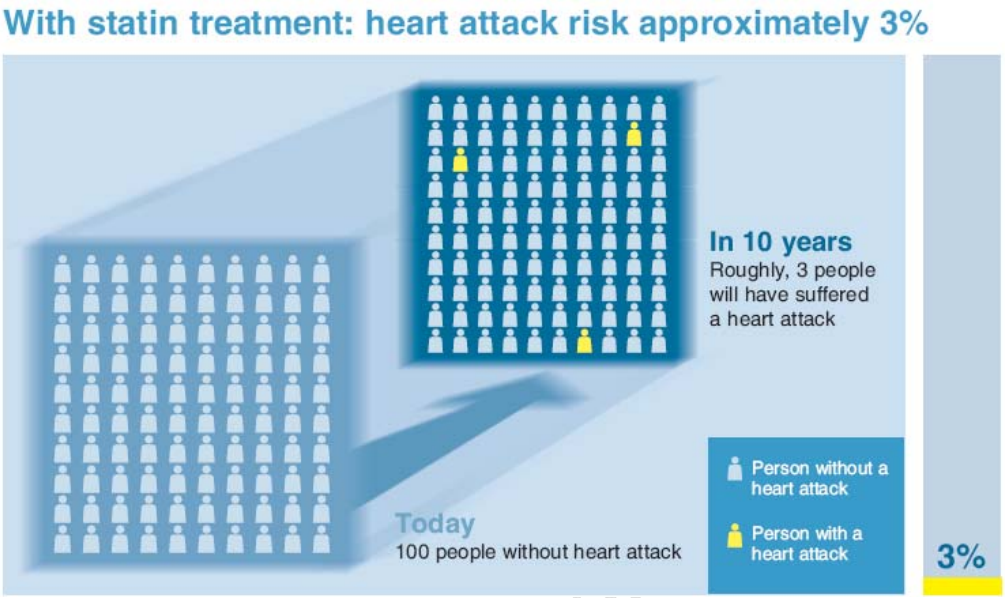
We will assume by way of example that your risk of a heart attack is about 4%. The risk at your age in someone without diabetes is about half as much, so around 2%.





Risk of Heart Attack Below 5%

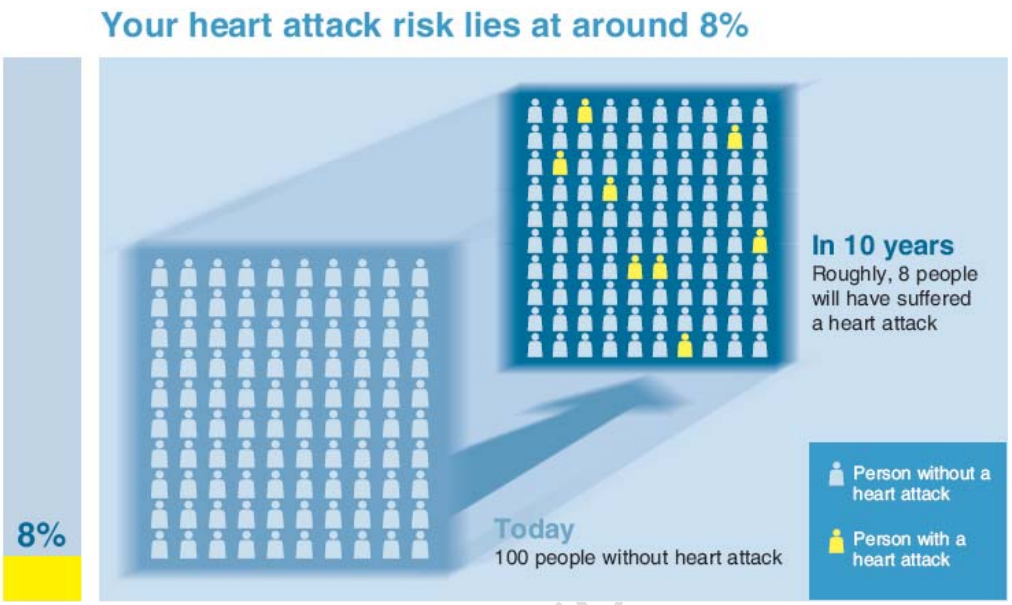
Taking Statins daily reduces the risk of heart attack by about 20% (1/5) [31]. Let us assume that you have a risk of heart attack of 4%. If you take Statins daily, this is thereby reduced to about 3.2%

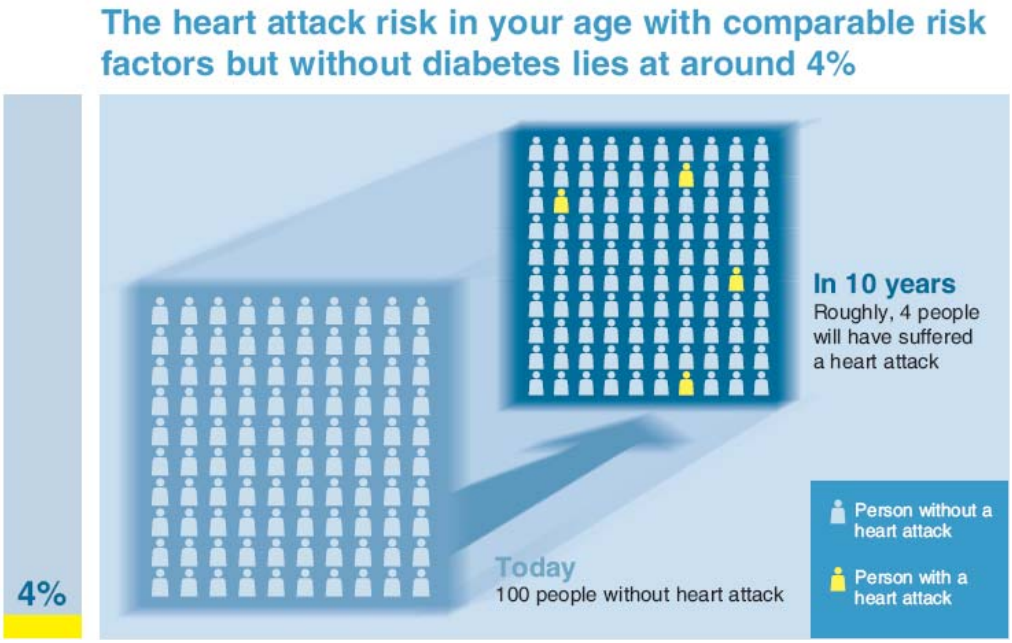


You can skip the next few pages. In these the effectiveness of Statins is described for people with higher risk of a heart attack is described. Please continue to read on Page 44 under “You Decide”.

Risk of Heart Attack Between 5 and 10%

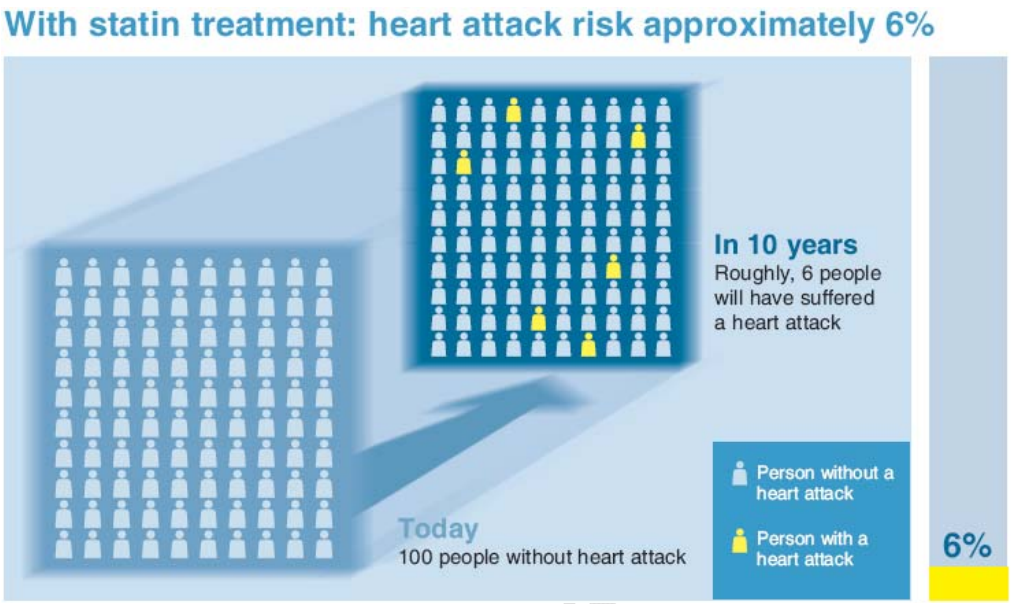
We will assume by way of example that risk of a heart attack is approximately 8%. The risk of a heart attack in someone of your age with similar risk factors but without diabetes is approximately ½ as high and lies at around 4%.





Risk of Heart Attack Between 5 and 10%

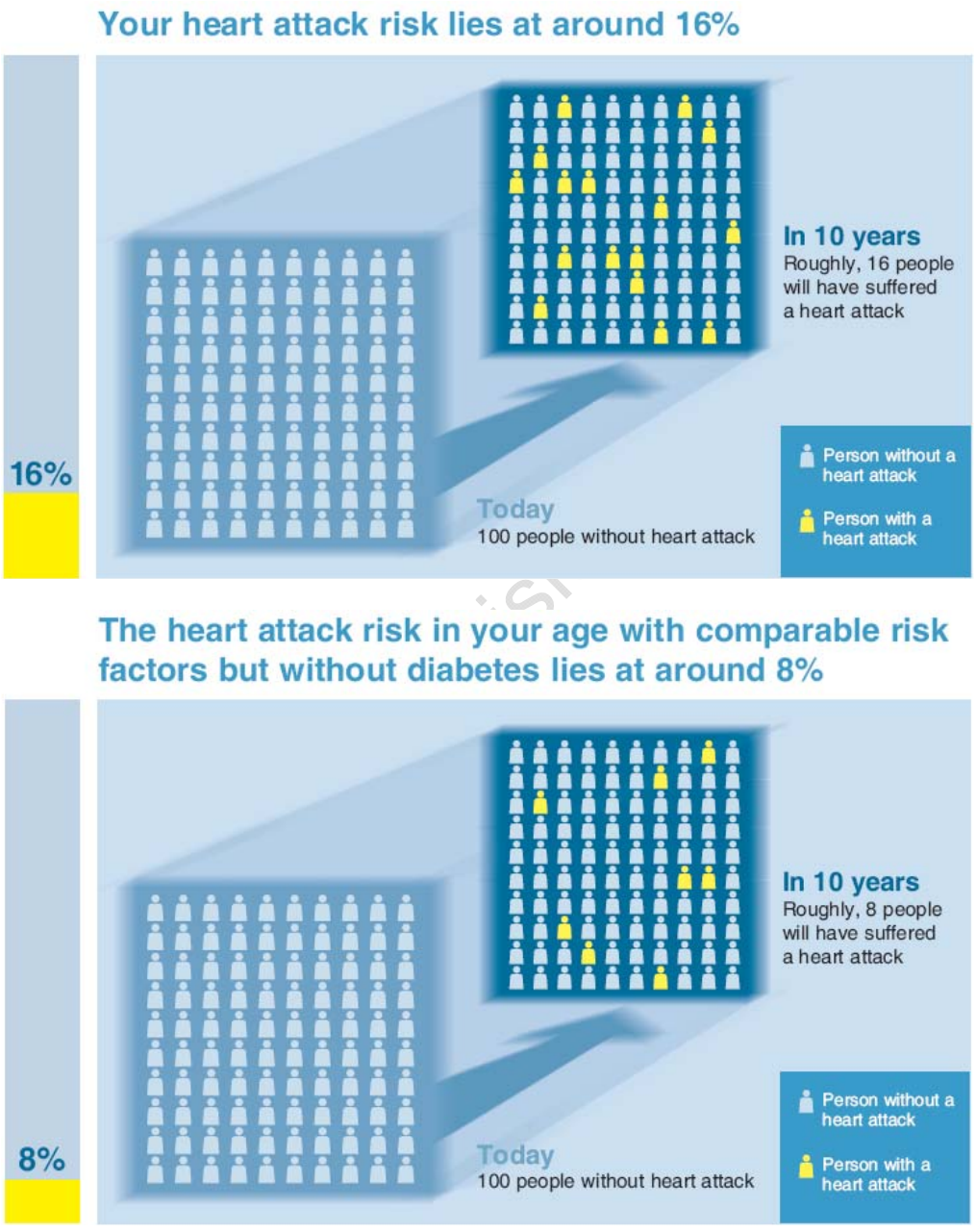
Taking Statins daily reduces the risk of heart attack by about 20% (1/5) [31]. Let us assume that you have a risk of heart attack of 8%. If you take Statins daily, this is thereby reduced to about 6%



You can skip the next few pages. In these the effectiveness of Statins is described for people with higher risk of a heart attack is described. Please, continue to read on Page 44 under “You Decide”.

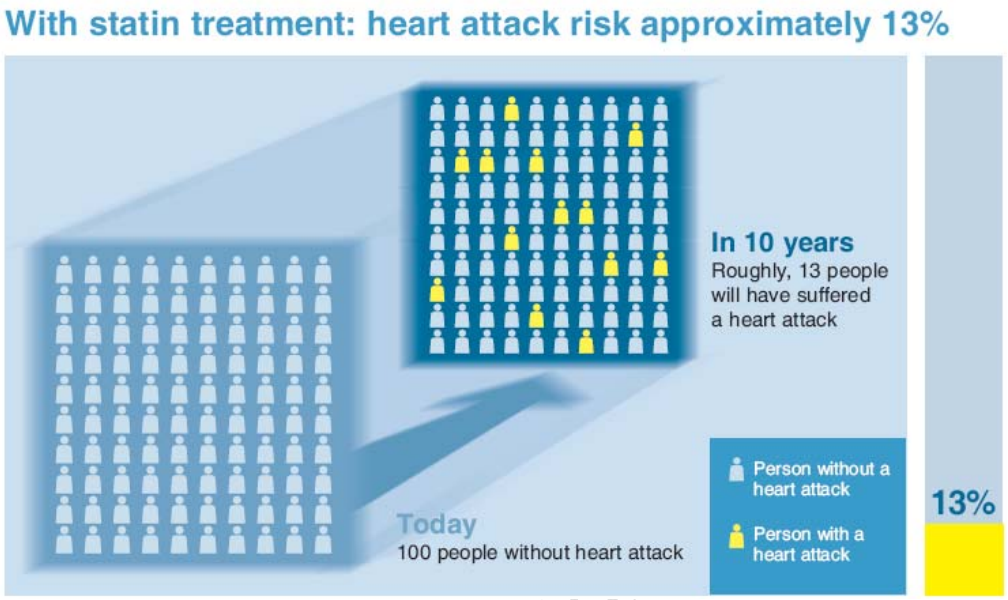
Risk of Heart Attack Between 10 and 20%

We will assume by way of example that risk of a heart attack is approximately 16%. The risk of a heart attack in someone of your age with similar risk factors but without diabetes is approximately ½ as high and lies at around 8%.



Risk of Heart Attack Between 10 and 20%

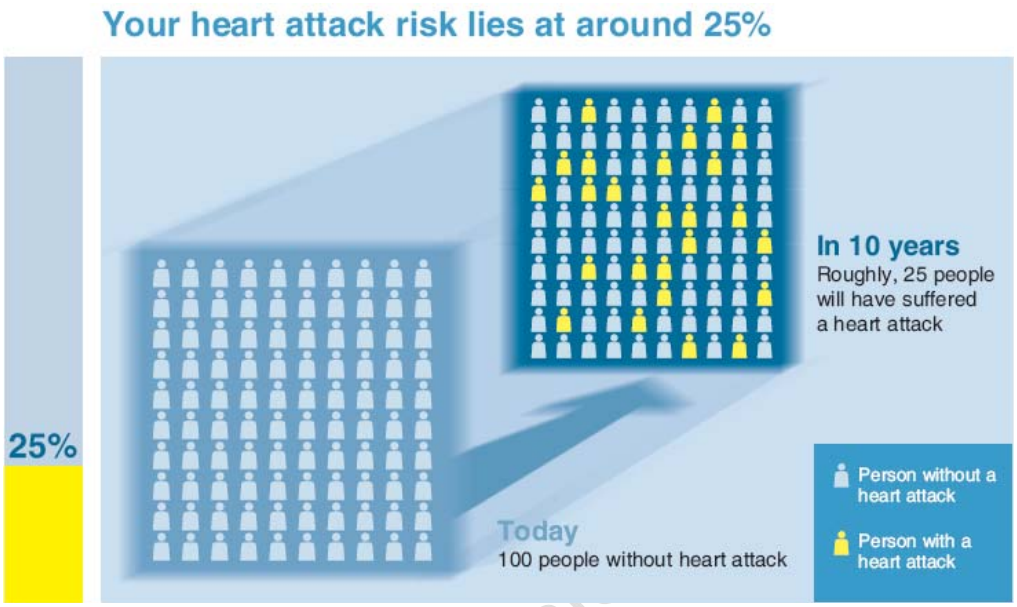
Taking Statins daily reduces the risk of heart attack by about 20% (1/5) [31]. Let us assume that you have a risk of heart attack of 16%. If you take Statins daily, this is thereby reduced to about 12,8%

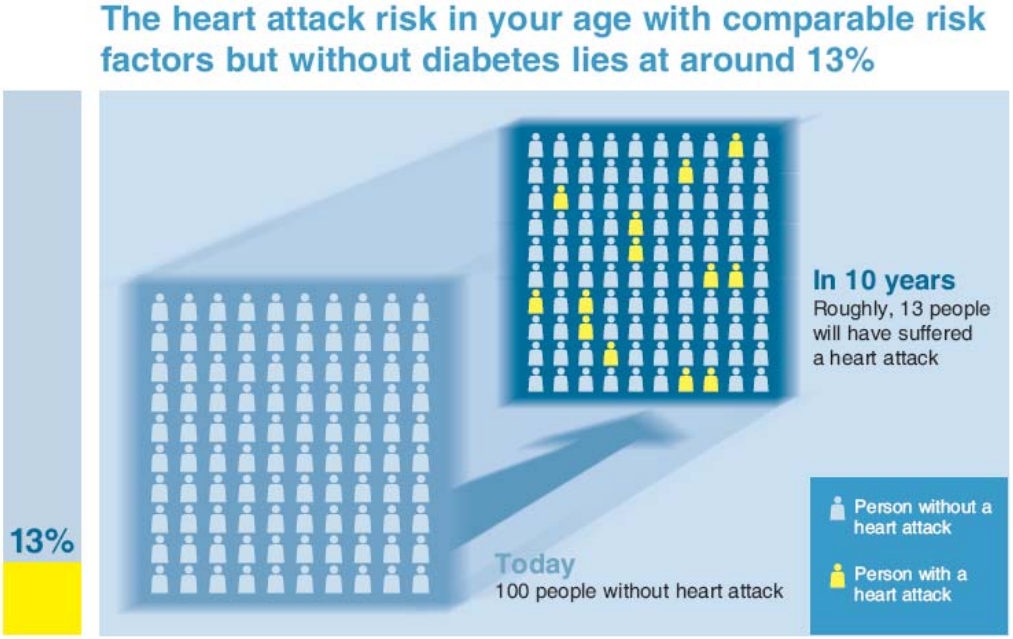


You can skip the next few pages. In these the effectiveness of Statins is described for people with higher risk of a heart attack is described. Please, continue to read on Page 44 under “You Decide”.

Risk of Heart Attack Between 20 and 30%

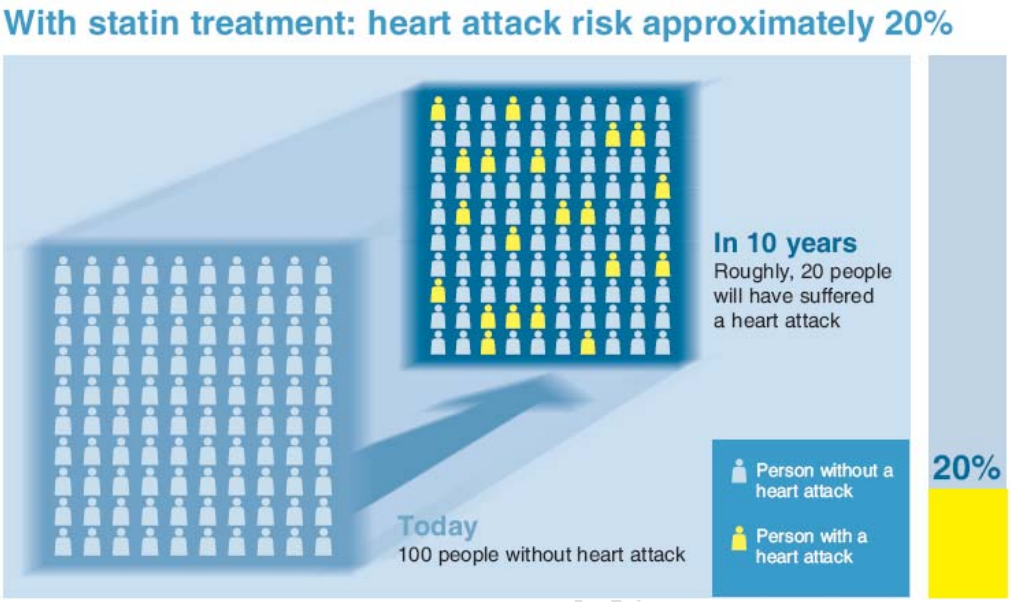
We will assume by way of example that risk of a heart attack is approximately 25%. The risk of a heart attack in someone of your age with similar risk factors but without diabetes is approximately ½ as high and lies at around 13%.





Risk of Heart Attack Between 20 and 30%

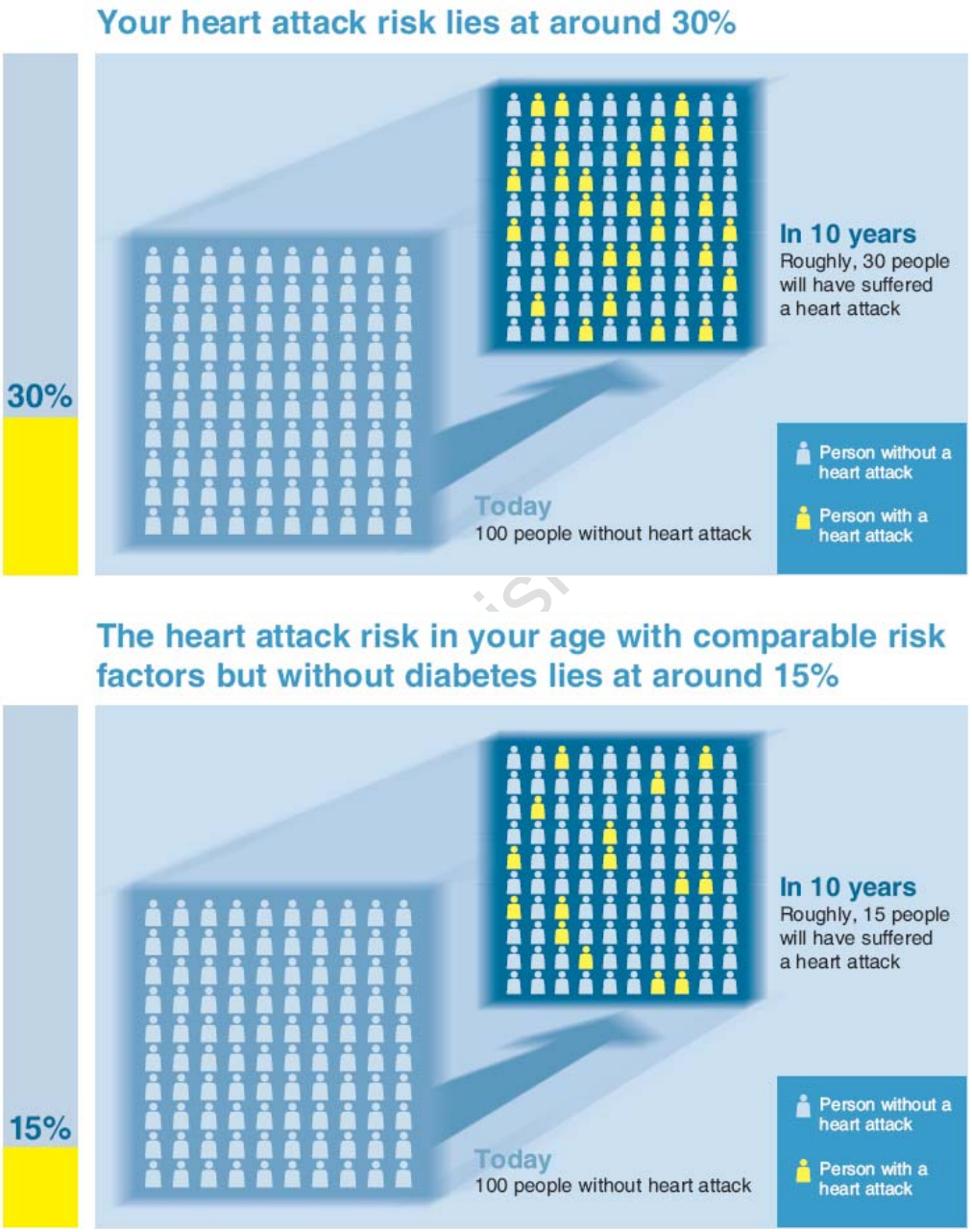
Taking Statins daily reduces the risk of heart attack by about 20% (1/5) [31]. Let us assume that you have a risk of heart attack of 25%. If you take Statins daily, this is thereby reduced to about 20%



You can skip the next few pages. In these the effectiveness of Statins is described for people with higher risk of a heart attack is described. Please, continue to read on Page 44 under “You Decide”.

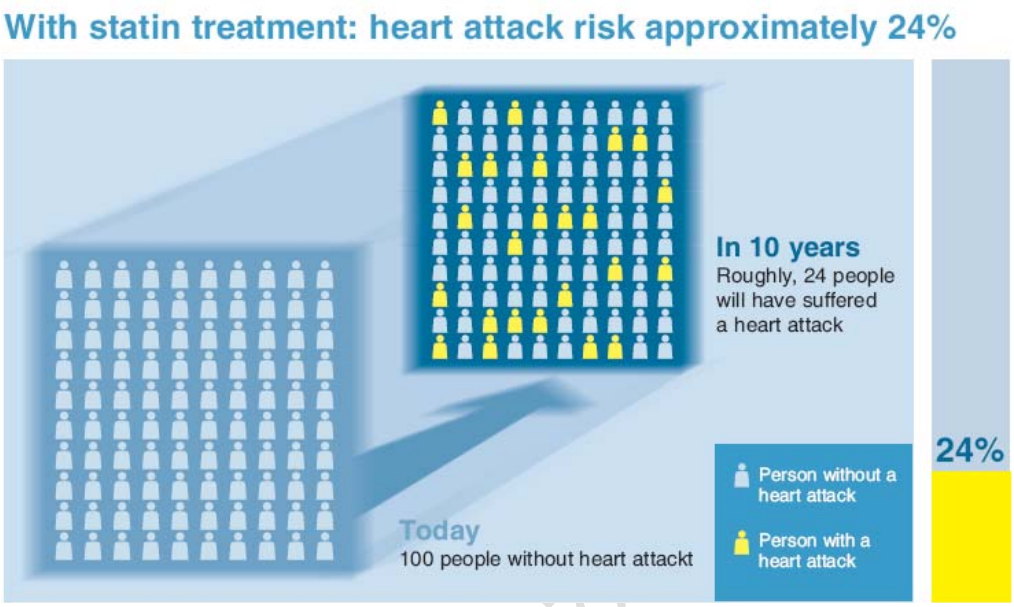
Risk of Heart Attack higher than 30%

We will assume by way of example that risk of a heart attack is approximately 30%. The risk of a heart attack in someone of your age with similar risk factors but without diabetes is approximately ½ as high and lies at around 15%.



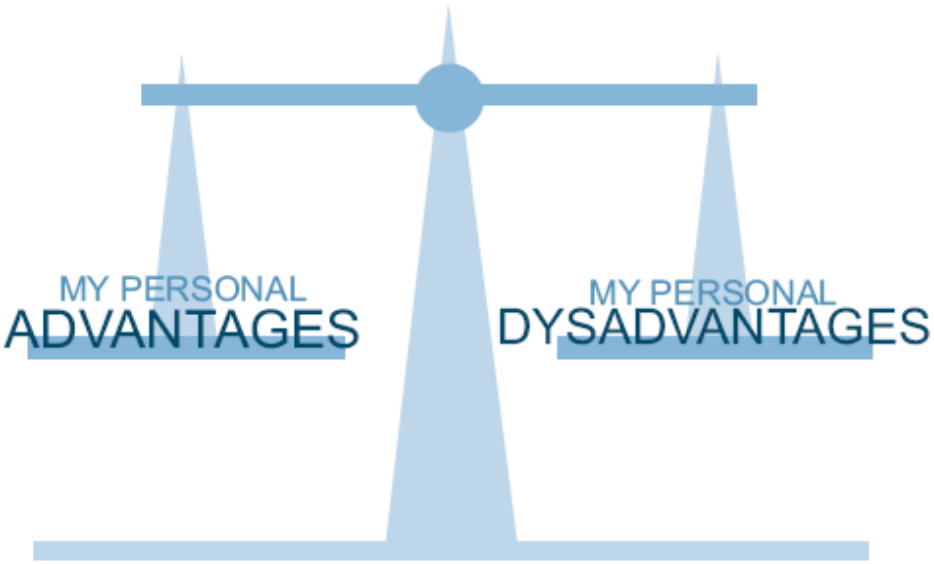
Risk of Heart Attack higher than 30%

Taking Statins daily reduces the risk of heart attack by about 20% (1/5) [31]. Let us assume that you have a risk of heart attack of 30%. If you take Statins daily, this is thereby reduced to about 24%



Please continue reading on the following page under “you decide”.

You Decide



This section should help you to make decisions for or against a preventative measure.

A “good decision” rests on careful weighing up of the pros and cons. A good decision can be a decision against a preventative measure. There is sufficient time to weigh up advantages and disadvantages. Such decisions do not need to be taken immediately.

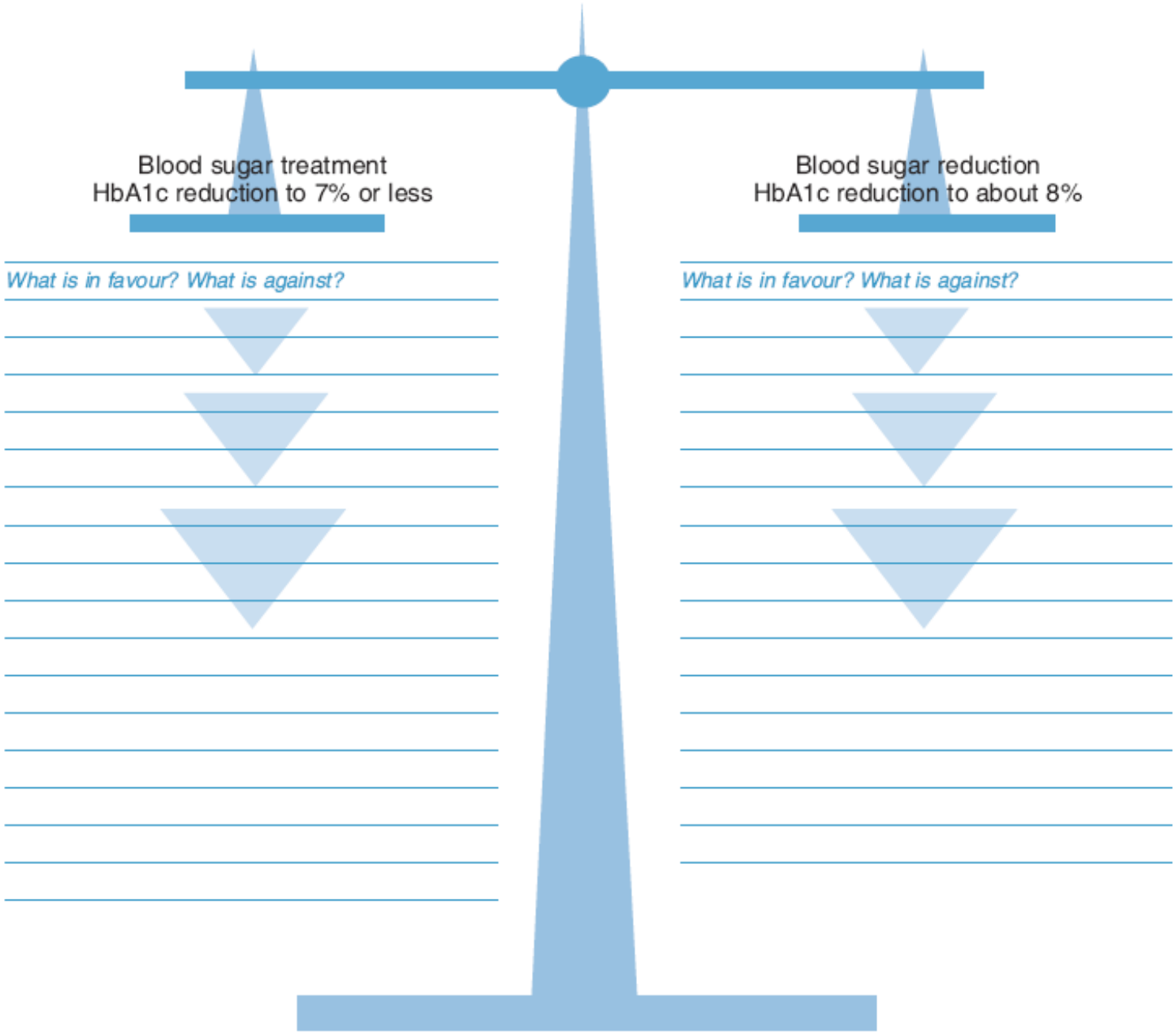
You Decide

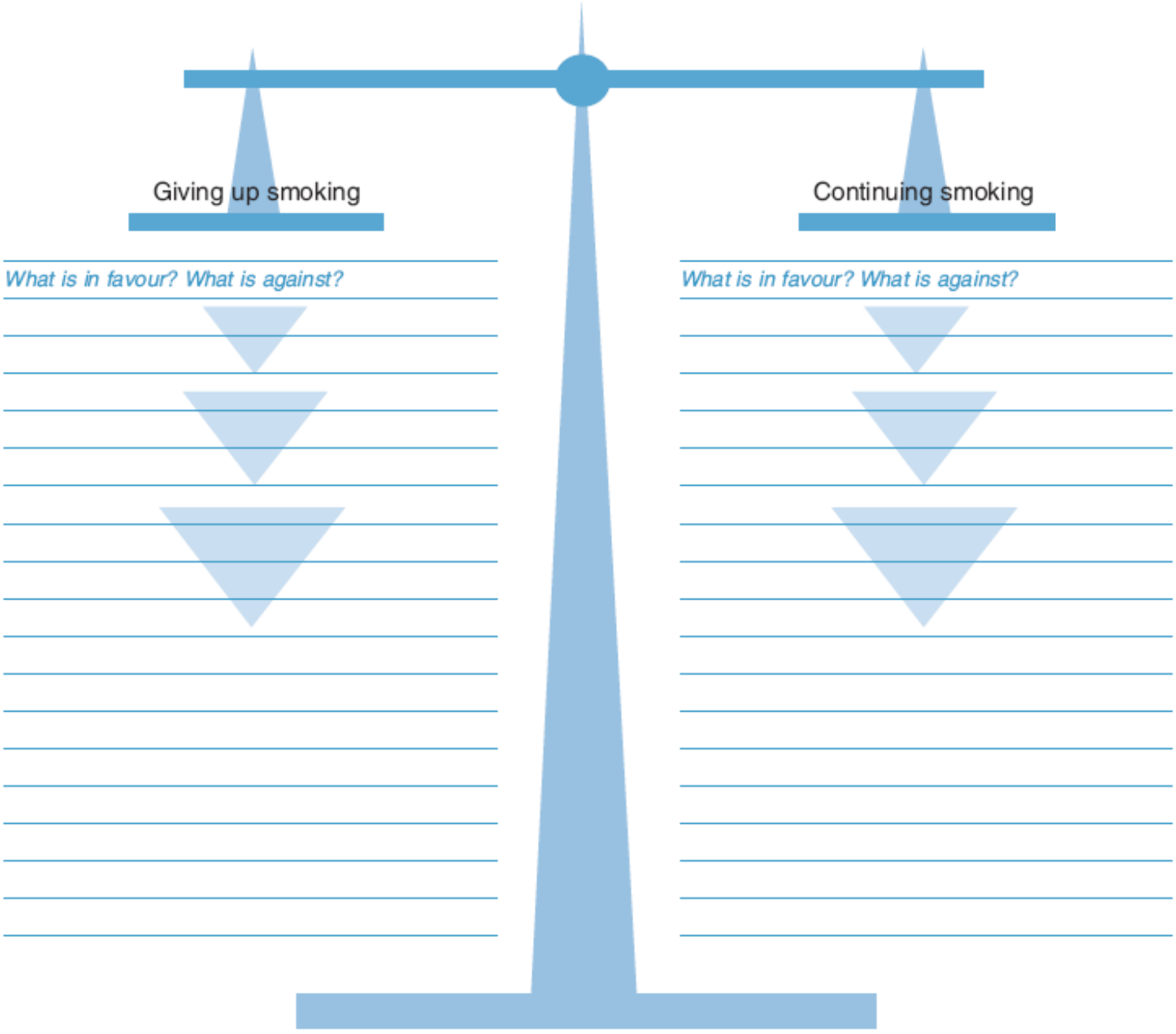
Before you make a decision, it is recommended that you read the relevant information again and discuss your thoughts with family and friends. If you have unresolved questions, you can discuss these with your Doctor.

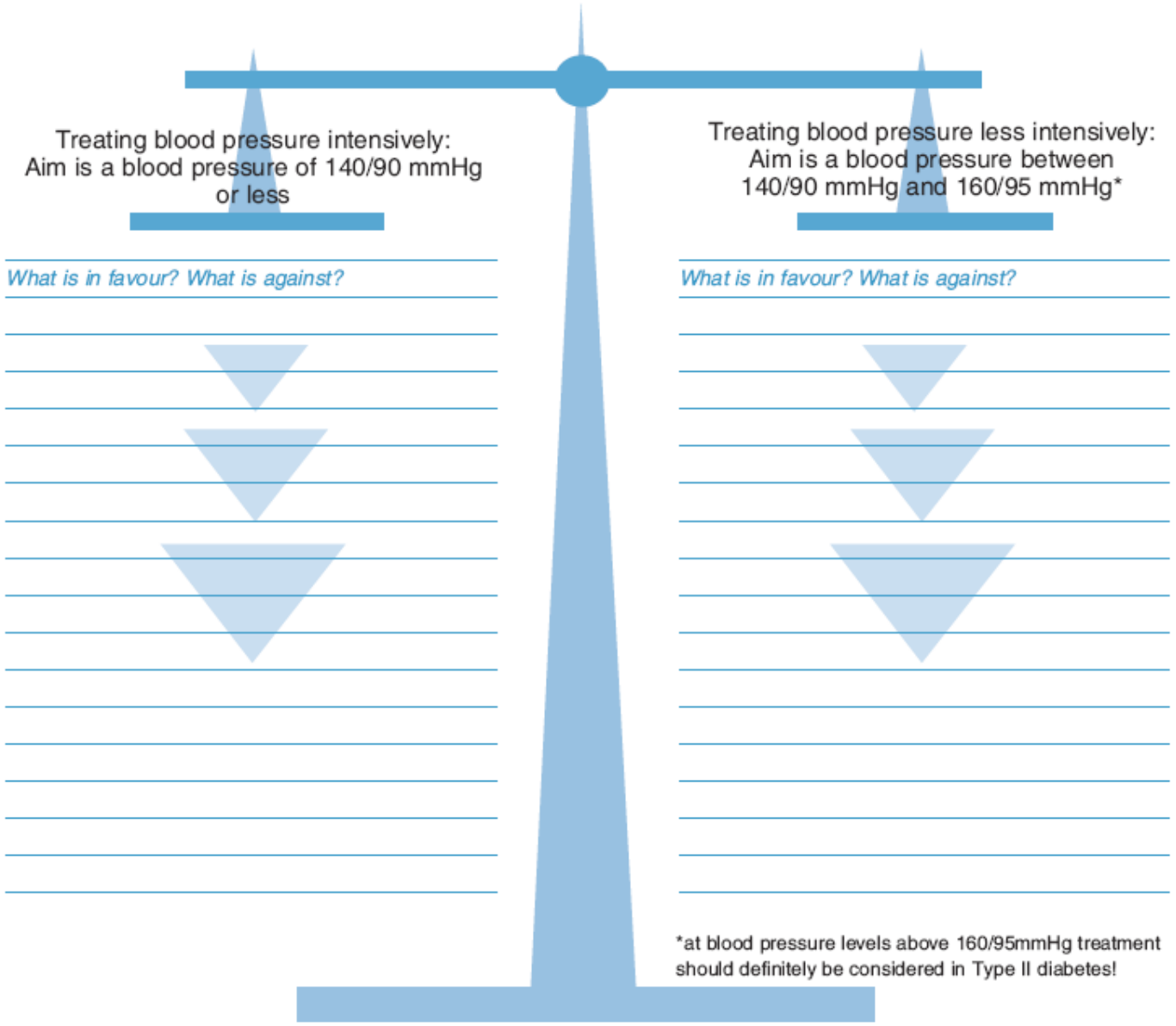
The following way of proceeding may help you to make your decision:

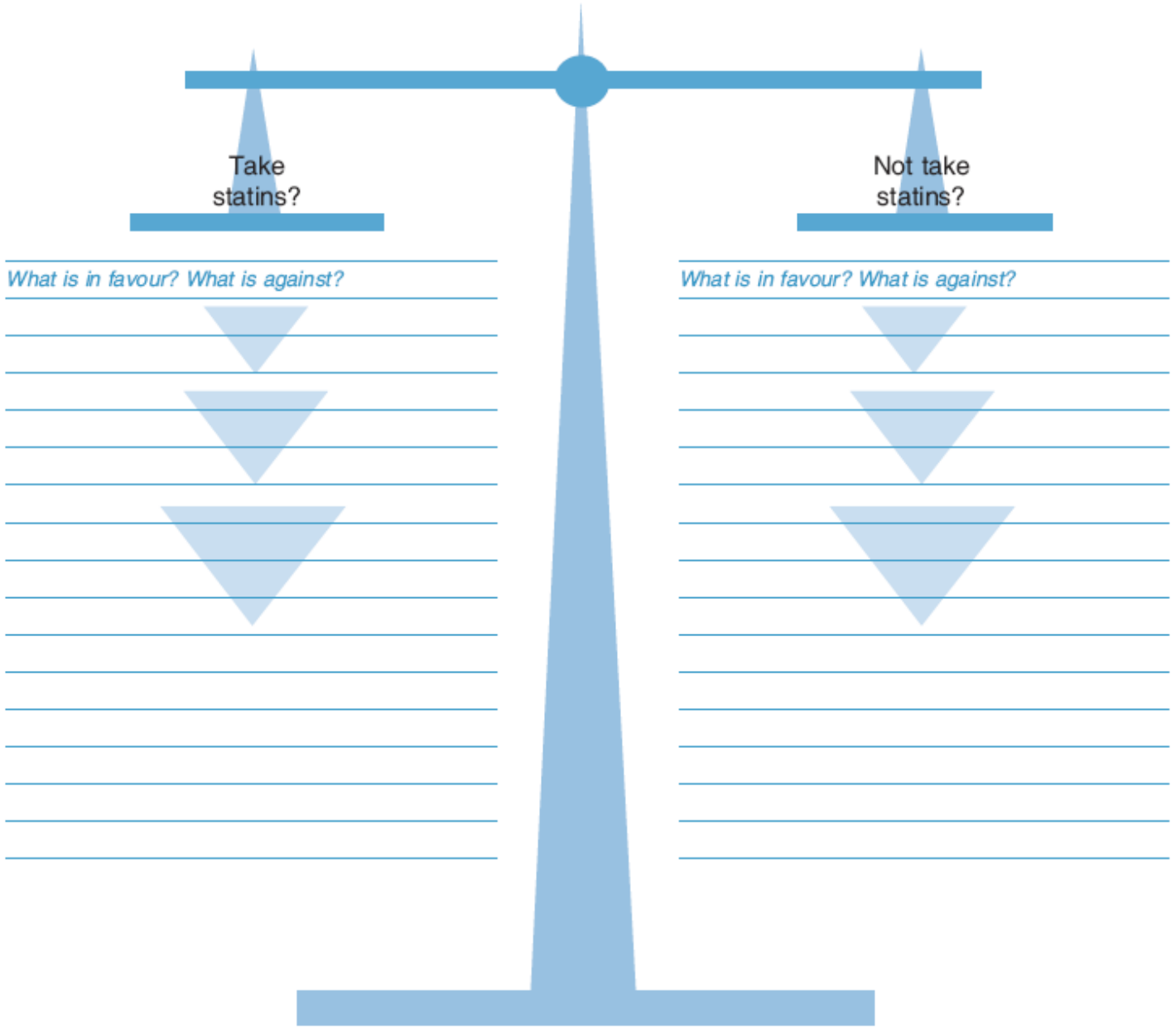
1. Read the information section of this decision aid a second time and make a note in the page margin of those aspects that are important to you in making your decision. If helpful, expand on your personal motivations though to move you towards or against a preventative measure.
2. Use the decision tables. They can be found on the following pages and should help to weigh up pro and cons and to sought the collected aspects and motivations.
   Ask yourself: “what speaks for or against the measure?” and “what speaks for or against the alternative?”.
3. Relate every individual aspect according to how you personally feel about it: “how important is this aspect for me?”. It can be helpful to distribute !!! or “score !!!”.

If you are now still undecided, repeat the procedure.


Blood sugar treatment
HbA1c reduction to 7% or less
What is in favour? What is against?
Blood sugar reduction
HbA1c reduction to about 8%
What is in favour? What is against?


Giving up smoking
What is in favour? What is against?
Continuing smoking
What is in favour? What is against?


Treating blood pressure intensively:
Aim is a blood pressure of 140/90 mmHg or less
What is in favour? What is against?
Treating blood pressure less intensively:
Aim is a blood pressure between 140/90 mmHg and 160/95 mmHg*
What is in favour? What is against?
*at blood pressure levels above 160/95mmHg treatment should definitely be considered in Type II diabetes!


Take statins?
Not take statins?
What is in favour? What is against?
What is in favour? What is against?

Planing and Putting into Action

This table should help you in putting your decisions into action

First of all enter the decisions you have made into column1. Now you can plan together with your Doctor, when you want to put your decisions into effect. Documentation: Here you can for example enter a date by which time you wish to achieve your goal and or a comment on what is preventing a decision or preventing you setting a goal. Under the heading blood pressure treatment you can for example enter what blood pressure level you wish to aim to achieve.

1. Decision	2. Putting the decision into action
Blood sugar control	**Please enter here**
☐ Undecided ☐ HbA1c around 8% ☐ HbA1c 7% or less	e.g. my goal is an HbA1c of ...
Smoking	**Please enter here**
☐ Not relevant to me ☐ Undecided ☐ End smoking ☐ Continue smoking	
Taking Statins	**Please enter here**
☐ Am already taking Statins ☐ Undecided ☐ No treatment for now ☐ Take Statins	
Lowering High Blood Pressure	**Please enter here**
☐ Not relevant to me ☐ Am already on treatment ☐ Undecided ☐ No treatment for now ☐ Training to lower blood pressure ☐ Blood pressure treatment	e.g. my aim is a blood pressure of

Appendix: Further Information

What are the estimations of heart attack risk based on?

Risk estimations are based on evaluations made in the past. In Germany, newly occurring heart attacks are counted in certain regions in which the population is considered to be represented. The findings of the Alsburg heart attack register for example are considered representative. The numbers countered are extrapolated to a period of 10 years and given in percentages [1]. This then counts as the risk of a heart attack for people who live in Germany. The extrapolation to a period of 10 years is arbitrary. One could just as well calculate the risk for five or fifteen years or even for life. The advantage of extrapolating to 10 years is the clarity and either overview that this time period allows.

In the setting of the structure disease management programme for Type II diabetes risk tables are used for risk estimation. They have been developed to estimate the heart attack risk of a person, taking into account the various risk factors. The influence of individual risk factors is included in the calculation, which provides a personal risk assessment in %. You may already be familiar with such tables from your Doctor.

The use of risk tables is however problematic. For one thing, they can give the impression that they could predict the personal risk of a heart attack exactly. Risk tables too are based on study observations in selected groups of people. The prediction corresponds to the risk of the group of people that was actually observed in the original studies. Whether the prediction is valid for you personally, even if the same risk factors are present as in this group, cannot be determined. Furthermore, risk estimations with risk tables are inaccurate [13]. The risk is usually overestimated [32-34].

What however is the alternative to risk tables? The risk estimations on which this decision aid is based relate to the statistical risk of the German population (? Heart attack register) [1], as well as the risk calculations that are produced by the PROCAM risk calculator [21].

Appendix: Further Information

The risk at estimations in this decision aid are deliberately not exact percentage figures but zones or areas of risk in which you can place yourself. These risk estimations should support you in judging how urgent preventative measures and what benefit you have from preventative measures: a high risk can be grounds to be more inclined to decide to take a preventative measure, a lower risk grounds to decide against this. In order to take such decisions, a precise risk prediction is not necessary. It is not about the precision of the estimation, but rather about being able to gain an approximate picture of your own risk.

Woran zeigt sich der Nutzen vorbeugender Maßnahmen?
Der Nutzen einer vorbeugenden Maßnahme zeigt sich daran, um wie viel
das Herzinfarktrisiko bei Durchführung der Maßnahme sinkt.
Üblicherweise wird dies als Risikoreduktion angegeben.

Angenommen,Ihr Herzinfarktrisiko beträgt 20%. Und angenommen Sie erwägen eine vorbeugende Maßnahme, die das Risiko um ein Viertel (25%) senken kann. Dann bedeutet dies eine absolute Risikosenkung um 5 Prozentpunkte (man sagt auch absolute Risikoreduktion von 5%).

Eine Risikoreduktion um ein Viertel bedeutet auch relative Risikoreduktion* von 25%. Bei einem Infarktrisiko von 20%, ist eine relative Risikoreduktion von 25% gleichbedeutend mit einer absoluten Risikoreduktion von 5%. Der Nutzen der vorbeugenden Maßnahme hängt also vom persönlichen Herzinfarktrisiko und der absoluten Risikoreduktion ab.

	Low risk	Medium risk	High risk
Heart attack risk without prevention	5%	10%	20%
Relative Riskreduction due to treatment	-25%	-25%	-25%
Heart attack risk with prevention	approx. 4%	approx. 8%	approx. 15%

* Relative Risikoreduktion bedeutet: die Reduzierung der Rate von Ereignissen (hier Herzinfarkte)
durch die vorbeugende Maßnahme, und zwar im Verhältnis (also relativ) zur Rate von Ereignissen
ohne diese Maßnahme.

Es ist also ein Unterschied, ob das Infarktrisiko 5% oder 30% beträgt. Vereinfacht gesagt: je höher das Infarktrisiko, desto größer der Effekt und
damit der Nutzen der vorbeugenden Behandlung.

Wenn mehrere vorbeugende Maßnahmen zusammenkommen, wird es komplizierter: Drei Maßnahmen, die jeweils das Herzinfarktrisiko um ein Viertel senken, senken es in Kombination nicht unbedingt um drei Viertel.
Risikoreduktionen lassen sich nicht ohne weiteres addieren. Nun könnte
man annehmen, dass sich das Risiko jeweils im Verhältnis zum neu berechneten Risiko Schritt für Schritt vermindert. Also: 20% Risiko minus
ein Viertel wären ca. 15%, minus ein Viertel wären ca. 11,5%, usw. Allerdings gibt es für diese Annahme bislang keinen wissenschaftlichen Beleg. Gegen diese Annahme spricht, dass die einzelnen Maßnahmen in
Wechselwirkung stehen. Es ist eher anzunehmen, dass sich die Wirksamkeit kombinierter Maßnahmen nicht genau berechnen lässt.

Auch scheint es nur möglich, das Risiko für einen begrenzten Zeitraum zu senken, etwa für 10 Jahre. Aussagekräftige Untersuchungen zu diesen
Fragen fehlen.

Soziale und wirtschaftliche Risikofaktoren

Vor allem Menschen mit geringem Einkommen sind in unserer Gesellschaft benachteiligt. Sie haben weniger Chancen auf Bildung, Beruf, soziale Absicherung und Gesundheit [4;35;36], sie tragen das größte Risiko zu erkranken oder vorzeitig zu sterben [4;35-41].

1. Wie stehen Einkommen und Infarktrisiko im Zusammenhang?
Wenn man die Bevölkerung nach der Höhe ihres Einkommens in vier gleich große Gruppen aufteilt, dann haben Männer aus dem unteren Viertel eine um zehn Jahre geringere Lebenserwartung als Männer aus dem obersten Viertel (72 gegenüber 82 Jahre); für Frauen beträgt der entsprechende Unterschied fünf Jahre (81 gegenüber 86 Jahre) [4]. Nach
Untersuchungen aus England und den USA haben Menschen im unteren
Einkommensdrittel ein mehr als doppelt so hohes Infarktrisiko als Menschen aus dem mittleren oder oberen Drittel [42].

2. Wie stehen Bildung und Gesundheit im Zusammenhang?

Höhere Sozialschichten sind meist besser gebildet, was ihre Gesundheitschancen erhöht. Je höher das Bildungsniveau, desto geringer ist das allgemeine Erkrankungs- und Sterberisiko [36;43] und desto geringer ist auch das Infarktrisiko [12].

Bildung schließt auch Informiertheit und Kompetenz zur eigenen Gesundheit und Krankheit mit ein. Menschen mit niedrigem Bildungsniveau mit Diabetes fühlen sich oft schlechter informiert und nehmen seltener an Diabetesschulungen teil [44]. Dies wiederum verschlechtert ihre Gesundheitschancen.

Die soziale Situation als Risikofaktor zu verstehen, stellt eine gesellschaftliche und persönliche Herausforderung dar. Die meisten Menschen sind vermutlich nicht „selbst schuld“ an ihrer sozialen Situation. Es ist schwierig und für manchen Menschen unmöglich, sich für eine bessere soziale Situation zu entscheiden und diese auch zu erreichen.

Es kann nicht vorhergesagt werden, wie stark die vielschichtigen sozialen Einflüsse das Infarktrisiko einer einzelnen Person erhöhen bzw. in welchem Umfang die Verbesserung der sozialen Verhältnisse das Infarktrisiko senkt [4]. Allerdings sollte das Verstehen der Zusammenhänge von sozialer Ungleichheit und Gesundheitschancen ein Schritt zur Verbesserung der Verhältnisse sein.

Es ist nicht vollständig geklärt, wie die gesundheitlichen Unterschiede zwischen den sozialen Schichten erklärt werden können. Die Häufung von Gesundheitsproblemen in den ärmeren Bevölkerungsschichten spricht für die Bedeutung des materiellen bzw. finanziellen Mangels. Auch die umgekehrte Wirkungsrichtung spielt vermutlich eine Rolle: Chronisch kranke und behinderte Menschen haben schlechtere Aussichten auf dem Arbeitsmarkt, unterliegen einem höheren Arbeitslosigkeitsrisiko und erzielen dementsprechend geringere Einkommen [43].

3. Weshalb sind die Erkrankungsrisiken in den unteren Sozialschichten erhöht?

Die Risikofaktoren Rauchen [43;45], Übergewicht, ungesunde Ernährungsweise und Mangel an sportlicher Betätigung [46;47] sind in den unteren Sozialschichten häufiger. Besondere Belastungen sind eine ungünstige Wohnlage, materielle Einschränkungen, soziale Instabilität in Erziehung und Familie und belastungsreiche Beschäftigungsverhältnisse, wie z.B. Lärm, Dämpfe, Hitze, Unfallgefahren, Monotonie, Zeitdruck und belastendes Verhalten von Vorgesetzten [4].

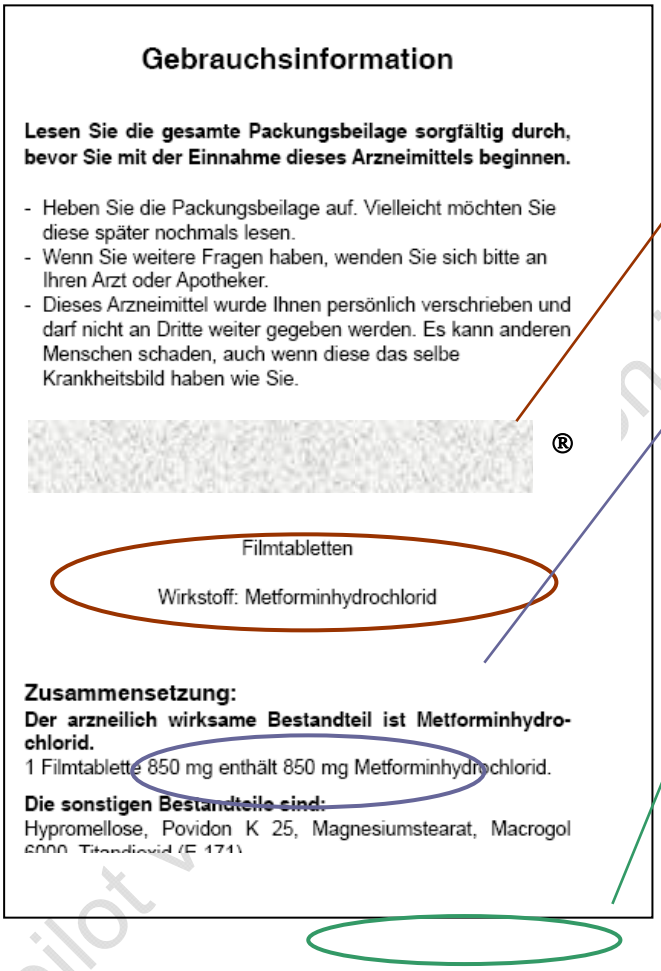
Menschen mit niedrigem Sozialstatus erleiden überdurchschnittlich häufig Diabetes und Herz-Kreislauf-Erkrankungen [4;11;12;48].

Wenn man die deutsche Bevölkerung in Unter-, Mittel- und Oberschicht aufteilt, dann ist das Risiko für Herzinfarkt in der unteren Sozialschichtgegenüber der Oberschicht um etwa 35% erhöht [11]. Nicht bekannt ist der Risikounterschied für Herzinfarkt zwischen den Sozialschichten bei Personen mit Typ 2 Diabetes.

Appendix: Drugs for Glucose Control

Auf den folgenden Seiten finden Sie Informationen zur Wirksamkeit der häufigsten Medikamente, die bei Typ 2 Diabetes zur Blutzuckerbehandlung verordnet werden.
Die Informationen sind nach Namen der Wirkstoffe sortiert.

So finden Sie heraus, welchen Wirkstoff Ihr Medikament enthält.
Auf der Packung und im Beipackzettel (Gebrauchsinformation) sind drei Namen angegeben:



Gebrauchsinformation

Lesen Sie die gesamte Packungsbeilage sorgfältig durch, bevor Sie mit der Einnahme dieses Arzneimittels beginnen.

- Heben Sie die Packungsbeilage auf. Vielleicht möchten Sie diese später nochmals lesen.
- Wenn Sie weitere Fragen haben, wenden Sie sich bitte an Ihren Arzt oder Apotheker.
- Dieses Arzneimittel wurde Ihnen persönlich verschrieben und darf nicht an Dritte weiter gegeben werden. Es kann anderen Menschen schaden, auch wenn diese das selbe Krankheitsbild haben wie Sie.

[redacted] ®

Filmtabletten

Wirkstoff: Metforminhydrochlorid

Zusammensetzung:
Der arzneilich wirksame Bestandteil ist Metforminhydrochlorid.
1 Filmtablette 850 mg enthält 850 mg Metforminhydrochlorid.

Die sonstigen Bestandteile sind:
Hypromellose, Povidon K 25, Magnesiumstearat, Macrogol 6000, Titandioxid (E 171)

1. der **Handelsname**, den das Medikament von der Pharma-Firma bekommen hat

2. der internationale **Name des Wirkstoffs**, z.B. Metforminhydrochlorid

3. der **chemische Name** (arzneilich wirksamer Bestandteil), z.B. Metforminhydrochlorid

Manchmal sind der internationale und der chemische Namen identisch.

Manche Medikamente enthalten mehrere Wirkstoffe (Kombinations-präparate).

Dieses Medikament enthält den Wirkstoff Metforminhydrochlorid

Information about METFORMIN

Information about METFORMIN

Information about XYZ

Glossary

Glossary

Glossary

Glossary

Literature Sources

[1] Gesundheitsberichterstattung des Bundes (2005) KORA Herzinfarktregister Augsburg des GSF-Forschungszentrums für Umwelt und Gesundheit. Daten zu Herzinfarkten in der Region Augsburg. http://www.gbe-bund.de/pls/gbe/, Zugriff am 18.8.2008.

[2] Bjartveit K, Tverdal A (2005) Health consequences of smoking 1-4 cigarettes per day. Tob.Control. 14, S. 315-320.

[3] Doll R, Peto R, Boreham J, Sutherland I (2004) Mortality in relation to smoking: 50 years' observations on male British doctors. BMJ 328, S. 1519-1528

[4] Wille E, Scriba P, Fischer G, Glaeske G, Kuhlmey A, Lauterbach K et al. (2005) Koordination und Qualität im Gesundheitswesen. Sachverständigenrat zur Begutachtung der Entwicklung im Gesundheitswesen.

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