



EAE laboratory standards and accreditation

P. Nihoyannopoulos*, Kevin Fox, Alan Fraser, Fausto Pinto,
on behalf of the Laboratory Accreditation Committee of the EAE

Hammersmith Hospital, NHLI, Imperial College London, W12 0NN, London, UK

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Abstract Laboratory standards have been set by the European Association of Echocardiography of the European Society of Cardiology, in order to homogenize the practice of echocardiography in Europe and therefore ultimately, to protect patients. These standards have been developed for transthoracic, transesophageal and stress Echocardiography into two levels; the *basic level*, set to provide basic laboratory standards for an optimal clinical service and the *advanced level*, which is set to establish a fewer number of advanced laboratories in each country, where by in addition to basic standards, they may be providing extensive teaching and research.

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Introduction

The mission of the EAE is to “Promote excellence in clinical diagnosis, research, technical development and education in cardiovascular ultrasound in Europe”.

The year 2003 was a milestone for European echocardiography because the first examinations for accreditation of individuals performing and reporting echocardiographic examinations took place.¹ While a number of countries had established the principle of national examinations in echocardiography, the process varied and there was a need to homogenise standards across

Europe. Three years on, the whole process has proved to be a huge success and more and more national societies are now adopting it.

The natural progression from accrediting individuals is to establish standards for echocardiographic laboratories whereby the examinations and the equipment used are appropriate for safeguarding patients. Following this, it is then natural to progress to accrediting echocardiography 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 are there to establish parameters that will improve standards for patient care and encourage a dialogue between institution and accreditation bodies. However, it is important to make these standards realistic and applicable to the majority of European institutions to improve quality.

* Corresponding author. Tel.: +44 020 8383 8156; fax: +44 020 8383 4392.

E-mail address: p.nihoyannopoulos@imperial.ac.uk (P. Nihoyannopoulos).

EAE provide a voluntary service and institutions will eventually need to submit their written request in order to be accredited. Importantly, European Standards on Echocardiography may serve as “ammunition” to take to managers of institutions in the fight for resources.

Aims

The aim of this process is to raise quality standards of practice and equipment across Europe in a uniform manner. It is also to protect staff (sonographers and doctors) working in echo laboratories from making an incorrect diagnosis and to protect patients from being given the wrong treatment. There is also a political arm to help departments negotiate purchases and upgrades of equipment with their local health authorities.

What this document does not provide is a legal framework for practice but represents a voluntary process of standards that must function within national and local regulations. It is designed to apply to *ALL* countries whatever their model of provision of echocardiography.

The basic structure of laboratory standards

Accreditation of individual echocardiographers alone cannot guarantee a high quality department. It is also necessary to have adequate machines, management and organization.

The establishment of laboratory accreditation will enable:

1. 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 accreditation examinations. Accredited laboratories will also have an important role to play in continuing professional development for already accredited individuals.
2. An assured quality of basic or advanced echocardiography for the patient.

In order to satisfy the progressively increasing sub-specialisation in echocardiography, laboratory standards may be available in three modules in the first wave of minimal standards:

1. Transthoracic echocardiography
2. Transoesophageal echocardiography
3. Stress echocardiography

Through this document, the term “echocardiographer” is used to include any person who is nationally authorised to perform echocardiography. We acknowledge that within some countries within EAE, cardiac ultrasound is performed by non-medical qualified echocardiographers. 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 recognised 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:

1. *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.
2. *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 most if not all echo modalities such as tissue Doppler, contrast and three-dimensional echocardiography.

Standard 1: transthoracic echocardiography

Recommendations for staffing and training (Table 1)

All centres should have a specialist Clinical Head and where appropriate, a Technical Head of Department. The Clinical Head should have specialist echocardiography training and should hold EAE accreditation or a National Society’s equivalent. 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 urgent clinical review in response to findings at echocardiography.

Where nationally permitted, sonographers independently performing and reporting studies

Table 1 Summary of criteria for rating transthoracic

Standard	Advanced
<i>Staff</i>	
Both clinical and technical heads of echocardiography	Clinical head performs at least one session including transthoracic studies each week
At least one echocardiographer holding EAE or national individual accreditation	Both technical and clinical heads have EAE/National accreditation
Technical head spends six or more sessions in echocardiography activities (including management or quality control)	
<i>Organisation/equipment</i>	
System of review for echocardiograms in place	Formal and systematic quality control
Provision for continuing education	Agreed minimum standards and imaging protocol for studies
Studies archived. Written reports within 24 h (see text)	List of indications for echo published internally
Most machines have 2nd harmonic imaging and full quantitation package	System of liaison with other departments to advise about timing of or results of studies
All machines have colour and stand-alone Doppler	At least two EAE/nationally accredited echocardiographers
No machine in regular use upgraded more than 7 years ago	Weekly departmental meetings
30–40 min allocated per standard study and up to 1 h for a complex study	Report database and digital archiving
Compliance with appropriate European and national personal data protection legislation	Available standard operating procedures
Rooms uncluttered and of adequate size	There should be regular teaching to junior doctors, fellows and sonographers with appropriate provision of teaching material (videos, CDs, books, etc.)
Appropriate provision of patient facilities and information	Evidence of scientific work produced by the department
List of indications for echocardiographic studies	Advanced quantitation (TDI, contrast, regurgitant volumes) when needed
Standardised examination protocol	History of success in training for EAE/national accreditation

unsupervised should be EAE accredited or national equivalent.

Continuing education should be provided to fulfil EAE re-accreditation 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, quality control in addition to performing echocardiograms.

Recommendations for organisation and equipment

Echo rooms used for inpatients on beds should preferably be at least 20 m² in area to allow sufficient patient and operator comfort.

Appropriate ventilation, heating, lighting and ancillary facilities should be in place. Echo machines generate a lot 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, pulsed Doppler and both steerable and stand-alone CW Doppler, as well as recording capabilities. They should also have a full quantitation package.

The machine should be serviced regularly.

There must be consideration of patient comfort, privacy, dignity and provision of adequate information.

There must be awareness of health and safety issues.

A report database should exist with facilities for storing and retrieving echo studies.

A separate viewing room is recommended for reviewing studies and offline reporting.

There should be appropriate physical storage space for equipment and supplies. A patient information leaflet should be available.

Recommendations for performing studies

The time allocated for a standard transthoracic study should be at least 30 min. An average routine echocardiographic study takes between 30 and 40 min. Frequently however, the study may be prolonged to 60 min or more when full quantification in complex valve pathology or congenital heart disease is required as well as application of new modalities such as TDI, three-dimensional and contrast echocardiography.

Allowing for all aspects of the job profile, an echocardiographer will perform an average of no more than 1500 studies per year (see [Appendix A](#)).

A list of indications for echocardiograms should be agreed in house.

A system for prioritising and filtering of requests should be in place, particularly for in-patients.

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.

Reports from routine studies should usually be issued on the day of the examination. For urgent or inpatient studies, at least a preliminary report should usually be issued immediately.

A mechanism must be in place for reporting cases which require urgent clinical attention. Emergency echos should also be stored.

Quality control in the form of regular audits and external reviews must be in place.

Recommendations for reporting studies

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 top of the report. These should contain cavity dimensions, and Doppler measurements/calculations.

In the description section, the valve anatomy, cavity size, 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.

The final report should be issued by an accredited echocardiographer. A clinical comment may be added when appropriate.

Standards for advanced level ([Table 1](#))

The centre must have accomplished all the minimal standards at basic level in transthoracic echocardiography.

For the advanced standards, scientific work, research and a publications list produced from the laboratory will be considered. A list of required criteria for rating a laboratory for advanced level is provided in [Table 1](#).

Staffing levels and workload appropriate to the number of trainees to ensure adequate clinical capacity.

Here emphasis is put on the employment of individuals with European or national accreditation.

There is a need for formal and systematic quality control according to written protocols.

There should be agreed minimum standards and imaging protocols for studies, written together with a list of indications for echocardiography.

There should be a system of liaison with other departments in place to advise about timing of results of studies. Ideally, results should be made available the same day as the examination.

There should be weekly departmental meetings based on clinical cases. Interaction with the rest of the cardiology department should be the norm and regular provision of feedback.

There should be a report database and digital archiving of all studies.

There should be a core library, e.g. three up to date echo textbooks and one general cardiology textbook in the department and access to cardiology journals electronically or within the hospital. Training material (tapes/CDs/digital cases, etc.) and internet access should be available to all staff.

Standard 2: transoesophageal echocardiography (TEE) ([see Table 2](#))

All the standards for transthoracic echocardiography should be applied, in addition to the following.

Recommendations for staffing and training

All centres should have a designated Head of TEE who will be actively leading the service as hands-on. The designated Head will usually be the Clinical

Table 2 Summary of criteria for rating transoesophageal

Standard	Advanced
<i>Staff</i>	
Designated Head of TEE Designated head should be performing or supervising at least 50 TEE annually	Head of TEE performs/supervising >50 studies each year Head of TEE has EAE/national accreditation Designated person, usually a nurse, to manage airway and recover the patient
<i>Organisation/equipment</i>	
Established protocols	Recovery area
Written informed consent	Minimum standards for studies established
Resuscitation equipment	List of indications for TEE agreed internally
Multiplane probe	Quality control of results, e.g. against surgery, pathology, other imaging
Routine use of:	Room at least 20 m ² in area
Suction, oxygen and pulse oximeter	Regular audits
BP monitor	Written standard operating procedures
Patient preparation including letter and pre-procedure checklist	History of success in training students
Provision for continuing education	Digital storage and retrieval
Provision for quality control	Provision of intra-operative services
Sedation used according to published guidelines	
Lockable drug cupboard	
Facilities for cleaning/sterilising the probe	

Head of Echocardiography and should perform or directly supervise at least 50 studies per annum. This is important for guaranteed patient safety and responsibility amongst other colleagues.

TEE 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 upon each country's regulatory authorities. The EAE recommends that whoever performs and reports TEEs should be appropriately trained and preferably have achieved TEE individual accreditation standards.

It is recommended that prior to a TEE examination, there has been a comprehensive transthoracic examination as the two examinations are considered complimentary.

Continuing education must be provided for all operators.

Process

Minimum standards for studies should be established and the head of TEE must be responsible for ensuring that all operators adhere to them. The procedure should be explained to the patient and a patient information leaflet should be provided.

Informed consent should be obtained and documented before the procedure. A list of indications for TEE should be agreed in each centre.

A preoperative checklist should be used prior to the examination ([Appendix A](#)).

Whenever sedation is used, it should be in accordance with national and/or European recommendations given for monitoring.

The TEE probe must be checked electrically at a frequency dependent on usage. A logbook of these checks must be kept.

The TEE probe should be cleaned after every study and sterilised when appropriate. Each laboratory should establish a written protocol.

The use of single-use latex sheaths should also be considered.

Recommendations for organisation and equipment

There should be appropriate provision of:

- Room size 20 m² minimum (ideally >25 m² in area)
- Air-conditioning or appropriate climate control should be available
- Couch with facility for head-down tilt
- Facilities for cleaning and sterilising the probe
- Storage cupboard for the probe
- Resuscitation apparatus and drugs
- Lockable drug cupboard with necessary antidotes
- Suction, oxygen and pulse oximeter

- ECG monitor
- Sphygmomanometer
- Facilities for recovery of the patient
- Protocols for patient care
- Equipment transducer should be multiplane and should have >5 MHz frequencies with PW, CW and CFM capabilities.

Standards for advanced level (Table 2)

The centre must have accomplished all the minimal standards at basic level in transthoracic echocardiography.

For the advanced standards, scientific work, research and a publications list produced from the laboratory will be considered. A summary list of required criteria for rating a laboratory for advanced level is provided in Table 2.

The clinical Head should hold EAE/national accreditation 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 TEE 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 be responsible for the patient's well-being 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 transthoracic 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 students and/or sonographers as well as junior doctors.

Images should be stored digitally and a database should be available for fast retrieval and comparison with other studies.

There should be provision of intra-operative services both for cardiac or non-cardiac surgery when needed. Intra-operative studies when performed should be documented, archived and reported.

Standard 3: stress echocardiography (Table 3)

All the standards for transthoracic echocardiography should have been completed in addition to the following.

Table 3 Summary of criteria for rating stress echocardiography

Standard	Advanced
<i>Staff</i>	
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 ILS or equivalent	
Head has a substantial experience of TTE and stress echo	
<i>Organisation/equipment</i>	
List if indications	Machine capable of changing MI 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 2nd harmonic imaging and TDI software	Capability for both pharmacological and exercise stress
Resuscitation facilities readily available	Additional quantification package should be available
Lockable drug cupboard	Standard operating procedures should be available
Blood pool contrast available	A history of training junior doctors
Provisions for continue educational activities	

Recommendations for staffing and training

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, coronarography, 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 and documented.

Any operator who reports the studies must be specially trained in stress echocardiography and be authorized by the clinical Head.

Each operator/reporter should perform or directly supervise and/or review at least 100 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.

A list of indications for stress echocardiograms should be agreed.

Appropriate protocols for studies should be established and the Head of Stress Echocardiography must be responsible for ensuring that all operators adhere to them.

There should be established protocols for acquisition and display. There should be capability for quad-screen display rather than simple video taping. The latter could act as a backup of data.

Quality control should be in the form of regular audits and comparison of results including but not exclusively coronary angiography. There must be a mechanism in place for feedback to assess clinical correlation and outcomes.

Recommendations for organisation and equipment

There should be appropriate provision of a designated room size minimum of 20 m² (preferred >25 m²).

Machines must be equipped with stress echocardiography software with minimal frame rate >40 frames/s, digital acquisition with ECG

triggering and synchronisation (quad screen). Provision of additional hardware and software for improving quantification (contrast agents and contrast specific software or tissue Doppler) 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.

For centres that they use a bicycle ergometer, this should have the possibility to position the patient in a 45° angle backwards and a 45° angle rotated to the left side.

Standards for advanced level (Table 3)

The centre must have accomplished at least the minimal standards at basic level in transthoracic echocardiography.

As previously, for the advanced standards, scientific work, research and a publications list produced from the laboratory will be considered. A summary list of required criteria for rating a laboratory for 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 advanced level, they should be performing at least 300 stress echoes annually, using more than just one modality (i.e. pharmacological and exercise).

The staffing levels and workload must be appropriate for the number of trainees to ensure adequate clinical capacity.

Each centre must have an EAE or a nationally accredited individual 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.

Access to paper and online journals for all staff. There should be a core library with up to date echo textbooks and a general cardiology textbook in the department and access to cardiology journals electronically 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 staff.

The laboratory must have a history of success in training students to EAE or national level.

Conclusions

In this document we have established agreed minimal standards for echocardiography laboratories in Europe at two levels. The basic level is aimed at satisfying the majority of echo laboratories in order to insure basic quality control. It is expected that only a few laboratories in each country will achieve advanced level of accreditation and these will be centres where competitive research and teaching is established.

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Appendix A 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 in situ	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)

Reference

1. Fox KF, Flachskampf F, Zamorano JL, Badano L, Fraser AG, Pinto FJ. Report on the first written exam held as part of the European Association of Echocardiography Accreditation Process in Adult Transthoracic Echocardiography. *Eur J Echo* 2004;5:320–5.