Echocardiography Laboratory Standards and Accreditation Guidelines for Adults: Report on the Echocardiography Association of the Interamerican Society of Cardiology (ECOSIAC)

Group of work about accreditation of the echocardiography association of the interamerican society of cardiology (ecosiac)

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WHY AN ACCREDITATION PROCESS IS IMPORTANT?

The group of work about the Accreditation in Echocardiography for Adults / Echocardiography Laboratory Standards (GTA) of the Echocardiography Association of the Interamerican Society of Cardiology (ECOSIAC) has as objective promoting the knowledge and quality standards of the echocardiography practice in all the countries belonging to ECOSIAC. After having made all the consultations, and following the experience in these processes of the American Society of Echocardiography and the European Association of Echocardiography, the GTA has developed an accreditation process for all echocardiography practitioners. While establishing a standard and inviting cardiologists and ultrasound technicians to have an accreditation, we are trying to promote the process of learning and increase the quality of the echocardiographies and the echocardiography laboratories at interamerican level. We are aware of the differences in the practice and learning of echocardiography in the different countries and our goal is the implementation of essential minimum requirements for the training of the person in charge of performing echocardiography and the realization of studies in echocardiography laboratory at interamerican level and give these tools to the different Societies of Cardiology and Committees, Boards or Societies of Echocardiography of countries belonging to ECOSIAC and not the establishment of rigid learning criteria.

WHY SHOULD WE ASK FOR THE ACCREDITATION?

First, *accreditation is a voluntary process* and it would not affect the status of the person who performs echocardiography or the laboratory within the countries members of the ECOSIAC. Accreditation aims to promote a standard that would give regulations about the learning of echocardiography and about the quality of service of the echocardiography laboratory. The documentation given by the accreditation process would initially work with the local or regional guides in case these are available. The main objective of ECOSIAC is to recognize, with a certificate, the persons in charge of performing echocardiographies and those laboratories which ask for the accreditation process. The accreditation process seeks to stimulate good learning practices and quality in the formation of the person in charge of performing echoardiographies through an optimal training in the different techniques, stimulate the learning through books, assistance to regional, national and international conferences, webcast, CDs, DVDs or any other way of teaching. Either the person in charge of performing an echocardiography, the technical staff, physicians and patients would benefit with the accreditation process as it involves training and compromise. Accreditation would be internationally recognized by all the countries members of ECOSIAC.

ACCREDITATION IN ADULT ECHOCARDIOGRAPHY

I. DEFINITION OF THE AREA

Nowadays, echocardiography is the imaging technique most used for the assessment of the anatomy and cardiovascular function. This technology based on ultrasound has grown rapidly in the last 40 years. The first registers used M mode; then registers of two-dimensional images appeared and then the use of different modalities of Doppler (pulsed, continuous, color flow, tissue). Nowadays, contrast echocardiography intravenous with the administration of microbubbles which enables an adequate definition of endocardial borders, a Doppler of higher quality and eventually studies of myocardial perfusion is being used. Although the echocardiographic examination is not invasive and is performed via transthoracic,

bougies with transducers in the distal end of an endoscope (transesophageal bougie) which allow images of high sharpness and quality and in many occasions allow clarifying doubts, are available. Ultrasonic technology may also insert transducers in the distal end of a thin catheter which allow the visualization of intravascular and intracoronary walls. The improvement in computational techniques allow the three-dimensional reconstruction of the heart (three-dimensional echocardiography), both by transthoracic or transesophageal via. It is not surprising that the quantity of clinical information provided by the echocardiography increased vertiginously in the lat years. Its different modalities of examination give an image in real time and very reliable of the anatomy and cardiac function. Doppler techniques provide accurate hemodynamic assessment, comparable with the one obtained through invasive methods. Time ago, cardiologists learned hemodynamic in the laboratory of catheterism; today, they learn in the laboratory of echocardiography. We can see how the hemodynamic study of cardiovascular patients has moved to echocardiography areas. (1-8)

Echocardiography is the process of choice for the detection of pericardial effusion, congenital and acquired valve disease and primary myocardial disease. Possibly, it is the most practical method for the assessment of ventricular function and the monitoring of the patients with different cardiovascular pathologies. The functional assessment of coronary lesions is made as routine through exercise stress echocardiography or using drugs (dobutamine, dipiridamol, adenosine) or through the non invasive determination of the coronary flow reserve. Echocardiography has a notable role in cardiovascular assessment and in the definition of perioperative cardiac risk of a high risk patient who will undergo a non cardiac surgery. (1-8)

The physician in charge of performing an echocardiography must know the different techniques that are used nowadays: M mode, two-dimensional (2D), three-dimensional (3D), pulsed Doppler, continuous Doppler, color Doppler, tissue Doppler, strain, strain rate, contrast studies, transesophageal studies, exercise and drugs stress studies, acoustic quantification, among others. For every new echocardiographic application there is a learning process. The physician should have knowledge, time and experience in order to perform a reliable examination.

As the echocardiography does not produce physical damage, is painless and you can repeat it the times you want, abuse of this technique is common. The performance of unnecessary examinations (sometimes with non-healthcare purposes) produces doubtful diagnosis generating confusion in the patient and greater costs to the health system.

Given the complexity of the echocardiographic examination and the clinical importance of the echocardiography in the diagnosis and treatment of cardiovascular disease, it is necessary to make specific training programs in echocardiography, as the diagnosis and cardiovascular therapy depend on the data provided by an echocardiogram. Due to its low cost, the rational use of this process may have an important impact in our health systems avoiding expensive and of higher risk examinations.

II. NAME AND DEGREE GIVEN BY THE PROGRAM

The program leads to the degree of *Expert or Specialist* in *Adult Echocardiography*, according to the legislation in each country.

III. PROFILE AND OBJECTIVES OF THE PROGRAM

1. Expert's or specialist's occupational profile

The *Expert or Specialist* in *Adult Echocardiography* needs a tertiary hospital for the complete training of his/her profession. Such hospital must have an integral cardiology department (hemodynamic, cardiovascular surgery, electrophysiology, etc). However, the professional would work in primary, secondary and/or tertiary hospitals, sanatoriums, centers with the necessary technology and safety to perform complete echocardiographic studies.

2. Objectives

2.1 General

Once finished the training, the professional would be able to obtain images and perform complete echocardiographic studies using the different available techniques: M mode, two-dimensional, Doppler in its different modalities, transesophageal and exercise or pharmacological stress studies, three-dimensional echo and with contrast, according with the level of objectives obtained. This would enable the professional to integrate the echocardiographic findings and make a diagnosis of the situation or pathology of the patient.

2.2. Specific

2.2.1. Advance competence and ability in the performance of a complete echocardiographic study (M mode, two-dimensional, pulsed Doppler, continuous Doppler, color Doppler, tissue Doppler with its different modalities, 3D echo).

2.2.2. Competence and ability in the performance of transesophageal echocardiography.

2.2.3. Competence and ability in the performance of exercise stress echocardiography.

2.2.4. Competence and ability in the performance of pharmacological stress echocardiography (dobutamine, dipiridamol) and in non invasive measurement of coronary flow reserve.

2.2.5. Competence and ability in the performance of contrast echocardiography.

2.2.6. Collaboration with the department of hemodynamic in the guided performance by echocardiography of special procedures (for example; balloon valvuloplasty, collocation of devices for the treatment of congenital cardiopathies, endomyocardial biopsy,

pericardiocentesis, etc.).

2.2.7. Collaboration with the department of cardiovascular surgery in the performance of surgical procedures (valvuloplasty, coronary revascularization, valve replacement) with the intraoperative use of transesophageal echocardiography and epicardial echocardiog raphy.

2.2.8. Collaboration with the department of anaesthesia in the echocardiographic assessment of the patient who will undergo a surgery. The above needs a deep knowledge of the conventional echocardiography and the exercise or pharmacological stress echocardiography.

2.2.9. Collaboration in intensive care units (general, coronary and cardiovascular surgery) in the performance of echocardiographic studies.

2.2.10. Collaboration with the emergency area in the diagnosis and immediate stratification of unstable patients or with diagnostic doubts (for example; infarction suspicion, aorta dissection, cardiac tamponade, pericarditis, pulmonary thromboembolism).

2.2.11. Competence in the performance of echocardiographic exams in critically ill patients.

IV. ACADEMIC ASPECTS OF THE PROGRAM

1. Admission requirements

a- Being a physician Specialist in Clinical Cardiology graduated in any Cardiology program of the country, authorized by the State competent organization (in some countries to have the complete training in internal Medicine is not a requirement, although the complete training is optional).

b- Comply with the requirements of choice of university or institution that endorse the program of specialization in echocardiography. The program of specialization in echocardiography must have the official support of the State organization in charge of giving legal support to the program and/ or the respective society of cardiology.

2. Schooling and education

a- The student of Echocardiography postgraduate will have an activity of time and dedication according to the tasks, practices and academic activities scheduled by the university or institution that endorse the program.

V. CURRICULAR STRUCTURE

1. Training

The suggested guides in this document describe the minimum requirements for the training of a general cardiologist in the performance and interpretation of echocardiographic exams in adult patients with acquired or congenital heart disease.

These guides follow, in general terms, the recommendations of the American Society of Echocardiography (ASE) and the European Association of Echocardiography (EAE). (9-14)

1.1. Training levels

The specialization in Adult Echocardiography involves different levels of training or complexity, defined according to the level of experience and competence in the performance and the analysis of the echocardiographic exam. It is important to mention that although the number of exams and the intervals of time for each level are suggested, the depth of knowledge and the quality of training are important factors.

FIRST LEVEL

Objective: Introductory experience
(3 months, perform at least 75 exams personally and interpret at least 150 echocardiogrphic studies)
The first level involves the comprehension of basic principles, indications, applications and technical limitations of echocardiography and the interrelation of this technique with other diagnostic methods.

It is recommended that the person under training stays 3 months exclusively at the echocardiography department. He/she must personally perform at least 75 exams and interpret at least 150 echocardiographic studies using the techniques of M mode, two-dimensional and Doppler.

All the studies of this level must be guided by an echocardiographist who supervises the performance and interpretation.

SECOND LEVEL

Objective: Experience to adopt the responsibility for the echocardiographic studies.
(3 months of additional training, perform at least other 75 exams personally and interpret at least other 150 echocardiographic studies)

The Second Level of training, under the supervision of a professional, must provide the experience and the necessary knowledge to be able to perform and interpret echocardiographic studies in M mode, two-dimensional and Doppler. In order to acquire the ability to autonomously interpret echocardiographic studies it is recommended to perform at least other 75 studies under supervision and to participate in the interpretation of other 150 Doppler echocardiographic studies (300 in total) in a period of 3 additional months.

THIRD LEVEL

Objective: Performance of special procedures
(6 months of additional training, personally perform at least other 150 exams and interpret at least other 450 echocardiographic studies)

The Third Level of complexity involves the knowledge and the performance of special ultrasound procedures (transesophageal, stress, intraoperative echocardiography, 3 D echo).

It is recommended that the person should perform echocardiographic studies during other 6 months, performing at least other 150 exams and interpret

Objective	First Level Introductory experience	Second Level Responsibility of the echocardiographic studies		Third Level Special procedures
Time		**3 months**	**3 months**	**6 months**
Number of exams				
Performed		75	75	150
Interpreted		150	150	450

Table 1. Minimum time of training in relation to the desired level.

other 450 echocardiographic studies including a great variety of congenital and acquired problems (a total of 12 months of training).

In order to obtain enough skill to administrate a laboratory of echocardiography it is recommended to learn administrative aspects of the echocardiography laboratory, acquire experience in projects of echocardiographic research and know the step forward in technology and the applications of cardiovascular ultrasound.

Once finished, the professional should have the responsibility for the supervision of cardiologists under training and the integration of the laboratory of echocardiography within the activities of the cardiology department of the hospital he/she is working.

The laboratory of echocardiography should follow the guides of continuous improvement of quality and ideally perform at least 2000 echocardiographic studies per year in order to guarantee the physician under training a wide experience.

A. The rotations that physicians make during their cardiology residence are not considered as they are part of the basic training of a cardiologist.
B. Periods of 3, 6, and 12 months are the minimum time of training, although what would be considered as most important is the number and the quality of performed studies.
C. Each level must be complemented with an approved theoretical and practical exam in the training institution or regulator and the issued certificate of the approved level by the director of the course, the chief of the laboratory of echocardiography and/or the chief of the department of cardiology.
D. *The progressive steps of the training in clinical echocardiography should be continuous: Level I must be followed by Level II. Level III is started once finished Level II.*

2. Training in transesophageal echocardiography

As a previous requirement it is asked to have experience in echocardiography, minimum Level II (6 months) and more than 300 cases of transthoracic echocardiography performed. The training should include the learning of the introduction of the transducer, bougies control, echograph control and experience in the interpretation.

2.1.Introduction of the transducer

In order to learn the technique of the introduction of the transducer it is necessary to know the anatomy of the oropharynx and esophagus. The practitioner should acquire ability in the introduction both in supine decubitus and left lateral decubitus. A minimum of 25 esophagus and stomach intubations must be performed in a variable time. This step should be guided by a cardiologist expert in transesophageal echocardiography or by an endoscopist gastroenterologist.

2.2.Experience in the use of the transducer and interpretation

It is recommended that the physician in training perform a minimum of 50 studies and interpret al least 100 more studies, supervised, of omniplanar transesophageal echocardiography (optional 3D).

2.3.Duration of the training

In order to acquire enough ability in the use of the transducer, the controls and the adequate interpretation of cardiovascular pathologies, a training of not less than 6 months is recommended.

3. Training in stress echocardiography

3.1.Requirements

As a previous requirement it is asked to have experience in echocardiography, at least Level II (6 months) and more than 300 cases of tranthoracic echocardiography performed. The training must include all the aspects of stress echocardiography: selection of patients, electrocardiographic analysis, knowing the different modalities of procedures (exercise, pharmacologic, handgrip, among others), interpretation of the symptoms, ability in obtaining echocardiographic studies during stress protocols and correct interpretation of wall motion and ventricular function (optional: coronary reserve, contrast studies). The recognition of artifacts, technical problems and possible pharmacological adverse effects should be considered.

Specific training in stress echocardiography should start when the director of the laboratory believe that the professional has enough experience in the analysis of movement of the ventricular wall at rest. The identification of changes induced by the procedure should start.

3.2.Requirements of the laboratory and the training supervisor

In general, the training should be done in those laboratories that perform a minimum of 30 stress echocardiography per month. The supervisor of the training should have Level III of training and enough

experience in the interpretation of stress echo (not less than 500 studies or 1 year of performing studies).

3.3.Number of exams
Direct supervision (next to the patient) in the performing of the first 50 exercise or pharmacological stress studies is recommended.
He/she should also make the interpretation of 100 more exams under direct supervision before starting to perform them by him/herself.

3.4.Duration of the training
In order to achieve an adequate experience in the interpretation of stress or pharmacological echocardiography, it is recommended a period training not less than 6 months.

4. Theoretical contents (Seminars)

4.1. ACC/AHA guidelines for the clinical application of echocardiography: indications of the echocardiography based on evidence.
4.2. How to perform an echocardiographic exam: measurements according to the American Society of Echocardiography and Eu ropean Society of Echocardiography recommendations.
4.3. Color Doppler: basic principles, implementation, and use of controls.
4.4. Ultrasonic characterization of tissue.
4.5. Tissue Doppler and its different modalities (speckle tracking).
4.6. Acoustic quantification and colorcinesis.
4.7. Myocardial contrast echocardiography.
4.8. Three-dimensional echocardiography (3D).
4.9. Assessment of left ventricle systolic function.
4.10. Assessment of left ventricle diastolic function.
4.11. Assessment of right ventricular function.
4.12. Assessment of left ventricular mass.
A. Measurement methods
B. Limitations
C. Comparison with other methods
4.13. Assessment of venous flow: pulmonary, superior and inferior vena cava and suprahepatic veins.
4.14. Cardiac tamponade, constrictive pericarditis.
4.15. Assessment of aortic regurgitation:
A. Jet diameter
B. Jet area
C. Regurgitant fraction
D. Hemipressure time
E. Vena contracta
4.16. Mitral regurgitation:
Semiquantitative parameters
A. Regurgitation duration
B. Doppler signal intensity
C. Jet area
D. Vena contracta
E.Retrograde systolic flow in pulmonary veins
F. Mitral flow Doppler
G. Left cavities diameter
Quantitative Parameters
A. Regurgitant volume
B. Regurgitant fraction
C. Effective regurgitant orificium
D. Quantitative assessment by PISA
4.17. Mitral stenosis assessment:
A. Valvular area by planimetry, hemipressure time, PISA
B. Mitral prevalvuloplasty assessment (Wilkins index, Abascal index, other indexes)
C. Indexes for the prediction of postvalvulo plasty mitral regurgitation
D. Treatment indications (percutaneous versus surgical valvuloplasty, valve replacement)
4.18. Aortic stenosis assessment:
A. Valve area by planimetry, Doppler
B. Gradients by Doppler
C. Aortic valve resistance
D. Surgical indication
4.19. Exercise stress echocardiography in the assess ment of valve disease
4.20. Exercise stress and drugs echocardiography (dobutamine, dipiridamol, adenosine)
4.21. Coronary flow reserve assessment
4.22. Myocardial viability assessment
4.23. Dilated cardiomyopathy echocardiography
4.24. Obstructive and non obstructive hypertrophic cardiomyopathy
4.25. Restrictive cardiomyopathy echocardiography
4.26. Transesophageal echocardiography com ments:
A. Clinical indications
B. Contraindications
C. Patient preparation
D. Exam technique
E. Complications
4.27. Echocardiography assessment of possible em bolic sources of cardiac origin.
4.28. Aortic dissection and aortic intramural hema toma assessment.
A. Classification criteria based on echocardio graphic findings
B. Complications
C. Prognosis
4.30. Prostheses assessment: mechanical and bio logical
4.31. Pulmonary hypertension assessment
A. Measurement methods
B. Acute cor pulmonale (pulmonary thrombo embolism)
C. Chronic cor pulmonale
D. Primary pulmonary hypertension
4.32. Assessment of the patient with acute myocar dial infarction:
A. Diagnosis
B. Complications
4.33. Hypertensive cardiopathy assessment:
A. left ventricular hypertrophy: diagnosis, types of hypertrophy
B. Prognosis on the echocardiographic data base
C. Indications of the limited echocardiogra

phy in hypertension
D. Possible impact of the echocardiography in the assessment and treatment of the patient with hypertension

4.34. Common congenital cardiopathies in adults

4.35. Complex cardiopathies in adults corrected during childhood

5. Strategies

5.1. The admitted physician should have exclusive dedication in the department of echocardiography during the period of his/her training. The training period should not be less than 1 year in order to achieve Level III.

5.2. He/she should comply with the requirements of each of the three levels.

5.3. He/she should participate in academic activities of the department which at least would be 2 weekly meetings where seminars and discussion of cases will be arranged.

5.4. He/she should present a weekly seminar about echocardiography (see Curricular structure, Seminars).

5.5. He/she should participate in research works within the department of echocardiography.

5.6. He/she must prepare an original research work as first author, according to the department of echocardiography and the Scientific Committee or the Research team of the institution where he/she attends the training (in Level III).

5.7. He/she must attend academic meetings or of clinical discussion organized by the institution.

5.8. Once completed each level an organized evaluation prepared by the team of professionals in echocardiography would be taken in order to analyze if the objectives are fulfilled. Once fulfilled these objectives the professional pass to the next level. Technical and academic ability as well as collaboration spirit and availability for work would be analyzed.

5.9. He/she should collaborate with the teaching of the cardiology interns rotating in the department.

5.10. During the training of the two first levels, decisions about the results of an echocardiographic study should be consulted with the department's responsible. He/she should take a dossier of studies which would be authorized by the Medical Director of the Department (it may be weekly or monthly) in order to certify that he/she has completed the number of studies required by the program.

VI. SYSTEMS OF EVALUATION

1. Conceptual theoretical practical evaluation once finished each rotation period.
2. Personal behaviour. Assistance and scientific performance during the training.
3. Research work: mark of the research work (Level III).

VI. DURATION OF THE PROGRAM

The program of Training in Adult Echocardiography in the three levels has a minimum duration of 1 year.

ACCREDITATION OF THE ECHOCARDIOGRAPHY LABORATORY

The Accreditation Guidelines in Echocardiography follow, in general terms, the American Society of Echocardiography (ASE), the Intersocietal Commission for the Accreditation of Ecocardiography Laboratories (ICAEL) and the European Association of Echocardiography (EAE) recommendations'. (9-17)

STAFF AND SUPERVISION

1. Medical Director of the Department

1.1. The Medical Director must be an echocardiographist physician legally qualified.

1.1.1. Medical Director's experience and training required:

The Medical Director should be a cardiologist legally qualified who comply one or more of the following requirements:

A. Having completed a formal training program of 12 months in an echocardiography program legally certified (Level III) and 12 months of practical experience with at least 150 studies performed and 450 interpreted.
B. Having completed a formal training program of 6 months in echocardiography (Level II) and one and a half year of experience including the performance of 300 studies and interpretation of at least 600 Doppler echocardiograms.
C. Three years of practical experience in echocardiography with at least 1800 interpretations of Doppler echocardiograms. He/she would also include the learning of administrative aspects of the echocardiography laboratory, experience in echocardiography research projects and knowing the latest step forward in technology and the applications of cardiovascular ultrasound.

1.1.2. Responsibilities of the Medical Director:

A. The Medical Director is responsible for the quality and the opportunity in the service given by the laboratory and the control of quality according to the current standards in the performance and interpretation of echocardiographic exams.
B. The Medical Director can supervise all the laboratory work or may delegate specific tasks to Associate Directors.
C. The Medical Director is responsible for the supervision of the competence and quality of the exams both of medical and technical staff.

1.1.3. Requirements of continuous education:

A. The Medical Director must assist to at least one

congress or annual course of echocardiography (local or international) and have the certificate proving his/her assistance. The conferences carried out in the institution where he/she works would be considered as part of the laboratory program in order to maintain the excellence in quality of the performance and interpretation of the echocardiographic exams. In his/her laboratory there should be study material as CDs, DVDs, books, echocardiography or cardiology journals, Internet and other materials related to teaching (information about academic meetings, national or international events).

Standard: Technical Director (15)

In some countries there are processes of training and certification for the Technician in Echocardiography. In others, echocardiographic exams can only be performed by echocardiographist cardiologists.

The standard of Technical Director is only applied to echocardiography laboratories with several qualified technicians or sonographers. (15)

1.2. The Technical Director must be a qualified sonographer

Note: In many cases, the Medical Director can also be the Technical Director of the laboratory. In this case, apart from complying with the requirements for being Medical Director, must also comply with the requirements required to be Technical Director.

1.2.1. Technical Director's experience and training required

The Technical Director must comply one or more of the following criteria:

A. A document/certificate or competence certifying him/her as Technician in Echocardiography.
B. Having completed a formal program of technology or cardiovascular ultrasound including clinical and technical experience supervised in the performance of echocardiographic exams. This program should be certified by a state organization.
C. Having completed 12 months of experience (35 hours per week) performing Doppler echocardiograms.

1.2.2. Responsibilities of the Technical Director:

The Technical Director reports directly to the Medical Director. Responsibilities include but they are not limited and can be delegated to other members of the staff.

A. All the laboratory tasks delegated by the Medical Director
B. General supervision of the technical and auxiliary staff
C. Delegation of responsibilities in the Technical or Auxiliary staff in case it is necessary
D. Daily technical operation of the laboratory (organization of the Technical staff, patients appointment, register of the laboratory data, organization of the procedures, priority in its performance, control of the time assigned to each exam, etc.).
E. Operation and maintenance of the laboratory equipment.
F. Supervising the compliment of quality standards in the performance of echocardiographic studies.
G. Working with the Medical Director and Medical and Technical staff in order to guarantee a timely and quality care for the patient.
H. Technical training.

1.2.3. Requirements of continuous education:

A. The Technical Director should demonstrate at least 10 hours per year of continuous education related to echocardiography. Half of the hours of continuous education can be obtained through the assistance to conferences of the department. Continuous education can be complemented with available learning materials in the laboratory (CDs, DVDs, videos, Internet, Web conferences) and national or regional courses/conferences.
B. Annual accumulated continuous education must be registered in files or available certificates for its verification.

Standard: Medical Staff of echocardiographists (15)

1.3. All members of the Medical Staff must be legally qualified physicians

1.3.1. Medical Staff experience and training required

Members of the Medical Staff must comply one or more of the following criteria:

A. Having completed a formal training program in echocardiography of 1 year of duration (Level III).
B. Having completed a training program in echocardiography of 6 months of duration including the interpretation of at least 300 Doppler echocardiograms (Level II).
C. Three years of practical experience in echocardiography including the interpretation of at least 900 Doppler echocardiograms.

1.3.2. Medical Staff responsibilities:

The Medical Staff perform and/or interprets clinical studies.

1.3.3. Continuous education requirements:

A. The Medical Staff must attend at least one congress or annual course of echocardiography (local or international) and have the certificate certifying its assistance. Those conferences given within the institution where he/she works would be considered as part of the laboratory program in order to maintain the quality in performance and the interpretation of the echocardiographic exams. Continuous education can be obtained through several methods. These methods include study materials, CDs, DVDs, books, echocardiography journals, Internet or other material inherent to teaching (academic meetings, national and international events).
B. Each year accumulated medical education must be filed and be available for its evaluation.

Standard: Technical Staff (15)

In some countries, there are training and

certification processes for Technicians in Echocardiography. In others, echocardiographic exams can only be performed by echocardiographist cardiologists.

Technical Staff standard is only applied to those echocardiography laboratories with several technicians or qualified sonographers. (15)

1.4. All members of the Technical Staff must be qualified sonographers

1.4.1.Technical Staff experience and training required:

A. An appropriated document in echocardiography.
B. Having completed and approved a cardiovascular ultrasound technology program including clinical experience and supervised didactics in echocardiography. This program must have currently legal support.

1.4.2. Responsibilities of the Technical Staff:

A. Members of the Technical Staff report to the Technical Director. The Technical Staff assume the responsibilities specified by the Technical Director and, in general, are responsible for the performing of clinical exams and other tasks.

1.4.3. Requirements of continuous education:

A. The Technical Staff must demonstrate at least 15 hours of continuous education related to echocardiography over a period of 3 years. All the hours must be related to echocardiography. Half of the hours of continuous education can be obtained through the assistance to the department conferences. Continuous education can be obtained through several methods. These include study material as CDs, DVDs, books, echocardiography or cardiology journals, Internet or other materials inherent to teaching (academic meetings, national or international events).
B. Each year accumulated medical education must be filed and be available for its evaluation.

Standard: Auxiliary Staff (15)

1.5.Auxiliary Staff (nursing, transportation, secretaries, cleaning staff)

The Technical Director must supervise the tasks corresponding to the support staff of the echocardiography laboratory.

PHYSICAL RESOURCES OF THE ECHOCARDIOGRAPHY LABORATORY

According to the American Society of Echocardiography recommendations' the echocardiography laboratory must be part of a tertiary level of complexity center and perform at least 2000 echocardiographic studies per year with the objective of guarantying the physician under training the enough experience in different cardiovascular pathologies. (9, 10)

Standard: Areas of exam (15)

2.1.Exams must be performed in a comfortable place giving privacy to the patient.

2.1.1. The correct performance of an echocardiogram requires the appropriate position of the patient, the echocardiograph and the physician or technician who performs the exam. Enough space in order to put the bed is necessary. Patients' privacy must be guarantee with doors or appropriate curtains.

2.2.Echocardiography laboratory needs high-tech equipment.

2.2.1.The echocardiography laboratory must have high-tech equipment with which a complete echocardiographic study should be performed, it must include M mode, two-dimensional, pulsed Doppler, continuous Doppler, tissue Doppler, software for digital imaging for the performance of exercise stress or pharmacological echocardiography and transesophageal bougie. It should have software for the performance of 3D echo and the new modalities of tissue Doppler (stain rate), as well as having the necessary equipment for an emergency (mainly during pharmacological or exercise transesophageal studies), as monitor, oximeter, cardioveter, transcutaneous pacemaker, Ambu, oxygen sample, endotracheal cannulae, drugs as atropine, adrenaline, nitroglycerine, solutions, etc.

Standard: Interpretation and storage methods (15)

2.3. It must be available in an adequate space for the interpretation of the echocardiography and the writing of reports.

There should be an available space for reading, discussion and interpretation of the study with the sonographer or other echocardiographists of the Medical Staff. There should also be a space for the storage of studies or stations of work with digital storage systems of the studies.

ARCHIVE OF THE EXAM DATA. INTERPRETATION OF THE EXAM, REPORTS OF THE EXAM, REGISTER OF THE LABORATORY

Standard: Echocardiographic exam data (15)

3.1. Methods for the obtaining and archive of the exam data for all the echocardiograms performed.

3.1.1. The echocardiography laboratory must have a system for the register and archive of echocardiographic data (images, measurements, conclusions) and must be available.

3.1.2.A permanent register of echocardiographic images and reports should be available. These must be filed according to the legal regulations established for the archive of medical registers. Regulations vary between 5 and 10 years. Echocardiographic data should be easily available in order to compare them with new exams.

3.1.3.The stored data must be systolic and diastolic images (or their digital equivalent) in real time of all cardiac valves, chambers and large vessels, and all those images that show the pathology. Means of archive include but are not limited to:

Videotapes (VHS): when using this type as a method of archive, it is necessary to register at least

5 to 10 cardiac cycles in real time for each modality of exam (M mode, two-dimensional and Doppler).

Paper: paper registers are acceptable methods of archive for M mode and Doppler information.

Digital storage: digital system of storage is currently the ideal method for storing and archiving information. Compared with videotape method, less cardiac cycles in real time for each exam modality (M mode, two-dimensional and Doppler) are necessary. When VHS tape images are converted to digital format, the laboratory must be sure of storing enough exam information for the archive and revision.

Standard: Interpretation of the exam (15-17)

3.2. Exams are interpreted and communicated by the laboratory Staff physician.

3.2.1. The echocardiogram report must be standardized at the laboratory. The laboratory physicians who interpret the exams must have uniform criteria of diagnosis and follow a similar report. (16, 17)

The report must show the content and results of the study.

A. The report must include, but not be limited to: Date of the study, name of the laboratory, name of the patient, date of birth or age of the patient, primary indication of the study, name of the physician or technician who performed the study and the name of the physician who ordered the study. The information must be enough in order to allow the identification and the consultation of previous studies.
B. A table of numerical data of M and two-dimensional mode obtained during the performance of the study. It includes standard measurements of cardiac cavities (left ventricle systolic and diastolic diameter, interventricular septum and posterior wall diastolic diameter, right ventricle diastolic dimension, left atrium in end of systole dimension, aortic ring, aortic root and ascendant aorta diameter) or any other measurement considered necessary according to the patient's pathology.
C. Both ventricles systolic function assessment. Systolic quantification and volume in special situations (for example, assessment of the post-infarction left ventricle ejection fraction during chemotherapy, monitoring of valve disease, heart failure, etc.)
D. A data table of Doppler in its different modalities. It must include Doppler of all cardiac valves, gradient measurement and valve areas when necessary.
E. Global assessment of diastolic function. It includes assessment of Doppler of mitral valve, septal and lateral mitral ring and pulmonary venous flow.
F. Use and report of three-dimensional images and new modalities of Doppler as strain rate and speckle tracking when available. Tissue Doppler and strain rate for the assessment of cardiac dyssynchrony.
G. Pericardium assessment (normal, thickened, effusion, signs of hemodynamic compromise, approximate amount of pericardial fluid).
H. Assessment of atrial septum. Presence or absence of aneurism. It is also convenient to suggest the study of foramen ovale permeable using agitated saline according to medical indications.
I. Assessment of inferior vena cava and supraheaptic veins (diameter, presence or absence of inspiratory collapse).
J. Conclusions must include a summary of the echocardiographic exam results containing clinical, therapeutic and prognostic importance. The text of the report must be consistent with quantitative data. Conclusions should not repeat specific data of the aforementioned report.
K. Reports must be written in computer and in an easy printing format, they must be signed by the physician and they must also have the name of the physician responsible for the interpretation and reading of the exam.

3.2.2. When the need of a preliminary report is considered, it must be clearly established that it is a preliminary report. The final report should be given 48 hours after the preliminary report.

3.2.3. Urgent reports should be given the same day of the exam.

3.2.4. The final report should be given 48 hours after the exam.

LABORATORY CERTAINTY AND PATIENT CONFIDENTIALITY

Standard: Laboratory certainty (15)

4.1.Requirements for the performance of transesophageal, exercise stress and pharmacological stress echocardiography.

4.1.1.For the performance of transesophageal echocardiography, the department must have oximeter, non invasive monitoring of blood pressure, cardioverter-defibrillator, oxygen source and pulmonary resuscitation equipment according to the international regulations. It should also have the appropriate methods for the disinfection of the bougies after their use. A person of the laboratory should explain the risks involved in the exam. The laboratory must have formats for the authorization of the patient's or relative's informed consent. The sign of the informed consent is essential for the performance of the exam.

4.1.2.For the performance of exercise stress echocardiography, the department must have the complete equipment for the stress test, manual or non invasive monitoring of blood pressure, cardioverter-defibrillator, oxygen source, and cardiopulmonary resuscitation equipment. A person of the laboratory should explain the risks involved in the exam. The laboratory must have formats for the authorization of the patient's or relative's informed consent. The sign of the informed consent is essential for the performance of the exam.

4.1.3.For the performance of pharmacological stress echocardiography (dobutamine, dipiridamol, ergonovine), the department must have infusion pumps, written protocols for the accurate infusion of drugs and the other described equipments for the performance of an exercise echocardiogram. A person of the laboratory should explain the risks involved in the exam. The laboratory must have formats for the authorization of the patient's or relative's informed consent. The sign of the informed consent is essential for the performance of the exam.

Standard: Patient confidentiality 4.2. The complete laboratory staff must adhere to professional principles of doctor-patient confidentiality.

Standard: To guarantee and maintain the laboratory quality

5.1. A written policy about how to maintain the quality of all the procedures performed in the laboratory is necessary. The maintenance quality program must be coherent and it must include, but not be limited to:

5.1.1.Ultrasound equipments maintenance

The adequate maintenance and the control of quality of ultrasound equipments are essential. The accurate in measurements and registers of ultrasound equipment is very important for the correct interpretation of the exam. The guidelines for the maintenance of the equipment include:

A. Register of the method and frequency of the maintenance of the ultrasound equipment.

B. The establishment and adherence to routine safety inspections and testing of the equipment of the laboratory.

C. The establishment and adherence to cleaning protocols of instruments including routine cleaning of parts of the equipment taking into account filters and transducers, according to the manufacturer's specifications.

5.1.2. Statistics of the number of procedures performed

Statistics of the total volume of the laboratory procedures and those performed annually by the staff in charge of performing them must be registered. These registers should allow an easy evaluation of the number of procedures performed each year by the laboratory and by each member of the Medical and Technical Staff. Registers include information about indication, performed exams, and main diagnosis.

5.1.3. Continuous medical education

Registered document of regular and specific education of echocardiography for all the medical and technical staff must be available. Reviewed topics, date of presentation, and the assistants of the Medical and technical Staff must be signed up. Continuous medical education can be obtained through other methods as CDs, DVDs, Internet, web conferences, and material obtained in conferences of the department of cardiology, or regional, national or international events. It is vital that the laboratory is involved in projects or lines of research in echocardiography.

5.1.4. Echocardiography conferences

At least 1 conference of echocardiography per month would be organized in the laboratory with the objective of maintaining the quality of learning of the medical and technical staffs, discuss difficult cases, compare results with other laboratories or with data informed in the medical bibliography.

5.1.5. Review of interesting cases

Peer review of the performance and interpretation of studies in order to determine quality, reliability of the echocardiographic exam. Both physicians and technicians must be involved in this process of peer review. Differences in the way of interpretation should be unified in order to achieve uniform diagnostic criteria of the laboratory and the production of the echocardiographic report.

5.1.6. Correlation and confirmation of the results

The echocardiographic results of the laboratory must be regularly compared with surgical findings and with the results of other diagnostic procedures as cardiac catheterisms, angiography, magnetic resonance, multislice computed tomography and perfusion studies with isotopes.

A. Correlation of transthoracic echocardiograms:
   Those patients who underwent transthoracic echocardiograms and other diagnostic methods (for example, cardiac catheterism, coronary angiography or nuclear perfusion studies) or surgical procedures, the results of transthoracic echocardiograms must be compared as routine regarding valve abnormalities and left ventricular function. The comparison studies for every physician of the laboratory responsible for the interpretation should be stored by the laboratory and given to the same physician. Statistics or evaluation methods in order to assess the global accuracy of the transthoracic echocardiograms performed in the laboratory should be created. A process of discussion or analysis in order to analyze the differences among the results of the echocardiographic exam and the results of other exams should be generated. The areas of appropriated correlation of transthoracic studies include, but are not limited to:
   1. - Left ventricular function
   2. - Regional wall motion abnormalities
   3. - Ejection fraction calculation
   4. - Aortic stenosis/ aortic regurgitation
   5. - Mitral stenosis/ mitral insufficiency
   6. - Pulmonary artery systolic pressure

B. Correlation of transesophageal echocardiograms:
   Those patients who underwent transesophageal echocardiograms and surgical repairs or other diagnostic methods (for example, coronary angiography, CT angiography, nuclear magnetic resonance), the results of transesophageal echocardiograms should be compared as routine regarding valve abnormalities, left ventricular function, and aorta alterations. . The comparison

studies for every physician of the laboratory responsible for the interpretation should be stored by the laboratory and given to the same physician. Statistics or evaluation methods in order to assess the global accuracy of the transesophageal echocardiograms performed in the laboratory should be created. A process of discussion or analysis in order to analyze the differences among the results of the echocardiographic exam and the results of other exams should be generated. The areas of appropriated correlation of transesophageal studies include, but are not limited to:

1. - Left ventricular function
2. - Regional wall motion abnormalities
3. - Presence and severity of valve dysfunction
4. - Presence or absence of thrombi or adenoids
5. - Presence or absence of aortic dissection, atheromas, hematomas or ruptures

C. Correlation of stress echocardiograms:
Those patients who underwent stress echocardiograms and other diagnostic methods (for example, coronary angiography or nuclear perfusion studies) or surgical procedures, the results of stress echocardiograms must be compared as routine regarding the degree of obstruction of the lesions assessed by angiography. The comparison studies for every physician of the laboratory responsible for the interpretation should be stored by the laboratory and given to the same physician. Statistics or evaluation methods in order to assess the global accuracy of stress echocardiograms performed in the laboratory should be created. A process of discussion or analysis in order to analyze the differences among the results of the echocardiographic exam and the results of other exams should be generated.

5.1.7. Keep a register of the quality maintenance

Regular registers of the maintenance process and control of quality of the laboratory should be archived. These registers must include statistics and the information provided in the aforementioned items described here. The registers must include a description of how information is used in order to improve the quality in the laboratory of echocardiography.

Standard: Levels of complexity of the laboratory (12)

6.1. Each laboratory of echocardiography belongs to a level of complexity related to:

1. Professional training of the Medical and/or Technical Staff of the laboratory.
2. The level of complexity of the institution to which the laboratory belongs to.
3. The inclusion of quality standards in the laboratory.
4. The complexity of the performed procedures.
5. The connection of the laboratory with programs of training of experts or specialists in echocardiography and clinical cardiology.
6. Active participation in projects or lines of research in echocardiography

6.1.1. Level I laboratory (low complexity). Able to perform studies of low complexity: M mode, 2D and Doppler.

6.1.2. Level II laboratory (medium complexity). Apart from performing studies of low complexity, able to perform studies of stress echocardiography and transesophageal echocardiogram.

6.1.3. Level III laboratory (high complexity). Apart from performing studies of low and medium complexity, able to perform three-dimensional echocardiography (3D/ 4D), two-dimensional strain, coronary flow reserve and coronary perfusion with contrast.

The grade of the laboratory not only should take into account the level of complexity of the exam but also the experience and professional training of the Medical and Technical Staffs of the laboratory, the monitoring of quality standards, the connection with centers of high complexity and with a programs of training of specialists or experts in echocardiography and the active participation of the laboratory in research projects.

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