Do five screening tools identify the same number of runners who require preexercise medical clearance? SAFER XXXIV

Running Title: Variation in pre-exercise screening questionnaires

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ABSTRACT

Objectives: Currently there are five international screening tools that are recommended to identify individuals who require pre-exercise medical clearance to reduce the risk of medical encounters during exercise. Therefore, the aim was to determine the percentage of race

entrants who are advised to obtain pre-exercise medical clearance and the observed agreement between these five different international pre-exercise medical screening tools. **Methods:** 76654 race entrants from the Two Oceans Marathon (2012–2015) that completed an online pre-race screening questionnaire. Five pre-exercise medical screening tools (American Heart Association (AHA), pre-2015 American College of Sport Medicine (ACSM), post-2015 ACSM, Physical Activity Readiness Questionnaire (PAR-Q), and the European Association of Cardiovascular Prevention and Rehabilitation (EACPR)) were retrospectively applied to all participants. The % (95%CI) race entrants requiring medical clearance identified by each tool and the observed agreement between tools (%) was determined.

Results: The % entrants requiring medical clearance varied from 6.7-33.9% between the five tools: 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 observed agreement was highest between the pre-2015 ACSM and EACPR (35.4%), for pre-2015 ACSM and PAR-Q (24.8%), PAR-Q and EACPR (24.8%), and lowest between the post-2015 ACSM and AHA (4.1%).

Conclusion: The percentage of race entrants identified to seek medical clearance (and observed agreement), varied considerably between pre-exercise medical screening tools. Further research should determine which tool has the best predictive ability in identifying those at higher risk of medical encounters during exercise.

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

INTRODUCTION

Even though the numerous health benefits 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 high-intensity exercise. The absolute risk of sudden death 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 non-cardiac serious life-threatening and moderate medical complications, including exertional heatstroke and acute kidney injury.[3] In order to decrease the likelihood of medical encounters (MEs) during an event or race, it is important to identify athletes who are at a higher risk for medical complications before they participate in endurance sports events.

There are various pre-exercise medical screening questionnaires / guidelines (referred to as "tools" hereafter) proposed by international professional medical bodies to identify individuals who may be at higher risk for medical complications during exercise including: 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 use different combinations of screening questions and algorithms, however the "outcome measure" is the same: *identify individuals who should seek medical clearance before exercising*. The 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 guidelines include the participant's medical history and identified CVD risk factors.[6] The post-2015 ACSM guidelines include the participant's medical history 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 to determine whether exercise participants would be able to engage in exercise or become more physically active. If any positives are recorded, it is recommended that medical clearance is required.[8] The EACPR guideline, which is one of the most comprehensive pre-exercise medical screening tools, requires health-related information, such as CVD symptoms, history of CVD, CVD risk factors and medication usage.[9,10] The EACPR is largely a combination of the pre-2015 ACSM and PAR-Q.[9]

There are no studies to date that have determined whether these different tools identify the same individuals that require pre-exercise medical clearance i.e. being at "higher risk" for medical complications during exercise. From a practical point of view, it is therefore unclear if the guidelines identify the same number and same individuals.

Therefore, the primary aim of this study was to determine the frequency of race entrants who are advised to obtain pre-exercise medical clearance when applying five different international pre-exercise medical screening tools, and the observed agreement between these tools. A secondary aim of the study was to determine which specific variables (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. This information is important for clinical decision making when selecting the most appropriate pre-exercise medical screening tool. We hypothesise that there will be large variation between the various screening tools in terms of the number of athletes identified requiring medical clearance.

MATERIALS AND METHODS

Study design and ethical considerations

This descriptive cross-sectional study of data collected from recreational endurance runners forms part of a larger research programme known as the SAFER (<u>S</u>trategies to reduce <u>A</u>dverse medical events <u>F</u>or the <u>E</u>xercise<u>R</u>) studies.[11] The study was approved by the Research Ethics Committees of the Faculty of Health Sciences at the respective university.

Participants (selection and description)

The Two Oceans Marathon takes place annually in Cape Town (South Africa) and consists of two race distances (21.1km and 56km) and attracts approximately 25 000 runners each year.[10]

Data collection

The completion of an online pre-exercise medical screening questionnaire was a mandatory component of the entry process to the races held from 2012-2015.[12] This questionnaire was developed for the SAFER studies and was based on questions 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 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/renal disease, immune system/haematological disease, and cancer); allergies; history of prescription medication use; and history of musculoskeletal injury.[2] The questionnaire has previously been described in detail.[2] Using the information collected by this bespoke 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 (see Supplementary Document for detailed analysis of the

questionnaires). An algorithm was developed for each of the five pre-exercise screening tools (using the questions from each of the five tools matched to the questions asked in the bespoke questionnaire) to identify individuals as 1) required to obtain medical clearance based on each of the five questionnaires' unique criteria, 2) not required to obtain medical clearance (mutually exclusive categories, and each participant is classified into one of the two).

Outcomes

The primary measure of outcome was the % 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 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. The third measure of outcome was the observed agreement (%) between the results from each of the different tools.

Statistical analysis

The race entrant demographic and pre-exercise medical screening data on race entrants was entered on an Excel spreadsheet (Microsoft 2010) and analysed using the SAS 9.4 software statistical programme. The demographic data was described using frequency analysis. Using the responses to all the questions relating to demographic (age group 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 requiring medical clearance was calculated (with 95% Cl). The statistical significance level is 5%, unless specified otherwise. 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. 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. The observed (overall and positive category) agreement was calculated for each screening tool to be able to compare the results (%). Kappa agreement values are not reported due to the large difference in marginals.

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 demographics of all the race entrants and consenting race entrants are shown in Table 1.

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

		All race entrants (n=106743)		• •	Study participants: consenting race entrants (n=76654)	
		n	%	n	%	p-value
Race distance	21.1km	64 740	60.7	47 069	61.4	0.0011*
	56km	42 003	39.4	29 585	38.6	0.0011
Sex	Males	61 815	57.9	44 042	57.5	0.0520
	Females	44 928	42.1	32 612	42.5	
Age categories	<u><</u> 30 years	27 710	26.0	20 168	26.3	
	31–40 years	35 049	32.8	25 045	32.7	0.3643
	41–50 years	26 964	25.3	19 340	25.2	
	\geq 50 years	17 020	15.9	12 101	15.8	

 Table 1: Demographics of all race entrants and of those who consented to their data being used for this study

*Study participants significantly different from 'All race entrants' ($p \le 0.05$)

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

The number and percentage (%; 95% CI) of race entrants identified as requiring medical clearance by each of the five pre-exercise medical screening tools is shown in Table 2.

The five pre-exercise medical screening tools identified a different percentage of entrants requiring medical clearance, except in the case of the Pre-2015 ACSM and the EACPR (both identified 33.9%). The EACPR identified the most (n=27115; 33.9%:) and the post-2015 ACSM identified the lowest percentage of entrants requiring medical clearance (6.7%).

Pre-exercise medical	n	% of all race entrants	% of all race entrants		
screening tool		(95% CIs)*			
АНА	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)			

Table 2: The number (n) and percentage (%; 95%CI) of race entrants identified as requiring medical clearance by the five pre-exercise medical screening tools (n=76 654)

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

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

A summary of the percentage of entrants identified by each of the five screening tools in each main domain of risk (expressed in four categories, based on the % of entrants identified) is presented in Table 3.

There was considerable variation between the pre-exercise medical screening tools' identification of entrants in each of the six main domains of risk (see Supplementary Table 1 for more detail). The EACPR and pre-2015 ACSM screening tools consistently identified the highest percentage of individuals at risk for five of the six main domains. For CVD risk factors, post-2015 ACSM identified the lowest percentage, with only 29%. For the identification of a history of any other chronic disease, all tools were highly inconsistent in the specific chronic disease, but overall the AHA tool identified the lowest percentage of entrants than any of the other tools (36%). Finally, for prescription medication use and a

history of musculoskeletal injury, the post-2015 ACSM identified a significantly lower

percentage of entrants compared to the other screening tools, with AHA the second lowest.

Table 3: Summary of the percentage of entrants identified by each of the five screening tools in each main domain of risk (expressed in four categories, based on the % of entrants identified requiring medical clearance)

Main domains of risk	АНА	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 % of entrants with the disease/domain (from Table 1) High (green): >75% entrants identified compared to reference

Intermediate (yellow): 50-75% entrants identified compared to reference

Low (orange): 25-49% entrants identified compared to reference

Very low (red): <25% entrants identified compared to reference

(further data available in Supplementary Table 1)

Observed agreement between the five pre-exercise medical screening tools

The observed agreement between the five pre-exercise medical screening tools is presented in

Table 4.

 Table 4: The observed agreement (overall and positive category) between the five pre

 exercise medical screening tools used to identify entrants requiring medical clearance

Pre-exercise	Observed Agreement					
medical screening tool	Pre-2015 ACSM	Post-2015 ACSM	PAR-Q	EACPR		
AHA	9.4%; 72.5%	3.2%; 88.4%	7.3%; 78.9%	9.4%; 72.5%		
Pre-2015 ACSM	-	6.1%; 69.9%	24.8%; 89.4%	35.4%; 99.9%		
Post-2015 ACSM	-	-	4.1%; 76.5%	6.1%; 69.9%		
PAR-Q	-	-	-	24.8%; 89.4%		
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

-: Either a comparison between the same two tools, or a replication of results hence left blank

positive category; overall category (yes + no)

The highest overall observed agreement was between the pre-2015 ACSM and EACPR preexercise medical screening tools (35.4%, since they use the same information). The lowest overall observed agreement was between the post-2015 ACSM and AHA (3.2%).

DISCUSSION

The main findings of this study were: 1) there was a wide variation in the % race entrants who were identified by the different screening tools as requiring pre-exercise medical clearance (ranging from 6.7% to 33.9%); 2) there was large variation between the five pre-exercise medical screening tools in the identification of entrants in each of the six main domains of risk; and 3) the agreement between the pre-exercise medical screening tools also varied from 3.2% to 35.4%.

Pre-exercise medical screening tools are recommended to identify individuals who are at higher risk for medical complications before they engage in moderate- to high-intensity exercise. Several international organisations have developed pre-exercise medical screening tools (AHA[4,5], pre-2015 ACSM[6], post-2015 ACSM[7], PAR-Q[8] and EACPR[9,10]) for this same purpose but these tools vary in the screening questions that are included. This makes it difficult for healthcare professionals to select the most appropriate pre-exercise medical screening tool. Some mass participation endurance events already implement screening tools to decrease the medical encounters during events. The common medical encounters in these events include fluid/electrolyte-related disorders, and the most serious conditions are usually cardiovascular-related conditions.[13,14] It is postulated that, based on the types of anticipated medical encounters an appropriate screening tool can be selected to identify individuals at risk for specific types of medical encounters prior to the event. Therefore, the choice of a screening tool to decrease medical encounters [15] could be guided by the expected types of medical encounters for a specific event.

To our knowledge, there are few studies where different screening tools have been applied to the same population. In one study, involving adults 40 years and older, the 2001–2004 National Health and Nutrition Examination Survey (NHANES) data were used to compare the pre-2015 ACSM pre-exercise medical screening tool to the PAR-Q pre-exercise medical screening tool.[16] The main finding was that 68.4% of participants would be referred to a medical doctor based on the PAR-Q, versus 94.5% of participants that would be referred to a medical doctor by the pre-2015 ACSM.[16] There were thus 72.4% participants that had the same referral status based on both these pre-exercise medical screening tools.[16] This affirms the results of our study regarding wide variation in numbers and agreement. In one other study, the pre-2015 ACSM and the post-2015 ACSM tool was applied to 553 university students prior to exercise prescription. The main findings was that the post-2015 ACSM

identified 32% fewer participants requiring medical clearance prior to exercise participation, compared to the pre-2015 ACSM tool.[17] This finding is likely due to the exclusion of age as a risk factor, and exclusion of other CVD in the post-2015 ACSM tool.

The large variation and differences in agreement between tools in our study are very likely related to the degree of overlap (or not) between the questions that are included in the screening tools. These differences are highlighted when comparing the percentage of individuals identified within each domain of risk. For example, the most extensive set of questions are included in the EACPR tool, as the EACPR tool is a combination of the pre-2015 ACSM and PAR-Q pre-exercise medical screening tools and includes the questions from both these two tools. This likely explains the very high agreement between the EACPR and the pre-2015 ACSM, and the relatively high agreement between the EACPR and PAR-Q tools. The EACPR also consistently identified the highest percentage of individuals at risk. The PAR-Q however, 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. The AHA excludes questions regarding age, other chronic medical conditions, but includes cardiac-related questions. The reason for the fair agreement between all other tools and the AHA, could be due to the AHA including questions about cardiac-related conditions only, and none about other chronic medical conditions. Therefore, only the cardiac-related questions asked in the other pre-exercise medical screening tools correlated with the AHA pre-exercise medical screening tool.

Agreement between the post-2015 ACSM and pre-2015 ACSM and the PAR-Q pre-exercise medical screening tools was low, with the lowest agreement being between the PAR-Q and the post-2015 ACSM. Regarding the 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 agreement between it and all the others. Whilst 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, it excludes many questions. The post-2015 ACSM excludes questions related to CVD risk factors, and the reasons given are: (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] Therefore, the post-2015 ACSM tool identified significantly fewer participants than the other tools for the category of "any risk factor for CVD". These differences between the tools explain why the percentage of identified entrants for pre-exercise medical clearance and the agreement ranges so much. In summary, there are large variations in identifying participants that require pre-exercise medical clearance when the five tools are applied, even though their outcome measure of *"identifying individuals who need medical clearance prior to exercising"* is the same. This is

likely due to the variation in the screening questions (number and type) in the tools, and where there is good agreement between tools, this is because tools such as the EACPR incorporate screening questions from other tools. There is a need for further research to determine if the incidence of medical encounters during high intensity exercise (such as during a mass community-based running event) are different in entrants that were identified as "cleared to participate" using the five different tools.

Limitations and strengths of the study, and recommendations regarding future research A strength of this study is the novel approach to compare outcomes of five international preexercise medical screening tools. The study has 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 exactly the same as in the original screening questions for the five screening tools (and the question related to pregnancy was not included). We acknowledge that our results could have been different if the participants had completed each of the original pre-exercise screening tools separately and on different occasions. Future research should investigate which guideline should be considered the "gold standard" to identify individuals at risk for medical complications during exercise (participants who require medical clearance prior to exercising), now that we know how different the tools are.

CONCLUSION

The results of this study highlight that there is significant variation in participants that are identified as requiring medical clearance before high-intensity exercise when five different international pre-exercise medical screening tools are applied to a population of running race entrants. For the clinician, this makes it difficult to decide which pre-exercise screening tool should be used in this setting. Future studies should investigate which tool has the highest sensitivity and specificity in identifying those who have a medical complication during the event.

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