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ECG-based Cardiac Screening Programs: Legal, Ethical and Logistical Considerations

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ABSTRACT

Screening asymptomatic people with a resting electrocardiogram (ECG) has been theorised to detect latent cardiovascular disease. However, resting ECG screening is not recommended for numerous populations, such as asymptomatic middle-aged (sedentary) people, as it is not sufficiently sensitive to detect coronary artery disease. While the issues raised in this article are largely common to all screening programs, this review focuses on two distinct programs: (1) screening elite athletes for conditions associated with sudden cardiac death (SCD); and (2) screening people aged ≥ 65 years for atrial fibrillation (AF). These two settings have recently gained attention for their promise and concerns regarding prevention of SCD and stroke, respectively. If screening is done, it must be done well. Organisations conducting screening must consider a range of legal, ethical and logistical responsibilities which arise from the beginning to end of the process. This includes consideration of who to screen, timing of screening, whether it is mandatory, consent issues, and auditing systems to ensure quality control. Good infrastructure for interpretation of ECG results according to expert guidelines, and follow-up testing for abnormal screening results, including a pathway to treatment, are essential. Finally, there may be significant implications for those diagnosed with cardiac disease, including insurance, employment, the ability to play sport and mental health issues. There are several legal risks, and the best protective measures are good communication systems, thorough clinical records, careful handling of eligibility questions for those diagnosed, and reference to expert guidelines as the standard of care.

Keywords: legal, ethical, screening, athletes, atrial fibrillation, sudden death

INTRODUCTION

Many electrocardiogram (ECG) screening programs exist internationally, usually with the key aim of using a resting ECG to screen asymptomatic people for potentially life-threatening cardiac diseases (Table 1). These programs have been trialled in broad age groups: young athletes (including elite athletes), middle-aged people (both sedentary and athletes) and older people (often aged ≥ 65 years). The rationale for screening athletes is that intense exercise represents a trigger for cardiac arrhythmias, meaning athletes may be at greater risk of sudden cardiac death (SCD). Screening has also been investigated in older populations at risk of thromboembolic complications of atrial fibrillation (AF). The rationale is that oral anticoagulants (OAC) have demonstrated efficacy in preventing stroke in individuals with AF, even if the person is asymptomatic. The groups for which screening is recommended vary, e.g., the European Association of Preventive Cardiology (EAPC) recommends screening (including a resting ECG) asymptomatic middle-aged/senior individuals engaging in high-intensity sport,¹ which is not generally recommended by other experts.^{2, 3} In Italy⁴ and Israel,⁵ ECG screening of all young athletes (of any level) is mandated, whereas in most other countries ECG screening of athletes is restricted to the elite level. We note that ECG screening in asymptomatic middle-aged sedentary people is not recommended by any leading bodies.^{2, 3}

While the issues raised are largely common to all screening programs, this review focuses on two distinct programs: (1) screening elite athletes for conditions associated with SCD; and (2) screening for AF in people aged ≥ 65 years. These programs were selected as they represent two of the largest, and increasingly common, cardiac screening programs. As with all discussions on screening, these issues relate to testing asymptomatic people. Those with suspicious symptoms and/or significant family history should seek specialist advice.⁶

(i) Rationale for screening elite athletes

SCD is a tragic outcome for athletes and their families. Although relatively rare, SCD is the leading cause of death for people playing sport.⁷ In the US, over 90 young athletes die suddenly each year (about 2 per 100,000 athletes per year).⁷ This rate is 2.5-fold higher than that of the age-matched non-athlete population.⁸ The risk of SCD, or sudden cardiac arrest, (SCA/D) varies according to age, gender, ethnicity,

sport and competitive level.⁹ In Australia, SCD in the young (aged 1-35 years) occurs in 1.3 per 100,000 people per year and approximately 15% occur either during exercise (11%) or immediately after exercise (4%).¹⁰ Competitive sport may be a significant risk factor for young people with genetic heart diseases, such as hypertrophic cardiomyopathy (HCM), arrhythmogenic cardiomyopathy, familial long QT syndrome, and catecholaminergic polymorphic ventricular tachycardia, that can lead to SCD without the athlete having any symptoms beforehand.

There is strong debate about whether screening programs are worthwhile in terms of preventing SCD in young people.¹¹ Data from Italy, where cardiac screening of athletes is mandated by law, is often cited as persuasive evidence in favour of screening: this study compared the incidence of SCD in the years before and during screening, showing a 90% reduction in the screened population.⁴ However, this success has not been mirrored in Israel, nor in various US programs.¹²

A detailed review by the American Medical Society for Sports Medicine (AMSSM) suggests the decision about screening should depend on the baseline risk of SCD in the relevant population, and the availability of required cardiology resources and infrastructure to properly conduct such a program.⁹ Many major organisations and sports governing bodies now recommend cardiac screening of athletes. For many, there is a “strong pragmatic argument” to screen as “a well-resourced professional organisation [has] a perceived need to...have taken every possible step to reduce this risk”.⁶ For professional athletes who are employees, there is also a work, health and safety argument in favour of screening as athletes are required to push their bodies in the course of employment, and any cardiac abnormalities raising the risk of SCD should be identified, as vigorous exercise can be a trigger. There is a substantial cost in running a screening program, with one model estimating a 20-year screening program of young US athletes would cost US\$10million per life saved.¹³ In the UK, the Football Association (FA) reported a cost of US\$342 per athlete for initial screening (including ECG and echocardiogram) and US\$102,782 per case of disease associated with SCD.¹⁴ Another UK program reported a cost of US\$87 per athlete screened (including ECG and taking into account follow-up costs).¹⁵

(ii) Rationale for AF screening

AF is the most common cardiac arrhythmia, and the prevalence rises steeply with age.¹⁶ Estimates are that 25% of middle-aged adults in Europe and the US will develop AF in their lifetime.¹⁷ About 1.4% of the population aged ≥ 65 have undiagnosed AF, which is commonly asymptomatic.¹⁶ Left untreated, AF results in an up to fivefold increased risk of stroke.¹⁶

Screening for AF in people aged ≥ 65 years is now recommended by numerous guidelines and expert consensus.¹⁶⁻¹⁹ Data are lacking on the outcomes of AF screening (e.g. reduction of stroke), and guidelines are based on the premise that the prognosis of screen-detected AF is similar to AF detected incidentally and will respond similarly to OAC.²⁰ Most guidelines recommend opportunistic screening, by pulse palpation or single-lead ECG. For those at high risk of stroke (CHA₂DS₂-VASc ≥ 2 in males or ≥ 3 in females), treatment with OAC can reduce stroke risk by 64% compared to control.^{17, 21} Economic assessments have generally found AF screening programs to be cost-effective.¹⁶

KEY ISSUES IN CARDIAC SCREENING

Once an organisation has decided to conduct a screening program, there are ensuing legal, ethical and logistical responsibilities. The primary point is that if screening is to be done, it must be done well.^{22, 23} Several papers helpfully contribute to these issues,²⁴⁻²⁷ but most emphasise the doctor's role (rather than the organisation's role), and focus on the end part of the process: treating individuals who have been diagnosed and/or preventing litigation. These aspects are important, but relate to a minority of patients and a small part of the process. There are many legal, ethical and logistical issues involved in designing/running an ECG screening program, from the beginning to the end of the process (Figure 1).

Eligibility

The first question is: who is eligible for screening? A key ethical issue with screening is that the condition, if found, must be serious enough to outweigh the negatives of screening (time, false positives, etc). Ideally, screening should be offered to sufficiently at-risk people. According to Bayes' theorem, the chance of a positive being a true positive is proportional to the baseline incidence in the population being screened.

In sport, some groups are much higher risk e.g. the annual risk of SCD for African/Afro-Caribbean (“black”) male basketballers is 1 in 4400,²⁸ and may be prioritised. Conversely, black athletes have demonstrably higher proportions of pathological ECG abnormalities, confounding interpretation. Athlete screening often commences at 16 years, given that ECG variability under this age is more common – the “juvenile ECG pattern”.²⁹ Arguably, athlete screening should be done early enough that the person has flexibility choose another career if a serious cardiac condition is detected. For AF, most guidelines use an age cut-off.^{17, 18}

Method of screening & frequency

Another important consideration is the method and frequency of screening, with a focus on compliance. Considerations include whether an opt-in or opt-out model works best, and/or whether systematic or opportunistic screening is more appropriate.

When screening athletes, it is important to consider whether an opt-in or opt-out model is preferable. Opt-out may produce a higher rate of compliance, though athletes should be given sufficient opportunity to make an informed decision about whether to participate. However, whether a program should be mandatory may be less important than developing a ‘best practice’ program: something that varies according to the population and resources available.²³

There has been debate about whether an ECG is required for athlete screening. While the ESC recommends an ECG,³⁰ the AHA recommends a history and physical but not ECG.¹¹ Evidence now suggests an ECG substantially improves sensitivity and specificity of screening compared with a clinical examination alone.^{6, 14} There are no clear recommendations about frequency of screening, but it appears a single screen at age 16 may not be sufficient,¹⁴ and every 2 years (under age 21), and every 5 years thereafter, may be more appropriate. This approach has recently been adopted by the FA.³¹ Refinements to athlete ECG interpretation criteria (the Seattle criteria³² and now the International criteria²⁹), have substantially improved diagnostic yield.

Most AF screening guidelines now recommending opportunistic, rather than systematic, screening.²⁰ As we have previously argued, the focus should be more on screening a higher proportion of the at-risk population in order to increase the

effectiveness of stroke prevention.²⁰ In terms of frequency, most guidelines recommend single time-point screening, as opposed to continuous ECG monitoring over a longer period which may detect “brief episodes of AF of questionable clinical significance”.²⁰ As we have noted, this will present challenges with the rise of wearable technology, e.g. smartwatches with AF-detection algorithms and ECG capability (Applewatch4), often worn by younger people at lower risk of stroke.²⁰ Evidence is lacking as to the ideal frequency, but current suggestions are for annual screening.¹⁶

Timing

Screening is often performed as an adjunct task, at a time that suits the doctor/practice or sporting organisation. However, practices/organisations must be aware of the potential implications and ensure there is time to obtain informed consent, and to organise follow-up if required, taking into account the person’s work, travel or playing commitments. The best model would vary according to circumstances, but in general it is preferable to give people advance notice, and to screen athletes in the off-season or, in our opinion, at least 10 working days before competing to ensure there is sufficient time to complete follow-up if required.

Consent issues

In general, patients must give informed consent before undergoing screening. This requires an understanding of the benefits and harms,³³ the accuracy of the test, risks, and the implications of an abnormal result.³⁴ Patient information materials often over-emphasise benefits and underplay harms and uncertainties.³⁵

Issues of capacity may also arise with younger or elderly people, who may be considered vulnerable populations. Children aged under 18 years can be vulnerable due a lack of capacity to make decisions, and power inequalities with adults.³⁶ Older patients can also be vulnerable, especially those with multiple chronic conditions.³⁷ These issues must be considered carefully to ensure the person is capable of understanding the process and implications of screening. People under 18 who are considered ‘mature minors’ may have capacity to consent to screening, although for

younger people (e.g. age 15), it may be prudent to obtain parental consent. Similar considerations may apply to elderly people, e.g. with dementia.

Second, the issue of consenting to 'half a screen' can be a problem. This occurs when a person consents to the initial test, but refuses (either overtly or covertly) to get follow-up as recommended. Importantly, there must be a system to identify those who have not completed required follow-up and a policy for what to do in this scenario. Defining what is a reasonable level of follow-up depends on the circumstances, but should be well documented. Completing the screening process can be more easily mandated for athletes who are employees, and elderly people who are regular patients of a practice.

Communication of results and pathway to treatment

All results must be reviewed, filed, communicated and followed up if required. ECG review must be completed by someone with relevant expertise. Athlete ECGs, must be reviewed by someone with specific expertise in best-practice interpretation guidelines²⁹ to reduce false positives. For AF, many single-lead devices have an automated algorithm for interpretation but those with a diagnosis of 'possible AF' must be verified, and those with an 'unclassified' diagnosis must also be reviewed. All 12-lead ECG automated diagnoses also require review. Other work up, including a review of the CHA₂DS₂-VASc stroke risk scores, and discussion of benefits and risks of treatment, should be done in accordance with guidelines.¹⁷

A well-established pathway to follow-up testing and treatment for anyone with a verified abnormal test result is crucial.¹⁶ In a sports setting, the required infrastructure for screening includes sufficient cardiology resources to ensure ECGs are interpreted by someone with relevant expertise and that abnormal screening results are followed up.⁹ The 'pathway to treatment' should include consideration of logistics, whether playing/training can continue before the test is complete, and cover players who are visiting temporarily. In *Izidor v Knight*³⁸, a college basketball player was screened and ultimately diagnosed with HCM. However, the clearance form was signed before the follow-up testing and diagnosis was complete. The athlete continued to play but died of SCD 6 weeks later. This case shows the importance of adhering to the screening policy and completing testing before providing clearance.

Communication and filing are crucial. Sub-optimal communication between patients and doctors is a major risk factor for negligence cases, and therefore a key area for prevention.³⁹ An abnormal result that is not read and/or followed up is risky. Even the best system will miss things occasionally, but this must be minimised.

Abnormal screening results and follow-up

A substantial number of people *will* require follow-up tests, and the person conducting screening must be prepared to counsel patients with an abnormal result. Approximately 5% of athletes screened will require extra testing.⁴⁰ Due to electrical and structural changes in the heart resulting from high level training, athlete ECG interpretation guidelines have been continuously refined and improved,⁴⁰ with the International Criteria(2017)²⁹ now the gold standard. This has substantially reduced false positives, with one study showing the proportion of abnormal ECGs falling from 21.8% (2010 ESC recommendations) to 4.3% (Refined criteria).¹⁵ Ultimately 0.3% of athletes in this study were diagnosed with a serious cardiac condition, and all these ECGs were abnormal irrespective of the interpretation criteria used.¹⁵ A reduced false positive rate decreases screening cost,¹⁵ and improves identification of pathology.⁴⁰ Anxiety is a key harm and can be reduced with timely communication and completion of follow-up tests.^{20, 41} Interestingly, a study of screening in US college athletes found ECG screening did not cause undue anxiety for the majority (including those with false positive results).⁴¹

For AF, approximately 12% of patients screened with a single-lead ECG will have an abnormal result (e.g. an automated result of possible AF or 'unclassified').⁴² 'Unclassified' results may be caused by conditions such as sinus tachycardia/bradycardia, left or right bundle branch block or multiple ectopic beats. Additional testing will include echocardiography.¹⁷ Potentially unnecessary additional testing may result from an AF diagnosis and is a significant concern of the US Preventive Services Task Force.⁴³

Importantly, there may be cases of 'false reassurance' as even the best program will miss some cases.¹⁴ For athletes, only 60% of the conditions associated with SCD are visible on ECG.⁴⁴ The dynamic nature of electrical cardiac problems means they can be missed, e.g. a single time-point screen may miss paroxysmal AF, leading to

intermittent ECG protocols.¹⁶ Thus, people undergoing screening must be informed of these limitations, and encouraged to report any symptoms in future.

Cardiac emergency response

The importance of having a documented and well-practised action plan in place for cardiac emergencies, ideally including access to automated external defibrillators (AEDs), cannot be overstated.⁹ Early recognition of SCA or stroke is crucial, and training relevant staff to identify symptoms can provide benefits well beyond the screened cohort. In sport, any non-traumatic collapse should be treated as cardiac until proven otherwise. For the elderly, educating practice staff, doctors and patients to be aware of stroke symptoms is key in promoting early access to treatment.

Program evaluation

All screening programs should be evaluated regularly to assess efficacy, benefits and harms. Reviews should also consider of any new scientific evidence that should be reflected in the program and/or current care, and should ideally include updates on education regarding cardiac emergency response (e.g. resuscitation and stroke recognition).

Issues for those diagnosed with a cardiac condition

For those diagnosed with a cardiac condition, there may be important implications for insurance, work, sport and mental health. As with all medico-legal issues, insurance rules vary by jurisdiction. Once diagnosed, any pre-existing heart condition can have implications for acquiring new insurance such as travel, health or life insurance. Premiums may be higher, exclusions added or cover refused. Some jurisdictions have protections for certain types of insurance e.g. Australian private health insurance is community-rated [*Private Health Insurance Act 2007(Cth)*], meaning everyone pays the same premium for the same product regardless of health status or claims history.

Genetic testing is important, especially for young people diagnosed before they have life insurance. In general, when applying for insurance, a person must disclose

relevant health information, including genetic tests. Some jurisdictions, offer little protection, e.g. in Australia, life insurers can use genetic test results to raise premiums, impose conditions or refuse insurance altogether if based on actuarial or statistical data [s46 *Disability Discrimination Act 1992*(Cth)], and can even ask whether an applicant *is considering or awaiting results*,⁴⁵ but cannot ask an applicant to have a genetic test. Other jurisdictions, including the UK, Canada and many European countries have banned insurers from using genetic test results.⁴⁶

Issues may arise regarding employment and driving, e.g. in the UK, AF is a notifiable condition and may prevent a person driving a bus/lorry.⁴⁷ Many countries regulate the use of genetic tests in employment, however it is unclear how this would apply to an athlete who is an employee (especially if disqualification is recommended and/or for an athlete who is, e.g., genotype-positive/phenotype-negative for HCM).²⁴

Importantly, there are substantial psychological implications for athletes disqualified from sport. As documented by Asif et al, these athletes may experience significant psychological distress and should be monitored and offered support.⁴⁸

Eligibility and disqualification from sport

A central issue for those diagnosed with a serious cardiac condition is eligibility to play sport. Historically, a paternalistic approach was favoured, with athletes 'disqualified' from competitive sport. While the ESC guidelines(2005)⁴⁹ remain generally more restrictive, a more permissive approach with a 'shared decision-making model' is included in the ACC guidelines(2015).⁵⁰ The ACC guidelines are more recent, and take into account research developments in risk stratification. However, there are many areas which require further research and most guidelines are mainly based on expert consensus.²⁷ Similarly, a model of 'empowerment' has been proposed, which allows athletes to choose the extent to which they participate in the eligibility decision.²⁷ The ethical implications of disqualification, particularly with screen-detected conditions in asymptomatic athletes, have been discussed comprehensively in a review which proposes an individualised approach with 'collaborative decision-making'.²⁴

Realistically, the physician's risk profile is as important as the athlete's. Legal and ethical responsibility is fundamental, and a doctor is less likely to 'forbid' participation if they unlikely to be blamed/liable. One option for sports is to have a group of

experts to assist with decisions (with the player's consent), as in the FA.¹⁴ There is also a question of what amount of cardiac risk an athlete is able to consent to in an organised setting, especially for minors, and where the athlete is an employee, general work, health and safety obligations apply to the employer. Sporting organisations also face substantial reputational (and other) risk if an athlete suffers SCA/D on television.

Litigation risks

Litigation is highly stressful and public, even for people/organisations ultimately vindicated. Laws are specific to each jurisdiction but the general legal duty is to provide best medical care available, based on the current state of scientific knowledge.²² The standard of care is often established by asking what the hypothetical 'reasonable' physician, exercising due care and skill, would have done in those circumstances? Expert guidelines may be persuasive evidence of the standard of care.⁵¹ The importance of having thorough, contemporaneous clinical notes, documenting any restrictions on activity, cannot be overstated.⁵¹ Specific areas of risk include:

- **Poor communication:** Good communication may not be sufficient to prevent all litigation, but is a strong protective measure.
- **Detecting disease, but not treating it:** if a condition is detected, a treatment decision must be made in a timely fashion. If an untreated patient suffers a stroke, it may constitute a breach of duty, as stroke may be a reasonably foreseeable outcome.⁵² One legal website specifically advertises services for AF patients who may have experienced negligence in OAC prescription.⁵³
- **Clearing someone with disease** is an obvious risk. ECGs, and any follow-up tests, must be completed and interpreted with due care and skill.²⁶ To the extent possible, guidelines should be followed.⁵⁴
- **Exclusion from sport:** guidelines are not consistent, but generally exclusion decisions need to be reasonable, well explained and based on a thorough scientific process.⁵⁵ There are several US cases where players sued unsuccessfully to challenge exclusion from sport, e.g. in *Larkin v Archdiocese of Cincinnati*⁵⁶ the Court held a football player with HCM could be excluded from

competing, even though he was willing to sign a waiver. Team physicians have a complex 'dual loyalty' between the athlete and the team's needs.⁵⁴ Ideally, decisions about eligibility should be decided by an expert panel (with the player's consent), and/or follow guidelines.

- **Waivers:** Beware. Courts often question waivers, which do not remove the doctor's legal obligation to conform to applicable standards of good medical practice.^{25, 51} Waivers between an adult professional athlete and a team physician may be enforceable, particularly where another specialist has cleared the player,⁵¹ but this raises a 'red flag' and potential 'doctor shopping' to get the desired opinion.²⁶
- **Any major adverse event** such as a stroke or SCA/D, especially in public and/or if it appears preventable, represents a major risk. Good documentation and notes, including informed consent and discussion of risks of non-compliance with treatment or activity restrictions, are important.²⁵ In *Gathers v Loyola-Marymount University*,⁵⁷ a basketball player was prescribed a beta-blocker for ventricular tachycardia but his dose was reduced to improve performance. Shortly afterwards, he suffered a SCD on television. His family sued the doctor and university for US\$32.5 million, although the case settled.

CONCLUSIONS

Many organisations, such as general practices and sports, are now conducting cardiac screening programs using a resting ECG. Any screening program involves some potential downsides, including anxiety, time, additional testing and cost. Screening is often performed as an adjunct task and therefore, very good systems are needed for communication, filing, and ensuring a pathway to treatment.

If screening of asymptomatic people is performed, it must be done well. Once an organisation has committed to screening, there are a range of legal, ethical and logistical responsibilities that must be addressed. This includes consideration of who to screen, timing and frequency, whether screening is mandatory, auditing systems and consent issues. Systems for communicating results and facilitating follow-up testing for abnormal results, including a pathway to treatment, are essential. Finally, there may be significant implications for those diagnosed with cardiac disease,

including insurance, employment, mental health and the ability to play sport. There are several legal risks, and the best protective measures physicians can take are to communicate well, keep thorough clinical records, (potentially) to involve a group of experts in eligibility questions, and to follow expert guidelines as the standard of care.

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Table 1: Resting ECG screening of asymptomatic individuals

| Group | Screening Population | Groups/organisations in favour | Arguments against | Summary |
|---|--|---|--|---|
| All young people | Cardiac conditions associated with SCD | Cardiac Risk in the Young (CRY), UK Mandated by law for young athletes (broadly defined) in Italy, ⁴ Israel ⁵ | * Expensive * Large number of false positives * Lack of evidence in support | Not recommended in most countries |
| Young elite athletes (age 16-35 years) | | Vast majority of major sporting organisations and guidelines, e.g.: * ESC ³⁰ * AHA (history and physical, not ECG) ¹¹ * International Olympic Committee * American Medical Society for Sports Medicine (AMSSM) ⁹ * Australasian College of Sport and Exercise Physicians (ACSEP) ⁵⁸ * FIFA * World Rugby | * Expensive * Need randomised trial evidence of benefit | Consider, if sufficient infrastructure available to support program |
| Middle-aged sedentary people (aged 35-64 years) | Acquired cardiac disease, arrhythmias | Some clinics | * Cannot detect coronary artery disease in absence of prior infarction * Generally low risk group for AF | Not recommended ^{2, 3} |
| Middle-aged/senior people engaging in physical activity | Acquired cardiac disease, arrhythmias | *EAPC, ¹ based on self-assessment of individual's cardiac risk and the intensity of exercise | * Individual risk assessment may be inaccurate * Cannot detect coronary artery disease in absence of prior infarction | Consider for higher risk individuals undertaking intense exercise |
| Elderly (age ≥65 years) | AF | Many guidelines recommend AF screening, including with a single-lead ECG, e.g.: * ESC ¹⁷ * AF-SCREEN ¹⁶ * Heart Foundation of Australia ¹⁸ * European Heart Rhythm Association (EHRA), Heart Rhythm Society (HRS) et al ¹⁹ | * Insufficient evidence of reduction of risk of screen-detected AF | Consider, if sufficient infrastructure available to support program |

FIGURE LEGENDS

Figure 1: Timeline of issues related to ECG screening

ECG, electrocardiogram; SCA, sudden cardiac arrest

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