Identifying leisure athletes at high risk for medical complications using five international pre-exercise screening tools

By

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DECLARATION

I, the undersigned, declare that the dissertation hereby submitted to the University of Pretoria for the degree MSc (Biokinetics) and the work contained therein is my own original work and has not previously, in its entirety or in part, been submitted to any university for a degree.

Signed ……

DEDICATION

I dedicate this to my husband, Hannes, and my parents.

ACKNOWLEDGEMENTS

First, I would like to acknowledge my Heavily Father, without whom it would not have been possible to establish my own practice while also completing my MSc in Biokinetics.

"With man this is impossible, but with God all things are possible" (Matthew 19:26).

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SYNOPSIS

Title Identifying leisure athletes at high risk for medical complications using five international pre-exercise screening tools

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Degree MSc Sport Science (Biokinetics)

Cardiorespiratory endurance (aerobic exercise) involves using large muscle groups during exercise of moderate to high intensities for extended periods of time. The numerous health benefits of regular participation in endurance exercise are undisputed. However, exercise sessions involve an increased risk of medical complications, including sudden cardiac arrest (SCA) or sudden death (SD). Prolonged endurance exercise, such as long-distance running, is also associated with other serious life-threatening and moderate medical complications, such as exertional heatstroke, serum electrolyte disturbances and acute kidney injury, which can affect various organ systems. In order to decrease the likelihood of medical encounters (MEs) during an event or race, it is therefore important to identify athletes who are at a higher risk for medical complications prior to allowing them to participate in endurance sports events. To achieve this objective, pre-exercise medical evaluation and medical screening procedures are recommended by several international sports federations and are implemented by a number of international professional medical bodies. Although until recently such recommendations were implemented mainly in younger elite athletic populations, pre-race medical screenings are now also being done for older recreational endurance runners. Various pre-exercise medical screening tools have been proposed for use by international professional medical bodies to identify individuals who may be at risk for medical complications. The pre-exercise screening tools that are commonly used to identify recreational athletes who should consult a medical practitioner before exercising are the following:

1. The 2011 American Heart Association (AHA) guidelines
2. The pre-2015 American College of Sports Medicine (ACSM) guidelines
3. The post-2015 American College of Sports Medicine (ACSM) guidelines

4. The 2002 Physical Activity Readiness Questionnaire (PAR-Q)

5. The 2011 European Association of Cardiovascular Prevention and Rehabilitation (EACPR) guidelines.

To date, the outcomes of these various tools and guidelines used to identify participants at risk of medical encounters during exercise (defined as those who are advised to undergo a pre-exercise medical evaluation) have not yet been compared, and such a comparison was the focus of this research.

The aim of this study was to determine the percentage of race entrants who are advised to obtain pre-exercise medical clearance by using five international pre-exercise medical screening tools, and also to determine the level of agreement between the tools. The domains of risk responsible for the large variation between the results produced by the five pre-exercise medical screening tools used to identify participants at higher risk for medical encounters during exercise were also established. The domains of risk included history of cardiovascular disease [CVD], symptoms of CVD, risk factors of CVD, a history of any chronic disease and chronic diseases affecting organ systems, prescription medication used and a history of musculoskeletal injury.

Raw data obtained from pre-race medical screening questionnaires completed by runners who participated in four consecutive Two Oceans Marathons (2012–2015), was analysed. Only information provided by consenting race entrants was included in this study.

It was found that there was a wide variation between the results obtained by using five international pre-exercise medical screening tools to identify individuals who require medical clearance, and therefore a considerable variation between the levels of agreement between the pre-exercise medical screening tools. In our population of recreational distance running race entrants, the pre-2015 ACSM and EACPR pre-exercise medical screening tools identified the most participants (33.9%) as needing medical clearance, while the post-2015 ACSM identified the smallest number (6.7%) of participants as needing medical clearance. There was a fair level of agreement between the result obtained when using the pre-2015 ACSM and EACPR pre-exercise medical screening tools ($K=1.00$; $p=0.05$), whereas the post-2015 ACSM and PAR-Q pre-exercise medical screening tools showed a poor level of agreement ($K=0.17$; $p<0.0001$).

Furthermore, there was a significant variation between the results of the pre-exercise medical screening tools used regarding the domains of risk identifying participants at higher risk for medical encounters during exercise, but no single domain could be identified as the cause of this inconsistency. The selection of a pre-exercise medical screening tool should be based on the purpose for which, and context in which the screening tool will be used. The pre-2015 ACSM and EACPR pre-exercise medical screening tools identified a high percentage of participants for all domains of risk, except any kidney/bladder disease. In order to identify participants at risk, we thus recommend that the pre-exercise medical screening tool should be chosen based on the needs of the event.

A limitation of this study was that the questions asked during the Two Oceans Marathon pre-exercise medical screening were not the same as the original questions asked in the five screening tools, such as those relating to pregnancy, general running and training information, general training surface information, and acute infection and illness, were omitted. The results might therefore have differed slightly if the participants had completed each of the pre-exercise screening tools separately.

The strengths of this study are that, to our knowledge, no previous studies have been undertaken to compare five international pre-exercise medical screening tools, and that the sample size was large and a good response rate was achieved (71.8% of the total entrants consented to the use of their data).

Key words: Pre-exercise medical screening tools, pre-exercise medical clearance, recreational endurance athletes, medical encounters

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LIST OF ABBREVIATIONS

SCA	Sudden Cardiac Arrest
SD	Sudden Death
MEs	Medical Encounters
AHA	American Heart Association
ACSM	American College of Sport Medicine
PAR-Q	Physical Activity Readiness Questionnaire
EACPR	European Association of Cardiovascular Prevention and Rehabilitation
CVD	Cardiovascular Disease
SAFER	**S**trategies to reduce **A**dverse medical events **F**or the **E**xercise**R**
CV	Cardiovascular
HR	Heart Rate
BP	Blood Pressure
CAD	Coronary Artery Disease
DM	Diabetes Mellitus
VO_2R	Oxygen Uptake Reserve
HRR	Heart Rate Reserve
METs	Metabolic Equivalents
WPA	Western Province Athletics
ASA	Athletics South-Africa
IAU	International Association of Ultrarunners
IAAF	International Association of Athletics Federations
CPR	Cardiopulmonary Resuscitation
SCORE	Systematic Risk Evaluation
BMI	Body Mass Index
ESC	European Society of Cardiology
ECG	Electrocardiogram
NHANES	National Health and Nutrition Examination Survey

CHAPTER 1: INTRODUCTION

1.1 INTRODUCTION AND MOTIVATION FOR THE STUDY

Cardiorespiratory endurance (aerobic exercise) involves using large muscle groups during exercise of moderate to high intensities for extended periods of time.[1] Although the numerous health benefits of regular participation in endurance exercise are undisputed,[2] there is an increased risk of medical complications during exercise sessions, including sudden cardiac arrest (SCA) or sudden death (SD).[2] Prolonged endurance exercise, such as long-distance running, is also associated with other serious life-threatening and moderate medical complications, such as exertional heatstroke, serum electrolyte disturbances and acute kidney injury, which can affect various organ systems.[3] In order to decrease the likelihood of medical encounters (MEs) during events or races, it is therefore important to identify athletes who are at a higher risk for medical complications before they participate in such events. To achieve this objective, the pre-exercise medical evaluation and medical screening procedures that are recommended by international sports federations are implemented by a number of international professional medical bodies. Although until recently such recommendations were implemented mainly in younger elite athlete populations, pre-race medical screening is now also being done for older recreational endurance runners. The various pre-exercise medical screening tools that have been proposed for use by international professional medical bodies to identify individuals who may be at higher risk for medical complications and are commonly used in pre-exercise screening to identify recreational athletes who should consult a medical practitioner before exercising are the following:

1. The 2011 American Heart Association (AHA) guidelines
2. The pre-2015 American College of Sports Medicine (ACSM) guidelines
3. The post-2015 American College of Sports Medicine (ACSM) guidelines
4. The 2002 Physical Activity Readiness Questionnaire (PAR-Q)
5. The 2011 European Association of Cardiovascular Prevention and Rehabilitation (EACPR) guidelines.

To date, the outcomes of these various tools and guidelines used to identify participants at risk of medical encounters during exercise (defined as those who are advised to undergo a pre-exercise medical evaluation) have not yet been compared, and such a comparison was the focus of this study.

The aim of this study was to determine the percentage of race entrants who are advised to obtain pre-exercise medical clearance by using five international pre-exercise medical screening tools, and to determine the level of agreement between the tools. The domains of risk responsible for the large variation between the results produced by the five pre-exercise medical screening tools used to identify participants at higher risk for medical encounters during exercise were also established. Those domains of risk were found to be a history of cardiovascular disease (CVD); symptoms of CVD; risk factors of CVD; a history of any chronic disease and chronic diseases by organ systems; a history of prescription medication use; and a history of musculoskeletal injury.

Raw data, obtained from pre-race medical screening questionnaires completed by runners who participated in four consecutive Two Oceans Marathons (2012–2015), was analysed. Only data from consenting race entrants was included in this study.

1.2 THE PURPOSE OF THE STUDY

As stated above, this research study used five international pre-exercise medical screening tools to determine the percentage of race entrants who are advised to obtain pre-exercise medical clearance and to establish the level of agreement between the tools. The domains of risk responsible for the large variation between the results produced by the five pre-exercise medical screening tools used to identify participants at higher risk for medical encounters during exercise were also established. Those domains of risk were found to be a history of CVD, symptoms of CVD, risk factors of CVD, a history of any chronic disease and chronic diseases by organ systems, a history of prescription medication used and a history of musculoskeletal injury.

1.3 OBJECTIVES OF THE STUDY

The specific objectives of this research were:

- To determine the percentage of race entrants who are advised to obtain pre-exercise medical clearance by using five international pre-exercise medical screening tools

- To determine the level of agreement between the five international pre-exercise medical screening tools

- To determine which domains of risk (history of CVD, symptoms of CVD, risk factors of CVD, history of any chronic disease and chronic diseases by organ systems, history of prescription medication use, history of musculoskeletal injury) are responsible for the significant inconsistency between the results obtained by using the five pre-exercise medical screening tools to identify participants who are more likely to experience medical encounters during exercise.

1.4 RESEARCH APPROACH

Raw data, obtained from pre-race medical screening questionnaires completed by runners who had participated in four consecutive Two Oceans Marathons (2012–2015), was analysed (Appendix A). A quantitative approach was used for the purpose of this study and only data from consenting race entrants was included (Appendix B). Demographic data regarding the race in which entrants participated were described using frequency analysis. Using the responses to all the questions relating to demographics (age and sex) and medical history, an algorithm was created for each of the five pre-exercise medical screening tools used to determine the need for medical clearance. This is the binary-scaled response variable (requiring medical screening or not) for each of the five pre-exercise medical screening tools. Using a Poisson regression model, the prevalence (%) of entrants identified by each tool as requiring medical clearance was calculated (with 95% Cl). The statistical significance level is 5%, unless specified otherwise. Using the Kappa statistic, the level of agreement with the other screening tools was then calculated for each screening tool. The following level of agreement classification scale was used to interpret the Kappa statistic. K-values of <0.20 indicate a poor level of agreement and values between 0.21 and 0.40 indicate a fair level of agreement. Those between 0.41 and 0.60 indicate a moderate level of agreement, those between 0.61 and 0.80 a good level of agreement, and those between 0.81and 1.00 a very good level of agreement.[4, 5] Using this same outcome response variable for each screening tool (medical clearance=yes), a Poisson regression model was used to determine the prevalence (% and 95% CIs) of entrants for each main domain, and individual response (%) was calculated for the whole population for each screening tool. Significant differences in the percentage of entrants identified by the pre-exercise medical screening tools in each main domain was determined by 95% confidence intervals that did not overlap. Ethical consent had already been obtained for the large

prospective cohort studies (REC numbers 433/2015 and 431/2015) entitled "Medical consequences in endurance sports. Two Oceans marathon longitudinal study: 2009-2015" and "Reducing Medical Complications and Injuries at Endurance Sports Events: A 5-year Longitudinal Study (2016-2020)" SAFER studies (C and D). Permission for the researcher to use the data for the completion of this MSc in Sport Science (Biokinetics) was obtained (Appendix E). Ethical approval for the study was granted (Appendix F).

1.5 RESEARCH DESIGN

This study, which was undertaken in an attempt to reduce the risk of medical complications during exercise, is a retrospective analysis of previously collected data and is a quantitative, cross-sectional observational study (REC number: 433/2015 and 431/2015).

1.6 RESEARCH PROCEDURE AND STRATEGY

Figure 1.1 outlines the research process and strategy followed for this study.

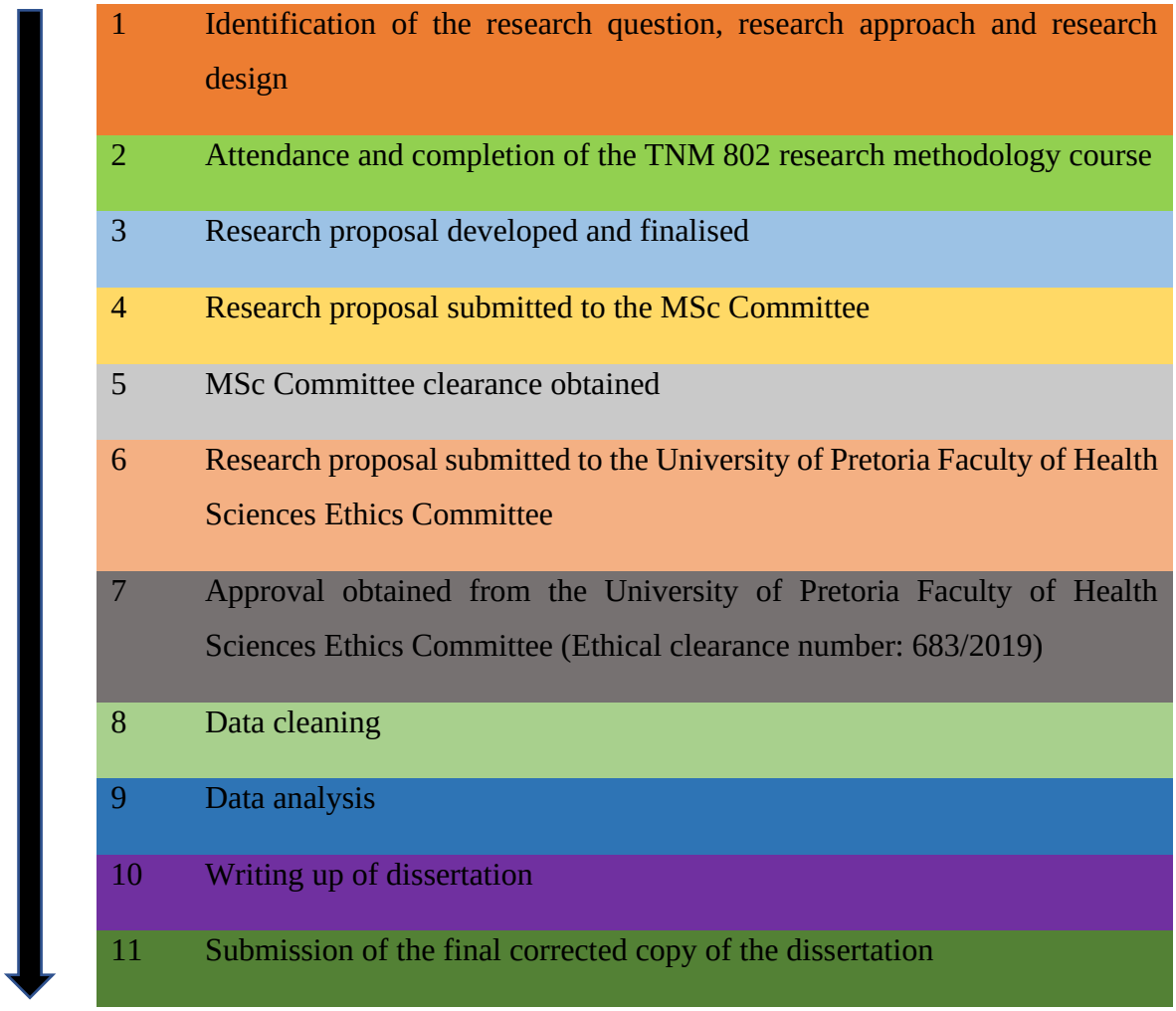

Figure 1.1: Flow diagram of the research process followed

1.7 STRUCTURE OF THE DISSERTATION

In Chapter 1, the research topic and the scope of the study are discussed. Chapter 2 consists of a literature review in which current literature on the themes pertinent to the study are explored and expanded upon. In Chapter 3, the first research study exploring the percentage of race entrants who were advised to obtain pre-exercise medical clearance using five international pre-exercise medical screening tools is discussed, as well as the establishment of the level of agreement between the results produced by the various tools for athletes who participated in four consecutive marathons (2012 – 2015), while Chapter 4 deals with the second research study during which domains responsible for the differences between the results produced by the five international pre-exercise screening tools regarding the identification of leisure athletes who were at high risk for medical complications were examined. The primary findings are presented in Chapter 5, which also contains a discussion of the strengths and limitations of the study, suggestions for future related research and a conclusion.

1.8 REFERENCES

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CHAPTER 2: LITERATURE REVIEW

2.1. CARDIORESPIRATORY ENDURANCE EXERCISE AND ENDURANCE RUNNING EVENTS

Cardiorespiratory endurance exercise involves the use of large muscle groups during exercise of moderate to high intensities for extended periods of time.[1] A substantial body of evidence exists of the numerous health benefits to be gained from engaging in regular physical activity. These benefits include reduced cardiovascular disease (CVD) risk factors (such as reduced body fat); improved cardiovascular (CV) and respiratory function (such as reduced heart rate (HR) and blood pressure (BP) for a given submaximal exercise intensity); and reduced risk for coronary artery disease (CAD), type II diabetes mellitus (DM), metabolic syndrome, stroke, breast and colon cancer, gallbladder disease and depression.[2, 3] Even though regular exercise, including long-distance running, has numerous health benefits, which include psychological, biological and social benefits, it also involves potential risks and adverse medical events have been recorded during endurance exercise events.[1, 4] However, the health benefits far outweigh any negative consequences (risk of adverse events) during exercise participation.[4] The risk of adverse events during exercise will be discussed in section 2.2.

It is important to note that different levels of intensity are related to endurance exercise. These intensities range from light (<40% Oxygen Uptake Reserve (VO_2R) or Heart Rate Reserve (HRR) to <3 Metabolic Equivalents (METs)); moderate (40% - <60% VO_2R or HRR, or 3–6 METs); and vigorous (≥60% VO_2R or HRR, or ≥6 METs).[4] The exercise "dose" recommended to derive health benefits from endurance exercise is: moderate intensity, endurance exercise at least five days a week; or vigorous intensity, endurance exercise at least three days a week; or a combination of the two: three to five days a week.[4]

Individuals can participate in various cardiorespiratory endurance activities and events, such as running, jogging, swimming and cycling. The increasing number of individuals participating in recreational long-distance running events, such as half-marathons (21.1 km), marathons (42.2 km) and ultra-marathons is evidence of the growing popularity of this form of recreational exercise.[2, 5] The focus of this study will be on the Two Oceans Marathon, which is a 21.1 km and a 56km endurance running event.

The 56 km Two Oceans Marathon is known as the world's most scenic marathon. The first 56 km race took place in 1970, with only 26 runners ready to face an unknown challenge.[6] Since

then, the race has grown in popularity and attracts athletes from all over the world. This mass community-based endurance sports event takes place annually, just before winter, in Cape Town, South Africa. More recently, other races were introduced and currently this event consists of various distances ranging from 2.5 km to 5 km fun runs to a 21 km half marathon and a 56 km ultramarathon.[6] Every year the two main events, the ultra-marathon (56 km) and the half-marathon (21.1 km), attract approximately 25 000 runners.[2] Males and females over the age of 20 years may enter the ultra-marathon race, while male and female participants in the half-marathon race must be at least 16 years of age.[6]

This is a pre-entry only event, and since 2012 it has been compulsory that, upon entry, each entrant complete a pre-race medical screening questionnaire.[6] The half-marathon and ultra-marathon events are held under the auspices of Western Province Athletics (WPA), Athletics South-Africa (ASA), International Association of Ultrarunners (IAU), and International Association of Athletics Federations (IAAF), and their rules and regulations apply.[6]

2.2. ADVERSE EVENTS AND MEDICAL ENCOUNTERS IN ENDURANCE RUNNING EVENTS

2.2.1 Defining medical encounters and serious (life-threatening) medical encounters

Recently, an international panel of experts published a consensus document that defines medical encounters and the severity of medical encounters.[7] In this thesis, the following international consensus definitions will be used:

A participant with a medical encounter of moderate severity is defined as: "*Any runner who required medical care on race day that was severe enough to warrant a medical assessment by a doctor, either at the medical facility at the end of the race, on route at the medical stations, or at one of the referral hospitals (for runners that were assessed by medical staff on the route)*".[7, 8]

A serious (life-threatening) medical encounter is defined as: "*A medical encounter that could result in death unless urgently diagnosed and treated*".[7, 8] These medical encounters include CV, fluid, metabolic, electrolyte and acid-base abnormalities, thermoregulatory, respiratory and central nervous system (CNS) abnormalities.[7, 8] Sudden cardiac arrest (SCA) can be defined as "*hemodynamic failure that results from an unexpected termination of cardiac-related activity, usually with no warning signs or symptoms, which could ultimately lead to sudden cardiac death"* (SCD).[9]

2.2.2. The risk associated with participation in endurance events

Evidence exists that medical encounters are more common in ultramarathon races than races over shorter distances.[10] Generally, healthy individuals with normal CV systems have a lower risk of CV events and it has been shown that there is no reason for healthy individuals to abstain from marathon running for fear of cardiac arrest.[4, 11] The risk for myocardial infarction (MI) (heart attack) and sudden cardiac arrest is low in healthy individuals who engage in physical activity of low to moderate intensity.[4] However, the risk of MI and/or sudden cardiac death increases when athletes with either occult or diagnosed CVD perform exercise of moderate to high intensity.[4, 12] The risk of these events occurring during exercise increases with the presence of CVD or risk factors associated with CVD in the individual.[4] Prolonged endurance exercise of moderate to high intensity (for example marathon running) has been associated with serious life-threatening cardiac events, such as atrial fibrillation.[13]

The series of studies titled **S**trategies to reduce **A**dverse medical events **F**or the **E**xercise**R** (SAFER) are aimed at minimising the risk of associated medical encounters, whether life-threatening or not, in endurance athletes.[8] These studies have identified risks associated with endurance events with a view to the implementation of strategies that will reduce medical encounters and adverse events. Distance running is associated with medical encounters that have the potential to negatively affect various organ systems.[8] It has been shown that exercise of moderate to high intensity may trigger sudden death and/or acute MI in both older and younger runners.[8] In a study involving marathon runners, it was reported that the occurrence of sudden cardiac death is more frequently seen in the 5th to 6th decade of life, with most deaths occurring in relatively experienced runners who have previously participated in marathon events.[14]

2.2.3. Strategies for minimising the risk associated with endurance events

It is important to identify the risk factors associated with medical encounters during 56 km and 21 km endurance events so that intervention programmes can be tested and developed.[15] In order to reduce the risk of a medical complication associated with physical activity, it is recommended that a medical examination and an exercise stress electrocardiogram should be part of the pre-exercise medical screening process for individuals who are at moderate to high risk.[4] A more comprehensive pre-exercise risk assessment may be required, such as combining the European Association of Cardiovascular Prevention and Rehabilitation (EACPR) pre-screening medical tool with an exercise electrocardiogram (ECG).[16] Studies have shown that this may benefit individuals with an intermediate or high risk of cardiac events, or those who

have a family history of premature CAD.[16] According to the ACSM, athletes who are at the highest risk and those with unstable CVD symptoms may benefit from a pre-screening medical evaluation.[4] Pre-exercise medical screening can also provide recommendations regarding the continuation, initiation, or progression of physical activity in order to prevent or minimise life-threatening cardiac events.[4, 17]

The SAFER study IV found that online pre-race acute illness medical screening and subsequent educational intervention prior to the endurance event can be implemented with success.[18] SAFER study VIII consisted of an eight-year observational study on medical encounter rates of Two Oceans race starters (56 km and 21.1 km).[1] The main finding was that when using an adapted EACPR medical screening tool, more than 30% of runners in this race would need a full pre-race medical assessment. However, this finding was based mainly on the occurrence of musculoskeletal conditions.[5] These guidelines were then revised to risk stratify race entrants according to 'very high', 'high', 'intermediate' and 'low' risk of medical encounters.[1] Furthermore, when introducing an educational intervention programme and an online pre-race medical screening programme at the Two Oceans Marathon race, reductions in medical encounters were documented.[1] A 29% reduction was found in all medical encounters and, most importantly, serious life-threatening medical encounters were reduced by 64%.[1] The current worldwide practice in endurance events therefore has the potential to be beneficially changed by introducing educational intervention strategies and pre-race medical screening.[1] The implementation of such programmes could thus improve the safety of endurance races worldwide.

2.2.4. Incidence and types of adverse events and medical encounters in endurance running events

The first SAFER study found that serious life-threatening medical encounters were higher in the 56 km event than in the 21 km event, with an incidence of 12.98 per 1 000 starters for all medical encounters in the former, and 0.65 per 1 000 starters for serious life-threatening medical encounters in the latter.[8] The most common medical encounters reported in this study were postural hypotension, musculoskeletal complications and dermatological complications.[8]

In a study conducted by using publicly available news and databases for half and full marathon race events in Sweden, it was established that a total of 1 156 271 endurance long-distance races (42 km and 21 km) had taken place during the period 2007 to 2016.[19] A total of 834 412 (72.2%) participants had finished the races, and 81% of the population were full marathon

participants.[19] The death rate during the abovementioned period was 0.24 per 100 000 finishers. Furthermore, it was found that, due to bystanders' increased knowledge of cardiopulmonary resuscitation (CPR) and the availability of defibrillators, the survival rates of SCA during training and races has increased in the past 15 years.[19] It has also been reported that marathon death rates had decreased, but that higher rates of SCA had occurred among half-marathon runners,[19] which may be as a result of half-marathon runners being insufficiently trained.[19]

Another study found that the sudden death rate in mass endurance events is between 0.4 and 3.3 per 100 000 race entrants.[7] The rate of other serious medical encounters (e.g. hyponatraemia) is between 16 and 155 per 100 000 race entrants.[7] Other serious medical encounters are, however, not commonly reported.

2.3. TYPES OF PRE-RACE MEDICAL SCREENING TOOLS AND RISK STRATIFICATION

We are aware of five tools that are commonly used in the pre-exercise screening of endurance athletes: the 2011 American Heart Association (AHA) guidelines; the pre-2015 American College of Sports Medicine (ACSM) guidelines; the post-2015 American College of Sports Medicine (ACSM) guidelines; the 2002 Canadian Physical Activity Readiness Questionnaire (PAR-Q); and the 2011 European Association of Cardiovascular Prevention and Rehabilitation (EACPR) guidelines. Each of these tools will now be briefly reviewed.

2.3.1. The 2011 American Heart Association (AHA) guidelines

These screening guidelines include a 14-point history and physical examination to determine whether a participant has existing CVD or risk factors for CVD.[20] A positive response to one or more screening questions in the questionnaire warrants a further evaluation by a qualified physician in order to cancel out any possible false positive answers.[20] Questions asked in this questionnaire require, among other things, information relating to personal history (such as chest pain and increased blood pressure) and family history (such as disability resulting from a heart disease that occurred in a close relative <50 years of age).

A potential limitation of this questionnaire is that it is recommended only for small cohorts of healthy, young athletes between 12 and 25 years of age, and not for large cohorts in the general population (so-called leisure athletes).[20] Another limitation is that the answers given could be false positive answers, which could lead to unnecessary visits to doctors.[20] Furthermore, the availability of well-trained medical staff with the ability to discern between false positive and positive answers is required.[20] An example of the questionnaire is provided in Figure 2.1.[20]

The 14-Element AHA Cardiovascular Screening Checklist for Congenital and Genetic Heart Disease

Personal history

Yes	No	
☐	☐	1. Chest pain/discomfort/tightness/pressure related to exertion
☐	☐	2. Unexplained syncope/near-syncope*
☐	☐	3. Excessive exertional and unexplained dyspnea/fatigue or palpitations, associated with exercise
☐	☐	4. Prior recognition of a heart murmur
☐	☐	5. Elevated systemic blood pressure
☐	☐	6. Prior restriction from participation in sports
☐	☐	7. Prior testing for the heart, ordered by a physician

Family history

Yes	No	
☐	☐	8. Premature death (sudden and unexpected, or otherwise) before age 50 attributable to heart disease in ≥1 relative
☐	☐	9. Disability from heart disease in close relative <50 y of age
☐	☐	10. Hypertrophic or dilated cardiomyopathy, long-QT syndrome, or other ion channelopathies, Marfan syndrome, or clinically significant arrhythmias; specific knowledge of certain cardiac conditions in family members

Physical Examination

Yes	No	
☐	☐	11. Heart murmur**
☐	☐	12. Femoral pulses to exclude aortic coarctation
☐	☐	13. Physical stigmata of Marfan syndrome
☐	☐	14. Brachial artery blood pressure (sitting position)***

**Judged not to be of neurocardiogenic (vasovagal) origin; of particular concern when occurring during or after physical exertion.*
***Refers to heart murmurs judged likely to be organic and unlikely to be innocent; auscultation should be performed with the patient in both the supine and standing positions (or with Valsalva maneuver), specifically to identify murmurs of dynamic left ventricular outflow tract obstruction.*
****Preferably taken in both arms.*

Figure 2.1: The 2011 American Heart Association (AHA) guidelines[20]

2.3.2. The pre-2015 American College of Sports Medicine (ACSM) guidelines

These guidelines are divided into two sections and use *true* statements to assess a participant's health status. Section I evaluates the participant's health history, for example a previous heart attack or heart surgery; symptoms, such as chest discomfort with exertion or dizziness; and other health issues, such as diabetes or asthma. Section II identifies CVD risk factors, such as smoking and prediabetes (Figure 2).[4] If any of the statements in Section I is marked 'true', the participant is advised to consult a qualified medical physician before engaging in exercise. If two or more of the statements in Section II are indicated as being true, the participant is also advised to consult a qualified doctor before engaging in exercise.[4]

Even though the pre-2015 ACSM pre-screening medical questionnaire is commonly recommended, it has rarely been evaluated in terms of its sensitivity.[21] The pre-2015 ACSM uses broad categories of CV risk and lacks specificity regarding symptoms,[21] which may result in unnecessary visits to doctors in order to obtain approval for participation in physical activity.[21]

In a study done on a sample of US adults aged 40 years and older, for which the pre-2015 ACSM pre-screening medical questionnaire was applied, it was found that more than 90% of the adults aged 40 years and older were advised to consult a doctor prior to initiating a physical activity programme.[21] This high referral rate may be due to the extent of the information covered by the questions included in the pre-2015 ACSM pre-screening medical questionnaire.[21] In order for a test to successfully measure what it is supposed to measure, it needs to be specific, which makes the effective use of the pre-2015 ACSM pre-screening medical questionnaire doubtful in the case of adults over the age of 40 years.[21] An example of the questionnaire can be seen in Figure 2.2.[21]

Assess your health status by marking all *true* statements

History
You have had:
___ a heart attack
___ heart surgery
___ cardiac catheterization
___ coronary angioplasty (PTCA)
___ pacemaker/implantable cardiac defibrillator/rhythm disturbance
___ heart valve disease
___ heart failure
___ heart transplantation
___ congenital heart disease

Symptoms
___ You experience chest discomfort with exertion
___ You experience unreasonable breathlessness
___ You experience dizziness, fainting, or blackouts
___ You experience ankle swelling
___ You experience unpleasant awareness of a forceful or rapid heart rate
___ You take heart medications

Other health issues
___ You have diabetes
___ You have asthma or other lung disease
___ You have burning or cramping sensation in your lower legs when walking short distance
___ You have musculoskeletal problems that limit your physical activity
___ You have concerns about the safety of exercise
___ You take prescription medications
___ You are pregnant

*If you marked any of these statements in this section, consult your physician or other appropriate health care provider before engaging in exercise. You may need to use a facility with a **medically qualified staff**.*

Cardiovascular risk factors
___ You are a man ≥45 yr
___ You are a woman ≥55 yr
___ You smoke or quit smoking within the previous 6 mo
___ Your blood pressure is ≥140/90 mm Hg
___ You do not know your blood pressure
___ You take blood pressure medication
___ Your blood cholesterol level is ≥200 mg · dL^{-1}
___ You do not know your cholesterol level
___ You have a close blood relative who had a heart attack or heart surgery before age 55 (father or brother) or age 65 (mother or sister)
___ You are physically inactive (*i.e.*, you get <30 min of physical activity on at least 3 d per week)
___ You have a body mass index ≥30 kg · m^{-2}
___ You have prediabetes
___ You do not know if you have prediabetes

*If you marked two or more of the statements in this section you should consult your physician or other appropriate health care as part of good medical care and progress gradually with your exercise program. You might benefit from using a facility with a **professionally qualified exercise staff**[a] to guide your exercise program.*

___ None of the above

You should be able to exercise safely without consulting your physician or other appropriate health care provider in a self-guide program or almost any facility that meets your exercise program needs.

[a]Professionally qualified exercise staff refers to appropriately trained individuals who possess academic training, practical and clinical knowledge, skills, and abilities commensurate with the credentials defined in *Appendix D*.

■ **FIGURE 2.2.** AHA/ACSM Health/Fitness Facility Preparticipation Screening Questionnaire. Individuals with multiple CVD risk factors (see *Table 2.2*) should be encouraged to consult with their physician prior to initiating a vigorous intensity exercise program as part of good medical care and should progress gradually with their exercise program of any exercise intensity. ACSM, American College of Sports Medicine; AHA, American Heart Association; CVD, cardiovascular disease, PTCA, percutaneous transluminal coronary angioplasty. Modified from (4).

Figure 2.2: The pre-2015 American College of Sports Medicine (ACSM) guidelines[21]

2.3.3. The post-2015 American College of Sports Medicine (ACSM) guidelines

In 2015, the revised ACSM guidelines were published, and these guidelines will be referred to as the post-2015 ACSM guidelines. The post-2015 ACSM guidelines focus on three main variables that are deemed to determine the risk of CV events related to exercise.[22] These variables are: (1) The individual's current physical activity level; (2) whether there are any signs or symptoms of known cardiovascular (i.e. peripheral artery, cardiac, or cerebrovascular disease), metabolic (i.e. Types 1 and II diabetes mellitus) or renal disease; and (3) the intensity at which the individual would like to exercise[22] (Figure 2.3).

These revised screening guidelines were implemented with the aim of minimising unnecessary visits to doctors in order to increase regular physical activity in all individuals, removing unnecessary barriers to do so.[22]

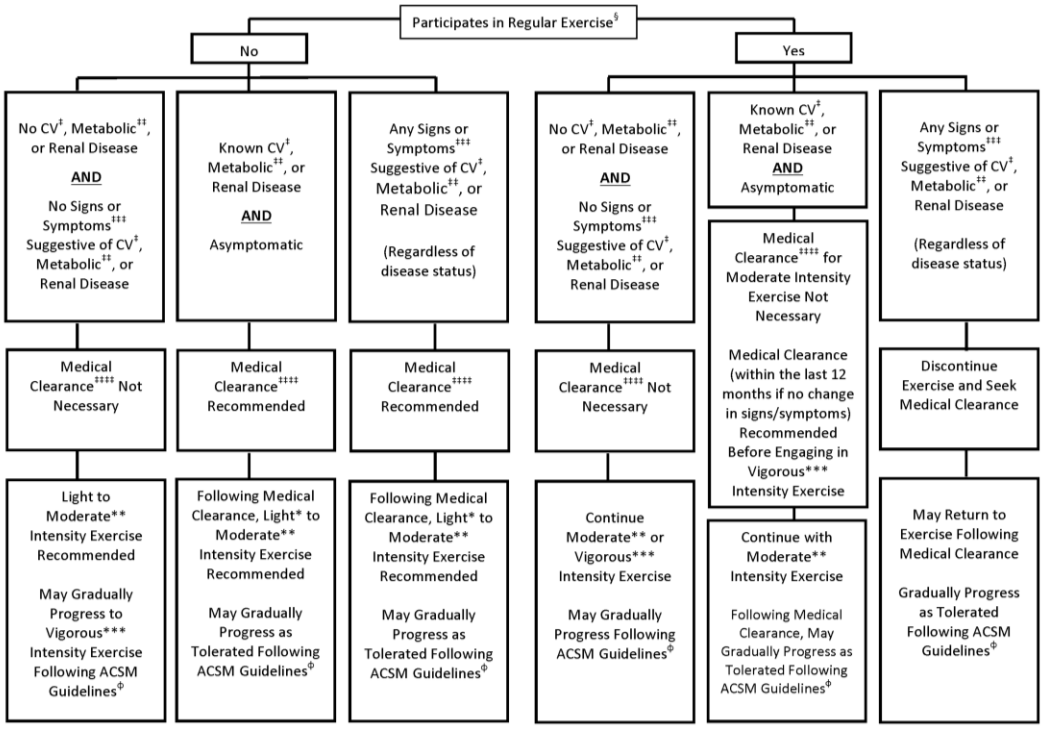


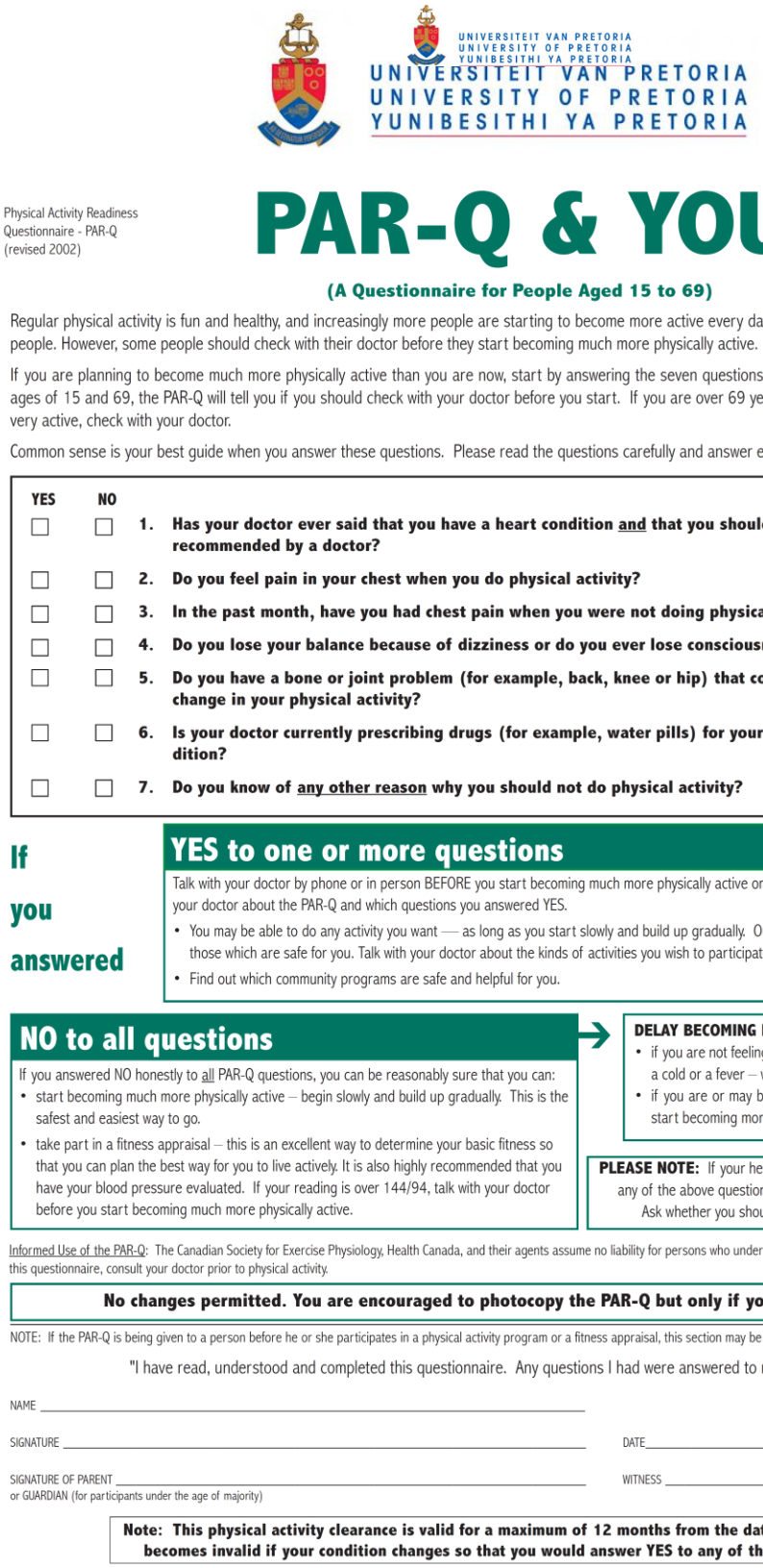
FIGURE 2—Exercise preparticipation health screening logic model for aerobic exercise participation.
§Exercise participation, performing planned, structured physical activity at least 30 min at moderate intensity on at least 3 d·wk^{-1} for at least the last 3 months.
***Light-intensity exercise, 30% to <40% HRR or $\dot{V}O_2R$, 2 to <3 METs, 9–11 RPE, an intensity that causes slight increases in HR and breathing.**
****Moderate-intensity exercise, 40% to <60% HRR or $\dot{V}O_2R$, 3 to <6 METs, 12–13 RPE, an intensity that causes noticeable increases in HR and breathing.**
*****Vigorous-intensity exercise ≥60% HRR or $\dot{V}O_2R$, ≥6 METs, ≥14 RPE, an intensity that causes substantial increases in HR and breathing.**
‡CVD, cardiac, peripheral vascular, or cerebrovascular disease.
‡‡Metabolic disease, type 1 and 2 diabetes mellitus.
‡‡‡Signs and symptoms, at rest or during activity; includes pain, discomfort in the chest, neck, jaw, arms, or other areas that may result from ischemia; shortness of breath at rest or with mild exertion; dizziness or syncope; orthopnea or paroxysmal nocturnal dyspnea; ankle edema; palpitations or tachycardia; intermittent claudication; known heart murmur; or unusual fatigue or shortness of breath with usual activities.
‡‡‡‡Medical clearance, approval from a health care professional to engage in exercise.
ΦACSM Guidelines, see *ACSM's Guidelines for Exercise Testing and Prescription, 9th edition*, 2014.

Figure 2.3: The post-2015 American College of Sports Medicine (ACSM) guidelines[22]

2.3.4. The 2002 Canadian Physical Activity Readiness Questionnaire (PAR-Q)

The PAR-Q, an example of which can be seen in Figure 2.4, is a medical screening tool completed by individuals who wish to undergo a fitness assessment or to become more physically active.[23] It consists of a seven-question battery designed to determine whether or not exercise participants would be able to engage in exercise or become more physically active (Figure 2.4).[24] Participants who answer positively to one or more questions in the PAR-Q are advised to consult a qualified medical doctor for pre-exercise medical clearance.[24] The PAR-Q includes questions enquiring, for example, whether the individual experiences chest pain, dizziness or joint problems, has a heart condition, currently uses medication, or feels that there may perhaps be a reason for refraining from exercise.[24]

Due to its conservative nature, the use of the PAR-Q can result in many 'false positive' results.[23] A 'false positive' answer, for instance, be given to Question 7, which asks whether the individual is aware of any reason for avoiding exercise, as the individual may give a positive answer due to, for example, having nothing more serious than a common cold.[23] Furthermore, the PAR-Q is only valid for individuals between the ages of 15 and 69 years, and it has been shown that at the age of 69 the health status of some individuals is much better than it was 25 years earlier.[23] If there is a positive response to any question on the PAR-Q, the individual is advised to obtain medical clearance to exercise. This could deter an individual who would have initially engaged in safe exercise from continuing to want to exercise.[23]



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Physical Activity Readiness Questionnaire - PAR-Q (revised 2002)

PAR-Q & YOU

(A Questionnaire for People Aged 15 to 69)

Regular physical activity is fun and healthy, and increasingly more people are starting to become more active every day. Being more active is very safe for most people. However, some people should check with their doctor before they start becoming much more physically active.

If you are planning to become much more physically active than you are now, start by answering the seven questions in the box below. If you are between the ages of 15 and 69, the PAR-Q will tell you if you should check with your doctor before you start. If you are over 69 years of age, and you are not used to being very active, check with your doctor.

Common sense is your best guide when you answer these questions. Please read the questions carefully and answer each one honestly: check YES or NO.

YES	NO	
☐	☐	**1. Has your doctor ever said that you have a heart condition and that you should only do physical activity recommended by a doctor?**
☐	☐	**2. Do you feel pain in your chest when you do physical activity?**
☐	☐	**3. In the past month, have you had chest pain when you were not doing physical activity?**
☐	☐	**4. Do you lose your balance because of dizziness or do you ever lose consciousness?**
☐	☐	**5. Do you have a bone or joint problem (for example, back, knee or hip) that could be made worse by a change in your physical activity?**
☐	☐	**6. Is your doctor currently prescribing drugs (for example, water pills) for your blood pressure or heart condition?**
☐	☐	**7. Do you know of any other reason why you should not do physical activity?**

If you answered

YES to one or more questions

Talk with your doctor by phone or in person BEFORE you start becoming much more physically active or BEFORE you have a fitness appraisal. Tell your doctor about the PAR-Q and which questions you answered YES.

- You may be able to do any activity you want — as long as you start slowly and build up gradually. Or, you may need to restrict your activities to those which are safe for you. Talk with your doctor about the kinds of activities you wish to participate in and follow his/her advice.
- Find out which community programs are safe and helpful for you.

NO to all questions

If you answered NO honestly to all PAR-Q questions, you can be reasonably sure that you can:

- start becoming much more physically active – begin slowly and build up gradually. This is the safest and easiest way to go.
- take part in a fitness appraisal – this is an excellent way to determine your basic fitness so that you can plan the best way for you to live actively. It is also highly recommended that you have your blood pressure evaluated. If your reading is over 144/94, talk with your doctor before you start becoming much more physically active.

DELAY BECOMING MUCH MORE ACTIVE:

- if you are not feeling well because of a temporary illness such as a cold or a fever – wait until you feel better; or
- if you are or may be pregnant – talk to your doctor before you start becoming more active.

PLEASE NOTE: If your health changes so that you then answer YES to any of the above questions, tell your fitness or health professional. Ask whether you should change your physical activity plan.

Informed Use of the PAR-Q: The Canadian Society for Exercise Physiology, Health Canada, and their agents assume no liability for persons who undertake physical activity, and if in doubt after completing this questionnaire, consult your doctor prior to physical activity.

No changes permitted. You are encouraged to photocopy the PAR-Q but only if you use the entire form.

NOTE: If the PAR-Q is being given to a person before he or she participates in a physical activity program or a fitness appraisal, this section may be used for legal or administrative purposes.

"I have read, understood and completed this questionnaire. Any questions I had were answered to my full satisfaction."

NAME _____

SIGNATURE _____ DATE _____

SIGNATURE OF PARENT or GUARDIAN (for participants under the age of majority) _____ WITNESS _____

Note: This physical activity clearance is valid for a maximum of 12 months from the date it is completed and becomes invalid if your condition changes so that you would answer YES to any of the seven questions.

Figure 2.4: The 2002 Canadian Physical Activity Readiness Questionnaire (PAR-Q)[24]

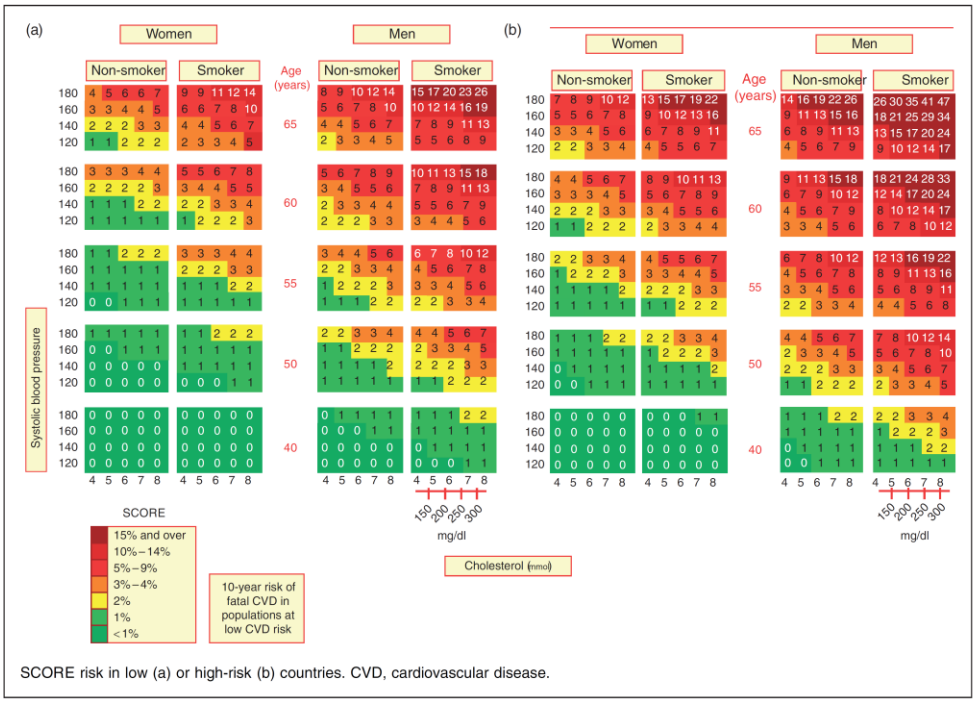
2.3.5. The 2011 European Association of Cardiovascular Prevention and Rehabilitation (EACPR) guidelines

The EACPR pre-exercise medical screening tool involves the use of an initial self-assessment of risk (done by a non-physician health professional or the participant) that makes use of a questionnaire such as the pre-2015 ACSM (discussed in section 2.4.2) or the PAR-Q (discussed in section 2.4.5).[25] The benefit of the self-assessment of risk is that it eliminates unnecessary obstacles towards an increased physical activity level in participants and can be easily used for large groups of participants.[25]

A more in-depth assessment is subsequently performed by a qualified physician. This assessment involves using the European Society of Cardiology (ESC) Systematic Coronary Risk Evaluation (SCORE) system (Figure 2.5),[25] which assesses CV risk in participants. Further consideration is then given to the following risk factors in order to identify an individual as a high-risk or low-risk profile participant.[25]

1. The presence of multiple risk factors for CVD, resulting in a 10-year risk of more than 5% now or if concluded to 60 years age in the SCORE chart
2. Raised total cholesterol (>8mmol/l); low-density lipoprotein-cholesterol (>6mmol/l), or blood pressure of >180/110 mmHg
3. Diabetes mellitus
4. A strong family history of premature CVD/CAD in first-degree relatives <50 years of age and a body mass index (BMI) of >28.

According to the SCORE system, a low-risk profile individual is a participant with a less than 5% 10-year risk, without the presence of a positive family history of CAD, diabetes mellitus, or a BMI of <28.[25]



SCORE risk in low (a) or high-risk (b) countries. CVD, cardiovascular disease.

Figure 1. SCORE risk in low (panel a) or high-risk (panel b) countries. CVD, cardiovascular disease.

Figure 2.5: The European Society of Cardiology (ESC) Systematic Risk Evaluation (SCORE) system[25]

2.3.6. Summary of the variables from the each of the five pre-screening tools used to identify participants who require medical clearance

Table 2.1 contains a summary of all the variables from the each of the five pre-screening tools used to identify participants requiring medical clearance.

Table 2.1: The variables from the five pre-screening tools that identify a participant as needing medical clearance

Variable	AHA		Pre-2015 ACSM		Post-2015 ACSM	PAR-Q	EACPR
	Automatic kickouts	**One risk factor plus age/ sex**	**When two or more are chosen, medical clearance is required**	**Automatic kickouts**	**Automatic kickouts**	**Automatic kickouts**	**Combination of pre-ACSM and PAR-Q**
Medical information: **Are you aware of, or have you ever been diagnosed with any risk factors for heart or blood vessel disease, including high blood cholesterol, a family member with heart disease, cigarette smoking, lack of physical activity, high blood pressure, being overweight or having diabetes mellitus?** **If yes, go to the next page.**							
High blood pressure	X	X	X				
High blood cholesterol		X	X				
Cigarette smoking		X	X				
Obesity (overweight)			X				
Diabetes mellitus		X		X	X		
Family history of heart disease (<50 years)	X		X				
History of heart disease in close family members (father,	X		X				

mother, brothers or sisters before the age of 50 years)							
Male > 45yrs		X	X				
Female > 55yrs		X	X				
Have you ever suffered from any heart or blood vessel conditions, including heart attack, undiagnosed chest pain, coronary artery bypass operation, angioplasty (balloon), heart failure, heart transplant, cardiac arrhythmia (abnormal heartbeat), rheumatic fever, heart murmur, cardiomyopathy, myocarditis, use of a pacemaker or inherited heart defect? **If yes, go to the next page.**				**X**	X	**X**	
Myocardial infarct (heart attack)				X	X	X	
Chest pain that has been diagnosed as "angina"	X			X	X	X	
Coronary artery bypass graft (CABG)				X	X	X	
Angioplasty (no stent)				X	X	X	
Angioplasty (with stent)				X	X	X	
Heart failure				X	X	X	
Heart transplant				X	X	X	
Arrhythmia				X	X	X	
Rheumatic fever					X	X	
Heart murmur	X				X	X	
Cardiomyopathy				X	X	X	
Myocarditis				X	X	X	

Use of a pacemaker				X	X	X	
Inherited conditions of the heart or blood vessels				X	X	X	
Any other form of heart or blood vessel disease (please specify)					X	X	
Do you currently suffer from any symptoms of heart or blood vessel disease, including swollen ankles, abnormal shortness of breath (with exercise), chronic dry cough, palpitations, chest pain, pain (or discomfort) in the neck, jaw, or arms at rest or during exercise, dizziness, fainting spells, and/or calf pain when running/walking?		AGED >40 YEARS X			X		
Swollen ankles		X		X	X		
Water retention		X		X	X		
Shortness of breath when sitting or lying down		X		X	X		
Shortness of breath with mild exercise	X	X		X	X		
Waking up with shortness of breath at night		X		X	X		
Palpitations with no dizziness		X		X	X		
Palpitations causing dizziness		X		X	X	X	
Chest pain when seated		X		X	X	X	

Chest pain when performing exercise	X	X		X	X	X	
Chest pain when you are emotionally stressed	X	X		X	X	X	
Pain (or discomfort) in the neck, jaw, arms at rest or during exercise		X			X		
Dizziness during exercise		X		X	X	X	
Fainting spells	X	X		X	X	X	
Chronic dry cough		X			X		
Painful calves when walking		X		X	X		
Have you ever collapsed (fallen down—not because of an accident—after which you needed medical attention) during, at the finish line or after a race or training session? **If yes, go to the next page**				X		X	
Have you ever collapsed during training or racing?				X X			
Do you currently suffer from any metabolic or hormonal disease, including diabetes mellitus, thyroid gland disorders, hypoglycaemia (low blood sugar),					X		

hyperglycaemia (high blood sugar), or heat intolerance? **If yes, go to the next page.**							
Hyperglycaemia (high blood sugar) (Pre-diabetes)			X		X		
Type 1: Insulin dependent (Diabetes Mellitus)		Age/ sex and X		X	X		
Type 2: Non insulin dependent (diabetes mellitus)		Age/ sex and X		X	X		
Underactive thyroid (hypothyroidism)					X		
Overactive thyroid (hyperthyroidism)					X		
Hypoglycaemia (low blood sugar)					X		
Heat intolerance					X		
Do you suffer from any respiratory (lung) disease, including asthma, emphysema (COPD), wheezing, cough, postnasal drip, hay fever, or repeated flu-like illness? **If yes, go to the next page.**				X			
Asthma (non-exercise-induced)				X			
Asthma (exercise-induced)				X			
Repeated infections in respiratory tract							
COPD (chronic obstructive pulmonary disease)				X			
Interstitial lung disease				X			
Cystic fibrosis				X			
Do you suffer from any kidney or bladder					X		

disease, or have a history of kidney or bladder disease, blood in the urine, loin pain, kidney stones, frequent urination, or burning during urination?							
Past history of kidney disease					X		
Past history of bladder disease					X		
History of blood in the urine					X		
Chronic loin pain					X		
History of kidney stones					X		
Frequent urination					X		
Burning sensation during urination					X		
Are you currently using any prescribed medication on a daily, weekly or monthly basis to treat chronic (long-term) medical conditions or injuries? **If yes, select at least one of the following:**				X			
Cholesterol-lowering medication		Age/ sex and X		X		X	
Medication to reduce blood pressure	X	Age/ sex and X		X		X	
Anti-allergy medication				X			
Medication to control heart rhythm				X	X	X	
Medication to treat heart failure				X	X	X	

Other medication to treat heart disease				X	X	X	
Medication (tablets) to treat Type II diabetes		Age/sex and X		X	X		
Insulin for diabetes		Age/sex and X		X	X		
Medication to treat anxiety				X			
Anti-depressants				X			
Anti-asthma medication				X			
Do you, or have you ever suffered from any symptoms of an injury sustained during your RUNNING career (muscles, tendons, bones, ligaments or joints)? **(NB: Answer 'Yes' only if an injury was so severe that it interfered with running, or required treatment, e.g. the use of medication, or required you to seek medical advice from a health professional)** **If you answered 'Yes', select at least one of the following:**				X		X	
Do you or did you, CURRENTLY OR IN THE PAST 12 MONTHS, suffer from any symptoms caused by a running injury				X		X	

(muscles, tendons, bones, ligaments or joints)? (NB: Only if an injury was severe enough to interfere with running, or required treatment, e.g. the use medication, or required you to seek medical advice from a health professional.)							

2.4. THE SENSITIVITY AND SPECIFICITY OF PRE-EXERCISE MEDICAL SCREENING TOOLS

Although the efficacy of pre-exercise medical screening has been researched with limited data, no comparative study of these five pre-screening medical questionnaires has been undertaken to date.

The consensus on evidence-based risk stratification and pre-exercise medical screening is that questionnaires, such as the PAR-Q and the pre-2015 ACSM, are highly effective in screening participants prior to engaging in physical activity.[26] However, it has been reported that the use of these screening tools may result in barriers to participation in physical activity, especially in the case of those individuals who are likely to benefit most from it, for example the elderly population with chronic medical conditions.[26] It has therefore been concluded that qualified health and exercise professionals should make use of new pre-exercise risk stratification and pre-exercise medical screening to reduce barriers and increase participation in exercise.[26]

A systematic review/meta-analysis of the sensitivity of screening history, ECG and physical examination to detect lethal cardiac disorders in athletes found that there was no general agreement regarding the ideal CV pre-exercise medical screening method.[27] For the purpose of this study, electronic databases containing information on the abovementioned screening methods and covering the period 1996 to 2014 (November) were searched.[27] and it was concluded that an ECG is the strategy that is most effective for screening for CVD in athletes.[27] It was also found that an ECG was ten times more sensitive than a physical examination and five times more sensitive than medical history, and that the use of only an athlete's medical history and a physical examination should be re-evaluated.[27] A study done on master athletes in which an ECG, the AHA questionnaire and the Framingham Risk Score (FRS) were compared found that a more comprehensive risk assessment might be needed, and that an ECG

may be indicated in master athletes with elevated cardiac risk.[16] In another study that focused on the CV evaluation for participants to prevent sudden death, the pros and cons of ECG inclusion in addition to a physical examination and medical history was outlined (Figure 2.6)[16].

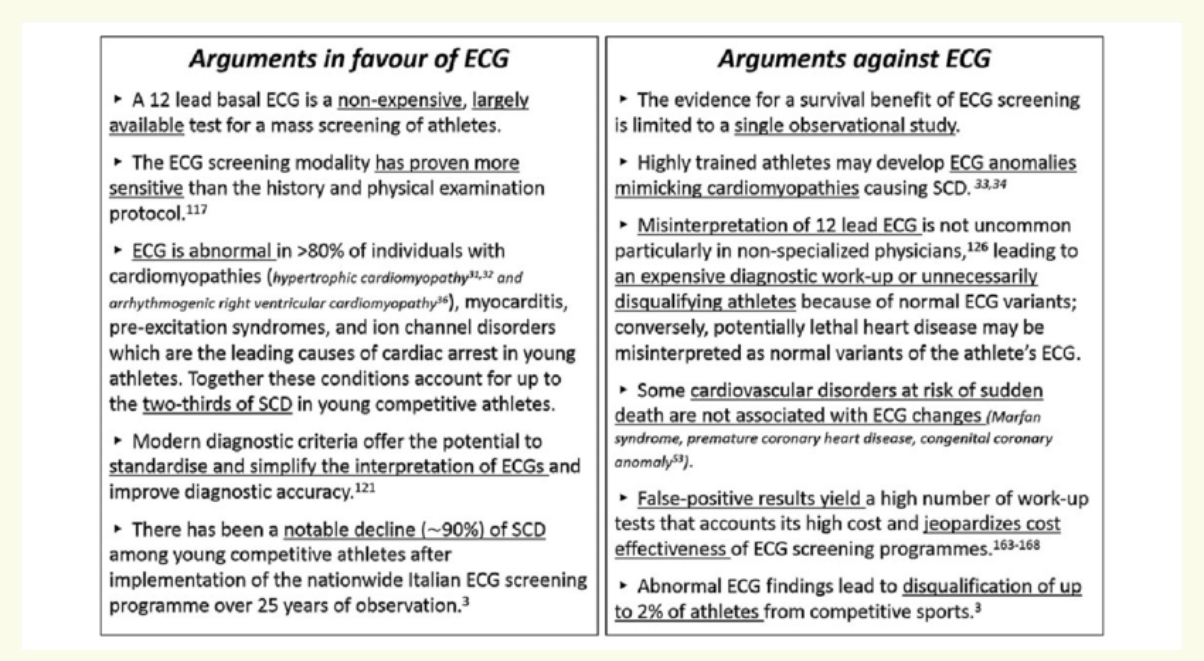


Figure 2.6: The pros and cons of ECG inclusion in addition to a physical examination and medical history[16]

2.5. SUMMARY AND CONCLUSION

Exercise has numerous health benefits. However, participation in prolonged endurance exercise of moderate to high intensity is associated with a higher risk of serious life-threatening medical encounters, including sudden cardiac arrest (SCA) and sudden death (SD).[1] It is therefore important to identify athletes who are at higher risk for medical complications before they participate in endurance sports events so as to reduce the likelihood of medical encounters (MEs) during the event or race. The availability of medical care facilities on the race day, and testing and establishing the effectiveness of prevention programmes, will ultimately protect the health of the athletes.[15]

In order to reduce the risk of acute medical encounters during distance running, it is important to develop an effective pre-exercise medical screening and evaluation procedure. The sensitivity and specificity of pre-exercise medical screening tools used with the aim of reducing acute medical encounters in endurance athletes participating in events, such as the Two Oceans Marathon, has not been well studied.[1] Therefore, it is important to compare the outcome of five

pre-race medical screening tools used to identify athletes who are potentially at risk for adverse events during mass community-based participation events. This could reduce the medical encounters that occur during these mass community-based participation endurance sports events and ultimately enhance overall race safety. Furthermore, identifying the most sensitive pre-screening medical tool for the identification of high-risk athletes (as opposed to low-risk athletes) may reduce the number of unnecessary visits to doctors to obtain clearance for participation in physical activity.

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CHAPTER 3: PAPER 1 - FIVE INTERNATIONAL PRE-EXERCISE MEDICAL SCREENING TOOLS VARY GREATLY WITH REGARD TO THEIR IDENTIFICATION OF RUNNING RACE ENTRANTS WHO REQUIRE MEDICAL CLEARANCE: SAFER STUDY XXVI

ABSTRACT

Background: The purpose of pre-exercise medical screening is to identify individuals who may be at risk of medical encounters (MEs) during exercise. Currently the use of five international pre-exercise medical screening tools is recommended to identify individuals who require pre-exercise medical clearance.

Aim: To determine the percentage of race entrants who are advised to obtain pre-exercise medical clearance by using five international pre-exercise medical screening tools, and to determine the level of agreement between those tools.

Methods: Data from running race entrants (Two Oceans Marathon) was collected over a period of four years (2012–2015). Five pre-exercise medical screening tools (the American Heart Association (AHA), the pre-2015 American College of Sport Medicine (ACSM), the post-2015 ACSM Physical Activity Readiness Questionnaire (PAR-Q), and the European Association of Cardiovascular Prevention and Rehabilitation (EACPR)) were applied by using information from pre-race medical screening questionnaires. The percentage (95%CI) of race entrants requiring medical clearance identified by each tool and the level of agreement between tools (kappa statistic) is reported.

Results: The percentage entrants requiring medical clearance for each tool was: 2011 EACPR (33.9%; 33.5-34.3); pre-2015 ACSM (33.9%; 33.5-34.3); PAR-Q (23.2%; 22.9-23.6); AHA (10.0%; 9.7-10.2); post-2015 ACSM (6.7%; 6.5-6.9). The level of agreement was high between the pre-2015 ACSM and the EACPR (K=1.00; p=0.05), moderate between the pre-2015 ACSM and the PAR-Q (K=0.75; p<0.0001) and the PAR-Q and EACPR (K=0.75; p<0.0001), but poor between the post-2015 ACSM and the PAR-Q (K=0.17; p<0.0001).

Conclusion: The percentage of race entrants identified as requiring medical clearance varied considerably (6.7–33.9%) between international pre-exercise medical screening tools. The level of agreement between the tools also varied and was good (≥ 0.75) for three of the five pre-exercise medical screening tools. Further research should determine which specific variables are responsible for identifying participants at higher risk for medical encounters during exercise.

Key words: Pre-exercise medical screening tools, pre-exercise medical clearance, recreational endurance athletes, medical encounters

INTRODUCTION

Even though the numerous health benefits to be gained through regular participation in exercise are undisputed, there is an increased risk of medical complications, such as acute myocardial infarction (AMI) or sudden cardiac death (SCD)[1, 2] during exercise. It has been reported that the absolute risk of sudden death (SD) in athletes participating in distance running races ranges between 1 in 50 000 to 1 in 200 000 race entrants.[2] Prolonged endurance exercise, such as long-distance running, is also associated with other serious life-threatening and moderate medical complications, including exertional heatstroke, serum electrolyte disturbances and acute kidney injury, which can affect various organ systems.[3] In order to decrease the likelihood of medical encounters (MEs) during the event or race, it is therefore important to identify athletes who are at a higher risk for medical complications before they participate in endurance sports events.

The various pre-exercise medical screening tools proposed by international professional medical bodies for the identification of individuals who may be at higher risk for medical complications during exercise include the following: 1) the 2011 American Heart Association (AHA) guidelines[4, 5]; 2) the pre-2015 American College of Sports Medicine (ACSM) guidelines[6]; 3) the post-2015 ACSM guidelines[7]; 4) the 2002 Physical Activity Readiness Questionnaire (PAR-Q)[8]; and 5) the 2011 European Association of Cardiovascular Prevention and Rehabilitation (EACPR) guidelines.[9, 10] Each of these five pre-exercise medical screening tools uses different combinations of questions and algorithms. The 2011 AHA screening guideline includes a 14-point history and physical examination to determine whether an individual has existing cardiovascular disease (CVD) or risk factors for CVD.[4, 5] The pre-2015 ACSM guideline includes the participant's health history and identified CVD risk factors.[6] The post-2015 ACSM guidelines removed certain sections and focused on (1) the individual's current physical activity level; (2) whether there are any signs or symptoms of known metabolic, cardiovascular, or renal disease; and (3) the intensity at which the individual would like to exercise.[7] The PAR-Q consists of seven questions asked to determine whether exercise participants would be able to engage in exercise or become more physically active. If any

positives are recorded, medical clearance is required.[8] The 2011 EACPR guideline, which is one of the most comprehensive pre-exercise medical screening tools, requires health-related information, for example information about CVD symptoms, CVD, medication usage and CVD risk factors.[9, 10] The EACPR is largely a combination of the pre-2015 ACSM and PAR-Q.[9]

To date no studies have been undertaken to determine whether they identify the same individuals as being at higher risk of medical complications during exercise. From a practical point of view, it is therefore not clear which guideline should be used as a pre-exercise screening tool to identify individuals at risk for medical complications during exercise as the results produced by the different screening tools have not yet been compared.

Therefore, the primary aim of this study is to determine and compare the frequency of race entrants who are advised to obtain pre-exercise medical clearance by applying five international pre-exercise medical screening tools to the same population of distance running race entrants. A secondary aim of the study is to determine the level of agreement between the five tools used to identify race entrants who are advised to undergo pre-exercise medical clearance before participating in exercise (high-risk individuals).

METHODS

Study design and ethical considerations

This descriptive cross-sectional study of data collected from recreational endurance runners who participated in the Two Oceans Marathon over a period of four years (2012–2015) forms part of a larger research programme known as the SAFER (**S**trategies to reduce **A**dverse medical events **F**or the **E**xercise**R**) studies[11] and was approved by the Research Ethics Committees of the Faculty of Health Sciences at the University of Cape Town (REC number 413/2015) and the Faculty of Health Sciences at the University of Pretoria (REC number 683/2019**)**.

Participants (selection and description)

The Two Oceans Marathon takes place annually in Cape Town (South Africa) and is Africa's largest distance running event. This mass community-based endurance running event consists of various race distances and attracts approximately 25 000 runners each year.[10]

Study participants

The completion of an online pre-exercise medical screening questionnaire was a mandatory component of the entry process to the races held from 2012 to 2015. Over the four years, 106 743 race entrants completed a pre-exercise medical screening questionnaire, and a total of 76 654 (71.8%) entrants consented to the use of their data for this study.

Data collection

Data collected from recreational endurance athletes who participated in successive Two Oceans Marathons from 2012 to 2015 was used for this study. It is a pre-entry only event, and since 2012 it has been compulsory, upon entry, for each entrant to complete a pre-exercise medical screening questionnaire.[12] This questionnaire was developed for the SAFER studies and was based on domains included in several international pre-exercise medical screening tools, including the EACPR, the pre-2015 ACSM and the PAR-Q guidelines.[2]

The following domains of pre-exercise medical screening information were included in the questionnaire: history of CVD; symptoms of CVD; risk factors for CVD; history of other chronic diseases (hormonal and metabolic disease, respiratory disease, nervous system disease, gastrointestinal disease, bladder or renal disease, immune system or haematological disease, allergies and cancer); history of prescription medication use; and history of musculoskeletal injury.[2] By using the information collected by using this questionnaire, the five most commonly used pre-exercise medical screening tools (AHA[4, 5], pre-2015 ACSM[6], post-2015 ACSM[7], PAR-Q[8] and EACPR[9, 10]) were applied to determine which entrants would require medical clearance prior to exercise for each pre-exercise medical screening tool.

Outcomes

Based on the answers provided to the questions in the pre-exercise screening questionnaires, an algorithm was developed for each of the five pre-exercise screening tools used to determine which individuals needed to obtain medical clearance. The primary measure of outcome was the number of race entrants for whom pre-exercise medical clearance was recommended by each of the five international pre-exercise medical screening tools (AHA[4, 5], pre-2015 ACSM[6], post-2015 ACSM[7], PAR-Q[8] and EACPR[9, 10]). A secondary measure was the level of agreement between the results obtained by using the different tools.

Statistical analysis

The race entrant demographic and pre-exercise medical screening data on 76 654 race entrants was entered on an Excel spreadsheet (Microsoft 2010) and analysed using the SAS Enterprise Guide (V7.1) statistical programme. The demographic data was described using frequency analysis. Using the responses to all the questions relating to demographic (age and sex) and medical history, an algorithm was created for each of the five pre-exercise medical screening tools used to determine the need for medical clearance. This is the binary-scaled response variable (whether requiring medical screening or not) for each of the five pre-exercise medical screening tools. Using a Poisson regression model, the prevalence (%) of entrants identified by each tool as needing medical clearance was calculated (with 95% Cl). The statistical significance level is 5%, unless specified otherwise. Using the Kappa statistic, the level of agreement was then calculated for each screening tool in order to be able to compare the results. The following level of agreement classification scale was used to interpret the Kappa statistic: K-values of <0.20 indicated a poor level of agreement; 0.21–0.40 a fair level of agreement; 0.41–0.60 a moderate level of agreement; 0.61-0.80 a good level of agreement; and 0.81–1.00 a very good level of agreement.[13, 14]

RESULTS

Demographics of study participants

A total of 76 654 race entrants from whom data was obtained during the four years (2012–2015) consented to their data being used and analysed for research purposes. The characteristics of all the race entrants and the participants in this study (consenting running race entrants) are shown in Table 3.1.

Table 3.1: Characteristics of all the race entrants and of those who agreed to their data being used for this study

		All race entrants (n=106743)		Study participants: consenting race entrants (n=76654)		
		n	%	n	%	p
Race distance	21.1 km	64 740	60.7	47 069	61.4	0.0011*
	56 km	42 003	39.4	29 585	38.6	
Sex	Males	61 815	57.9	44 042	57.5	0.0520
	Females	44 928	42.1	32 612	42.5	
Age categories	≤ 30 years	27 710	26.0	20 168	26.3	0.3643

	31–40 years	35 049	32.8	25 045	32.7	
	41–50 years	26 964	25.3	19 340	25.2	
	≥ 50 years	17 020	15.9	12 101	15.8	

p: p-value – all running race entrants vs consenting entrants as study participants

*Study participants significantly different from 'All race entrants' (p≤ 0.05)

A comparison between all the race entrants and consenting race entrants showed no significant difference with regard to the sex (p=0.0520) and age (p=0.3643) categories. There was, however, a significant difference in the race distance category (p=0.0011), with more consenting race participants in the 21.1 km race and fewer in the 56 km race.

Percentage (%) race entrants who were identified as needing medical clearance by the five different pre-exercise screening tools

The total number and percentage (%; 95% CI) of consenting race entrants identified as needing medical clearance by the five pre-exercise medical screening tools are depicted in Table 3.2.

Table 3.2: Race entrants needing medical clearance, as identified by the five pre-exercise medical screening tools: Number (n) and percentage of all race entrants (%; 95% CI) (n=76 654)

Pre-exercise medical screening tool	n	% of all race entrants (95% CIs)
AHA	8402	10.0 (9.7-10.2)
Pre-2015 ACSM	27111	33.9 (33.5-34.3)
Post-2015 ACSM	5366	6.7 (6.5-6.9)
PAR-Q	18983	23.2 (22.9-23.6)
EACPR	27115	33.9 (33.5-34.3)

AHA: American Heart Association
Pre-2015 ACSM: Pre-2015 American College of Sports Medicine
Post-2015 ACSM: Post-2015 American College of Sports Medicine
PAR-Q: Physical Activity Readiness Questionnaire
EACPR: European Association of Cardiovascular Prevention and Rehabilitation

The pre-exercise medical screening tools identified the following percentages of entrants requiring medical clearance: 2011 EACPR pre-exercise medical screening tool – 27 115 entrants (33.9%; 33.5–34.3); Pre-2015 ACSM – 27 111 entrants (33.9%; 33.5–34.3); PAR-Q – 18 983 entrants (23.2%; 22.9-23.6); AHA pre-exercise medical screening tool – 8 402 entrants (10.0%; 9.7–10.2); and Post-2015 ACSM –5 366 entrants (6.7%; 6.5–6.9).

Level of agreement between the result obtained by using five pre-exercise medical screening tools

The level of agreement (Kappa statistic; 95% Cl) between the pre-exercise medical screening tools is presented in Table 3.3.

Table 3.3: The level of agreement between the results of the pre-exercise medical screening tools used to identify entrants requiring medical clearance (Kappa statistic, 95% CI)

	Kappa statistic									
Pre-exercise medical screening tool	AHA		Pre-2015 ACSM		Post-2015 ACSM		PAR-Q		EACPR	
	Kappa (95% Cl)	p-value	Kappa (95% Cl)	p-value	Kappa (95% Cl)	p-value	Kappa (95% Cl)	p-value	Kappa (95% Cl)	p-value
AHA			0.29 (0.28 – 0.29)	<0.0001	0.29 (0.25-0.30)	<0.0001	0.30 (0.30-0.31)	<0.0001	0.29 (0.28-0.29)	<0.0001
Pre-2015 ACSM					0.20 (0.19-0.20)	<0.0001	0.75 (0.75-0.76)	<0.0001	1.00 (1.00-1.00)	0.05
Post-2015 ACSM							0.17 (0.16-0.18)	<0.0001	0.20 (0.20-0.20)	<0.0001
PAR-Q									0.75 (0.75-0.76)	<0.0001
EACPR										

AHA: American Heart Association
Pre-2015 ACSM: Pre-2015 American College of Sports Medicine
Post-2015 ACSM: Post-2015 American College of Sports Medicine
PAR-Q: Physical Activity Readiness Questionnaire
EACPR: European Association of Cardiovascular Prevention and Rehabilitation

The level of agreement between the screening tools was as follows: There was a very high level of agreement between the pre-2015 ACSM and EACPR pre-exercise medical screening tools (K=1.00; p=0.05); a high level of agreement between the pre-2015 ACSM and PAR-Q pre-exercise medical screening tools (K=0.75; p<0.0001) and the PAR-Q and EACPR pre-exercise medical screening tools (K=0.75; p<0.0001); and a low level of agreement between the post-2015 ACSM and PAR-Q pre-exercise medical screening tools (K=0.17; p<0.0001).

DISCUSSION

The use of pre-exercise medical screening tools is important as a way to identify individuals who are at high risk for medical complications before they start participating in engage in moderate- to high-intensity exercise. Several pre-exercise medical screening tools (AHA[4, 5], pre-2015 ACSM[6], post-2015 ACSM[7], PAR-Q[8] and EACPR[9, 10]) have been developed for this purpose. To our knowledge, no studies have yet been conducted to establish whether these pre-

exercise medical screening tools identify the same individuals, which makes it difficult to select the most appropriate pre-exercise medical screening tool. Therefore, the primary aim of this study was to test five international pre-exercise medical screening tools in order to determine what percentage of race entrants are advised by each to obtain pre-exercise medical clearance. A secondary aim was to determine the level of agreement between the different screening tools regarding their recommendation that individuals who were screened should undergo pre-exercise medical clearance before participating in exercise. The main finding of this study was that when five international pre-exercise medical screening tools were applied to a large group of running race entrants, there was a significant variation in the percentage of race entrants who were identified by the different screening tools as needing to obtain pre-exercise medical clearance (ranging from 6.7% to 33.9% of all race entrants). The level of agreement between the results obtained by using these pre-exercise medical screening tools was also very varied and ranged from poor (K=0.17) to good (K=1.00.)

Percentage of entrants identified by each of the five pre-exercise medical screening tools as needing to obtain medical clearance prior to participation

Our main finding after using the five screening tools was that there was a considerable difference between the percentage of individuals (6.7% to 33.9%) who were advised to obtain medical clearance. Since we are not aware of any studies that reported on the percentage of participants in a distance running event who were advised to obtain clearance based on the use of international pre-exercise screening guidelines, it was not possible to compare our findings with those of other similar studies. One study undertaken in the United States (2001–2004 National Health and Nutrition Examination Survey (NHANES)), involved adults of ≥40 years who wished to participate in exercise. The pre-2015 ACSM was used as a pre-exercise medical screening tool and it was found that 95.5% of the women and 93.5% of the men would require medical screening prior to participation in exercise.[15] However, since this study involved an older, sedentary population, the results cannot be compared to our population of running race entrants.

In our study we found that the pre-2015 ACSM and EACPR pre-exercise medical screening tools identified the highest percentage of participants (33.9%) as needing medical clearance, while the post- 2015 ACSM identified only 6.7%. This outcome was expected as 1) the questions asked in the EACPR and pre-2015 ACSM tools are the most extensive, and 2) the EACPR includes the questions from both the pre-2015 ACSM and the PAR-Q pre-exercise

medical screening tools. The PAR-Q identified the second most participants (23.2%) as needing medical clearance. The PAR-Q pre-exercise medical screening questionnaire contains only seven broad and non-specific questions, for example whether the participant has ever been informed by a doctor that he or she has a heart condition or high blood pressure. No explanation is given of what is considered to be a heart condition. The PAR-Q also does not consider older individuals, which could lead to fewer participants being identified as needing medical clearance than when they are included in an athletic population. In a randomised controlled trial involving individuals over the age of 18 years who were randomly selected from the Australian Commission's electoral roll[16] and who engaged in moderate to vigorous exercise five or more days per week (thus a broad range of recreational athletes), the PAR-Q pre-exercise medical screening tool indicated that 20.2% of the participants required medical clearance.[16] The AHA pre-exercise medical screening tool identified the second least participants (10%) as needing medical clearance. The AHA does not include a question about the participant's age, which could possibly lead to fewer participants being identified as needing medical clearance. Furthermore, the AHA pre-exercise medical screening tool asks only cardiac-related questions and no questions about, for example, metabolic diseases, musculoskeletal conditions and any other chronic medical conditions. A study that was done in 2019 on a group of young athletes compared the use of the AHA pre-exercise medical screening tool to the use of ECGs to test athletes for cardiac abnormalities[17] and found that, based on the responses to the AHA questionnaire, 22.5% of the athletes required medical clearance. When the AHA questionnaire was used in this study, the specificity (68.0%), sensitivity (18.8%) and positive predictive value (0.3%) was much lower than when an ECG was used to identify athletes at high risk for cardiac-related complications (specificity (97.5%), sensitivity (87.5%) and positive predictive value (13.6%)).[17] The researchers in this study concluded that the use of the AHA pre-exercise medical screening tool as the primary way of identifying athletes at risk for cardiac-related complications should be re-evaluated.[17] The post-2015 ACSM identified the lowest percentage of participants as needing medical clearance (6.7%). The reason for this could be the that the post-2015 ACSM guidelines exclude CVD risk factors for the following reasons: (1) Even though the absolute risk of AMI and SCD is higher during vigorous exercise than at rest, the absolute risk of AMI and SCD is very low. (2) Physically inactive individuals are at a greater risk for CV events than those who are physically active. (3) It has been found that conventional CVD risk factor assessment prior to exercise may be overly conservative due to the high incidence of CVD risk factors among participants.

(4) There is no need to risk-stratify individuals prior to engagement in exercise. (5) Since participants with pulmonary disease are not at an increased risk for fatal or non-fatal CV complications before, during or after exercise, they do not require pre-exercise medical clearance.[7] When a study that involved adults 40 years and older and used the 2001–2004 NHANES and the same data as previously discussed, was repeated and instead used the post-2015 ACSM pre-exercise medical screening tool, it was found that 54.2% of participants required medical clearance before any exercise and 2.6% required medical clearance before participating in vigorous exercise.[18]

The level of agreement between the pre-exercise medical screening tools

The level of agreement between the pre-exercise medical screening tools varied from poor (K=0.17) to very good (perfect) (K=1.00). The EACPR is a combination of the pre-2015 ACSM and PAR-Q pre-exercise medical screening tools, which explains the very high level of agreement between the EACPR and the pre-2015 ACSM, and the relatively high level of agreement between the EACPR and PAR-Q pre-exercise medical screening tools. The abovementioned study involving adults 40 years and older for which the same data and the 2001–2004 NHANES were used, compared the results of the pre-2015 ACSM pre-exercise medical screening tool to the PAR-Q pre-exercise medical screening tool[15] and found that they produced similar results for 72.4% of the participants.[15] Furthermore, a study done on participants requiring medical clearance prior to exercise found that, when compared to the EACPR and post-2015 ACSM pre-exercise medical screening tools, the pre-2015 ACSM showed a higher degree of sensitivity to diagnosing cardiovascular conditions.[19] There was a fair level of agreement between the PAR-Q and AHA (K=0.30), pre-2015 ACSM and AHA (K=0.29), post-2015 ACSM and AHA (K=0.29), and the EACPR and AHA (K=0.29) pre-exercise medical screening tools. The reason for the fair level of agreement between the pre-2015 ACSM, post-2015 ACSM, PAR-Q and EACPR pre-exercise medical screening tools and the AHA pre-exercise medical screening tool could be that the AHA includes questions about cardiac-related conditions only, and none about other chronic medical conditions. Therefore, only the cardiac-related questions asked in the pre-2015 ACSM, post-2015 ACSM, PAR-Q and EACPR pre-exercise medical screening tools correlated with the AHA pre-exercise medical screening tool. Agreement between the post-2015 ACSM and pre-2015 ACSM (K=0.20), the EACPR (K=0.20) and the PAR-Q (K=0.17) pre-exercise medical screening tools was low, with the lowest agreement being between the PAR-Q and the post-2015 ACSM. As previously mentioned, the post-2015 ACSM not only excluded age as a risk factor, but also

other CVD risk factors. The post-2015 ACSM includes the following as a flow diagram: (1) the individual's current physical activity level; (2) whether there are any signs or symptoms of known metabolic, cardiovascular, or renal disease; and (3) the intensity at which the individual would like to exercise. With regard to its nature and the scope of the questions asked, the post-2015 ACSM differs greatly from the other pre-exercise medical screening tools, hence the low level of agreement between them. The post-2015 ACSM is the only tool that requires information about the individual's current physical activity level and the level of intensity at which he/she would like to exercise. This could thus give rise to the addition of these sections to a new pre-exercise medical screening tool. A study done on university students prior to exercise prescription, using the pre-2015 ACSM and the post-2015 ACSM, found that, compared to the pre-2015 ACSM, the Post-2015 ACSM resulted in one-third (32%) fewer participants being referred for medical clearance prior to exercise participation.[20]

LIMITATIONS AND STRENGTHS OF THE STUDY, AND RECOMMENDATIONS REGARDING FUTURE RESEARCH

A strength of this study is that, to our knowledge, no previous studies have been undertaken to compare five international pre-exercise medical screening tools. Furthermore, the study had a large sample size and the response rate (71.8% of the total number of entrants) was good. A limitation of this study is that the questions asked were not the same as the original screening questions included in the five screening tools used for the Two Oceans Marathon pre-exercise medical screening (and some questions, including those relating to pregnancy, were omitted). Therefore, it is possible that the results could have been slightly different if the participants had completed each of the pre-exercise screening tools separately. Further research is required to determine which specific variables are responsible for the considerable variation in the percentages of entrants identified by the different pre-exercise screening tools as requiring medical clearance. The sensitivity and specificity of each of the pre-exercise medical screening tools also need to be investigated to assist with the selection of the most appropriate tool.

CONCLUSION

The results of this study show that there is a significant variation between the five international pre-exercise medical screening tools with regard to the identification of individuals who require medical clearance, therefore the level of agreement between them varied considerably. In our population of recreational distance running race entrants, the pre-2015 ACSM and EACPR pre-exercise medical screening tools identified the most participants as needing medical clearance

(33.9%); and the post-2015 ACSM identified the smallest number (6.7%). There was a high level of agreement between the pre-2015 ACSM and EACPR pre-exercise medical screening tools (K=1.00; p=0.05). The post-2015 ACSM and PAR-Q screening tools showed a low level of agreement (K=0.17; p<0.0001). Further research on the various pre-exercise medical screening tools is required to determine which variables are responsible for identifying the participants at high risk for medical complications prior to participation.

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CHAPTER 4: PAPER 2 – THE DOMAINS RESPONSIBLE FOR THE DIFFERENCES BETWEEN FIVE INTERNATIONAL PRE-EXERCISE SCREENING TOOLS IN IDENTIFYING LEISURE ATHLETES AT HIGH RISK FOR MEDICAL COMPLICATIONS: A QUANTITATIVE, CROSS-SECTIONAL OBSERVATIONAL SAFER STUDY INVOLVING 76 654 RUNNERS

ABSTRACT

Background: Pre-exercise medical screening is needed in order to identify individuals with a high risk of developing medical complications during or after exercise. Although the level of agreement between five international pre-exercise medical screening tools has been determined, the specific domains responsible for the differences between these tools have not yet been researched.

Aim: The aim of this study is to determine which domains of risk (history of cardiovascular disease [CVD], symptoms of CVD, risk factors of CVD, history of any chronic disease and chronic diseases by organ systems, history of prescription medication use and history of musculoskeletal injury) are responsible for the considerable variation between the five pre-exercise medical screening tools in identifying participants at higher risk for medical encounters during exercise.

Methods: Data was collected over a period of four years (2012–2015) from entrants in the Two Oceans Marathon. This is a pre-entry only event and since 2012 it has been compulsory for all entrants to complete a pre-exercise medical questionnaire. This questionnaire was developed for the SAFER studies and was based on domains that are included in several international pre-exercise medical screening tools, among others in the EACPR, the pre-2015 ACSM and the PAR-Q guidelines. Using the information collected by means of this questionnaire, the five pre-exercise medical screening tools were applied to determine whether they identified the same race entrants as requiring pre-exercise medical clearance. This information was further used to determine the specific differences within each of the domains of risk.

Results: Considerable variation was found to exist between pre-exercise medical screening tools with regard to the identification of entrants at risk in each of the six main domains. With regard to a history of CVD, the AHA identified a significantly smaller number of participants than any of the other pre-exercise medical screening tools. For symptoms of CVD, the AHA and the PAR-Q pre-exercise medical screening tools identified a significantly smaller number of participants than the other tools, and for risk factors for CVD, the post-2015 ACSM tool

identified significantly fewer participants than any of the other tools. The results obtained by using the five screening tools for the identification of a history of any other chronic disease varied greatly, and with regard to prescription medication use and a history of musculoskeletal injury the AHA and the post-2015 ACSM identified a significantly lower percentage of entrants than the other three screening tools.

Conclusion: No single domain could be identified as the cause of variability between the pre-exercise screening tools. The selection of a pre-exercise medical screening tool should be based on the purpose for, and the context in which the screening tool will be used. The pre-2015 ACSM and the EACPR pre-exercise medical screening tools identified a high percentage of participants for all domains of risk, except for any kidney/bladder disease.

Key words: Pre-exercise medical screening tools, pre-exercise medical clearance, recreational endurance athletes, medical encounters

INTRODUCTION

The health benefits of exercise are well documented.[1] An increased level of physical activity is strongly associated with a reduction in all-cause and cardiovascular mortality.[2] However, vigorous physical activity can increase the risk of cardiovascular complications, including sudden cardiac arrest, sudden cardiac death and other serious life-threatening non-cardiac medical encounters (ME).[2] Many years of high-volume prolonged endurance exercise has also been linked to an increased risk of chronic cardiovascular complications, such as exercise-induced cardiac biomarker release, increased coronary artery calcification, atrial fibrillation and myocardial fibrosis.[2] It has been reported that the absolute risk of sudden death (SD) in athletes participating in marathon (and similar) races ranges between 1 in 50 000 and 1 in 200 000.[3] To reduce the risk of medical encounters (MEs) during physical activity, it is important to identify athletes at higher risk for medical complications before they participate in physical exercise. The identification of high-risk individuals is related mainly to cardiovascular risk (known history of cardiovascular disease (CVD), symptoms of CVD and risk factors for CVD), but diseases in other organ systems and the use of prescription medication are also associated with increased risk of MEs during exercise.

A number of pre-exercise medical screening tools have been developed by international professional medical bodies to identify individuals who may be more prone to developing medical complications during exercise. These include the following: 1) the 2011 American Heart Association (AHA) guidelines[4, 5]; 2) the Pre-2015 American College of Sports Medicine (ACSM) guidelines[6]; 3) the Post-2015 American College of Sports Medicine (ACSM) guidelines[7]; 4) the 2002 Physical Activity Readiness Questionnaire (PAR-Q)[8]; and 5) the 2011 European Association of Cardiovascular Prevention and Rehabilitation (EACPR) guidelines.[9, 10] Each of the aforementioned tools uses different combinations of questions and algorithms in the main domains of risk. The 2011 AHA screening guideline includes a 14-point history and physical examination to detect existing CVD or risk factors for CVD.[4, 5] The Pre-2015 ACSM guidelines include the participant's health history and identified CVD risk factors,[6] but removed certain sections and focused on (1) the individual's current physical activity level; (2) whether there are any signs or symptoms of known metabolic, cardiovascular, or renal disease; and (3) the intensity at which the individual would like to exercise.[7] The PAR-Q consists of seven questions formulated to determine whether exercise participants would be able to engage in exercise or become more physically active. If any positives are recorded, medical clearance is required.[8] The 2011 EACPR, which is a combination of the pre-2015 ACSM and the PAR-

Q[9] guidelines, is one of the most comprehensive pre-exercise medical screening tools and requires health-related information, such as information on CVD symptoms, CVD, medication usage and CVD risk factors.[9, 10] Although some research has been conducted on the use of the various pre-exercise medical screening tools used to identify participants who may be at higher risk for medical complications during exercise, this research was, to our knowledge, conducted in isolation by using a single pre-screening tool with no comparison with other similar tools. Specifically, no study has been undertaken to determine whether different tools identify the same participants as needing medical clearance. In the study described in Chapter 3, the percentage of distance running race entrants identified as requiring medical clearance varied significantly (from 6.7 to 33.9%) between international pre-exercise medical screening tools: 2011 EACPR (33.9%); pre-2015 ACSM (33.9%); PAR-Q (23.2%); AHA (10.0%); post-2015 ACSM (6.7%). The level of agreement also varied considerably and was high between pre-2015 ACSM and EACPR (K=1.00; p=0.05), moderate between pre-2015 ACSM and PAR-Q (K=0.75; p<0.0001) and PAR-Q and EACPR (K=0.75; p<0.0001), but low between post-2015 ACSM and PAR-Q (K=0.17; p<0.0001). The next step is to determine which specific variables are responsible for the substantial differences between the five screening tools with regard to their identification of participants at higher risk for medical encounters during exercise.

Therefore, the primary aim of this study is to determine which specific variables in six main domains of risk (history of CVD, symptoms of CVD, risk factors of CVD, history of any chronic disease and chronic diseases by organ systems, history of prescription medication use and history of musculoskeletal injury) are responsible for the variation between the results obtained when using the five pre-exercise medical screening tools to identify participants at higher risk for medical encounters during exercise. This information is important for clinical decision making when selecting the most appropriate pre-exercise medical screening tool.

METHODS

Study design and ethical considerations

This descriptive cross-sectional study, which entails the analysis of data collected from recreational endurance athletes who participated in the Two Oceans Marathon over a period of four years (2012–2015), forms part of a larger research programme known as the SAFER (**S**trategies to reduce **A**dverse medical events **F**or the **E**xercise**R**) studies,[11] which was approved by the Research Ethics Committees of the Faculty of Health Sciences at the

University of Cape Town (REC number 413/2015) and the Faculty of Health Sciences at the University of Pretoria (REC number 683/2019**)**.

Participants (selection and description)

The Two Oceans Marathon is Africa's largest running event and takes place annually in Cape Town (South Africa). It is a mass community-based endurance sports event consisting of races run over various distances and attracts approximately 25 000 runners each year.[10]

Study participants

The online completion of a pre-exercise medical screening questionnaire was a mandatory component of the entry process to the race. Over the four years, 106 743 race entrants completed the questionnaire, and 76 654 (71.8% of the total population) agreed to the use of their information for this study.

Data collection

The data collected from recreational endurance athletes who participated in the Two-Oceans Marathon over a four-year period (2012–2015) was used in this study. This a pre-entry only event and since 2012 it has been compulsory for all entrants to complete a pre-exercise medical questionnaire.[12] This questionnaire was developed for the SAFER studies and was based on domains addressed in several international pre-exercise medical screening tools, including the EACPR, the Pre-2015 ACSM and the PAR-Q guidelines.[3]

The following domains of medical information were requested during the pre-exercise screening: history of CVD; symptoms of CVD; risk factors for CVD; history of other chronic diseases (hormonal and metabolic disease, respiratory disease, nervous system disease, gastrointestinal disease, bladder or renal disease, immune system or haematological disease, allergies, and cancer); history of use of prescription medication; and history of musculoskeletal injury.[3] Using the information collected by means of this questionnaire, the five most commonly used pre-exercise medical screening tools (AHA[4, 5], pre-2015 ACSM[6], post-2015 ACSM[7], PAR-Q[8] and EACPR[9, 10]) were applied to determine the percentage of race entrants who were identified by each screening tool in the six abovementioned main domains of risk.

Outcome variables

Based on the answers provided to the questions in the pre-exercise medical screening tool, an algorithm was developed for each of the five tools to determine the need for medical clearance.

The primary measure of outcome was the percentage of entrants that each of the five screening tools identified within six main domains of risk: 1) history of CVD; 2) symptoms of CVD; 3) risk factors for CVD; 4) history of any chronic disease and chronic diseases by organ systems; 5) history of prescription medication use; and 6) history of musculoskeletal injury. A secondary measure of outcome reported was the percentage of race entrants identified by each of the five screening tools for specific variables within each of the six main domains of risk.

Statistical analysis

The race entrant demographic data and pre-race medical screening data provided by 76 654 race entrants was entered on an Excel spreadsheet (Microsoft 2010) and analysed by using the SAS Enterprise Guide (V7.1) statistical programme. Using the responses to all questions regarding demographics (age and sex) and medical history (chronic disease and medication use), an algorithm was created for each of the five pre-exercise medical screening tools used to determine the need for medical clearance. This is the binary-scaled response variable (whether medical screening is required or not) for each of the five pre-exercise medical screening tools. The prevalence of medical screening for each tool was obtained (with 95% Cl) and reported in Chapter 3. Using this same outcome response variable for each screening tool (medical clearance=yes), a Poisson regression model was used to determine the prevalence (% and 95% CIs) of entrants for each main domain, and for each screening tool individual response (%) was calculated for the whole population. Significant differences in the percentage of entrants identified by the pre-exercise medical screening tools in each main domain were determined by 95% confidence intervals that did not overlap.

RESULTS

A total of 76 654 race entrants gave consent for the data obtained during the four years (2012–2015) to be used and analysed for research purposes. The numbers of race entrants who reported any specific variable within each of the main domains of risk for the pre-exercise medical screening tools are as follows: 2011 EACPR pre-exercise medical screening tool (27 115), the pre-2015 ACSM (27 111), the PAR-Q (18 983), the AHA (8 402) and the post-2015 ACSM (5 366).

Race entrants identified by the five medical screening tools as being within the main domains of risk

The numbers and percentages (with 95%CI) of race entrants identified by the five screening tools as being within each of the six main domains of risk (history of CVD, symptoms of CVD, risk factors for CVD, history of any chronic disease and chronic diseases by organ systems, prescription medication use, and a history of musculoskeletal injury) are presented in Table 4.1.

Table 4.1: The numbers and percentages (with 95%CI) of race entrants identified by the five screening tools as being within the six main domains of risk (history of CVD, symptoms of CVD, risk factors for CVD, history of any chronic disease and chronic diseases by organ systems, prescription medication use and a history of musculoskeletal injury) (total n=76654)

	AHA (n=8402)		Pre-2015 ACSM (n=27111)		Post-2015 ACSM (n=5366)		PAR-Q (n=18983)		EACPR (n=27115)	
Main domain of risk	n	% (95%CI)	n	% (95%CI)	n	% (95%CI)	n	% (95%CI)	n	% (95%CI)
1. Any history of CVD	1001	**1.31 (1.23-1.39)**	1410	1.84 (1.74-1.93)	1410	1.84 (1.74-1.93)	1410	1.84 (1.74-1.93)	1410	1.84 (1.74-1.93)
2. Any symptoms of CVD	588	**0.77 (0.71-0.83)**	804	1.05 (0.98-1.12)	853	1.11 (1.04-1.19)	552	**0.72 (0.66-0.78)**	804	1.05 (0.98-1.12)
3. Any risk factor for CVD	6560	8.56 (8.36-8.76)	7643	9.97 (9.76-10.18)	2255	**2.94 (2.82-3.06)**	5576	7.27 (7.09-7.46)	7643	9.97 (9.76-10.18)
≥2 CVD risk factors	2202	2.87 (2.75-2.99)	2392	3.12 (3.00-3.24)	800	**1.04 (0.97-1.12)**	1704	2.22 (2.12-2.33)	2392	3.12 (3.00-3.24)
4. Any other chronic disease	1661	**2.17 (2.06-2.27)**	4685	6.11 (5.94-6.28)	3474	**4.53 (4.38-4.68)**	2629	**3.43 (3.30-3.56)**	4686	6.11 (5.94-6.28)
Any metabolic endocrine disease	665	**0.87 (0.80-0.93)**	1853	2.42 (2.31-2.53)	2111	2.75 (2.64-2.87)	886	**1.16 (1.08-1.23)**	1853	2.42 (2.31-2.53)
Any respiratory disease	1218	**1.59 (1.50-1.68)**	7081	9.24 (9.03-9.44)	988	**1.29 (1.21-1.37)**	2665	**3.48 (3.35-3.61)**	7081	9.24 (9.03-9.44)
Any kidney / bladder disease	332	**0.43 (0.39-0.48)**	755	0.98 (0.92-1.05)	1121	1.46 (1.38-1.55)	539	**0.70 (0.64-0.76)**	755	0.98 (0.92-1.05)
History of cancer	329	**0.43 (0.38-0.48)**	733	0.96 (0.89-1.03)	209	**0.27 (0.24-0.31)**	478	0.62 (0.57-0.68)	733	0.96 (0.89-1.03)
Nervous system / Psychiatric	482	**0.63 (0.57-0.68)**	1556	2.03 (1.93-2.13)	499	**0.65 (0.59-0.71)**	875	1.14 (1.07-1.22)	1557	2.03 (1.93-2.13)
Haematological / Immune disease	122	**0.16 (0.13-0.19)**	427	0.56 (0.50-0.61)	156	**0.20 (0.17-0.24)**	232	0.30 (0.26-0.34)	427	0.56 (0.50-0.61)
GIT disease	501	**0.65 (0.60-0.71)**	1508	1.97 (1.87-2.07)	459	**0.60 (0.54-0.65)**	984	1.28 (1.20-1.36)	1509	1.97 (1.87-2.07)
5. Any prescription medication use	4409	**5.75 (5.59-5.92)**	10143	13.23 (12.99-13.47)	2753	**3.59 (3.46-3.72)**	6214	8.11 (7.91-8.30)	10143	13.23 (12.99-13.47)

	AHA (n=8402)		Pre-2015 ACSM (n=27111)		Post-2015 ACSM (n=5366)		PAR-Q (n=18983)		EACPR (n=27115)	
6. Any musculo-skeletal injuries	2497	**3.26 (3.13-3.38)**	14766	19.26 (18.98-19.54)	1660	**2.17 (2.06-2.27)**	14766	19.26 (18.98-19.54)	14766	19.26 (18.98-19.54)

Bold text indicates a significantly lower number of participants identified

The main observation made from Table 4.1 is that there is considerable variation between the pre-exercise medical screening tools' identification of entrants in each of the six main domains of risk. The EACPR screening tool consistently identified the highest percentage of individuals at risk for all six main domains. For the first domain (any history of CVD), the AHA identified a significantly lower number of participants than the other pre-exercise medical screening tools. For the second domain (symptoms of CVD), the AHA and PAR-Q pre-exercise medical screening tools identified significantly fewer participants than the other tools, and in the third domain (risk factors for CVD), the post-2015 ACSM tool identified a significantly smaller number of participants than any of the other tools. Similarly, for the sub-category of the third domain (≥2 CVD risk factors) the post-2015 ACSM tool also identified a significantly smaller number of participants than any of the other tools. For the fourth domain, the identification of a history of any other chronic disease by the five screening tools was highly inconsistent. The AHA tool identified a significantly lower percentage of entrants with a history of chronic disease than any of the other tools. Furthermore, the post-2015 ACSM and the PAR-Q identified a significantly lower percentage of entrants compared to the pre-2015 ACSM and the EACPR. In subcategories of the fourth domain (chronic disease in different organ systems), the AHA and the post-2015 ACSM identified a significantly lower percentage of entrants, except for kidney or bladder disease, in which case only the AHA identified a significantly lower percentage (Table 1). Finally, for the fifth (prescription medication use) and sixth (history of musculoskeletal injury) domains, the AHA and post-2015 ACSM identified a significantly lower percentage of entrants compared to the other three screening tools.

Race entrants identified by the five screening tools for specific variables within each of the main domains of risk

First domain of risk (history of CVD)

The number and percentage of entrants identified by each of the five screening tools within the first main domain (history of CVD), is presented in Table 4.2.

Table 4.2: The numbers and percentages of entrants identified by each of the five screening tools within the first main domain of risk (history of CVD) (n=76654)

Pre-exercise medical screening tool	AHA (n=8402)		Pre-2015 ACSM (n=27111)		Post-2015 ACSM (n=5366)		PAR-Q (n=18983)		EACPR (n=27115)	
	n	%	n	%	n	%	n	%	n	%
History of CVD										
Myocardial infarct (heart attack)	132	0.17	148	0.19	148	0.19	148	0.19	148	0.19
Chest pain that has been diagnosed as "angina"	80	0.1	80	0.1	80	0.1	80	0.1	80	0.1
Coronary artery bypass graft (CABG)	79	0.1	81	0.11	81	0.11	81	0.11	81	0.11
Angioplasty (no stent)	25	0.03	28	0.04	28	0.04	28	0.04	28	0.04
Angioplasty (with stent)	172	0.22	182	0.24	182	0.24	182	0.24	182	0.24
Heart failure	5	0.01	7	0.01	7	0.01	7	0.01	7	0.01
Heart transplant	0	0	0	0	0	0	0	0	0	0
Arrhythmia	161	0.21	309	0.4	309	0.4	309	0.4	309	0.4
Rheumatic fever	56	0.07	135	0.18	135	0.18	135	0.18	135	0.18
Heart murmur	347	0.45	346	0.45	347	0.45	347	0.45	347	0.45
Cardiomyopathy	1	0	8	0.01	8	0.01	8	0.01	8	0.01
Myocarditis	16	0.02	41	0.05	41	0.05	41	0.05	41	0.05
Use of pacemaker	20	0.03	30	0.04	30	0.04	30	0.04	30	0.04
Inherited conditions of the heart or blood vessels	32	0.04	37	0.05	37	0.05	37	0.05	37	0.05
Any other form of heart or blood vessel disease	118	0.15	208	0.27	211	0.28	211	0.28	211	0.28

AHA: American Heart Association
Pre-2015 ACSM: Pre-2015 American College of Sports Medicine
Post-2015 ACSM: Post-2015 American College of Sports Medicine
PAR-Q: Physical Activity Readiness Questionnaire
EACPR: European Association of Cardiovascular Prevention and Rehabilitation
CVD: Cardiovascular disease

In the first main domain (history of CVD), the AHA identified significantly fewer participants than the other pre-exercise medical screening tools (Table 4.1). The main observation made from Table 4.2 is that when compared to the other tools, the AHA identified a lower percentage of participants with any history of the following specific CVDs: arrhythmia, rheumatic fever, cardiomyopathy, myocarditis and any other form of heart or blood vessel disease.

Second main domain of risk (a history of symptoms of CVD)

The numbers and percentages of entrants identified by each of the five screening tools within the main Domain of risk II (history of symptoms) of CVD are presented in Table 4.3.

Table 4.3: The numbers and percentages of entrants identified by each of the five screening tools within the second main domain of risk (history of symptoms of CVD) (n=76654)

Pre-exercise medical screening tool	AHA (n=8 402)		Pre-2015 ACSM (n=27 111)		Post-2015 ACSM (n=5 366)		PAR-Q (n=18 983)		EACPR (n=27 115)	
	n	%	n	%	n	%	n	%	n	%
Symptoms of CVD										
Swollen ankles	105	0.14	141	0.18	141	0.18	97	0.13	141	0.18
Water retention	52	0.07	70	0.09	70	0.09	52	0.07	70	0.09
Shortness of breath when sitting or lying down	15	0.02	21	0.03	21	0.03	13	0.02	21	0.03
Shortness of breath with mild exercise	115	0.15	115	0.15	115	0.15	68	0.09	115	0.15
Waking up with shortness of breath at night	8	0.01	10	0.01	10	0.01	7	0.01	10	0.01
Palpitations with no dizziness	55	0.07	80	0.1	80	0.1	52	0.07	80	0.1
Palpitations that make you dizzy	19	0.02	25	0.03	25	0.03	25	0.03	25	0.03
Chest pain when sitting	16	0.02	27	0.04	27	0.04	27	0.04	27	0.04
Chest pain when performing exercise	32	0.04	32	0.04	32	0.04	32	0.04	32	0.04
Chest pain when emotionally stressed	65	0.08	65	0.08	65	0.08	65	0.08	65	0.08
Pain (or discomfort) in the neck, jaw, arms at rest or during exercise	98	0.13	132	0.17	159	0.21	92	0.12	132	0.17
Dizziness during exercise	98	0.13	144	0.19	144	0.19	144	0.19	144	0.19
Fainting spells	48	0.06	48	0.06	48	0.06	48	0.06	48	0.06
Chronic dry cough	37	0.05	45	0.06	51	0.07	31	0.04	45	0.06
Painful calves when walking	137	0.18	240	0.31	240	0.31	131	0.17	240	0.31
Have you ever collapsed during training or racing?	219	0.29	781	1.02	190	0.25	781	1.02	781	1.02

AHA: American Heart Association
Pre-2015 ACSM: Pre-2015 American College of Sports Medicine
Post-2015 ACSM: Post-2015 American College of Sports Medicine
PAR-Q: Physical Activity Readiness Questionnaire
EACPR: European Association of Cardiovascular Prevention and Rehabilitation
CVD: Cardiovascular disease

In the second domain (history of symptoms of CVD), the AHA and PAR-Q pre-exercise medical screening tools identified significantly fewer participants than any of the other tools (Table 4.1). The main observation made from Table 4.3 is that, compared with the other screening tools, the AHA and PAR-Q identified a lower percentage of participants with the following specific symptoms of CVD: swollen ankles and painful calves when walking. The

results of all the tools varied with regard to pain (or discomfort) in the neck, jaw, arms at rest or during exercise. Compared with the other pre-exercise screening tools, the AHA identified the lowest percentage of participants with any symptoms of CVD for the following risk factors: palpitations that make you dizzy, chest pain when sitting and dizziness during exercise. The post-2015 ACSM and AHA both showed a lower percentage of participants identified with "collapse during training or racing" than the other tools. With regard to one risk factor, namely shortness of breath with mild exercise, the PAR-Q also identified a lower percentage than the other pre-exercise medical screening tools.

Third main domain of risk (risk factors for CVD)

The numbers and percentages of entrants identified by each of the five screening tools in the third main domain of risk (risk factors for CVD) are presented in Table 4.4.

Table 4.4: The numbers and percentages of entrants identified by each of the five screening tools within the third main domain of risk (risk factors for CVD) (n=76 654)

Pre-exercise medical screening tool	**AHA (n=8 402)**		**Pre-2015 ACSM (n=27 111)**		**Post-2015 ACSM (n=5 366)**		**PAR-Q (n=18 983)**		**EACPR (n=27 115)**	
	n	%	n	%	n	%	n	%	n	%
Risk Factors for CVD										
High blood pressure	3 097	4.04	2 904	3.79	732	0.95	2 479	3.23	2 904	3.79
High blood cholesterol	2 296	3.0	3 295	4.3	780	1.02	2 591	3.38	3 295	4.30
Cigarette smoking	495	0.65	880	1.15	238	0.31	444	0.58	880	1.15
Obesity (overweight)	326	0.43	517	0.67	162	0.21	302	0.39	517	0.67
Diabetes mellitus	449	0.59	714	0.93	714	0.93	339	0.44	714	0.93
Family history of heart disease (<50 years)	1 552	2.02	1 263	1.65	404	0.53	810	1.06	1 263	1.65
History of heart disease in close family members	1 160	1.51	961	1.25	310	0.40	689	0.90	961	1.25
>40 years	6259	8.17	13289	17.34	3 165	4.13	10 063	13.13	13 291	17.34
Male >45 years	4070	5.31	6210	8.10	1 525	1.99	4 991	6.51	6 211	8.1
Female >55 years	557	0.73	784	1.02	182	0.24	519	0.68	784	1.02
>65 years	930	1.21	553	0.72	187	0.24	463	0.60	553	0.72

AHA: American Heart Association
Pre-2015 ACSM: Pre-2015 American College of Sports Medicine
Post-2015 ACSM: Post-2015 American College of Sports Medicine
PAR-Q: Physical Activity Readiness Questionnaire
EACPR: European Association of Cardiovascular Prevention and Rehabilitation
CVD: Cardiovascular disease

In the third domain (risk factors for CVD), the post-2015 ACSM tool identified significantly fewer participants than any of the other tools (Table 4.1). The main observation made based on the information in Table 4.4 is that the percentage of participants with the following specific risk factors for CVD: high blood pressure, high blood cholesterol, cigarette smoking, obesity (overweight) and a family history of heart disease identified by the post-2015 ACSM tool was lower than the percentages identified by the other four pre-exercise medical screening tools. The PAR-Q identified the lowest percentage of participants with risk factors for CVD.

Fourth main domain of risk (history of chronic disease)

The numbers and percentages of entrants identified by each of the five screening tools in the fourth main domain of risk (history of chronic disease) are presented in Table 4.5.

Table 4.5: The numbers and percentages of entrants identified by each of the five screening tools in the fourth main domain of risk (history of chronic disease) (n=76 654)

	AHA (n=8 402)		Pre-2015 ACSM (n=27 111)		Post-2015 ACSM (n=5 366)		PAR-Q (n=18 983)		EACPR (n=27 115)	
	n	%	n	%	n	%	n	%	n	%
Other chronic disease										
Hyperglycaemia (high blood sugar) (pre-diabetes)	66	0.09	94	0.12	110	0.14	60	0.08	94	0.12
Type I: Insulin dependent (diabetes mellitus)	78	0.10	201	0.26	201	0.26	72	0.09	201	0.26
Type II: Non-insulin dependent (diabetes mellitus)	234	0.31	309	0.40	309	0.40	177	0.23	309	0.40
Underactive thyroid (hypothyroidism)	187	0.24	898	1.17	975	1.27	361	0.47	898	1.17
Overactive thyroid (hyperthyroidism)	31	0.04	114	0.15	136	0.18	55	0.07	114	0.15
Hypoglycaemia (low blood sugar)	93	0.12	275	0.36	393	0.51	178	0.23	275	0.36
Heat intolerance	35	0.05	78	0.10	102	0.13	49	0.06	78	0.10
Asthma (non-exercise-induced)	317	0.41	2 054	2.68	219	0.29	655	0.85	2 054	2.68
Asthma (exercise-induced)	329	0.43	1 939	2.53	257	0.34	762	0.99	1 939	2.53
Repeated infections in respiratory tract	60	0.08	244	0.32	59	0.08	134	0.17	244	0.32
COPD (chronic obstructive pulmonary disease)	8	0.01	16	0.02	3	0	7	0.01	16	0.02
Interstitial lung disease	1	0	1	0	1	0	1	0	1	0
Cystic fibrosis	2	0	4	0.01	0	0	0	0	4	0.01
Past history of kidney disease	45	0.06	112	0.15	160	0.21	81	0.11	112	0.15
Past history of bladder disease	24	0.03	88	0.11	123	0.16	60	0.08	88	0.11
History of blood in the urine	44	0.06	118	0.15	173	0.23	82	0.11	118	0.15
Chronic loin pain	5	0.01	6	0.01	8	0.01	6	0.01	6	0.01
History of kidney stones	160	0.21	312	0.41	501	0.65	227	0.30	312	0.41
Frequent urination	70	0.09	174	0.23	240	0.31	130	0.17	174	0.23
Burning during urination	53	0.07	137	0.18	200	0.26	99	0.13	137	0.18

AHA: American Heart Association
Pre-2015 ACSM: Pre-2015 American College of Sports Medicine
Post-2015 ACSM: Post-2015 American College of Sports Medicine
PAR-Q: Physical Activity Readiness Questionnaire
EACPR: European Association of Cardiovascular Prevention and Rehabilitation

In the fourth domain (history of chronic disease), the identification of other chronic diseases by the five screening tools varied greatly (Table 4.1). Note the following observations based on the information contained in Table 4.5 for specific chronic diseases: When compared with the other three pre-exercise medical screening tools, the AHA and the post-2015 ACSM identified a lower percentage of participants with other chronic diseases for "repeated infections in the respiratory tract". The AHA identified a lower percentage of participants with other chronic disease than the other four screening tools for the following risk factors: underactive thyroid (hypothyroidism), overactive thyroid (hyperthyroidism), hypoglycaemia (low blood sugar), heat intolerance, past history of kidney disease, past history of bladder disease, history of blood in the urine, history of kidney stones, frequent urination and a burning sensation during urination. The percentage of participants with other chronic diseases identified by the post-2015 ACSM for the risk factors asthma (non-exercise-induced) and asthma (exercise-induced) was lower than the percentages identified by the other four tools, and the PAR-Q identified a lower percentage of participants with other chronic diseases for the risk factors hyperglycaemia (high blood sugar) (pre-diabetes), Type I: insulin-dependent diabetes mellitus and Type II non-insulin-dependent diabetes mellitus than the other tools.

Fifth main domain of risk (use of prescription medication)

The numbers and percentages of entrants identified by each of the five screening tools in the fifth main domain of risk (use of prescription medication) are presented in Table 4.6.

Table 4.6: The numbers and percentages of entrants identified by each of the five screening tools in the fifth main domain of risk (use of prescription medication) (n=76 654)

Pre-exercise medical screening tool	**AHA (n=8 402)**		**Pre-2015 ACSM (n=27 111)**		**Post-2015 ACSM (n=5 366)**		**PAR-Q (n=18 983)**		**EACPR (n=27 115)**	
	n	%	n	%	n	%	n	%	n	%
Use of medication										
Cholesterol-lowering medication	1 760	2.30	2 379	3.10	649	0.85	2 379	3.1	2 379	3.1
Blood pressure-lowering medication	2 482	3.24	2482	3.24	604	0.79	2 482	3.24	2 482	3.24
Anti-allergy medication	163	0.21	682	0.89	134	0.17	317	0.41	682	0.89
Medication to control heart rhythm	59	0.08	66	0.09	66	0.09	66	0.09	66	0.09
Medication to treat heart failure	32	0.04	33	0.04	33	0.04	33	0.04	33	0.04
Other medication to treat heart disease	118	0.15	136	0.18	136	0.18	136	0.18	136	0.18
Medication (tablets) to treat Type II diabetes	210	0.27	294	0.38	294	0.38	170	0.22	294	0.38

Insulin for diabetes	90	0.12	258	0.34	258	0.34	107	0.14	258	0.34
Medication to treat anxiety	96	0.13	516	0.67	126	0.16	257	0.34	516	0.67
Anti-depressant medication	252	0.33	1 325	1.73	212	0.28	587	0.77	1 325	1.73
Anti-asthma medication	417	0.54	2 035	2.65	486	0.63	848	1.11	2 035	2.65

AHA: American Heart Association
Pre-2015 ACSM: Pre-2015 American College of Sports Medicine
Post-2015 ACSM: Post-2015 American College of Sports Medicine
PAR-Q: Physical Activity Readiness Questionnaire
EACPR: European Association of Cardiovascular Prevention and Rehabilitation

In the fifth domain (use of prescription medication), the AHA and the post-2015 ACSM identified a percentage of entrants that was significantly lower than the percentages identified by the other three screening tools (Table 4.1). The main observations made with regard to the information contained in Table 6 are as follows: The AHA identified a lower percentage of participants using insulin for diabetes, medication to treat anxiety and anti-asthma medication; the post-2015 ACSM identified a lower percentage of participants using cholesterol-lowering medication, blood-pressure-lowering medication, anti-allergy medication and anti-depressant medication, and the PAR-Q identified a lower percentage of participants using medication (tablets) to treat Type II diabetes mellitus compared to the other four pre-exercise medical screening tools.

DISCUSSION

Various pre-exercise medical screening tools have been developed to identify individuals who are at higher risk for medical complications before they engage in exercise of moderate to high intensity. To our knowledge, no data is available to determine whether the five screening tools under discussion identify the same individuals in the main domains of risk. The main findings of this study are: 1) With regard to the identification of entrants in each of the six main domains of risk, there was considerable variation between the results obtained when using the five pre-exercise medical screening tools. 2) For any history of CVD, the AHA identified significantly fewer participants than any of the other pre-exercise medical screening tools. 3) For symptoms of CVD, the AHA and the PAR-Q pre-exercise medical screening tools identified significantly fewer participants than the other tools. 4) For risk factors for CVD, the post-2015 ACSM tool identified significantly fewer participants than any of the other tools. 5) For other chronic diseases, the identification of a history of any other chronic disease by the five pre-exercise medical screening tools varied greatly. 6) For prescription medication use and a history of musculoskeletal injury, the AHA and the post-2015 ACSM identified a significantly lower percentage of entrants than the other three screening tools.

Entrants identified by each of the five screening tools in the six main domains of risk

Table 4.7 below contains a summary of the percentages of entrants identified by each of the five pre-exercise medical screening tools in the six main domains of risk (expressed in four categories, based on the percentage of entrants).

Table 4.7: Summary of the of the percentages of entrants identified by each of the five pre-exercise medical screening tools in the six main domains of risk (expressed in four categories, based on the percentage of entrants)

Main domains of risk	AHA	Pre-2015 ACSM	Post-2015 ACSM	PAR-Q	EACPR
1. History of CVD	Intermediate (71%)	High (100%)	High (100%)	High (100%)	High (100%) *
2. Symptoms of CVD	Intermediate (69%)	High (95%)	High (100%) *	Intermediate (64%)	High (95%)
3. Risk factors for CVD	High (86%)	High (100%)	Low (29%)	Intermediate (73%)	High (100%) *
>2 CVD risk factors	High (92%)	High (100%)	Low (34%)	Intermediate (71%)	High (100%) *
4. Other chronic disease	Low (36%)	High (100%)	Intermediate (74%)	Intermediate (56%)	High (100%) *
Any metabolic endocrine disease	Low (32%)	High (88%)	High (100%) *	Low (42%)	High (88%)
Any respiratory disease	Very low (17%)	High (100%)	Very low (14%)	Low (38%)	High (100%) *
Any kidney/bladder disease	Low (29%)	Intermediate (67%)	High (100%) *	Low (48%)	Intermediate (67%)
History of cancer	Low (45%)	High (100%)	Low (28%)	Intermediate (65%)	High (100%) *
Nervous system/Psychiatric	Low (31%)	High (100%)	Low (32%)	Intermediate (56%)	High (100%) *
Haematological/Immune disease	Low (29%)	High (100%)	Low (36%)	Intermediate (54%)	High (100%) *
GIT disease	Low (33%)	High (100%)	Low (30%)	Intermediate (65%)	High (100%) *
5.Prescription medication use	Low (43%)	High (100%)	Low (27%)	Intermediate (61%)	High (100%) *
6.Musculoskeletal injury	Very low (17%)	High (100%)	Very low (11%)	High (100%)	High (100%) *

*: Reference – the screening tool with the highest percentage of entrants (from Table 1)
High: >75% of entrants identified compared to reference
Intermediate: 50-75% of entrants identified compared to reference
Low: 25–49% of entrants identified compared to reference
Very low: <25% of entrants identified compared to reference

As previously mentioned, considerable variation occurs between the pre-exercise medical screening tools with regard to their identification of entrants in each of the six main domains of risk. The EACPR screening tool consistently identified the highest percentage of individuals at risk (high). This is because the EACPR included the questions from both the pre-2015 ACSM and the PAR-Q (with those asked in the EACPR being the most extensive). In the first main domain of risk (any history of CVD), the AHA identified significantly fewer participants than any of the other pre-exercise medical screening tools. The AHA pre-exercise medical screening tool excludes most of the history of CVD categories, which explains the low

prevalence in this category. For the second main domain of risk (symptoms of CVD), the AHA and the PAR-Q pre-exercise medical screening tools identified significantly fewer participants than the other tools. The AHA and the PAR-Q do not include all the symptoms of CVD categories, and the questions are related to only one specific situation. For example, the AHA only asks whether the individual has unexplained dyspnoea associated with exercise, and not whether dyspnoea is experience during the night, or when sitting or lying down, which results in some participants being excluded. In the third main domain of risk (risk factors for CVD), the post-2015 ACSM tool identified significantly fewer participants than the other tools. Similar results were found for the subcategory of the third domain ($\geq$2 CVD risk factors), with the post-2015 ACSM tool having identified significantly fewer participants than the other tools. The post-2015 ACSM pre-exercise medical screening tool excludes CVD risk factors, which explains the low identification for this domain of risk.

For the fourth main domain of risk (a history of any other chronic disease), the identification of entrants at risk by the five screening tools varied significantly. Compared to the other tools, the AHA tool identified a considerably lower percentage of entrants with a history of chronic disease. The AHA excludes any other chronic disease and metabolic endocrine disease, which explains the low prevalence in these categories. In the fourth domain, the post-2015 ACSM and the PAR-Q identified significantly lower percentages of entrants than the Pre-2015 ACSM and the EACPR. In the subcategories of the fourth domain (chronic disease in different organ systems), the pre-2015 ACSM and EACPR generally identified a significantly higher percentage of entrants with chronic diseases in specific organ systems (Table 4.1). The EACPR pre-exercise medical screening tool is a combination of the pre-2015 ACSM and the PAR-Q pre-exercise medical screening tools. This explains why the pre-ACSM and EACPR pre-exercise medical screening tools identified the same percentage of participants. Finally, for the fifth and sixth domains of risk (prescription medication use and history of musculoskeletal injury respectively) the percentage of entrants identified by the AHA and the post-2015 ACSM was significantly lower than the percentages identified by the other three screening tools. The AHA and the post-2015 ASCM do not include questions on prescription medication use and musculoskeletal injury, which explains why they identified significantly lower percentages of participants using prescription medication and having a history of musculoskeletal injury.

As shown above, the EACPR and the pre-2015 ACSM identified a high percentage of entrants for all six domains of risk (classified as high), while the results for the other three screening

tools (AHA, post-2015 ACSM and PAR-Q) ranged from very low to high for the six domains of risk.

Entrants identified by each screening tool in the six main domains of risk

First domain of risk: History of CVD

Recording the history of CVD is a very important part of a medical evaluation.[13] The presence of heart murmurs was the most prevalent specific history of CVD reported in all the pre-exercise medical screening tools. The second most reported condition in this category (except for the AHA pre-exercise medical screening tool) was arrhythmia. As previously mentioned, when compared with the other tools, the AHA identified a lower percentage of participants with any history of the following specific CVDs: arrhythmia, rheumatic fever, cardiomyopathy, myocarditis, and any other form of heart or blood vessel disease. The AHA does not include questions on rheumatic fever and myocarditis. Furthermore, even though questions about arrhythmia, cardiomyopathy and any other form of heart or blood vessel disease are asked, they are very specific.

Second domain of risk: Symptoms of CVD

In all the pre-exercise medical screening tools, with the exception of the post-2015 ACSM, the most reported CVD symptom was collapse during training or racing. Various studies have shown that the primary cause of exercise-associated collapse is the pooling of blood in the lower extremities after the cessation of running due to transient postural hypotension.[14-18] Even though collapse as a result of transient postural hypotension has been shown to be an outcome of a non-cardiac cause, syncope during exercise can be an indication of a cardiac disorder.[18] The AHA and PAR-Q pre-exercise medical screening tools identified significantly fewer participants than the other three tools. The AHA does not include questions on swollen ankles and painful calves when walking. Even though questions about palpitations, chest pain and dizziness are asked, those questions are broad or relate to only one situation. For example, the AHA asks whether a person has palpitations associated with exercise, but not whether the palpitations are accompanied by dizziness. The PAR-Q does not include any questions on swollen ankles, painful calves when walking and shortness of breath during mild exercise, hence the lower percentages reported in these categories.

Third domain of risk: Risk factors for CVD

In all five pre-exercise medical screening tools, the most-reported risk factor for CVD among entrants needing medical clearance was ">40 years of age". Masters athletes (participants above the age of 35 years) are at an increased risk for CVD.[19] The presence of two or more chronic conditions (known as multiple co-morbidities) is common among older adults.[20] Skeletal muscle mass and function, immune system function, cognitive function, endocrine system function and gut health have been shown to decrease with age.[21] To some extent, these physiological changes explain the increased risk with increasing age, and the reason for the particular way in which the screening tools were designed. The post-2015 ACSM identified significantly fewer participants with CVD risk factors than any of the other tools. The low identification of CVD risk factors by the post-2015 ACSM is due to the fact that it does not include risk factors as a category/question. The PAR-Q identified a lower percentage of participants with risk factors for CVD for diabetes mellitus than the other four pre-exercise medical screening tools. The PAR-Q does include a question on whether a participant has been diagnosed with any other medical condition, but it lacks the specificity that is important in questions asked in a questionnaire. Non-specific questions could lead to participants being excluded.

Fourth domain of risk: Other chronic diseases

The highest other chronic diseases reported were exercise-induced asthma (EIA) for the AHA and PAR-Q; non exercise-induced asthma for the pre-2015 ACSM and the EACPR; and hypothyroidism for the post-2015 ACSM. It has been reported that the incidence of EIA in the general population is between 8 12%, and may be even higher in elite endurance athletes.[15] Symptoms are more likely to occur with an increase in training intensity.[15] Limited studies have been done linking hypothyroidism specifically to endurance running athletes. The identification of other chronic diseases by the five pre-exercise medical screening tools varied significantly, which could again be due to the nature of the questions asked (specific/non-specific), or the exclusion of questions about a specific chronic disease.

Fifth domain of risk: Use of medication

The prevalence of participants who reported that they used blood-pressure-lowering medication was similar and the highest for all the tools. A history of using cholesterol-lowering medication was the highest for the post-2015 ACSM pre-exercise medical screening tool. However, when the number of identified participants with high blood pressure and cholesterol

was compared to the number of those actually taking prescription medication for the treatment of those conditions it was found to be much lower.[22] A survey involving 42 471 United States adults found that even though there was a high prevalence of familial hypercholesterolemia (FH), only approximately 50% of participants with FH used cholesterol-lowering medication.[22] The AHA and the post-2015 ACSM both identified a significantly lower percentage of entrants using prescription medication than the other three screening tools. The AHA and post-2015 ACSM screening tools do not include questions on prescription medication use.

Sixth domain of risk: Musculoskeletal injury

The pre-2015 ACSM, the PAR-Q and the EACPR indicated the highest prevalence of musculoskeletal injury (Table 4.1). As previously mentioned, the EACPR pre-exercise medical screening tool is a combination of the pre-2015 ACSM and PAR-Q pre-exercise medical screening tools, which explains why the same percentage of participants were identified by all three tools. Since these pre-exercise medical screening tools are also the only tools that include questions on musculoskeletal injury, it is clear why the AHA and the post-2015 ACSM indicated significantly lower percentages of participants using prescription medication.

LIMITATIONS AND STRENGTHS OF THE STUDY, AND RECOMMENDATIONS FOR FUTURE RESEARCH

To our knowledge, no studies have yet been undertaken to compare five international pre-exercise medical screening tools. Another strength of this study was its large sample size and the good response rate (71.8% of the total entrants consented to the use of their data). It is possible that results could differ slightly if the participants completed each of the pre-exercise screening tools separately. Future studies need to investigate the sensitivity and specificity of each of the pre-exercise medical screening tools and specific questions to determine which of them most accurately identify athletes at risk of a medical complication during exercise.

SUMMARY AND RECOMMENDATIONS

In the domain history of CVD, all the pre-exercise medical screening tools except the AHA identified a high percentage of participants, which indicates that any of the other four pre-exercise medical screening tools (pre-2015 ACSM, post-2015 ACSM, PAR-Q or EACPR) can be used to screen participants in this domain of risk. In the domain symptoms of CVD, three pre-exercise medical screening tools (pre-2015 ACSM, post-2015 ACSM and EACPR) identified a high percentage of participants and can therefore be used to screen participants in this domain of risk. The AHA, pre-2015 ACSM and EACPR screening tools identified a high

percentage of participants in the domain risk factors for CVD and are therefore suitable for screening participants in this domain of risk. In the domain other chronic disease, the pre-2015 ACSM and EACPR tools identified a high percentage of participants for the following sub-domains: any metabolic endocrine disease, any respiratory disease, history of cancer, nervous system/psychiatric disease, haematological/immune disease, and GIT disease, indicating that they can be used to screen participants in these sub-domains of risk. In the subdomain any metabolic endocrine disease the post-2015 ACSM also identified a high percentage of participants and can therefore also be used to screen participants in this subdomain. In the subdomain any kidney/bladder disease, only the post-2015 ACSM identified a high percentage of participants, which makes it the only pre-exercise medical screening tool recommended for screening for kidney/bladder disease. In the domain use of prescription medication, the high percentages of participants identified by the pre-2015 ACSM and the EACPR show that either of these pre-exercise medical screening tools can be used to screen participants in this domain of risk. In the domain musculoskeletal injury, the pre-2015 ACSM and the EACPR identified a high percentage of participants, which means that both can be recommended for screening participants in this domain of risk.

Significant variability clearly exists between the results produced by the five pre-exercise medical screening tools used to identify participants at higher risk for medical encounters during exercise in the various domains of risk. No single domain can be identified as the cause of the abovementioned variability. The selection of pre-exercise medical screening tools should be based on the purpose for, and the context in which the screening tool will be used. The pre-2015 ACSM and EACPR pre-exercise medical screening tools identified a high percentage of participants for all domains of risk, except for any kidney/bladder disease. We thus recommend that the decision regarding which pre-exercise medical screening should be used to identify participants at risk should be based on the needs of the event.

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CHAPTER 5: FINDINGS, LIMITATIONS, STRENGTHS, CONCLUSION AND RECOMMENDATIONS

The purpose of this study was to determine the percentage of race entrants who are advised to obtain pre-exercise medical clearance by using five international pre-exercise medical screening tools, and to determine the level of agreement between the tools. In addition, the domains of risk responsible for the significant variation between the results produced by the five pre-exercise medical screening tools used for identifying participants at higher risk for medical encounters during exercise were also determined. Those domains of risk are history of cardiovascular disease [CVD], symptoms of CVD, risk factors of CVD, history of any chronic disease and chronic diseases by organ systems, history of prescription medication use and history of musculoskeletal injury.

5.1 PRIMARY FINDINGS

The primary findings were as follows:

1) The percentage of entrants requiring medical clearance for each tool was: 2011 EACPR: 33.9%; 33.5–34.3); pre-2015 ACSM: 33.9%; 33.5–34.3; PAR-Q: 23.2%; 22.9–23.6; AHA: 10.0%; 9.7–10.2); post-2015 ACSM: 6.7%; 6.5–6.9).
2) The level of agreement was high between the pre-2015 ACSM and the EACPR ($K=1.00$; $p=0.05$), moderate between the pre-2015 ACSM and the PAR-Q ($K=0.75$; $p<0.0001$) and the PAR-Q and the EACPR ($K=0.75$; $p<0.0001$), but poor between the post-2015 ACSM and the PAR-Q ($K=0.17$; $p<0.0001$).
3) Considerable variation was noted between the results produced by the pre-exercise medical screening tools with regard to the identification of entrants in each of the six main domains of risk. For history of CVD, the AHA identified significantly fewer participants than any of the other pre-exercise medical screening tools, while the AHA and PAR-Q pre-exercise medical screening tools identified significantly fewer participants for symptoms of CVD than the other tools. The post-2015 ACSM tool identified significantly fewer participants than the other tools for risk factors for CVD. The identification of a history of any other chronic disease varied greatly between the five screening tools. With regard to the use of prescription medication and a history of musculoskeletal injury, the percentages of entrants identified by the AHA and the post-2015 ACSM were significantly lower than those identified when the other three screening tools were used.

5.2 LIMITATIONS

A limitation of this study was that the questions asked during the Two Oceans Marathon pre-exercise medical screening were not the same as the original questions asked in the five screening tools, such as those relating to pregnancy, general running and training information, general training surface information, and acute infection and illness, were omitted. The results might therefore have differed slightly if the participants had completed each of the pre-exercise screening tools separately.

5.3 STRENGTHS

To our knowledge, no other studies have yet been undertaken to compare five international pre-exercise medical screening tools. Another strength is that a large sample size was used and the response rate was good, with 71.8% of the total number of entrants consenting to the use of their data.

5.4. CONCLUSION

The results of this study show considerable variations between five international pre-exercise medical screening tools used to identify individuals who require medical clearance before participating in endurance races. The level of agreement between the pre-exercise medical screening tools varied significantly. In our population of recreational distance running race entrants, the pre-2015 ACSM and EACPR pre-exercise medical screening tools identified the most participants (33.9%) as needing medical clearance, while only 6.7% were identified for medical clearance by the post-2015 ACSM tool. There was a good level of agreement between the pre-2015 ACSM and EACPR pre-exercise medical screening tools ($K=1.00$; $p=0.05$), whereas the post-2015 ACSM and PAR-Q pre-exercise medical screening tools showed a poor level of agreement ($K=0.17$; $p<0.0001$).

Furthermore, there was substantial variability between the results obtained from the pre-exercise medical screening tools regarding the domains of risk identifying participants at higher risk for medical encounters during exercise. No one domain could be identified as the cause of the inconsistency between the results obtained when using the pre-exercise screening tools. The choice of a pre-exercise medical screening tool should be based on the purpose for, and the context in which it will be used. The pre-2015 ACSM and EACPR pre-exercise medical screening tools identified a high percentage of participants for all domains of risk, except for any kidney/bladder disease. We thus recommend that the choice of a pre-exercise medical

screening tool to be used to identify participants at risk should be based on the needs of the event.

5.5 RECOMMENDATIONS

Future studies should be undertaken to investigate the sensitivity and specificity of the different pre-exercise medical screening tools and specific questions to determine which are able to most accurately identify athletes at risk of a medical complication during exercise. In the domain of history of CVD, all the pre-exercise medical screening tools except the AHA tool identified a high percentage of participants, indicating that any of the following pre-exercise medical screening tools can be used to screen participants in this domain of risk: the pre-2015 ACSM, post-2015 ACSM, PAR-Q and EACPR. In the domain of a symptoms of CVD, three pre-exercise medical screening tools (the pre-2015 ACSM, post-2015 ACSM and EACPR) identified a high percentage of participants, which indicates that any of those three pre-exercise medical screening tools are suitable for screening participants in this domain of risk. In the domain of risk factors for CVD, a high percentage of participants were identified by the AHA, the pre-2015 ACSM and the EACPR, all of which can therefore be used to screen participants in this domain of risk. In the domain of other chronic diseases, the pre-2015 ACSM and EACPR both identified high percentages of individuals for the following subdomains: any metabolic endocrine disease, any respiratory disease, history of cancer, nervous system/psychiatric disease, haematological/immune disease and GIT disease, and can therefore be used for screening participants in those subdomains of risk. The post-2015 ACSM screening tool also identified a high percentage of individuals in the subdomain any metabolic endocrine disease and can therefore be used to screen participants in this subdomain of risk. In the subdomain any kidney/bladder disease, only the post-2015 ACSM identified a high percentage of participants, which indicates that only this pre-exercise medical screening tool can be used for screening participants for kidney/bladder disease. The pre-2015 ACSM and EACPR screening tools identified high percentages in the domain of prescription medication use and are therefore suitable for screening participants in this domain of risk. Finally, the high percentage of participants identified by the pre-2015 ACSM and EACPR indicates that these two pre-exercise medical screening tools can be used to screen participants in this domain of risk.

APPENDICES

APPENDIX A: PRE-SCREENING MEDICAL QUESTIONNAIRE COMPLETED BY RACE ENTRANTS

Information preceding the medical questionnaire

Dear Runner,

Medical information required during race entry process

In 2012, the Old Mutual Two Oceans Marathon Medical Team conducted an online medical questionnaire that was completed by approximately 25 000 participants. Every year, more than 700 runners receive medical care at the medical facilities – both on the route, as well as at the medical tent at the finish. By reviewing the results of the completed pre-race online questionnaires, we were able to pre-plan for the necessary medical care and ensure sufficient staff and facilities were available in 2012.

The preliminary results from the 2012 race show that there were significant reductions in the incidence of all medial admissions to our medical facility. More importantly, there was a very significant decrease in serious life-threatening medical complications during the 2012 event.

Following this success, we have upgraded our goal and the present focus is to further prevent as many medical events as possible in order to make this not only the most beautiful but also the safest race on the running calendar!

Due to the successful implementation of the questionnaire and the information it yielded in 2012, the Medical Team in conjunction with the event organisers decided to continue making this medical questionnaire a part of the registration process for 2013. The questionnaire is therefore included in the online registration process for completion by all runners.

The medical questionnaire consists of a series of yes/no questions relating to your medical history, previous medical complications during races or training and common running injuries. If you are healthy and have no injuries, it will take approximately 5 minutes to complete (a bit longer if there are medical details you need to enter). In the interests of your health and safety, the medical team may contact you before or after the race for further information about any medical conditions or injuries you may have.

Please take the necessary time and care to complete this section of the entry form as accurately as possible. In addition, at the end of this questionnaire, we will also ask you to consider that the medical information be used for on-going medical research so that we can continue with our effort to improve medical care and race safety.

Prof. Martin Schwellnus, and the rest of the Medical Team

Page 1 questions (all compulsory fields)

Please note that we require you to provide answers to all the questions

General running and training information

For how many years have you been a recreational runner?* (Please select from the dropdown box)		years
For how many years have you participated in distance races?* (Please select from the dropdown box)		years
In the last 12 months, on average, how many times a week do you run (train and race) (Please select from the dropdown box)?*		per week
In the last 12 months, what is your average weekly training distance in km?* (Please select from the dropdown box)		km/week
In the last 12 months, what is your average training speed? (Please select from the dropdown boxes – minutes box and seconds box) *		min/km
What is your current body weight (mass) to the nearest KILOGRAM?*		kg
What is your height in CENTIMETRES?*		cm

Page 2 questions (all compulsory fields)

General training surface information

In the past 12 months, please indicate the average percentage time that you run on a treadmill?		% time on treadmill
In the past 12 months, please indicate the average percentage time that you road running on tar/concrete/brick roads or surfaces?		% time on tar roads
In the past 12 months, please indicate the average percentage time that you do trail running on gravel roads (e.g. jeep tracks)?		% time on gravel roads
In the past 12 months, please indicate the average percentage time that you do trail running on footpaths/single tracks?		% time on footpaths / single tracks

Page 3 questions (yes/no compulsory)

Medical information

- **You will now be guided through a series of 17 questions that relate to your medical history**
- **The questions are mostly in a yes/no format and should take you only a few minutes to complete, unless you have medical conditions in which case you will be directed to provide more information**
- **Please read these questions carefully and complete the information as accurately as possible**

- **Please note that this information is vital for your safety on race day and for our planning of the medical care**
- **The information is NOT intended to prevent you from running on race day**
- **Please be as accurate and comprehensive as you can in providing this information**

Are you aware or have you ever been diagnosed with any risk factors for heart or blood vessel disease, including high blood cholesterol, a family member with heart disease, cigarette smoking, lack of physical activity, high blood pressure, being overweight or having diabetes mellitus (sugar sickness)?

- ○ Yes
- ○ No

If no response, go to next page

If yes response, then drop down the following box on same page (compulsory to select at least one)

Please tick the appropriate condition/s that you suffer/ed from

You may tick more than one box if needed

- ☐ High blood pressure
- ☐ High blood cholesterol
- ☐ Cigarette smoking
- ☐ Obesity (overweight)
- ☐ Diabetes mellitus
- ☐ Family history of heart disease (< 50 years)

Page 4 questions (yes/no compulsory)

Have you ever suffered from any heart or blood vessel conditions, including heart attack, undiagnosed chest pain, coronary artery bypass operation, angioplasty (balloon), heart failure, heart transplant, cardiac arrhythmia (abnormal heart beat), rheumatic fever, heart murmur, cardiomyopathy, myocarditis, use of a pacemaker or inherited heart defect?

- ○ Yes
- ○ No

If no response, go to next page

If yes response, then drop down the following box on same page (compulsory to select at least one)

Please tick the appropriate condition/s that you suffer/ed from (you may tick more than one box if needed)

- ☐ Myocardial infarct (heart attack)
- ☐ Chest pain that has been diagnosed as "angina"
- ☐ Coronary artery bypass graft (CABG)
- ☐ Angioplasty (no stent)
- ☐ Angioplasty (with stent)
- ☐ Heart failure
- ☐ Heart transplant
- ☐ Arrhythmia
- ☐ Rheumatic fever
- ☐ Heart murmur
- ☐ Cardiomyopathy
- ☐ Myocarditis
- ☐ Use of a pacemaker
- ☐ Inherited conditions of the heart or blood vessels
- ☐ Any other form of heart or blood vessel disease (please specify)

Page 5 questions (yes/no compulsory)

Do you currently suffer from any symptoms of heart or blood vessel disease including swollen ankles, abnormal shortness of breath (with exercise), chronic dry cough, palpitations, chest pain, pain (or discomfort) in the neck, jaw, or arms at rest or during exercise, dizziness, fainting spells, and/or calf pain when running/walking?

- ○ Yes
- ○ No

If no response, go to next page

If yes response, then drop down the following box on same page (compulsory to select at least one)

Please tick the appropriate condition/s that you suffer/ed from (you may tick more than one box if needed)

- ☐ Swollen ankles
- ☐ Water retention
- ☐ Shortness of breath when sitting or lying down
- ☐ Shortness of breath with mild exercise
- ☐ Waking up with shortness of breath at night
- ☐ Palpitations with no dizziness
- ☐ Palpitations that make you dizzy
- ☐ Chest pain when sitting
- ☐ Chest pain when performing exercise
- ☐ Chest pain when you are emotionally stressed
- ☐ Pain (or discomfort) in the neck, jaw, arms at rest or during exercise
- ☐ Dizziness during exercise
- ☐ Fainting spells
- ☐ Chronic dry cough
- ☐ Painful calves when walking

Page 6 questions (yes/no compulsory)

Have you ever collapsed (fell down not because of an accident, needing medical attention) during, at the finish or after a race or training session?

- ○ Yes
- ○ No

If no response, go to next page

If yes response, then drop down the following questions on the same page (compulsory to select / complete fields)

Have you ever collapsed during training or racing?

- ○ Training
- ○ Racing
- ○ Training and racing

How many times have you collapsed in training session or races during the last five years?

races:

training session:

How many times have you collapsed in training session or races during the last 12 months (1 year)?

When you collapse, does it mostly occur before or after the finish line / completion of the training session?

- Before the finish
- After the finish

What is the cause of your collapse?

- Dehydration
- Heat illness
- Hyponatraemia
- Low blood pressure
- Low blood sugar
- Other condition, please specify

Page 7 questions (yes/no compulsory)

Have you ever in your running career suffered from muscle cramping (painful, spontaneous, sustained spasm of a muscle) during or immediately (within 6 hours) after running (in training or competition)?

- Yes
- No

If no response, go to next page

If yes response, then drop down the following questions on the same page (compulsory to select / complete fields) – may need to split over two pages as there are a number of questions

For how many years have you suffered from cramping?

Did you suffer from cramping during or after running in the last 12 months?

- Yes
- No

In the last 10 races or training sessions, how many times have you experienced cramping?

Races /10:

Training sessions /10:

What treatment/s have you had that successfully relieved an acute cramp?

You can tick more than one

- Stretching
- Resting
- Drinking fluid
- Ice application
- Massage
- Magnesium
- Salt (tablets or solution)
- Other, please specify

At what point in the race or training run do you usually first experience cramping?

- First quarter
- Second quarter
- Third quarter
- Fourth quarter
- After the race
- No pattern

- [ ] Other, please specify

In which muscle do you usually cramp?

Please tick the muscle in which cramps most frequently occur

- [ ] Calves
- [ ] Hamstrings
- [ ] Quadriceps (thigh)
- [ ] Foot muscles
- [ ] Other, please specify

Have you ever suffered from cramping in your whole body (arms and legs)?

- ○ Yes
- ○ No

Have you ever been admitted to hospital following cramping?

- ○ Yes
- ○ No

Have you ever been confused or in a coma during or after a cramping episode?

- ○ Yes
- ○ No

Have you ever had "dark urine" in the 3 days following a cramping episode?

- ○ Yes
- ○ No

If you cramp, how severe is the cramp usually?

Please tick one box

- ○ Mild: < 5 minutes and you are able to continue exercising
- ○ Moderate: 5-15 minutes and you are able to continue exercising

- Severe: >15 minutes or if you have to STOP exercising

Page 8 questions (yes/no compulsory)

Do you currently suffer from any metabolic or hormonal disease including diabetes mellitus, thyroid gland disorders, hypoglycaemia (low blood sugar), hyperglycaemia (high blood sugar), or heat intolerance?

- Yes
- No

If no response, go to next page

If yes response, then drop down the following box on same page (compulsory to select at least one)

Please tick the appropriate condition/s that you suffer/ed from

You may tick more than one box if needed

- Hyperglycaemia (high blood sugar) (Pre-diabetes)
- Type 1: Insulin dependent (Diabetes Mellitus)
- Type 2: Non insulin dependent (Diabetes Mellitus)
- Underactive thyroid (hypothyroidism)
- Overactive thyroid (hyperthyroidism)
- Hypoglycaemia (low blood sugar)
- Heat intolerance

Page 9 questions (yes/no compulsory)

Do you suffer from any respiratory (lung) disease including asthma, emphysema (COPD), wheezing, cough, postnasal drip, hay fever, or repeated flu like illness?

- Yes
- No

If no response, go to next page

If yes response, then drop down the following box on same page (compulsory to select at least one)

Please tick the appropriate condition/s that you suffer/ed from

You may tick more than one box if needed

- ☐ Asthma (Non exercise-induced)
- ☐ Asthma (Exercise-induced)
- ☐ Wheezing during exercise
- ☐ Cough during exercise
- ☐ Post nasal drip
- ☐ Allergies/hay fever (ear, nose, throat)
- ☐ Repeated infections in respiratory tract
- ☐ Previous lung complaints
- ☐ COPD (Chronic obstructive pulmonary disease)
- ☐ Interstitial lung disease
- ☐ Cystic fibrosis
- ☐ Other respiratory complaints

Page 10 questions (yes/no compulsory)

Do you suffer from any gastrointestinal disease including heartburn, nausea, vomiting, abdominal pain, weight loss or gain (> 5kg), a change in bowel habits, chronic diarrhoea, blood in the stools, or past history of liver or gallbladder disease?

- ○ Yes
- ○ No

If no response, go to next page

If yes response, then drop down the following box on same page (compulsory to select at least one)

Please tick the appropriate condition/s that you suffer/ed from

You may tick more than one box if needed

- ☐ Heartburn
- ☐ Nausea/vomiting

- [ ] Abdominal pain
- [ ] Weight loss (>5kg) in the last 2 years
- [ ] Weight gain (>5kg) in the last 2 years
- [ ] A change in bowel habits over the last year
- [ ] Chronic diarrhoea
- [ ] Blood in stool
- [ ] Abdominal complaints during exercise
- [ ] Liver/gallbladder disease
- [ ] Other gastrointestinal complaints

Page 11 questions (yes/no compulsory)

Do you suffer from any diseases of the nervous system including past history of stroke or transient ischaemic attack (TIA), frequent headaches, epilepsy, depression, anxiety attacks, muscle weakness, nerve tingling, loss of sensation, or chronic fatigue?

- ○ Yes
- ○ No

If no response, go to next page

If yes response, then drop down the following box on same page (compulsory to select at least one)

Please tick the appropriate condition/s that you suffer/ed from

You may tick more than one box if needed

- [ ] Stroke or transient ischaemic attack
- [ ] Frequent headaches
- [ ] Epilepsy
- [ ] Depression
- [ ] Anxiety attacks
- [ ] Other psychological/psychiatric conditions
- [ ] Muscle weakness
- [ ] Nerve tingling/loss of sensation

- [ ] Chronic fatigue
- [ ] Other nervous system complaints

Page 12 questions (yes/no compulsory)

Do you suffer from any disease of the kidney or bladder including past history of kidney or bladder disease, blood in the urine, loin pain, kidney stones, frequent urination, or burning during urination?

- ○ Yes
- ○ No

If no response, go to next page

If yes response, then drop down the following box on same page (compulsory to select at least one)

Please tick the appropriate condition/s that you suffer/ed from

You may tick more than one box if needed

- [ ] Past history of kidney disease
- [ ] Past history of bladder disease
- [ ] History of blood in the urine
- [ ] Chronic loin pain
- [ ] History of kidney stones
- [ ] Frequent urination
- [ ] Burning during urination

Page 13 questions (yes/no compulsory)

Do you suffer from any disease of the blood or immune system including anaemia, recurrent infections, HIV/AIDS, leukaemia, or are you using any immunosuppressive medication?

- ○ Yes
- ○ No

If no response, go to next page

If yes response, then drop down the following box on same page (compulsory to select at least one)

Please tick the appropriate condition/s that you suffer/ed from

You may tick more than one box if needed

- ☐ Past history of anaemia
- ☐ Past history of cancer of the blood cells (leukaemia)
- ☐ Past history of cancer of the lymphatic system (lymphoma)
- ☐ Past history of blood disorders
- ☐ History of HIV/AIDS
- ☐ History of a depressed immune system

Page 14 questions (yes/no compulsory)

Do you suffer from any growths or cancer including a past history of cancer?

- ○ Yes
- ○ No

If no response, go to next page

If yes response, then drop down the following box on same page (compulsory to select at least one)

Please tick the appropriate condition/s that you suffer/ed from

You may tick more than one box if needed

- ☐ Past history of cancer
- ☐ Current undiagnosed growth

Page 15 questions (yes/no compulsory)

Do you suffer from any allergies including a past history of allergies to medication, plant material or animal material?

- ○ Yes
- ○ No

If no response, go to next page

If yes response, then drop down the following box on same page (compulsory to select at least one)

Please tick the appropriate condition/s that you suffer/ed from

You may tick more than one box if needed

- ☐ Past history of allergies to medication
- ☐ Past history of allergies to plant material
- ☐ Past history of allergies to animal material
- ☐ History of any other allergies

Page 16 questions (yes/no compulsory)

At the moment, do you use any prescribed medication on a daily, weekly or monthly basis to treat chronic (long-term) medical conditions or injuries?

- ○ Yes
- ○ No

If no response, go to next page

If yes response, then drop down the following box on same page (compulsory to select at least one)

Pease tick the type of medication/s that you are taking from the list below:

You may tick more than one box if needed. If your medication type is not on the list please enter it in the free text box that is below the list.

- ☐ Cholesterol lowering medication
- ☐ Blood pressure lowering medication
- ☐ Medication to control heart rhythm
- ☐ Medication to treat heart failure
- ☐ Other medication to treat heart disease
- ☐ Medication (tablets) to treat type 2 diabetes
- ☐ Insulin for diabetes
- ☐ Medication to treat anxiety
- ☐ Anti-depressant medication

- [ ] Anti-asthma medication
- [ ] Other medication (please list in box below)

Page 17 questions (yes/no compulsory)

Have you ever in your running career used medicines to treat injuries in the week before or during a race – including anti-inflammatory drugs, cortisone (pills, or injection), or pain killers?

- ○ Yes
- ○ No

If no response, go to next page

If yes response, then drop down the following boxes on same page (compulsory to select at least one)

Which of the following medicines have you used in the past to treat an injury in the week just BEFORE a race?

- [ ] Paracetamol (e.g. Panado, Tylenol)
- [ ] Non-steroidal anti-inflammatories (e.g. Voltaren, Cataflam)
- [ ] Cortisone (pills)
- [ ] Cortisone injection
- [ ] Codeine
- [ ] Anti-inflammatory gels/creams/patches
- [ ] Any other pain killers

Which of the following medicines have you used in the past to treat an injury DURING a race?

- [ ] Paracetamol (e.g. Panado, Tylenol)

- [ ] Non-steroidal anti-inflammatories (e.g. Voltaren, Cataflam)
- [ ] Cortisone (pills)
- [ ] Cortisone injection
- [ ] Codeine
- [ ] Anti-inflammatory gels/creams/patches
- [ ] Any other pain killers

Page 18a questions (yes/no compulsory)

If no, proceed to Page 19

If yes, proceed to 18b

Do you or did you suffer from any symptoms of a running injury (muscles, tendons, bones, ligaments or joints) IN YOUR RUNNING CAREER?

(NB: Only if an injury is/was severe enough to interfere with running, or require treatment e.g. use medication, or require you to seek medical advice from a health professional)

- ○ Yes
- ○ No

Injury 1

Page 18b questions (yes/no compulsory)

Do you or did you suffer from any symptoms of a running injury (muscles, tendons, bones, ligaments or joints) IN THE PAST 12 MONTHS OR CURRENTLY?

(NB: Only if an injury is/was severe enough to interfere with running, or require treatment e.g. use medication, or require you to seek medical advice from a health professional)

- ○ Yes
- ○ No

If no response to 18b, go to next page

If yes response to 18b, then drop down the following box on same page (compulsory to select at least one)

Pease tick if past or current:

- ○ Past
- ○ Current

How long ago did you first become aware of the injury? (months)

[ ]

Please indicate which side of your body is injured (if applicable)

- ○ Right
- ○ Left
- ○ Both

Please indicate which anatomical area is/was injured (single select)

- ☐ Head
- ☐ Neck
- ☐ Face
- ☐ Front chest
- ☐ Back chest
- ☐ Shoulder
- ☐ Upper arm
- ☐ Elbow
- ☐ Forearm
- ☐ Wrist
- ☐ Finger
- ☐ Lower back
- ☐ Hip
- ☐ Groin muscle
- ☐ Hip muscle (including gluteus / buttock muscles)
- ☐ Hamstring muscle

- [ ] Quadriceps muscle
- [ ] Calf muscle
- [ ] Knee
- [ ] Shin / Lower leg
- [ ] Achilles
- [ ] Ankle
- [ ] Foot
- [ ] Other, please specify

Please indicate the type of structure that was injured (single select)

- [ ] Muscle (e.g. strain)
- [ ] Ligament (e.g. sprain)
- [ ] Tendon
- [ ] Joint (e.g. arthritis)
- [ ] Bone (e.g. bruise or stress fracture)
- [ ] Other, please specify

Please indicate if your injury was any of the following common running injuries (single select)

- [ ] Patellofemoral pain
- [ ] Iliotibial band (ITB)
- [ ] Plantar fasciitis
- [ ] Achilles tendon injury
- [ ] Lower back pain
- [ ] Hip muscle injury (including gluteus / buttock muscles)
- [ ] Hamstring injury
- [ ] Quadriceps muscle injury
- [ ] Calf muscle injury
- [ ] Shin splints (bone)
- [ ] Shin splints (muscle/tendon)
- [ ] Lower leg compartment syndrome

- [ ] Foot pain
- [ ] Heel pain
- [ ] Other, please specify

Please indicate the severity of the injury

- ○ I only experience symptoms after exercise
- ○ I experience symptoms during exercise, but it does not interfere with exercise
- ○ I experience symptoms during exercise that may interfere with my training/ competition
- ○ I am so painful that I may not be able to train or compete

Please indicate how your injury was treated to date (you can tick more than one)?

- [ ] Rest
- [ ] Tablets
- [ ] Stretches
- [ ] Cortisone injection
- [ ] Physiotherapy
- [ ] Other injection
- [ ] Surgery
- [ ] Orthotics
- [ ] Strengthening exercises
- [ ] Equipment change

Would you like to list another important injury?

- ○ Yes
- ○ No

If no response, go to next page

If yes response, then drop down the following box on same page (compulsory to select at least one)

(At this point, there is an option to complete details for more than one injury using the same data capture procedure for the first injury)

Page 19 questions (yes/no compulsory) (Can this question only come up after certain questions – listed in email)

Have you consulted with a medical doctor in the last 12 months to obtain medical clearance that you can safely participate in endurance running?

- ○ Yes
- ○ No

If no response, go to next page

If yes response, then drop down the following box on same page (compulsory to select at least one)

If yes, please indicate which of the following procedure formed part of the medical assessment for clearance to participate in endurance running? (you may tick more than one box if needed)

- ☐ Your doctor spoke to you only
- ☐ Your doctor spoke to you and examined you physically
- ☐ You performed an exercise test but no ECG (electrical leads attached to your chest to measure the hearts response to exercise)
- ☐ You performed an exercise test with an ECG (electrical leads attached to your chest to measure the hearts response to exercise)
- ☐ You had an echocardiogram (a sonar of the heart to examine the structure of the heart)
- ☐ You had blood tests for cholesterol
- ☐ You had other blood tests
- ☐ You had other tests (please specify)

After seeing your medical practitioner please indicate which of the following applied?

- ○ My doctor did not give clearance for me to run
- ○ My doctor did give clearance for me to run but with some restrictions and guidelines on safe participation
- ○ My doctor did give clearance to run with no restrictions

Exercise and symptoms of an acute infection

Symptoms of acute illness and infections such as flu, gastro-enteritis (upset stomach) and other infections (e.g. bladder) are more common in athletes just before a race (after periods of peak training). Exercising with symptoms of an infection can increase the risk of medical complications during the race.

The symptoms of infections vary but include the following: generally not feeling well, fever, general muscle pain, general joint pain, general tiredness, headache, sore throat, blocked or runny nose, sore ears, cough, wheeze, diarrhoea, nausea, vomiting, or abdominal cramps/pain.

Please answer the following question so that we can give you advice:

Question 1:

Do you have any of these symptoms of acute illness (today or in the last 7 days)?

No ☐

Yes ☐

Question 2: Symptoms of an acute infection or illness (if yes to question 1)

Symptoms of an acute infection or illness You indicated that you have symptoms of an acute illness **(today or in the last 7 days)** **Please indicate which symptoms do you have?** (Please tick on all the symptoms you have i.e. you may chose more than one) (Based on your responses, you will be sent some information to assist you)	☐ Fever ☐ Sore throat ☐ Runny nose ☐ Blocked nose ☐ Sore ears ☐ Wheezing ☐ Cough ☐ General muscle pains ☐ General joint pains ☐ Headache ☐ General tiredness ☐ Nausea ☐ Vomiting ☐ Diarrhoea ☐ Abdominal pain or cramps ☐ Skin rash / infection ☐ Symptoms of a bladder infection ☐ Any other symptoms (Please specify:)_____

APPENDIX B: PARTICIPANT INFORMATION AND CONSENT FORM

Page 20 questions (yes/no compulsory)

Consent for medical information to be used for research purposes

You do also have the opportunity to volunteer that the information on these medical questionnaires can be used for ongoing medical and scientific research to improve race safety and medical care.

The Clinical Sport and Exercise Medicine Research Group of the UCT/MRC Research Unit for Exercise Science and Sports Medicine based at the Sports Science Institute of South Africa, in collaboration with the race organizers and the medical team conducts on-going research to improve race safety (protecting the health of the athlete and reducing injury risk). Your participation in this research effort is to improve safety and is entirely voluntary. Please read through the Participant information and then you will be given the opportunity to consent that your information in the medical questionnaires can be included in research studies, and that you can be contacted about participating in other components of the research project that relate to muscle cramps and injuries.

Participant information of the research studies:

The main aim of these studies is to determine if there are any factors that can be identified before the race that will predict whether an athlete is likely to develop a medical problem (including cramps and injuries) during or after the race. The details of the studies are as follows:

At the race entry and registration, a web-based (or a paper-based) questionnaire detailing personal particulars and medical information, will be completed as part of the race entry and race registration requirements.

The completion of a questionnaire is not associated with any risk. Questionnaire and other clinical data (paper and electronic) will be kept confidential, will be kept secure, and will not be made available to any party other than the medical and research team without the consent of the individual participant.

You may be contacted before or after the race (by telephone or email), for further information, advice and participation in research related to injuries or a medical condition (such as cramps) that you developed before, during or after the race.

Volunteering to make medical information available for ongoing research has no direct benefit to an individual athlete. However, the long term anticipated benefits of this research are to identify factors that may predispose an increased risk of medical consequences and injury in endurance athletes. This information will eventually assist athletes in decreasing their risk of medical complications and injuries during racing and training.

Consent to participate in the research study

I understand that I am free to volunteer to participate in the study on pre-race predictors (including medical history, medication use, and injuries) of medical complications that may occur in runners before, during and immediately after the race

I understand that my participation in this research project may have no direct benefits to me during the race. However, I understand that my participation in the research project will advance the medical and scientific knowledge related to endurance sports. Therefore, information gathered through my participation in this project could advance the future medical care, training advice and performance of endurance athletes.

I have read the participant information and am satisfied that the procedures and concepts have been explained to me in full.

I agree that all the questionnaire information, my performance during the race, together with all the other data collected from the various components of this study may be used to answer scientific questions about the medical conditions, injuries, physiological responses and measures of performance associated with the preparation, participation in and completion of a race.

I have been informed that the individual data derived from my participation will remain confidential

I understand that the data obtained from this study may be used for the research components of higher degrees at the University of Cape Town.

I understand that the Research Ethics Committee of the Faculty of Health Sciences at the University of Cape Town has approved the protocol for this research study (REC number 441/2012).

I understand that this research study will be covered by a liability insurance policy with the University of Cape Town, but that this cover only applies to illness and injury as a result of the research study and not as a result of participating in the race.

I understand that each of the medical practitioners involved in the research study on athletes will have up to date professional medical insurance.

I understand that I can contact members of the research team should I have any questions related to the study. Contact details of the research team are as follows: +27 21 650 4567

I hereby consent to participate in this study, and that I can be contacted for information about research studies on injuries and muscle cramping.

I understand that I may withdraw from this study at any time without further question.

Consent to allow medical information in this questionnaire to be used in ongoing research

☐ Yes, I give consent that the information from the medical questionnaires can be used in ongoing research

☐ No, I do not give consent that the information form the medical questionnaires can be used in ongoing research

APPENDIX C: ETHICAL APPROVAL FOR THE ORIGINAL STUDY (REC NUMBER: 433/2015)

The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federal wide Assurance.
- FWA 00002567, Approved dd 22 May 2002 and Expires 20 Oct 2016.
- IRB 0000 2235 IORG0001762 Approved dd 22/04/2014 and Expires 22/04/2017.

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Health Sciences Research Ethics Committee

1/10/2015

Approval Certificate
New Application

Ethics Reference No.: 433/2015

Title: MEDICAL CONSEQUENCES IN ENDURANCE SPORTS. TWO OCEANS MARATHON LONGITUDINAL STUDY: 2009-2015

Dear Martin Schwellnus

The **New Application** as supported by documents specified in your cover letter dated 27/08/2015 for your research received on the 31/08/2015, was approved by the Faculty of Health Sciences Research Ethics Committee on its quorate meeting of 30/09/2015.

Please note the following about your ethics approval:
- Ethics Approval is valid for 5 years
- Please remember to use your protocol number (**433/2015**) on any documents or correspondence with the Research Ethics Committee regarding your research.
- Please note that the Research Ethics Committee may ask further questions, seek additional information, require further modification, or monitor the conduct of your research.

Ethics approval is subject to the following:
- The ethics approval is conditional on the receipt of 6 monthly written Progress Reports, and
- The ethics approval is conditional on the research being conducted as stipulated by the details of all documents submitted to the Committee. In the event that a further need arises to change who the investigators are, the methods or any other aspect, such changes must be submitted as an Amendment for approval by the Committee.

We wish you the best with your research.

Yours sincerely

*** Kindly collect your original signed approval certificate from our offices, Faculty of Health Sciences, Research Ethics Committee, H W Snyman South Building, Room 2.33 / 2.34.*

Dr R Sommers; MBChB; MMed (Int); MPharMed.
Deputy Chairperson of the Faculty of Health Sciences Research Ethics Committee, University of Pretoria

The Faculty of Health Sciences Research Ethics Committee complies with the SA National Act 61 of 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 and 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes 2004 (Department of Health).

☎ 012 354 1677 🖷 0866516047 deepeka.behari@up.ac.za http://www.healthethics-up.co.za
✉ Private Bag X323, Arcadia, 0007 - 31 Bophelo Road, HW Snyman South Building, Level 2, Room 2.33, Gezina, Pretoria

APPENDIX D: ETHICAL APPROVAL FOR THE ORIGINAL STUDY (REC NUMBER: 431/2015)

The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federal wide Assurance.
- FWA 00002567, Approved dd 22 May 2002 and Expires 20 Oct 2016.
- IRB 0000 2235 IORG0001762 Approved dd 22/04/2014 and Expires 22/04/2017.

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Health Sciences Research Ethics Committee

29/10/2015

Approval Certificate
New Application

Ethics Reference No.: 431/2015

Title: Reducing Medical Complications and Injuries at Endurance Sports Events: A 5-year Longitudinal Study (2016-2020) SAFER STUDIES

Dear Martin Schwellnus

The **New Application** as supported by documents specified in your cover letter dated 16/10/2015 for your research received on the 16/10/2015, was approved by the Faculty of Health Sciences Research Ethics Committee on its quorate meeting of 28/10/2015.

Please note the following about your ethics approval:
- Ethics Approval is valid for 5 years
- Please remember to use your protocol number (**431/2015**) on any documents or correspondence with the Research Ethics Committee regarding your research.
- Please note that the Research Ethics Committee may ask further questions, seek additional information, require further modification, or monitor the conduct of your research.

Ethics approval is subject to the following:
- The ethics approval is conditional on the receipt of 6 monthly written Progress Reports, and
- The ethics approval is conditional on the research being conducted as stipulated by the details of all documents submitted to the Committee. In the event that a further need arises to change who the investigators are, the methods or any other aspect, such changes must be submitted as an Amendment for approval by the Committee.

We wish you the best with your research.

Yours sincerely

*** Kindly collect your original signed approval certificate from our offices, Faculty of Health Sciences, Research Ethics Committee, H W Snyman South Building, Room 2.33 / 2.34.*

Dr R Sommers; MBChB; MMed (Int); MPharMed.
Deputy Chairperson of the Faculty of Health Sciences Research Ethics Committee, University of Pretoria

The Faculty of Health Sciences Research Ethics Committee complies with the SA National Act 61 of 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 and 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes 2004 (Department of Health).

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APPENDIX E: PERMISSION TO USE THE DATA

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Health Sciences

Professor Martin Schwellnus
MBBCh, MSc (Med), MD, FACSM, FFIMS
Director: Institute for Sport, Exercise Medicine and Lifestyle Research
Faculty of Health Sciences
University of Pretoria
South Africa

9 August 2019

To: Chair: Masters Committee / Research Ethics Committee
University of Pretoria

Professor Martin Schwellnus
MBBCh, MSc (Med), MD, FACSM, FFIMS
Director: Sport, Exercise Medicine and Lifestyle Institute (SEMLI)
Director: IOC Research Center, South Africa
Faculty of Health Sciences
University of Pretoria
South Africa

Letter of permission to access data for research

This letter is to confirm that Prof Martin Schwellnus of the University of Pretoria is the principle investigator of the project with the title "**Medical consequences in endurance sports. Two Oceans marathon longitudinal study: 2009-2015**" and "**Reducing Medical Complications and Injuries at Endurance Sports Events: A 5-year Longitudinal Study (2016-2020) SAFER STUDIES"**. These studies have Research Ethics clearance from the Faculty of Health Sciences Research Ethics Committee at the University of Pretoria (REC reference number: 433/2015, 431/2015).

A master's student, Ms Chanel Booyzen (Student#:13004842), will be conducting a study, in fulfillment of an "MSc Sport Science (Biokinetics)" degree at the University of Pretoria, on a sub-component of the study above. The focus of her study will be **"Identifying leisure athletes at high risk for medical complications using five international pre-exercise screening tools"**.

I hereby give permission that the student can conduct novel research on the raw dataset, and therefore can access the data that were collected for the study.

Please feel free to contact me if any further information is required.

Yours sincerely

Prof. Martin Schwellnus (MBBCh, MSc(Med), MD, FACSM. FFIMS)
Full Professor: Sport and Exercise Medicine
Faculty of Health Sciences
University of Pretoria
South Africa

APPENDIX F: ETHICAL APPROVAL

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Health Sciences

Institution: The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federal wide Assurance.
- FWA 00002567, Approved dd 22 May 2002 and Expires 03/20/2022.
- IORG #: IORG0001762 OMB No. 0990-0279 Approved for use through February 28, 2022 and Expires: 03/04/2023.

15 April 2021

Approval Certificate
Annual Renewal

Ethics Reference No.: 683/2019
Title: Identifying leisure athletes at high risk for medical complications using five international pre-exercise screening tools.

Dear Ms C Booyzen

The **Annual Renewal** as supported by documents received between 2021-03-25 and 2021-04-14 for your research, was approved by the Faculty of Health Sciences Research Ethics Committee on 2021-04-14 as resolved by its quorate meeting.

Please note the following about your ethics approval:
- Renewal of ethics approval is valid for 1 year, subsequent annual renewal will become due on 2022-04-15.
- Please remember to use your protocol number (683/2019) on any documents or correspondence with the Research Ethics Committee regarding your research.
- Please note that the Research Ethics Committee may ask further questions, seek additional information, require further modification, monitor the conduct of your research, or suspend or withdraw ethics approval.

Ethics approval is subject to the following:
- The ethics approval is conditional on the research being conducted as stipulated by the details of all documents submitted to the Committee. In the event that a further need arises to change who the investigators are, the methods or any other aspect, such changes must be submitted as an Amendment for approval by the Committee.

We wish you the best with your research.

Yours sincerely

Professor Werdie (CW) Van Staden
MBChB MMed(Psych) MD FCPsych(SA) FTCL UPLM
***Chairperson**: Faculty of Health Sciences Research Ethics Committee*

The Faculty of Health Sciences Research Ethics Committee complies with the SA National Act 61 of 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 and 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes, Second Edition 2015 (Department of Health)

Research Ethics Committee
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www.up.ac.za

Fakulteit Gesondheidswetenskappe
Lefapha la Disaense tša Maphelo

APPENDIX G: DECLARATION OF HELSINKI

Special Communication

World Medical Association Declaration of Helsinki
Ethical Principles for Medical Research Involving Human Subjects

World Medical Association

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended by the:
29th WMA General Assembly, Tokyo, Japan, October 1975
35th WMA General Assembly, Venice, Italy, October 1983
41st WMA General Assembly, Hong Kong, September 1989
48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
52nd WMA General Assembly, Edinburgh, Scotland, October 2000
53rd WMA General Assembly, Washington, DC, USA, October 2002 (Note of Clarification added)
55th WMA General Assembly, Tokyo, Japan, October 2004 (Note of Clarification added)
59th WMA General Assembly, Seoul, Republic of Korea, October 2008
64th WMA General Assembly, Fortaleza, Brazil, October 2013

Preamble

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.

   The Declaration is intended to be read as a whole and each of its constituent paragraphs should be applied with consideration of all other relevant paragraphs.

2. Consistent with the mandate of the WMA, the Declaration is addressed primarily to physicians. The WMA encourages others who are involved in medical research involving human subjects to adopt these principles.

General Principles

3. The Declaration of Geneva of the WMA binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act in the patient's best interest when providing medical care."

4. It is the duty of the physician to promote and safeguard the health, well-being and rights of patients, including those who are involved in medical research. The physician's knowledge and conscience are dedicated to the fulfilment of this duty.

5. Medical progress is based on research that ultimately must include studies involving human subjects.

6. The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best proven interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.

7. Medical research is subject to ethical standards that promote and ensure respect for all human subjects and protect their health and rights.

8. While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.

9. It is the duty of physicians who are involved in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects. The responsibility for the protection of research subjects must always rest with the physician or other health care professionals and never with the research subjects, even though they have given consent.

10. Physicians must consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.

11. Medical research should be conducted in a manner that minimises possible harm to the environment.

12. Medical research involving human subjects must be conducted only by individuals with the appropriate ethics and scientific education, training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional.

APPENDIX H: DECLARATION OF ORIGINALITY

DECLARATION OF ORIGINALITY

UNIVERSITY OF PRETORIA

The Department of **Physiology** places great emphasis upon integrity and ethical conduct in the preparation of all written work submitted for academic evaluation.

While academic staff teach you about referencing techniques and how to avoid plagiarism, you too have a responsibility in this regard. If you are at any stage uncertain as to what is required, you should speak to your lecturer before any written work is submitted.

You are guilty of plagiarism if you copy something from another author's work (eg a book, an article or a website) without acknowledging the source and pass it off as your own. In effect you are stealing something that belongs to someone else. This is not only the case when you copy work word-for-word (verbatim), but also when you submit someone else's work in a slightly altered form (paraphrase) or use a line of argument without acknowledging it.

You are not allowed to use work previously produced by another student. You are also not allowed to let anybody copy your work with the intention of passing if off as his/her work.

Students who commit plagiarism will not be given any credit for plagiarised work. The matter may also be referred to the Disciplinary Committee (Students) for a ruling. Plagiarism is regarded as a serious contravention of the

University's rules and can lead to expulsion from the University.

The declaration which follows must accompany all written work submitted while you are a student of the Department of **Physiology**. No written work will be accepted unless the declaration has been completed and attached.

Full names of student: Ms C Smith

Student number: 13004842

Topic of work: Identifying leisure athletes at high risk for medical complications using five international pre-exercise screening tools

Declaration

1. I understand what plagiarism is and am aware of the University's policy in this regard.

2. I declare that this **dissertation** (eg essay, report, project, assignment, dissertation, thesis, etc) is my own original work. Where other people's work has been used (either from a printed source, Internet or any other source), this has been properly acknowledged and referenced in accordance with departmental requirements.

3. I have not used work previously produced by another student or any other person to hand in as my own.

4. I have not allowed, and will not allow, anyone to copy my work with the intention of passing it off as his or her own work.

SIGNATURE