KCE REPORT 324

Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
Belgian Health Care Knowledge Centre

# THE USE OF STATINS IN THE PRIMARY PREVENTION OF CARDIOVASCULAR DISEASE: AN ONLINE TOOL FOR SHARED-DECISION MAKING





KCE REPORT 324
HEALTH TECHNOLOGY ASSESSMENT

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# LIST OF ABBREVIATIONS

| ABBREVIATION | DEFINITION |
|---|---|
| CPG | Committee for Practice Guidelines |
| CVD | Cardiovascular Disease |
| DA | Decision Aid |
| ESC – EAS | European Society of Cardiology – European Atherosclerosis Society |
| EuroSCORE | European Systemic Coronary Risk Estimation |
| HDL | High Density Lipoprotein |
| IDL | Intermediate Density Lipoprotein |
| LDL | Low Density Lipoprotein |
| NIHDI | National Institute for Health and Disability Insurance (RIZIV – INAMI) |
| PROCAM | Prospective Cardiovascular Münster |
| RCT | Randomized Clinical Trial |
| SCORE | Systematic Coronary Risk Estimation |
| SDM | Shared Decision Making |
| TC | Total Cholesterol |
| VLDL | Very Low Density Lipoprotein |

# SCIENTIFIC REPORT

# 1 BACKGROUND: THE USE OF STATINS TO REDUCE CARDIOVASCULAR RISK

This report is a follow-up on the KCE report HTA 306 on the effect of statins (cholesterol-lowering drugs ) in the primary prevention of Cardiovascular Disease (CVD) published in January 2019.[1] This report is mainly based on information contained in that previous report, but it but also contains some recent new evidence. Its main aim is to develop an electronic decision aid to enhance shared decision making (SDM) between patients and physicians on preventive measures in the primary prevention of CVD. We defined primary prevention, in this context, as the avoidance of a first CVD event.

## 1.1 Cardiovascular risk and risk reduction

CVD remains a major cause of morbidity and mortality worldwide. In Europe as a whole (WHO European region), it represents almost half the causes of death, although in many countries in Western Europe CVD has been overtaken by cancer as the main cause of death.[2]

Prevention of CVD is a strategy to avoid early CV morbidity and mortality. It is defined as a coordinated set of actions, either at the population level by promoting healthy lifestyle behaviour, or targeted at individuals by controlling their cardiovascular risk factors (e.g. tackling unhealthy lifestyle through improved diet, enhanced physical activity, smoking cessation or reducing lipid or blood pressure levels with appropriate medications).[3]

Reducing increased lipid levels is important for the prevention of CVD events.[4] Statins (HMG-CoA reductase inhibitors) are currently the main class of lipid-lowering drugs and their use reduces the risk of CVD-associated morbidity and mortality.

***Dyslipidaemia*** is a trouble of function and/or concentration of plasmatic lipids. It includes a number of lipid metabolism troubles that may increase the risk of arterial calcification and early atherosclerosis, in interaction with other CV risk factors. Cholesterol is present in blood as lipoproteins which are classified according to their density and their dimensions: VLDL (very low density lipoprotein), IDL (intermediate density lipoprotein), LDL (low density lipoprotein) and HDL (high density lipoprotein). The other components of lipoproteins are triglycerides, phospholipids and apolipoproteins.[4]

***Total cholesterol*** (TC) is the quantity of cholesterol present in all lipoproteins. The most important fraction of cholesterol is LDL (80%). Its role is to transport cholesterol to cells. It has been shown that total and LDL cholesterol are strong predictors of coronary artery diseases: a 10% of total cholesterol increase is associated with an increase of 20% of coronary artery disease. Conversely, a decrease of 40mg/dl of LDL is associated with a decrease of 20% of coronary artery diseases.[5] The strength of this association depends on other risk factors such as increasing age, male gender, smoking, hypertension, diabetes or low HDL rate. Total and LDL cholesterol are key elements for the prevention of cardiovascular diseases, because they can be managed consequently by healthy lifestyle or by drugs.[4, 6]

***High Density Lipoprotein*** (HDL) cholesterol is important in the process to bring back excess cell cholesterol to the liver in a process known as reverse cholesterol transport. HDL also has anti-inflammatory, anti-oxidant and anticoagulant properties. The relationship between HDL cholesterol and cardiovascular risk is complex. HDL is probably not directly associated with CVD, but may be a risk factor of dyslipidemia: the increase of HDL cholesterol observed with a better lifestyle represent a marker of reduced CVD risk.[7, 8]

The ESC/EAS (European Society of Cardiology and European Atherosclerosis Society) guidelines for the management of dyslipidaemias recommend initiation of prevention of CVD events with drug therapy in individuals depending upon the total CVD mortality risk as assessed with the (European) Systematic Coronary Risk Estimation (SCORE) and on the LDL-Cholesterol (LDL-C) level with or without taking into account HDL-Cholesterol levels (HDL-C).[4]

Intervention strategies can be summarised as:[4]

- For very high risk patients, LDL cholesterol reduction of at least 50% from baseline and an LDL cholesterol goal of less than 55mg/dl are recommended.
- For high risk patients, LDL cholesterol reduction of at least 50% from baseline, and an LDL cholesterol goal of less than 70mg/dl are recommended.
- For moderate risk patients, an LDL cholesterol goal of less than 100mg/dl should be considered.
- For low risk patients, an LDL cholesterol goal of less than 116mg/dl may be considered.

## 1.2 The effect of statins in primary prevention

A healthy lifestyle is the most effective way of reducing the risk of cardiovascular disease and its consequences (KCE report 306).[1] Yet since 2002, the annual number of people who use cholesterol-lowering drugs from the family of statins in Belgium increased from 400 000 to 1 500 000.

Currently, 25% of the population aged 40 and above take these drugs. Despite decreases in price due to the fact that all statins at this moment are available in a generic form, their total cost for the National Health Insurance still stands at around 130 million euros annually (2016).[1] Moreover, the analysis of individual consumption in a sample of the population shows that, in Belgium, approximately 50% of new statins users do not take this treatment correctly or terminate their therapy early.[1]

By lowering the blood cholesterol levels, statins are supposed to decrease the risk of myocardial infarction and cerebrovascular accidents in primary prevention, that is, in persons who have not yet suffered a CVD. But in terms of actual benefit for health, their adverse effects should also be taken into account. The adverse effects are supposedly infrequent, but poorly

documented and can potentially be serious. Since we know that the potential benefits are limited for individuals with a low baseline risk, while their risk of adverse effects remains unchanged, carefully weighing the pros and cons before prescribing them is important.

In this perspective, the 2019 ESC/EAS Guidelines recommends that prescribing a statin should include a shared decision-making approach that engages the patient in a discussion before initiating treatment, especially when it is being considered for primary prevention of CVD.[4] A similar recommendation is also formulated in the Belgian consensus document from NIHDI.[9] A recent systematic review of Randomized Clinical Trials (RCTs) showed that patient-education initiatives (such as providing CVD risk information or dynamic decision-support tools) demonstrated promising results.[10]

Therefore, in this report we develop an online decision-making tool to help physicians to assess the benefits and risks for each patient, and to enable them to reach a "shared and informed" decision on whether or not to take statins.

# 2 TOWARDS SHARED DECISION MAKING IN PRESCRIBING STATINS: THEORETICAL FRAMEWORK

This project aims to develop a tool to use in a Shared Decision Making (SDM) approach during a patient visit. In this section, we will first review the evidence underlying the relevance of this approach and the use of decision aid tools to support it, then we will review the different ways of assessing CVD risk, and finally, we will focus on the available tests allowing to support the decision-aid process for the prescription of statins in primary prevention.

## 2.1 Shared decision making and decision aids

### *2.1.1 The SDM approach*

"Shared decision making (SDM) connotes a process in which physicians and patients share the decision-making process, which is conducted through one or more face-to-face encounters." (Rimer et al., p.1216[11]) with the aim that the patient:

1. understands the risk or seriousness of the disease or condition to be prevented or treated;
2. understands the nature of the preventive service, including its risks, benefits, alternatives and uncertainties;
3. has weighed his or her personal values regarding the potential benefits and harms associated with the service;
4. has engaged in decision making at a level at which he or she desires and feels comfortable.[12]

The SDM approach derives from;[13]

- ethical and legal factors related to patients rights, i.e. patient consent to treatment and the principle of 'informed choice' about available alternatives of the treatment:
- the consumers right movement, i.e. patient autonomy, control and patient chalelenge ti physician authority;
- the changing nature of medical practice in the last decades, i.e. the shift from acute care to chronic care where sickness is any more a temporary status, and implies a potentially long-term physician-patient relationship with monitoring and adjustment of the treatment in which patient and physician are both involved.

Whether or not the overall benefit-harm balance justifies the use of medication for an individual patient cannot be determined by a guideline committee, a healthcare system, or even the attending physician; the individual patient has the fundamental right to decide whether or not taking a drug is worthwhile.[14] This requires an evidence-informed and patient-centred approach.[12, 15, 16]

Evidence-based decisions are based on a thorough understanding of current information regarding the natural course of the disease (in this case: the individual risk of developing CVD without intervention) and the anticipated outcomes of alternative forms of management (in this case: individual absolute risk reduction of CVD under statins, individual risk of harms with statins). Specific information about the range of outcomes expected after starting any medication – including benefits, harms, and out-of-pocket expenses – needs to be thoroughly reviewed, assessed and synthesized, as is also mentioned in the report of the Belgian consensus conference in 2014.[9] The health professionals and their patients need to rely on high-quality evidence to make their decisions. This requires high-quality literature reviews of clinical efficacy and cost-effectiveness.[16, 17]

Patient-centred decisions actively involve patients as much as possible and incorporate patients' preferences, values, and their clinical background in the decision-making process.[14, 15] For example, in primary prevention of CVD, there is a need to balance longevity benefits against medication disutility.[18]

SDM has to be achieved following 4 steps:

1. "The professional informs the patient that a decision is to be made and that the patient's opinion is important;
2. the professional explains the options and the pros and cons of each relevant option;
3. the professional and the patient discuss the patient's preferences; the professional supports the patient in the deliberation;
4. the professional and patient discuss the patient's decisional role preference, make or defer the decision and discuss possible follow up" (Stiggelbout, 2015[19], p.1173).

More recently a three-talk model was developed and adapted:[20]

1. Team talk: "let's work as a team to make a decision that suits you the best"
2. Option talk: "let's compare the possible options"
3. Decision talk: "Tell me what matters most to you for this decision"

### 2.1.2 *Decision aids to support SDM*

To help people make informed choices when faced with complex decisions, a number of multi-criteria decision-making methods have been developed.[15] One popular approach in this field are the so-called decision aids. There is good evidence that the use of patient decision aids may improve patient understanding, empower engagement and self-efficacy, and reduce decisional conflict and support decision making.[21]

Specifically in the case of statins prescription, it was shown that the use of such decision aids enhances communication about the risks and benefits of using statins, improves patient's knowledge, perception of the risk with and without the medicine and satisfaction in people with diabetes. Nevertheless

no significant differences were found in decisional conflict, anxiety, consultation time or compliance.[22, 23]

KCE already produced decision aids in the past, notably in the field of cancer screening (KCE report 216 and KCE report 224).[24, 25] The breast cancer screening decision aid[25] was designed to be introduced in communication tools about breast cancer screening in order to increase informed choice. While the PSA for screening decision aid[24] was developed to support SDM.

## 2.2 Existing systems to assess the cardiovascular risk

There are several systems for assessing the cardiovascular risk. Cardiovascular risk scores are statistical models that include a combination of different risk factors. Each one has a potential impact on the development of cardiovascular disease. The stronger the relation between the risk factor and the disease, the more the risk factor is important. Including the selected risk factors in a multivariate analysis (Cox or Weibull models are generally used) leads to a statistical model that allows the calculation of a *"risk score"* for individual patients. The quality and clinical relevance of a risk score depends on the studied population (size, age, country and year of inclusion), the covariates (according to their effects on the disease), and the duration of the follow-up. Each statistical model has to be validated by internal validation (comparison of the result of the score assessed by the model with the effective CV risk on the studied population) and external validation (comparison of the result of the score and the effective scores in an external population).

Many risk assessment systems are currently available: the Framingham models,[26, 27] the Systematic Coronary Risk Estimation (SCORE),[28] the CV risk estimation model from the Scottish Intercollegiate Guidelines Network (ASSIGN),[29] the Q-Risk,[30] the Prospective Cardiovascular Munster Study (PROCAM),[31, 32] Reynolds,[33, 34] CUORE,[35] the Pooled Cohort equations,[36] and Globorisk.[37-39]

The choice of which risk score to use is complicated due to the fact that guidelines and scientific societies use and recommend different ones, according to their local target population or audience. We will give more detail on the most frequently used ones hereafter, and we compare them in Table 1.

### 2.2.1 *The Framingham model*

The Framingham model was the first risk score to demonstrate the importance of controlling multiple risk factors (blood pressure, total cholesterol, high density lipoprotein cholesterol, smoking, glucose intolerance and left ventricular hypertrophy). The Framingham Heart study cohort consisted of 5573 members, aged from 30 to 74 years, recruited from 1968 through 1975 and followed up during 12 years.[27] All patients included were free of diagnosed cardiovascular disease or cancer. The assessed outcomes were myocardial infarction (MI), coronary heart disease (CHD), death from CHD, stroke, all CVD (ie. CHD, stroke and peripheral vascular disease) and death from CVD. In 2008 equations have been recalibrated and gender-specific CVD functions were developed to predict individual outcomes.[26]

The Framingham score predicts **global CV risk and not only CV death**. A 10-year risk ≥20% is considered as high. It has the advantage that it is based on a rather large cohort but its downside is that this cohort can be considered as historical and that it is exclusively originating from the United States. This score is still widely used; it is recommended by the US National Cholesterol Education Program (NCEP)[40] guideline and the Canadian Cardiovascular Society (CCS) guideline.[41]

### 2.2.2 *The Systematic Coronary Risk Estimation (SCORE)*

The European Society of Cardiology (ESC) Committee for Practice Guidelines (CPG) advocates using the Systematic Coronary Risk Estimation (SCORE) model based on the large European SCORE database.[4, 6, 28] SCORE was developed on the basis of a cohort of 117 098 men and 88 080 women from 11 European countries. A core element of this CVD risk assessment system is that risk is defined as the absolute 10 year probability of having a **fatal** cardiovascular event, in contrast to the Framingham score for a composite endpoint. The risk assessment table is organised by gender (M/F) and smoking status (Yes/No); for each of those four groups the table

indicates the 10-year risk estimate based on age, systolic blood pressure (SBP) and either the total cholesterol level or the total/HDL cholesterol ratio. This risk assessment table originally came in two versions, one for high risk European countries and another one for low risk countries. Belgium is considered to be in the group of low risk countries. Over the years several adaptations have been made: calibration by country (including for Belgium)[42], inclusion of HDL-C as risk factor[43] and recently the inclusion of the modifying effect of age fr the other risk factors, with the aim of reducing the overestimation of risk in older persons.[4]

### 2.2.3 The CV risk estimation model from the Scottish Intercollegiate Guidelines Network (ASSIGN)

The CV risk estimation model from the Scottish Intercollegiate Guidelines Network (ASSIGN) score was developed on the basis of a cohort of more than 12 000 patients from the Scottish Heart Health Extended cohort. This system focuses on 1-year risk of cardiovascular disease events. It includes variables as family history and social deprivation in addition to the 'classical' risk factors of the Framingham risk score. This system is recommended by SIGN (Scottish Intercollegiate Guidelines Network).[44]

### 2.2.4 The Q-Risk

The Q-Risk is another system developed in the United Kingdom. The characteristic of that system is that it is based on data from general practices which are not a random representative sample of the population. Its number of patients is substantial: more than one million of non-diabetic patients. The Q-risk also includes variables as family history and social deprivation. This scale is recommended by the NICE guidelines on lipid modification.[45]

### 2.2.5 The Prospective Cardiovascular Munster Study (PROCAM)

The Prospective Cardiovascular Munster Study (PROCAM, Germany) provided two models focusing on either the prediction of major coronary events or cerebral ischemic events. Data is coming from the PROCAM study, a prospective study that included more than 20 000 men and women who worked in factories in the north-west of Germany. It includes variables such as age, gender, LDL and HDL cholesterol, triglycerides, diabetes, smoking, family history of myocardial infarction and systolic blood pressure. This score is recommended by the International Task Force for Prevention of Coronary Disease.[46]

### 2.2.6 The Reynolds risk score

The Reynolds risk score was initially developed for women alone. Later, a risk score was also developed for men. It includes family history of CVD, and biomarkers such as high intensity C-reactive protein and haemoglobin A1C in addition to the risk factors included in the Framingham risk score. This score is recommended by the American College of Cardiology Foundation/American Heart Association (ACCF/AHA) Guideline.[47]

### 2.2.7 The Pooled Cohort equations

The American College of Cardiology and American Heart Association (ACC/AHA) proposed new equations to estimate the 10 year risk for developing a first atherosclerotic cardiovascular disease (ASCVD) event. The sample used for algorithm development closely represents the US population, including African-Americans and Caucasians.[36]

### 2.2.8 The Globorisk

Globorisk is a cardiovascular disease equation that can be recalibrated for application in 182 countries. The prediction model was defined using data from 8 prospective studies. For each country, they used data from national health surveys to estimate the proportion of the population at different levels of cardiovascular disease risk. Risk scores were recalibrated using country-specific mean risk factor levels and CVD rates for each sex and age group in each countries.[37-39]

**Table 1 – Comparison of existing systems to assess the cardiovascular risk**

| | Framingham | SCORE | ASSIGN | QRISK | PROCAM | REYNOLDS |
|---|---|---|---|---|---|---|
| Data | Prospective studies : Framingham Heart Study | Pooled prospective studies | SHHEC Prospective study | QRESEARCH database | Prospective Cardiovascular Münster Study | Randomized controlled trials. |
| Population | General population in Framingham. Inclusion: 1968–1971, 1971–1975, 1984–1987 | 12 Prospective studies from 11 European countries Inclusion: 1972–1991 | Random sample from general population in Scotland Inclusion: 1984–1987 | Data collected from 1993 to 2008 | prospective study of men and women at work in the north-west of Germany Inclusion: 1978-1995 | Women: Health service employees, Inclusion 1993–1996. Men: Physicians, Inclusion : 1997 |
| Sample size | 3 969 Men and 4 522 women | 117 098 Men and 88 080 women | 6 540 Men and 6757 women | 1.28 Million (QRISK1) and 2.29 million (QRISK2) | 18 460 men and 8 515 women | 24 558 Women, 10 724 men |
| Statistical method | Cox : 10 year risk of CHD events | Cox and Weibull : 10-Year risk of CVD mortality | Cox : 10-Year risk of CVD events | Cox: 10-Year risk of CVD events | Cox model for stroke, Weibull model for 10-year major coronary events: | Cox: 10-Year risk of incident MI, stroke, coronary revascularization, or cardiovascular death |
| Age range | 30-75 | 40-65 | 30-74 | 35-74 | 20-75 | 45-80 |
| CV risk factors | Gender, age, total cholesterol, HDL cholesterol, SBP, smoking status, diabetes, hypertensive treatment | Gender, age, total cholesterol or total cholesterol/HDL cholesterol ratio, SBP, smoking status. Versions for use in high- and low-risk countries | Gender, age, total cholesterol, HDL cholesterol, SBP, smoking (no. of cigarettes), diabetes, area-based index of deprivation, family history | QRISK1: Gender, age, total cholesterol to HDL cholesterol ratio, SBP, smoking status, diabetes, area-based index of deprivation, family history, BMI, antihypertensive treatment. QRISK2 also includes ethnicity and chronic diseases | Age, gender, LDL and HDL cholesterol, triglycerides, diabetes, smoking, and systolic blood pressure | Gender, age, SBP, smoking, hs-CRP, total cholesterol, HDL cholesterol, family history of premature MI (parent _age 60 y), HbA1C if diabetic |
| Recommended by guidelines | NCEP guidelines, CCS guidelines. Other national guidelines recommend adapted versions | European guidelines on CVD prevention | Recommended by SIGN | NICE guidelines on lipid modification | International Task Force for Prevention of Coronary Disease | ACCF/AHA Guideline |

*Adapted from [38];*
*CVD : Cardiovascular disease ; SBP: systolic blood pressure ; NCEP: National Cholesterol Education Program ; CCS: Canadian Cardiovascular Society ; SIGN: Scottish Intercollegiate Guidelines Network ; NICE: National institute for health and care excellence ; ACCF/AHA: American College of Cardiology Foundation/American Heart Association*

## 2.3 Existing decision aids for statin use

Decision aids for statin use are useful to integrate patients' preferences in the decision process, to share the decision with the GP but also because GP's tend to overestimate the survival gain of statin therapy.[48]

No such decision aids adapted to Belgian patients exist in the field of statin-based prevention of CVD. However, examples are found in other countries.

In the UK, **NICE** proposes a 23-pages 'paper' decision aid about taking/prescribing statins or not, based on the recommendations about the use of statins in NICE's guidance on lowering cholesterol to reduce the risk of CHD and stroke.[49a] This document presents narrative information on coronary heart disease and stroke, the way to lower the risk and the role of statins in a question and answer format. A self-administrated questionnaire is proposed to help the patient to clarify the relative importance of the explained issues. Graphics show the different levels of risk for cardiovascular disease (coronary heart disease and stroke) over 10 years in groups of 100 people, and the effects of 20 mg atorvastatin daily it has on that risk compared with no statin treatment. For each level of risk, the same information is shown in two different ways (scales or coloured "smileys") because some people prefer one format to the other.

**The NHS – National Prescribing Centre** proposes a 6-pages 'paper' decision aid,[50b] "to assist health professionals in consultations with patients for whom treatment with a statin is being considered, for primary or secondary prevention of cardiovascular (CV) events. It relates to patients considering whether or not to take a statin at standard doses (simvastatin 40 mg, pravastatin 40 mg or atorvastatin 10 mg, or a lower dose if appropriate because of interactions or intolerability of higher doses)" (p1). The first page is aimed at physicians to inform them about how statins reduce the risk of CV events. A decision aid with coloured "smileys" compares the risk of a CVD event in 10 years for 100 people taking statins compared to no statin treatment.

In Germany, the **Arriba software** supports physicians in individually weighing these and many other questions in the consultation with their patients. The possible options are visualised on the basis of epidemiological and clinical data in a patient-centred way. Several modules are available, including one focusing on cardiovascular prevention. (https://arriba-hausarzt.de/module/kardiovaskul%C3%A4re-pr%C3%A4vention)

It estimates individual risk factor weights (including physical activity, food and smoking cessation), and the probability of future illnesses (heart attack, stroke). The risk calculation is based on the Framingham formula. Several visual outputs are available.

In USA, the **Mayo clinic** has set up a Shared Decision Making National Resource Centre[c]. They have developed several decision aid tools in various domains, including one online tool dedicated to the choice of taking/prescribing statins or not.[14] This online tool is available in English, Spanish, Chinese, Arabian and French. The French-speaking version was developed for Switzerland, and was adapted to local epidemiologic data.[51]

The tool combines a risk calculator and a decision aid.

The risk calculator allows us to choose between several risk assessment methods (according to regional specificities), but all of them are based on the assessment of the risk of myocardial infarction.

- ACC/AHA ASCVD, Framingham or Reynolds for the English, the Spanish, the Chinese and the Arabic versions
- PROCAM (Prospective Cardiovascular Münster) for the Swiss tool

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a https://www.nice.org.uk/guidance/cg181/resources/patient-decision-aid-pdf-243780159

b https://www.parksmed.co.uk/wp-content/uploads/2013/09/Statins_Patient-decision-aids.pdf

c https://statindecisionaid.mayoclinic.org/index.php/site/index?lang=en_gb

All versions calculate the current CV risk of the patients with their actual treatment (no statin, standard or high dose statin) and then allow for comparing it with a hypothetic risk of a patient with the same parameters but taking another form of treatment (again: no statin, standard or high dose statin).

Results are presented as coloured bullets representing 100 persons with the original situation of the patient (no treatment, standard or high dose treatment) compared to 100 with the chosen intervention (no treatment, standard or high dose treatment). Issues are displayed in the same window, presenting the cost of the treatment, side effects, daily routine issue and other benefits of the treatment. The physician has the possibility to add notes and a standardized document summarising the decision aid process can be printed or mailed.

# 3 METHODOLOGY: DEVELOPMENT OF THE BELGIAN TOOL

The decision to develop a new decision aid to support the practitioners in their discussion with patients about prescribing statins or not faced us with the following five choices:

1. the format of the decision aid (paper or online),
2. the choice of the CV risk assessment system to be used,
3. the way we would calculate the impact of the statins on the assessed CV risk (i.e. the algorithms to be implemented in the tool),
4. the choice of the texts and charts to show the results and
5. the choice of the technical characteristics of the website.

## 3.1 Choice for an online tool (KCE)

One particularity of the decision process about statin prescription is that it depends on individual parameters. A generic, static, decision aid would not be sufficient; we had to make it interactive in order to be able to adapt the information to the baseline risk of every individual patient. A decision aid based on a paper version would require numerous sheets (one by level of baseline risk) which would make the handling complex, not mentioning the costs and the logistics required for the dissemination of the tool. For these reasons, we quickly opted for an interactive online tool.

The choice to develop an online tool was also a demand from the GP's themselves, when attending meetings on the previous KCE HTA report on statins (see KCE report 306).[1] They were the ones who suggested such a tool, and they asked for something handy and practical, avoiding paper tools.

We considered the possibility to ask the Mayo Clinic to develop a tool for us (as was done with the Swiss data) but we finally decided to create our own tool. There were several reasons for this decision. Firstly, Belgian data does not allow to calculate the risk for heart attacks like the tool of the Mayo Clinic,

and Belgian practitioners are more familiar with the SCORE system which calculates the risk of dying from a CV event in the next 10 years. Secondly, the Mayo Clinic collects data that becomes their property and that falls under US legislation, while we have to comply with the European data protection rules (GDPR). Thirdly, we preferred to remain owner of the tool, allowing us to host it on the KCE website.

Nevertheless, because of the quality of the Mayo Clinic Statins choice decision aid, we inspired ourselves on its features.

## 3.2 Choice of the risk assessment system SCORE

We choose to base the development of our tool on the Systematic Coronary Risk Estimation (SCORE). There are several reasons for this choice:

- SCORE is widely known and used in Belgium, and there is a recalibrated version for Belgium.
- The recommendation by the European Society of Cardiology and the European Society of Atherosclerosis to use the SCORE system for European populations.4, 6
- The fact that SCORE is based on data from 12 European studies, including 205 178 patients and 7 934 cardiovascular deaths.
- The most recent inclusion years (until 1991).
- The ease of use.

### *3.2.1 The Systematic Coronary Risk Estimation (SCORE)*

The original version of SCORE was created in 2003 and used age, gender, smoking, systolic blood pressure and total cholesterol as risk factors. A parallel version was also calibrated with the total/HDL cholesterol ratio, and after evaluation, the authors concluded that the two systems classify persons to very similar levels of risk. Therefore, the system with total/HDL cholesterol ratio has no advantage over the system with total cholesterol alone.[28] The combination of these risk factors allows for the calculation of the risk for cardiovascular death in the next 10 years. The SCORE distinguishes four categories of risk:

1. Very high risk (>10%): generally concerns patients with existing CV or atherosclerotic disease.
2. High risk (5%-10%): generally concerns patients aged >55years with one isolated high-risk factor.
3. Moderate risk (1-5%): generally concerns young or middle aged patients with one isolated high-risk factor. It should be seen as a warning for the patient to adapt his/her lifestyle, or to correct the concerned risk factor.
4. Low risk (<1%): young patients with all CV risk factors under control.

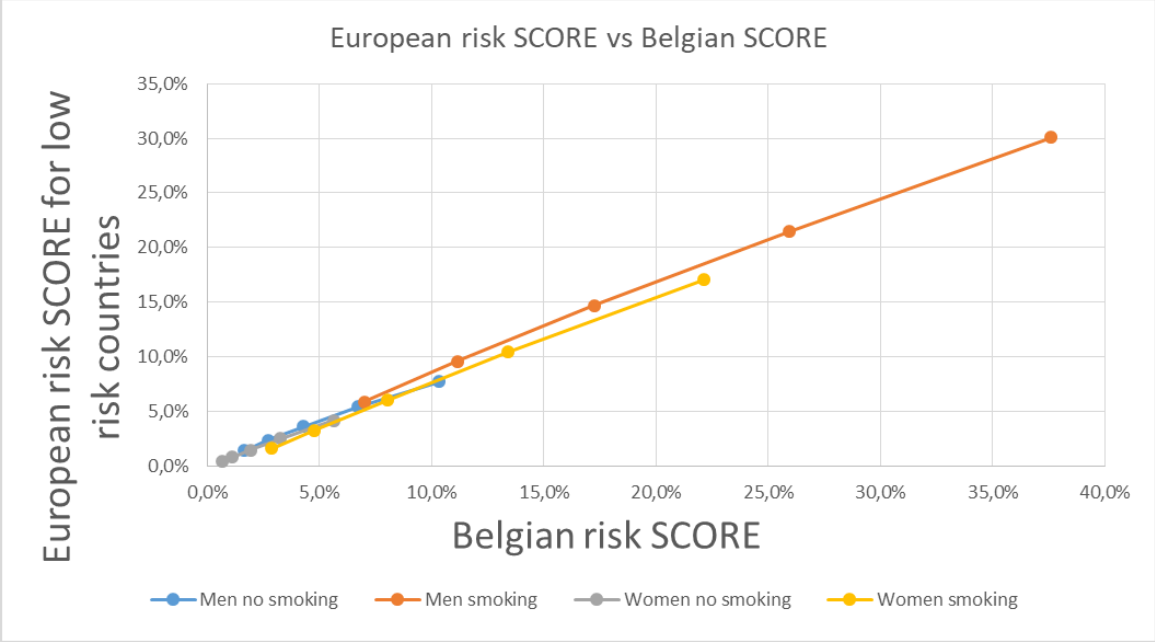
The results are presented as coloured charts so physicians can easily see the risk category for a given patient. However, these SCORE charts have limitations. As mentioned previously, other factors may influence the CV risk such as obesity, sedentary life, metabolic syndrome, triglyceride levels, family history of cardiovascular disease, hyperhomocysteinemia, high level of hs-CRP or ApoB, or even social deprivation. These are not included in the calculation of the SCORE. Patients with diabetes, chronic kidney disease or familial hypercholesterolemia should automatically be considered as (very) high risk and thus are not categorized in the tool. That is why the evaluation of the CV risk score should be seen in its clinical context with the knowledge of the physician about his patient.

A new version of SCORE was developed in 2009, as the relationship between HDL cholesterol and CV mortality was demonstrated. This new version included both total and HDL cholesterol as separate variables.[43]434141. The calibration of the new version of SCORE was derived from a subset of the initial dataset, where HDL values were available. This new version of SCORE was recommended by the European society of cardiology since 2016, particularly for levels of risk just below 5%.[6] Recently, another adaptation of the SCORE was presented taking the modifying effect of age on each of the risk parameters into account. This slightly changes the paper charts but, unfortunately, the formulae behind this recent adaptation have not yet been published.[4]

### 3.2.2 *The Belgian version of SCORE*

Countries were encouraged to develop local versions of SCORE based on local epidemiological evidence. Belgium developed its recalibrated version of SCORE in 2005.[42, 52] In Figure 1, the comparison between European and Belgian versions of SCORE are shown according to gender and smoking status. The relation between Belgian and European SCORE for low risk countries is very good ($R^2$=0.99), even though Belgian risks are higher than the European SCORE for low risk countries.

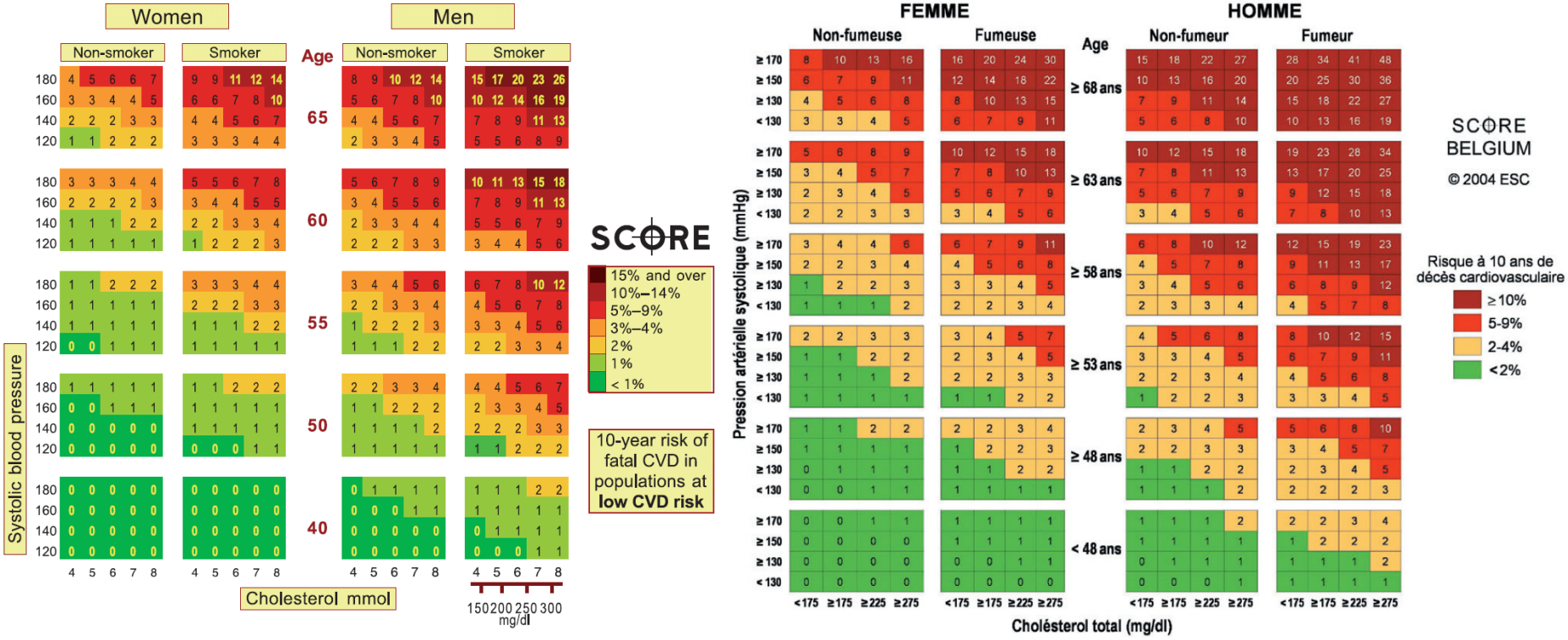
**Figure 1 – Correspondence between European risk SCORE for low risk countries and Belgian risk SCORE**



The interpretation of the charts (presented in Figure 2) is the same for both SCOREs, but the representation is different. In the European SCORE, the charts give exact risk estimates for specific values of age, SBP and total cholesterol, and these thresholds must be interpreted as the middle value of the group at risk. For example, the risk given for age 60 includes the group of age of 58 to 62 years, but the calculation is the exact risk estimated for age=60. On the contrary, the Belgian SCORE chart gives average risk estimates for a group. For example the risk given for age 60 also includes the age group of 58 to 62 years, but the calculation is the average risk for age 58 to 62 years.

Another difference between both charts is that in the European SCORE cholesterol is given in mmol/l, while in the Belgian SCORE cholesterol is given in mg/dl. The conversion factor is 1mmol/l=0.2586*1mg/dl.

**Figure 2 – European risk SCORE for low risk countries (left) and Belgian risk SCORE (right) charts**



When the second version of SCORE was published (with the addition of HDL cholesterol),[43] there was a project to adapt it for the Belgian version, but it turned out to be impossible because the required HDL cholesterol values were missing in the Belgian databases. Therefore, a multiplier system based on the European SCORE was proposed to calculate the impact of HDL cholesterol on cardiovascular risk recalibrated SCORE versions for Belgium.[53]

***Limitations***: SCORE only evaluates the risk for **CV death**, which implies that the baseline CV risks are less elevated and that the difference between estimated CV risk with and without the use of a statin may seem less important. The interpretation of SCORE should first be done by the category of risk. If the test shows that the patient moves to a lower risk category when taking a statin, the reduction of CV risk could be considered as relevant. Pure CV morbidity is not assessed by SCORE, and consequences of CV morbidity can also be important and cause important reductions of quality of life. SCORE is a CV assessment system that is used since a long time while knowing this limitation, and the threshold of patients at risk have been adapted as a consequence: a patient is considered at high risk when the SCORE is 5%, in comparison with the Framingham morbidity score that assesses both CV mortality and morbidity. There, the high risk threshold is considered to be 20%. Clearly, if the impact on CV death is high, it will also be high on CV morbidity.

The ESC EAS guidelines indicated that in men the total CVD event risk is approximately three times higher than the risk of fatal CVD and that this factor is somewhat higher in women.[4] This means that the difference between estimated CV risk with and without the use of a statin may also be multiplied by approximately three to estimate the reduction of the total (i.e. fatal and non-fatal) CV event risk.

SCORE should be interpreted in its clinical context and should not blindly be used in patients with specific conditions such as diabetes mellitus, chronic kidney disease or familial hypercholesterolemia and other conditions that increase CV risk. Those conditions should be considered as '*risk modifiers'* that independently increase the CV risk. Current recommendations consider that presence of these conditions should be associated with the highest risk category. Moreover, other factors may influence the CV risk such as obesity, sedentarity, metabolic syndrome, family history of CV disease, evidence of pre-clinical atherosclerosis, high rates of triglycerides, CRP, fibrinogen or ApoB, as well as social deprivation. The interpretation of the CV SCORE must therefore be done with the GP, taking into account the whole clinical context of his patient.

Another inconvenience is that the age is limited to 65 year. Given the current population this age limit is low, but it is inherent to the algorithm used. We should note that in the ESC guidelines 2019 that were recently published, new SCORE tables are presented which revised the CV risks and with an extension of the age limit to 70 years.[4] Unfortunately, no detailed data about these new SCORE formulae are published yet.

### 3.2.3 *Calculation of the SCORE in the decision aid tool*

In the development of the tool, we implemented the algorithms of the (European) SCORE and of the Belgian SCORE that were found respectively in the original papers of Cooney et al.[43] and of De Bacquer et al.[42]. Algorithms were calibrated for age values between 40 and 65 years, systolic blood pressure values between 100 and 180 mmHg and total cholesterol between 100 and 300 mg/dl.

Three different sets of equations were implemented:

- Equations of SCORE from Cooney.[43]

The calculation of SCORE was implemented with and without HDL cholesterol as a risk factor. The baseline Cox survival was not available. We therefore used the Weibull baseline survival for low risk countries as described in the paper of Conroy.[28]

Baseline survival (S0): survival at the baseline level of risk factors (TC = 6mmol/l, SBP = 120mmHg, non-smoker, with or without HDL = 1mmol/l). Calculated with Weibull survival using the parameters α and ρ (see Table 2)

**Table 2 – Parameters of the baseline Weibull survival**

| | | CHD | nCHD |
|---|---|---|---|
| **Men** | α | -22,1 | -26,7 |
| | ρ | 4,71 | 5,64 |
| **Women** | α | -29,8 | -31 |
| | ρ | 6,36 | 6,62 |

Equation 1: Beta coefficients are shown in Table 3.

- For *CHD*: Survival functions for CHD at current age, adjusted to risk factor levels:

$$S(age)_{CHD} = [S_0(age)] * exp\{(\beta_{TC} * TC_6) + (\beta_{SBP} * SBP_{120}) + (\beta_{Smoking} * Smoking) + (\beta_{HDLc} * HDLc_1)\}$$

$$S(age10)_{CHD} = [S_0(age10)] * exp\{(\beta_{TC} * TC_6) + (\beta_{SBP} * SBP_{120}) + (\beta_{Smokingl} * Smoking) + (\beta_{HDLc} * HDLc_1)\}$$

- For nCHD: Repeat these functions for nCHD enpoint

where *CHD*: coronary heart disease; *nCHD*: non Coronary heart disease; $TC_6$= cholesterol level (mmol/l) – 6mmol/l; $SBP_{120}$= SBP level – 120mmHg; $Smoking$ = 1 if smoker, 0 if non-smoker; $HDLc_1$ = HDLc level (mmol/l) – 1mmol/l

**Table 3 – Beta coefficients for risk factors in the HDL-C function and the function without HDL-C. Beta coefficients are per 1 mmol/increase in HDL-C and TC, per 1mmHg increase in SBP and comparing current smoker to non-current smoker.**

| | Women | | | |
|---|---|---|---|---|
| | **CHD mortality endpoint** | | **Non-CHD CVD mortality endpoint** | |
| | *Model without HDL-C* | *Model with HDL-C* | *Model without HDL-C* | *Model with HDL-C* |
| $\beta_{HDLc}$ | - | -1.196 (-1.561 , -0.830) | | -0.744 (-1.158 , -0.330) |
| $\beta_{TC}$ | 0.137 (0.040 , 0.234) | 0.176 (0.082 , 0.271) | -0.138 (-0.258 , -0.017) | -0.103 (-0.224 , 0.018) |
| $\beta_{SBP}$ | 0.013 (0.007 , 0.018) | 0.011 (0.006 , 0.017) | 0.018 (0.012 , 0.024) | 0.017 (0.011 , 0.023) |
| $\beta_{Smoking}$ | 0.619 (0.323 , 0.915) | 0.647 (0.350 , 0.943) | 0.800 (0.463 , 1.138) | 0.826 (0.488 , 1.164) |
| | **Men** | | | |
| | **CHD mortality endpoint** | | **Non-CHD CVD mortality endpoint** | |
| | *Model without HDL-C* | *Model with HDL-C* | *Model without HDL-C* | *Model with HDL-C* |
| $\beta_{HDLc}$ | - | -0.796 (-0.989 , -0.602) | - | -0.227 (-0.526 , 0.072) |
| $\beta_{TC}$ | 0.230 (0.185 , 0.276) | 0.230 (0.185 , 0.275) | -0.007 (-0.091 , 0.077) | -0.003 (-0.087 , 0.081) |
| $\beta_{SBP}$ | 0.017 (0.014 , 0.019) | 0.017 (0.014 , 0.019) | 0.020 (0.016 , 0.024) | 0.020 (0.016 , 0.024) |
| $\beta_{Smoking}$ | 0.627 (0.513 , 0.742) | 0.606 (0.491 , 0.720) | 0.548 (0.357 , 0.740) | 0.544 (0.352 , 0.736) |

CHD: coronary heart disease; nCHD: non Coronary heart disease; HDLc= High density lipoprotein cholesterol; TC: total cholesterol; SBP: systolic blood pressure

Equation 2: 10 year survival probability for each endpoint:

For *CHD*: $S_{10}(age)_{CHD} = \frac{S(age10)_{CHD}}{S(age)_{CHD}}$

For *nCHD*: $S_{10}(age)_{nCHD} = \frac{S(age10)_{nCHD}}{S(age)_{nCHD}}$

Equation 3: 10 year risk of CVD (coronary and non-coronary) mortality:

$$CVDrisk_{10}(age) = 1 - [S_{10}(age)_{CHD} * S_{10}(age)_{nCHD}]$$

- Equations *of SCORE, adapted version for Belgium*, from De Bacquer et al.[42]

First, the expected 10 years cumulative CVD mortality rates in function of age was described by a fitted quadratic Poisson model, separately for men and women. These mortality rates are fitted for ages between 40 and 84 years. Coefficients are shown in
Table 4.

- For an age $a_i$: $R_0(a_i) = exp\{x + y * a_i + z * a_i^2\}$

Secondly, the estimation of the average age and sex-specific risk factor levels was also fitted.

- Systolic blood pressure (in mmHg): $E[SBP(a_i)] = x + y * a_i + z * a_i^2$
- Total cholesterol (in mg/dl): $E[TC(a_i)] = x + y * a_i + z * a_i^2$ in mg/dl
- Smoking (1 or 0): $E[SM(a_i)] = \frac{1}{\{1+exp[x+y*a_i+z*a_i^2]\}}$

**Table 4 – Coefficient for the calculation of the Belgian SCORE**

| | Women | | | Men | | |
|---|---|---|---|---|---|---|
| | *x* | *y* | *z* | *x* | *y* | *z* |
| $R_0$ | -10.81103 | 0.1046701 | 0.000200 | -10.21151 | 0.1388529 | -0.000309 |
| SBP | 110.11034 | -0.03908 | 0.00874 | 136.37639 | -0.50559 | 0.00913 |
| TC | 81.22894 | 3.96723 | -0.01730 | 148.52651 | 2.55392 | -0.01773 |
| Smoking | 1.09684 | -0.0139384 | 0.000213 | 2.56219 | -0.0818877 | 0.001222 |

Finally, with the local characteristics, the original SCORE was recalibrated using the same estimate of the relative impact of cardiovascular risk factors on the probability of fatal CVD. The result was that for a person i with given age ai,

The 10-year fatal CVD risk could be approximated by: $1-\left(1-R_0(a_i)\right)^{exp\{\lambda_1(SBP_i-E[SBP(a_i)])+\lambda_2(TC_i-E[TC(a_i)])+\lambda_3(SM_i-E[SM(a_i)])\}}$

With $\lambda_1$=0.0185592, $\lambda_2$=0.004595 and $\lambda_3$=0.7213618.

- Equations of Belgian SCORE with HDL cholesterol

For the adaptation of the Belgian SCORE including HDL we copied the methodology of Descamps et al.[53] who developed a multiplier system to calculate the impact of HDL cholesterol on the cardiovascular risk estimate.

The multiplier is calculated on the basis of the European SCORE. For a HDL value $b$, the multiplier is the ratio between the SCORE calculated with HDL cholesterol= $b$, by the SCORE calculated with HDL cholesterol=reference. The references HDL cholesterol corresponds to the average HDL cholesterol in the Belgian population: 1 mmol for men and 1.2 mmol for women.

Multiplier= $\frac{SCORE\ with\ HDL\ cholesterol=b}{SCORE\ with\ HDL\ cholesterol=reference}$ and Belgian HDL SCORE=Multiplier*Belgian SCORE

## 3.3 Quantification of the benefit of prescribing a statin

The effects of the statins on the reduction of the LDL cholesterol levels are very variable from one person to another. Statins have been classified in a NICE guideline according to the average intensity of the effect: 20%-30% is a low intensity reduction of LDL-C; 31%-40% is a medium intensity reduction and above 40% is a high intensity reduction.[1, 45] However, the value of calculating the effect of statin use only as a function of their intensity is limited, because of the variable effect of statins in individual patients.

Moreover, statins are used both in the primary and secondary prevention of CVD. The reduction of the relative risk for cardiovascular disease (CVD), CV events and CV mortality has been shown to be similar in individuals at different levels of risk, but the absolute risk reduction is obviously much greater in those who are at high risk. For this tool, and in this analysis, we focus on primary prevention, meaning patients with relatively low cardiovascular risk who did not experience a cardiovascular event previously.

The systematic review described in our previous HTA report 306B showed that statin treatment was associated with a decreased risk of cardiovascular mortality (RR, 0.72 after 2 to 6 years [95% CI, 0.59 to 0.88]).[1] Therefore, the baseline risk in the tool is the estimate of cardiovascular mortality without statin use (SCORE), while the CVD risk when using statins is reduced by 28%. It could be interesting to adapt this effect specifically to the Belgian population as it has been done for the SCORE. However, no data are available to do so.

## 3.4 Development of the content of the tool

We decided that this decision aid tool should combine the interactivity of the Mayo Clinic tool with the informative quality of the NICE decision aid. During its development, we kept in mind that it was intended for use by general practitioners during consultation to support the decision making process between the physician and the patient on the need to use – or not use – statins in the primary prevention of cardiovascular events and mortality. Such a tool should aim at empowering the patient to make an informed shared decision. The information provided to patients on the advantages and disadvantages of taking statins should also be strictly neutral and based on the best available evidence.

### *3.4.1 Structure and content of the website*

The website comprises four sections (Tabs)

1. **The homepage** of the website displays:
    - some information about its intended use (shared decision-making, to be used during a consultation);
    - some preliminary information for the practitioner on the calculation of the cardiovascular risk;
    - the limitations of the tool (i.e. not intended for use in patients with diabetes, with chronic kidney disease, with a history of cardiovascular problems or with familial hypercholesterolemia);
    - a hyperlink towards the test page.
2. **The test page** only shows an interactive form when the user first arrives on the test page. The sequence is then as follows:
    a. Choice between the Belgian or European Systematic Coronary Risk Evaluation (SCORE).
    b. Entering the patient's parameters (age, gender, smoking behaviour, systolic blood pressure, total and HDL cholesterol levels). Note that the test is intended for patients:
        - between 40 and 65 years of age;
        - with a blood pressure value between 100 mmHg and 180 mmHg;
        - with a total cholesterol level between 100 mg/dl (3 mmol) and 300 mg/dl (8 mmol);
        - with a HDL cholesterol level between 10 mg/dl (0.25 mmol) and 100 mg/dl (3 mmol).

Entering parameters that trespass these values leads to a disclaimer reminding the threshold values and advising a discussion with the GP about the risk of the high values of the concerned parameter.

    c. Clicking on the "Calculate" button.
    d. The result of the test is displayed:

- the risk level of the patient is expressed as Low/Moderate/High/Very high.
    - a visual representation of the risk of CV death in the next ten years with and without statins. The result is graphically displayed as a comparison between 100 individuals with the same baseline risk level as the patient without taking statins and 100 individuals with the same risk level as the patient but taking statins.

    e. A PDF file can be generated with the calculated risk level, the graphic comparison and some information about cholesterol and CV risk. This document can be printed and given to the patient and / or recorded in the medical file.

Two remarks:

- The effect of the statins is calculated on the basis of a meta-analysis study of primary prevention of CVD.1 We didn't make any difference between the doses because they depend on the design of the study, and the dose effect is very variable amongst patients. It is the role of the GP to define the specific statin, the dose needed and the target LDL cholesterol level.
- While the financial aspect of the intervention theoretically has to be included in decision aids, we did not address it because the cost of statins is rather low for the patient in Belgium (12-25 € per year) and should obviously not impact the decision. Bypassing this information makes the quantity of information lighter and therefore eases the readability of the text.

3. The patient information page: the tool also proposes a "patient information" page about cholesterol and CV risk. This section is specifically intended for patients, while the rest of the website is mainly intended for use by healthcare practitioners (i.e. GP's) during the contact with the patient. The content of this patient information section was largely inspired by the NICE patient decision aid "Taking a statin to reduce the risk of coronary heart disease and stroke".49It provides general information about:
    - cholesterol;
    - health implications of high cholesterol;
    - cardiovascular risk;
    - effects of a healthy lifestyle;
    - effects of statins;
    - side effects of statins;
    - use of statins.
4. The 'About this site' page: this page provides information on the evidence underlying the tool and a link towards this scientific report. It also displays the logos of the scientific organisations who gave their approval to the tool

### 3.4.2 *Writing style*

The text was first developed in French because it was the mother tongue of the main researchers; it was then translated into Dutch by a native speaker.

The formulation of our former KCE decision aids on breast cancer screening and on prostate cancer screening was used to write the prototype. The language used was as simple as possible.

The text was tested on patients (see further).

### 3.4.3 *Text drafting*

The texts of the decision aid were written in several editing rounds in French by KCE researchers, in accordance to the International Patient Decision Aid Standards (IPDAS) criteria.

### 3.4.4 *Text simplification*

The decision aid is meant to be accessible to anyone who visits the website. It is important that the information given is clearly understandable by all its users. Therefore the source text underwent a simplification process in order to facilitate its readability, i.e. applying the scientific evidence on how to build the content of patient decisions aids (importance of simple language and clear messages, neutrality of information to empower the reader) and calling upon writing techniques that facilitate the readability of texts. The initial readability level of the text was targeted at 'lower secondary education'. However, after simplifying the text for this level of education, the medical precision of the content was compromised because medical information was formulated as to avoid terminology where possible. The research team agreed that a compromise was needed between readability and precise formulation of medical information. Therefore, the team agreed to target the level of readability at 'higher secondary education'.

**Reformulation of the existing texts:** The Dutch and French texts have been rephrased as simple as possible by a native speaker of the research team (use of short sentences, active verb conjugation and short paragraphs). This revision was carried out in different editing rounds and under the supervision of experts from the KCE, in order to ensure that the 'simplifications' retained the content and structure of the original texts. A total of four different documents were produced (see Appendix 2.1): the *Home* and *About this site* pages, the *Patient information* section, the *Test results* text and the *Patient letter*.

**No identical texts:** obviously, the aim was to achieve consistency between both language versions. However, the structuration of the Dutch and French languages sometimes require language specific peculiarities. The content of the message remains identical in both languages, regardless of linguistic formulation.

## 3.5 Technical development of the tool

### *3.5.1 The choice of technical specifications required for the development*

In the past, KCE developed different tools for a better understanding and use of its guidelines (see http://lowbackpain.kce.be; http://preop.kce.be; and https://kce.fgov.be/en/a-decision-aid-for-an-informed-choice-when-patient-asks-for-psa-screening). In the current case, the tool has to support the caregiver in conducting a conversation with a patient on the prescribing (or not) of statins.

The development of the website was entrusted to an external developer after a call for tenders (LEF).

The tool was developed by LEF using a Web a custom content management system (CMS) without a proprietary database (LEFCMS) based on HTML 5, Javascript and CSS technologies. The CMS stores information in "text" files using "JavaScript Object Notation" (JSON), it allows users (in this case, the KCE) to access it by ID and password and create content via an editing interface using the Markdown markup language.

The product site is multilingual (NL and FR)d, "responsive" (the layout adapts to the type of screen used: computer, tablet, smartphone) and adequately meets Web accessibility standards. The product site also meets privacy requirements such as the General Data Protection Regulations (GDPR). The site has been tested on current web browsers (Chrome, Edge, Firefox, Safari) under the various current operating systems (Android, iOS, macosx, Windows 10).

The chosen technical platform offers a good durability to the tool: compliance with Web standards, simple Web hosting, few technical updates to be planned. To ensure accessibility, the application was tested for compliance with the Web Content Accessibility Guidelines (WCAG) 2.0.

Great care was taken to ensure optimal user experience. The font style and size were chosen to comply with the standard guidelines for readability. The application has a responsive layout that supports most displays across laptops, personal computers, tablets, and smartphones.

The colours and style of the "smileys" in the tool were chosen to make sure the differences between them would be maximally visible for most people, including those with colour blindness.

[d] Other languages could be provided in the future if there is a particular need.

### 3.5.2 The development progress of the tool

Three version of the tool were published. The "commit log" of the tool which described the different building steps is available in appendix 4.

- The Alpha version: a version for KCE team.

The development of the first draft was done after the KCE team brainstormed on its potential general design and subdivisions: homepage, test page with the implementation of the algorithms (original version of SCORE), the patient information page, and the "about this site" page.

While KCE remained in charge of the content of the website, LEF provided a framework that could display the large amount of information in the most convenient way for the user.

The process of further refining the content of the website was done in an iterative manner: the LEF team suggested several possible building blocks and structures, while the KCE team gave their feedback, together finding the best way to display the information.

Both the Dutch and French versions were built together.

- The Beta 1 version: a version for stakeholders

After the KCE team finished the preliminary versions and adjusted the content in the two languages, the Beta 1 version was presented during the stakeholder meeting (on the 2nd of May 2019). The objectives of this step were to evaluate the content, opinions on readability, possible errors and typos, user friendliness, and to collect other remarks useful to improve both the content and the display

Several aspects were discussed e.g. information present on the tool; design; limitations of the algorithms; units used for variables; explanation of the effect of statin; the inclusion of HDL in the calculation of the SCORE. An adaptation of the content and the algorithm of SCORE has been done.

- The Beta 2 version: the test version

This version of the tool has been tested by GP's. With their feedback, some last adaptations of the content have been done.

### 3.5.3 Ongoing improvement of the tool

This tool will continue to be improved in the future in 4 different ways:

- *Feedback from the users:* The user has the possibility to give remarks or suggestions by clicking on the links at the bottom of the page ("Avez-vous des remarques ou suggestions concernant ce site web?" – "Hebt U opmerkingen over of suggesties voor deze website?)". Every feedback will lead to an answer or/and an adaption of the website by KCE.
- *Collection of general informations about the website*: KCE can follow statistics of the website tool via *Matomo* (previously *Pickwik*). The information concerns the number of visits, the language used, the location (country, region and city, depending on the internet connection of the user), the visit page of the site and the way of access to the site (via KCE site or browser or direct to the tool). All this information will be anonymous and will be analysed in order to evaluate the utilisation of the tool.
- *Implementation of other languages*: the tool will also be available in German (planned in 2020). Other language are possible if necessary.
- *Implementation of other algorithms:* in case of availability of new data, other algorithms may be implemented in the tool. For example the SCORE published in the ESC guidelines from 2019 where no data are currently available. When details are published, this new SCORE may be implemented in the tool.

# 4 ASSESSING THE VALUE OF THIS TOOL

## 4.1 Validation of the algorithms

### 4.1.1 Method

The main reason for this validation effort was to ensure that the result of the algorithms used in this interactive tool are comparable to the CVD risk estimates given by the published SCORE charts. Three correspondences were analysed:

- To verify the **correspondence of risk classification** according to the results of the SCORE charts and of the tool, a cross tabulation has been performed between the tool and the chart risk classification (low, moderate, high, very high). The independence of each cell has been tested by the Chi square test with Fisher correction when appropriate. A final table shows the percentage of different classification in risk of patients between the chart and the tool, calculated as $\frac{number\ of\ patient\ with\ different\ classification}{Total\ of\ patients} * 100$.
- **Linear correlations** were performed for the chart and the tool risk value for each chart of age 55, 60 and 65 years, and categories (i.e. women non-smoker, women smoker, men non-smoker and men smoker).
- Graphical representations of the **differences in CV risk** given by the chart and the tool.

### 4.1.2 Results

#### 4.1.2.1 Correspondence of risk classification between the SCORE charts and the tool:

For each cell of the ESC SCORE chart, we made a cross classification of the risk category given by the ESC SCORE chart and by this tool using the ESC algorithm (see Table 5 for women and Table 6 for men). For each group in the SCORE chart, for example for non-smoking women, there are 100 (= 5 x 20) possible categories, depending on total cholesterol and SBP (see Figure 2). The columns represent the results of our tool while the rows show the results of the SCORE charts. On the diagonal line of the cross tabulation (marked in grey) are the categories that are classified identically by both the tool and the SCORE charts.

For example in non-smoking women (Table 5) with low HDL (= 0.8mmol/l, i.e. first case in the upper left of the table), 81% (54+27) was identified similarly by both tools. The remaining 19% was classified in a higher risk category by the SCORE charts. If we move to higher HDL values (and thus lower risks), the number of differently classified cases decreases: for HDL=1: 11% classified differently; for HDL=1.4: 8% and for HDL=1.8: 9%. Similarly, if we go to the higher risks the number of differently classified categories increases: for example in women smokers, for an HDL=1 24% were classified differently. We do not observe a similar phenomenon in men (Table 6) where the risk differently classified rates are stable in each category and is about 8 to 15%.

For the Belgian SCORE, risk differently classified rates are equivalent in both genders, and are about 8%. The percentage of different classification of risks between the charts and the tool for women and men are summarized in Table 7.



### Table 5 – Correspondence of risk classification between the charts and the tool for women

| | | | Tool value | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | WOMEN NO SMOKER | | | | p-value | WOMEN SMOKER | | | | p-value |
| | | | Low | Medium | High | Very high | | Low | Medium | High | Very high | |
| Chart value | SCORE with HDL=0.8mmol/l | Low | 54 | 0 | 0 | 0 | <0.001 | 29 | 1 | 0 | 0 | <0.001 |
| | | Medium | 12 | 27 | 0 | 0 | | 6 | 38 | 0 | 0 | |
| | | High | 0 | 7 | 0 | 0 | | 0 | 12 | 7 | 0 | |
| | | Very high | 0 | 0 | 0 | 0 | | 0 | 0 | 7 | 0 | |
| | SCORE with HDL=1.0mmol/l | Low | 62 | 0 | 0 | 0 | <0.001 | 34 | 0 | 0 | 0 | <0.001 |
| | | Medium | 8 | 27 | 0 | 0 | | 10 | 36 | 0 | 0 | |
| | | High | 0 | 3 | 0 | 0 | | 0 | 10 | 6 | 0 | |
| | | Very high | 0 | 0 | 0 | 0 | | 0 | 0 | 4 | 0 | |
| | SCORE with HDL=1.4mmol/l | Low | 74 | 0 | 0 | 0 | <0.001 | 51 | 0 | 0 | 0 | <0.001 |
| | | Medium | 8 | 18 | 0 | 0 | | 9 | 31 | 0 | 0 | |
| | | High | 0 | 0 | 0 | 0 | | 0 | 4 | 5 | 0 | |
| | | Very high | 0 | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | |
| | SCORE with HDL=1.8mmol/l | Low | 86 | 0 | 0 | 0 | <0.001 | 65 | 0 | 0 | 0 | <0.001 |
| | | Medium | 9 | 5 | 0 | 0 | | 5 | 27 | 0 | 0 | |
| | | High | 0 | 0 | 0 | 0 | | 0 | 3 | 0 | 0 | |
| | | Very high | 0 | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | |
| | Belgian SCORE | Low | 40 | 3 | 0 | 0 | <0.001 | 20 | 5 | 0 | 0 | <0.001 |
| | | Medium | 1 | 31 | 0 | 0 | | 0 | 36 | 0 | 0 | |
| | | High | 0 | 1 | 4 | 0 | | 0 | 1 | 13 | 0 | |
| | | Very high | 0 | 0 | 0 | 0 | | 0 | 0 | 1 | 4 | |

### Table 6 – Correspondence of risk classification between the charts and the tool for men

| | | | Tool value | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | MEN NO SMOKER | | | | p-value | MEN SMOKER | | | | p-value |
| | | | Low | Medium | High | Very high | | Low | Medium | High | Very high | |
| Chart value | SCORE with HDL=0.8mmol/l | Low | 24 | 2 | 0 | 0 | <0.001 | 14 | 0 | 0 | 0 | <0.001 |
| | | Medium | 1 | 48 | 0 | 0 | | 0 | 36 | 0 | 0 | |
| | | High | 0 | 6 | 14 | 0 | | 0 | 6 | 22 | 0 | |
| | | Very high | 0 | 0 | 3 | 2 | | 0 | 0 | 6 | 16 | |
| | SCORE with HDL=1.0mmol/l | Low | 28 | 0 | 0 | 0 | <0.001 | 16 | 1 | 0 | 0 | <0.001 |
| | | Medium | 2 | 51 | 0 | 0 | | 0 | 38 | 0 | 0 | |
| | | High | 0 | 5 | 11 | 0 | | 0 | 8 | 20 | 0 | |
| | | Very high | 0 | 0 | 1 | 2 | | 0 | 0 | 5 | 12 | |
| | SCORE with HDL=1.4mmol/l | Low | 33 | 2 | 0 | 0 | <0.001 | 20 | 0 | 0 | 0 | <0.001 |
| | | Medium | 5 | 47 | 0 | 0 | | 1 | 43 | 0 | 0 | |
| | | High | 0 | 4 | 8 | 0 | | 0 | 10 | 16 | 0 | |
| | | Very high | 0 | 0 | 1 | 0 | | 0 | 0 | 4 | 6 | |
| | SCORE with HDL=1.8mmol/l | Low | 42 | 1 | 0 | 0 | <0.001 | 23 | 1 | 0 | 0 | <0.001 |
| | | Medium | 3 | 46 | 0 | 0 | | 3 | 47 | 0 | 0 | |
| | | High | 0 | 5 | 3 | 0 | | 0 | 6 | 12 | 0 | |
| | | Very high | 0 | 0 | 0 | 0 | | 0 | 0 | 5 | 3 | |
| | Belgian SCORE | Low | 15 | 6 | 0 | 0 | <0.001 | 4 | 4 | 0 | 0 | <0.001 |
| | | Medium | 0 | 38 | 0 | 0 | | 0 | 27 | 1 | 0 | |
| | | High | 0 | 0 | 15 | 0 | | 0 | 1 | 20 | 0 | |
| | | Very high | 0 | 0 | 1 | 5 | | 0 | 0 | 2 | 21 | |

**Table 7 – Classification differences between the charts and the tool**

| % of different classification | WNS | WS | MNS | MS |
|---|---|---|---|---|
| SCORE with HDL=0.8mmol/l | 19,0% | 26,0% | 12,0% | 12,0% |
| SCORE with HDL=1mmol/l | 11,0% | 24,0% | 8,0% | 14,0% |
| SCORE with HDL=1.4mmol/l | 8,0% | 13,0% | 12,0% | 15,0% |
| SCORE with HDL=1.8mmol/l | 9,0% | 8,0% | 9,0% | 15,0% |
| Belgian SCORE | 6,3% | 8,8% | 8,8% | 10,0% |

#### *4.1.2.2 Linear correlations between the chart and the tool risk value:*

Linear correlation modelling (presented in Figure 13 to Figure 20 in the appendix) has been performed between the risk SCORE given by the chart and the exact risk SCORE given by the tool.

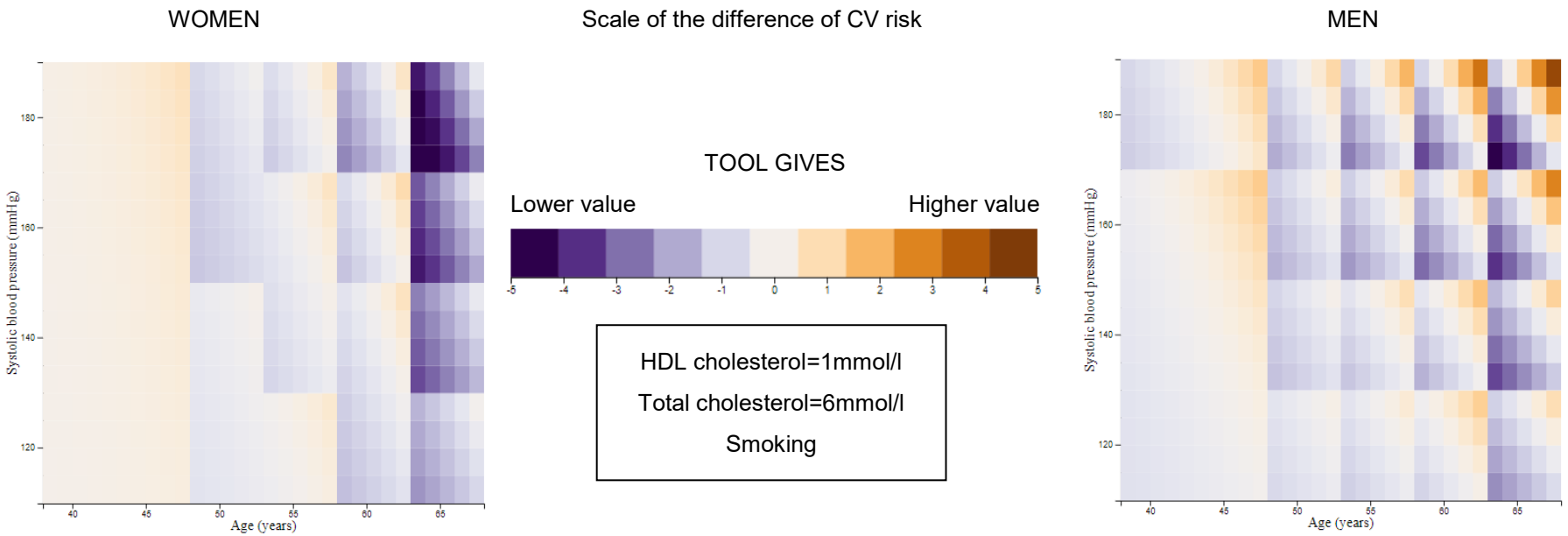
For the European risk SCORE: In men, all correlation coefficients are 0.99. In women, the correlation coefficients are lower than 0.99, with an underestimation of the risk for the tool.

For the Belgian SCORE, the linear correlation is very good for both men and women with a correlation coefficient equal to 0.99 (Figure 21 and Figure 22 in appendix).

#### *4.1.2.3 Graphical representation of the difference of the CV risk given by the chart and the tool:*

According to the ESC rule: “Find the cell nearest to the person’s age, cholesterol and SBP values, bearing in mind that risk will be higher as the person approaches the next age, cholesterol or SBP category”, a series of 2 by 2 table, for gender, HDL, smoking status and total cholesterol fixed were constructed. In Figure 3, an example of one of the graphical representations is shown. It shows the difference between the two values. As anticipated, the differences increase when approaching the limits of the risk category.

**Figure 3 – Graphical representation of the difference in CV mortality risk given by the chart and the tool.**




*fixed HDL=1mmol/l, smoking=1 and total cholesterol =6mmol/l,*

In women, for high risk values, we see a difference that can reach 5%. As shown in the figure, the central value of this category of patients is also estimated lower by the tool by around 3%, and the extreme value reaches up to 5% of difference. This phenomenon is not present in men, where the middle value of this category of patient is equivalent in the chart and the tool, and the upper and lower extreme values are equally extended from the middle value (+ 5% for upper extreme and -5% for lower extreme).

### *4.1.3 Discussion*

For the majority of cases, the difference between the chart and the tool does not exceed 2% of risk and the different classification of cases is lower than 15%, mainly in the low and moderate risk categories.

In women with high risk results, we observe a difference that can reach 5% and in this range of risks the difference in classification is nearly 30%. As shown in Figure 3, the central value of this category of patients is also

underestimated by the tool by around 3%, and the extreme value reaches up to 5% of difference. This phenomenon is not present in men, where the middle value of this category of patient is similar in the chart and the tool, and the upper and lower extreme values are equally extended from the middle value (+ 5% for upper extreme and -5% for lower extreme). Similarly, the linear correlation indicates that the worst estimation is for women where $R^2$ is lower than 99%, contrary to men.

We conclude that the tool estimates the CV risk lower in women, compared with risks given by the charts. This can be fully attributed to the fact that, unfortunately, we did not have access to the baseline Cox survival function, despite repeated demands to the authors of the original studies.

The "Cox hazard model" that has been used for creating the SCORE charts is a strictly statistical approach that cannot be reproduced without access to the original patient data. Therefore, without access to this baseline survival tabulation, it is currently impossible to fully recreate the SCORE tables using the available publications and supplementary information. An important consequence of this is the fact that the online application is forced to use a hybrid approach in which the publically available parameters for a Weibull survival function from the 2003 Conroy methodology are combined with the updated hazard coefficients from the 2009 publication by Cooney.[28, 43]

The assessment of the application versus the SCORE tables also pointed directly to a fundamental issue with the table-based approach: for bio parameters (TC, SBP or HDL) or age that are close to the edges of the intervals used in the SCORE table, there is a significant risk of different classification, especially in high risk "regions" of the table (high TC, low HDL, high SBP, advanced age). When using the SCORE tables, it should in fact be recommended that an average is used between two scores for high(er) risk patients where one or more bio parameters fall "between" the values indicated on the brackets.

Nevertheless, the official SCORE tends to be corrected downwards in recent publications, motivated by observations in European countries that there is an overestimation in the SCORE for "high risk patients". Besides, in 2016, a SCORE for older patients (SCORE OP) was published, that has been fitted for patients aged 60 to 75 years), and that revised the CV risk downwards.[54]

Moreover, the new ESC EAS guidelines that were recently published in 2019 present a new SCORE table which revised the CV risks downwards using an adjustment for the modifying effect of age on all risk factors, and an extension of limit of age to 70 years.[4].

**The new SCORE published in the 2019 ESC guidelines**

At the moment of the publication of our present report, no detailed data about this new SCORE are published yet, only the resulting charts have been published. Despite repeated attempts we were not able to gain access to the underlying functions.

The new SCORE charts published in the 2019 ESC guidelines have confirmed an observation that we also made during the assessment, namely the fact that the risk calculation becomes problematic at higher ages. Another age bracket (70y) was added for this reason. However, it wouldn't be prudent to extend the online application in a similar way as the discrepancies between the Weibull hazard function and the "Cox hazard model" will most likely increase. Another point to notice is that the 2019 ESC guidelines have omitted the HDL cholesterol, regardless of the fact that it still is considered a significant factor. The reason for this omission is unclear, but it can be assumed that having multiple SCORE tables for different HDL values is unpractical in a clinical practice. However, the online tool does not have this drawback and can easily process HDL values without significantly complicating the risk determination process. For low HDL values (= high risk) this omission introduces a significant risk of misclassification by the SCORE tables as opposed to the (theoretically more correct) online calculation.

The same issue of significantly diverting values can be observed in "extremely high risk" bio-parameter values as well. These are values of TC, HDL, SBP that are **outside** the available brackets in the SCORE tables. Just like with the age parameter in the previous point, there is a significant misclassification risk for people with very low HDL, very high TC or very high SBP when using the SCORE tables. Taking into account the available (normal) distribution of these bio-parameters, this concerns a significant portion of the patient group. For the online application, this cannot be compensated as it is unclear how reliable the formula based approach still

is for these patients. However, the online application will not show a score for bio-parameters outside these bounds and will supply a warning instead. The ESC guidelines do mention this aspect in the introduction to the tables, but not on the tables themselves.

These recent modifications reflect the fact that the CV risk assessment is a difficult issue and that the SCORE is not a gold standard. There are a lot of CV risk modifiers and variations between individuals that are difficult to take into account. SCORE remains a useful tool for a risk estimation that may help patients and physicians to discuss the necessity to adopt measures (pharmaceutical or otherwise) to decrease CV risk.

## 4.2 Assessment of the text readability

This decision aid, designed to be used by general practitioners with their patients, is also accessible to any individual visiting the website on purpose or by chance. These surfers might come across this decision aid as well and should be provided with information that is readable for typical users. 'Typical users' are therefore defined as people who may one day be faced with the decision to use statins or not. Given this definition, the general population is considered 'typical user' in this study.

Often, medical information is difficult to understand for a large part of the population because of complex formulations and jargon. BSM/Tempera ensured supervision of the medical content of the texts through a continuous and in-depth collaboration with KCE experts. A second screening of the text was performed on the readability of the text for 'ordinary' people.

The content was therefore extensively tested on its readability through various tests on 1/ the complexity of the text (technical readability testing) and 2/ its 'simplicity' for the 'ordinary' reader ('real world' readability test).

### *4.2.1 Technical readability statistics - Readability indicators*

Readability indicators were calculated for the two reformulated texts (see Appendix 2.2 and 0). The indicators used are based on the Flesch Reading Ease Test, originally designed for English. The Flesch test is based on a balanced ratio of the amount of syllables per word & words per sentence. Language specific modifications to the original Flesch Reading Ease Test are necessary. Due to English and Dutch or French being two different languages, the amount of words per sentence and syllables per word is different, therefore skewing the interpretation of the outcome. The adaptations to the original formula consist in altering the coefficients in the formula to suit the nature of the Dutch or French language. The outcome is a score, with a maximum of 100. These scores are grouped into categories corresponding to the educational level for which the text is readable.

- For the Dutch version, an adaptation of the Flesch Reading Ease Test was used.The text resulted in a readability score of 47 out of 100. This score indicates that the text can be understood by pupils in the last year of secondary school.
- For the French version, a Flesch Reading Ease Score adapted for the French language was used and resulted in a score of 53.3. This stands for text understandable by pupils from the last three years of secondary school.

These results are deemed acceptable, given the necessary and frequent use of numerous rather complex medical terms such as Systematic Coronary Risk, cardiovascular risk, cholesterol, statins, etc.

### *4.2.2 Measuring text comprehensibility*

The 'real world' text comprehensibility test aims to measure whether the target group understands the text's message. Successful readability or comprehensibility is achieved when the members of the target group find and understand the information in the text.

#### 4.2.2.1 Developing a readability test

**Characteristics of a readability test**

A readability test measures the extent to which the messages of a text are correctly understood by a target group. Central to the concept of readability is to find out whether a person can find the correct information and interpret it correctly. To this end, respondents are first asked to read a text at their own pace and then to answer several questions about its content. In this project, the questions were created based on the following characteristics:

- they ask for facts: they ask about actions and advice that can be directly derived from the text. The answer must be found without interpretation. This makes it possible to clearly determine between correct and incorrect answers;
- they are neutral: there is no 'good' or 'bad' answer but answering requires the reading of the text;
- they have an unambiguous answer: the interviewer should be in no doubt as to whether the interviewer's answer is correct or incorrect. This requirement is essential to ensure a reliable quantitative analysis;
- the test battery approaches 'readability' through different capacities:
  - reading comprehension: is the information correctly understood?
  - structuring reading: does the text convey the right key messages?

A readable text is a text that allows most of its readers to find and understand the information they need. It is important to stress that the concept of 'readability' has nothing to do with the ability to memorise or to reproduce information. For instance, as the information in a website is readily available at any time to the respondent, there is no point in measuring whether anyone can reproduce information by heart.

#### 4.2.2.2 Readability test for the statins tool

The readability test for the statins tool consisted of fifteen questions covering four topics addressed by the decision aid:

- purpose of the decision aid : 2 questions;
- statins : 6 questions;
- cardiovascular risk : 6 questions;
- health allegations : 1 question.

The Dutch and French questionnaires are included in this report as Appendix 2.2 and 0. Location of the answers throughout the text is shown.

There is no widely accepted standard to measure readability; the evaluation of readability is best demonstrated by its comprehensibility to respondents without advanced schooling.

This study established a threshold of 64 percent (0.80*0.80):

- 80 percent of the respondents having found the correct location of the information;
- and 80 percent of the respondents being able to produce the correct answer to the question.

Apart from the fact that a high threshold indicates readability, no convincing justification for one threshold or another exists.

**The 15 readability test questions**

What are the five factors that determine your cardiovascular risk?

What is the purpose of this tool?

1. How can you know your risk of dying from a heart attack or stroke?
2. Is there enough evidence of the effect of foods that promise to lower cholesterol?
3. Which two groups of people are at higher risk of having a stroke?
4. What are the two main causes of death in Belgium?
5. What are the two main possible side effects of statins?
6. Do you have to rush to make a decision about whether or not to take statins?
7. What should you do if you decide to take statins while taking other medications?
8. What are the four main habits to reduce your cardiovascular risk?
9. What do statins do?
10. Out of 100 patients taking statins, how many will have diabetes?
11. For which people is this test not valid?
12. How often should you take statins if you decide to take this medicine?
13. For men, how much greater is the risk of having a heart attack or stroke within ten years without dying from it than the risk of having a heart attack or stroke and dying from it?

**Test procedure:** The readability test was carried out in an identical manner for each respondent:

1. A short, neutral introduction by the examiner to explain the context of the test and the test procedure;
2. The respondent reads the texts without a time limit. The variable 'time' in relationship to readability is captured as a secondary indication of readability. Using a stopwatch to record respondents needed time to read a text proves problematic for two reasons. Firstly, time needed to read a text holds no valuable information for readability. Respondents might read slowly and understand everything, or fast and understand nothing. Secondly, and more importantly, doing so would jeopardize the *real world setting* of the test, and possibly rush respondents in their reading. Therefore, interviewers made an estimate of the time respondents needed to retrieve answers to questions in the documents. Data were captured as 'more, or less than thirty seconds needed'.
3. In an individual interview, the readability questions are presented orally and in writing to the interviewee. The interviewee has the text at hand and is asked to lookup the answers in it. In case of unclear answers, the interviewer asked follow-up questions until a clear and unambiguous answer is reached.

**Monitoring search behaviour:** How a person behaves when faced with a text, how she looks up the answer, the 'findability' of the information, all this provides important clues on the readability of a text. Therefore, the respondents and their search behaviour were observed during the readability test. Difficult search behaviour observed was analysed in order to adapt the text where necessary.

#### 4.2.2.3 A readability test with 20 people

The readability test was carried out with 20 respondents, equally divided between the Dutch-speaking and French-speaking language groups.

Most of the participants answering the readability test were recruited at random, by asking passers-by. Respondents were recruited in urban environments. Shopping streets, a library café and a popular square were chosen as recruiting sites. People with an estimated age over forty were approached with the question to participate in a readability test. They were given a short introduction on the aim of the research project, before moving on to the readability test description. Over a period of three days, ten respondents were recruited. All respondents were contacted on weekdays, between 10 a.m. and 4 p.m.

Additionally, a limited number were acquaintances of the researchers. These people were selected on (relatively advanced) age and (relatively low) educational level.

It may be noted that the number of 20 respondents implies a small scale and indicative survey. Using elaborate criteria within a population of 20 respondents borders on false precision.

The test took place in a face-to-face setting and was carried out by the researchers on this project. Most interviews were concluded within a time frame of forty minutes, including a first reading of the texts and the full questioning session.

The respondents were recruited with a view to ensuring a good representation of women (eleven) and men (nine). Twelve out of twenty respondents had an average schooling level, having attended secondary school level education, or lower.

The participants were aged between 19 and 71, with an average age of 54.5 years. Three respondents were younger than 40, two currently took statins and three more had, at some point, discussed the use of statins with a general practitioner.

The interviewer presented the texts to the participants and asked them to read them carefully. No time limit was imposed, as in 'real life', where there is usually no time limit whilst somebody reads a text at their own leisure.

When the respondent finished reading, the fifteen open ended questions were asked one by one. The text of each question was also presented in writing, so that the respondent could not be mistaken about the precise content of the question.

Each question was answered by the respondent, while using the documents to look up the answer

After answering the questions, a discussion took place about the participants' evaluation of their comprehension of the documents. They were also asked to give general feedback on the 'readability' of the texts.

#### 4.2.2.4 Test results

**Text was found readable:** the readability test scored 69 percent for correct answers. This passes the threshold of 64 percent. The respondents with an average schooling level (upper secondary school) scored 65 percent and thus reached the threshold. Furthermore, respondents gave an average rating of 8/10 regarding the readability of the documents and the text can therefore be described as comprehensible for the majority of 'ordinary' people.

**Differences between subgroups:** however, the test results varied according to the different subgroups within the population. The most important difference is found between the language groups, with French-speaking respondents reaching 81 percent of correct answers, compared to 57 percent for the Dutch-speaking respondents. This result can be explained by the fact that the tests were conducted by different researchers in the French and Dutch language parts. The Dutch-speaking interviewer did not summon the Dutch-speaking respondents to look up the answer in the documents when answering a question from memory or from their beliefs and/or knowledge on the matter. The 'spontaneous' answers of the Dutch-speaking respondents were thus often incomplete but the discussion that followed the test itself allowed to deduce that they considered the text as

readable. Respondents cited and commented on information that was new to them. This illustrates that they did understand this new information.

Respondents aged above 65 (score 61 percent) and men (score 59 percent) almost reached the threshold of success but remained slightly below it. The section of text over statins scored quite well with a score of 81 percent. The section evoking the cardiovascular risk was deemed less readable and attained the score of 59 percent. This can be explained by the fact that for the questions related to this topic, respondents tended to answer immediately, based upon their memory or their personal knowledge. The final editing adapted the information related to this matter.

**Layout and structure impact on readability:** Respondents sometimes encountered difficulties in finding the correct answers in the text. Although they remembered reading the information, they struggled to pinpoint where they had 'seen' it. Several causes can be identified:

- Some information appears several times in the text, which makes it seem more important. Some respondents tend to identify this information as an answer, even if it was not the expected answer.
- Some words are written in bold, and therefore catch the reader's eye. This renders other pieces of information less visible.
- Respondents do not use the headings of the text to find specific information. For example, they do not look at the headings, but only at the text. The intertitles used do not always adequately refer to the information contained in the paragraph, so that the reader does not look for information in that section.
- The text contains a number of lists that group elements. In the text there are five such lists. When respondents are asked questions referring to these lists, wrong combinations of elements of these lists were sometimes given as a response. For example, when asked 'What are the five factors that influence your cardiovascular risk?' a number of respondents answered the four measures to reduce cardiovascular risk + one item from the correct list.
- The text does not provide sufficient visual structure to find information easily. To illustrate, a number of respondents remembered having read the information about evidence for food products that promise to lower cholesterol in a text frame. For these respondents tracing back this information was much easier than for other respondents.

**Overlap in content:** some information appears multiple times throughout the texts, within the same section or across sources. Overlapping information is not always perfectly consistent. This (inconsistent) overlap in information makes it more difficult for the reader to find the exact information. *For instance, the homepage, patient information and test result mention that the test cannot be used with certain types of patients. However, the information is slightly different in each section.*

**Standard knowledge:** the effect of cholesterol and lifestyle importance is a publicly well-known topic. Therefore, respondents generally have some knowledge about this subject. When answering factual questions, respondents already know about the subject and tend to respond with this knowledge. Regardless of whether this information is correct, or is presented in the text. *For example, when asked "*What are the five factors that influence your cardiovascular risk*"; some respondents answer "hereditary factors", or "diet". However, these responses do not appear in the text.*

**Difficult sentences:** some sentences prove difficult to understand for respondents. A particularly challenging one is the following: "*For men, how much greater is the risk of having a heart attack or stroke within ten years without dying from it than the risk of having a heart attack or stroke and dying from it?* Even when respondents knew the answer, they still struggled to grasp the meaning of this particular sentence.



**Table 8 – Overview of the readability results**

| Characteristic of participants | Category | Number of participants | Average readability score |
|---|---|---|---|
| Age group | Under 40 years | 3 | 86% |
| | 40-65 years | 11 | 68% |
| | Over 65 years | 6 | 64% |
| | | | |
| Gender | Women | 11 | 76% |
| | Men | 9 | 61% |
| | | | |
| Language | Dutch | 10 | 57% |
| | French | 10 | 81% |
| | | | |
| Educational level | Higher education, university | 1 | 90% |
| | Higher education, non-university | 7 | 72% |
| | Upper secondary | 11 | 65% |
| | Lower secondary (or lower) | 1 | 63% |
| Section of the text | The decision aid (2 questions) | 20 | 62% |
| | Cardiovascular risk (6 questions) | 20 | 67% |
| | Statins (6 questions) | 20 | 89% |
| | Allegations (1 question) | 20 | 75% |
| | | | **Threshold 64%** |

#### 4.2.2.5 *Recommendations for text adaptation according to the test results*

After analysing the results of the readability test, a number of adaptations were recommended.

- Make sure that information that is repeated more than once is formulated identically.
- Make the 'patient information' text collapsible in order to provide an overview and structure: text only becomes visible when an intertitle is clicked on which obliges the user to use the intertitles.
- Use reading aids such as bullet points.
- Lists that are written in bullet points are preferable to lists that are written in sentences when it comes to finding this information in the text again. The three questions with the best scores for finding information in the text again were all lists written in bullet points.

## 4.3 Tool assessment by the general practitioners

The next step in the development of the decision aid was to put it in the hands of the general practitioners (GP's) for whom this tool is intended. In doing so, we wanted to allow them to use the tool in consultation with their patients to gather their views on their experience.

An invitation to test the online decision aids was published in the newsletters of Domus Medica (Dutch-speaking part of Belgium) and SSMG (Société scientifique de médecine Générale — French-speaking part of Belgium) on the 1st of July 2019 (see Appendix 3.1 and Appendix 3.2). Interested GP's filled in an expression of interest form and chose either:

- to simply test the tool in consultation and provide feedback using an online questionnaire;
- to test the tool indepth through:
  - a face-to-face preliminary interview on the prototype tool;
  - a test of the tool with at least four patients + filling out a 'patient form' after each test;
  - a face-to-face debriefing interview on their experience with the tool.

All registered GP's were contacted by email to inform them of the registration of their participation and inform them that they would be contacted once the website was ready for the test.

### 4.3.1 Methodology

#### 4.3.1.1 *Interview-based assessment*

**Procedure**

The plan was to recruit twelve GP's for this phase. The aim of the interviews with GP's was to obtain qualitative data on using the decision aid during consultations in the development process of the tool, not to assess the SDM process in itself, or its impact on the decision.
A target number of six GP's for both linguistic groups was set. This number was chosen to obtain sufficient information on the subject, and respect time and budget constraints. Among the Dutch speaking group of volunteering GP's a selection needed to be made. An even number of male and female GP's were contacted for the interview-based assessment. Among the French speaking group of volunteering GP's, no selection could be made. All voluntary GP's were invited for the interview-based assessment.

Due to a delay in the development of the website and time constraints, it was decided not to conduct exploratory interviews as initially planned. Instead, the physicians were contacted by e-mail to explain the process and deadlines (and to provide them with instructions for the use of the online decision aid see Appendix 3.3.1 and Appendix 3.3.2). All these documents were also addressed by regular mail with six exemplars of the form to fill out as a record of the test with patients. Researchers called GP's individually to thank them for their participation in the study, to answer any questions they may have about the tool or the test protocol and to plan the final face-to-face interviews. GP's could contact the researchers with their questions at all times by mail or phone.

GP's received a fee of € 150 for their participation.

**Measures**

Socio-demographic data were collected from GP's in the online registration form.

GP's were invited to test the online tool with at least four of their patients and fill out an evaluation form after each test. In those forms, data on patients' age, gender, educational level and reason for consultation were collected. Participating GP's were not given precise instructions on how to select patients to test the decision aid. GP's where thus free to choose the patients with whom they tested it. Only a minimal amount of four patients per GP was asked. Obviously, they were free to test the decision aid with more patients. No maximum amount of patients was given.

The concluding face-to-face interviews on the experiences of the GP's with the decision aid tool aimed to test the acceptability and usability of the tool. The interviews were based on an interview-guide adapted from our previous research on decision aids. It consisted of six parts (see Appendix 3.3.3 and Appendix 3.3.4) and questioned:

- the context in which cholesterol is adressed during consultation;
- the GP's evaluation of the tool itself and its usability;
- the impact of the decision aid on the duration and content of the consultation;
- the impact of the use of the tool on patients' decision-making;
- the patients' reactions towards the decision aid;GP's' remarks and suggestions for improvement.

The interviews were conducted in a semi-structured format. Interviewers used a list of topics that needed to be addressed during the interview, but let GP's respond freely. Results from interviews where grouped together per topic. General implications where formulated based on these results and confirmed with results from the feedback sheets GP's completed.

Because of the small number of interviews, no specific software was used to analyse the results.

#### *4.3.1.2 Online assessment*

**Procedure**

In order to collect additional feedback, other GP's were given the opportunity to test the tool by simply using it during consultation and communicating their evaluation by means of an online assessment. Those GP's were personally contacted by email on July 18th and at the last week of August, to remind them to fill in the evaluation form.

They were invited to:

- read the instructions on how to use the tool and the test procedure (in adocument attached);
- discover the online tool;
- use the tool in consultation with one or more of their patients;
- only complete the online evaluation survey once, no later than 31/8/2019.

GP's could contact the researchers with questions at any time by mail or phone. For their participation, participants who so wished could take part in a prize draw for a gourmet meal for two.

**Survey**

The online questionnaire, published through the KCE LimeSurvey-account, consisted of 4 parts (see appendix XXX). Closed questions using Likert rating scales, adapted from our previous research, but also based on SDM-Q-DOC[e] were used to examine:

- the context of the tool's use;
- the patients' point of view;
- the shared decision-making process;
- the evaluation of the web tool.

The questionnaire also included some sociodemographic questions and asked GP's about their overall satisfaction with the tool and their recommendations. Respondents could comment and/or explain some of their answers and one open-ended question asked to elicit feedback on how to improve the decision aid.

Each GP was allowed to answer only once, to avoid biased data. Indeed, if GP's with a positive attitude towards the decision aid – and therefore using it several times – could share their ongoing feedback by filling out multiple surveys, this would give more weight to their feedback than the answers of GP's with a negative attitude, who might test the decision aid only once.

Each GP could give feedback, even if he only used the decision aid with one patient.

[e] Shared Decision Making Questionnaire — physician version, see Scholl I., Kriston L., Dirmaier J., Bucholz A., Härter M. (2012), Development and psychometric properties of the Shared Decision Making Questionnaire — physician version (SDM-Q-Doc), Patient Education and Counseling 88 (201) 28'-290. This questionnaire assess the physician' perception of the shared decision making process.

### *4.3.2 Results*

#### *4.3.2.1 Interview-based assessment*

Altogether, twelve Dutch speaking and seven French-speaking physicians with an interest in decision aids registered online to participate in the in-depth testing. This was more than the foreseen number of six GP's per language group. Therefore, a selection was made of the participants to assure an even gender distribution. The availability of GP's to test the decision aid for six weeks during the summer was also taken into consideration and this made it possible to eliminate several GP's who were on vacation. Twelve physicians (see Table 9) were given access to the website as of the 7th of June 2019.

Six of the GP's were Dutch-speaking and six were French-speaking; there were six women and six men. They had an average of fourteen years of clinical experience as a GP (range: less than a year to thirty-five years) and came from five different Belgian provinces.

**Table 9 – GP Characteristics (n=12)**

| Characteristics | N (%) |
|---|---|
| **Gender** | |
| • Male | 6 (50) |
| • Female | 6 (50) |
| **Province** | |
| • Antwerp | 3 (25) |
| • Brussels Capital Region | 3 (25) |
| • East Flanders | 2 (16) |
| • Liège | 1 (8) |
| • Namur | 1 (8) |
| • Walloon Brabant | 2 (16) |
| **Language** | |
| • Dutch | 6 (50) |
| • French | 6 (50) |
| **Years of experience** | |
| • Less 1 year | 1 (8) |
| • 1-5 years | 3 (24) |
| • 6-10 years | 2 (16) |
| • 11-20 years | 1 (8) |
| • 21-30 years | 4 (32) |
| • 31 + years | 1 (8) |
| **Type of practice** | |
| • Individual | 1(8) |
| • Shared | 11 (92) |

Between the 1st of July and the 19th of September 2019, eleven of the twelve GP's took part in a 30 to 45 minute face-to-face interview to give their feedback on the decision aid (unfortunately, one debriefing interview could not take place due to the absence of a GP).

The interviews went very well. Even though one GP had not completed any patient forms, forty-eight patients' forms were filled out. Several GP's used the tool with patients for whom they did not complete a form. This happened if the patient was out of the tool's authorised age-range or when the GP had already filled out the four requested forms.

Some GP's notified explicitly that the use of the decision aid was part of a study they were participating in. One GP even asked a patient to come for a consultation because this patient had been asking questions on statins a week before the beginning of the test.

**Table 10 – Patients Characteristics (n=48)**

| Characteristics | N (%) |
|---|---|
| **Gender (n=47)** | |
| • Male | 20 (43) |
| • Female | 27 (57) |
| **Age** | |
| • Average | 57 |
| • Range | 40-67 |
| **Estimation of patients educational level by GP(n=47)** | |
| • Primary school | 1 (2) |
| • Lower secondary school | 7 (15) |
| • Higher secondary school | 24 (51) |
| • University college/University | 15 (32) |
| **Reason for consultation** | |
| • Check-up | 38 (79) |
| • Other | 10 (21) |

**Context and use of the decision aid by GP's**

**Cholesterol in the consultation room:**

In our study, cholesterol was addressed either by the patient or by the doctor mostly during (annual) check-up consultations.

Cholesterol was brought up by the GP in the following circumstances:

- when a new patient who has just changed GP is treated with statins;
- following an annual check-up, depending on the results of the blood test;
- in the event of suspicions of a substantial risk;
- when a patient asks their GP questions about it, or asks to have their cholesterol measured.

The reasons why the patient addressed the cholesterol treatment issue were for example:

- following a cardiovascular incident when asked to contact their attending physician after discharge from hospital to initiate drug treatment;
- after a visit to a cardiologist, to get a second opinion from their GP, or a confirmation of the prescription;
- when there is a media report on the subject and possible alternative treatments (such as red rice yeast for example);
- when a relative is treated to "lower their cholesterol".

Patients are especially interested in the values of their cholesterol, but they do not necessarily know about (their) cardiovascular risk.

> *« Parfois, les patients viennent suite à un bilan de l'hôpital parce qu'ils ont fait un AVC. Et ils viennent avec une lettre de sortie qui dit : voir le médecin traitant ou instaurer une statine. Mais les patients qui sortent de l'hôpital et à qui on a prescrit les statines viennent en disant qu'ils se sont renseignés et qu'ils ne veulent pas les prendre. Les questions viennent parfois suite à des émissions télé. Et du coup ils veulent mesurer leur cholestérol. »*

**Patients are asking their GP questions:**

It is interesting to note that, according to the interviewed GP's, cholesterol and the possible treatments such as statins are the subjects patients most often want to discuss with their GP. These are some of the topics patients ask about:

- I live a healthy life, how comes my cholesterol is high, why is that?
- If my parents have high cholesterol, will it be the same for me?
- I know someone with the same amount of cholesterol who does/doesn't take statins, why don't/do I have to?
- What are the side effects of statins?
- Is red rice yeast a full-fledged alternative to statins?

**Use of risk assessment scores:**

One way to address the issues raised by patients is to conduct a cardiovascular risk assessment. The GP's interviewed often used the following tools:

- paper S.C.O.R.E. risk charts;
- electronic health record (EHR) programmes such as Careconnect;
- the ABCDEFG technique;
- the fact sheets proposed by the journal Prescrire;
- the SSMG fact sheets;
- the tool developed by Domus Medica;
- …

One GP even developed their own algorithm.

**Overall impressions when using the tool with patients during consultations**

**The tool requires little time investment:**

GP's said they had to accept that they would lose a little time discovering the decision aid and its specificities in order to gain time while using it during the consultation. After this first step, they considered that the tool was intuitive, fast, convenient and easy to integrate in a consultation. It worked well and avoided "pulling out a small card" to calculate a patient's risk.

*"Gaat sneller, makkelijk in gebruik. Met patiënt zeggen van "wacht we gaan eens kijken of je pillen zou moeten nemen tegen de cholesterol"."*

Almost half of the GP's found that the decision aid did not require more time than the other tools they use. The other half found that the use of the tool lengthened the consultation (by five minutes on average) namely because they had to enter the date, share and explain the result and answer the patient's questions.

**The graphic illustration is unanimously accepted:**

The decision aid was perceived as an effective way to visualize the cardiovascular risk and to illustrate the impact of a possible treatment with statins.

*"De overtuigingskracht voor onnodig gebruik is sterk. Typische dames met een cholesterol van 240, zonder andere risico's, hebben er weinig baat bij om statines te gebruiken. Het hierbij visueel kunnen tonen is heel nuttig."*

Patients found the visual risk representation of cardiovascular risk in terms of 100 patients very clear. It prevents any misinterpretation (which could happen with SCORE charts).

*"Ja, er is geen of weinig uitleg nodig, ze zeiden bijvoorbeeld: "maakt dat maar zoveel verschil?" Ene patiënt zegt voor dat ene groene manneke doe ik het niet ("ik begin er niet aan") en de andere patiënt zegt voor dat ene groene manneke doe ik het wel. "*

The tool was also used to show patients that the impact of quitting smoking (by ticking "non-smoker" instead of "smoker" in the tool[f]) is greater than the impact of taking statins.

The tool supposedly did not contain superfluous information. GP's also considered that it was truly intended for interaction with the patient, which is not the case with charts like SCORE that are clearly intended for physicians.

All GP's used the tool on their desktop and turned their screen towards their patients to show the result of the risk evaluation. One GP however disliked having to "put a screen between her and her patients", and therefore favoured the paper SCORE risk charts.

**Some patients require more time than others:**

Some GP's decided not to test the tool with non-Dutch-speaking or non-French-speaking patients, fearing that it would be too difficult to explain.

Depending on the patient's profile, the use of the tool elicited more or less questions. Some GP's had a feeling that higher educated patients tended to ask more questions, whereas others asserted that less educated patients needed more explanations in order to be able to understand the result.

*"Vooral bij kortgeschoolden: kunnen er heel goed mee weg, duurt nog geen vijf minuten om in te vullen en te bespreken als er al laboresultaten zijn.*
*Hoger opgeleiden kunnen er iets minder mee aan de slag. Kunnen*

[f] this was used as a proxy by GP's even if « quitting smoking » cannot be considered as equal to « being a non-smoker »

*veel sneller gewogen beslissen, maar willen alles bespreken. Stellen meer vragen en willen meer informatie."*

**The tool is almost neutral:**

The tool could be perceived as discouraging the use of statins.

*« La plupart des items du site sont des items de diminution à prescrire. C'est un très bon site pour combattre la prescription abusive. «*

*« … 'info/outils aux patients est plutôt défavorable aux statines car parlent des effets secondaires négatifs. »*

The tool could also turn out to be counterproductive, for example, when a patient 'misinterprets' the effect of statins or decides to opt for a statin treatment as an easy way out, as opposed to changing unhealthy habits (e.g. instead of quitting smoking).

*« J'ai l'impression que le visuel provoque une surestimation de l'effet d'un traitement; c'est-à-dire: on ne regarde pas la toute grande majorité des personnes pour lesquelles la prise ou non d'une statine ne fait aucune différence, mais on ne regarde que la petite minorité (les 2 - 3 ) où il y a un changement de "1 vie sauvé": mentalement, cela donne l'impression de (par exemple) "1 vie sauvée sur 3". »*

*"Het laten zien dat stoppen met roken veel meer effect heeft, is handig. Anderzijds kan het ook verkeerd uitdraaien, dat patiënten liever statines nemen dan stoppen met roken."*

**The decision aid clearly impacts the shared decision process:**

According to the GP's, the tool allows patients to understand more quickly what their cardiovascular risk is. Information is clear to the patient and the visualization is intuitively easy to understand, regardless of education or age. If, in exceptional cases, the patient does not understand the result intuitively, the physician is perfectly able to give an explanation, after which the patient understands the information in all cases. According to GP's, the objective of supporting the shared decision-making process is thus achieved.

We were told that 35 patients out of the 42 tested decided not to take a statin. Almost half of the GP's believe the use of the tool combined with their explanations led to that decision.

*"We nemen de beslissing samen tijdens de consultatie. We geven ook de boodschap mee dat het risico met de leeftijd evolueert. De patiënten voelen zich gesterkt in hun beslissing, meer dan zonder de tool. Ze durven anders al eens vragen "waarom moet ik dat niet nemen?"."*

A physician may not wish to have their opinion questioned by the tool, so a physician may not use the tool when convinced of the need for the patient to take statins.

*« … utilisé l'outil que quand il y avait non indication. Car quand je savais qu'il fallait en donner, je ne voulais pas être contredit par l'outil ou ne voulais pas tout de suite parler des effets secondaires. …pas envie d'avoir un argument de plus contre le médicament. »*

And of course, there are always patients who prefer a doctor's recommendation to their own choice and signal it to their GP.

*"sommigen verwachten echter hapklare 'instructies' van de arts. Willen liever niet zelf beslissen"*

**Information sharing:**

The tool makes it possible to print the risk assessment results. Most GP's found this feature interesting and were willing to print and/or email this document to their patients if they requested it.

*"… zou het resultaat graag meegeven of delen. Ook een A4'tje op papier meegeven zou nuttig zijn. Een folder in begrijpelijke taal waarvoor het dient, wat de benefits zijn, de neveneffecten en waarop ze moeten letten."*

The risk assessment results should preferably be automatically integrated as well as the decision made, the treatment prescribed... into the patient's individual medical record. If this encoding needs to be done manually, the process, although interesting, becomes less attractive.

*« … ce genre d'outil doit être lié au DMI. Un onglet « calcul du score KCE ». Mais il faut que les outils soient validés par des organismes indépendants pour que ce soit fiable, régulièrement remis en question et uniformisé pour que ce soit partageable avec les autres collègues. »*

**The patient information section is for patients:**

Only two physicians read the whole section on patient information, particularly in order to master the tool. This section is perceived as encouraging the patients to consult this information, and some more in-depth content would be appreciated, particularly about dietary advice and healthy lifestyle counseling. The patient information could be perceived as focusing too much on potential side effects.

*"Interessant zou zijn om eventueel conservatieve maatregelen om cholesterol te verlagen te beschrijven onder andere door te specifiëren welke voedingen de patiënt zou moeten vermijden."*

**Appraisal of the tool by patients**

**The Internet is everywhere today, including the doctor's office:**

Most patients responded positively to their GP's use of a decision aid tool. Nevertheless, for cultural reasons, some patients did not wish to be informed about an alternative to drug treatment or said they did not go to the doctor to see him/her do an online search.

*« La plupart des patients utilisent le web au quotidien donc logique que cela soit dans une consultation chez le médecin »*

*« … des patients ingénieurs informatiques d'origine d'Inde. Ils ont l'habitude de : un problème, un médicament. Ils veulent tout savoir, et veulent un médicament. C'est plus difficile de leur expliquer qu'il y a peut-être d'autres solutions. »*

**The decision aid is an externally validated confirmation of the GP's point of view:**

The use of a tool validated by an external independent authority could be perceived as giving the patients an objective opinion. For example, the result of the cardiovascular risk assessment allowed some of them to go against a prescription from the cardiologist with complete confidence.

*« Ce type d'outil soutient le médecin. C'est intéressant de pouvoir montrer à certains patients qu'un organisme officiel, indépendant s'intéresse à cette problématique. Cela permet également de « prouver » l'évaluation - du risque cardiovasculaire - faite par le médecin »*

#### *4.3.2.2 Online assessment*

Thirty Dutch-speaking and thirty-seven French-speaking physicians registered online to use the tool during consultations and proceeded to do an online assessment of the tool.

Twenty-two GP's finally completed the survey, seven were Dutch-speaking and fifteen were French-speaking. This sample is comparable to the sample of physicians who participated in the interviews in terms of medical practice experience and the type of practice.

GP's used the tool with an average of four patients (range 1-10).

**Table 11 – GPs' Characteristics (n=22)**

| Characteristics | N (%) |
|---|---|
| **Gender (n=20)** | |
| • Male | 8 (40) |
| • Female | 12 (60) |
| **Province** | |
| • Brussels Capital Region | 6 (27%) |
| • East Flanders | 1 (5%) |
| • Liège | 3 (14%) |
| • Limburg | 3 (14%) |
| • Namur | 1 (5%) |
| • Hainaut | 8 (36%) |
| **Language** | |
| • Dutch | 7 (32) |
| • French | 15 (68) |
| **Years of experience** | |
| • Average | 13 |
| • Range | 2-38 |
| **Type of practice** | |
| • Individual | 6 (27%) |
| • Shared | 18 (77%) |

The response rate (22/67) is quite good for an online survey, considering the holiday period and the delay between the call for participation and the effective launch of the survey.

**In view of the size of the sample, no statistically sound conclusions representative of a larger population can be drawn from it**. Nevertheless, **the results illustrate a few distinct tendencies** presented below. All the flat sorting can be found in Appendix 3.4.3.

**Online respondents confirmed the statements of the interviewed physicians and their expectations**:

**GP's prefer to use the Belgian SCORE:** Only three GP's reported using the European SCORE, these GP's used the Belgian SCORE with their patients.

**Most GP's used the tool on a desktop or laptop:** Mobile devices such as smartphones or tablets were not popular. Only 2 out of 22 GP's used the tool on their smartphone. No tablet was used in the sample.

**A screen is the most popular way to display the results**: Two thirds of GP's shared the outcome of the test with their patient by making use of their screen, either on a screen visible to the patient, or by turning their screen towards the patient. On rare occasions, GP's used a smartphone (2/22) or showed the result on a printed version (2/22).

**Limited time investment**: The required time investment when using the tool in a consultation was less than five minutes for roughly three quarters of the GP's who gave feedback online. A fifth of the GP's needed between five and ten minutes to use the tool. In only one case, more than ten minutes were necessary.

**Sharing the printed result is a desired functionality**: Half of the GP's would hand a printed version of the result to the patient to take home if the option becomes available (they were not permitted to hand the result to their patients at that stage of the development of the tool). Therefore only 6 out of 22 GP's printed the result of the test. Only 5 out 22 GP's were interested in sharing the result with their patients via e-mail. Similarly, only 4 out of 22 saved the results to the patients' medical file.

**Nearly half of the GP's used the 'information for the patient' tab**: This information was used by 10 out of 22 GP's, which is more than in the sample of GP's who tested the decision aid and gave feedback through a face-to-face debriefing. Not all information in this tab was used. Some paragraphs were used more often than others. The paragraphs consulted the most often included:

- 8 out of 10 GP's: Why is too much cholesterol bad for your health?
- 8 out of 10 GP's: How can you lower your cardiovascular risk?
- 8 out of 10 GP's: Side effects of statins

The least used paragraphs are:

- 3 out of 10 GP's: How long does a treatment with statins take?
- 3 out of 10 GP's: Do statins interact with other medicines?
- 3 out of 10 GP's: What is the purpose of the test?
- 2 out of 10 GP's: To summarize, what questions should you ask yourself before starting a treatment with statins?

Even if they did not show patient information during the consultation, seven GP's out of ten declared this information to be sufficient.

**The tool clearly impacts the decision:** After seeing the risk evaluation, most patients made a decision during the consultation about whether to take statins or not. For those who did not decide, follow-up consultations eventually took place. From the GP's' perspective, patients appreciated the use of the tool as well as the shared decision-making process. According to them, using the online tool has contributed to shared decision-making. The vast majority of respondents therefore strongly agree with the following statements:

- I informed my patient that there are different treatment options for their health issue;
- I explained precisely the advantages and disadvantages of all of the treatment options to my patient;
- I helped my patient understand all the information;
- I asked my patient which treatment option they preferred;

Nine out of ten GP's felt their patient weighed the pros and cons of different treatment options in a discussion with them and that they often reached an agreement on how to proceed from there.

*« Prend du temps mais augmente probablement la compliance. Permet d'être discipliné sur le fait de consacrer du temps à la discussion aussi aux autres sujets que le traitement médicamenteux et de s'attarder sur l'hygiène de vie. »*

**General practitioners are satisfied with the decision aid**: Nearly all GP's indicated the intention to continue using the tool. In only one case, a GP indicated that they did not intend to continue using the tool. Likewise, two thirds indicated being satisfied with the decision aid. Roughly 8 out of 10 GP's would recommend the decision aid to a colleague. Only one GP stated that they do not to see how the decision aids added value.

*"Zeer gemakkelijk, voornamelijk het visuele vonden de patiënt interessant om te vergelijken hoe het zou zijn met of zonder behandeling. Ik heb ook bij 1 jonge patiënt (actief roker, hypercholesterolemie en 44 jaar) getoond hoe de situatie zou zijn over 10 jaar en zijn risico significant stijgt. Dit werd voor de patiënt motiverend beschouwd om hier nu actief iets aan te doen op een conservatieve manier."*

### 4.3.3 Further comments and suggestions

At the end of the face-to-face interview and in the online survey, GP's had the opportunity to make comments and suggestions to improve the tool.

**No technical issues**: Doctors have encountered very few technical issues when using the tool. One GP mentioned that he compared the result of the risk calculation with the SCORE risk chart and found no match. Another GP indicated that when he changed one of the parameters, the graphic representation of cardiovascular risk disappeared. On the other hand, a GP had the opportunity to test the tool with someone who was colour blind and the person was perfectly able to distinguish the differences between the emoticons. Finally, several GP's recommended that the tool be provided with a simple URL.

**Make the tool available for other caregivers**: Several GP's indicated that the tool should be shared with other healthcare professionals, such as cardiologists, dieticians and pharmacists (as part of the cholesterol "point of care"). In this context, several GP's stressed the importance of speaking with a single voice, especially since cardiologists seem prompt to prescribe statins. Other GP's believe that the patients themselves should be allowed to use the tool to evaluate the evolution of their cardiovascular risk. For some GP's, this can only be done if a secure access can be granted to the patients.

*Vlaanderen heeft tool gezondheidsgids en in die tool komt een SCORE en dan staat er bijv. "overweeg statines". Zou goed zijn daar een link te zetten naar deze tool zodat patiënten kunnen doorklikken*

**Extend scope and limits**: Several GP's regretted the limits of the tool. They suggested to:

- *Extend the age limit* - many GP's have patients aged above 75. These patients take care of themselves, their health and feel abandoned by medicine when a tool does not take them into account;

  *« augmentation de la norme d'âge car les conditions sont très limitées. Les patients de 75/ 80 ans qui sont en pleine forme, et qui prennent encore des statines car le médecin généraliste déprescrit et le cardio represcrit. Il n'existe aucun outil pour réfléchir à leur cas. »*

- *take other factors into account* - such as people with diabetes or with a history of cardiovascular disease (for example, by introducing an X2 factor);

  *"Het is niet duidelijk dat het niet gebruikt mag worden voor mensen met een familiale hypercholesterolemie. Zou ook nuttig zijn om dit wel mogelijk te maken. Bijvoorbeeld door factor x2 in te voeren op het risico De morbiditeitspercentages ontbreken. Kans op een CVA zonder te sterven, maar bijvoorbeeld wel in een rolstoel te zitten ontbreekt"*

- *allow multiple simulations to happen simultaneously* – one GP indicated that they would find it interesting to allow a direct comparison between two patient profiles (for example a smoker vs. a non-smoker). A visualization of four risk charts would allow such comparison of profiles.

- *expand the printable result* with advice and principles for a healthy ifestyle (e.g. dietary guidelines);

- translate decision aid into other languages such as German and Arabic.

**Time investment can be limited:** by integrating the tool into medical health record programs such as Careconnect. The automatic data introductions make the tool more user-friendly.

*"Het is lastig dat de waarden niet geïntegreerd zijn. Je verliest er tijd mee. Hoe minder clicks, hoe beter"*

Adapt content to patients :

- *Include morbidity risk,* as the risk of cardiovascular incidents is higher than risk of dying. Several doctors regret that the references are made with mortality percentages only;

- *Add an image of cholesterol*, seeing what it looks like can help understand the necessity to take action;

- Add links to other patient information sources such as thuisarts.nl;

  *"Het zou goed zijn om mensen te kunnen doorverwijzen naar de website vanaf de versie definitief is: bekijk het eens rustig en dat ze daarna kunnen terugbellen/terugkomen voor feedback"*

- *Provide information and recommendations for a healthy lifestyle*. These recommendations should be included in the printable document;

- Discuss the issue of red rice yeast.

Adapt content to GP's:

- *Clarify the use of the Belgian versus the European SCORE*, as some GP's do not know which one they should use in which circumstance. Some even question the differences between the two SCORE;

  *"Altijd de Belgische, die is standaard ingesteld. Ik dacht dat ik de Europese enkel moest gebruiken als er iemand met niet-Belgische origine op consultatie kwam. Was me niet duidelijk waarom ik een andere berekening zou moeten selecteren"*

- Integrate the Domus Medica overview table;
- *Add information about types of statins*, this simplifies the choice of the adequate type of statin;
- Add links to other GP information sources such as :
  - BCFI (CBIP) Centre Belge d'Information Pharmacothérapeutique ;
  - Farmaka.be ;
  - De gezondheidsgids.

### 4.3.4 Limitations

Both data collection methods are qualitative approaches aiming to develop a tool to be used in a SDM approach. They do not assess the process of the SDM itself nor the impact of it. Other approaches are required to evaluate this.

Regarding the readability assessment of the text, it is important to notice that it was assessed using a paper version of the tool, (alpha version) whereas the tool itself is online. This could have an impact on the way patients search for information and capture it: for example horizontal reading compared to vertical reading (on a computer screen) or interactive versus static text, etc… Nevertheless the complexity of the text as a whole was assessed.

While it is not an objective of a qualitative approach, we remind that a statistically representative sample was intended. We searched for a sample of potential users, no more than that. Therefore, we selected twelve volunteering GP's as the intention was to gather as much useful feedback as possible.

It can be assumed that in the population of GP's in Belgium a variation in interest and degree of sensibilisation to shared decision making exists. This variation could affect the use of a decision aid in clinical practice. This hypothesis was not addressed in the methodology of this research. Firstly, because it was not included in the scope of this research. Secondly, given the selection method of GP's (voluntary basis), no significant variation in interest or sensibilisation would presumably exist between them. All participating GP's can be assumed to be interested, given their willingness to assess the tool.

As a result of the voluntary method of recruitment, a large majority of participating GP's works in group practices which is not representative for the Belgian population of GP's. It could be assumed that GP's working in group practices have more time for patients. The same is presumably true for other variables as well, such as the method of payment of the practitioner (lump sum per patient or fee-for-service).

Capturing data afterwards has an inherent risk of memory failure. Respondents might not, or not correctly remember information. An interpretation by GP's of their patients' experience has not the same validity as a direct observation of patients' behaviour. Therefore, it is important to underline that any results on patients' behaviour or appreciation stems from the GP's interpretations of their patients. A method which avoids these problems is direct observation through camera recording. However, given the acceptability in the Belgian context of this method and the feasibility regarding time and budget constraints, this option was not achievable. Moreover, such data collection requires an ethical committee's approval which impacts the planning. Because the aim of our data collection was to help the development of the tool and not capture patient experience, such design was considered not appropriate.

GP's did not receive instructions on the profile of patients to test the decision aid on. It is possible that there is a (unconscious) selection bias of patients. For example, patients with higher levels of education might be selected more frequently. This could have an impact on their experience with the tool.

Finaly, we collected sufficient data to proceed but cannot claim to have reached data saturation, which was not targeted in the first place.

## 4.4 Recommendations to adapt the texts

- Make sure that information that is repeated more than once is formulated identically
- Making the text collapsible online to provide an overview and structure: text only becomes visible when an intertitle is clicked on, the user is obliged to use the intertitles.
- Use reading aids such as bullet points.
- Lists that are written in bullet points are preferable to lists that are written in sentences when it comes to finding this information in the text again. The three questions with the best scores for finding information in the text again are all lists written in bullet points.

# 5 THE BELGIAN TOOL

## 5.1 The website

The tool is available at www.statines.kce.be in French and Dutch.

The text of the website was adapted, taking into account the recommendations based on the results of the qualitative testing.

**Figure 4 – The statin website**




After having chosen the language of the website, the user arrives on the homepage explaining the purpose and conditions of use of the website (Figure 5 – Homepage of the website (French and Dutch)Figure 5):

> *"This website is intended to help the doctor and the patient to decide together whether or not to use a drug from the "statins" group. Statins can help lower cholesterol and thus help reduce the risk of heart attack or stroke. It proposes a test to be used by the doctor during the consultation with his patient.*

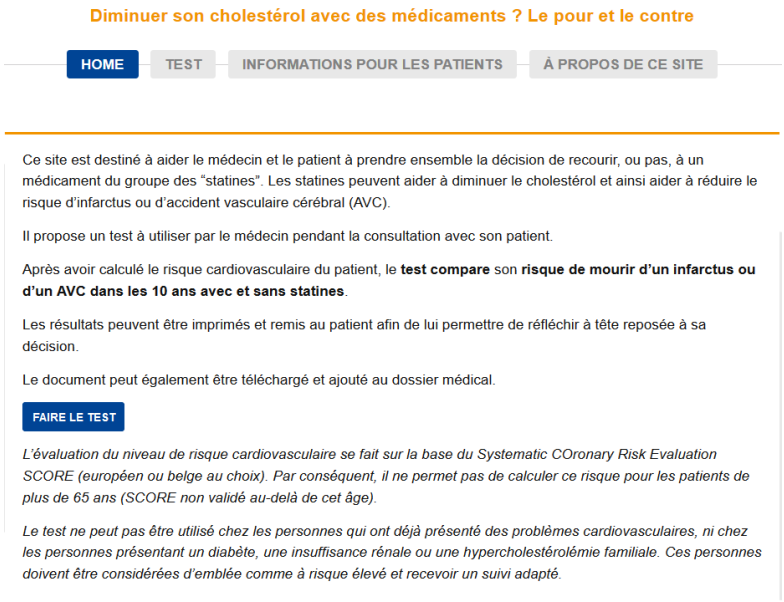
*After calculating the patient's cardiovascular risk, the test compares the patient's risk of dying of a heart attack or stroke within 10 years with and without statins.*

*The results can be printed or downloaded. In this way, the patient can dispose of it and reflect, with a rested head, on his decision.*

*The downloaded document can be added to the patient's medical record.*

*The assessment of the level of cardiovascular risk can be done, at choice, on the basis of the European or Belgian SCORE (Systematic COronary Risk Evaluation). The test cannot be used for patients with diabetes, or who have a family history of cardiovascular problems, or familial hypercholesterolemia. These people must be considered high-risk from the outset and receive appropriate follow-up."*

## Figure 5 – Homepage of the website (French and Dutch)



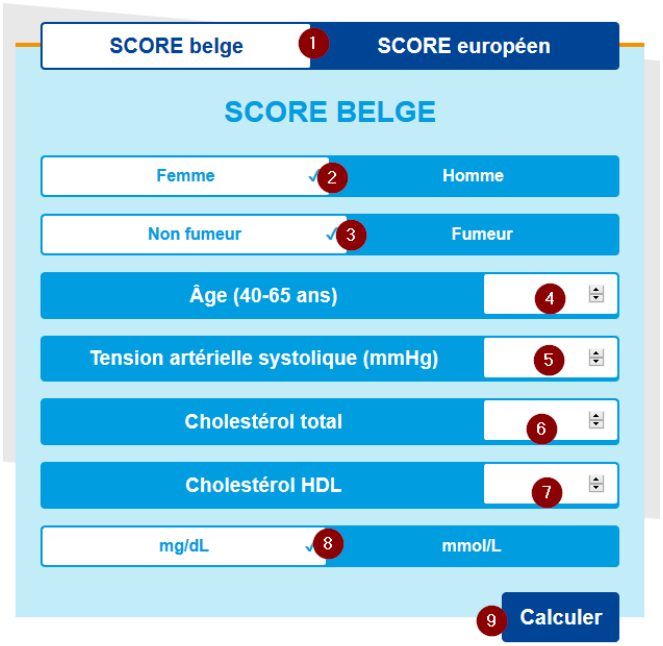



## 5.2 The ‘Test’ tab

By clicking on the "do the test" button on the homepage, the user arrives on a new page with a table allowing to enter the patient data necessary for the calculation of SCORE.

### *5.2.1 Data entries*

**Figure 6 – Data entries for the test (French and Dutch)**



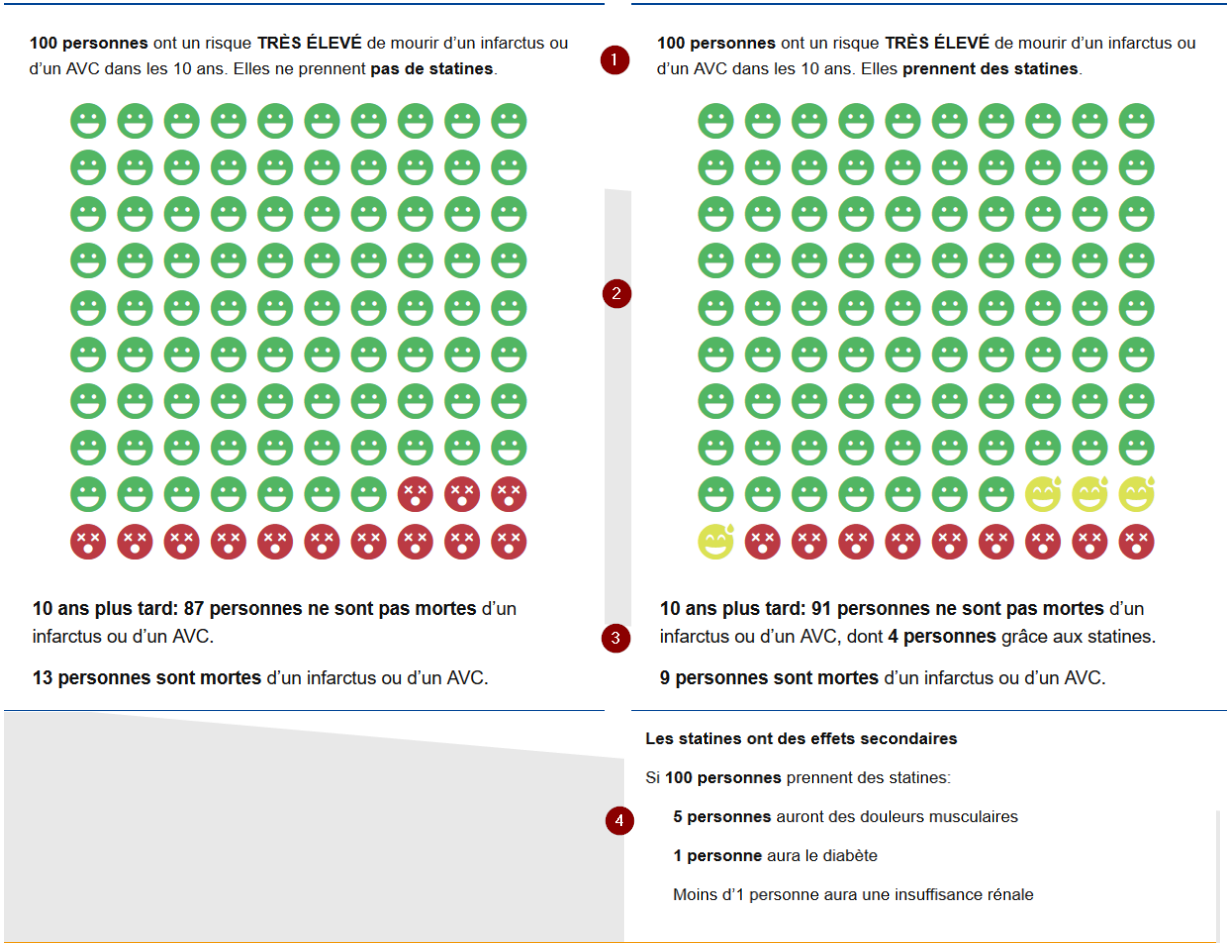




1. Click to choose between the Belgian or the European SCORE
2. Click to choose the gender
3. Click to choose smoking status
4. Introduce age (between 40 and 65 year-old)
5. Introduce systolic blood pressure (100-180mmHg)
6. Introduce total cholesterol (100-300 mg/dl or 3 -7.8mmol)
7. OPTIONAL: Introduce HDL cholesterol (10-200 mg/dl or 0.25-0.3 mmol)
8. Click to choose the cholesterol measure unit
9. Click to calculate the SCORE

### 5.2.2 *The results of the test and the decision aid*

**Figure 7 – Results of the test (French and Dutch)**

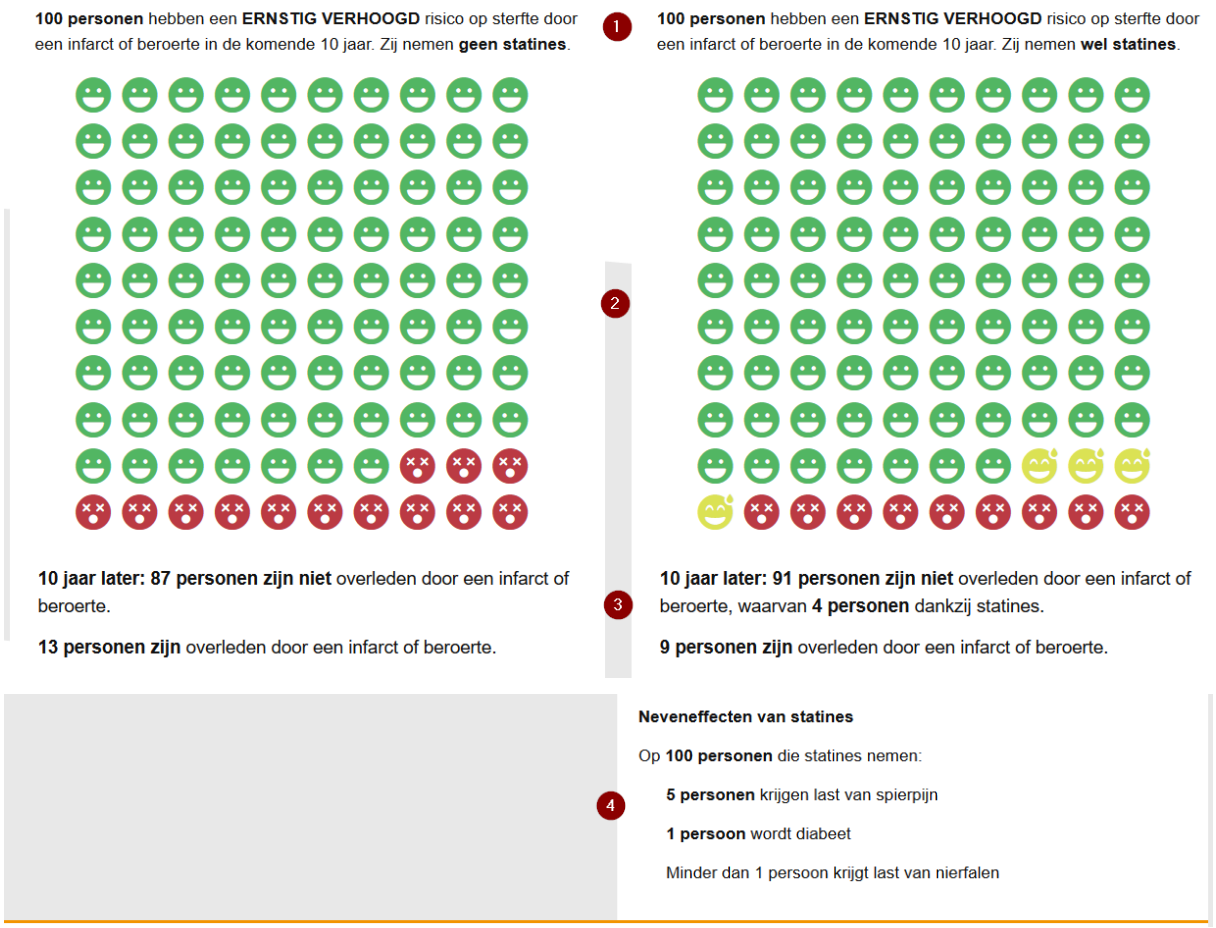



1. The first sentence *"100 people have a VERY HIGH risk of dying from a heart attack or stroke within 10 years."* includes the level of CV death risk calculated by the SCORE. The second sentence indicates the use of not of statins "*They (don't) take statins."*

2. 2x100 'smileys' representing people with the same CV risk as the patient's one are presented. In the left side of the picture none of them take statins. In the right side, they all take statins. Smileys are green if they will be alive 10 years later, red if they will be dead. In the right column, yellow smileys are representing people 'saved' thanks to the statin use.

3. The same information than the one presented by the smileys is explained in sentences: *"10 years later: 87 people did not die of a heart attack or stroke.*
*13 people died of a heart attack or stroke."* VS *"10 years later: 90 people did not die of a heart attack or stroke, including 3 people thanks to statins.*
*10 people died of a heart attack or stroke.*

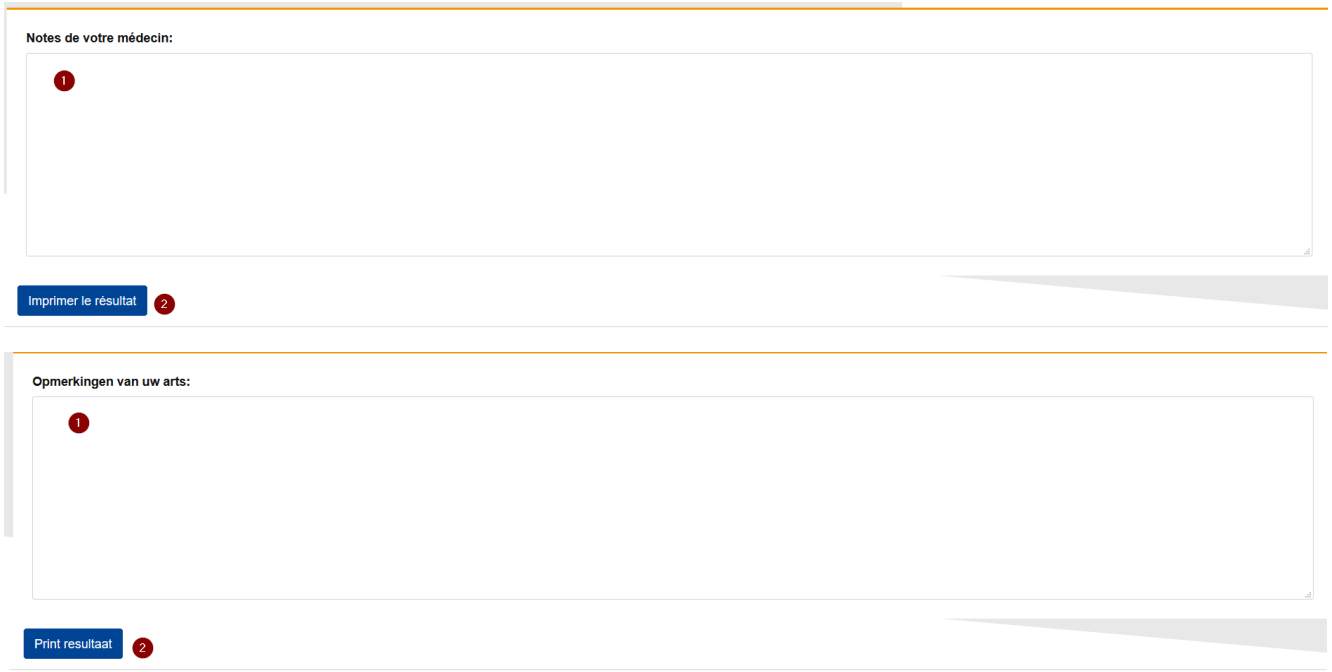
4. Adverse events of statins are presented "Statins have side effects: *If 100 people are taking statins: 5 people will have muscle aches and pains; 1 person will have diabetes; Less than 1 person will have kidney failure "*




*Results for a man, smoker, 56 year-old, 146 mmHg, 280 mg/dl, 10 mg/dl with Belgian SCORE*

The GP could then (see next figure) **(1)** add some notes and if they want to **(2)** print or save the results (by printing it in a pdf): the website will generate a pdf mentioning the results of the test (level of risk and iconography), the notes of the physicians and some information to the patient (see further).The saved as pdf results could be saved in the medical file of the patient.

**Figure 8 – Comments and printing or saving of the results**




### *5.2.3 The printed / saved results*

The generated pdf mentions:

1. the CV risk level
2. first preventive measure to take in order to low the CV risk
3. the decision aid
4. the disclaimer about the ‘eigible’ patients for the test
5. information about side effects of statines
6. additional notes from the GP

## Figure 9 – Printed/saved results

KCE

### Dois-je prendre un médicament du groupe des statines pour diminuer mon risque cardiovasculaire ?

Votre niveau de risque cardiovasculaire (risque de mourir d'un infarctus ou d'un accident vasculaire cérébral (AVC) dans les 10 ans à venir) est **TRÈS ÉLEVÉ**

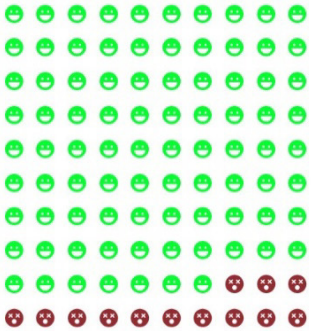
**Les premières mesures pour diminuer le risque cardiovasculaire sont :**

- arrêter de fumer ;
- manger plus équilibré ;
- réduire votre consommation d'alcool ;
- faire plus d'exercice physique.

**Ces mesures ne suffisent pas ? Alors, votre médecin traitant peut vous prescrire un médicament du groupe des statines pour diminuer votre cholestérol.** Vous prenez la décision du traitement ensemble.

Ces graphiques comparent votre risque de mourir d'un infarctus ou d'un AVC dans les 10 prochaines années **sans et avec statines.**

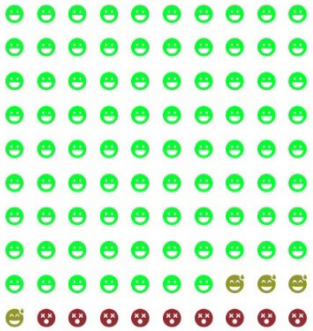
**100 personnes** ont un risque **TRÈS ÉLEVÉ** de mourir d'un infarctus ou d'un AVC dans les 10 ans. Elles ne prennent **pas de statines.**



**10 ans plus tard: 87 personnes ne sont pas mortes** d'un infarctus ou d'un AVC.

**13 personnes sont mortes** d'un infarctus ou d'un AVC.

**100 personnes** ont un risque **TRÈS ÉLEVÉ** de mourir d'un infarctus ou d'un AVC dans les 10 ans. Elles **prennent des statines.**



**10 ans plus tard: 91 personnes ne sont pas mortes** d'un infarctus ou d'un AVC, dont **4 personnes** grâce aux statines.

**9 personnes sont mortes** d'un infarctus ou d'un AVC.

Voir informations importantes sur la page suivante

KCE

### Moet ik een geneesmiddel van de statines groep nemen om mijn cardiovasculair risico te verminderen?

Uw cardiovasculair risico (kans op overlijden door een infarct of beroerte in de komende 10 jaar) is **ERNSTIG VERHOOGD**

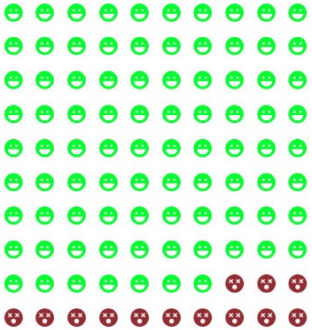
**De belangrijkste maatregelen om het cardiovasculair risico te beperken zijn:**

- stoppen met roken;
- evenwichtiger eten;
- uw alcoholconsumptie verminderen;
- regelmatiger bewegen.

**Volstaan deze maatregelen niet ? Dan kan uw arts u een geneesmiddel van de statines groep voorschrijven om uw cholesterol te verlagen.** De beslissing om deze behandeling te starten neemt u samen met uw arts.

Deze grafieken vergelijken uw risico op overlijden door een infarct of een beroerte in de komende 10 jaar **met en zonder** statines.

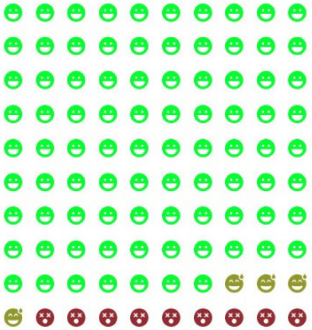
**100 personen** hebben een **ERNSTIG VERHOOGD** risico op sterfte door een infarct of beroerte in de komende 10 jaar. Zij nemen **geen statines**.



**10 jaar later: 87 personen zijn niet** overleden door een infarct of beroerte.

**13 personen zijn** overleden door een infarct of beroerte.

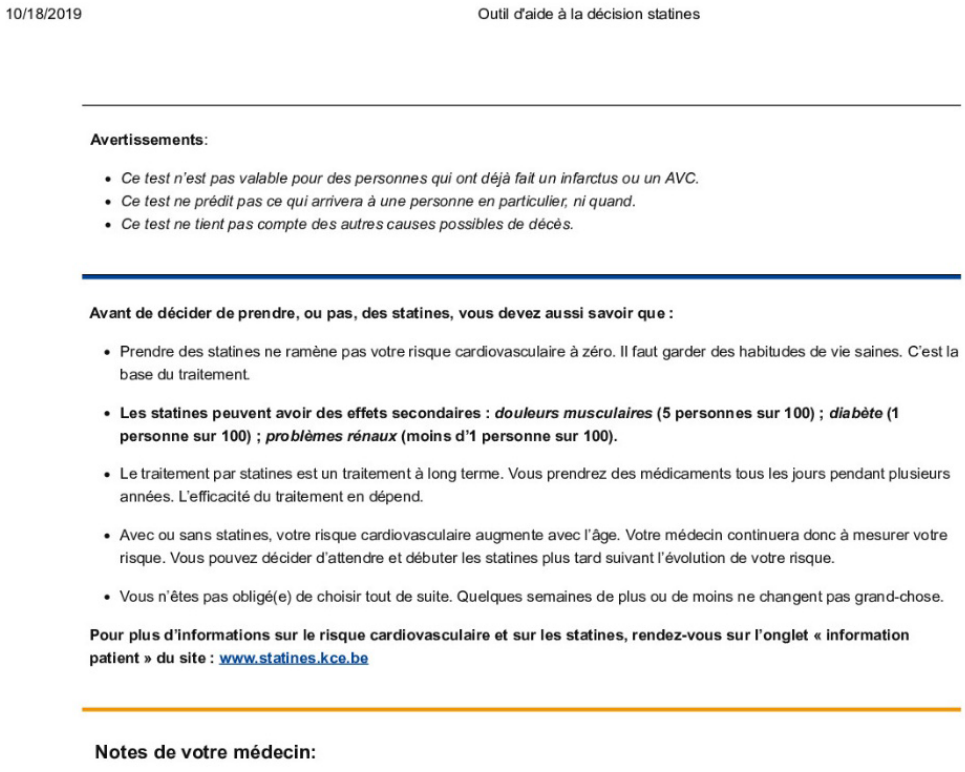
**100 personen** hebben een **ERNSTIG VERHOOGD** risico op sterfte door een infarct of beroerte in de komende 10 jaar. Zij nemen **wel statines**.



**10 jaar later: 91 personen zijn niet** overleden door een infarct of beroerte, waarvan **4 personen** dankzij statines.

**9 personen zijn** overleden door een infarct of beroerte.

Zie belangrijke info op volgende pagina



10/18/2019 Outil d'aide à la décision statines

**Avertissements**:

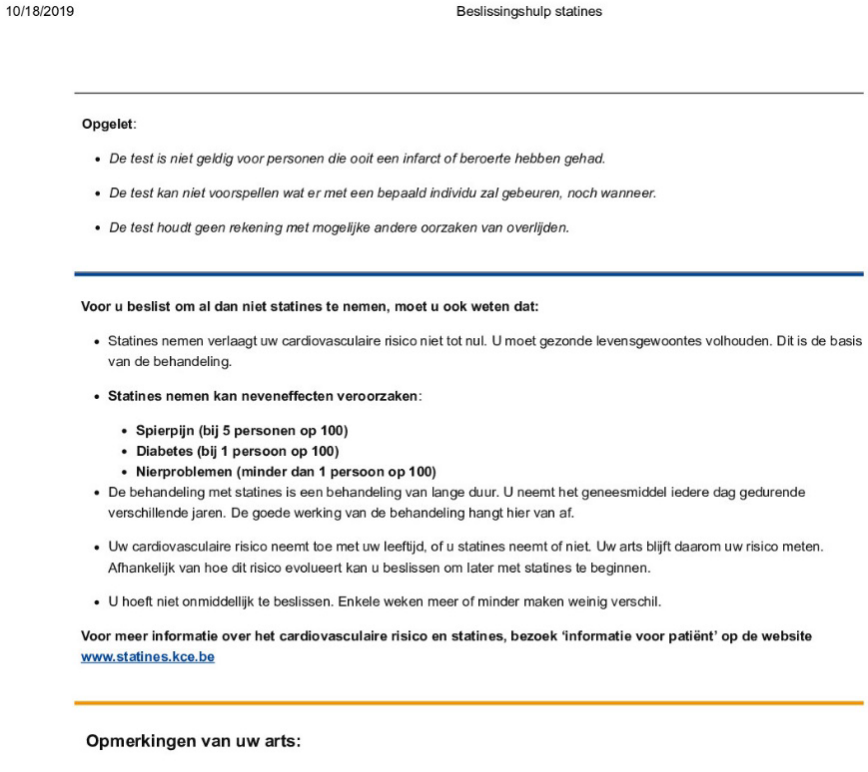
- *Ce test n'est pas valable pour des personnes qui ont déjà fait un infarctus ou un AVC.*
- *Ce test ne prédit pas ce qui arrivera à une personne en particulier, ni quand.*
- *Ce test ne tient pas compte des autres causes possibles de décès.*

**Avant de décider de prendre, ou pas, des statines, vous devez aussi savoir que :**

- Prendre des statines ne ramène pas votre risque cardiovasculaire à zéro. Il faut garder des habitudes de vie saines. C'est la base du traitement.
- **Les statines peuvent avoir des effets secondaires : *douleurs musculaires* (5 personnes sur 100) ; *diabète* (1 personne sur 100) ; *problèmes rénaux* (moins d'1 personne sur 100).**
- Le traitement par statines est un traitement à long terme. Vous prendrez des médicaments tous les jours pendant plusieurs années. L'efficacité du traitement en dépend.
- Avec ou sans statines, votre risque cardiovasculaire augmente avec l'âge. Votre médecin continuera donc à mesurer votre risque. Vous pouvez décider d'attendre et débuter les statines plus tard suivant l'évolution de votre risque.
- Vous n'êtes pas obligé(e) de choisir tout de suite. Quelques semaines de plus ou de moins ne changent pas grand-chose.

**Pour plus d'informations sur le risque cardiovasculaire et sur les statines, rendez-vous sur l'onglet « information patient » du site : www.statines.kce.be**

**Notes de votre médecin:**



10/18/2019 Beslissingshulp statines

**Opgelet**:

- *De test is niet geldig voor personen die ooit een infarct of beroerte hebben gehad.*
- *De test kan niet voorspellen wat er met een bepaald individu zal gebeuren, noch wanneer.*
- *De test houdt geen rekening met mogelijke andere oorzaken van overlijden.*

**Voor u beslist om al dan niet statines te nemen, moet u ook weten dat:**

- Statines nemen verlaagt uw cardiovasculaire risico niet tot nul. U moet gezonde levensgewoontes volhouden. Dit is de basis van de behandeling.
- **Statines nemen kan neveneffecten veroorzaken**:
  - **Spierpijn (bij 5 personen op 100)**
  - **Diabetes (bij 1 persoon op 100)**
  - **Nierproblemen (minder dan 1 persoon op 100)**
- De behandeling met statines is een behandeling van lange duur. U neemt het geneesmiddel iedere dag gedurende verschillende jaren. De goede werking van de behandeling hangt hier van af.
- Uw cardiovasculaire risico neemt toe met uw leeftijd, of u statines neemt of niet. Uw arts blijft daarom uw risico meten. Afhankelijk van hoe dit risico evolueert kan u beslissen om later met statines te beginnen.
- U hoeft niet onmiddellijk te beslissen. Enkele weken meer of minder maken weinig verschil.

**Voor meer informatie over het cardiovasculaire risico en statines, bezoek 'informatie voor patiënt' op de website www.statines.kce.be**

**Opmerkingen van uw arts:**

## 5.3 The 'Information for the patients' tab

Because the website will be available also for patients, we have included information for them. The page is presented in Figure 10:

*"**You have too much cholesterol....***

*Yet you have balanced your diet and are exercising*

*Taking medication may reduce your risk of heart attack or stroke*

*Here is some information to help you weigh the pros and cons.*

- Why is too much cholesterol bad for your health?
- What is cardiovascular risk?
- How to know your cardiovascular risk?
- How can you reduce your cardiovascular risk?
- What is a statin drug?
- Do statins have any side effects?

- How long does statin treatment last?
- Do statins alter the effect of other drugs?
- In summary, what are the questions to ask yourself before taking statins?
- What is the purpose of this test?"

**Figure 10 – Information for the patients - menu (French and Dutch)**



## Figure 11 – Content of the information for the patients (French and Dutch)

### Pourquoi trop de cholestérol est-il mauvais pour la santé?

Le cholestérol est une graisse qui circule dans le sang. Le cholestérol peut boucher les artères du **cœur**. Cela peut causer des douleurs dans la poitrine (angine de poitrine). Et parfois même provoquer une crise cardiaque (**infarctus**).
Le cholestérol peut aussi boucher les artères du **cerveau** et causer un **accident vasculaire cérébral** (AVC ou « thrombose cérébrale »). Cet accident peut abîmer des zones importantes du cerveau (hémiplégie, aphasie, etc.). Les fonctions perdues reviennent parfois complètement, en partie, ou pas du tout. Cela dépend de la gravité de l'AVC. **L'infarctus et l'AVC sont les causes les plus courantes de décès en Belgique**.

### Qu'est-ce que le risque cardiovasculaire?

Le risque cardiovasculaire correspond au **risque de faire un infarctus ou un accident vasculaire cérébral (AVC)**. Le risque cardiovasculaire augmente avec **l'âge**. En général, il est plus grand chez les hommes que chez les femmes. Les autres **facteurs de risque** bien connus sont **le cholestérol, le tabac** et **l'hypertension artérielle**. Les personnes diabétiques ou insuffisantes rénales ont un risque plus important que la moyenne.

### Comment connaître votre risque cardiovasculaire?

Votre médecin peut évaluer votre risque cardiovasculaire. Pour cela, il se base sur votre âge, votre sexe, votre tension artérielle, votre taux de cholestérol et le fait que vous fumiez ou pas. D'autres facteurs de risque peuvent également intervenir, notamment l'obésité, la sédentarité, l'histoire familiale ou les triglycérides sanguins, mais ils ne sont pas pris en compte dans le test proposé sur ce site. C'est pour cette raison qu'il est important que l'évaluation du risque se fasse avec votre médecin traitant, qui connaît tous ces éléments. Votre médecin peut répéter régulièrement cette évaluation, par exemple tous les ans.

### Comment diminuer votre risque cardiovasculaire?

Les premières mesures pour diminuer votre risque cardiovasculaire sont : **arrêter de fumer**, **manger plus équilibré**, **réduire votre consommation d'alcool**, et__faire plus d'exercice physique.__
Votre médecin peut vous donner des conseils diététiques et sportifs. Il peut vous soutenir si vous décidez d'arrêter de fumer.
**Ces mesures ne suffisent pas ?** Votre médecin peut vous proposer de prendre un médicament du groupe des statines. Vous prenez la décision du traitement ensemble. **Un mode de vie sain reste la base du traitement.**
*NB: L'industrie alimentaire propose beaucoup de produits pour faire baisser le cholestérol (comme certaines boissons, yaourts et matières grasses contenant des « stérols » et « stanols » dérivés des plantes, ou des acides gras oméga-3). Contrairement à ce que dit la publicité, il n'y a pas de preuves suffisantes que ces produits aident à diminuer le risque cardiovasculaire global.*

### Waarom is teveel cholesterol slecht voor uw gezondheid?

Cholesterol is een vet dat in het bloed circuleert.
Cholesterol kan **hartslagaders** verstoppen. Dit kan pijn in de borst veroorzaken (angina pectoris). Soms kan dit zelfs een **hartaanval** (infarct) veroorzaken.
Cholesterol kan ook de bloedvaten in de **hersenen** verstoppen en een **beroerte** veroorzaken. Zo'n accident kan belangrijke zones in de hersenen beschadigen (met gevolgen zoals halfzijdige verlamming, verlies van het spraakvermogen, etc.). De verloren functies komen soms gedeeltelijk of geheel terug, soms ook niet. Dit hangt af van de ernst van de beroerte.
**Infarcten en beroertes zijn de belangrijkste doodsoorzaken in België.**

### Wat is het cardiovasculaire risico?

Het cardiovasculaire risico is **het risico om een hartaanval of beroerte te krijgen**. Het cardiovasculaire risico neemt toe met de **leeftijd**. In het algemeen is dit risico groter bij mannen dan vrouwen. Andere **risicofactoren** zijn **cholesterol**, **roken** en **hoge bloeddruk**. Personen met diabetes of nierfalen hebben een hoger dan gemiddeld risico.

### Hoe uw cardiovasculaire risico bepalen?

Uw arts kan uw cardiovasculaire risico nagaan. Daarvoor baseert hij zich op uw leeftijd, geslacht, bloeddruk, cholesterolniveau en of u rookt of niet. Andere risicofactoren kunnen ook een rol spelen, waaronder obesitas, te weinig lichaamsbeweging, familiale voorgeschiedenis of bloedtriglyceriden, maar hiermee houdt de huidige test geen rekening. Daarom is het belangrijk dat uw behandelende arts de risicobeoordeling doet, want hij is op de hoogte van al deze elementen. Uw arts kan dit risico regelmatig evalueren, bijvoorbeeld ieder jaar.

### Hoe uw cardiovasculaire risico verkleinen?

De belangrijkste ingrepen om uw cardiovasculaire risico te beperken zijn **stoppen met roken**, **evenwichtiger eten**, uw **alcoholconsumptie verminderen** en **vaker bewegen**.
Uw arts kan u adviseren over uw voeding en uw fysieke beweging. Hij kan u ondersteunen als u beslist te stoppen met roken.
**Volstaan deze ingrepen niet?** Uw arts kan u voorstellen om een geneesmiddel van de statines groep te nemen. U neemt de beslissing over deze behandeling samen. **Gezonde levensgewoontes blijven de basis van de behandeling.**
*NB: De voedingsindustrie promoot veel producten om uw cholesterol te verlagen (zoals bepaalde drankjes, yoghurts en plantaardige vetstoffen met « sterolen » en « stanolen » of met omega-3). In tegenstelling met wat in de reclames wordt beweerd is er onvoldoende bewijs dat deze producten helpen om uw algemene cardiovasculaire risico te beperken.*

### Qu'est-ce qu'un médicament du groupe des statines?

Les statines sont des médicaments qui font **baisser le cholestérol dans le sang.** Les statines vendues en Belgique sont la simvastatine (Zocor®), l'atorvastatine (Lipitor®), la rosuvastatine (Crestor®), la fluvastatine (Lescol®) et la pravastatine (Prareduct®). Prendre des statines ne ramène pas votre risque cardiovasculaire à zéro.

### Les statines ont-elles des effets secondaires ?

Les études montrent que sur 100 personnes qui prennent des statines :
-5 personnes ont des **douleurs aux muscles** (surtout les 3 premiers mois)
-1 personne devient **diabétique** dans les 5 ans à cause du médicament
-Exceptionnellement, des personnes ont des **problèmes rénaux**, parfois graves

### Combien de temps dure un traitement par statines ?

Le traitement par statines est un traitement à long terme. Vous prendrez des médicaments **tous les jours pendant plusieurs années**. L'efficacité du traitement en dépend. Vous devez donc être convaincu de faire le bon choix. Mais vous pourrez bien sur changer d'avis.
Votre risque cardiovasculaire augmente avec l'âge. **Votre médecin continuera donc à mesurer votre risque, avec ou sans statines.** Vous pouvez attendre et débuter des statines plus tard, suivant l'évolution de votre risque cardiovasculaire.

### Les statines modifient-elles l'effet d'autres médicaments?

Certains médicaments peuvent modifier l'effet des statines. Les statines peuvent aussi influencer les effets de certains médicaments.
Signalez à votre **médecin** ou à votre **pharmacien** si vous prenez : d'autres médicaments, des médicaments à base de plantes ou des compléments alimentaires.

### En résumé, quelles sont les questions à vous poser avant de prendre des statines?

Pour vous aider à préparer la discussion avec votre médecin, voici quelques questions à vous poser:
-Suis-je prêt(e) à prendre un médicament tous les jours pendant plusieurs années ?
-Suis-je prêt(e) à prendre le risque d'avoir des douleurs musculaires légères (comme 5 personnes sur 100) ?
-Suis-je prêt(e) à prendre le risque de devenir diabétique (comme 1 personne sur 100) ?
-Suis-je prêt(e) à prendre le risque d'avoir des problèmes rénaux graves (comme moins d'1 personne sur 100) ?
-Suis-je prêt(e) à prendre le risque d'avoir des interactions avec d'autres médicaments ?
**Vous ne devez pas choisir tout de suite.** Quelques semaines de plus ou de moins ne changent pas grand-chose. Prenez le temps de réfléchir aux informations de ce site avant de prendre votre décision avec votre médecin.

### Wat zijn geneesmiddelen van de statines groep?

Statines zijn geneesmiddelen die **de cholesterolwaarden in het bloed doen dalen**. De in België verkochte statines zijn simvastatine (Zocor®), atorvastatine (Lipitor®), rosuvastatine (Crestor®), fluvastatine (Lescol®) en pravastatine (Prareduct®).

### Hebben statines neveneffecten?

Onderzoeken tonen aan dat van de 100 personen die statines nemen, zijn er:
-5 personen die **spierpijn** krijgen (vooral in de eerste 3 maanden),
-1 persoon die **diabeet** wordt binnen 5 jaar door de behandeling
-uitzonderlijk, minder dan één persoon die **nierproblemen** krijgen, soms ernstig.

### Hoe lang duurt een behandeling met statines?

De behandeling met statines is een behandeling van lange termijn. U moet de geneesmiddelen **iedere dag nemen gedurende meerdere jaren**. De effectiviteit van de behandeling hangt hiervan af. U moet daarom overtuigd zijn van uw beslissing. U kan te allen tijde van idee veranderen.
Uw cardiovasculaire risico neemt toe met uw leeftijd. **Uw arts zal daarom uw cardiovasculaire risico blijven meten, met of zonder statines.** U kan wachten en later met statines beginnen, volgens de evolutie van uw cardiovasculaire risico.

### Kan ik statines nemen in combinatie met andere geneesmiddelen?

Bepaalde geneesmiddelen kunnen het effect van statines beïnvloeden. Statines kunnen ook het effect van bepaalde geneesmiddelen beïnvloeden.
Overleg zeker met uw **arts** of **apotheker** als u andere geneesmiddelen neemt, of geneesmiddelen op basis van planten, of voedingssupplementen.

### Samenvatting. Waarover moet u nadenken alvorens statines te nemen?

Om u te helpen bij het gesprek met uw arts zijn hier enkele vragen die u zich kan stellen:
-Ben ik bereid om dagelijks en gedurende meerdere jaren een geneesmiddel te nemen?
-Ben ik bereid om het risico te nemen om spierpijn te krijgen (bij 5 op de 100 personen)?
-Ben ik bereid om het risico te nemen om diabeet te worden (bij 1 op de 100 personen)?
-Ben ik bereid om het risico te nemen om ernstige nierproblemen te krijgen (bij minder dan 1 op de 100 personen)?
-Ben ik bereid om het risico te nemen op interacties met andere geneesmiddelen?
**U hoeft niet onmiddellijk te beslissen.** Enkele weken meer of minder maken weinig verschil. Neem uw tijd om over de informatie op deze website na te denken voor u samen met uw arts een beslissing neemt.



▾ **À quoi sert de faire ce test?**

**ATTENTION : Ce qui suit s'adresse uniquement aux personnes qui n'ont jamais fait d'infarctus ou d'AVC.** Le choix de prendre des statines doit être bien pesé. Les statines aident à réduire votre risque cardiovasculaire, mais elles peuvent avoir d'autres conséquences. Le test proposé sur ce site web vous permet de parler avec votre médecin des possibles avantages et risques des statines. Ainsi vous pouvez faire un « choix éclairé ».
**Ce site web** permet à votre médecin traitant de **comparer votre risque de mourir d'un infarctus ou d'un AVC dans les 10 ans à venir *avec et sans statines*.**

▾ **Wat is de bedoeling van deze test?**

**AANDACHT : Het onderstaande richt zich enkel aan personen die nooit een infarct of beroerte hebben gehad.** De keuze om statines te nemen moet goed doordacht gebeuren. Statines helpen om uw cardiovasculaire risico te verkleinen. Ze kunnen echter ook neveneffecten hebben. De test die op deze website voorgesteld wordt helpt om met uw arts **de mogelijke voordelen en risico's van statines te bespreken**. Zo kan u een geïnformeerde keuze maken.
**Deze website** stelt uw huisarts in staat om **uw kans op overlijden door een infarct of beroerte in de komende 10 jaar *met* en *zonder* statines te vergelijken**.

## 5.4 The 'about this site' tab

The page mentions:

- that the tool has to be used during the consultation by the GP and the patient;
- the source of the SCORE;
- the source of the data (KCE report 306) ;
- the link to the present report;
- that the tool is approuved by the GP's Belgian scientific societies.

## Figure 12 – The 'about this site' page (French and Dutch)






# 6 DISSEMINATION OF THE ONLINE TOOL

The dissemination of the Staine online tool takes place in applying the classical communication strategy of the KCE for any newly approved report.

## 6.1 Website

As for each KCE report, the present report is published on the KCE website in the month following its approval by the Board of Directors. The tool will be generally accessible and can be found following two ways:

- First, a specific page is created, dedicated to this scientific report, with a short introductory text. Different documents can be downloaded or accessed from this page:
    - This scientific report which details the research process including methodological steps and results. It is written in English, since it is the language of the (Belgian and international) scientific community and allows a widespread dissemination of the research, beyond the national borders.
    - A 10-page summary which outlines in a clear and fluid language the context and the method of development of the tool, more accessible for lay readers, including primary healthcare practitioners and patients. For this reason, the summary is available in French and Dutch.
    - A clearly visible button allowing a direct access to the online tool is provided.
- Second, a specific page on the KCE website gathers all practical tools developed so far by KCE (https://kce.fgov.be/en/support-tools-for-medical-consultation).

## 6.2 Press

On the same day as the publication of the report on the website, a press release is sent to approximately 300 journalists including the medical press. The press release is a two-page text written for journalists; it contains all information that can be interesting for the targeted public, in French and Dutch.

## 6.3 Social media and newsletters

KCE will also publish a link towards the online tool via its Twitter, LinkedIn and Facebook accounts.

Moreover, the stakeholders that have collaborated on the HTA report and/or the tool development will be informed about the availability of the tool and will be requested to disseminate it through their respective networks, via their own newsletter, social media and/or website.

Finally, KCE also publishes a specific newsletter dedicated to general practitioners. This newsletter is published whenever KCE wishes to share relevant information with this specific public. In early 2020, the present online decision-aid for the prescription of statins in primary prevention will be published. A special issue of the newsletter will be devoted to this publication.

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# APPENDICES

## APPENDIX 1. ASSESMENT OF THE ALGORITHMS

**Figure 13 – Linear correlations between the chart and the tool risk value of SCORE in women with HDL cholesterol=0.8mmol/l, in non-smoker (left panel) and smoker (right panel).**

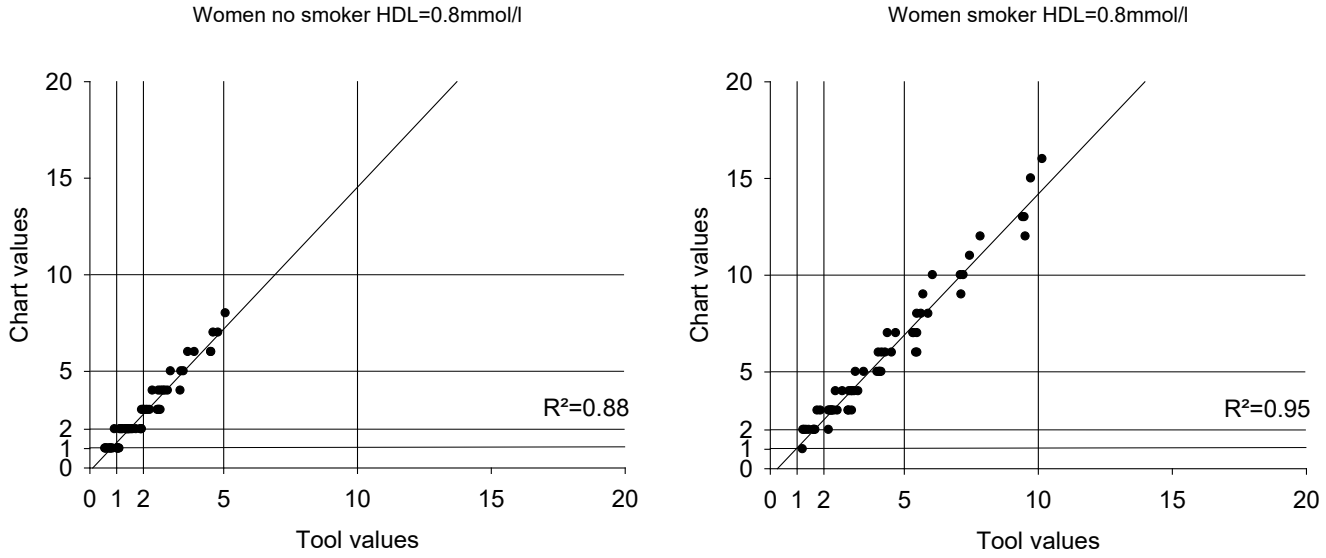


**Figure 14 – Linear correlations between the chart and the tool risk value of SCORE in men with HDL cholesterol=0.8mmol/l, in non-smoker (left panel) and smoker (right panel).**

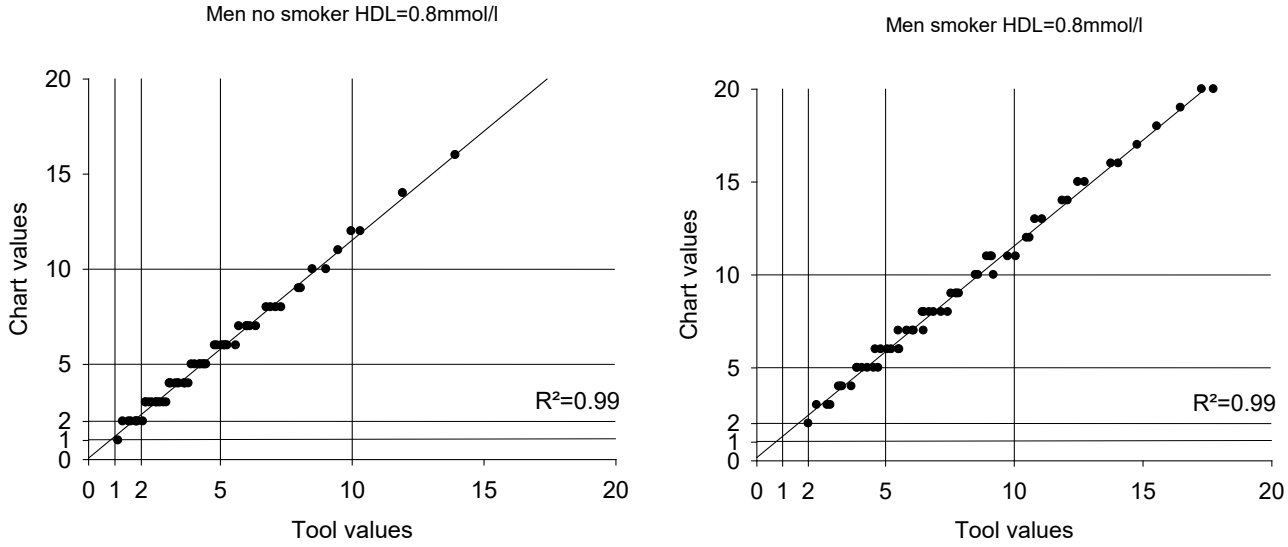


**Figure 15 – Linear correlations between the chart and the tool risk value of SCORE in women with HDL cholesterol=1mmol/l, in non-smoker (left panel) and smoker (right panel).**

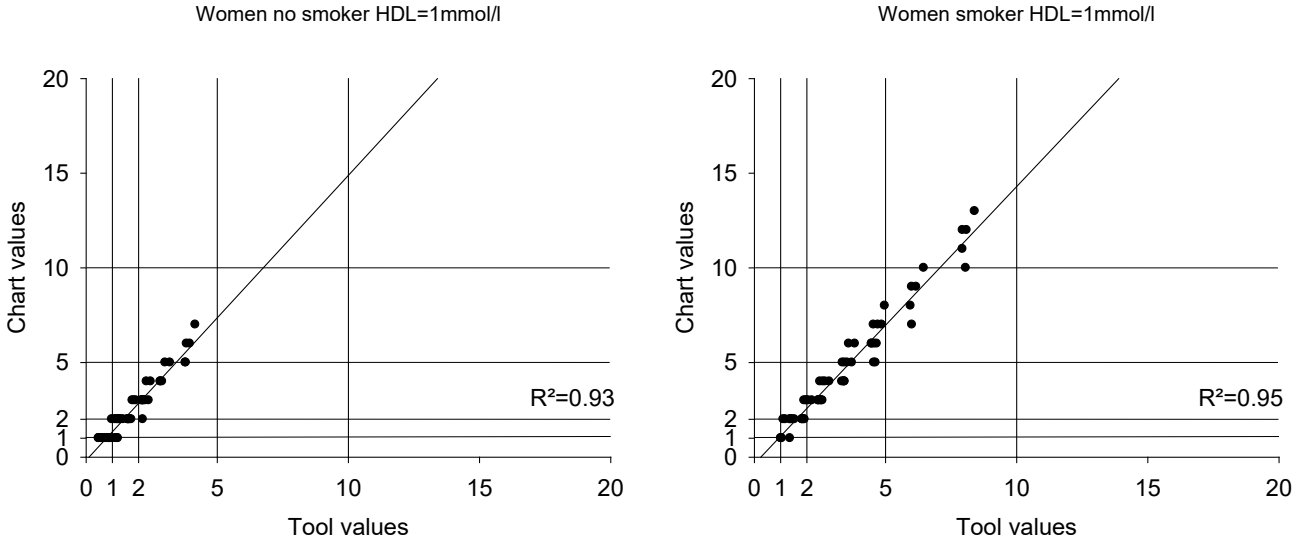


**Figure 16 – Linear correlations between the chart and the tool risk value of SCORE in men with HDL cholesterol=1mmol/l, in non-smoker (left panel) and smoker (right panel).**

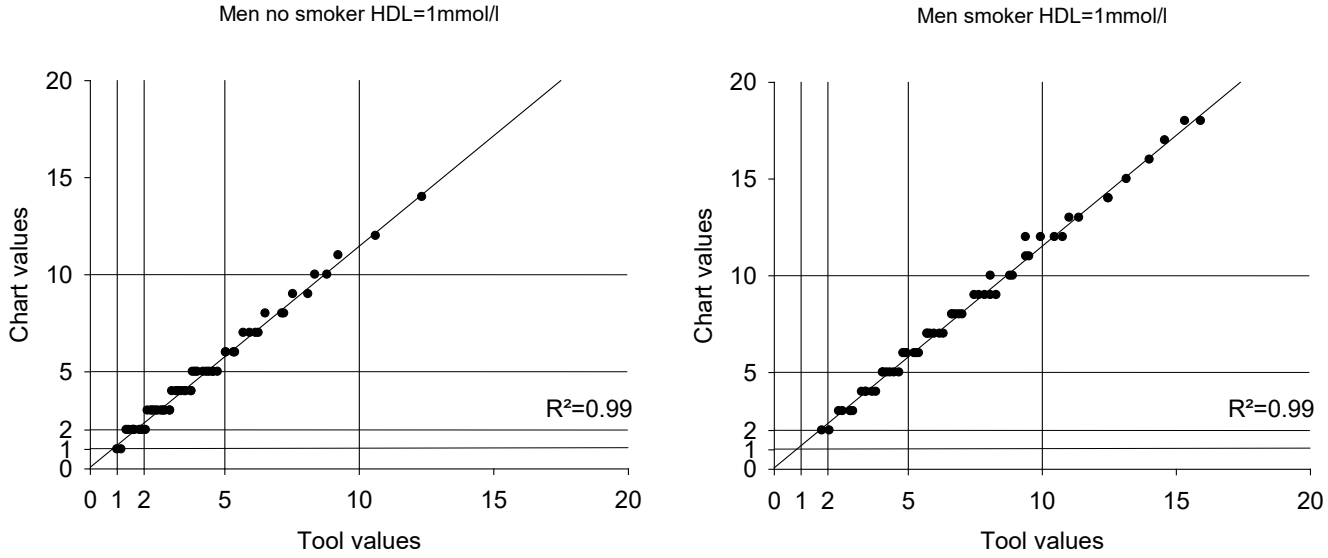


**Figure 17 – Linear correlations between the chart and the tool risk value of SCORE in women with HDL cholesterol=1.4mmol/l, in non-smoker (left panel) and smoker (right panel).**

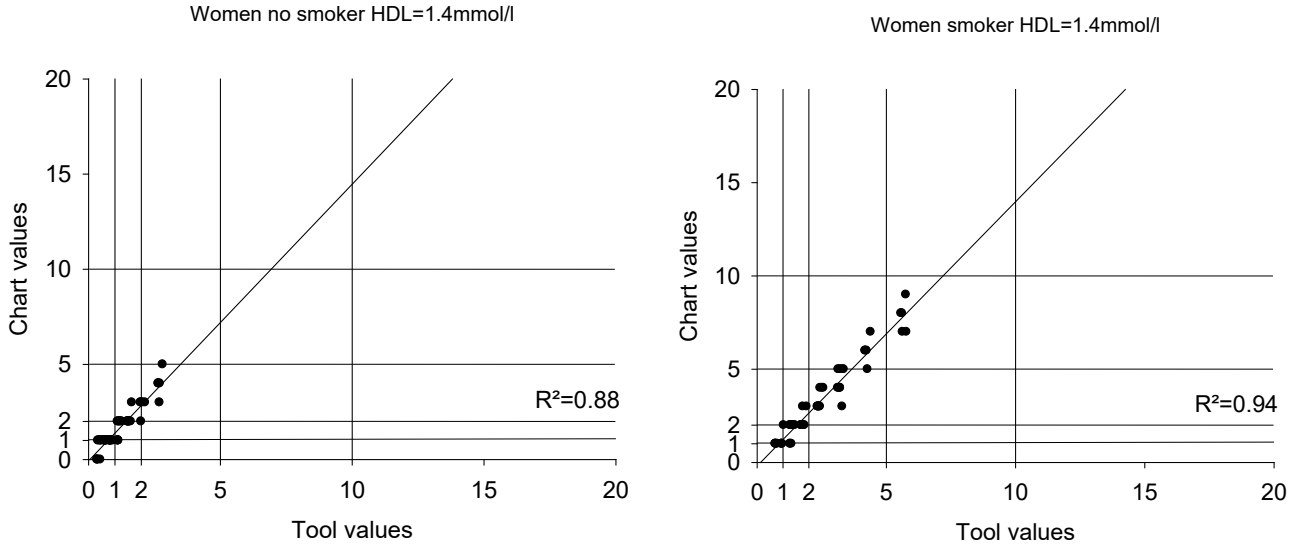


**Figure 18 – Linear correlations between the chart and the tool risk value of SCORE in men with HDL cholesterol=1.4mmol/l, in non-smoker (left panel) and smoker (right panel).**

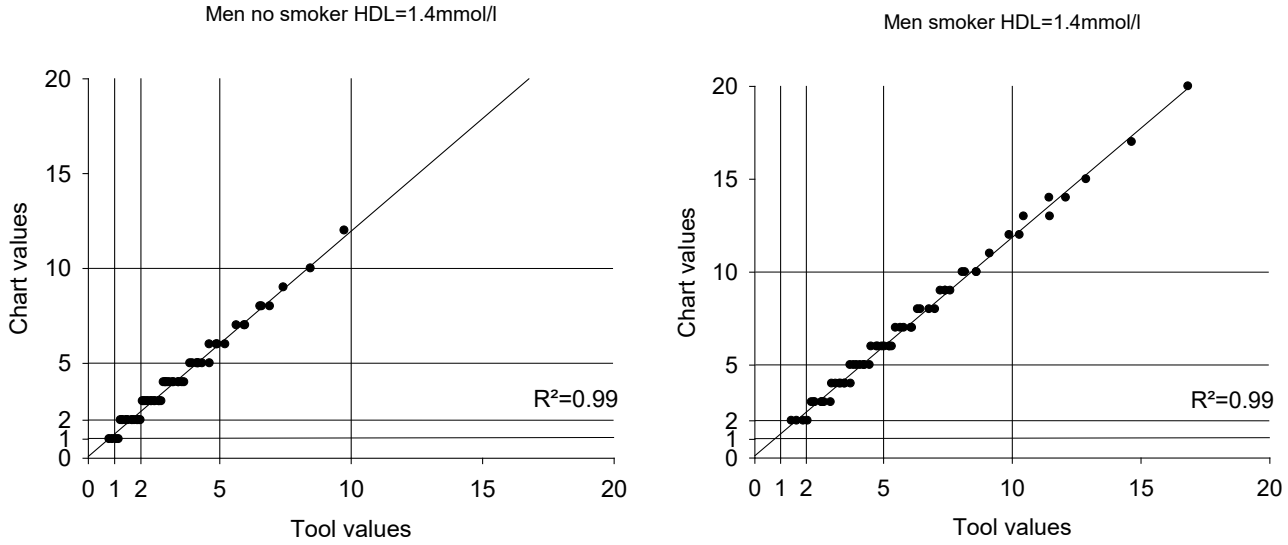


**Figure 19 – Linear correlations between the chart and the tool risk value of SCORE in women with HDL cholesterol=1.8mmol/l, in non-smoker (left panel) and smoker (right panel).**

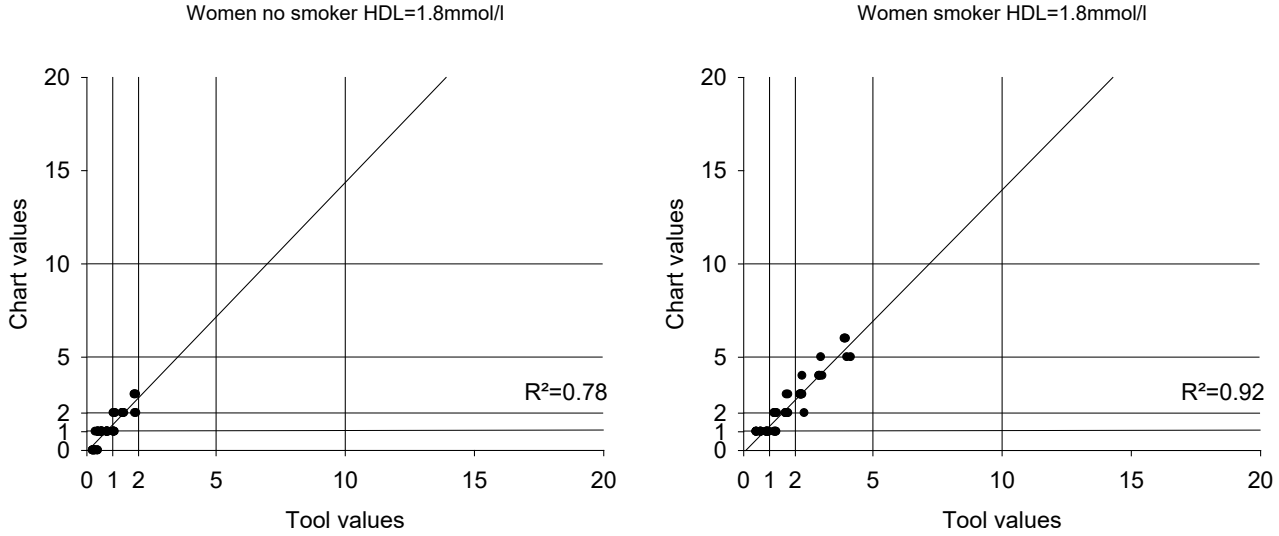


**Figure 20 – Linear correlations between the chart and the tool risk value of SCORE in men with HDL cholesterol=1.8mmol/l, in non-smoker (left panel) and smoker (right panel).**

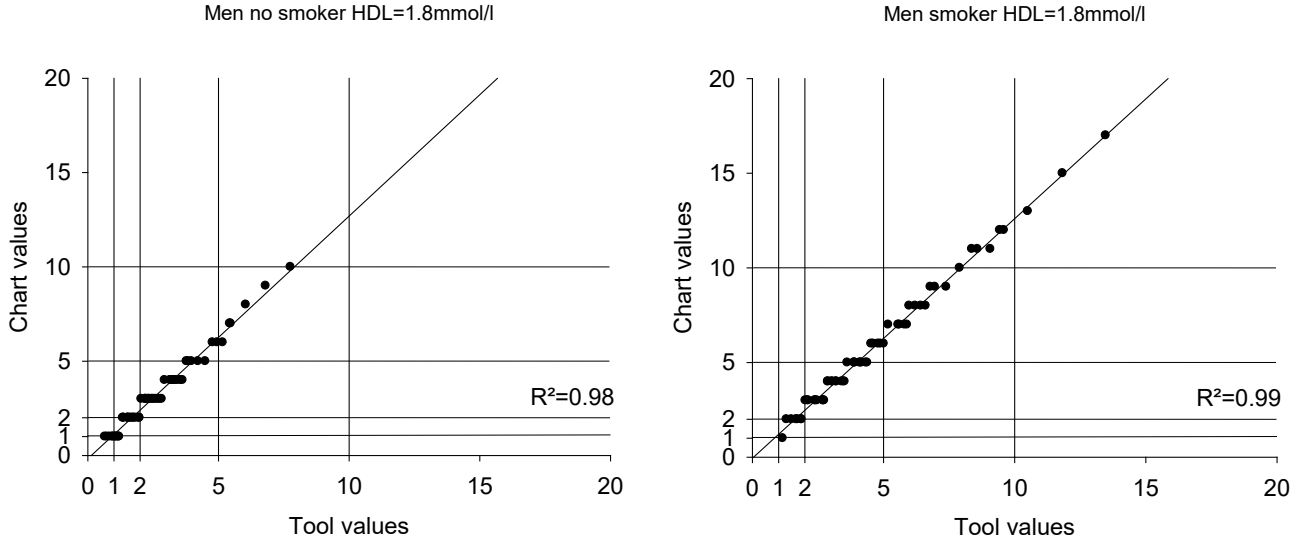


**Figure 21 – Linear correlations between the chart and the tool risk value of Belgium SCORE in women, in non-smoker (left panel) and smoker (right panel).**

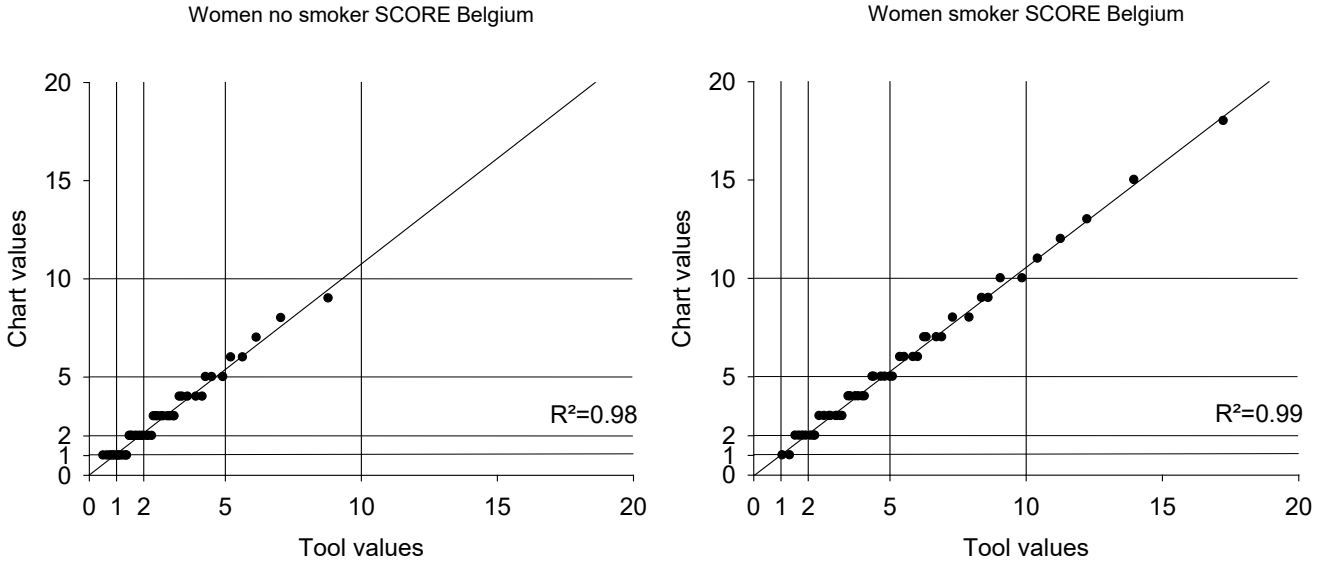
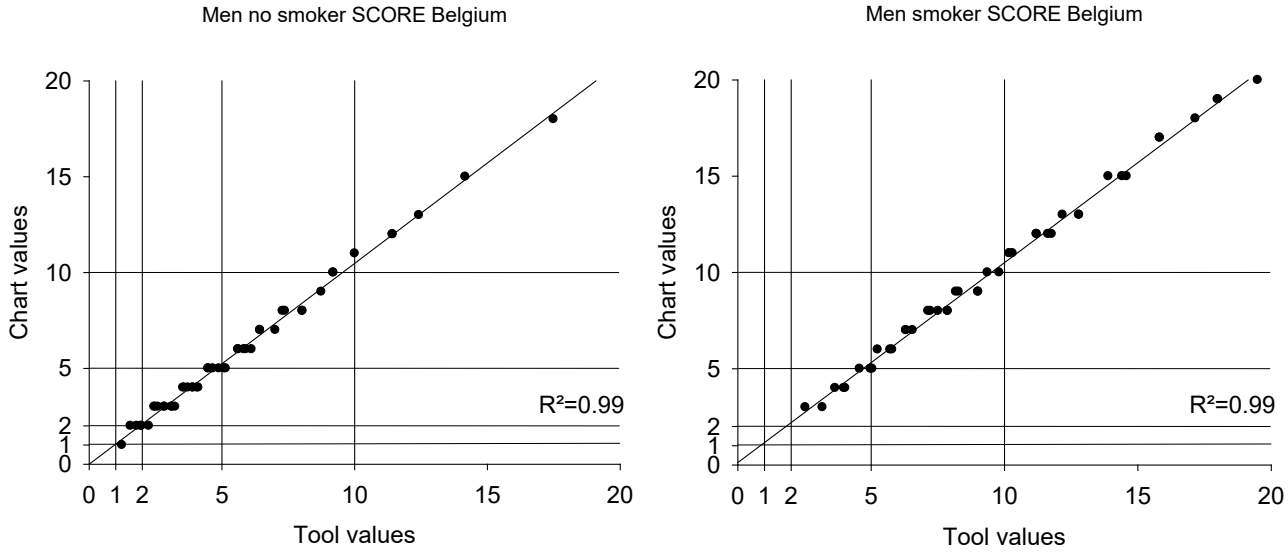


**Figure 22 – Linear correlations between the chart and the tool risk value of Belgium SCORE in men, in non-smoker (left panel) and smoker (right panel).**



# APPENDIX 2. ASSESMENT OF THE TEXTS

## Appendix 2.1. Texts

### Appendix 2.1.1. *Home page - Dutch*

**Cholesterol verminderen met geneesmiddelen?**

**De voordelen en de nadelen**

Deze website is bedoeld om huisartsen en patiënten te helpen om samen te beslissen om al dan niet een geneesmiddel van de ”statines” groep te nemen om het risico op een infarct of beroerte te verminderen.

Hij bevat een test die de arts kan gebruiken tijdens de consultatie met zijn patiënt.

De test berekent het cardiovasculaire risico van de patiënt. Vervolgens vergelijkt de test het **risico op overlijden door een infarct of beroerte in de komende 10 jaar met en zonder statines.**

De resultaten worden afgedrukt of gedownload (pdf). Zo kan de patiënt in alle rust nadenken over de beslissing.

Het pdf document kan worden toegevoegd aan het medisch dossier van de patiënt.

**Start de test**

De evaluatie van het cardiovasculaire risico kan gebeuren op basis van de Europese of Belgische S.CO.R.E. (Systematic COronary Risk Evaluation).

De test mag niet gebruikt worden voor diabetespatiënten, personen met een voorgeschiedenis van cardiovasculaire problemen of met hypercholesterolemie in de familie. Deze mensen moeten beschouwd worden als hebbende een verhoogd risico en moeten een gepaste opvolging krijgen.

De test is gebaseerd op de gegevens uit het rapport XXXXXXX (**hyperlink)**, gepubliceerd in mei 2017 door KCE. Meer informatie over de ontwikkeling van de website is te vinden in het rapport XXXXXXX (**hyperlink).**

**Deze test voor gezondheidszorg is goedgekeurd door:**

### Appendix 2.1.2. *Results page - Dutch*

**Berekening van het risico op overlijden door infarct of beroerte in de komende 10 jaar**

Opgelet:

**- De test is niet geldig voor personen die ooit een infarct of beroerte hebben gehad.**

**- De test kan niet voorspellen wat er met een bepaald individu zal gebeuren, noch wanneer.**

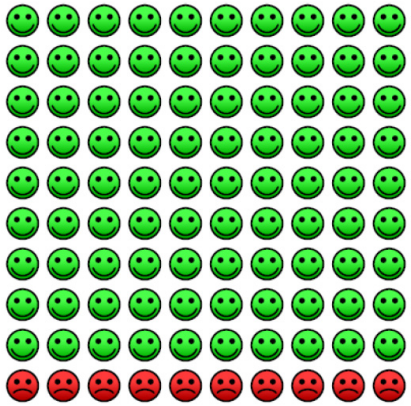
**- De test houdt geen rekening met mogelijke andere oorzaken van overlijden.**

Uw kans op overlijden door een infarct of beroerte in de komende 10 jaar is : LAAG / MIDDELMATIG / VERHOOGD / ERNSTIG VERHOOGD

**Vergelijking van het risico op overlijden door een infarct of beroerte in de komende 10 jaar, met en zonder statines.**

## Zonder statines

**100** personen hebben een **laag risico** op overlijden door een infarct of beroerte in de komende 10 jaar. Zij nemen **geen statines**.

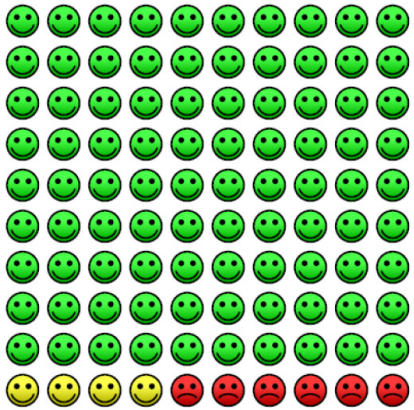


**10 jaar later :**

**90** personen zijn niet overleden door een infarct of beroerte
**10** personen zijn overleden door een infarct of beroerte

## Met statines

**100** personen hebben een **laag risico** op overlijden door een infarct of beroerte in de komende 10 jaar. Zij nemen **wel statines**.



**10 jaar later :**

**94** personen zijn niet overleden door een infarct of beroerte, waarvan **4 personen** dankzij statines
**6** personen zijn overleden door een infarct of beroerte

| **Bijwerkingen van statines:**<br>**100 personen die statines nemen:** |
|---|
| **5** personen krijgen last van spierpijn<br>**1** persoon wordt diabeet<br>**Minder dan 1** persoon krijgt last van nierfalen |

## Appendix 2.1.3. *Patient information page- Dutch*

**U heeft te veel cholesterol…**

**Nochtans eet u gevarieerd en beweegt u regelmatig**

**Geneesmiddelen kunnen uw risico op infarct of beroerte verkleinen**

**Deze informatie kan u helpen bij het afwegen van de voor- en nadelen**

**Waarom is te veel cholesterol slecht voor uw gezondheid?**

Cholesterol is een vet dat in het bloed circuleert.

Cholesterol kan hartslagaders verstoppen. Dit kan pijn in de borst veroorzaken (angina pectoris). Soms kan dit zelfs een hartaanval (infarct) veroorzaken.

Cholesterol kan ook de bloedvaten in de hersenen verstoppen en een beroerte veroorzaken. Zo'n accident kan belangrijke zones in de hersenen beschadigen (met gevolgen zoals halfzijdige verlamming, verlies van het spraakvermogen, etc.). De verloren functies komen soms gedeeltelijk of geheel terug, soms ook niet. Dit hangt af van de ernst van de beroerte.

Infarcten en beroertes zijn de belangrijkste doodsoorzaken in België.

**Wat is het cardiovasculaire risico?**

Het cardiovasculaire risico is het risico om een hartaanval of beroerte te krijgen. Het cardiovasculaire risico neemt toe met de leeftijd.

In het algemeen is dit risico groter bij mannen dan vrouwen.

Andere risicofactoren zijn cholesterol, roken en hoge bloeddruk.

Personen met diabetes of nierfalen hebben een hoger dan gemiddeld risico.

Hoe uw cardiovasculaire risico bepalen?

Uw arts kan uw cardiovasculaire risico evalueren. Daarvoor baseert hij zich op uw leeftijd, geslacht, bloeddruk, cholesterolniveau en of u rookt of niet.

Uw arts kan dit risico regelmatig evalueren, bijvoorbeeld ieder jaar.

**Hoe uw cardiovasculaire risico verkleinen?**

**De belangrijkste ingrepen om uw cardiovasculaire risico te beperken zijn:**

- stoppen met roken;
- evenwichtiger eten;
- uw alcoholconsumptie verminderen;
- vaker bewegen.

Uw arts kan u adviseren over uw voeding en uw fysieke beweging. Hij kan u ondersteunen als u beslist te stoppen met roken.

De voedingsindustrie promoot veel producten om uw cholesterol te verlagen (zoals bepaalde drankjes, yoghurts en plantaardige vetstoffen met « sterolen » en « stanolen » of met omega-3). In tegenstelling met wat in de reclames wordt beweerd, is er onvoldoende bewijs dat deze producten helpen om uw algemene cardiovasculaire risico te beperken.

**Volstaan deze ingrepen niet?**

Uw arts kan u voorstellen om een geneesmiddel van de statines groep te nemen.

U neemt de beslissing over deze behandeling samen.

Gezonde levensgewoontes blijven de basis van de behandeling.

**Wat zijn geneesmiddelen van de statines groep?**

Statines zijn geneesmiddelen die de cholesterolwaarden in het bloed doen dalen. De in België verkochte statines zijn simvastatine (Zocor®), atorvastatine (Lipitor®), rosuvastatine (Crestor®), fluvastatine (Lescol®) en pravastatine (Prareduct®).

Beslissing voor behandeling moet doordacht gebeuren

**AANDACHT : Het onderstaande richt zich enkel aan personen die nooit een infarct of beroerte hebben gehad.**

De keuze om statines te nemen moet goed doordacht worden. Statines helpen om uw cardiovasculaire risico te verkleinen. Ze kunnen echter ook neveneffecten hebben. Deze website helpt om met uw arts de **mogelijke voordelen en risico's van statines te bespreken**. Zo kan u een geïnformeerde keuze maken.

De behandeling met statines is een behandeling van lange termijn. U moet de geneesmiddelen **iedere dag nemen gedurende meerdere jaren.** De effectiviteit van de behandeling hangt hiervan af. U moet daarom overtuigd zijn van uw beslissing. U kan ten allen tijde van idee veranderen.

**U hoeft niet onmiddellijk te beslissen.** Enkele weken meer of minder maken weinig verschil. Neem uw tijd om over de informatie op deze website na te denken voor u samen met uw arts een beslissing neemt.

Uw cardiovasculaire risico neemt toe met uw leeftijd. Uw arts zal daarom uw cardiovasculaire risico blijven meten, met of zonder statines.

U kan wachten en later met statines beginnen, volgens de evolutie van uw cardiovasculaire risico.

**Voordelen en nadelen van statines**

Mensen die samen met hun arts beslissen om al dan niet statines te nemen, stellen zich vragen over:

***De behandeling met statines dag tot dag***

De behandeling bestaat vaak uit **dagelijks** een pil nemen. U volgt deze behandeling **gedurende meerdere jaren**.

***De invloed van statines op het cardiovasculaire risico***

Statines kunnen helpen om uw cholesterolwaarde te verlagen. Op die manier verkleinen ze uw cardiovasculaire risico.
Deze website stelt uw huisarts in staat om uw kans op overlijden door een infarct of beroerte in de komende 10 jaar **met** en **zonder** statines te vergelijken.

Het risico om binnen de komende tien jaar een infarct of beroerte te krijgen *zonder eraan te overlijden* is bij mannen gemiddeld 3 keer hoger dan het risico op een dodelijk infarct of beroerte en bij vrouwen gemiddeld 4 keer hoger.

***Neveneffecten van statines***

Onderzoeken tonen aan dat van de 100 personen die statines nemen:

- 5 personen spierpijn krijgen. Vooral in de eerste 3 maanden.
- 1 persoon diabeet wordt binnen 5 jaar door de behandeling.
- uitzonderlijk krijgen personen nierproblemen. Soms ernstig.

***Statines nemen met andere geneesmiddelen***

Bepaalde geneesmiddelen kunnen het effect van statines beïnvloeden.
Statines kunnen ook het effect van bepaalde geneesmiddelen beïnvloeden.
Overleg zeker met uw arts of apotheker als u:

- geneesmiddelen neemt;
- geneesmiddelen op basis van planten neemt;
- voedingssupplementen neemt.

**Samenvatting. Waarover moet u nadenken alvorens statines te nemen?**

Om u te helpen bij het gesprek met uw arts zijn hier enkele vragen die u zich kan stellen:

Ben ik bereid om:

Dagelijks en gedurende meerdere jaren een geneesmiddel te nemen?

Het risico te nemen om spierpijn te krijgen (bij 5 op de 100 personen)?

Het risico te nemen om diabeet te worden (bij 1 op de 100 personen)?

Het risico te nemen om ernstige nierproblemen te krijgen (bij minder dan 1 op de 100 personen)?

Het risico te nemen op interacties met andere geneesmiddelen?

## Appendix 2.1.4. *Patient letter - Dutch*

**Moet ik een geneesmiddel van de statines groep nemen om mijn cardiovasculair risico te verminderen?**

Datum : xx/yy/2019

Uw cardiovasculair risico (kans op overlijden door een infarct of beroerte in de komende 10 jaar) is geëvalueerd door de SCORE / EUROSCORE test:
Uw risico is LAAG / MIDDELMATIG / VERHOOGD / ERNSTIG VERHOOGD

Het resultaat is afhankelijk van uw leeftijd, geslacht, bloeddruk, van uw cholesterolwaarde en het feit dat u rookt of niet.

**De belangrijkste maatregelen om uw cardiovasculair risico te beperken zijn:**

- stoppen met roken;
- evenwichtiger eten;
- uw alcoholconsumptie verminderen;
- regelmatiger bewegen.

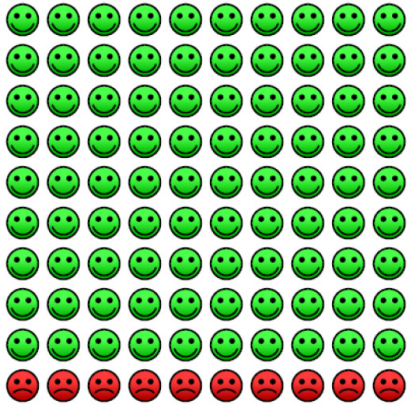
**Volstaan deze maatregelen niet? Dan kan uw arts u een geneesmiddel van de statines groep voorschrijven.** De beslissing om deze behandeling te starten neemt u samen met uw arts.

Deze grafieken vergelijken uw risico op overlijden door een infarct of een beroerte in de komende 10 jaar **met en zonder** statines.

Opgelet:

- De test is niet geldig voor personen die ooit een infarct of beroerte hebben gehad.
- De test kan niet voorspellen wat er met een bepaald individu zal gebeuren, noch wanneer.
- De test houdt geen rekening met mogelijke andere oorzaken van overlijden.

**100** personen hebben een **laag risico** op overlijden door een infarct of beroerte in de komende 10 jaar. Zij nemen **geen statines**.

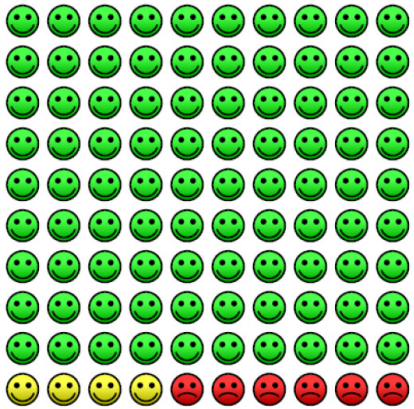


**10 jaar later :**

**90** personen zijn niet overleden door een infarct of beroerte

**10** personen zijn overleden door een infarct of beroerte

**100** personen hebben een **laag risico** op overlijden door een infarct of beroerte in de komende 10 jaar. Zij nemen **wel statines**.



**10 jaar later :**

**94** personen zijn niet overleden door een infarct of beroerte, waarvan **4 personen** dankzij statines

**6** personen zijn overleden door een infarct of beroerte

Voor u beslist om al dan niet statines te nemen, moet u weten dat :

- Statines nemen verlaagt uw cardiovasculaire risico niet tot nul. U moet gezonde levensgewoontes volhouden. Dit is de basis van de behandeling.
- Statines nemen kan neveneffecten veroorzaken :
  - Spierpijn (bij 5 personen op 100)
  - Diabetes ( bij 1 persoon op 100)
  - Nierproblemen (minder dan 1 persoon op 100)
- De behandeling met statines is een behandeling van lange duur. U neemt het geneesmiddel iedere dag gedurende verschillende jaren. De goede werking van de behandeling hangt hier van af.
- Uw cardiovasculaire risico neemt toe met uw leeftijd, of u statines neemt of niet. Uw arts blijft daarom uw risico meten. Afhankelijk van hoe dit risico evolueert, kan u beslissen om later met statines te beginnen.

U hoeft niet onmiddellijk te beslissen. Enkele weken meer of minder maken weinig verschil.

**Voor meer informatie over het cardiovasculaire risico en statines, bezoek 'informatie voor patiënt' op de website www.statines.kce.be**

| Opmerkingen van uw arts : |
|---|
| |

## Appendix 2.1.5. *Home page – French*

**Diminuer son cholestérol avec des médicaments ?**
**Le pour et le contre**

Ce site est destiné à aider le médecin et le patient à prendre ensemble la décision de recourir, ou pas, à un médicament du groupe des « statines » afin de réduire le risque d'infarctus ou d'accident vasculaire cérébral (AVC).

Il propose un test à utiliser par le médecin pendant la consultation avec son patient.

Après avoir calculé le risque cardiovasculaire du patient, le test compare **son risque de mourir d'un infarctus ou d'un AVC dans les 10 ans avec et sans statines.**

Les résultats peuvent être imprimés ou téléchargés (pdf). Ainsi le patient peut en disposer et réfléchir, à tête reposée, à sa décision.

Le document pdf peut être ajouté au dossier médical du patient.

**Faire le Test**

L'évaluation du niveau de risque cardiovasculaire peut se faire sur la base du S.C.O.R.E (Systematic COronary Risk Evaluation) européen ou belge.

Le test ne peut pas être utilisé pour les patients diabétiques, avec des antécédents familiaux de problèmes cardiovasculaires ou une hypercholestérolémie familiale. Ces personnes doivent être considérées d'emblée comme à risque élevé et recevoir un suivi adapté.

Le test se base sur les données du rapport HTA XXXXX **(lien)** publié en mai 2017 par le KCE.

**Les informations relatives au développement du site web sont présentées dans le rapport XXX (lien)**

## Appendix 2.1.6. *Result page - French*

**Calcul du risque de mourir d'un infarctus ou d'un AVC dans les 10 prochaines années**

AVERTISSEMENTS :

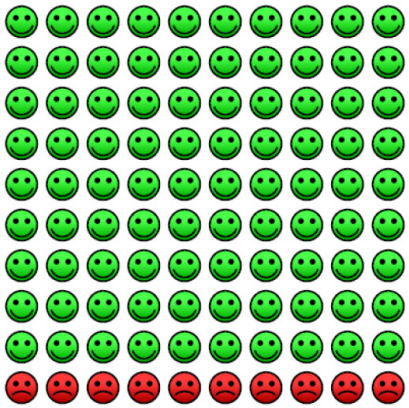
- Ce test n'est pas valable pour des personnes qui ont déjà fait un infarctus ou un AVC.
- Ce test ne prédit pas ce qui arrivera à une personne en particulier, ni quand.
- Ce test ne tient pas compte des autres causes possibles de décès.

Votre risque de mourir d'un infarctus ou d'un accident vasculaire cérébral (AVC) dans les 10 ans à venir : FAIBLE/ MODERE/ELEVE/TRES ELEVE

**Comparaison du risque de mourir d'un infarctus ou d'un AVC dans les 10 prochaines années avec et sans statines**.

## Sans statines

**100** personnes ont un **risque faible** de mourir d'un infarctus ou d'un AVC dans les 10 ans. Elles ne prennent **pas de statines.**



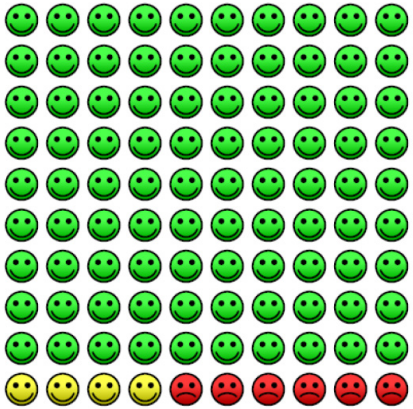
**10 ans plus tard :**

**90** personnes ne seront pas mortes d'un infarctus ou d'un AVC

**10** personnes seront mortes d'un infarctus ou d'un AVC

## Avec statines

**100** personnes ont un **risque faible** de mourir d'un infarctus ou d'un AVC dans les 10 ans. Elles prennent des **statines.**



**10 ans plus tard :**

**94** personnes ne seront pas mortes d'un infarctus ou d'un AVC, dont

**4** personnes grâce aux statines

**6** personnes seront mortes d'un infarctus ou d'un AVC

| **<u>Les statines ont des effets secondaires</u> :100 personnes prennent des statines:** |
|---|
| **5** personnes auront des douleurs musculaires |
| **1** personne aura le diabète |
| **Moins d'1** personne aura une insuffisance rénale |

## Appendix 2.1.7. *Patient information page - French*

**Vous avez trop de cholestérol…**

**Pourtant vous avez équilibré votre alimentation et vous faites de l'exercice physique**

**Prendre des médicaments pourrait réduire votre risque d'infarctus ou d'AVC**

Voici quelques informations pour vous aider à peser le pour et le contre

- Pourquoi trop de cholestérol est-il mauvais pour la santé ?

Le cholestérol est une graisse qui circule dans le sang.

Le cholestérol peut boucher les artères du **cœur**. Cela peut causer des douleurs dans la poitrine (angine de poitrine). Et parfois même provoquer une crise cardiaque (**infarctus**).

Le cholestérol peut aussi boucher les artères du **cerveau** et causer un **accident vasculaire cérébral** (AVC ou « thrombose cérébrale »). Cet accident peut abimer des zones importantes du cerveau (hémiplégie, aphasie, etc.). Les fonctions perdues reviennent parfois complètement, en partie, ou pas du tout. Cela dépend de la gravité de l'AVC.

L'infarctus et l'AVC sont les causes les plus courantes de décès en Belgique.

- Qu'est-ce que le risque cardiovasculaire ?

Le risque cardiovasculaire correspond au risque de faire un infarctus ou un accident vasculaire cérébral (AVC).

Le risque cardiovasculaire augmente avec l'âge. En général, il est plus grand chez les hommes que chez les femmes.

Les autres facteurs de risque bien connus sont **le cholestérol,** le tabac et l'hypertension artérielle.

Les personnes diabétiques ou insuffisantes rénales ont un risque plus important que la moyenne.

- Comment connaître votre risque cardio-vasculaire ?

Votre médecin peut évaluer votre risque cardio-vasculaire. Pour cela, il se base sur votre âge, votre sexe, votre tension artérielle, votre taux de cholestérol et le fait que vous fumiez ou pas.

Votre médecin peut évaluer ce risque régulièrement, par exemple tous les ans.

- Comment diminuer votre risque cardio-vasculaire ?

**Les premières mesures pour diminuer votre risque cardio-vasculaire sont :**

- arrêter de fumer ;
- manger plus équilibré ;
- réduire votre consommation d'alcool ;
- faire plus d'exercice physique.

Votre médecin peut vous donner des conseils diététiques et sportifs. Il peut vous soutenir si vous décidez d'arrêter de fumer.

L'industrie alimentaire propose beaucoup de produits pour faire baisser le cholestérol (comme certaines boissons, yaourts et matières grasses contenant des « stérols » et « stanols » dérivés des plantes, ou des acides gras oméga-3). Contrairement à ce que dit la publicité, il n'y a pas de preuves suffisantes que ces produits aident à diminuer le risque cardio-vasculaire global.

**Ces mesures ne suffisent pas ?**

Votre médecin peut vous proposer de prendre un médicament du groupe des statines.

Vous prenez la décision du traitement ensemble.

Un mode de vie sain reste la base du traitement.

- Qu'est-ce qu'un médicament du groupe des statines ?

Les statines sont des médicament qui font baisser le cholesterol dans le sang. Les statines vendues en Belgique sont la simvastatine (Zocor®), l'atorvastatine (Lipitor®), la rosuvastatine (Crestor®), la fluvastatine (Lescol®) et la pravastatine (Prareduct®).

- Réfléchir avant de décider d'un traitement

**ATTENTION : Ce qui suit s'adresse uniquement aux personnes qui n'ont jamais fait d'infarctus ou d'AVC.**

Le choix de prendre des statines doit être bien pesé. Les statines aident à réduire votre risque cardio-vasculaire. Mais elles peuvent avoir d'autres conséquences. Ce site web vous permet de parler avec votre médecin des **possibles avantages et risques des statines**. Ainsi vous pouvez faire un «choix éclairé».

Le traitement par statines est un **traitement à long terme**. Vous prendrez des médicaments **tous les jours pendant plusieurs années**. L'efficacité du traitement en dépend. Vous devez donc être convaincu de faire le bon choix. Mais vous pourrez bien sur changer d'avis.

**Vous ne devez pas choisir tout de suite**. Quelques semaines de plus ou de moins ne changent pas grand-chose. Prenez le temps de réfléchir aux informations de ce site avant de prendre votre décision avec votre médecin.

Votre risque cardio-vasculaire augmente avec l'âge. Votre médecin **continuera donc à mesurer votre risque, avec ou sans statines.**

Vous pouvez attendre et débuter des statines plus tard, suivant l'évolution de votre risque cardio-vasculaire..

- Avantages et désavantages des statines ?

Les personnes qui doivent décider, avec leur médecin, de prendre ou non des statines se posent des questions sur :

### Le traitement par statines au jour le jour

Le traitement est souvent d'**un comprimé par jour**. Vous prenez ce traitement pendant **plusieurs années**.

### L'Influence des statines sur le risque cardio-vasculaire

Les statines peuvent aider à faire baisser votre taux de cholestérol. Donc votre risque cardio-vasculaire diminue.

Ce site web permet à votre médecin traitant de comparer votre risque de mourir d'un infarctus ou d'un AVC dans les 10 ans à venir **avec** et **sans** statines.

Le risque de faire un infarctus ou un AVC dans les 10 ans *sans en mourir* est en général 3 fois plus élevé pour les hommes et 4 fois plus élevé pour les femmes que le risque d'en mourir.

### Les effets secondaires des statines

Les études montrent que sur 100 personnes qui prennent des statines :

- **5 personnes** ont des **douleurs aux muscles**. Surtout les 3 premiers mois.
- **1 personne** devient **diabétique** dans les 5 ans à cause du médicament.
- Exceptionnellement, des personnes ont des problèmes rénaux, parfois graves.

### La prise des statines avec d'autres médicaments

Certains médicaments peuvent modifier l'effet des statines.

Les statines peuvent aussi influencer les effets de certains médicaments.

Signalez à votre médecin ou à votre pharmacien si vous prenez :

  - des médicaments ;
  - des médicaments à base de plantes ;
  - des compléments alimentaires.

- En résumé, quelles sont les questions à vous poser avant de prendre des statines ?

Pour vous aider à préparer la discussion avec votre médecin, voici quelques questions à vous poser :

Suis-je prêt(e) à …

- Prendre un médicament tous les jours pendant plusieurs années ?
- Prendre le risque d'avoir des douleurs musculaires légères (comme 5 personnes sur 100) ?
- Prendre le risque de devenir diabétique (comme 1 personne sur 100) ?
- Prendre le risque d'avoir des problèmes rénaux graves (comme moins d'1 personne sur 100) ?
- Prendre le risque d'avoir des interactions avec d'autres médicaments ?

### Appendix 2.1.8. *Patient letter – French*

**Dois-je prendre un médicament du groupe des statines pour diminuer mon risque cardiovasculaire ?**

Date : xx/yy/2019

Votre niveau de risque cardiovasculaire (risque de mourir d'un infarctus ou d'un accident vasculaire cérébral (AVC) dans les 10 ans à venir) a été évalué par le test SCORE/EUROSCORE:

Votre risque est FAIBLE/ MODERE/ELEVE/TRES ELEVE

Le résultat dépend de votre âge, de votre sexe, de votre tension artérielle, de votre taux de cholestérol et du fait que vous fumiez ou pas.

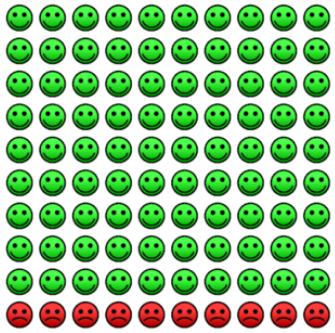
**Les premières mesures pour diminuer votre risque cardiovasculaire sont :**

- arrêter de fumer ;
- manger plus équilibré ;
- réduire votre consommation d'alcool ;
- faire plus d'exercice physique.

**Ces mesures ne suffisent pas ? Alors, votre médecin traitant peut vous prescrire un médicament du groupe des statines**. Vous prenez la décision du traitement ensemble.
Ces graphiques comparent votre risque de mourir d'un infarctus ou d'un AVC dans les 10 prochaines années **sans et avec** statines.

**Sans statines**

**100** personnes ont un **risque faible** de mourir d'un infarctus ou d'un AVC dans les 10 ans. Elles ne prennent **pas de statines.**



**10 ans plus tard :**

**90** personnes ne seront pas mortes d'un infarctus ou d'un AVC

**10** personnes seront mortes d'un infarctus ou d'un AVC

**Avec statines**

**100** personnes ont un **risque faible** de mourir d'un infarctus ou d'un AVC dans les 10 ans. Elles prennent des **statines.**



**10 ans plus tard :**

**94** personnes ne seront pas mortes d'un infarctus ou d'un AVC, dont **4** personnes grâce aux statines

**6** personnes seront mortes d'un infarctus ou d'un AVC

AVERTISSEMENTS :

- Ce test n'est pas valable pour des personnes qui ont déjà fait un infarctus ou un AVC.
- Ce test ne prédit pas ce qui arrivera à une personne en particulier, ni quand.
- Ce test ne tient pas compte des autres causes possibles de décès.

**Avant de décider de prendre, ou pas, des statines, vous devez savoir que :**

- Prendre des statines ne ramène pas votre risque cardio-vasculaire à zéro. Il faut garder des habitudes de vie saines. C'est la base du traitement.
- Les statines peuvent avoir des effets secondaires :
  - douleurs musculaires (5 personnes sur 100) ;
  - diabète (1 personne sur 100) ;
  - problèmes rénaux (moins d'1 personne sur 100).
- Le traitement par statines est un traitement à long terme. Vous prendrez des médicaments tous les jours pendant plusieurs années. L'efficacité du traitement en dépend.
- Avec ou sans statines, votre risque cardio-vasculaire augmente avec l'âge. Votre médecin continuera donc à mesurer votre risque. Vous pouvez décider d'attendre et débuter les statines plus tard suivant l'évolution de votre risque.

Vous n'êtes pas obligé(e) de choisir tout de suite. Quelques semaines de plus ou de moins ne changent pas grand-chose.

**Pour plus d'informations sur le risque cardio-vasculaire et sur les statines, rendez-vous sur l'onglet « information patient » du site : www.statines.kce.be.**

Notes de votre médecin :

## Appendix 2.2. Readability questionnaire - Dutch

| | Leesbaarheidstest beslissingshulp statines |
|---|---|
| 1 | Welke 5 zaken bepalen uw risico op een infarct of beroerte? |
| 2 | Waarvoor dient deze tool? |
| 3 | Hoe kan u uw risico op sterfte door een infarct of beroerte te weten komen? |
| 4 | Is er voldoende bewijs voor het effect van voedingsmiddelen die beloven cholesterol te verminderen? |
| 5 | Welke twee soorten mensen hebben een verhoogd risico op een infarct of beroerte? |
| 6 | Wat zijn de twee belangrijkste doodsoorzaken in België? |
| 7 | Wat zijn de twee belangrijkste mogelijke bijwerkingen van statines ? |
| 8 | Moet u zich haasten om een beslissing nemen rond het nemen van statines of niet? |
| 9 | Wat moet u doen als u beslist statines te nemen terwijl u andere medicijnen gebruikt? |
| 10 | Wat zijn de voornaamste vier gewoontes om uw cardiovasculaire risico te beperken? |
| 11 | Wat doen statines? |
| 12 | Op 100 patiënten die statines nemen, hoeveel krijgen er last van diabetes? |
| 13 | Voor wie is de berekening van het cardiovasculair risico op basis van de tool niet geldig? |
| 14 | Hoe vaak moet u dit geneesmiddel nemen indien u besluit het te nemen? |
| 15 | Hoeveel keer groter is de kans op een infarct of beroerte zonder eraan te overlijden dan de kans op een dodelijke infarct of beroerte bij mannen in de komende 10 jaar? |

| | | | | |
|---|---|---|---|---|
| **1** | Van welke 5 zaken is uw risico op een infarct of beroerte afhankelijk? | Antwoord juist? | JA O | NEE O |
| | *Leeftijd, geslacht, bloeddruk, cholesterolwaarde en rookgedrag.* (Brief patiënt, p.1 bovenaan / Info patiënt, p.2 bovenaan) | Locatie juist? | JA O | NEE O |
| | | Langer dan 30 seconden om antwoord te vinden? | JA O | NEE O |
| | Opmerkingen: | | | |
| **2** | Waarvoor dient deze tool? | Antwoord juist? | JA O | NEE O |
| | *Om te helpen beslissen of u statines gaat nemen of niet.* (Homepage, bovenaan ) | Locatie juist? | JA O | NEE O |
| | | Langer dan 30 seconden om antwoord te vinden? | JA O | NEE O |
| | Opmerkingen: | | | |
| **3** | Hoe kan u uw risico op sterfte door een infarct of beroerte te weten komen? | Antwoord juist? | JA O | NEE O |
| | *Uw arts kan dit berekenen.* (Info patiënt, p.2 bovenaan / Brief patiënt, p.3 midden) | Locatie juist? | JA O | NEE O |
| | | Langer dan 30 seconden om antwoord te vinden? | JA O | NEE O |
| | Opmerkingen: | | | |
| **4** | Is er voldoende bewijs voor het effect van voedingsmiddelen die beloven cholesterol te verminderen? | Antwoord juist? | JA O | NEE O |
| | *Neen.* (Info patiënt, p.2 midden) | Locatie juist? | JA O | NEE O |
| | | Langer dan 30 seconden om antwoord te vinden? | JA O | NEE O |
| | Opmerkingen: | | | |
| **5** | Welke twee soorten mensen hebben een hoger dan gemiddeld risico op een infarct of beroerte? | Antwoord juist? | JA O | NEE O |
| | *Mensen met diabetes en mensen met nierfalen.* (Info patiënt, p.1 onderaan) | Locatie juist? | JA O | NEE O |
| | | Langer dan 30 seconden om antwoord te vinden? | JA O | NEE O |
| | Opmerkingen: | | | |
| **6** | Wat zijn de twee belangrijkste doodsoorzaken in België? | Antwoord juist? | JA O | NEE O |
| | *Infarcten en beroertes.* (Info patiënt, p1 midden) | Locatie juist? | JA O | NEE O |
| | | Langer dan 30 seconden om antwoord te vinden? | JA O | NEE O |
| | Opmerkingen: | | | |
| **7** | Wat zijn de twee belangrijkste mogelijke bijwerkingen van statines ? | Antwoord juist? | JA O | NEE O |
| | *Spierpijn & diabetes.* (Info patiënt, p.4 midden) | Locatie juist? | JA O | NEE O |
| | | Langer dan 30 seconden om antwoord te vinden? | JA O | NEE O |
| | Opmerkingen: | | | |
| **8** | Moet u zich haasten om een beslissing nemen rond het nemen van statines of niet? | Antwoord juist? | JA O | NEE O |
| | *Neen.* (Info patiënt, p.3 midden / Brief patiënt, p.3 onderaan) | Locatie juist? | JA O | NEE O |
| | | Langer dan 30 seconden om antwoord te vinden? | JA O | NEE O |
| | Opmerkingen: | | | |
| **9** | Wat moet u doen als u beslist statines te nemen terwijl u andere medicijnen gebruikt? | Antwoord juist? | JA O | NEE O |
| | *Uw arts of apotheker raadplegen.* (Info patiënt, p.4 onderaan) | Locatie juist? | JA O | NEE O |

| | | | | |
|---|---|---|---|---|
| | | Langer dan 30 seconden om antwoord te vinden? | JA O | NEE O |
| | Opmerkingen: | | | |
| **10** | Wat zijn de voornaamste vier maatregelen om uw cardiovasculaire risico te beperken? | Antwoord juist? | JA O | NEE O |
| | *Stoppen met roken, gevarieerd eten, alcoholgebruik beperken & regelmatig sporten.* (Brief patiënt, p.1 midden / Info patiënt, p.2 midden) | Locatie juist? | JA O | NEE O |
| | | Langer dan 30 seconden om antwoord te vinden? | JA O | NEE O |
| | Opmerkingen: | | | |
| **11** | Wat doen statines? | Antwoord juist? | JA O | NEE O |
| | *Deze doen de cholesterolwaarden in het bloed zakken.* (Info patiënt, p.3 bovenaan) *Risico op een infarct of beroerte verminderen.* (Homepage, bovenaan) | Locatie juist? | JA O | NEE O |
| | | Langer dan 30 seconden om antwoord te vinden? | JA O | NEE O |
| **12** | Op 100 patiënten die statines nemen, hoeveel krijgen er last van diabetes? | Antwoord juist? | JA O | NEE O |
| | *1.* ( Info patiënt, p.4 midden / Resultaat test, achterzijde / Brief patiënt, p.3 bovenaan) | Locatie juist? | JA O | NEE O |
| | | Langer dan 30 seconden om antwoord te vinden? | JA O | NEE O |
| | Opmerkingen: | | | |

| | | | | |
|---|---|---|---|---|
| **13** | Voor wie is de berekening van het cardiovasculair risico op basis van de tool niet geldig? | Antwoord juist? | JA O | NEE O |
| | Mensen die nog ooit een infarct of beroerte hadden. (Brief patiënt, p.1 onderaan / Resultaat test bovenaan) Diabetespatiënten, personen met voorgeschiedenis van CV problemen, hypercholesterolemie in de familie. (Homepage, onderaan) | Locatie juist? | JA O | NEE O |
| | | Langer dan 30 seconden om antwoord te vinden? | JA O | NEE O |
| | Opmerkingen: | | | |
| **14** | Hoe vaak moet u dit geneesmiddel nemen indien u besluit het te nemen? | Antwoord juist? | JA O | NEE O |
| | Dagelijks. (Brief patiënt, p.3 midden / Info patiënt, p.3 midden) | Locatie juist? | JA O | NEE O |
| | | Langer dan 30 seconden om antwoord te vinden? | JA O | NEE O |
| | Opmerkingen: | | | |
| 15 | Hoeveel keer groter is de kans op een infarct of beroerte zonder eraan te overlijden dan de kans op een dodelijk infarct of beroerte bij mannen in de komende 10 jaar? | Antwoord juist? | JA O | NEE O |
| | Gemiddeld 3 keer groter. (Info patiënt, p4 bovenaan) | Locatie juist? | JA O | NEE O |
| | | Langer dan 30 seconden om antwoord te vinden? | JA O | NEE O |
| | Opmerkingen: | | | |

Hoe goed vindt u de tekst op een schaal van 1 tot 10?
Tien betekent heel erg goed, 1 betekent helemaal niet goed.

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|

| Deelnemersinformatie | | |
|---|---|---|
| Naam | | |
| Geslacht | | |
| Leeftijd | | |
| Opleiding | ○ Lagere school<br>○ Lager secundair (beroeps / technisch / algemeen) | ○ Hoger secundair (beroeps / technisch / algemeen)<br>○ Hogeschool<br>○ Universiteit |
| Gebruikt u Statines? | | |
| Heeft u al eens over Statines gesproken met uw arts? | | |
| Opmerkingen op de tekst? | | |
| Kent u iemand die statines neemt? | | |

## Appendix 2.3. Readability questionnaire – French

| Test de lisibilité – outil d'aide à la décision statines | |
|---|---|
| 1 | Quels sont les 5 éléments qui déterminent votre risque d'ACV ? |
| 2 | Quel est le but de cet outil ? |
| 3 | Comment pouvez-vous connaitre votre risque de mourir d'un infarctus ou d'un ACV ? |
| 4 | Existe-t-il suffisamment de preuves de l'effet des aliments qui promettent de réduire le cholestérol ? |
| 5 | Quels sont les 2 groupes de personnes qui ont un risque plus élevé de faire un ACV? |
| 6 | Quelles sont les 2 principales causes de décès en Belgique ? |
| 7 | Quels sont les deux principaux effets secondaires possibles des statines ? |
| 8 | Est-ce que vous devez vous dépêcher de prendre une décision concernant la prise de statines ou non? |
| 9 | Que devez-vous faire si vous décidez de prendre des statines tout en prenant d'autres médicaments ? |
| 10 | Quelles sont les quatre principales habitudes pour réduire votre risque cardiovasculaire ? |
| 11 | Que font les statines ? |
| 12 | Sur 100 patients qui prennent des statines, combien auront le diabète ? |
| 13 | Pour quelles personnes ce test n'est-il pas valable ? |
| 14 | À quelle fréquence devriez-vous prendre ce médicament si vous décidez de le prendre ? |
| 15 | Chez les hommes, combien de fois le risque de faire un infarctus ou un AVC dans les 10 ans sans en mourir est-il plus élevé que le risque de faire un infarctus ou un ACV et d'en mourir ? |

| | | | | |
|---|---|---|---|---|
| **1** | Quels sont les 5 éléments qui déterminent votre risque d'AVC | **Réponse correcte ?** | OUI O | NON O |
| | *Age, sexe, tension, niveau de cholestérol, comportement de fumeur* *(* Lettre patients, p.1 en haut §3 Ou Info patients p1 en bas*)* | **Emplacement correct ?** | OUI O | NON O |
| | | **Plus de 30 sec pour trouver la réponse ?** | OUI O | NON O |
| | Remarques : | | | |
| **2** | Quel est le but de cet outil ? | **Réponse correcte ?** | OUI O | NON O |
| | *Vous aider à décider si vous devez ou non prendre des statines* (page d'accueil, en haut §1 ) | **Emplacement correct ?** | OUI O | NON O |
| | | **Plus de 30 sec pour trouver la réponse ?** | OUI O | NON O |
| | Remarques : | | | |
| **3** | Comment pouvez-vous connaitre votre risque de mourir d'un infarctus ou d'un AVC ? | **Réponse correcte ?** | OUI O | NON O |
| | *Votre médecin peut évaluer votre risque cv* (Info patient p.2, en bas, en dessous du titre ) *ou Page d'accueil, §3)* | **Emplacement correct ?** | OUI O | NON O |
| | | **Plus de 30 sec pour trouver la réponse ?** | OUI O | NON O |
| | Remarques :: | | | |
| **4** | Existe-t-il suffisamment de preuves de l'effet des aliments qui promettent de réduire le cholestérol ? | **Réponse correcte ?** | OUI O | NON O |
| | *Non.* (Info patients , p2, cadre, avant dernière ligne) | **Emplacement correct ?** | OUI O | NON O |
| | | **Plus de 30 sec pour trouver la réponse ?** | OUI O | NON O |
| | Remarques : | | | |
| **5** | Quels sont les 2 groupes de personnes qui ont un risque plus élevé de faire un AVC ? | **Réponse correcte ?** | OUI O | NON O |
| | *Les diabétiques et les personnes en insuffisance rénale.* (Info patients, p.1 dernière ligne de l'avant dernière question) | **Emplacement correct ?** | OUI O | NON O |
| | | **Plus de 30 sec pour trouver la réponse ?** | OUI O | NON O |
| | Remarques : | | | |
| **6** | Quelles sont les 2 principales causes de décès en Belgique ? | **Réponse correcte ?** | OUI O | NON O |

| | | | | |
|---|---|---|---|---|
| | *Les infarctus et les AVC*<br>(Info patients, p.1, dernier ligne première question) | **Emplacement correct ?** | OUI<br>O | NON<br>O |
| | | **Plus de 30 sec pour trouver la réponse ?** | OUI<br>O | NON<br>O |
| | Remarques : | | | |
| | Quels sont les deux principaux effets secondaires possibles des statines ? | **Réponse correcte ?** | OUI<br>O | NON<br>O |
| | *Douleurs musculaires et diabète.*<br>(Info patients,p.4, haut de page) | **Emplacement correct ?** | OUI<br>O | NON<br>O |
| | | **Plus de 30 sec pour trouver la réponse ?** | OUI<br>O | NON<br>O |
| | Remarques : | | | |
| **8** | Est-ce que vous devez vous dépêcher de prendre une décision concernant la prise de statines ou non? | **Réponse correcte ?** | OUI<br>O | NON<br>O |
| | *Non.*<br>(Info patients, p.3 'vous ne devez pas choisir tout de suite ou lettre patients p2.) | **Emplacement correct ?** | OUI<br>O | NON<br>O |
| | | **Plus de 30 sec pour trouver la réponse ?** | OUI<br>O | NON<br>O |
| | Remarques :: | | | |
| **9** | Que devez-vous faire si vous décidez de prendre des statines tout en prenant d'autres médicaments ? | **Réponse correcte ?** | OUI<br>O | NON<br>O |
| | *Consulter votre pharmacien ou médecin.*<br>(Info patients, p.3, milieu) | **Emplacement correct ?** | OUI<br>O | NON<br>O |
| | | **Plus de 30 sec pour trouver la réponse ?** | OUI<br>O | NON<br>O |
| | Remarques : | | | |

| | | | | |
|---|---|---|---|---|
| **10** | Quelles sont les quatre premières mesures pour réduire votre risque cardiovasculaire ? | **Réponse correcte ?** | OUI O | NON O |
| | *Arrêter de fumer, manger plus équilibré, limiter la consommation d'alcool et faire plus d'exercice physique.* (Lettre patients , en haut ou info patients p2) | **Emplacement correct ?** | OUI O | NON O |
| | | **Plus de 30 sec pour trouver la réponse ?** | OUI O | NON O |
| | Remarques : | | | |
| **11** | Que font les statines ? | **Réponse correcte ?** | OUI O | NON O |
| | *Elles abaissent le taux de cholestérol* (Info patient, p.3 dernier §) | **Emplacement correct ?** | OUI O | NON O |
| | | **Plus de 30 sec pour trouver la réponse ?** | OUI O | NON O |
| | Remarques : | | | |
| **12** | Sur 100 patients qui prennent des statines, combien auront le diabète ? | **Réponse correcte ?** | OUI O | NON O |
| | *1.* Info patient, p.4 en haut Ou Résultat test, en bas Ou Lettre patient p.2 , 2è §) | **Emplacement correct ?** | OUI O | NON O |
| | | **Plus de 30 sec pour trouver la réponse ?** | OUI O | NON O |
| | Remarques : | | | |
| **13** | Pour quelles personnes ce test n'est-il pas valable ? | **Réponse correcte ?** | OUI O | NON O |
| | *Les personnes n'ayant pas eu d'infarctus ni d'AVC* (Lettre patients p1. Avertissement ligne 1 Ou Info patients, p.3 en haut 'attention') | **Emplacement correct ?** | OUI O | NON O |

| | | | | |
|---|---|---|---|---|
| | | **Plus de 30 sec pour trouver la réponse ?** | OUI O | NON O |
| | Remarques : | | | |
| **14** | **À quelle fréquence devriez-vous prendre ces médicaments si vous décidez de les prendre ?** | **Réponse correcte ?** | OUI O | NON O |
| | *Tous les jours.*<br>(Lettre patients, p.2, 3e bullet<br>Ou Info patient, p.3 en bas<br>Ou mentionné dans les questions info patients p3) | **Emplacement correct ?** | OUI O | NON O |
| | Remarques : | **Plus de 30 sec pour trouver la réponse ?** | OUI O | NON O |
| **15** | **Chez les hommes, combien de fois le risque de faire un infarctus ou un AVC dans les 10 ans sans en mourir est-il plus élevé que le** | **Réponse correcte ?** | OUI O | NON O |
| | **risque de faire un infarctus ou un AVC et d'en mourir ?** | | | |
| | 3 X plus élevé<br>(info patient p. 3 dernière ligne) | **Emplacement correct ?** | OUI O | NON O |
| | Remarques : | **Plus de 30 sec pour trouver la réponse ?** | OUI O | NON O |

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|
| Pas bon du tout | | | | | | | | | Très bon |

Comment évaluez vous ce texte, sur une échelle de 1 à 10
*Un = pas bon du tout, dix = très bon.*

| Information répondant | | |
|---|---|---|
| Nom | | |
| Sexe | • <br>○ Masculin <br>○ Féminin | |
| Age | | |
| Code postal domicile | | |
| Niveau d'études | ○ Ecole primaire <br>○ Secondaire inférieur (professionnel / technique / general) | ○ Secondaire supérieur <br>○ (professionnel / technique / géneral) <br>○ Haute école <br>○ Université |
| Profession | ○ Actif : <br>○ Inactif : | Profession : |
| Utilisez vous/avez vous déjà utilisé des statines? | | |
| Avez-vous déjà parlé de statines avec votre médecin ? | | |
| Connaissez-vous quelqu'un qui prend des statines ? | | |
| Remarques sur le texte | | |

# APPENDIX 3. ASSESMENT OF THE TOOL BY GP'S

## Appendix 3.1. Call for Dutch-speaking GP's in Domus Medica newsletter

**Het KCE zoekt artsen om een beslissingshulp te testen bij het voorschrijven van statines ter primaire preventie**

Het Federaal Kenniscentrum voor de Gezondheidszorg (KCE) ontwikkelt een online beslissingshulp voor huisartsen, om tijdens de consultatie te gebruiken. Deze beslissingshulp zal gebaseerd zijn op het SCORE algoritme, en zal het cardiovasculaire risico van de patiënt weergeven, met of zonder statines, op basis van een aantal paramaters (leeftijd, geslacht, rookgedrag, cholesterol, bloeddruk,…).

Voordat de tool definitief online wordt geplaatst, wil het KCE deze graag door huisartsen in de praktijk laten testen.

Er zijn twee mogelijkheden:

- u test de tool eenvoudigweg tijdens een consultatie, en geeft ons feedback via een online vragenlijst;
- u test de tool grondig: inleidend interview over het prototype van de tool, test van de tool gedurende vier weken met patiënten, evaluatie van de tool, debriefinggesprek. Voor dit alles ontvangt u een onkostenvergoeding van €150. De gesprekken duren maximaal 45 minuten en vinden eind april - mei 2019 plaats, bij u in de praktijk, of op een door u gekozen locatie.

| |
|---|
| Ik wens…<br>○ de tool tijdens consultaties te testen en mijn feedback via een online vragenlijst te delen.<br>○ de tool grondig te testen: voorbespreking over het prototype van de tool, tool testen met patiënten gedurende 4 weken, evaluatie van de tool, nabespreking. |
| Bedankt voor uw interesse.<br>Gelieve uw e-mailadres in te vullen om de tool te testen en online te beoordelen.<br><br>De onderzoekers van het project contacteren u eind april/begin mei om de tool te testen tijdens uw consultaties en online te beoordelen. |

| |
|---|
| Onder de deelnemende artsen zal een loting gebeuren waarbij de winnaar een gastronomisch diner voor 2 personen krijgt. |
| Bedankt voor uw interesse.<br>Gelieve de onderstaande informatie in te vullen om de tool grondig te testen.<br><br>De onderzoekers van het project contacteren u per telefoon om een eerste afspraak te maken eind april/begin mei. Een onkostenvergoeding van 150€ is voorzien. Deze wordt betaald na het debriefinggesprek. |
| Naam |
| Voornaam |
| Aantal jaar ervaring als huisarts |
| Praktijk<br>○ individueel<br>○ groepspraktijk<br>○ andere |
| Postcode |
| E-mailadres |
| Telefoonnummer<br><br>Het meest geschikte moment om mij te contacteren is |
| Adres |

Wij danken u voor uw inschrijving en nemen spoedig contact op.

Verstuur antwoorden.

Bedankt voor uw antwoorden.

## Appendix 3.2. Call for French-speaking GP's in SSMG newsletter

**Le KCE recherche des médecins pour tester un outil d'aide à la décision sur la prescription de statines en prévention primaire**

Le Centre fédéral d'Expertise des Soins de Santé (KCE) développe un outil interactif d'aide à la décision pour les médecins généralistes, à utiliser pendant la consultation. Cet outil sera basé sur l'algorithme SCORE et permettra de visualiser le risque cardiovasculaire du patient avec et sans statines, en fonction de quelques paramètres (âge, sexe, tabagisme, cholestérol, tension artérielle).

Le KCE souhaite faire tester cet outil par des médecins généralistes avant sa mise en ligne définitive.

Deux possibilités :

- tester simplement l'outil en consultation et faire part de vos remarques à l'aide d'un questionnaire en ligne. Un tirage au sort parmi les médecins participants désignera le gagnant d'un repas gastronomique pour 2 personnes.
- tester l'outil de manière approfondie : entretien préalable sur le prototype de l'outil, test de l'outil pendant quatre semaines avec des patients, évaluation de l'outil, entretien de débriefing. Un défraiement de 150 € est prévu pour cette modalité. Les entretiens durent 45 minutes maximum et auront lieu à votre cabinet ou à l'endroit de votre choix, fin avril et mai 2019.

Personne de contact : Karin RONDIA +32 (0)475 769 766

Je souhaite...

Veuillez sélectionner une réponse ci-dessous

- tester l'outil en consultation et faire part de mes remarques à l'aide d'un questionnaire en ligne
- tester l'outil de manière approfondie : entretien préalable sur le prototype de l'outil, test de l'outil pendant quatre semaines avec des patients, évaluation de l'outil, entretien de débriefing

Merci pour votre intérêt. **Pour tester l'outil en ligne, merci de bien vouloir indiquer votre adresse e-mail**

Les chercheurs en charge du projet vous contacteront fin avril/début mai afin de tester l'outil lors de vos consultations et donner un feed-back en ligne.

Un tirage au sort parmi les médecins participants désignera le gagnant d'un repas gastronomique pour 2 personnes.

**Merci pour votre intérêt. Pour tester l'outil de manière approfondie, veuillez compléter les informations suivantes**

Nom :

Prénom :

Années d'expérience en tant que médecin généraliste :

Cabinet :

- individuel
- de groupe
- Autre :

Code postal :

Adresse e-mail :

Numéro de téléphone :

Voici le moment opportun pour me contacter par téléphone :

Adresse :

# Appendix 3.3. In dept assessment

## Appendix 3.3.1. *Mail and instructions for GP's - Dutch*

Beste dokter,

U heeft zich opgegeven om een online beslissingshulp te testen bij het voorschrijven van statines in primaire preventie, ontwikkeld door het KCE.

Het KCE vertrouwt op Tempera voor de evaluatie van de beslissingshulp in het gebruik door huisartsen met hun patiënten.

Het verloop van het testproces ziet er als volgt uit:

7. U leest de handleiding over de beslissingshulp en het testen (in bijlage).
8. U verkent de beslissingshulp online: http://demostatins.kce.eenwereldmetlef.be.s3-website-eu-west-1.amazonaws.com/fr/
9. Wij bellen u op om eventuele vragen te beantwoorden, en om een afspraak te maken voor het debriefinggesprek. Dit gesprek gaat door bij u op kantoor, eind juni/begin juli.
10. U test de beslissingshulp met minstens 4 patiënten. Bij iedere test vult u een evaluatiefiche in (zie KCE_Statines_evaluatiefiche in bijlage)
11. Tijdens een debriefinggesprek van 30 à 45 minuten, bij u op kantoor, geeft u de ingevulde evaluatiefiches af. Er wordt besproken wat uw indrukken over de beslissingshulp zijn en wat de meerwaarde in de consultatie is. Een onkostenvergoeding van €150 is hiervoor voorzien. U ontvangt deze na het gesprek.

Vandaag worden de verschillende documenten in bijlage u per post toegestuurd, op die manier hoeft u ze niet zelf af te drukken.

U zal gecontacteerd worden per telefoon vanaf dinsdag 11 juni om te controleren of u bijkomende vragen hebt alvorens aan de slag te gaan met de beslissingshulp te testen. Tijdens dit telefoongesprek wordt meteen ook een afspraak voor het debriefinggesprek gemaakt.

U kan in geval van vragen ten allen tijde contact opnemen via pieter.steyaert@tempera.be of telefonisch op 03/270.38.04.

Bedankt voor uw deelname en tot binnenkort,

Pieter Steyaert

Bijlagen: handleiding gebruik beslissingshulp en test & evaluatiefiche

**Handleiding test online beslissingshulp KCE "Cholesterol verminderen met geneesmiddelen? De voor- en nadelen"**

**Over het project**

Het Federaal Kenniscentrum voor Gezondheidszorg (KCE) ontwikkelt een beslissingshulp in de vorm van een website, met test. De beslissingshulp is ontworpen voor gebruik door huisartsen tijdens consultaties met hun patiënten. Deze is bedoeld ter ondersteuning in de discussie tussen arts en patiënt over de noodzaak om statines te gebruiken ter primaire preventie van cardiovasculaire accidenten. De test is gebaseerd op KCE rapport 306 HTA, dat werd gepubliceerd in januari 2019.

**Over het gebruik**

Waarop moet u letten? — Het gebruiken van de beslissingshulp door artsen in de consultatie is bedoeld om inzicht te krijgen in

het gebruiksgemak van de website en test

het technische functioneren van de website en test

de duidelijkheid van de informatie

de duidelijkheid van het resultaat van de test

de meerwaarde van de beslissingshulp in het discours met uw patiënt

de invloed van de beslissingshulp op het beslissingsproces van de patiënt

**Gebruik van het feedbackformulier —** Wanneer u een consultatie afwerkt waarin u de beslissingshulp (website en/of test) gebruikt hebt vult u een feedbackformulier in. U kan dit ofwel onmiddellijk na de consultatie doen, of op het einde van de werkdag. Per consultatie waarin de beslissingshulp gebruikt wordt dient een feedbackformulier ingevuld te worden. U krijgt feedbackformulieren toegestuurd via de post. In de begeleidende e-mail vindt u een PDF bestand terug dat u kan afdrukken, moest u onvoldoende formulieren hebben om al uw consultaties te beoordelen.

**Aantal patiënten —** De beslissingshulp dient gebruikt te worden met ten minste 4 patiënten. Het staat u vrij meer dan 4 consultaties te doen indien u daar de mogelijkheid toe hebt. Een groter aantal consultaties komt de resultaten van het onderzoek ten goede.

**Het debriefingsgesprek —** Het testen van de beslissingshulp in consultaties met patiënten wordt afgesloten met een persoonlijk gesprek. Tijdens dit gesprek worden uw indrukken over de beslissingshulp besproken. Het gesprek wordt ondersteund met de resultaten op uw eigen feedbackformulieren.

**Over de website**

**Homepage —** De homepage van de website bevat informatie over het bedoelde gebruik van de website. Daarnaast bevat deze een hyperlink naar de test, alsook informatie over de berekening van het cardiovasculaire risico.

**Test —** In de test kunt u de leeftijd, geslacht en het rookgedrag van de patiënt invoeren, naast systolische bloeddruk, totale cholesterol en HDL cholesterol. U kunt daarnaast kiezen voor een berekening op basis van de Belgische of Europese S.CO.R.E. Het resultaat is een visuele weergave van de kans op sterfte door een cardiovasculair accident in de komende tien jaar met en zonder statines.

**Patiënteninfo —** Het tabblad 'patiënteninfo' bevat achtergrondinformatie voor de patiënt over

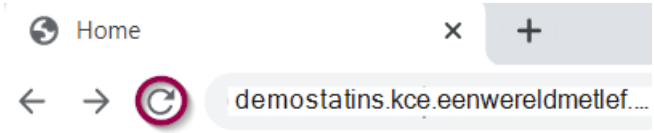
- cholesterol
- gezondheidsimplicaties van verhoogde cholesterolwaarden
- het cardiovasculaire risico
- het effect van een gezonde levensstijl
- Het effect van statines
- De neveneffecten van statines
- Het gebruik van statines

**Over deze website —** Informatie over het ontwikkelen van de test en website is terug te vinden onder het tabblad 'over deze website'.

**Open de link in uw browser —** In de begeleidende e-mail vindt u de link naar de beslissingshulp terug. Het is aangeraden om de link op te slaan bij uw favorieten, of op uw bureaublad. Op deze manier vindt u deze snel terug wanneer u het wil gebruiken. U kan ook onderstaande URL zelf invoeren:

http://demostatins.kce.eenwereldmetlef.be.s3-website-eu-west-1.amazonaws.com/nl/

Indien de website niet functioneert kan u de pagina opnieuw laten laden. Dit kan u doen door op dit symbool te klikken . Dit bevindt zich in de linkerbovenhoek van uw browser.







U kan ook de CTRL en R toets tezamen indrukken. Volstaat dit niet? Dan kan u door uw taalkeuze te bevestigen of te wijzigen de website herladen.

**Gebruik in de consultatie —** U besluit zelf wanneer in de consultatie u de test wil uitvoeren. U gebruikt de test door de waarden voor de patiënt in te voeren en het resultaat met uw patiënt te bespreken.

**Patiënten —** De test op de website is bedoeld voor gebruik met patiënten

- tussen de 40 en 65 jaar
- met een bloeddrukwaarde tussen de 100 mmHg en 180 mmHg
- met een totale cholesterolwaarde tussen de 100 mg/dl (3 mmol) en 300 mg/dl (8 mmol)
- met een HDL cholesterolwaarde tussen de 10 mg/dl (0,25 mmol) en 100 mg/dl (3 mmol).

De berekening van het cardiovasculaire risico op basis van de Systematic Coronary Risk Evaluation (S.CO.R.E.) is beperkt in het gebruik. De test mag daarom niet gebruikt worden voor patiënten met

diabetes

personen met een voorgeschiedenis van cardiovasculaire problemen

met hypercholesterolemie in de familie.

**Beperkingen —** De website en test in hun huidige vorm en functionaliteit zijn een testversie. Dat houdt in dat u deze niet mag verspreiden. U mag geen afgedrukte resultaten of de pdf-versie verspreiden, noch meegeven met de patiënt. U mag ook geen informatie over het project delen met anderen.

**Contact —** Tempera, Pieter Steyaert: pieter.steyaert@tempera.be, 03 270 38 04

## Appendix 3.3.2. *Mail and instructions for GP's – French*

Docteur,

Vous avez accepté de tester un **outil en ligne d'aide à la décision (site web) sur la prescription de statines en prévention primaire développé par le KCE**.

Le KCE a confié à BSM l'évaluation de cet outil dans son utilisation par les médecins généralistes avec leurs patients. Au vu du temps requis pour le développement du site web, nous vous proposons de procéder de la sorte :

12. Vous prenez connaissance du mode d'emploi de l'outil et des modalités de test (voir le document ' Mode d'emploi outil et test' en annexe)
13. Vous découvrez l'outil en ligne : http://demostatins.kce.eenwereldmetlef.be.s3-website-eu-west-1.amazonaws.com/fr/
14. Nous avons un contact téléphonique afin de répondre à vos éventuelles questions, et déjà fixer une date pour un entretien de débriefing, à votre cabinet, fin juin/début juillet.
15. Vous testez l'outil avec au moins 4 de vos patients. A chaque test, vous complétez une fiche-patient (voir fiche 'Patient' en annexe).

16. Lors d'un entretien de débriefing de 30 à 45 minutes, à votre cabinet, vous nous remettez les différentes fiches-patient complétées, et nous échangeons sur votre perception de l'outil, vos impressions et celles de vos patients. En dédommagement de votre participation, un défraiement de 150€ est prévu. Vous le percevrez après l'entretien de débriefing.

Nous vous envoyons, ce jour, les différents documents en annexe de ce mail par courrier postal afin de vous éviter de devoir les imprimer.

Nous vous contacterons par téléphone en début de semaine prochaine afin de voir si tout est en ordre pour vous permettre de commencer à utiliser l'outil avec vos patients, et fixer le rdv de débriefing.

Nous sommes évidemment joignables pour toute question (s.janssens@bsm-management.be ou 0497 135 884).

Merci de votre participation et à très vite,

Sabine Janssens

*Annexes :* Mode d'emploi outil d'aide à la décision & Fiches -patient (6)

**Mode d'emploi du test de l'outil en ligne d'aide à la décision du KCE**

**À propos du projet**

Le Centre fédéral d'Expertise des Soins de Santé (KCE) développe un outil d'aide à la décision sous la forme d'un site web, avec un test. L'outil d'aide à la décision est destiné à être utilisé par les médecins généralistes pendant la consultation. Il soutient la discussion entre médecin et patient sur la nécessité d'utiliser des statines en prévention primaire des accidents cardio-vasculaires. Le test qu'il propose est basé sur les données du rapport KCE 306 HTA publié en janvier 2019.

**À propos de votre utilisation de l'outil**

**Objectifs** — Le but du test de l'outil par les médecins généralistes avec leurs patients est de rassembler des informations à propos de :

- La facilité d'utilisation du site web et du test
- Le fonctionnement technique du site et du test
- La clarté de l'information
- La clarté du résultat du test
- La valeur ajoutée de l'aide de décision pour les échanges avec vos patients
- L'influence de l'outil sur le processus décisionnel des patients

**Utilisation de la fiche-patient —** Lorsque vous avez terminé une consultation pendant laquelle vous avez utilisé l'outil d'aide à la décision (site web et/ou test), remplissez une fiche-patient. Vous pouvez le faire immédiatement après la consultation ou en fin journée. Les fiches-patient vous seront envoyés par la poste. Dans le courriel ci-joint, vous trouverez une fiche au format PDF que vous pouvez imprimer si vous n'avez pas assez de formulaires pour évaluer toutes vos consultations.

**Nombre de patients —** Nous vous demandons d'utiliser l'outil d'aide à la décision avec au moins 4 patients. Nous vous demandons de compléter une fiche par consultation/patient. Vous pouvez évidemment tester l'outil avec plus de patients, si vous en avez la possibilité. Un plus grand nombre de consultations sera bénéfique pour les résultats de l'étude.

**L'entretien de débriefing —** Le test de l'outil d'aide à la décision se termine par un entretien. Au cours de ce rendez-vous, nous aborderons votre perception de l'outil, et parcourrons ensemble les différentes fiches-patients complétées.

**À propos du site web**

**Page d'accueil—** La page d'accueil du site mentionne l'objectif poursuivi par le site web. Elle contient un hyperlien vers le test, ainsi que des informations sur la détermination du risque cardiovasculaire.

**Test—** Dans le test, vous complétez l'âge, le sexe et le comportement tabagique du patient, ainsi que la tension artérielle systolique, le cholestérol total et le cholestérol HDL. Vous pouvez opter pour un calcul basé sur le S.CO.R.E. belge ou européen. Le résultat est une représentation visuelle du risque de décès par accident cardiovasculaire dans les dix prochaines années avec et sans statines.

**Information patients —** Cet onglet propose aux patients des informations générales sur :

- Le cholestérol
- Les répercussions sur la santé d'un taux de cholestérol élevé
- Le risque cardiovasculaire
- Les effets d'un mode de vie sain
- Les effets des statines
- Les effets secondaires des statines
- L'utilisation des statines

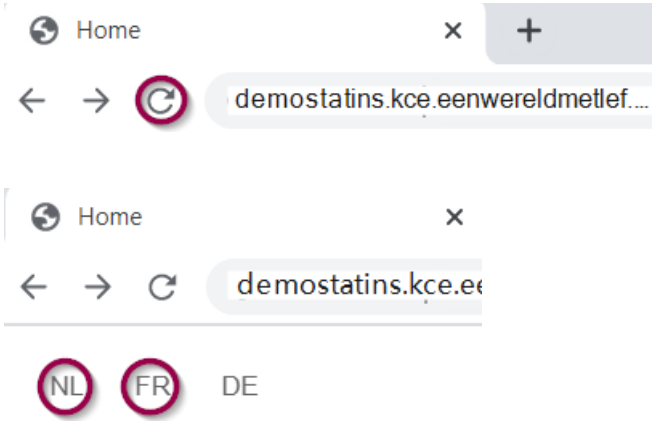
**À propos de ce site —** Cet onglet donne des informations sur le développement du site web et du test.

**Ouverture du lien dans votre navigateur —** Vous trouverez le lien vers le site web dans le mail. Il est conseillé d'ajouter le lien à vos favoris, ou de l'enregistrer sur le bureau de votre ordinateur. De cette façon, vous pourrez y accéder rapidement lorsque vous voudrez utiliser l'outil d'aide à la décision.

Vous pouvez également saisir vous-même l'URL ci-dessous :

http://demostatins.kce.eenwereldmetlef.be.s3-website-eu-west-1.amazonaws.com/fr/index.html

Si le site ne fonctionne pas, vous pouvez rafraichir la page en cliquant sur ce symbole ↻, situé en haut à gauche dans la barre du navigateur :




Vous pouvez également appuyer simultanément sur les touches CTRL et R. Si cela ne fonctionne toujours pas, vous pouvez recharger le site en cliquant sur la langue de votre choix.

**Utilisation de l'outil d'aide à la décision pendant la consultation —** Vous utilisez le test en saisissant les valeurs pour le patient et en discutant du résultat avec votre patient. Vous avez la possibilité d'imprimer le résultat du test ou de l'enregistrer.

**Patients —** Le test disponible sur le site web est à utiliser avec des patients :

- Agés de 40 à 65 ans
- Avec une tension artérielle comprise entre 100 mmHg et 180 mmHg
- Avec une valeur de cholestérol total entre 100 mg/dl (3 mmol) en 300 mg/dl (8 mmol)
- Avec une valeur de cholestérol HDL comprise entre 10 mg/dl (0,25 mmol) et 100 mg/dl (3 mmol).

Le calcul du risque cardiovasculaire sur base du Systematic Coronary Risk Evaluation (S.CO.R.E.) comporte des restrictions. Pour cette raison, le test ne peut être utilisé pour des patients :

- Diabétiques
- avec des antécédents familiaux de problèmes cardiovasculaires
- avec une hypercholestérolémie familiale

**Limitations—** Le site Web et le test dans leur forme et leur fonctionnalité actuelles sont des versions-test. Cela signifie que vous ne pouvez pas les diffuser. Vous ne pouvez pas transmettre aux patients une version PDF ou imprimée des résultats. Vous ne pouvez pas non plus communiquer d'informations sur ce projet.

**Contact —** BSM-Management, Sabine Janssens, s.janssens@bsm-management.be , 0497 135 884

## Appendix 3.3.3. *Interview guide - Dutch*

### Aanvaarding van de beslissingshulp

**Hoe komt het nemen van statines in de consultatie ter sprake?**

- Wie snijdt het onderwerp aan, arts of patiënt?
- Hoe verloopt de conversatie?
- Zijn er andere beslissingshulpen die u tot nu toe gebruikte?
- Gebruikt u andere informatie tijdens de conversatie?
  - Welke?
  - Wanneer?
  - Met welk doel?
- Welke vragen stelde de patiënt (over cholesterol)?

**Wat is de meerwaarde van de beslissingshulp tijdens deze conversaties?**

- Zou u het blijven gebruiken?
- Waarom wel of niet?
- Wat zou er moeten veranderen / zou u graag anders zien?

**Hoe zou u deze beslissingshulp vergelijken met andere beslissingshulpen?**

**Wat is de impact van het gebruik van de beslissingshulp op de consultatie?**

- Impact op de duurtijd?
- Verliep het gesprek anders dan zonder de beslissingshulp?

### Test met patiënten

**Aantal tests**

- Zijn er patiënten die binnen de doelgroep vielen, waarmee u de beslissingshulp niet getest hebt?
  - Waarom?

**Verloop van de tests**

- Hoe verliepen de tests?
- Hoe heeft u de beslissingshulp gebruikt?

- Op PC, tablet, smartphone?
- Hoe heeft u de informatie aan de patiënt getoond? Scherm gedraaid?
- Heeft u de PDF geprint?
- Zou u deze meegeven met de patiënt?
- Zou u de resultaten met de patiënt delen?
- Zou u de resultaten aan het patiëntendossier toevoegen?

**Algemene indruk**

- Hoe reageerden de patiënten?
  - Geïnteresseerd?
  - Begrepen ze de informatie?
  - …
- Hoe beïnvloedde het gebruik van de beslissingshulp de consultatie?
  - Duurde langer?
  - Stelde de patiënt vragen? Welke?
- Hoe beïnvloedde het gebruik van de beslissingshulp hun beslissing?
  - Gedeelde beslissing?
- Hoe beoordeeld u het testingproces?

Analyse individuele fiches

**Individuele fiches overlopen.**

- Commentaar op testen en fiches vragen

Beoordeling van de beslissingshulp

**Welke aanpassingen of verbeteringen zouden naar toekomstig gebruik toe moeten gebeuren?**

- Vormelijke aanpassingen?
- Inhoudelijke aanpassingen?

## Appendix 3.3.4. *Interview guide – French*

### A. *La consultation, le cholestérol et les statines*

***Comment la prise de statines est-elle abordée lors d'une consultation ?***

- Qui aborde le sujet ? Dans quel contexte ?
- Déroulement de la conversation ?
- Utilisez-vous des outils et/ou de l'information ? Lesquels ? Quand ? Evaluation ?
  - ➔ Comment est évalué le risque cardio-vasculaire ?
- Quelles questions les patients posent-ils à propos du cholestérol ?
- Quelles questions les patients posent-ils à propos des statines ?

### B. Le déroulement des tests auprès des patients

**Nombre de tests effectués ?**

- Y a-t-il des patients réunissant les conditions auprès desquels l'outil n'a pas été testé et pourquoi ?

**Déroulement des tests**

- Demander au médecin de décrire *comment se sont déroulés les tests*
- Demander au médecin quel S.C.O.R.E a été le plus utilisé (belge et/ou européen) et pourquoi
- Demander au médecin de décrire *comment il a utilisé l'outil*
  - Quel support : PC/Tablette/smartphone/autre
  - Comment a t'il montré l'information au patient (écran tourné vers patient, PC/Tablette/smartphone/papier…)
  - Impression du pdf : oui/non
  - Si c'était possible, aurait-il transmis le pdf au patient : non/oui, lors de la consultation/oui, via mail
  - Si c'était possible, aurait-il sauvegardé le pdf dans dossier patient : oui/non et pourquoi

**Impression globale des patients**

- *Comment les **patients** ont-ils réagi à l'outil ?*
  - Ont-ils apprécié l'utilisation d'un outil web ?
  - Ont-ils apprécié la démarche de prise de décision partagée ?
  - Ont compris/n'ont pas compris les visuels
  - …

**Impact de l'outil sur la consultation :** *Comment l'utilisation de l'outil a-t-il influencé les consultations ?*

- Impact sur la durée de la consultation ? (+ durée d'utilisation moyenne de l'outil ?)
- Impact sur le contenu de la consultation ? (discussion/le patient a posé des questions)

**Impact de l'outil sur la prise de décision**

- Comment l'utilisation de l'outil a-t-il influencé la prise de décision des patients ?
- Quels éléments ont le plus d'impact sur la décision ?
- De quelle manière l'outil web favorise t'il une prise de décision partagée ?

**Analyse des fiches individuelles :**

- Parcourir chacune des fiches avec le médecin
  - Demander au médecin de commenter le test et les fiches

## C. Evaluation de l'outil

**Impression et satisfaction globale de l'utilisation de l'outil ?**

**Quelle est la valeur ajoutée de l'outil web pour la décision partagée ?**

**Quel est l'avis du médecin sur l'information aux patients ?**

- A-t-il consulté cette information ?
- A-t-il utilisé cette information (et si oui, laquelle) en présence des patients ?
- Conseillerait-il aux patients d'aller consulter cette information ?
- Modifications/améliorations souhaitées ?

**Comparaison de l'outil avec d'autres outils**

- Avantages (points forts de l'outil)
- Désavantages (points perfectibles de l'outil)

**Le médecin envisage t-il de continuer à utiliser l'outil**

- **oui/non/pourquoi,**
- **moyennant quelles modifications…**

**Quelles améliorations/ modifications faut-il apporter à l'outil en vue d'une utilisation future ?**

- Quant au fond :
- Quant à la forme :

**Le médecin recommanderait-il l'utilisation de l'outil à des confrères ?**

## D. Fin de l'entretien

**Y a-t-il des choses à ajouter, qui n'ont pas encore été évoquées ci-avant ?**

# Appendix 3.4. Online survey

## Appendix 3.4.1. *Online questionnaire - Dutch*

**Context van het gebruik van de online beslissingshulp**

1. **Ik heb de beslissingshulp met … patiënten getest** ***Vul het aantal patiënten in***
   **U kan opmerkingen toevoegen:**
2. **Ik gebruikte voornamelijk:**

   **Indien u de beslissingshulp testte met meerdere patiënten en u gebruikte beide types van S.C.O.R.E., gelieve aan te duiden welke S.C.O.R.E. u het vaakst gebruikte**
   - De Belgische S.C.O.R.E.
   - De Europese S.C.O.R.E.

   **U kan opmerkingen toevoegen:**
3. **Ik heb de beslissingshulp gebruikt:** ***Meerdere antwoorden zijn mogelijk***
   - Met een laptop
   - Met een vaste computer
   - Met een tablet
   - Met een smartphone

   **U kan opmerkingen toevoegen**:
4. **Gemiddeld duurde het gebruiken van de beslissingshulp tijdens een raadpleging voor mij:**
   - Minder dan 5 minuten
   - Tussen de 5 en 10 minuten
   - Meer dan 10 minuten

   **U kan opmerkingen toevoegen:**
5. **Ik heb de resultaten van de S.C.O.R.E. test getoond aan mijn patiënten:** ***Meerdere antwoorden zijn mogelijk***
   - Op het scherm van mijn laptop, gedraaid naar de patiënten
   - Op het scherm van mijn vaste computer, die zichtbaar is voor de patiënten
   - Op een tablet
   - Op een smartphone

- Op een afgedrukt exemplaar
- Ik heb de resultaten niet getoond

**U kan opmerkingen toevoegen:**

6. **Ik heb de PDF met resultaten geprint voor de patiënten:**
   - Ja
   - Nee

   Leg uw antwoord uit:

   _____

   **U kan opmerkingen toevoegen:**

7. **Vanaf mogelijk (u werd gevraagd geen resultaten te delen met de patiënt zolang de beslissingshulp in testfase is) zal ik de resultaten met de patiënt delen:**
   - Ja,
     - via mail
     - door hen het afgedrukte document mee te geven
   - Nee

     Zo nee, waarom niet?

     _____

     **U kan opmerkingen toevoegen**:

8. **Ik heb de testresultaten opgeslagen in het patiëntendossier**
   - Ja
   - Nee

     Zo nee, leg uw antwoord uit:

     _____

     **U kan opmerkingen toevoegen**:

9. **Ik gebruikte de informatie uit het tabblad 'Informatie voor de patiënten'**
   - Ja, ik gebruikte de volgende items:
     - Waarom is te veel cholesterol slecht voor uw gezondheid?
     - Wat is het cardiovasculaire risico?
     - Hoe uw cardiovasculaire risico bepalen?
     - Hoe uw cardiovasculaire risico verkleinen?
     - Wat zijn geneesmiddelen van de statines groep?
     - Hebben statines neveneffecten?
     - Hoe lang duurt een behandeling met statines?
     - Kan ik statines nemen in combinatie met andere geneesmiddelen?
     - Samenvatting. Waarover moet u nadenken alvorens statines te nemen?
     - Wat de bedoeling van deze test?
   - Nee, waarom niet?

**Het standpunt van de patiënten**

10. **Volgens mij waarderen de patiënten het gebruik van de beslissingshulp:**
    - 1 (helemaal niet akkoord)
    - 2
    - 3
    - 4 (helemaal akkoord)
    - Ik weet het niet

    **U kan opmerkingen toevoegen:**

11. **Volgens mij waardeerden de patiënten het gedeelde beslissingsproces:**
    - 1 (helemaal niet akkoord)
    - 2
    - 3
    - 4 (helemaal akkoord)
    - Ik weet het niet

**U kan opmerkingen toevoegen:**

12. **Volgens mij heeft het gebruik van de beslissingshulp bijgedragen aan de gedeelde besluitvorming:**
    - 1 (helemaal niet akkoord)
    - 2
    - 3
    - 4 (helemaal akkoord)
    - Ik weet het niet

    **U kan opmerkingen toevoegen:**

**Gedeelde besluitvorming**

13. **Indien u één patiënt ontving: Wat was de aanleiding (probleem of diagnose) voor de raadpleging waarbij u de beslissingshulp gebruikte?**

    _____

    **Indien u meerdere patiënten ontving: Wat waren de aanleidingen (probleem of diagnose) voor de raadplegingen waarbij u de beslissingshulp gebruikte?**

    _____

14. **Volgens uw ervaringen met de beslissingshulp, in hoeverre bent u akkoord met de volgende uitspraken?**
    - 1 (helemaal niet akkoord)
    - 2
    - 3
    - 4 (helemaal akkoord)
    - Ik weet het niet

- Ik heb de patiënt duidelijk gemaakt dat er een beslissing moest worden genomen.

- Ik wilde precies weten hoe mijn patiënt wilde deelnemen aan de besluitvorming.
- Ik vertelde mijn patiënt dat er verschillende behandelingsmogelijkheden waren voor zijn toestand.
- Ik heb mijn patiënt specifiek de voor- en nadelen van elk van de behandelingsopties uitgelegd.
- Ik heb mijn patiënt geholpen alle informatie te begrijpen.
- Ik vroeg mijn patiënt welke behandeloptie hij verkoos.
- Mijn patiënt en ik wogen zorgvuldig de voor- en nadelen van verschillende behandelingsopties af.
- Mijn patiënt en ik hebben samen een behandeloptie gekozen.
- Mijn patiënt en ik zijn akkoord over hoe verder te gaan.

**15. Welke gevallen ervaarde u? Het besluit**
- werd gevormd tijdens de raadpleging, na gebruik van de online beslissingshulp
- komt bij een latere raadpleging, die al gepland is
- komt bij een latere raadpleging, die nog niet gepland is
- Andere:

**16. Indien de beslissing tijdens de raadpleging is genomen, geef dan aan wat is besloten (bijvoorbeeld welke behandeling):**

**17. Volgens mij zijn dit de elementen die de grootste invloed hebben op de besluitvorming:**

**18. Ik zal de online beslissingshulp in de toekomst opnieuw gebruiken met patiënten om hun cardiovasculaire risico te evalueren**
- Zeker niet
- Waarschijnlijk niet
- Waarschijnlijk
- Zeker
- Ik weet het niet

**U kan opmerkingen toevoegen**:

**Evaluatie van de webtool**

**19. Volgens mij is deze beslissingshulp een meerwaarde voor gedeelde besluitvorming tussen arts en patiënt**
- 1 (helemaal niet akkoord)
- 2
- 3 (neutraal)
- 4
- 5 (helemaal akkoord)

**U kan opmerkingen toevoegen:**

**20. Volgens mij is de voorgestelde informatie voor patiënten op het tabblad 'informatie voor patiënten' voldoende**
- 1 (helemaal niet akkoord)
- 2
- 3 (neutraal)
- 4
- 5 (helemaal akkoord)

**U kan opmerkingen toevoegen:**

**21. Hoe tevreden bent u in het algemeen over de beslissingshulp?**
- Zeer ontevreden
- Erg ontevreden
- Tevreden, noch ontevreden
- Tevreden
- Zeer tevreden

**U kan opmerkingen toevoegen**:

**22. Bent u van plan om deze beslissingshulp te blijven gebruiken?**
- Zeker niet
- Waarschijnlijk niet
- Waarschijnlijk
- Zeker

**U kan opmerkingen toevoegen:**

**23. Zou u het gebruik van deze beslissingshulp aanbevelen aan een collega?**
- Zeker niet
- Waarschijnlijk niet
- Waarschijnlijk
- Zeker

**U kan opmerkingen toevoegen**:

**24. U kan opmerkingen toevoegen of suggesties ter verbetering van de beslissingshulp:**

**25. Hoe evalueerde u, voorafgaand aan het testen met de beslissingshulp, het cardiovasculaire risico van uw patiënten?**
- Met het gebruik van een risicotabel op basis van het Belgische S.C.O.R.E.
- Met het gebruik van een risicotabel op basis van Europese S.C.O.R.E.
- Andere:
  Bij andere, verklaar:

**U kan opmerkingen toevoegen:**

**De enquête is nu voltooid, bedankt voor uw medewerking**

## Appendix 3.4.2. *Online questionnaire - French*

**Contexte d'utilisation de l'outil web**

1. **J'ai utilisé l'outil d'aide à la décision avec …. patients** ***Compléter le nombre de patients***

   **Commentaires :**

2. **J'ai utilisé :**

   ***si vous avez testé l'outil avec plusieurs patients et utilisé les 2 types de S.C.O.R.E, choisissez le S.C.O.R.E que vous avez le plus utilisé***
   - Le S.C.O.R.E belge
   - Le S.C.O.R.E européen

   **Commentaires :**

3. **J'ai utilisé l'outil d'aide à la décision :** ***Plusieurs réponses possibles***

   - Sur un ordinateur portable
   - Sur un ordinateur fixe
   - Sur une tablette
   - Sur un smartphone

   **Commentaires :**

4. **La durée moyenne d'utilisation de l'outil en consultation est de :**
   - Moins de 5 minutes
   - Entre 5 à 10 minutes
   - Plus de 10 minutes

   **Commentaires :**

5. **J'ai montré les résultats du test S.C.O.R.E aux patients :** ***Plusieurs réponses possibles***
   - Sur l'écran de mon ordinateur portable, en le tournant vers les patients
   - Sur l'écran de mon ordinateur fixe qui est visible par les patients
   - Sur l'écran
   - Sur une tablette
   - Sur mon smartphone

   **Commentaires :**

6. **J'ai imprimé le pdf à destination des patients**
   - Oui
   - Non

   Expliquez votre réponse :

   _____

   **Commentaires :**

7. **Je trouve utile de transmettre ce document aux patients**
   - Oui, par mail
   - Oui, en leur remettant le document imprimé par mes soins
   - Non

   Si non, expliquez votre réponse :

   _____

   **Commentaires :**

8. **J'ai sauvegardé les résultats du test dans le dossier du patient**
   - Oui
   - Non

   Si non, expliquez votre réponse :

   _____

   **Commentaires :**

9. **J'ai utilisé de l'information contenue dans l'onglet 'Informations pour les patients'**
   - Non
   - Oui

   Si oui cochez la/les rubrique(s) consultée(s) :

   - *Pourquoi trop de cholestérol est-il mauvais pour la santé?*
   - *Qu'est-ce que le risque cardiovasculaire?*
   - *Comment connaître votre risque cardiovasculaire?*
   - *Comment diminuer votre risque cardiovasculaire?*
   - *Qu'est-ce qu'un médicament du groupe des statines?*
   - *Les statines ont-elles des effets secondaires ?*
   - *Combien de temps dure un traitement par statines ?*
   - *Les statines modifient-elles l'effet d'autres médicaments?*
   - *En résumé, quelles sont les questions à vous poser avant de prendre des statines?*
   - *À quoi sert de faire ce test?*

**Le point de vue des patients**

10. **De mon point de vue, les patients ont apprécié l'utilisation d'un outil en ligne**
    - 1 (pas du tout d'accord)
    - 2
    - 3 (neutre)
    - 4
    - 5 (tout à fait d'accord)

    **Commentaires :**

11. **De mon point de vue, les patients ont apprécié la démarche de décision partagée**
    - 1 (pas du tout d'accord)
    - 2
    - 3 (neutre)
    - 4
    - 5 (tout à fait d'accord)

    **Commentaires :**

12. **De mon point de vue, l'utilisation de l'outil en ligne a contribué à une prise de décision partagée**
    - 1 (pas du tout d'accord)
    - 2
    - 3 (neutre)
    - 4
    - 5 (tout à fait d'accord)

    **Commentaires :**

**La prise de décision partagée**

13. **Pour la/une des consultations durant laquelle vous avez utilisé l'outil web, merci d'indiquer la raison de la consultation (par exemple quel problème, pour quel diagnostic :**

    _____

14. **Pour chacune des 9 affirmations ci-après, indiquez votre niveau d'accord ou de désaccord :**

    - 1 (pas du tout d'accord)
    - 2
    - 3 (neutre)
    - 4
    - 5 (tout à fait d'accord)

- J'ai clairement indiqué au patient qu'il fallait prendre une décision.
- Je voulais savoir précisément comment mon patient souhaitait participer à la prise de décision.
- J'ai informé mon patient qu'il existait différentes options de traitement pour son problème de santé.
- J'ai expliqué précisément à mon patient les avantages et inconvénients de chacune des options de traitement.
- J'ai aidé mon patient à comprendre l'ensemble des informations.
- J'ai demandé à mon patient quelle option de traitement il préférait
- Mon patient et moi avons pesé minutieusement le pour et le contre des différentes options de traitement.
- Mon patient et moi avons choisi ensemble une option de traitement
- Mon patient et moi sommes parvenus à un accord sur la façon de procéder

15. **La prise de décision**
    - Est survenue pendant la consultation, après l'utilisation de l'outil web
    - Surviendra lors d'une consultation ultérieure, déjà fixée
    - Surviendra lors d'une consultation ultérieure, non-encore prévue
    - Autre :

16. **Si la décision a été prise pendant la consultation, merci d'indiquer ce qui a été décidé (par exemple quel traitement) :**

    _____

17. **De mon point de vue, les éléments ayant le plus d'impact sur la prise de décision sont :**

    _____

18. **J'utiliserai l'outil web avec les patients dans le futur afin de réévaluer leur niveau de risque cardio-vasculaire**
    - Certainement pas
    - Probablement pas

- Neutre
- Probablement
- Certainement

**Commentaires :**

**Evaluation de l'outil web**

19. **De mon point de vue, cet outil est une plus-value pour la prise de décision partagée**
    - 1 (pas du tout d'accord)
    - 2
    - 3 (neutre)
    - 4
    - 5 (tout à fait d'accord)

    **Commentaires :**

20. **De mon point de vue, l'information proposée aux patients dans l'onglet 'Informations aux patients' est suffisante**
    - 1 (pas du tout d'accord)
    - 2
    - 3 (neutre)
    - 4
    - 5 (tout à fait d'accord)

    **Commentaires :**

21. **Globalement, dans quelle mesure êtes-vous satisfait de l'outil d'aide à la décision ?**
    - Très insatisfait
    - Assez insatisfait
    - Neutre
    - Assez satisfait
    - Très satisfait

    **Commentaires :**

22. **Envisagez-vous de continuer à utiliser cet outil ?**
    - Certainement pas
    - Probablement pas
    - Neutre
    - Probablement
    - Certainement

    **Commentaires :**

23. **Recommanderiez-vous l'utilisation de cet outil d'aide à la décision à un confrère**
    - Certainement pas
    - Probablement pas
    - Neutre
    - Probablement
    - Certainement

    **Commentaires :**

24. **Remarques et/ou suggestions d'amélioration de l'outil web :**
25. **Avant de tester cet outil web, comment évaluiez-vous le niveau de risque cardio-vasculaire de vos patients ?**

- Au moyen d'une table de risque de S.C.O.R.E belge
- Au moyen d'une table de risque de S.C.O.R.E européen
- Autre :
  Si autre, précisez :

**Commentaires :**

**Cette enquête est à présent terminée, nous vous remercions pour votre aide précieuse**

## Appendix 3.4.3. *Flat sorting*

| 1. Langue de départ | | |
|---|---|---|
| **Fr.** | 15 | 68% |
| **Nl.** | 7 | 32% |
| **Totaal** | 22 | 100% |
| 2. Avec combien de patients avez-vous utilisé l'outil? | | |
| **Gem.** | 4 | |
| **Min.** | 1 | |
| **Max.** | 10 | |
| 3. J'ai utilisé principalement | | |
| **Le S.C.O.R.E. belge** | 19 | 86% |
| **Le S.C.O.R.E. européen** | 3 | 14% |
| **Totaal** | 22 | 100% |

| 3.b. Si vous souhaitez ajouter un commentaire par rapport à l'utilisation du SCORE |
|---|
| **Zeer gemakkelijk doordat hypercholesterolemie moeilijk te bepalen is of deze behandeld dient te worden of niet. Nadeel is dat er geen rekening wordt gehouden met familiale belasting die toch belangrijk was. (1 patiënt volgens tool geen statine in primaire preventie noodzakelijk, maar niet-rokende/obese broer had een hartinfarct op 52 jaar net zoals zijn vader.)** |
| **Ik gebruikte vroeger al de kaartjes, met daarop de risicoreductie.<br>Ook handig en visueel aantrekkelijk!** |
| **2 problèmes;<br>- l'âge limité à 65 ans<br>- et le plus important peut-être , seule est prise en compte la mortalité. Hors la morbidité (AVC et infar non fatals) devrait aussi être prise en compte:<br>c'est aussi cela que l'on veut éviter au patient en traitant leurs facteurs de risque cardio-vasculaires.<br>Ne pas prendre en compte la diminution du risque d'AVC et d'infar suite au traitement par statine est aussi trompeur que d'exagérer les résultats attendus<br>de ce tratiement.<br>Vous pensez, à juste titre, qu'un patient mort d'AVC ou d'infar alors qu'on n'avait décidé de ne pas traiter son cholestérol ne nous en fera pas le reproche :-)** |
| **Mais il n'en est pas de même pour les accidents vasculaires non fatals, mais au conséquences importantes: hémiplégie, réduction des capacités d'efforts physique , apahsie... Tout cela est ignoré!** |
| **la limite d'âge** |
| **Fijn instrument, gebruikte dit om het cardiovasculair risico aan de patiënt uit te leggen en uit te leggen waarom best niet... of wel te starten met statine** |

| 4.a. J'ai utilisé l'outil d'aide à la décision : [Sur un ordinateur portable] | | |
|---|---|---|
| **Oui** | 10 | 45% |
| **Non** | 12 | 55% |
| **Totaal** | 22 | 100% |
| 4.b. J'ai utilisé l'outil d'aide à la décision : [Sur un ordinateur fixe] | | |
| **Oui** | 12 | 55% |
| **Non** | 10 | 45% |
| **Totaal** | 22 | 100% |
| 4.c. J'ai utilisé l'outil d'aide à la décision : [Sur une tablette] | | |
| **Oui** | 0 | 0% |
| **Non** | 22 | 100% |
| **Totaal** | 22 | 100% |
| 4.d. J'ai utilisé l'outil d'aide à la décision : [Sur un smartphone] | | |
| **Oui** | 2 | 9% |
| **Non** | 20 | 91% |
| **Totaal** | 22 | 100% |
| 5. En consultation, j'ai utilisé l'outil pendant en moyenne… | | |
| **Moins de 5 minutes** | 17 | 77% |
| **Entre 5 à 10 minutes** | 4 | 18% |
| **Plus de 10 minutes** | 1 | 5% |
| **Totaal** | 22 | 100% |

| 6.a. J'ai montré les résultats du test S.C.O.R.E aux patients : [Sur l'écran de mon ordinateur portable, en le tournant vers les patients] | | |
|---|---|---|
| **Oui** | 6 | 27% |
| **Non** | 16 | 73% |
| **Totaal** | 22 | 100% |

| 6.b. J'ai montré les résultats du test S.C.O.R.E aux patients : [Sur l'écran de mon ordinateur fixe qui est visible par les patients] | | |
|---|---|---|
| **Oui** | 8 | 36% |
| **Non** | 14 | 64% |
| **Totaal** | 22 | 100% |

| 6.c. J'ai montré les résultats du test S.C.O.R.E aux patients : [Sur une tablette] | | |
|---|---|---|
| **Oui** | 0 | 0% |
| **Non** | 22 | 100% |
| **Totaal** | 22 | 100% |

| 6.d. J'ai montré les résultats du test S.C.O.R.E aux patients : [Sur mon smartphone] | | |
|---|---|---|
| **Oui** | 2 | 9% |
| **Non** | 20 | 91% |
| **Totaal** | 22 | 100% |

| 6.e. J'ai montré les résultats du test S.C.O.R.E aux patients : [Sur le papier imprimé] | | |
|---|---|---|
| **Oui** | 2 | 9% |
| **Non** | 20 | 91% |
| **Totaal** | 22 | 100% |

| 6.f. J'ai montré les résultats du test S.C.O.R.E aux patients : [Je n'ai pas montré les résultats'] | | |
|---|---|---|
| **Oui** | 4 | 18% |
| **Non** | 18 | 82% |
| **Totaal** | 22 | 100% |

| 6.g. J'ai montré les résultats du test S.C.O.R.E aux patients : [Autre] |
|---|
| **sur portable mais avec écran externe** |

| 6.h. Si vous souhaitez ajouter un commentaire par rapport à l'utilisation de l'outil en consultation |
|---|
| **Zeer gemakkelijk, voornamelijk het visuele vonden de patiënt interessant om te vergelijken hoe het zou zijn met of zonder behandeling. Ik heb ook bij 1 jonge patiënt (actief roker, hypercholesterolemie en 44 jaar) getoond hoe de situatie zou zijn over 10 jaar en zijn risico significant stijgt. Dit werd voor de patiënt motiverend beschouwd om hier nu actief iets aan te doen op een conservatieve manier.** |
| **Il faudrait ajouter une case diabétique, hypercholestérolémie familiale. Sinon on ne fait pas attention et on n'est pas dans les bons critères** |
| **handig, onmiddellijk resultaat** |
| **L'outil semble surtout pertinent dans les situations où une statine est indiquée. Dans ce cas-là, le pictogramme avec les bonhommes verts et rouges permet de visualisées les "vies sauvées par la statine" par le patient, ce qui a un effet percutant.<br>Le problème se pose peut-être dans les situations où une statine n'est pas recommandée par les guidelines. Le pictogramme peut cependant montrer des petits bonhommes rouges dans le groupe sans statine et le patient ne voit que ça. J'ai l'impression que ça pourrait augmenter la demande d'être mis sous statine par le patient de manière non justifiée. c'est vrai que la décision doit être partagée mais il y a les recommandations internationales d'une part et les critères inami de remboursement d'autre part auxquels il faut coller.** |
| **J'ai l'impression que le visuel provoque une surestimation de l'effet d'un traitement; c'est-à-dire: on ne regarde pas la toute grande majorité des personnes pour lesquelles la prise ou non d'une statine ne fait aucun différence, mais on ne regarde que la petite minorité (les 2 - 3 ) où il y a un changement de "1 vie sauvé": mentalement, cela donne l'impression de (p ex) "1 vie sauvé sur 3"** |

| 7. J'ai imprimé le pdf à destination des patients | | |
|---|---|---|
| **Oui** | 6 | 27% |
| **Non** | 16 | 73% |
| **Totaal** | 22 | 100% |

| 8. Quand ce sera possible*, je compte transmettre ce document aux patients | | |
|---|---|---|
| **Oui** | 12 | 55% |
| **Non** | 1 | 5% |

| | | |
|---|---|---|
| **Je ne sais pas** | 9 | 41% |
| **Totaal** | 22 | 100% |
| 9.a. Je compte le leur transmettre... [par mail] | | |
| **Oui** | 5 | 42% |
| **Non** | 7 | 58% |
| **Totaal** | 12 | 100% |
| **N/A** | 10 | |
| 9.b. Je compte le leur transmettre... [en leur remettant le document imprimé par mes soins] | | |
| **Oui** | 12 | 100% |
| **Totaal** | 12 | 100% |
| **N/A** | 10 | |
| 9.c. Je compte le leur transmettre... [Autre] | | |
| **garder dans le dossier dispo, sur le RSW si possible** | | |
| 9.d. Pourquoi pas ? | | |
| **Pour éviter d'imprimer et épargner les arbres** | | |
| 10. J'ai sauvegardé les résultats du test dans le dossier du patient | | |
| **Oui** | 4 | 18% |
| **Non** | 18 | 82% |
| **Totaal** | 22 | 100% |
| 10.b. Pourquoi pas ? | | |
| **pas de lien direct** | | |
| **Omdat het nog een testversie was, er werd in de mail vermeld nog op te passen met de tool te delen. Is sowieso wel later interessant de PDF toe te voegen aan het dossier.** | | |
| **Je n' y ai pas pensé** | | |
| **dat leek mij niet "vanzelf" te gaan, alleen via een omweg** | | |
| **demande du temps pour retranscrire à nouveau toutes les données dans le dossier** | | |
| **vergeten** | | |
| **Cela ne m'est pas venu à l'esprit<br>A la réflexion je noterais dans le dossier le fait d'avoir utilisé le document et le % avec et sans statine<br>On peut imaginer un bouton à la fin du test qui copie ces données dans le presse papier** | | |
| **toujours en test** | | |
| **Je ne savais pas que cetait possible** | | |
| **Je le connais** | | |
| **un item est déjà prévu dans le programme informatique avec le calcul du risque cardiovasculaire. Je l'utilise lors de la décision de démarrer un traitement par statine ou pas. un échéancier collé à l'item permet d'aillerus un rappel pour une réévaluation de la situation annuellement.** | | |
| **pas nécessaire** | | |
| **Testfase** | | |
| **mon logiciel ne le permet pas pour le moment** | | |
| **Omdat het ik het cardiovasculair risico gewoon noteer in het dossier** | | |
| 10.c. Si vous souhaitez apporter des commentaires relatifs au pdf | | |
| **Cela serait intéressant pour expliquer notre choix de traitement ou d abstention, avoir une preuve, et le remontrer au patient, permettre également un comparatif** | | |
| 11. J'ai utilisé de l'information contenue dans l'onglet 'Informations pour les patients' | | |
| **Oui** | 10 | 45% |
| **Non** | 12 | 55% |
| **Totaal** | 22 | 100% |

| 12.a. Cochez la/les rubrique(s) consultée(s) [Pourquoi trop de cholestérol est-il mauvais pour la santé?] | | |
|---|---|---|
| **Oui** | 8 | 80% |
| **Non** | 2 | 20% |
| **Totaal** | 10 | 100% |
| **N/A** | 12 | |
| 12.b. Cochez la/les rubrique(s) consultée(s) [Qu'est-ce que le risque cardiovasculaire?] | | |
| **Oui** | 6 | 60% |
| **Non** | 4 | 40% |
| **Totaal** | 10 | 100% |
| **N/A** | 12 | |
| 12.c. Cochez la/les rubrique(s) consultée(s) [Comment connaître votre risque cardiovasculaire?] | | |
| **Oui** | 4 | 40% |
| **Non** | 6 | 60% |
| **Totaal** | 10 | 100% |
| **N/A** | 12 | |
| 12.d. Cochez la/les rubrique(s) consultée(s) [Comment diminuer votre risque cardiovasculaire?] | | |
| **Oui** | 8 | 80% |
| **Non** | 2 | 20% |
| **Totaal** | 10 | 100% |
| **N/A** | 12 | |
| 12.e. Cochez la/les rubrique(s) consultée(s) [Qu'est-ce qu'un médicament du groupe des statines?] | | |
| **Oui** | 5 | 50% |
| **Non** | 5 | 50% |
| **Totaal** | 10 | 100% |
| **N/A** | 12 | |
| 12.f. Cochez la/les rubrique(s) consultée(s) [Les statines ont-elles des effets secondaires ?] | | |
| **Oui** | 8 | 80% |
| **Non** | 2 | 20% |
| **Totaal** | 10 | 100% |
| **N/A** | 12 | |
| 12.g. Cochez la/les rubrique(s) consultée(s) [Combien de temps dure un traitement par statines ?] | | |
| **Oui** | 3 | 30% |
| **Non** | 7 | 70% |
| **Totaal** | 10 | 100% |
| **N/A** | 12 | |
| 12.h. Cochez la/les rubrique(s) consultée(s) [Les statines modifient-elles l'effet d'autres médicaments?] | | |
| **Oui** | 3 | 30% |
| **Non** | 7 | 70% |
| **Totaal** | 10 | 100% |
| **N/A** | 12 | |
| 12.i. Cochez la/les rubrique(s) consultée(s) [En résumé, quelles sont les questions à vous poser avant de prendre des statines?] | | |
| **Oui** | 2 | 20% |
| **Non** | 8 | 80% |
| **Totaal** | 10 | 100% |
| **N/A** | 12 | |

| 12.j. Cochez la/les rubrique(s) consultée(s) [À quoi sert de faire ce test?] | | |
|---|---|---|
| **Oui** | 3 | 30% |
| **Non** | 7 | 70% |
| **Totaal** | 10 | 100% |
| **N/A** | 12 | |

| 12.k. Si vous souhaitez apporter des commentaires relatifs à l'info patients |
|---|
| **Pas très didactique visuellement.. Ce serait pratique d'avoir un lien pour que le patient puisse regarder librement les questions** |
| **meestal in de lijn van de verwachtingen: geen medicatie nodig, belang van andere maatregelen, en vooral ook de bijwerkingen v statines schrikken mensen af** |

| 13.a. Quel(s) cas de figure avez-vous rencontré(s) ? La prise de décision... [Est survenue pendant la consultation, après l'utilisation de l'outil web] | | |
|---|---|---|
| **Oui** | 16 | 73% |
| **Non** | 6 | 27% |
| **Totaal** | 22 | 100% |

| 13.b. Quel(s) cas de figure avez-vous rencontré(s) ? La prise de décision... [Surviendra lors d'une consultation ultérieure, déjà fixée] | | |
|---|---|---|
| **Oui** | 3 | 14% |
| **Non** | 19 | 86% |
| **Totaal** | 22 | 100% |

| 13.c. Quel(s) cas de figure avez-vous rencontré(s) ? La prise de décision... [Surviendra lors d'une consultation ultérieure, non-encore prévue] | | |
|---|---|---|
| **Oui** | 5 | 23% |
| **Non** | 17 | 77% |
| **Totaal** | 22 | 100% |

| 13.d. Quel(s) cas de figure avez-vous rencontré(s) ? La prise de décision... [Je ne sais pas] | | |
|---|---|---|
| **Oui** | 1 | 5% |
| **Non** | 21 | 95% |
| **Totaal** | 22 | 100% |

| 14. De mon point de vue, les éléments ayant le plus d'impact sur la prise de décision sont : |
|---|
| **De patiënten diende nog geen beslissing ter plaatse te nemen.** |
| **risque cardiovasculaire** |
| **Als het niet nodig is, kan je dit visueel aan de patiënt laten zien.<br>Als het wel nodig is, idem, en heb je soms net iets meer in handen om hem/haar te overtuigen.** |
| **le visuel du risque** |
| **Les effets secondaire (surtout diabète)** |
| **Le risque de faire un accident vasculaire dans les 5 ans** |
| **Pour ma part: les guidelines ESC de 2016 et les critères remborsement INAMI<br>Pour le patient; le pictogramme des 100 visages verts et rouges? Très percutant** |
| **le bénéfice-risque** |
| **sterfte<br>nevenwerkingen van de statines** |

| 15. J'utiliserai l'outil web avec les patients dans le futur afin de réévaluer leur niveau de risque cardio-vasculaire | | |
|---|---|---|
| **Certainement** | 9 | 41% |
| **Probablement** | 10 | 45% |
| **Probablement pas** | 1 | 5% |
| **Je ne sais pas** | 2 | 9% |
| **Totaal** | 22 | 100% |

| 16.a. Que pensez-vous des affirmations suivantes? [De mon point de vue, les patients ont apprécié l'utilisation del l'outil] | | |
|---|---|---|
| **Tout à fait d'accord** | 7 | 32% |
| **D'accord** | 10 | 45% |
| **Je ne sais pas** | 5 | 23% |
| **Totaal** | 22 | 100% |

| 16.b. Que pensez-vous des affirmations suivantes? [De mon point de vue, les patients ont apprécié la démarche de décision partagée] | | |
|---|---|---|
| **Tout à fait d'accord** | 10 | 45% |
| **D'accord** | 9 | 41% |
| **Pas d'accord** | 1 | 5% |
| **Je ne sais pas** | 2 | 9% |
| **Totaal** | 22 | 100% |

| 16.c. Que pensez-vous des affirmations suivantes? [De mon point de vue, l'utilisation de l'outil en ligne a contribué à une prise de décision partagée] | | |
|---|---|---|
| **Tout à fait d'accord** | 7 | 32% |
| **D'accord** | 10 | 45% |
| **Pas d'accord** | 1 | 5% |
| **Je ne sais pas** | 4 | 18% |
| **Totaal** | 22 | 100% |

| 17. Quel était le motif initial de la consultation durant laquelle vous avez utilisé l'outil (par exemple quel problème, pour quel diagnostic) ? |
|---|
| **vrouw van 40j, eerste bloedname met cholesterolmeting, cholesterol 250.<br>Dan moet ik zeggen: "het staat hier duidelijk in het rood, maar we gaan niets doen".<br>Dan is het veel makkelijker: als ik u al dan niet pillen geef, het gaat over 100 groene mannetjes, en gij kunt "kiezen" voor nevenwerking of niet.<br>Dat is overtuigender vind ik, want de patiënt wordt gek gemaakt over zijn cholesterol door reclame allerhande (becel, benecol, rode rijst, ... )** |
| **résultat de prise de sang hypercholestérolémie** |
| **évaluation du risque cardio vasculaire** |

| 18. Quels étaient les motifs initiaux des consultations durant lesquelles vous avez utilisé l'outil (par exemple quel problème, pour quel diagnostic) ? |
|---|
| **Algemene controle voor patiënten** |
| **prise de sang générale, sans motif particulier** |
| **Jaarlijkse bloedcontroles voornamelijk, waarbij ook telkens de vraag naar het meten v cholesterol gesteld werd.** |
| **hypercholestérolémie en prévention primaire après une prise de sang** |
| **renouvellement de médicaments, vérifications de TA** |
| **démarrage d'un traitement par statines** |
| **Consultation de routine, mise au point et bilan de santé** |
| **prescription de médicaments, plaintes infectieuses** |
| **prise de sang (bilan complet ou sen cas de prise de médicaments) , renouvellement d'ordonnance pour autre chose** |
| **Contrôle biologique, par exemple au cours d'un diabète** |
| **bespreken jaarlijks bloedonderzoek** |
| **examen préventif; controle de la TA** |

| 19.a. D'après votre expérience avec cet outil, que pensez-vous des affirmations suivantes? [J'ai clairement indiqué au patient qu'il fallait prendre une décision.] | | |
|---|---|---|
| **Tout à fait d'accord** | 4 | 18% |
| **D'accord** | 9 | 41% |
| **Pas d'accord** | 5 | 23% |
| **Pas du tout d'accord** | 1 | 5% |
| **Je ne sais pas** | 3 | 14% |
| **Totaal** | 22 | 100% |

| 19.b. D'après votre expérience avec cet outil, que pensez-vous des affirmations suivantes? [Je voulais savoir précisément comment mon patient souhaitait participer à la prise de décision.] | | |
|---|---|---|
| **Tout à fait d'accord** | 2 | 9% |
| **D'accord** | 10 | 45% |
| **Pas d'accord** | 5 | 23% |
| **Pas du tout d'accord** | 2 | 9% |
| **Je ne sais pas** | 3 | 14% |
| **Totaal** | 22 | 100% |

| c. D'après votre expérience avec cet outil, que pensez-vous des affirmations suivantes? [J'ai informé mon patient qu'il existait différentes options de traitement pour son problème de santé.] | | |
|---|---|---|
| **Tout à fait d'accord** | 10 | 45% |
| **D'accord** | 8 | 36% |
| **Pas d'accord** | 2 | 9% |
| **Pas du tout d'accord** | 1 | 5% |
| **Je ne sais pas** | 1 | 5% |
| **Totaal** | 22 | 100% |

| 19.d. D'après votre expérience avec cet outil, que pensez-vous des affirmations suivantes? [J'ai expliqué précisément à mon patient les avantages et inconvénients de chacune des options de traitement.] | | |
|---|---|---|
| **Tout à fait d'accord** | 8 | 36% |
| **D'accord** | 11 | 50% |
| **Pas d'accord** | 1 | 5% |
| **Pas du tout d'accord** | 1 | 5% |
| **Je ne sais pas** | 1 | 5% |
| **Totaal** | 22 | 100% |

| 19.e. D'après votre expérience avec cet outil, que pensez-vous des affirmations suivantes? [J'ai aidé mon patient à comprendre l'ensemble des informations.] | | |
|---|---|---|
| **Tout à fait d'accord** | 8 | 36% |
| **D'accord** | 10 | 45% |
| **Pas d'accord** | 1 | 5% |
| **Pas du tout d'accord** | 1 | 5% |
| **Je ne sais pas** | 2 | 9% |
| **Totaal** | 22 | 100% |

| 19.f. D'après votre expérience avec cet outil, que pensez-vous des affirmations suivantes? [J'ai demandé à mon patient quelle option de traitement il préférait] | | |
|---|---|---|
| **Tout à fait d'accord** | 9 | 41% |
| **D'accord** | 8 | 36% |
| **Pas d'accord** | 3 | 14% |
| **Pas du tout d'accord** | 1 | 5% |
| **Je ne sais pas** | 1 | 5% |
| **Totaal** | 22 | 100% |

| 19.g. D'après votre expérience avec cet outil, que pensez-vous des affirmations suivantes? [Mon patient et moi avons pesé minutieusement le pour et le contre des différentes options de traitement.] | | |
|---|---|---|
| **Tout à fait d'accord** | 10 | 45% |
| **D'accord** | 6 | 27% |
| **Pas d'accord** | 4 | 18% |
| **Pas du tout d'accord** | 1 | 5% |
| **Je ne sais pas** | 1 | 5% |
| **Totaal** | 22 | 100% |

| 19.h. D'après votre expérience avec cet outil, que pensez-vous des affirmations suivantes? [Mon patient et moi avons choisi ensemble une option de traitement] | | |
|---|---|---|
| **Tout à fait d'accord** | 8 | 36% |
| **D'accord** | 10 | 45% |
| **Pas d'accord** | 1 | 5% |
| **Pas du tout d'accord** | 1 | 5% |
| **Je ne sais pas** | 2 | 9% |
| **Totaal** | 22 | 100% |

| 19.i. D'après votre expérience avec cet outil, que pensez-vous des affirmations suivantes? [Mon patient et moi sommes parvenus à un accord sur la façon de procéder] | | |
|---|---|---|
| **Tout à fait d'accord** | 9 | 41% |
| **D'accord** | 10 | 45% |
| **Pas du tout d'accord** | 1 | 5% |
| **Je ne sais pas** | 2 | 9% |
| **Totaal** | 22 | 100% |

| 20. Si vous souhaitez apporter des commentaires relatifs à la prise de décision partagée |
|---|
| **Zo werk ik het liefst, maar het is niet altijd vanzelfsprekend (bij iets minder begaafde patiënten moet je soms toch nog knopen doorhakken).** |
| **Prend du temps mais augmente probablement la compliance. Permet d'être dscipliné sur le fait de consacrfer du temps à la discussion aussi aux autres sujets que le traitement médicamenteux et de s'atarder sur l'hygiène de vie.** |

| 21. De mon point de vue, l'information proposée aux patients dans l'onglet 'Informations aux patients' est suffisante | | |
|---|---|---|
| **Tout à fait d'accord** | 3 | 14% |
| **D'accord** | 12 | 55% |
| **Pas d'accord** | 3 | 14% |
| **Je ne sais pas** | 4 | 18% |
| **Totaal** | 22 | 100% |

| 22. De mon point de vue, cet outil est une plus-value pour la prise de décision partagée | | |
|---|---|---|
| **Tout à fait d'accord** | 7 | 32% |
| **D'accord** | 12 | 55% |
| **Pas d'accord** | 1 | 5% |
| **Je ne sais pas** | 2 | 9% |
| **Totaal** | 22 | 100 % |

| 23. Si vous souhaitez apporter des commentaires relatifs à la plus-value de l'outil |
|---|
| **Eventueel conservatieve maatregelen om cholesterol te verlagen: specifiëren welke voedingen te vermijden.** |
| **informatie voor patiënten, misschien nog toe te voegen: "mijn buurvrouw slikt rode rijst pillen, zou ik dat ook niet beter doen" (want dat loopt toch wel de spuigaten uit)** |
| **mee met de tijd (elektronisch)** |
| **cfr commentaires au point 1 utilisation du tableau score** |
| **expliquer au patient: "c'est quoi" le cholestérol et la différence entre le" bon" et le "mauvais",la fonction du cholestérol** |
| **C'est une plus-value dans la discussion, mais le problème c'est d'essayer de faire comprendre la balance bénéfice-risque d'un traitement sur une cohorte quand le patient ne s'intéresse bien sûr qu'à son risque particulier.** |
| **l'intérêt ou non de l'usage des statines apparaît très clairement, les valeurs chiffrées sont limpides** |

| 24. Globalement, dans quelle mesure êtes-vous satisfait de l'outil d'aide à la décision ? | | |
|---|---|---|
| **Très satisfait** | 3 | 14% |
| **Assez satisfait** | 11 | 50% |
| **Assez insatisfait** | 3 | 14% |
| **Ni satisfait, ni insatisfait** | 5 | 23% |
| **Totaal** | 22 | 100 % |

| 25. Envisagez-vous de continuer à utiliser cet outil ? | | |
|---|---|---|
| **Certainement** | 11 | 50% |
| **Probablement** | 7 | 32% |
| **Probablement pas** | 1 | 5% |
| **Je ne sais pas** | 3 | 14% |
| **Totaal** | 22 | 100 % |

| 26. Recommanderiez-vous l'utilisation de cet outil d'aide à la décision à un confrère? | | |
|---|---|---|
| **Certainement** | 10 | 45% |
| **Probablement** | 7 | 32% |
| **Probablement pas** | 3 | 14% |
| **Je ne sais pas** | 2 | 9% |
| **Totaal** | 22 | 100% |

| 27. Quelles remarques et/ou suggestions souhaiteriez-vous nous communiquer afin d'améliorer l'outil en ligne? |
|---|
| **Visuellement pas très attractif** |
| **in app vorm?** |
| **inclure la morbidité et pas seulement la mortalité dans la prise de décision** |
| **Excellente idée d'essayer de rationnaliser la prescription des statines et d'apporter des éléments soutenant l'intégration d'une discussion et décision partagée avec le patient. Petit doute sur le pictogramme (dans les situations à faible risque) qui interpelle fort le patient, même en cas de risque ne nécessitant a priori pas la mise en route d'une statine.** |
| **traduire en pourcentage<br>élargir la tranche d'âge, en effet pour beaucoup de patients, je n'ai pu l'utiliser car ils avaient plus de 65 ans** |

| 28.a. Avant de tester cet outil en ligne, comment évaluiez-vous le niveau de risque cardio-vasculaire de vos patients ? [Au moyen d'une table de risque de S.C.O.R.E belge] | | |
|---|---|---|
| **Oui** | 18 | 82% |
| **Non** | 4 | 18% |
| **Totaal** | 22 | 100% |

| 28.b. Avant de tester cet outil en ligne, comment évaluiez-vous le niveau de risque cardio-vasculaire de vos patients ? [Au moyen d'une table de risque de S.C.O.R.E européen] | | |
|---|---|---|
| **Oui** | 5 | 23% |
| **Non** | 17 | 77% |
| **Totaal** | 22 | 100% |

| 28.c. Avant de tester cet outil en ligne, comment évaluiez-vous le niveau de risque cardio-vasculaire de vos patients ? [Je n'utilisais aucun outil] | | |
|---|---|---|
| **Non** | 22 | 100% |
| **Totaal** | 22 | 100% |

| 28.d. Avant de tester cet outil en ligne, comment évaluiez-vous le niveau de risque cardio-vasculaire de vos patients ? [Autre] |
|---|
| **berekening in mijn EMd geintegreerd** |
| **Outil aide Mayo Clinic** |

| 29. Nom, Prénom |
|---|
| **XXX** |

| 30. Années d'expérience en tant que médecin généraliste | |
|---|---|
| **Gem.** | 13 |
| **Min.** | 2 |
| **Max.** | 38 |

| 31.a. Cabinet individuel | | |
|---|---|---|
| **Oui** | 6 | 27% |
| **Non** | 16 | 73% |
| **Totaal** | 22 | 100% |

| 31.b. Cabinet de groupe | | |
|---|---|---|
| **Oui** | 17 | 77% |
| **Non** | 5 | 23% |
| **Totaal** | 22 | 100% |

| 31.c. Cabinet autre | |
|---|---|
| **Maison médicale** | 1 |



# APPENDIX 4. COMMIT LOG OF THE TOOL

| Time | Code commit |
|---|---|
| 2019-10-08 17:10:36 +0200 | Logo's on main page |
| 2019-10-04 10:12:53 +0200 | Inspringen bullets in firefox print |
| 2019-10-02 15:22:55 +0200 | Emoji's in old Edge evrsion |
| 2019-10-01 17:32:20 +0200 | Re-fixed Firefox print |
| 2019-10-01 16:31:39 +0200 | [KCESTAT-115] #close #comment Cookie-form hidden on PDF |
| 2019-10-01 10:52:57 +0200 | updated kce-common |
| 2019-10-01 10:45:17 +0200 | Cookie consent |
| 2019-09-27 14:29:37 +0200 | Bugfix: Variable and translatable risk_factor in top part of patient results |
| 2019-09-17 12:09:37 +0200 | Revert "tool changes" |
| 2019-09-09 15:10:35 +0200 | Inlcude images |
| 2019-09-09 15:04:27 +0200 | images from /dist/ |
| 2019-09-05 15:10:28 +0200 | Set up head |
| 2019-09-05 15:09:41 +0200 | Defering and async loading scripts, css, bootstrap etc. |
| 2019-07-15 13:26:16 +0200 | Added more significant digits to ESC weights |
| 2019-07-09 14:32:37 +0200 | [KCESTAT-58] #close #comment translations for tool-labels |
| 2019-07-05 17:10:48 +0200 | Updated kce-common |
| 2019-07-03 11:00:44 +0200 | Re-fix IE |
| 2019-07-01 16:43:36 +0200 | Accessibility fixes |
| 2019-06-19 18:15:33 +0200 | removed console.log statements |

| | |
|---|---|
| 2019-06-19 18:10:41 +0200 | Code cleanup |
| 2019-06-19 17:34:11 +0200 | Finished ESC report |
| 2019-06-19 16:39:30 +0200 | [KCESTAT-103] #close #comment screen reader |
| 2019-06-17 11:51:43 +0200 | Smiley fix for regular print |
| 2019-06-17 11:41:41 +0200 | [KCESTAT-101] #close #comment  PDF print in Firefox |
| 2019-06-16 11:42:38 +0200 | First version without errors |
| 2019-06-14 18:03:28 +0200 | Starting subdivision |
| 2019-06-12 22:55:16 +0200 | First working heatmap |
| 2019-06-12 16:20:04 +0200 | Fixed for IE 11 |
| 2019-06-12 14:38:37 +0200 | IE fix for preventDefault |
| 2019-06-12 14:23:44 +0200 | Added browser compatibility list: > 0.25% market share, not dead |
| 2019-06-12 14:04:14 +0200 | Solved merge conflict |
| 2019-06-12 13:58:36 +0200 | Fix for IE, replace console logging with debug |
| 2019-06-12 12:15:44 +0200 | Browser based output |
| 2019-06-11 13:44:42 +0200 | lambda test |
| 2019-06-08 12:42:14 +0200 | First pass verification (without HDL correction) |
| 2019-06-07 17:19:37 +0200 | Temp: working ESC tool, no compatibilty for Edge/IE |
| 2019-06-07 17:11:15 +0200 | Revert to 518a555a8f69c2ce22dbb2eba32cbb7c9607db79 |
| 2019-06-07 17:05:42 +0200 | Revert "[KCESTAT-97] #close #comment Fixes layout issue on edge and IE" |
| 2019-06-07 16:52:36 +0200 | tool changes |
| 2019-06-07 14:43:14 +0200 | Tool compatibility for Edge |
| 2019-06-07 12:46:29 +0200 | Versioning for webpack |



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| 2019-06-07 11:56:11 +0200 | webpack test |
| 2019-06-07 11:34:27 +0200 | Fix for Navbar Toggle |
| 2019-06-07 10:37:02 +0200 | [KCESTAT-97] #close #comment Fixes layout issue on edge and IE |
| 2019-06-05 15:29:22 +0200 | . |
| 2019-06-05 15:27:21 +0200 | [KCESTAT-96] #close |
| 2019-06-05 11:32:39 +0200 | [KCESTAT-95] #close #comment Variable results, md preserved |
| 2019-06-05 10:19:00 +0200 | [KCESTAT-94] #close #comment added page-break element to print |
| 2019-06-04 17:22:50 +0200 | Styling risk-factor |
| 2019-06-04 15:34:33 +0200 | [KCESTAT-82] #close #comment titles on langSelect |
| 2019-06-04 14:45:43 +0200 | Even more PDF styling |
| 2019-06-04 12:48:51 +0200 | [KCESTAT-85][KCESTAT-86] #close |
| 2019-06-04 11:08:44 +0200 | Print-functions, printer helper |
| 2019-06-03 22:28:55 +0200 | Conflict fixes processForm |
| 2019-06-03 22:19:27 +0200 | Fix for layout issues |
| 2019-06-03 21:32:12 +0200 | merge |
| 2019-06-03 21:19:40 +0200 | [KCESTAT-67][KCESTATSUP-41] |
| 2019-06-03 17:51:52 +0200 | PDF print: page breaks |
| 2019-06-03 17:30:02 +0200 | preliminary md fix |
| 2019-06-03 17:28:55 +0200 | . |
| 2019-06-03 17:28:13 +0200 | markdown test |
| 2019-06-03 15:33:20 +0200 | merge |
| 2019-06-03 15:29:31 +0200 | [KCESTAT-76] |

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| 2019-06-03 11:54:59 +0200 | Clean-up |
| 2019-06-03 11:52:30 +0200 | Fix dev start |
| 2019-06-03 11:45:06 +0200 | [KCESTAT-78] #close #comment Disclaimer alignment |
| 2019-05-29 18:10:01 +0200 | Added outPath to sass config |
| 2019-05-29 17:15:04 +0200 | . |
| 2019-05-29 16:54:36 +0200 | Live reloading, source mapping and general refactoring |
| 2019-05-28 18:37:25 +0200 | Refactored using light-weight kce-commons |
| 2019-05-28 18:23:53 +0200 | Major refactoring |
| 2019-05-28 16:52:09 +0200 | Layout changes as requested by KCE |
| 2019-05-28 15:31:50 +0200 | [KCESTAT-61] #close #comment markdown content |
| 2019-05-28 11:56:27 +0200 | [KCESTAT-57] #close #comment Adds target _blank to external links |
| 2019-05-27 13:53:58 +0200 | . |
| 2019-05-27 13:48:19 +0200 | Recent build push |
| 2019-05-27 12:55:34 +0200 | [KCESTAT-50] #close #comment disclaimer text |
| 2019-05-24 13:52:47 +0200 | [KCESTAT-45] #close #comment Hide notes field |
| 2019-05-24 11:03:43 +0200 | [KCESTAT-46][KCESTAT-47] |
| 2019-05-23 17:41:22 +0200 | Tool width |
| 2019-05-23 17:30:49 +0200 | Small styling improvements |
| 2019-05-23 17:24:28 +0200 | [KCESTAT-41] tool hardcoded on 2nd place |
| 2019-05-23 16:39:07 +0200 | details-summary |
| 2019-05-23 16:36:01 +0200 | [KCESTAT-43] #close #comment detail-summary |
| 2019-05-23 15:22:10 +0200 | [KCESTAT-39] |



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| 2019-05-23 10:38:03 +0200 | Footer fix |
| 2019-05-23 10:35:31 +0200 | Footer fix |
| 2019-05-23 10:23:24 +0200 | Markdown in footer fix |
| 2019-05-21 15:23:10 +0200 | Fixed unit corrections and HDL correction for women |
| 2019-05-21 14:22:00 +0200 | Correction factor HDL for women |
| 2019-05-21 13:50:58 +0200 | Refactored script building and fixed language navigation |
| 2019-05-21 13:12:45 +0200 | [KCESOA-40] #close |
| 2019-05-21 13:10:47 +0200 | [KCESTAT-40] #close #comment No language-select on non-existing languages |
| 2019-05-21 12:03:53 +0200 | Latest tool code |
| 2019-05-21 10:48:10 +0200 | Pre-merge |
| 2019-05-20 16:04:32 +0200 | Revert to work with older lambda |
| 2019-05-20 14:42:10 +0200 | [KCESTAT-38] #close #comment Menu items on toolpage + Reworked JS |
| 2019-05-17 20:58:40 +0200 | merge [KCESTAT-14][KCESTAT-24] #close |
| 2019-05-17 15:51:41 +0200 | make tool result printable |
| 2019-05-17 10:52:00 +0200 | Update HTML Structure |
| 2019-05-16 17:29:11 +0200 | Fix for languageSelection page |
| 2019-05-16 17:08:31 +0200 | Move bootstrap to ‘Common’ |
| 2019-05-16 16:56:37 +0200 | Move assets to ‘Common’ |
| 2019-05-16 16:43:47 +0200 | Style update |
| 2019-05-16 15:24:49 +0200 | Template fixes for languages + tool-specific |
| 2019-05-16 14:34:28 +0200 | navigation fix |

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| 2019-05-15 16:54:37 +0200 | Language-selection page + temporary multi-lingual tool workaround + logical template-naming |
| 2019-05-13 17:32:50 +0200 | Fixed HDL requirement |
| 2019-05-13 16:42:41 +0200 | HDL adjusted formulas |
| 2019-05-10 13:13:24 +0200 | point to correct configId |
| 2019-05-06 19:27:36 +0200 | Improve CSS and Images |
| 2019-05-06 17:01:34 +0200 | Border consistency |
| 2019-05-06 16:48:43 +0200 | Result Emojis layout |
| 2019-05-06 15:47:48 +0200 | [KCESTAT-3] #close Backdrop fix |
| 2019-05-06 15:39:08 +0200 | Style Tool Input |
| 2019-05-02 16:30:29 +0200 | Eliminated mathjs entirely plus some small fixes |
| 2019-05-02 16:22:55 +0200 | lambda from private submodule test |
| 2019-05-02 15:57:22 +0200 | Lambda test |
| 2019-05-02 15:56:10 +0200 | updated lambda test |
| 2019-05-02 12:23:51 +0200 | Sizing/layout result-block |
| 2019-05-02 12:12:12 +0200 | Fix vertaling titels emojis |
| 2019-05-02 12:09:31 +0200 | Emoji spacing |
| 2019-05-02 12:07:07 +0200 | Externalised ESC weights to json file |
| 2019-05-02 11:53:49 +0200 | Eliminated mathjs package, added json config and f weights for be score |
| 2019-05-02 11:42:09 +0200 | . |
| 2019-05-02 11:05:36 +0200 | push to lambda |
| 2019-05-02 10:31:57 +0200 | Clearing results when switching tabs |



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| 2019-05-02 10:27:42 +0200 | emoji size |
| 2019-05-02 10:16:09 +0200 | Translations and min/max error messages |
| 2019-05-02 10:07:16 +0200 | Updated demo |
| 2019-05-02 09:58:33 +0200 | tool bg |
| 2019-05-02 09:58:10 +0200 | styling changes tool and font-sizing |
| 2019-05-02 09:24:22 +0200 | Working ESC scoring |
| 2019-05-02 09:14:25 +0200 | Updated font-awesome |
| 2019-05-02 08:56:24 +0200 | All kinds of tool fixes |
| 2019-05-01 23:29:08 +0200 | Added translation function for labels, etc in tool |
| 2019-05-01 22:49:57 +0200 | Working BE scoring system |
| 2019-05-01 21:41:50 +0200 | Tweak tool input |
| 2019-05-01 21:41:30 +0200 | Update common submodules |
| 2019-05-01 15:49:24 +0200 | live data |
| 2019-05-01 15:35:59 +0200 | routing fix |
| 2019-05-01 15:12:39 +0200 | template changes |
| 2019-05-01 14:38:49 +0200 | template changes |
| 2019-05-01 14:30:26 +0200 | Template changes for demo |
| 2019-04-30 16:57:25 +0200 | Basic template for pages |
| 2019-04-30 16:20:10 +0200 | Webpack included in data-fetching |
| 2019-04-30 15:58:17 +0200 | get data from CMS, new layout |
| 2019-04-30 15:48:42 +0200 | Building with Webpack and new formulas |
| 2019-04-18 17:34:12 +0200 | Fixed #KCESTAT-7 incorrect bin usage |

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| 2019-04-11 13:07:17 +0200 | Results |
| 2019-04-11 11:34:48 +0200 | Update common styling |
| 2019-04-11 11:27:29 +0200 | Style Tool input |
| 2019-04-10 11:11:55 +0200 | Added (experimental) formula for ESC score |
| 2019-04-08 10:21:15 +0200 | Added Bootstrap SCSS files to source |
| 2019-04-08 09:56:49 +0200 | Added debugging |
| 2019-04-08 09:45:40 +0200 | Async/await style config, added error page |
| 2019-04-06 20:53:19 +0200 | Added error page |
| 2019-04-06 12:30:44 +0200 | Added warnings and some cleanup |
| 2019-04-06 10:50:46 +0200 | Fixing out of bounds input |
| 2019-04-05 17:15:41 +0200 | Better active links |
| 2019-04-05 16:39:16 +0200 | Extra styling + variable text in results |
| 2019-04-05 12:28:52 +0200 | BE & ESC versions working |
| 2019-04-02 18:06:05 +0200 | Form validation and clean-up |
| 2019-04-02 15:11:06 +0200 | Correct ESC calculations |
| 2019-04-02 13:34:20 +0200 | Input based tool |
| 2019-04-02 12:51:43 +0200 | Working statins calculator |
| 2019-04-02 12:24:11 +0200 | add kce-common submodule |
| 2019-03-26 15:30:39 +0100 | Add labels below range input |
| 2019-03-26 14:54:52 +0100 | Dot files |
| 2019-03-26 14:40:03 +0100 | Initial commit |