

# Updated standards and processes for accreditation of echocardiographic laboratories from The European Association of Cardiovascular Imaging

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Standards for echocardiographic laboratories were proposed by the European Association of Echocardiography (now the European Association of Cardiovascular Imaging) 7 years ago in order 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 reaccreditation criteria, and the current status and future prospects of the laboratory accreditation process.

**Keywords** Accreditation • Reaccreditation • Echocardiography • Echocardiography laboratory • Quality standards

## Introduction

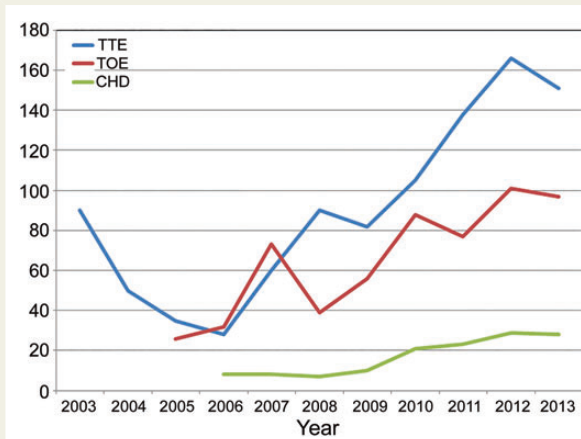
The mission of the European Association of Cardiovascular Imaging (EACVI) is 'to promote excellence in clinical diagnosis, research, technical development, and education in cardiovascular imaging in Europe and worldwide'. The goals of certification and accreditation under the 'aegis' of the EACVI are 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 will focus specifically on individual certification and laboratory accreditation in echocardiography.

While a number of countries had established the principle of national examinations in echocardiography, the process varied and

there was a desire to adopt common standards across Europe.<sup>1,2</sup> The EACVI wants to work closely with those countries aiming for this objective.

Over the past 10 years, numerous echocardiographers have completed the European examination process and achieved individual certification for competence in performing echocardiography for adult transthoracic (TTE), transoesophageal (TOE), and congenital heart disease studies (CHD) (<http://www.escardio.org/communities/EACVI/accreditation/TTE/Pages/fully-certified-individuals.aspx>)<sup>3</sup> (Figure 1). An echocardiography facility wishing to ensure high-quality care for its patients requires adequately trained and experienced personnel to interpret and perform echocardiograms. To attain and maintain high standards, however, individual skill is insufficient and a proper infrastructure and organization are also needed. As a consequence, the

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**Figure 1** Number of individuals fully certified in relation to the year in which they sat the exam. TTE: transthoracic echocardiography; TOE: transoesophageal echocardiography; CHD: congenital heart disease.

natural progression is from certifying individuals to establishing standards for echocardiographic laboratories, whereby the examinations and the equipment used are appropriate for clinical competence. Following this, it is then rational to progress to accrediting echocardiographic laboratories that are conforming to the established standards in as many European countries as possible so that there is uniformity across Europe. The 'regulations' in each country aim to establish parameters that will improve patient care, homogenize the practice of echocardiography across Europe, while encouraging a dialogue between institutional and accreditation bodies. On the other hand, it is also important to make these standards realistic and applicable to the majority of European institutions.

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<sup>1</sup> 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 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.<sup>1,4</sup>

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 and
- (ii) a secured quality of basic or advanced echocardiography for the patient. To satisfy the progressively increasing sub-specialization in echocardiography, laboratory standards are available in three modules:
  - (a) Transthoracic echocardiography (TTE)
  - (b) Transoesophageal echocardiography (TOE) and
  - (c) Stress echocardiography.

Through 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 and teaching with state-of-the-art equipment performing all echo modalities, such as Doppler tissue imaging (DTI), contrast, three-dimensional (3D), and speckle tracking echocardiography.

## Transthoracic echocardiography

### Basic standard

#### Personnel and training recommendations

All centres should have a specialist Clinical Head and where appropriate, a Technical Head of Department (*Table 1*). The Clinical Head should have specialist echocardiographic training and should hold EACVI certification or a recognized National Society's individual adult TTE certification equivalent or a Level III training (American Society of Echocardiography) plus a valid NBE (American National

**Table 1** Summary of criteria for rating transthoracic echocardiography

Basic standard	Advanced standard
<b>Staff</b>	
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 <sup>®</sup> ) 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
<b>Organization/equipment</b>	
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 a stand-alone CW Doppler probe
At least one machine has a stand-alone CW 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, and 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

Board of Echocardiography) certification (Examination of Special Competence in Adult Echocardiography—ASCeXAM<sup>®</sup>). In the last option, an additional EACVI individual TTE certification practical e-logbook of 250 clinical cases is also required. His/her job description should include setting clinical guidelines and policy, performing studies, training doctors and sonographers, audit, and clinical meetings. He/she should set up a system for reviewing requests and reports, and taking urgent clinical actions in response to echocardiographic findings.

Where nationally permitted, sonographers independently performing and reporting studies unsupervised should possess an EACVI or a recognized national equivalent certification. Continuing education should be provided to fulfil EACVI re-certification requirements or to a similar level. There should be a small library of relevant reference textbooks and/or access to an electronic library and educational material within the department. The job profile of an echocardiographer (either medical or non-medical) includes training, self-education, audit, and quality control in addition to performing echocardiograms.

### Organization and facilities recommendations

Echo rooms used for inpatients on beds should allow sufficient patient and operator comfort and privacy even when examinations are performed with portable ultrasound machines (typically ~20 m<sup>2</sup>). Appropriate ventilation, heating, lighting, and ancillary facilities should be in place. Echo machines generate significant amounts of heat and if the room is not properly ventilated, there is risk of shortening the lifespan of the machine and making the patient and operator very uncomfortable.

Echo machines must have the capacity for comprehensive imaging, including M-mode, second-harmonic imaging, colour mapping, both pulsed and steerable continuous wave (CW) Doppler, as well as DTI. They should also have full quantitation package and recording capabilities. At least one echo machine must have a stand-alone CW Doppler probe. The machines should be serviced regularly and must be maintained in good operating condition. A cleaning programme that includes scheduled cleaning of the echo machines and other equipment's components, including filters and transducers, according to the service instructions of the manufacturer is considered important.

A service agreement with the vendor is also preferable in order to maintain hardware and update with a new software.

There must be consideration of patient comfort, privacy, dignity, and provision of adequate information prior to the examination. There must be awareness of health and safety issues as well as infection control. A report database should exist within the laboratory with facilities for storing and retrieving echo studies usually for at least 5 years. Digital storage in DICOM format is the preferred way for archiving and exchanging data of the echo studies.<sup>2</sup>

A separate viewing room is recommended for reviewing studies and offline reporting. This will ensure a more efficient use of the equipment, without interruptions to wait for the echocardiographer to look at the images to prepare the report, and proper time and tranquillity for the reporting physician, without interfering with the workflow of the lab. There should be appropriate physical storage space for equipment and supplies. A patient information leaflet should be available.

### Recommendations to perform, report, and store echocardiographic studies

The time allocated for a standard TTE study should be at least 30 min. An average routine echocardiographic study takes between 30 and 40 min.<sup>2</sup> Frequently, however, the study may be prolonged to 60 min or more when full quantification in complex valve pathology or CHD is required as well as application of new modalities such as DTI, two-dimensional (2D) speckle, strain, 3D, and contrast echocardiography.<sup>5</sup>

Allowing for all aspects of the job profile, an echocardiographer should perform an average of no more than 1500 studies per year.

A list of indications for echocardiograms should ideally comply with current international recommendations or be agreed in house. A system for prioritizing and filtering of requests should be in place, particularly for inpatients. Minimum standards for studies and study protocols should be established internally and a consistent format for reports must be applied. Requirements of appropriate European and national personal data protection legislation must be complied with in connection with data storage and treatment. It is recommended that reports of routine studies are issued on the day of the examination or within 24 h at the latest. For urgent or inpatient studies, at least a preliminary report should be provided promptly and written in the patient's notes. A system for reporting cases who require urgent clinical attention must be present. Quality control in the form of regular audits and external reviews must be in place.

The main report should be logical and descriptive. It should contain three sections: the measurements, the descriptive part, and the conclusion. The section on the measurements should be clearly identifiable on the report. These should contain cavity dimensions, and Doppler measurements/calculations. In the description section, the valve anatomy, cavity size, and global and regional ventricular function of both the left and the right heart should be described. The conclusion should be accurate and concise, relevant to the request.<sup>2</sup> A clinical comment may be added when appropriate. The final report must be typewritten, signed, and issued by the interpreting physician or a certified sonographer. An electronic password protected signature is encouraged. In case handwritten signatures are used, the echocardiographers who approved the report should be clearly identifiable (stamped name or addition of a personalized stamp). Stamped reports without properly set signatures are considered

unacceptable. Digital storage in DICOM format is the preferred way for archiving and exchanging data of the echo studies. Emergency echo studies should also be stored.<sup>6</sup>

## Advanced standard

The centre must have accomplished all the minimal standards at basic level in TTE (*Table 1*). To achieve the advanced level scientific work, research and a publications list produced from the laboratory will be considered.

Staffing levels and workload appropriate to the number of trainees to ensure adequate clinical capacity is required. To ensure adequate operational standards, emphasis is put on the employment of echocardiographers with European or national certification. Organizational aspects that may be relevant for an advanced level echo lab are: (i) digital recording of both reports and images. All reports should, as a rule, be issued on the day of the examination;<sup>2</sup> (ii) need for formal and systematic quality control according to written protocols; (iii) minimum data sets of measurements and imaging protocols for studies, written together with a list of indications for echocardiography; and (iv) system of liaison with other departments to notify timing of studies and how to prepare the patients (medications, fast, venous line, etc.). Additional organizational procedures that will improve the overall quality and consistency of reports among echocardiographers are: (i) the weekly departmental meetings based on clinical case review; (ii) the constant interaction with the other cardiovascular imaging branches (cardiac magnetic resonance, computerized tomography, nuclear cardiology, and coronary angiography) and the rest of the cardiology department as well as cardiothoracic unit; (iii) a core library, e.g. at least three up to date echo textbooks and one general cardiology textbook and preferably access to cardiology journals and updated books electronically either in the department or within the hospital. Current guidelines relevant to the performance and practice of echocardiography should be available. Training material (tapes/CDs/digital cases, etc.) and internet access should be available to all the staff.

## Transoesophageal echocardiography

### Basic standard

All the standards for TTE should be applied, in addition to the following (*Table 2*).

#### Personnel and training recommendations

All centres should have a designated Head of TOE who will be actively leading the service as hands-on. The designated Head will usually be the Clinical Head of Echocardiography and should perform or directly supervise at least 50 studies per annum. This is important to guarantee patient safety and responsibility among other colleagues. TOE studies require an operator with appropriate training, a cardiac-trained nurse and/or an assistant physician, and preferably, a sonographer. Specifically, who may be an operator depends very much on each country's regulatory authorities. The EACVI recommends that whoever performs and reports TOEs should be appropriately trained having obtained TOE individual certification or being supervised by a certified echocardiographer. It is recommended

**Table 2** Summary of criteria for rating transoesophageal echocardiography

Basic standard	Advanced standard
<b>Staff</b>	
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
<b>Organization/equipment</b>	
Established protocols and list of indications for TOE agreed internally	Recovery area
Room typically 20 m <sup>2</sup> in area	Minimum standards for studies established
Written informed consent	Quality control of results, e.g. against surgery, pathology, and 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
<i>Routine use of:</i>	Provision of intraoperative 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	

that, prior to a TOE examination, there has been a comprehensive TTE as the two examinations are considered complementary. Continuing education must be provided for all operators.

### Recommendations to perform and organize a TOE service, and related facilities

A well-organized TOE service should have in place: (i) a minimum standard for study performance according to different cardiovascular diseases and the head of TOE must be responsible for ensuring that all operators adhere to them; (ii) a procedure to explain to the patient exam performance and duration, and a patient information leaflet; (iii) informed consent forms; and (iv) a list of indications for TOE which follows the EACVI recommendations.<sup>7</sup> A pre-procedural checklist should be used prior to the examination (Appendix).

Whenever sedation is used, it should be in accordance with national and/or European recommendations given for monitoring.<sup>7</sup> The TOE probe should be cleaned after every study and sterilized when appropriate. The TOE probe must be checked electrically at a frequency dependent on usage and a logbook of these checks must be kept. Each laboratory should establish a written protocol. The use of single-use latex sheaths should also be considered. Recommendations for organization and equipment:

There should be appropriate provision of:

- (i) room size typically ~20 m<sup>2</sup> (ideally >25 m<sup>2</sup> in area),
- (ii) air-conditioning or appropriate climate control,
- (iii) couch with facility for head-down tilt,
- (iv) facilities for cleaning and sterilizing the probe,

- (v) storage cupboard for the probe,
- (vi) resuscitation apparatus and drugs,
- (vii) lockable drug cupboard with necessary antidotes,
- (viii) suction, oxygen, and pulse oximeter,
- (ix) ECG monitor,
- (x) sphygmomanometer,
- (xi) facilities for recovery of the patient,
- (xii) protocols for patient care, and
- (xiii) equipment transducer should be multiplane and should have >5 MHz frequencies with pulsed wave (PW), CW, and colour Doppler capabilities.

### Reporting and storing recommendations

The report must precisely describe the findings and conclusions of the study, and it must also include at least the following information:

*Comments on:* ventricles, atria, left atrial appendage, valves, interatrial septum, pericardium, and all visible parts of the thoracic aorta.<sup>7</sup> The section on measurements is not always essential if a complete complementary TTE study precedes the TOE study. Additional measurements should be mandatory if the TOE study was performed to add specific information for the clinical work up of the patient (e.g. candidates to interventional cardiology, full quantitation in patients with valvular regurgitation,<sup>8</sup> PW Doppler evaluation of emptying velocities at the left atrial appendage in candidates for cardioversion, etc.). These should contain cavity dimensions, and Doppler measurements/calculations. Finally, if any cardiac or other structure is not well visualized, this must be clearly stated in the report.

Additional information is considered mandatory and adds important information for the index or future studies: (i) medication used (e.g. sedative and contrast); (ii) easiness of probe insertion; and (iii) complications (if any).<sup>7</sup> A record of unsuccessful attempts to perform the TOE and/or complications should be kept for quality control. Recording and storage recommendations match those of the TTE standards.

## Advanced standard

The centre must have accomplished all the minimal standards at the basic level in TTE (Table 2). For the advanced standards, scientific work, research, and a publication list produced from the laboratory will be considered. A summary list of required criteria for rating a laboratory for advanced level in TOE is provided in Table 2.

The clinical Head should hold EACVI or recognized national certification in TOE and will be responsible for the overall quality of service provision within the institution. He/she should be directly hands-on by performing or supervising at least 50 TOE annually and be available to provide an expert opinion when needed.

There should be a designated person, usually a nurse, to manage the airway and recover the patient. In some places, the sonographer may check and supervise the patient's condition and safety. The staffing levels and workload must be appropriate for the number of trainees to ensure adequate clinical capacity. A recovery area will need to be provided to respect the patient's dignity. A set of minimum standards and written indications for studies need to be established. These could be separate or jointly with the TTE indications. A standard operating procedures document should be available.

Results must undergo quality control, e.g. against surgery, pathology, or other imaging modalities such as magnetic resonance imaging or computed tomography, and regular audits must be performed. The laboratory should demonstrate a history of success in training junior

doctors as well as students and/or sonographers. Images should be stored digitally and a database should be available for fast retrieval and comparison with other studies. There should be provision of intraoperative services for both cardiac and non-cardiac surgery when needed. Intraoperative studies when performed should be documented, archived, and reported. Three-dimensional imaging as an adjunct to 2D is considered a powerful modality, and its use is recommended in the criteria for an advanced level.

## Stress echocardiography

### Basic standard

All the standards for TTE should have been completed in addition to the following (Table 3):

#### Personnel and training recommendations

All centres should have a designated Head of Stress Echocardiography who will be directly involved in stress echoes and will be considered to be the expert opinion leader within the department. He/she should be directly involved in performing or supervising and ultimately reporting at least 100 stress echocardiographic studies annually. Overall, to provide a sufficient quality of stress echoes, a minimum of 100 examinations annually should be performed in the laboratory by a designated team. A detailed specific request form including indication for stress, symptoms, history of coronary artery disease if known (previous myocardial infarction, coronary angiography, stent, or surgery) medications as well as the presence of any allergies, asthma, prostatism or glaucoma should be clearly listed. The procedure should be explained to the patient and documented. Any operator who reports stress echo studies must be specially trained in stress echocardiography and authorized by the clinical Head.

**Table 3** Summary of criteria for rating stress echocardiography

Basic standard	Advanced standard
<b>Staff</b>	
Designated Head of Stress Echocardiography	Head maintains CME 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 ALS or equivalent	
Head has a substantial experience of TTE and stress echo	
<b>Organization/equipment</b>	
List of indications, provision of information to the patient, and written informed consent	Machine capable of changing MI and have a 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 LV opacification available	A history of training junior doctors
Provisions for continue educational activities	

ALS, Advanced Life Support; CME, Continuous Medical Education; MI, Mechanical index; LV, Left Ventricle.

Each operator/reporter should perform or directly supervise and/or review at least 100 stress echo studies per year. Continuing education must be provided for those performing and interpreting the studies. At least one member of staff performing the study should possess formal qualifications in intermediate or advanced life support.

Mandatory requirements for an accredited stress echo lab should include:<sup>9</sup> (i) a shared list of acceptable indications in accordance with the current EACVI recommendations; (ii) appropriate protocols for stress echo performance, acquisition, and display according to each stressor (i.e. exercise, dobutamine, dipyridamole, adenosine, etc.) and cardiac condition to be investigated. The Head of Stress Echocardiography must be responsible for ensuring that all operators adhere to them; (iii) procedures to explain the patient the exam, risks and benefits, as well as to collect informed consent; and (iv) a form to annotate complications. Regular audits, comparison of results with other techniques including but not exclusively coronary angiography, clinical correlation, and outcome studies should be performed to check accuracy of the test and quality control.

#### Recommendations about stress echo organization and related facilities

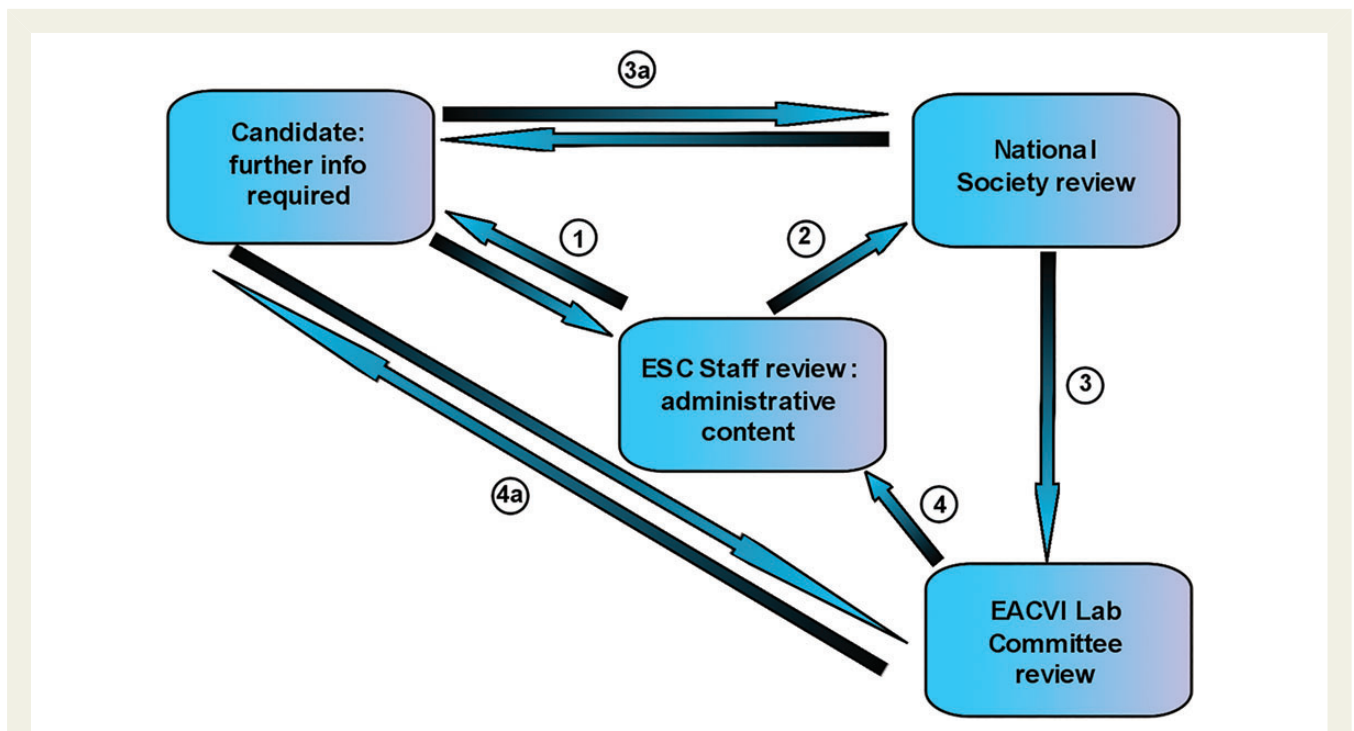
There should be appropriate provision of a designated room size, typically ~20 m<sup>2</sup> (preferred >25 m<sup>2</sup>). Machines must be equipped with a dedicated stress echocardiography software with a minimal frame rate of >40 frames/s, digital acquisition with ECG triggering, and synchronization with capability for quad screen display. Simple videotaping is considered inadequate and can only be used as a

backup of digital data. Provision of additional hardware and software for improving endocardial border definition and quantification (contrast agents and contrast-specific software or tissue imaging) should be available. Infusion syringe for pharmacological stress and/or equipment for exercise stress, e.g. bicycle, should be available. An ECG monitor and recorder as well as sphygmomanometer should be available. Resuscitation apparatus and drugs must be readily available and patients should be supervised at least 30 min after finishing the test. For centres which use a bicycle ergometer, this should have the possibility to position the patient approximately in a 45° backwards and a 45° rotated to the left side.

#### Advanced standard

The centre must have accomplished at least the minimal standards at the basic level in TTE (Table 3). As previously, for the advanced standards, scientific work, research, and a publication list produced from the laboratory will be assessed. A summary list of required criteria for rating a laboratory for the advanced level is provided in Table 3. The clinical Head must be directly involved in performing or supervising as well as reporting at least 100 stress echocardiographic studies annually. However, for the stress echo laboratory to qualify for the advanced level, they should be performing at least 300 stress echoes annually, using both pharmacological and exercise echocardiography.

The staffing levels and workload must be appropriate for the number of trainees to ensure adequate clinical capacity. Each centre must have an EACVI or a nationally certified individual

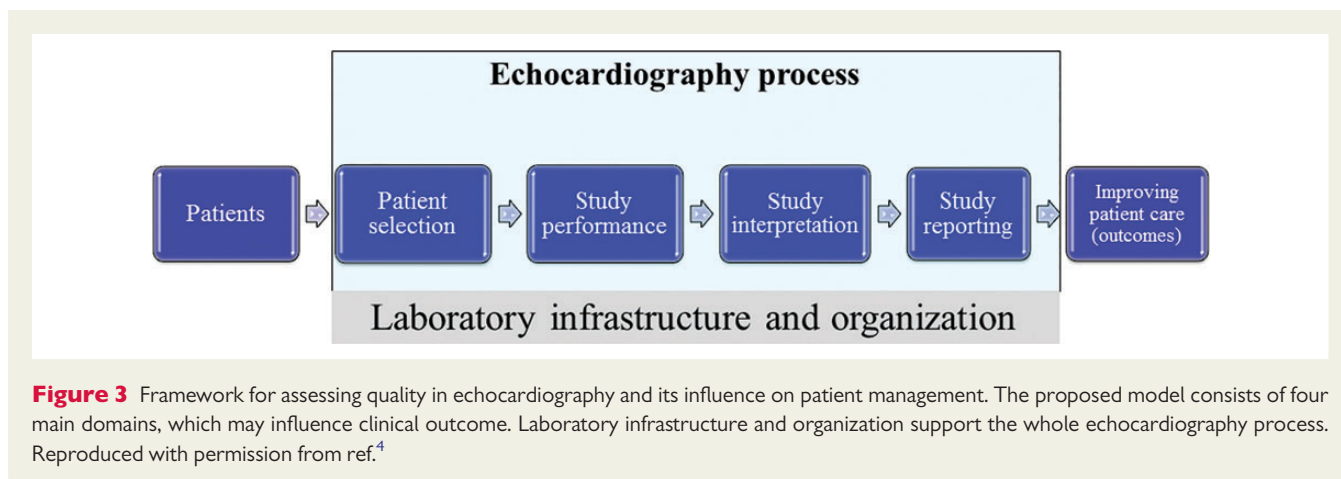


**Figure 2** Review of the grading process. Applications are sent initially to the ESC staff. Double arrows: when data are missing the reviewer requests further information. The candidate sends the corrected/completed info. This exchange could happen a number of times if necessary.

**Table 4** Action items and quality measures in the 'dimensions of care' framework for echocardiography

Step	Quality goals	Action items	Quality measures
Laboratory infrastructure	Ensure baseline standards for equipment and staff proficiency	Apply for standard laboratory accreditation EAE and/or national certification for both sonographers and physicians. Aim for advanced laboratory accreditation for stress echo and TOE. Monitor the number of studies performed/ reported by each sonographer/physician.	Percentage of echo studies performed by certified sonographers. Percentage of echo studies performed/reported by certified physicians CME credits for both sonographers and clinicians.
Patient selection	Appropriateness	Introduce appropriateness criteria for TTE, TOE, and stress echocardiography. Develop specific study order forms to help referring clinicians in selecting appropriate indications. Monitor case-mix of echo studies.	Percentage studies meeting appropriateness criteria. Percentage of in- and outpatient studies reported as normal.
Study performance	Diagnostic quality studies	Adopt EACVI recommendations for standardization of performance, digital storage, and reporting of echocardiographic studies. <sup>2</sup> Adopt EACVI recommendations for stress echo. <sup>9</sup> Adopt EACVI recommendations for TOE. <sup>7</sup> Ensure adequate time for each echo modality. Develop specific protocols for the use of contrast.	Number of studies reviewed monthly for completeness by the clinical and/or technical head of the laboratory. Percentage of complete studies according to EACVI recommendations. <sup>2</sup> Percentage of non-interpretable studies. Number of studies performed/interpreted daily by each sonographer/physician. Percentage of studies performed with the use of contrast.
	Patient safety	Monitoring in- and outpatient waiting list. Develop specific time-frame for performing the echo study according to the clinical priority. Monitoring major complications of stress echo (death, acute myocardial infarction, and major arrhythmias) and of TOE.	Percentage of patients who were studied within the pre-defined time-frame set for each clinical priority. Percentage of patients with documented signed informed consent prior to TOE or stress echo. Percentage of unsuccessful intubations in patients in whom TEE was attempted.
Study interpretation	Accuracy	Adopt existing standards for measuring and interpreting echo studies. <sup>2</sup> Compare results with other imaging techniques or with surgical findings. Adopt digital archiving of images and data. <sup>2</sup>	Percentage of patients with an explicit clinical indication to echo. Percentage of patients with abnormal stress echo and normal coronary arteries at coronary angiography. Bias and limits of agreement of LV volumes vs. cardiac MR or nuclear. Bias and limits of agreement of transaortic gradients with cardiac catheterization. Number of studies reviewed monthly for interpretation by the clinical head of the laboratory.
	Reproducibility	Develop procedures for determining intra- and inter-reader variability of reporting physicians.	Intra- and inter-reader reproducibility of LV ejection fraction Intra- and inter-reader reproducibility of aortic/prosthetic effective orifice area.
Reporting	Completeness	Develop computerized software for structured reporting for all echo modalities. <sup>2</sup> Adopt minimal data sets for comprehensive reporting of echo studies. <sup>2</sup>	Percentage of reports meeting requirements of the minimal data set for reporting. <sup>2</sup> Percentage of reports in which the clinical indication for the study has been clearly stated. Percentage of reports in which a comparison with previous studies (when available) has been provided.
	Timelines	Define procedures to provide timely report to referring physicians.	
Improved patient care (outcomes)	Satisfaction	Develop customer satisfaction assessment tools.	Percentage of patients/referring physicians reporting a satisfaction score above a pre-determined value.
	Impact on clinical management	Develop methods for measuring patient outcomes and impact on medical decision making.	Percentage of patients referred to cardiac scintigraphy after a definitively positive or negative stress echo for coronary artery disease.





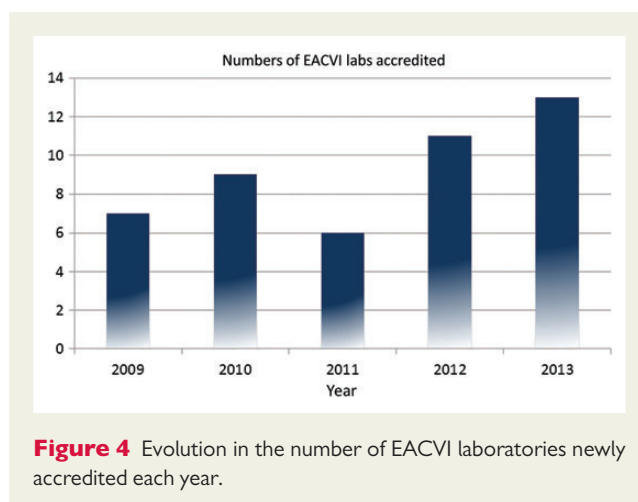
responsible for training. He/she will act as the local expert and opinion leader who will also hold overall responsibility for quality control and safety.

There should be guaranteed access to local, national, and international meetings for staff involved in stress echocardiography. Regular weekly departmental case review sessions should be held. There should be a core library with at least three up to date echo textbooks and one general cardiology textbook and preferably access to cardiology journals and updated books electronically either in the department or within the hospital. Training material (tapes/CDs/digital cases, etc.) should be available in the department and internet access should be available to all the staff. The laboratory must have a history of success in training students to the EACVI or national level.

To obtain advanced level accreditation in any modality, a laboratory must offer all three modalities (TTE, TOE, and stress echocardiography) and must reach the advanced standard for TTE.<sup>10</sup>

## 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 physicians members of the echo lab staff should hold a valid individual TTE certification as described in *Table 1* as a prerequisite 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 2*). 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,<sup>4</sup> as summarized in Table 4 and Figure 3.

## 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:
  - (a) preference to be hosting centres for EACVI grants (i.e. prestige and reimbursement),
  - (b) preference in participation in specific EACVI educational projects (e.g. e-learning),
  - (c) preference to be hosting centres for fellowships, and
  - (d) preference in the selection of location for educational courses and meetings.
- (ii) Scientific:
  - (a) preference in participation in specific EACVI multicentric scientific projects.<sup>11</sup>
- (iii) Research:
  - (a) strong preference for research programmes.<sup>12</sup>
- (iv) Economical:
  - (a) preference to be selected as sites for trials involving echo substudies with clear quality control requirements.

## Reaccreditation 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 reaccreditation should be more flexible, accessible, and faster 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 reaccreditation have to fill in a new application form containing appropriate fields for the 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.

## Current status of accredited laboratories and future aspects

To date, 46 laboratories received European accreditation (Figure 4). Details about the accredited labs can be found on the relevant EACVI accreditation webpage (<http://www.escardio.org/communities/EACVI/accreditation/lab/Pages/accredited-laboratories.aspx>).

It was an EACVI Board's decision to allow applications from laboratories in countries outside Europe/ESC countries, provided they strictly follow the same process and meet all the required recommendations. So far, two laboratories from outside Europe/ESC countries have successfully completed the process and were issued accreditation diplomas.

The ongoing development of the new ESCel platform, apart from an educational and collaborative tool between the ESC and National Societies, 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.<sup>1</sup> 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, reaccreditation criteria, and possible incentives/benefits for the accredited laboratories to encourage applications.

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**Conflict of interest:** None declared.

## Appendix

### Transoesophageal echocardiography

#### Example transoesophageal echocardiography checklist

Hospital name: \_\_\_\_\_

Department name: \_\_\_\_\_

Non-invasive procedure checklist and record of procedure:

Patient name Ward \_\_\_\_\_

Hospital number Consultant \_\_\_\_\_

Date \_\_\_\_\_

1. Patient identity band	Yes/No
2. Consent form signed	Yes/No
3. Drug chart	Yes/No
4. Venflon <i>in situ</i>	Yes/No
5. History of swallowing difficulties	Yes/No
a. Haemoptysis	Yes/No
b. Oesophageal surgery	Yes/No
6. Previous endoscopy	Yes/No

If yes, any problems:

7. Diabetes/epilepsy/asthma/alcohol habits \_\_\_\_\_

8. Blood sugar (if diabetic) BM: \_\_\_\_\_

9. Allergies Yes/No \_\_\_\_\_

10. INR if anticoagulated \_\_\_\_\_

11. Capped teeth/crowns Yes/No \_\_\_\_\_

12. Dentures Present/Removed/Not applicable \_\_\_\_\_

13. Nil by mouth from \_\_\_\_\_

14. Blood pressure pre-procedure \_\_\_\_\_

15. Oxygen saturation on air \_\_\_\_\_

16. Escort present (if outpatient) Yes/No \_\_\_\_\_

Checklist completed by \_\_\_\_\_ (signature)

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