

SYNTHESIS

CARDIOVASCULAR PRE-PARTICIPATION SCREENING IN YOUNG ATHLETES



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EVALUATION OF THE EFFICACY OF A CARDIOVASCULAR PRE-PARTICIPATION SCREENING PROGRAM IN YOUNG ATHLETES (14-34 YEARS)

ANJA DESOMER, SOPHIE GERKENS, IMGARD VINCK, CHRISTIAN LEONARD, MATTIAS NEYT, DOMINIQUE PAULUS, HANS VAN BRABANDT



■ FOREWORD

Dear reader, what would you say to a little hypothetical exercise?

Every year, we regrettably see a number of fatal accidents on our motorways that are due to a failure of the vehicle's steering mechanism – and it affects fairly new cars, too. Owing to a slight increase in slack from speeds of 100 to 110 km/h and over, a vibration can occur that is quickly amplified and this sometimes leads to a loss of control over the steering, with possibly disastrous consequences. The government feels that it has a moral obligation to do something about this, takes its responsibility and decides that from now on, a test certificate for the steering mechanism is a condition for obtaining the motorway sticker, even for vehicles that are only two to four years old (don't worry, it's only a hypothetical exercise). One thorny detail: at this stage, no-one knows whether a test like this will actually reduce the number of victims of such accidents.

The test centres in turn assume their responsibility and adjust their equipment so that it is sufficiently sensitive not to miss any problems. This inevitably leads to an increase in the number of red cards, with a request to have the vehicle inspected, and if necessary repaired, and to present it for testing again. In practice, however, the equipment available produces an anomalous result in 5 % of vehicles that do not actually have any problem. The consequences are considerable. Out of one million relatively new cars, one in twenty does not pass the test. That means 50 000 garage visits and re-tests, whereas in fact only around 3000 of the vehicles really have a potentially dangerous problem (of which 750 will slip through the maze of controls anyway). In addition to the remaining 2250 which are actually largely identified and 'dealt with' by their garage mechanic, there are also another 1 % of the vehicles in good condition (i.e. just under 500 of these 50 000) in which all these diligent mechanics think they have found a defect nevertheless and think they have to repair it. Are you following so far? Because it gets better! Of these 2250+500 repair jobs to such a vital component, done at almost as many different garages, here and there something goes wrong: an even greater slack than before, a forgotten wheel bolt, etc., leading to one or two fatal accidents a year. Net gain? A big question mark. Net loss: a great deal of inconvenience and needless expense for a huge number of people.

OK, so that's enough imagining. And yet. The motorway sticker was invented, but the figures are precisely those taken from the study in front of you. Replace the steering mechanism test with an ECG and our message is clear. Doing sport is fun and healthy, and above all, don't let the fun be spoilt by unnecessary and even harmful medicalisation. We're not expecting applause all round for this advice, and we realise that the emotional arguments are real. But our job is to present you with data that are as objective as possible. We hope we've said enough to arouse your curiosity. Happy reading!

Christian LÉONARD
Deputy general director

Raf MERTENS
General director



■ SYNTHESIS

This is the English summary of the full scientific report with a short presentation of the main results on the effectiveness of cardiovascular pre-participation screening in young athletes (14-34y), completed with a critical appraisal of the Italian screening program. In the full report (available in English) more results are presented on the Belgian current practice and ethical considerations. This synthesis is also available in Dutch and French (see KCE website).

1. OBJECTIVES

A young athlete collapsing and dying during a sports event is a devastating incident with substantial impact on the lay community. In more than half of non-traumatic deaths on the sports field, an underlying unsuspected cardiovascular disease appears to be the responsible underlying condition.¹ In an attempt to try to prevent such tragedies, pre-participation screening for cardiovascular disease has been advocated. The reasoning is that a medical examination can identify or raise suspicion for an increased risk for sudden cardiac death (SCD) in an asymptomatic person, and that appropriate action can eliminate or at least reduce this risk.

1.1. What is “screening”?

This report adopts the definition of “screening” as presented in the seminal paper by Wilson and Jungner²: “the presumptive identification of unrecognized disease or defect, by the application of tests, examinations, or other procedures which can be applied rapidly. Screening tests sort out apparently well persons who probably have a disease from those who probably do not”.



2. AIM AND SCOPE

The aim of this report is to assess the effectiveness of cardiovascular pre-participation screening to prevent SCD in non-professional athletes, aged 14-34 years. In its most basic format, cardiovascular pre-participation screening consists of taking a personal and family history with a physical examination. To increase the sensitivity of such basic examination, it has been advocated to include an electrocardiogram (ECG) in the screenings protocol.³ The target population are young people who plan to become a member of a sports club/federation, or who want to participate in a mass sports event. Individuals with cardiac or other symptoms - including serious anxiety with respect to sports participation – do not qualify for screening, but are considered “patients”. They are not included in the scope of this study.

The report addresses the following research questions:

1. What is the clinical effectiveness of cardiovascular pre-participation screening of asymptomatic young, non-professional athletes (14-34y)? Both the benefit in terms of SCD prevention as potential harms (overdiagnosis and overtreatment) are to be considered.
2. What is the cost-effectiveness of cardiovascular pre-participation screening of young, non-professional athletes?
3. What is the current practice concerning legal regulations, legal liability of physicians and sports clubs involved in pre-participation screening and existing Belgian initiatives? What are the implications from the point of view of insurers?
4. What ethical issues must be considered in pre-participation screening?

3. INTERVENTIONS OUT OF THE SCOPE OF THIS STUDY

Other cardiac tests, such as exercise-ECG, echocardiography and genetic testing will also not be discussed in this report.

The immediate management of sudden cardiac arrest (SCA) in athletes with the aim to prevent death, i.e. bystander cardiopulmonary resuscitation, the implementation of emergency medical services and the availability and use of automatic external defibrillators are beyond the scope of the present report.



4. RESULTS

4.1. Effectiveness of cardiovascular pre-participation screening

Sudden cardiac death in a young individual is a devastating event. Appropriate measures to prevent such tragedies would be more than welcome.

This report, which can be seen as an update of the report from the Belgian Superior Health Council (Hoge Gezondheidsraad - Conseil Supérieur de la Santé),⁴ has tried to give an answer on the question if cardiovascular pre-participation screening is useful.

4.1.1. *Clinical effectiveness of cardiovascular pre-participation screening*

The **clinical benefit** of pre-participation screening in reducing SCD of young athletes is presently not fully clear. There is however no doubt that SCD in this population is a very rare event. Therefore, in the absence of a perfect diagnostic test, pre-participation screening inevitably induces a huge number of false-positives, leading to **overdiagnosis and overtreatment** of the healthiest segment of the population.

Based on the scientific data provided in the full report, we can assume that out of 1 million screened young people, a cohort of 50 000 to 300 000 individuals will be identified that will be suspected of having a disease that may lead to SCD. Further investigations will identify 2250 among them that are affected by a disease. The large majority of those will never die suddenly or will even never have any symptom of the disease (see Figure 1).

The most prevalent diseases are WPW (1360 per million) and HCM (450 per million). Some experts argue that asymptomatic people with one of those conditions do not need to be treated. Other experts will proceed to catheter ablation or ICD implantation in selected individuals. They argue that, although it has not been shown that these interventions reduce the risk of SCD, there is a pathophysiological rationale for it. However, those treatment modalities have their proper mortality risk which appears to be of a similar magnitude of the SCD risk of asymptomatic affected individuals. This means that it cannot be taken for granted that lives will be saved because of the detection of those diseases at screening. This statement is confirmed by the

fact that the incidence of SCD is not lower in Italy, where screening is mandatory, as compared to other countries (US, France) where there is no systematic screening.

In Belgium it can be expected that yearly up to 10 young people may suddenly die during sports. Whereas the chance is low that pre-participation screening will save 1 of those individuals, it is possible that 1 life will be lost because of overdiagnosis and overtreatment.

Among the initially suspected 50 000 to 300 000 individuals, a final diagnosis will remain unclear in an estimated 2000 to 3000 of them because downstream diagnostic techniques are not 100% performant.

Eventually, around 5000 of the original 1 million screenees (i.e. 0.5%) will be labelled as suffering from a cardiac disease. This may lead to temporary or lifelong disqualification from competitive sports, psychological harm, and (lifelong) medical follow-up and treatment with unknown benefit.

David Sackett, the father of Evidence-Based Medicine, argues that curative and preventive medicine are absolutely and fundamentally different in their obligations and implied promises to the individuals whose lives they modify.⁵ He further explains that, when patients are looking for help, the doctor promises to do his best without guaranteeing that his interventions will succeed. In contrast, in preventive medicine, the fundamental promise a doctor makes must be that, on average, the involved symptomless individual will be the better for it. Accordingly, the presumption that justifies the medical intervention must be based on the highest level of randomised evidence that the preventive manoeuvre will do more good than harm. Without evidence from positive randomised trials it cannot be justified soliciting the well to accept any personal health intervention.⁵

The lack of solid evidence of the benefit of cardiovascular pre-participation screening, and the certainty of the harms it induces, makes that such screening cannot be defended.

The Belgian Superior Health Council acknowledged the absence of hard scientific evidence favouring cardiovascular screening and recommended against mandatory screening.⁴ However, based on the conviction of professionals involved in the report, and the presumed societal support for screening, it positively recommended a strictly supervised cardiovascular pre-participation screening in young people who want to participate in competitive sports, with the inclusion of an ECG. In a recently published



assessment of the ECG as a screening test in young individuals, the American Heart Association concludes that there is insufficient information available to support universal ECG screening for cardiovascular disease in asymptomatic young people, both in competitive athletes and in the general youthful population.⁶

4.1.2. Cost-effectiveness of cardiovascular pre-participation screening

Concerning the **cost-effectiveness**, there are no reliable economic evaluations with convincing results showing that pre-participation screening in young athletes provides value for money. Based on optimistic assumptions, a one-time cardiovascular pre-participation screening seems not cost-effective or might even be a dominated alternative if we take into account the impact on the quality of life. Moreover, results are even worse for a yearly screening (unlikely to be cost-effective).

Our calculations for the Belgian setting showed that a cardiovascular screening consisting of the combination of history, physical examination and a rest-ECG (every four years or more often)^a, would be expensive and potentially harmful, compared to the uncertain benefits (see Figure 1).

4.1.3. Liability of the physician in the Belgian context

The implementation of a screening program can also have consequences on the extent of **liability** of the physician. Malpractice liability for failure to discover latent, asymptomatic cardiovascular diseases requires proof that the physician did not act in line with the accepted medical practice in his/her specialty (fault) and that the proper utilisation of the appropriate methods would likely have discovered the underlying medical condition (causality). Up to now the inconsistency between existing guidelines, are likely to exonerate the physician from any proof of fault.

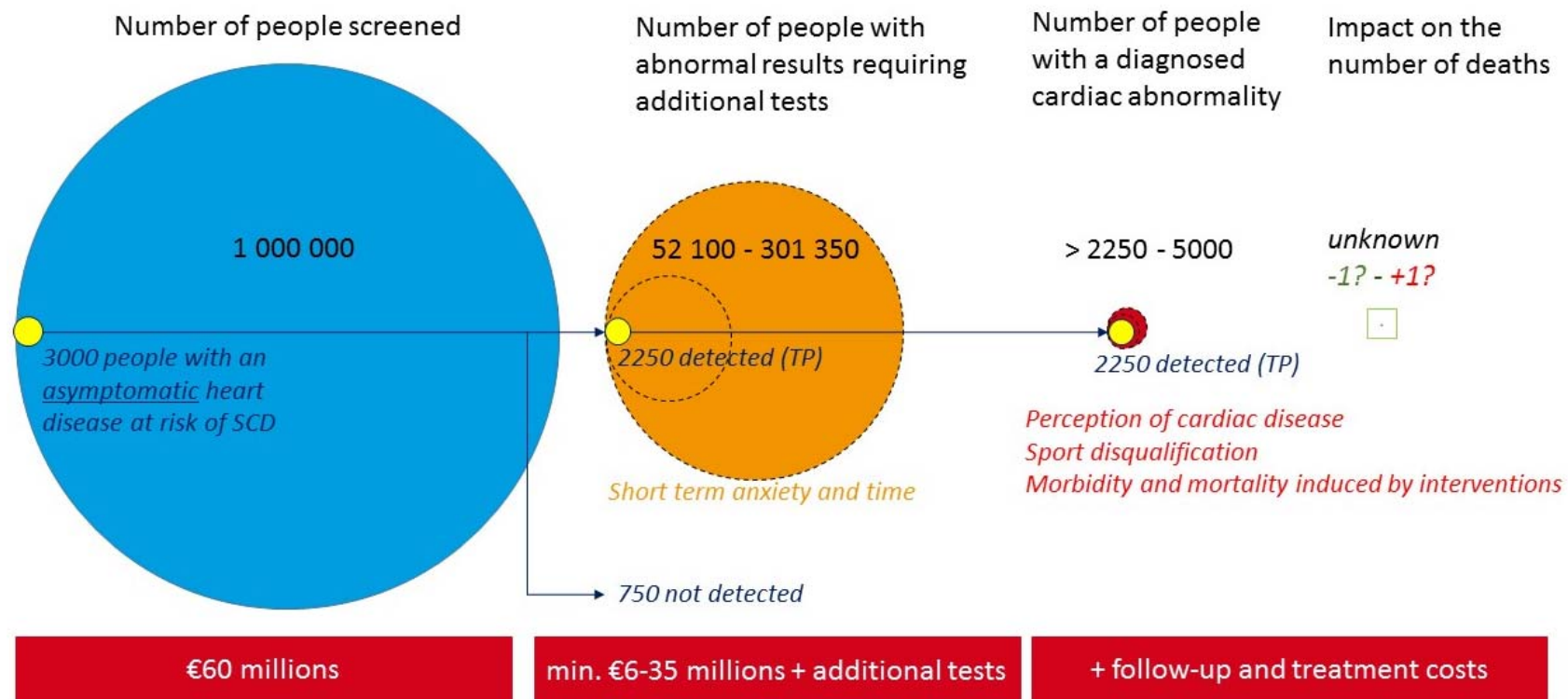
Athletes involved in a pre-participation screenings program are considered as patients, as defined in the Patients' Rights Act. This implies amongst others that an athlete should correctly be informed about the potential benefits and harms of cardiovascular pre-participation screening.

With or without the obligation to be screened, it remains the responsibility of the physician to inform the athlete on the potential benefits and harms linked to a cardiovascular pre-participation screening program.

^a As specified in the report of the Belgian Superior Health Council



Figure 1 – Impact of a cardiovascular pre-participation screening with H&P and ECG in Belgium (for a sensitivity of 0.75 and a specificity between 0.70 and 0.95)



TP: True Positive; SCD: Sudden Cardiac Death



4.2. Critical appraisal of the Italian screening program

4.2.1. Main results of the Veneto Study

The Italian experience is the most known example of the implementation of a pre-participation screening. Since 1971 an annual pre-participation screening of competitive athletes (combined screening protocol with rest-ECG) is mandatory. Nevertheless this national screening program, only data is published from the Veneto region on the screening period 1979 until 2004 in athletes aged 12-35 years. The annual incidence of SCD decreased by 90% from 3.6/100 000 person-years in 1979-1980 to 0.4/100 000 person-years in 2003-2004. In 9% of the athletes further examination was needed and 2% were ultimately disqualified from participation in competitive sports. Since the persons who tested negative in the first screening round were not retested with additional tests, the proportion of false-negatives in the general population is unknown. Also the published paper lack to report the number of false positives.

4.2.2. Critical appraisal and ethical considerations

In the 2006 paper, the authors conclude: "*The incidence of sudden cardiovascular death in young competitive athletes has substantially declined in the Veneto region of Italy since the introduction of a nationwide systematic screening.*"⁷ It is clear that by using this wording, they avoid to fall pray of the "post hoc ergo propter hoc" logical fallacy. A causal relationship between screening and a declining SCD rate cannot be assumed here because of a number of methodological weaknesses of the study, more particular its mere observational nature and the lack of an unscreened control athlete population. In fact, the authors use historic data retrieved during a 2 years pre-screening period (1979-1980) as a reference for assessing the impact of screening over the ensuing 22 years (1982-2004).

The yearly event rate was very low, ranging from 4 cases per year at the start of the study to 1 case per year during the final years. Such low absolute numbers are very sensitive to minor variations, and may be affected by e.g. the adjudication of the cause of death, administrative mistakes, or whether or not a resuscitation of a given SCA victim succeeded. Furthermore, over a time period of more than 20 years, there may have been a substantial change in the composition of the study population, e.g. the proportion of females (of whom it is known that they have a much lower SCD risk) may have increased as time went by. The paper does not provide data in this respect. Observational data suggest that the gradual implementation of emergency action plans and the widespread use of automatic external defibrillators has improved the survival of athletes who developed a SCA.⁸

Experience in Israel, where a mandatory pre-participation screening program was introduced in 1997, indicated a substantial variation in the yearly incidence of SCD. Israel researchers compared their findings that were based on reports of SCD in the general media, with the Italian data as shown in Figure 2. They stress that, if one compares SCD rates during the 2 years preceding the enforcement of screening in Israel with the mortality at the end of the study (as was done in the Italian study), one could conclude that the Israel screening strategy is extremely effective (D to G in Figure 2). It is only when one reviews the entire study period and compares the 12- year period before screening with the 12-year period after screening (from point C to G in Figure 2) that it becomes obvious that this apparent mortality reduction is most likely related to a year-to-year variation and may illustrate a regression-to-the-mean of the SCD incidence rate.^{6,9}



Figure 2 – Variation in reported SCD rates in athletes across studies.

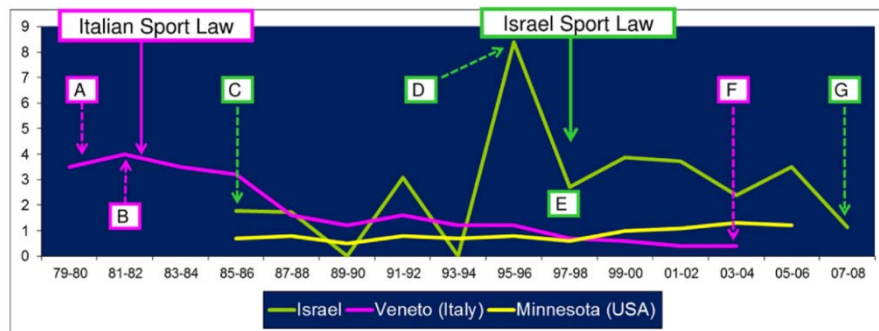


Figure extracted from Steinvil et al.⁹ Data refer to the annual incidence of SCD per 100,000 person-years reported in Italy,⁷ Israel,⁹ and the US¹⁰.

Of note, the incidence rate in the late screening period in Italy does not significantly differ from SCD rates observed in the same era in countries that did not have a mandatory screening program. The mortality rate of athletes in Minnesota (1993 to 2004) was close to that in Italy (Veneto 0.87 per 100 000 person-years vs 0.93 in Minnesota (Figure 2).¹ In France, a nationwide survey from 2005-2010 revealed a similar number, 0.98 cases per 100 000 person-years.¹¹

Based on the abovementioned reflections we think that the decreased incidence rate of SCD in Italy during the study was not causally related to the pre-participation screening. Several other authors have also expressed such doubts.^{9, 12-14}

However, over the years and with no new confirmative evidence, the authors apparently became convinced on a causal relationship between SCD rate and pre-participation screening in Veneto. This becomes clear if one considers the papers they published in consecutive years in leading medical journals. In a 2008 paper they conclude “Pre-participation cardiovascular evaluation of competitive athletes essentially based on ECG seems according to the long-term Italian experience, to be a lifesaving strategy that

adequately meets the criteria for a good screening program”.¹⁵ A few years later, they write that “The available evidence, based on the long-running Italian experience, indicates that ECG screening has to be considered an efficient health strategy for prevention of SCD of young competitive athletes. It meets the most important Wilson and Jungner’s criteria”.^{16, 17} Always referring to the same data, in 2013 it sounds as follows: “Pre-participation screening based on a 12-lead electrocardiogram (ECG) is effective in identifying athletes with potentially lethal cardiovascular disease and saves lives by disqualifying them from competitive sports activity.”¹⁸

A number of the objections we summarised in our critical appraisal might be clarified by the Italian investigators if they would provide access to other unpublished Italian data. Firstly, although the Italian screening program is a truly national initiative, published data come only from one small region of this country (Veneto). It would be informative to know to what extent the Veneto data are representative of Italy overall.¹³ Secondly, published data about the (remarkably high) pre-screening SCD incidence in Veneto are limited to the years 1979-1980 and are based on no more than 14 cases. Other sources report that annual pre-participation screening in Italy became mandatory by law in 1971.^{4, 19} Therefore, one would expect that mortality data during those early years would be available. Thirdly, so far no screening or mortality data from the years after 2004 have been published. These would allow to better appreciate the random variation in SCD incidence.

Researchers from the UK tried to obtain additional data from the Italian screening program via a formal request from Mr. Jeremy Hunt, the UK Secretary of State for Health, to the Minister of Health in Italy, to no avail.¹⁴ Upon our request in June 2014, professor Corrado responded that “we are analysing the SCD rates in the last decade (period 2005-2014)”. So far, we did not yet receive more data.

Given the facts that both the scientific and lay communities are largely influenced by the published data from Italy, we think that the Italian investigators have the moral duty to make their data publicly available with no further delay.



■ RECOMMENDATIONS^b

To the involved authorities, the responsible of the sports federations and the concerned physicians

- Within the current available scientific knowledge, KCE recommends that no cardiovascular pre-participation screening should be requested in young, non-professional athletes by enrollment in a sports federations or sports mass event. After all not sufficient elements are available to presume that the trade-off between benefits and harms of such a screening would be beneficial.
- This report does not concern screening in athletes older than 34 years neither on the usefulness of screening to prevent other sports injuries. KCE recommends that before guideline or regulations are developed on these topics, an independent evaluation of the benefits and harms should be performed.
- The KCE recommends that independent and scientific underpinned information material should be developed on the potential benefits and harms of cardiovascular pre-participation screening. This information should be available for the athletes, the parents, the sports federations, the physicians, the physiotherapists and other involved care professionals.

^b The KCE has sole responsibility for the recommendations.



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COLOPHON

Title:	Cardiovascular pre-participation screening in young athletes – Synthesis
Authors:	Anja Desomer(KCE), Sophie Gerkens (KCE), Imgard Vinck (KCE), Christian Léonard (KCE), Mattias Neyt (KCE), Dominique Paulus (KCE), Hans Van Brabandt (KCE)
Project coordinator:	Dominique Paulus (KCE)
Reviewers:	Wendy Christiaens (KCE), Pascale Jonckheer (KCE)
External experts and stakeholders:	Nancy Barette (Vlaams Ministerie van Cultuur, Jeugd, Sport en Media), Nicole Bossaerts (kabinet Vlaams Minister van Sport), Pedro Brugada (UZ Brussel), Luk Buyse (Vereniging voor Sport- en Keuringsartsen (SKA)), Stefaan Callens (Callens Advocatenkantoor), Serge Carabin (Direction Générale de la Santé), Ann Ceuppens (Onafhankelijke Ziekenfondsen – Mutualités Libres), Karen Colaert (Vlaams Agentschap Zorg en Gezondheid), Isabelle Dagneaux (UCL), Guy De Backer (UZ Gent; Hoge Gezondheidsraad), Xavier de Béthune (Mutualité Chrétienne – Christelijke Mutualiteit), Daniel De Wolf (UZ Gent), Nicolas Estienne (Estienne & Callewaert), Marc Francaux (UCL), Marc Gewillig (UZ Leuven), Joeri Guillaume (Socialistische Mutualiteiten – Mutualités Socialistes), Olivier Gurne (UCL), Bart Hannes (Ethias), Hein Heidbüchel (Jessa Ziekenhuis), Mickaël Hiligsmann (ULg), Mark Lamotte (IMS Health Consulting), Stéphane Moniotte (Cliniques Universitaires Saint-Luc), Frank Pauwels (Vereniging voor Sport- en Keuringsartsen (SKA)), Laurent Ravez (Université de Namur), Isabelle Reussens (Advocatenkantoor Janssens), Peter Roossens (Advocatenkantoor Curia), Bert Suys (UZ Leuven), Tom Teulingkx (Vereniging voor Sport- en Keuringsartsen (SKA)), Johan Van Acoleyen (Vereniging voor Sport- en Keuringsartsen (SKA)), Nathalie Van de Vyver (Domus Medica), Eddy Van Den Bosch (Arena nv), Maurice Vanbellinghen (Test Aankoop – Test-Achat), Pieter Vandenbulcke (Vlaams Agentschap Zorg en Gezondheid), Jacques Vanderstraeten (Société Scientifique de Médecine Générale), Paul Verwilghen (Ministère Wallon de l'Agriculture, de la Nature, de la Ruralité, du Tourisme et des Sports), Antonine Wyffels (RIZIV – INAMI), Marc Xhonneux (Direction Générale du Sport, Fédération Wallonie-Bruxelles)
External validators:	Lieven Annemans (Universiteit Gent), J. Hoogsteen (Maxima Medisch Centrum, Nederland), Henri Nielens (Cliniques Universitaires St-Luc)
Acknowledgements:	Nicolas Fairon (KCE), Luc Hourlay (KCE), the representatives of the sports federations
Other reported interests:	Membership of a stakeholder group on which the results of this report could have an impact: Bert Suys (child cardiology; BVK), Luk Buyse (SKA), Frank Pauwels (SKA) Fees or other compensation for writing a publication or participating in its development: Maurice Vanbellinghen (articles for Test-Aankoop concerning screening) Payments to speak, training remuneration, subsidised travel or payment for participation at a conference: Bart Hannes (lectures by order of the Vlaamse Trainerschool (BLOSO), Hein Heidbuchel (Seattle conference (FIFA), CRY conference London)



Presidency or accountable function within an institution, association, department or other entity on which the results of this report could have an impact: Marc Xhonneux (Direction Generale du Sport, Fédération Wallonie-Bruxelles), Pieter Vandenbulcke (team responsible of the section Preventie of the Vlaams Agentschap Zorg en Gezondheid), Daniel De Wolf (head of department cardiology-pediatrics UZ Gent), Marc Gewillig (child cardiology UZ Leuven), Tom Teulingks (president SKA), Johan Van Acoleyen (board membre SKA), Karen Colaert (theme policymaker 'screening' within the section Algemene Preventie van Zorg en Gezondheid), Luk Buyse (SKA), Frank Pauwels (SKA)

Layout: Ine Verhulst

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- **Finally, this report has been approved by common assent by the Executive Board (see <http://kce.fgov.be/content/the-board>).**
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Publication date: 26 March 2015
Domain: Health Technology Assessment (HTA)
MeSH: Cardiovascular system; mass screening; electrocardiography
NLM Classification: WA245
Language: English
Format: Adobe® PDF™ (A4)
Legal depot: D/2015/10.273/29
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How to refer to this document?

Desomer A, Gerkens S, Vinck I, Léonard C, Neyt M, Paulus D, Van Brabandt H. Cardiovascular pre-participation screening in young athletes – Synthesis. Health Technology Assessment (HTA) Brussels: Belgian Health Care Knowledge Centre (KCE). 2015. KCE Reports 241Cs. D/2015/10.273/29.

This document is available on the website of the Belgian Health Care Knowledge Centre.