

Appropriateness criteria for cardiovascular imaging use in clinical practice: a position statement of the ESC/EACVI taskforce

Madalina Garbi¹, Gilbert Habib^{2,3}, Sven Plein⁴, Danilo Neglia^{5,6}, Anastasia Kitsiou⁷, Erwan Donal⁸, Fausto Pinto⁹, Jeroen Bax¹⁰, Stephan Achenbach¹¹, Bogdan A. Popescu¹², Thor Edvardsen¹³, Luigi P. Badano¹⁴, Alexandros Stefanidis¹⁵, Chiara Bucciarelli-Ducci¹⁶, Genevieve Derumeaux^{17,18}, Jose Luis Zamorano¹⁹, Thomas F. Lüscher²⁰, Gerald Maurer²¹, and Patrizio Lancellotti^{22*}

¹King's Health Partners, King's College Hospital NHS Foundation Trust, London, UK; ²Aix-Marseille Université, Marseille, France; ³Department of Cardiology, La Timone Hospital, Marseille, France; ⁴Multidisciplinary Cardiovascular Research Centre & The Division of Cardiovascular and Diabetes Research, Leeds Institute of Genetics, Health and Therapeutics, University of Leeds, Leeds, UK; ⁵Cardiovascular Department, University of Pisa, Pisa, Italy; ⁶CNR Institute of Clinical Physiology, Pisa, Italy; ⁷Cardiology Department, Sismanoglio Hospital, Athens, Greece; ⁸Cardiologie, CIC-IT804, CHU RENNES et LTSI INSERM U 1099, UNiversité Rennes 1, Rennes CEDEX Rennes, France; ⁹Cardiology Department, CCUL, CAML, University of Lisbon, Lisbon, Portugal; ¹⁰Department of Cardiology, Leiden University Medical Centre, Leiden, The Netherlands; ¹¹Department of Cardiology, University of Erlangen, Erlangen, Germany; ¹²Department of Cardiology, University of Medicine and Pharmacy 'Carol Davila'—Eurocolab, Institute of Cardiovascular Diseases, Bucharest, Romania; ¹³Department of Cardiology, Oslo University Hospital, Rikshospitalet and University of Oslo, Oslo, Norway; ¹⁴Department of Cardiac, Thoracic and Vascular Sciences, University of Padua, School of Medicine, Padua, Italy; ¹⁵1st Department of Cardiology, Echocardiography Laboratory, General Hospital of Nikea, Piraeus, Greece; ¹⁶Bristol NIHR Cardiovascular Biomedical Research Unit (BRU), Bristol Heart Institute, University of Bristol, Bristol, UK; ¹⁷DHU A-TVb, Institut Mondor de Recherche Biomédicale, Unité Inserm 955-équipe 8, University Hospital Henri Mondor, Créteil, France; ¹⁸Assistance Publique-Hôpitaux de Paris, Paris, France; ¹⁹University Hospital Ramón y Cajal, Madrid 28034, Spain; ²⁰University Hospital, Zürich, Switzerland; ²¹Division of Cardiology, Second Department of Medicine, Medical University of Vienna, Vienna, Austria; and ²²Department of Cardiology, GIGA Cardiovascular Sciences, Heart Valve Clinic, CHU du Sart Tilman, University of Liège Hospital, Liège 4000, Belgium

Received 19 January 2014; accepted after revision 2 February 2014; online publish-ahead-of-print 17 March 2014

There is a growing interest from the scientific community in the appropriate use of cardiovascular imaging techniques for diagnosis and decision making in Europe. To develop appropriateness criteria for cardiovascular imaging use in clinical practice in Europe, a dedicated taskforce has been appointed by the European Society of Cardiology (ESC) and the European Association of Cardiovascular Imaging (EACVI). The present paper describes the appropriateness criteria development process.

Keywords Cardiovascular imaging • Appropriateness criteria • Development process • Guidelines

Introduction

Cardiovascular imaging is characterized by continuously evolving technology developments in all modalities and increasing diversification of clinical indications for diagnosis, follow-up, and treatment of disease.¹ Use in clinical practice varies, mainly depending on local availability of technology, expertise and funds and based on the clinician's choice. Assistance with decision making both regarding the choice of imaging modality in a certain clinical scenario and regarding the future development of availability at local, national, and European level becomes essential. To provide this assistance, a dedicated taskforce has been appointed by the European Society of Cardiology (ESC) and the European Association of Cardiovascular Imaging

(EACVI) with the specific aim to define appropriateness criteria for cardiovascular imaging use in clinical practice in Europe.

Definition

The appropriateness criteria will be evidence-, guidelines-, and best practice-based criteria for the appropriate use of cardiovascular imaging modalities in clinical practice.² Their evidence-based character implies periodic update to acknowledge new research findings. Their guidelines-based character implies validity of appropriateness criteria within the same boundaries as the respective guidelines (for example, national appropriateness criteria based on national

* Corresponding author. Tel: +32 4 366 71 94; Fax: +32 4 366 71 95, Email: plancellotti@chu.uhg.ac.be

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guidelines/European appropriateness criteria based on European Guidelines). Their best practice-based character implies involvement of experts and centres of excellence to complement existing evidence and current guidelines.

The appropriateness criteria are not legal documents; they are meant to assist decision making rather than to strictly prescribe an approach.³ The criteria cannot be exhaustive; they only refer to certain selected high impact clinical scenarios.

Background

The need to define appropriateness criteria for the use of diagnostic modalities in clinical practice was recognized over two decades ago in the American healthcare system. Appropriateness criteria for the selection, use, and reimbursement of an imaging test were developed in response to demand from medical professionals, society, and regulators. The first appropriateness criteria for the selection of an imaging test in specific clinical conditions were developed by the American College of Radiology, with aim to assist referring physicians with decision making. Regarding cardiovascular imaging, appropriateness criteria for the use of an imaging test encompassing various imaging modalities, a range of clinical scenarios, and several clinical indications were developed by the American College of Cardiology Foundation (ACCF) Appropriate Use Criteria Taskforce in collaboration with the American Heart Association as well as relevant societies and colleges for each modality. Appropriateness criteria were developed for echocardiography,⁴ stress echocardiography,⁵ cardiac computed tomography,⁶ cardiac magnetic resonance imaging,⁷ and cardiac radionuclide imaging.⁸ Appropriateness of diagnostic imaging use in clinical practice audit has been performed by Medicare (American federal government insurance program) with the aim to restrict reimbursement to appropriate indications.

More recently, the ESC and the EACVI have recognized the need to develop appropriateness criteria for the use of cardiovascular imaging modalities in Europe.

Bringing on a better understanding of physiology, pathology, disease progression, and effect of treatment, cardiovascular imaging developments have been an important factor in the development of cardiac care. Based on continuously growing evidence, cardiovascular imaging modalities play central roles in disease diagnosis, follow-up, management planning, and in the guidance of intervention. Nevertheless, cardiovascular imaging modalities are also prone to inappropriate use because their perceived low risk does not discourage referrals, while a multitude of factors encourage them. Referrals for imaging tests may be made by imaging cardiologists, but also by non-imaging cardiologists, hospital general medicine physicians, primary care doctors, and specialists from all medical and surgical fields. Inevitably, the background of knowledge of the referrer will vary. Availability of clear appropriateness criteria and guidance will be of particular benefit to non-cardiology referrers. Not only will appropriateness criteria inform the referrer, but they will also support the decision not to request a test without concerns that such a decision could be considered as negligence. Defensive medical practice explains many imaging requests. Depriving patients of diagnostic tests is perceived as a liability more than exposing patients to unnecessary tests, particularly as referring for imaging tests often matches patient's expectations. Furthermore, patients may even

demand referral for imaging tests. In case of existence or co-existence of a private healthcare system, reimbursement may represent an incentive for referring and performing unnecessary imaging tests.

Aims

The appropriateness criteria will be developed with the aim to ensure the best use of cardiovascular imaging diagnostic resources for a given individual, the rational use of cardiovascular imaging resources for all individuals in need of diagnosis, the most efficient use of available funds for society, and the judicious implementation of evolving technology and evidence in clinical practice.

The best use of cardiovascular imaging diagnostic resources for a given individual implies a series of considerations. Both under-use and over-use of diagnostic modalities and techniques should be avoided. Under-use of imaging modalities may result in incomplete or incorrect diagnosis. Over-use of imaging modalities and techniques may expose individuals to unnecessary risk (for example, radiation, contrast media, and stress agents) and may delay diagnosis and/or treatment for the respective individuals and for other individuals waiting for the same test. Overutilization has been defined as the use of diagnostic imaging procedures, where circumstances indicate that they are unlikely to improve patient outcome. Timing is a major consideration for diagnostic imaging; under conditions of limited resources, the appropriate use of a test for a certain individual may be delayed by inappropriate use of the respective test for another individual. This second individual may have been well served by an alternative test. The alternative use of cardiovascular imaging modalities, with their advantages and disadvantages, should be described by the appropriateness criteria. Risk vs. benefit considerations should inform the choice of test. The 'risk' refers not only to side effects (e.g. allergic reaction to contrast agents), but also to the consequences of a false-positive or a false-negative test and to the appropriate test delay due to an initially wrong test choice. For example, a false-positive functional imaging test can result in exposure to unnecessary coronary angiography in a patient with non-cardiac chest pain. Also, a false-negative functional imaging test may lead to the incorrect exclusion of coronary artery disease as the cause of a patient's symptoms, potentially depriving that patient of secondary prevention and increasing the risk of events. Furthermore, invasive coronary angiography and revascularization can be delayed by unnecessary functional imaging in a patient with exertional angina refractory to medical treatment. Finally, the inappropriate escalated use of imaging can also be a source of potential 'treatment cascades'.

The rational use of cardiovascular imaging resources for all individuals in need of diagnosis implies the use of resources for the appropriate patients avoiding delay due to inappropriate 'wait list', which includes patients in no need for the respective test. It also implies the planned development of availability to allow appropriate criteria-based use of modalities.

The most efficient use of available funds for society implies selection of the most cost-effective test for a certain indication and use only of necessary diagnostic tests. While discouraging inappropriate expenses, appropriateness criteria encourage appropriate expenses and not the under-use of diagnostic tests.

The judicious implementation of evolving technology and evidence in clinical practice is ensured by a dynamic character of the

appropriateness criteria, with periodic updates. Systematic review and critical appraisal of published spontaneous research will inform this periodic update. Furthermore, answers to specific questions will be sought through research planned and conducted at the request of the taskforce. The planned research will aim to close gaps in evidence regarding risks, benefits, and cost-effectiveness of using a certain imaging modality in a certain clinical scenario.

Challenges

The development of appropriateness criteria will face process-related challenges and challenges related to the existence of multiple imaging modalities and multiple realities within Europe (countries/health systems/local variations in availability).

The first challenge is to define the appropriateness of an imaging test. The first attempts to determine appropriateness referred to therapeutic procedures, which can be straightforward characterized based on their therapeutic benefit.² In the case of imaging tests, the characterization is not straightforward; the benefit of performing the test is more difficult to define and varies with the precise indication for the test. For example, the benefit of performing a functional imaging test in coronary artery disease varies with the precise indication, which can be diagnosis, prognosis (risk stratification), or management guidance.

Characterizing an imaging test as appropriate is made even more challenging by the existence of several alternative tests with slightly different characteristics. For example, functional imaging tests have different sensitivities, specificities, and negative and positive predictive values in the assessment of coronary artery disease, being more or less appropriate for each precise indication. A test with a high negative predictive value would be more appropriate for risk stratification, whereas a test with high sensitivity would be more appropriate for diagnosis of disease. Certainly, if invasive investigation would be rather avoided in a certain patient because of comorbidities, high specificity and not high sensitivity becomes more appropriate. In between two tests with similar performance for a specific indication, the more cost-effective test becomes appropriate. The performance of an imaging test is influenced by equipment characteristics and expertise used to perform and report the test, making recommendations even more difficult to underpin and validate.

The ESC and the EACVI aim to encourage homogeneous standardized cardiovascular diagnosis and management in Europe. Cardiovascular imaging plays a central role in diagnosis, management planning, and the guidance of procedures. As such, cardiovascular imaging is an important target for standardization with aim to promote homogeneous care; the development of cardiovascular imaging appropriateness criteria will serve this aim. The appropriateness criteria will be patient-centred, encouraging similar approach in similar clinical scenarios across Europe but from a realistic perspective, acknowledging the existence of variation in resources and potential. As such, appropriateness criteria for both best practice and alternative acceptable practice should be defined. Challenges facing the taskforce in regard with the development of realistic appropriateness criteria in this context are:

- (i) Integration of knowledge regarding current local guidelines and more so regarding current practice considered as excellent care

in each country, because determination of appropriateness should mirror actual clinical care.

- (ii) Understanding the impact of each particular healthcare system (national or private provision of care and/or insurance system) in clinical practice.
- (iii) Assimilation of information regarding currently existent resources, and material potential for developments.

Development process

The first appropriateness criteria development method was described by a RAND Corporation and UCLA (University of California, Los Angeles) team for medical and surgical procedures.³ The method was used by the American College of Radiology in the development of the first appropriateness criteria for imaging. Method adjustments to suit cardiovascular imaging appropriateness criteria development were proposed by the ACCF.² Individually rating each cardiovascular imaging modality before selecting the appropriate modality for each indication was proposed by the ACCF.

The ESC/EACVI taskforce intends to follow the development process steps already described in the American literature, making necessary adjustments for a diverse European reality but a common European cardiovascular imaging association (Figure 1).

The determination of appropriateness criteria will start with the appointment of a panel of reviewers consisting of experts in each cardiovascular imaging modality and of a voting panel,² which will also include non-imaging cardiologists with expertise in fields of cardiology highly dependent on imaging for diagnosis and management planning (i.e. interventional cardiology and heart failure), general cardiologists, and other stakeholder representatives (physicians referring for imaging tests, healthcare services reimbursement system representatives, and other healthcare professionals). Associations, Working Groups, and National Societies will be asked to recommend voting panel members. The RAND and UCLA team described method recommends a voting panel with a minimum of 7 and a maximum of 15 members,³ and the use of an interview-based selection process to limit the numbers in the case of multiple candidates. In our case, the panel composition and the number of panel members will be adjusted to better represent the multinational heterogeneous European reality.

Because cardiovascular imaging appropriateness criteria cannot be defined exhaustively for every possible clinical scenario encountered in cardiology, the ESC/EACVI taskforce will have to select high impact clinical scenarios. These clinical scenarios should be selected because they have high incidence or prevalence, high morbidity or mortality, high cost associated with diagnosis or management, or simply because the definition of appropriateness criteria in these scenarios is highly likely to make a significant difference to clinical practice. Comprehensive explicit presentation of the clinical scenarios will aim to ensure correct interpretation by the voting panel involved in scoring appropriateness of tests for each indication.

Systematic critical review of existent evidence, best practice, and current ESC guidelines and ESC/EACVI-related position papers and recommendation documents will be performed by the panel of experts for each selected high impact clinical scenario.^{9–11} Evidence tables and a review summary will be generated to inform the definition of cardiovascular imaging indications. The cardiovascular

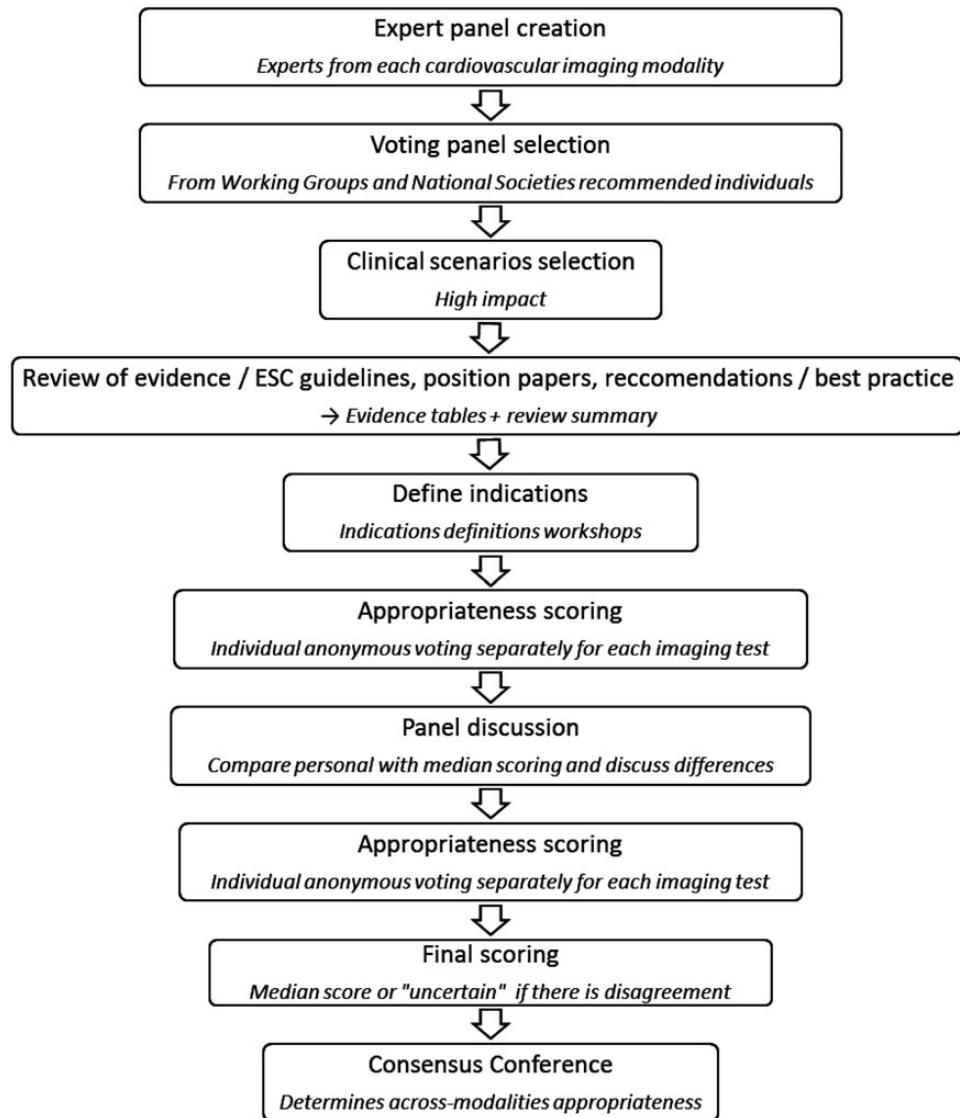


Figure 1: Appropriateness criteria development process.

imaging indications will be defined based on imaging taskforce and expert panel consensus during indications definition workshops.

The next step will be the appropriateness scoring of tests for the selected cardiovascular imaging indications, based on anonymous voting by panel members. Initial independent scoring will be followed by panel discussion of results and by a final round of independent scoring as previously proposed by RAND–UCLA and ACCF (modified Delphi method). During the panel discussion, each panel member will have the opportunity to compare his or her own results with the overall scoring and to ask for any needed clarifications. Disagreements will be discussed with the sole purpose to validate them (to ensure that they are not simply due to misunderstanding) and not to eliminate them. The described 1–9 scoring system (Figure 2) will be used:

- (i) Score 1–3 denotes an inappropriate test for the selected indication.
- (ii) Score 4–6 denotes uncertain appropriateness, which means that either more evidence is needed in this regard (taskforce planned research will have to be conducted in this case, particularly for indications with high incidence or prevalence) or further clinical details are needed to determine the appropriate test.
- (iii) Score 7–9 denotes an appropriate test for the selected indication.

The median score from the final round of voting will determine the appropriateness score for a particular test. Regardless of their median score, tests for which there is significant disagreement in between panel members will be characterized as having uncertain appropriateness. We could consider that disagreement exists when more than three panel members score a test outside the median score range, whereas agreement exists when no more than two

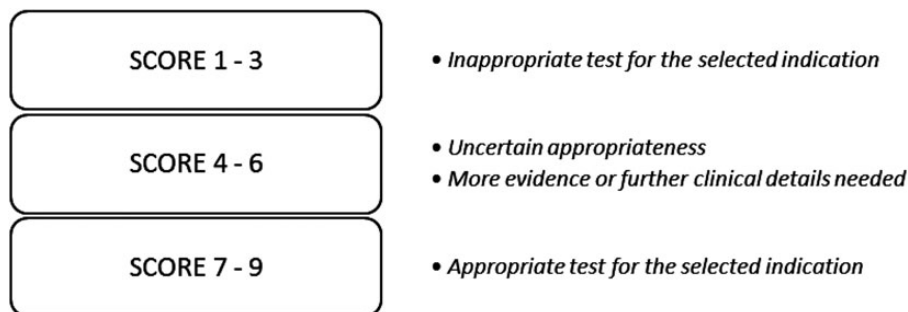


Figure 2: Appropriateness scoring.

panel members score the test outside the median score range. Complex statistical methods to define agreement and disagreement have been described and will be used if necessary.

The final step will be the determination of cardiovascular imaging appropriateness per clinical indication across modalities.⁹ This step will not be necessary in situations where a single imaging modality was rated as appropriate. In situations where more than one imaging modality was rated as appropriate, cost-effectiveness, performance, side effects, associated risks, and clinical outcomes will be considered in the preferred modality selection process. Cost-effectiveness will play an important role in the case of high impact clinical indications. The cost-effectiveness is determined not only by the direct cost of the test, but also by the indirect cost resulting from the need of a second test because of poor performance of the first test.

The EACVI multi-modality appropriateness criteria will be determined by group judgement of experts from all cardiovascular imaging modalities in a Consensus Conference.³ The need for further robust evidence in the multi-modality field is acknowledged; both randomized studies to compare imaging modalities for a particular indication and studies of outcomes are necessary.

The appropriateness criteria will be updated at regular intervals. This will typically follow a 3-year cycle, but earlier updates may become necessary in case new relevant evidence or developments become available.

Application of appropriate use documents

The appropriateness criteria, statement papers, educational material supporting clinical implementation, and all related documents will be made available online and also actively distributed to the European Commission, the European National Societies, Working Groups and Associations, National Healthcare Authorities, Healthcare Insurances, Social Security Systems, and patients' associations. It is expected that the distribution will cascade from National level to Local Healthcare Authorities, Healthcare Commissioning Groups, and Hospital Managers.

To assist clinical decision making and the selection of an appropriate imaging test for a certain indication, web-based tools and apps will be developed. Appropriateness criteria-related education initiatives will focus particularly on inappropriate indications, which will be

clearly and explicitly stated on web-based materials, apps, pocket cards, and posters for use at the point of delivery (imaging laboratories) and at the point of request (family doctors' surgeries and hospital outpatient clinics).

The appropriate use documents will inform and guide clinical practice, prioritization of workload in imaging laboratories, demand and capacity planning, development of workforce, resources and local facilities, as well as funding and reimbursement of cardiovascular imaging. Tests assigned 'uncertain appropriateness' should not be excluded from clinical use; recently evolved applications of cardiovascular imaging or rare indications often fall into this category because of limited supporting evidence.

The appropriate use documents will become an essential practical tool and a strong argument in the hands of all cardiovascular imaging stakeholders:

- (i) Beneficiary (patients and referring physicians) for requesting or not requesting tests.
- (ii) Providers (performing physicians and departments) for accepting or rejecting referrals.
- (iii) Authority (Healthcare and Social Security Systems) for regulation and financial rationalization.

Perspectives and future directions

The appropriateness criteria will be patient-centred, facilitating the best use of cardiovascular imaging resources for an individual in need of a test while at the same time encouraging the best use of material resources for the entire society, structured development of resources, efficient financial expenditure, and homogenization of care across Europe.

Access to patient imaging records would improve the use of cardiovascular imaging avoiding duplication of tests in between institutions and unnecessary premature repetition of tests at follow-up. Images and not only reports should be made available, should be standardized, comparable, transferable, and compatible with reanalysis. Currently, access to imaging file is restricted by governance policies, by communication means limitations, and by the existence of vendor-specific imaging storage and analysis packages. Future taskforce appropriateness documents will highlight these issues to alert National Societies, Healthcare Authorities, and the industry.

It is envisaged that, in the future, questions based on clinical scenarios meant to assess appropriate selection of imaging tests and appropriate exclusion of inappropriate tests will be introduced in cardiovascular imaging modalities certification and accreditation exams and also in cardiology, cardiac surgery, and general medicine speciality exams. Moreover, it is envisaged that performed tests appropriateness audit will be introduced as a laboratory accreditation and reaccreditation requirement. Clinical practice audit may suggest the need to restrict the right to request cardiovascular imaging tests to cardiologists only or may justify broadening of the referral pull based on correct use of appropriate use algorithms. Furthermore, justification of broadening of the referral pull may come from an audit of performed tests appropriateness and of accepted vs. rejected referrals, audit which may suggest that the imaging specialist is a reliable gatekeeper.

The appropriateness criteria themselves will be subjected to audit to determine their actual patient care benefit and their actual financial impact.¹²

Conclusion

Due to growing demand for diagnostic cardiovascular imaging, the development of criteria which aid appropriate use and planning of availability becomes essential. By establishing appropriateness criteria, the ESC/EACVI Taskforce aims to safeguard the interest of the patients, society, and the European Cardiovascular Imaging Community while promoting homogeneous healthcare provision, implementation of guidelines and of evidence.

Conflict of interest: none declared.

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