European Heart Journal – Cardiovascular Imaging (2014) **15**, 1188–1193
doi:10.1093/ehjci/jeu057

Updated standards and processes for accreditation of echocardiographic laboratories from The European Association of Cardiovascular Imaging: an executive summary

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Received 8 March 2014; accepted after revision 10 March 2014

Standards for echocardiographic laboratories were proposed by the European Association of Echocardiography (now the European Association of Cardiovascular Imaging) 7 years ago, to raise standards of practice and improve the quality of care. Criteria and requirements were published at that time for transthoracic, transoesophageal, and stress echocardiography. This paper reassesses and updates the quality standards to take account of experience and the technical developments of modern echocardiographic practice. It also discusses quality control, the incentives for laboratories to apply for accreditation, the re-accreditation criteria, and the current status and future prospects of the laboratory accreditation process.

Keywords Accreditation • Re-accreditation • Echocardiography • Echocardiography laboratory • Quality standards

Introduction

The mission of the European Association of Cardiovascular Imaging (EACVI) is 'to promote excellence in clinical diagnosis, research, technical development, and education in cardiovascular imaging in Europe and worldwide'. The goals of certification and accreditation under the 'aegis' of the EACVI are to protect patients from undergoing cardiovascular imaging examinations performed by unqualified persons and/or in an inappropriate environment, and to set European standards for competence and excellence in this field. The present document is an executive summary focusing specifically on laboratory accreditation in echocardiography.

A more detailed version of this document can be found on the Journal website.[1]

The EACVI provides a voluntary service of lab accreditation and institutions need to submit their applications in order to be accredited. Laboratories fulfilling or wishing to fulfil the European standards on echocardiography will also have a strong argument to use when they request appropriate resources to improve their services.

Aims

This paper appraises the published minimum standards[2] for accreditation of echocardiographic facilities, but also intends to spread the philosophy of homogenizing the echocardiographic practice and equipment across Europe. Laboratory accreditation is designed to apply to all countries whatever their model of provision of

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echocardiography in order to improve the patients' care in a way similar across Europe.

This update is needed because cardiovascular ultrasound is an ever-growing and developing technology, with an increasing list of clinical indications and state of the art practices.

The document also discusses: the policy of the EACVI concerning incentives and benefits for accredited laboratories, the change in the review process involving members of the National Societies (NS), criteria for reaccreditation, quality-control measures, and the current status and future aspects of laboratory accreditation.

The basic structure of laboratory standards

Certification of individual echocardiographers alone cannot guarantee a high-quality department. It is also necessary to have adequate equipment, management, and organization.[2,3]

The establishment of laboratory accreditation will enable:

(i) The development of local autonomy in echocardiography, e.g. the ability to train doctors and sonographers in echocardiography and to encourage trainees to sit the individual certification examinations. Accredited laboratories will also have to assure continuing professional development for already certified individuals.

(ii) A secured quality of basic or advanced echocardiography for the patient. To satisfy the progressively increasing subspecialization in echocardiography, laboratory standards are available in three modules

   (a) transthoracic echocardiography (TTE);
   (b) transoesophageal echocardiography (TOE);
   (c) stress echocardiography.

Throughout this document, the term 'echocardiographer' is used to include any person who is nationally authorized to perform echocardiography. We acknowledge that in some countries within the EACVI, non-medical qualified echocardiographers perform cardiac ultrasound. Throughout this document, the term 'sonographer' is used to mean a non-medical echocardiographer and subsumes the terms clinical physiologist, nurse, cardiac or echocardiography technician, and/or radiographer. It is also recognized that while the vast majority of echo laboratories will need to provide only a routine clinical service to their institution, a number of laboratories will have also academic endeavours with commitments to teaching and research. To this end, there will be two levels of minimal standards leading to respective laboratory accreditations.

(i) *The basic standard*: this will aim to fulfil 'mandatory' requirements offering an adequate basic clinical service. It is postulated that the majority of echocardiographic services in each country will fulfil these basic requirements.

(ii) *The advanced standard*: this will aim to fulfil requirements and offer an advanced service with state-of-the-art equipment and is also accredited for training and research. For this level, it will be necessary for the laboratories to have a history of research as well as teaching with state-of-the-art equipment performing all echo modalities such as Doppler tissue imaging, contrast, three-dimensional, and speckle tracking echocardiography.

Grading process of applications

Laboratories eligible for the EACVI Laboratory Accreditation programme have to meet the following requirements: (i) being established for at least 3 years and (ii) at least one of the senior physician members of the echo-lab staff should hold a valid individual TTE certification as described in *Tables 1–3* as a pre-requisite for the standard level of the TTE module of lab accreditation. Laboratory applications are submitted through an online platform enclosing several forms and certifications and are first checked for their administrative content. If the data are incomplete the applicants will be contacted and asked to supply missing information within 1 month. After this initial step, the EACVI adopted a revised strategy in terms of the grading process of new applications. This novel policy creates a direct chain of communication between the NS/EACVI reviewers and the applying laboratory (*Figure 1*). The involvement of NS will make the process more efficient while also reinforcing the partnership between the NS and the EACVI. In the beginning, senior NS-EACVI members will be involved in the accreditation process taking action as 'local NS representatives' and after this initial phase members of the EACVI Lab Committee will review the application.

Upon review by the NS Representative, the EACVI Laboratory Accreditation SubCommittee will review the index application, discuss the initial recommendation and finalizes the investigation. A possible rejection of an application does not preclude a second revision by the committee after the applicant lab has adopted a number of recommended changes/improvements.

Quality-control measures

As the applications are online and the reviewing of applications is largely a paper-based one with reviewers assessing self-reported documents and data submitted by the laboratories, it was felt necessary to implement an additional level of quality-control check. Thus, starting with 2012, every year a number of accredited laboratories, randomly selected, are visited onsite by a team of two EACVI and one NS representative. The visit is announced in advance and the lab prepares a number of documents and information for this purpose. The aim of such visits is to assure the accuracy of the information submitted and to provide support for improvements. In case of discrepancies, corrective measures are suggested within a certain timeframe. The EACVI Board and laboratory accreditation committee considered this as an important 'post-accreditation' addition to the existing 'pre-accreditation' quality-control measures (http://www.escardio.org/communities/EACVI/accreditation/lab/Pages/process.aspx).

Apart from these external measures/verifications, this writing committee reinforces the internal laboratory quality-control recommendations contained in the document on training, competence, and quality improvement in echocardiography[3] (*Figure 2*).

Benefits for the accredited laboratories

The current strategy of the EACVI regarding accredited laboratories is not only promoting excellence and encouraging quality improvement but also giving prospects for rewards

(i) Educational
- preference to be hosting centres for EACVI grants (i.e. prestige and reimbursement)
- preference in participation in specific EACVI educational projects (e.g. e-learning)
- preference to be hosting centres for fellowships
- preference in the selection of location for educational courses and meetings

(ii) Scientific
- preference in participation in specific EACVI multicentric scientific projects[4]

(iii) Research
- strong preference for research programmes[5]

(iv) Economical
- preference to be selected as sites for trials involving echo substudies with clear quality-control requirements.

Re-accreditation process

The aims of reaccreditation are to maintain quality standards for the labs already accredited by the EACVI, while also keep on meeting the standards of clinical competence. The process for re-accreditation should be more flexible, accessible, and faster

Table 1 Summary of criteria for rating transthoracic echocardiography

Basic standard	Advanced standard
Staff	
Both clinical and technical heads of Echocardiography	Clinical head performs at least one session including transthoracic studies each week
The clinical head holds a valid EACVI or recognized NS individual adult TTE certification or a Level III training (American Society of Echocardiography) plus a valid NBE (American National Board of Echocardiography) certification (Examination of Special Competence in Adult Echocardiography-ASCeXAM®) with an EACVI TTE individual certification practical e-logbook	Both technical and clinical heads possess individual TTE certifications as described for the standard level
Technical head spends six or more sessions in echocardiography activities (including management or quality control)	At least two echocardiographers hold EACVI or recognized NS adult TTE certification
Organization/equipment	
Studies archived. Written reports of routine studies issued within 24 h at the latest	Digital archiving of both reports and images for all studies (scheduled and emergency). Written reports issued on the day of the examination
System of review for echocardiograms in place	Formal and systematic quality control
Standardized examination protocol and list of indications for echocardiographic studies	Agreed minimum standards, standardized examination protocol and list of indications for echocardiographic studies
Provision for continuing education	System of liaison with other departments to advise about timing of or results of studies
All machines have second harmonic imaging and full quantitation package	Less than 1500 studies per echocardiographer per annum
All machines have colour and spectral Doppler	All machines have stand-alone continuous wave Doppler probes
At least one machine has stand-alone continuous wave Doppler probe	Weekly departmental meetings
No machine in regular use upgraded >7 years ago	Available standard operating procedures
Maintenance and scheduled service programme of echo machines	A core library with echo and general cardiology textbooks and preferably access to cardiology journals and updated books electronically
30–40 min allocated per standard study and up to 1 h for a complex study	There should be regular teaching to junior doctors, fellows and sonographers with appropriate provision of teaching material (videos, CDs, books, etc)
Compliance with appropriate European and national personal data's protection legislation	Advanced quantitation (tissue imaging, 3D, contrast, regurgitant volumes) when needed
Rooms uncluttered and of adequate size	Evidence of scientific work produced by the department
Appropriate provision of patient facilities and information	History of success in training for EACVI/national accreditation

Table 2 Summary of criteria for rating transoesophageal echocardiography

Basic standard	Advanced standard
Staff	
Designated head of TOE	Head of TOE performs/supervises >50 studies each year
Designated head should be performing or supervising at least 50 TOE annually	Head of TOE has the EACVI/recognized NS certification in TOE
	Designated person, usually a nurse, to manage airway and recover the patient
Organization/equipment	
Established protocols and list of indications for TOE agreed internally	Recovery area
Room typically 20 m^2 in area	Minimum standards for studies established
Written informed consent	Quality control of results, e.g. against surgery, pathology, other imaging
Provision for continuing education	Regular audits
Resuscitation equipment	Written standard operating procedures
Provision for quality control	History of success in training students
Thorough and precise report	Digital storage and retrieval
Routine use of	Provision of intra-operative services
Patient preparation including letter and pre-procedural checklist	3D imaging is recommended
Multiplane probe	
Suction, oxygen and pulse oximeter, BP monitoring	
Sedation used according to published guidelines	
Lockable drug cupboard	
Facilities for cleaning/sterilizing the probe	
Electrical safety testing for TOE probe	

Table 3 Summary of criteria for rating stress echocardiography

Basic standard	Advanced standard
Staff	
Designated head of stress echocardiography	Head maintains continuous medical education for stress echo
Performing a minimum of 100 studies/year per laboratory	More than 300 studies/year per laboratory
Studies performed by at least two people, one of whom is a clinician. At least one must have advanced life support or equivalent	
Head has a substantial experience of TTE and stress echo	
Organization/equipment	
List of indications, provision of information to the patient and written informed consent	Machine capable of changing mechanical index and have full digital stress echo package
ECG and BP monitoring capabilities (see text for details)	Audit of results against angiography or other independent standard
Established appropriate protocols	Advanced software dedicated to contrast imaging
Machine with second harmonic imaging and TDI software	Capability for both pharmacological and exercise stress
Resuscitation facilities readily available and record of complications	Additional quantification package should be available
Lockable drug cupboard	Standard operating procedures should be available
Contrast agent for left ventricle opacification available	A history of training junior doctors
Provisions for continue educational activities	

than the initial. The intention of the committee is to encourage a straightforward, less complex, and less expensive process for reaccreditation. The criteria and requirements for reaccreditation are identical with the initial ones. Applicants for re-accreditation have to fill in a new application form containing appropriate fields for description of changes that have possibly occurred since the first accreditation was issued. Documentation of the reaccreditation process must be kept on file and available for inspection upon request. The Accreditation committee might still conduct site visits after successful reaccreditation.

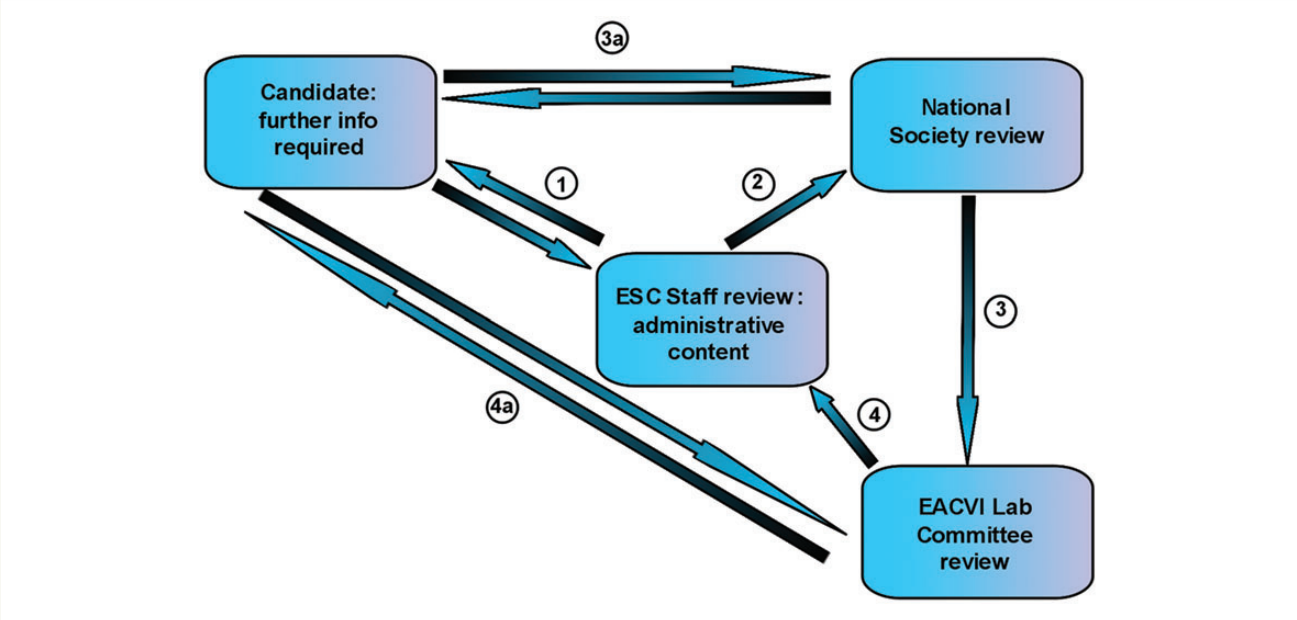

Figure 1: Review of the grading process. Applications are sent initially to the ESC staff. Double arrows: when data are missing the reviewer requests further information. The candidate sends the corrected/completed information. This exchange could happen a number of times if necessary.

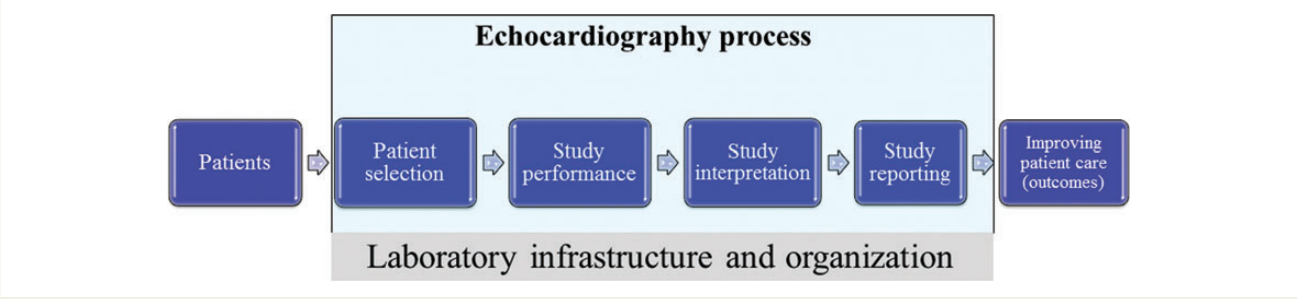

Figure 2: Framework for assessing quality in echocardiography and its influence on patient management. The proposed model consists of four main domains which may influence clinical outcome. Laboratory infrastructure and organization support the whole echocardiography process. Reproduced with permission from Ref. 3.

Current status of accredited laboratories and future aspects

To date, 46 laboratories received European accreditation. Details about the accredited labs can be found on the relevant EACVI accreditation webpage.

Applications from laboratories in countries outside Europe/ESC countries are allowed, provided they strictly follow the same process and meet all the required recommendations.

The ongoing development of the new ESCel platform, apart from an educational and collaborative tool between the ESC and NS will also assist training and accreditation in several modules and subspecialties. The purpose of this platform is the provision of a user-friendly, flexible, modular software tool while reducing the costs related to education, training, and certification/accreditation in Europe. After a period of repeated testing, demonstrations, and simulation, the ESCel will be implemented for the needs of the EACVI, both for individual certification and lab accreditation. This implementation is supposed to make the whole accreditation process easier for both the applicant laboratories and the assessors.

Conclusions

In this document, we raised the standards for echocardiography laboratories as initially set in the former document.[2] These updated recommendations were reassessed to recognize facilities of either standard or advanced level of laboratory accreditation. Important new topics included in this update are related to quality control,

re-accreditation criteria, and possible incentives/benefits for the accredited laboratories to encourage applications.

Acknowledgements

The following individuals constitute the current Echocardiography Laboratory Accreditation Committee (2012-2014). We are deeply grateful for all their hard work. Dr Alexandros Stefanidis (Greece, Accreditation Chair), Dr Nuno Cardim (Portugal, Co-chair), Dr Fausto Rigo (Italy, Co-chair), Dr George Athanassopoulos (Greece), Dr Luigi Badano (Italy), Dr Roland Brandt (Germany), Dr Ole Breithardt (Germany), Mr David Dawson (UK), Dr Kevin Fox (UK), Dr Piotr Hoffman (Poland), Dr Patrizio Lancellotti (Belgium), Dr Aleksandar Neskovic (Serbia), Dr Hans Joachim Nesser (Austria), Dr Petros Nihoyannopoulos (UK), Dr Bogdan A. Popescu (Romania), Dr Simon Ray (UK), Dr Rick Steeds (UK), Dr Heikki Ukkonen (Finland).

Conflict of interest: none declared.

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IMAGE FOCUS

doi:10.1093/ehjci/jeu072
Online publish-ahead-of-print 17 June 2014

It's just a coronary milking-like effect . . . or maybe not: posterolateral artery compression caused by a ventricle pseudoaneurysm

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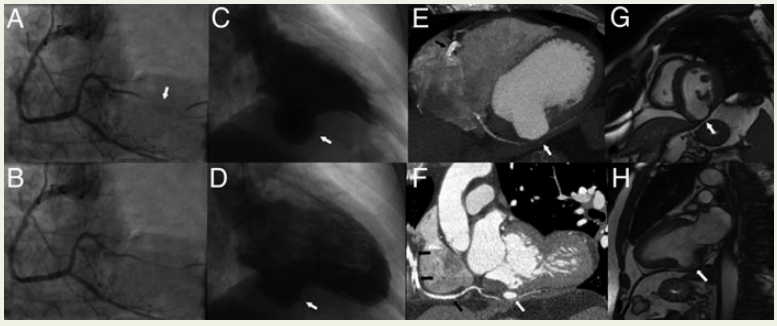

A 57-year-old man was referred to our catheterization laboratory due to angina complaints on exertion and an inconclusive treadmill stress test. He had a history of stent implantations in the right coronary artery (RCA) and left anterior descending (LAD) artery 2 years before. Current coronary angiography (see Supplementary data online, *Video S1*) showed neither *de novo* coronary stenosis nor stent restenosis. Instead, a large posterolateral branch (PLB) of the RCA with complete compression throughout its middle segment during systole (*Panel A*), but with unimpaired diastolic blood flow (*Panel B*), was noticed. Left ventriculography (see Supplementary data online, *Video S2*) showed a large pseudoaneurysm in the inferolateral wall with the PLB crossing below it (*Panels C* and *D*), subsequently confirmed by computed tomography (*Panels E* and *F*) and cardiac magnetic resonance imaging (*Panels G* and *H*). Because of the patient symptoms and the high risk of rupture of the pseudoaneurysm over time, surgical repair was performed, achieving successful outcome and uneventful recovery. The patient remains asymptomatic after 6-month follow-up. Coronary artery constriction by a pseudoaneurysm mimicking an angiographically milking effect is an exceptional finding that resembles the milking effect of myocardial bridging, the latter being almost exclusively demonstrated in the LAD.

Coronary angiography images showing the PLB of the RCA compressed on its middle segment during systole (*Panel A*) but with preserved blood flow during diastole (*Panel B*). Left ventriculogram images showing the large pseudoaneurysm in the inferolateral wall of the LV during systole (*Panel C*) and during diastole (*Panel D*). Computed tomography scan images with reconstruction of the RCA (*Panels E* and *F*) showing the previously implanted stents (black arrows), and the course of the PLB below the pseudoaneurysm with the absence of contrast along its middle segment due to extrinsic compression by the pseudoaneurysm (white arrow). Cardiac magnetic resonance images (*Panels G* and *H*) showing the pseudoaneurysm (arrow) with a large thrombus inside.

Conflict of interest: none declared.

Supplementary data are available at *European Heart Journal – Cardiovascular Imaging* online.