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The Echocardiography Society of Saudi Heart Association Recommendation on Quality and Laboratory Accreditation Guideline and Standards

Abdulhalim Jamal Kinsara

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Abdulhalim Jamal Kinsara [a,*], Sami Ghazal [b], Ahmad S. Omran [c], Esra Aleid [b]

[a] Department of Cardiology, Ministry of National Guard Health Affair, King Saud Bin Abdulaziz University for Health Sciences, COM-WR, King Abdullah International Medical Research Center, Jeddah, Saudi Arabia
[b] Saud Al Babtain Cardiac Center, Dammam, Saudi Arabia
[c] Department of Anesthesia and Pain Management, Toronto General Hospital, University Health Network, University of Toronto, Canada

Abstract

Objective: **To create the Saudi Arabian Society of Echocardiography Accreditation Commission Guidelines and Standards.**

Method: **A review of available the North American and European accreditation guidelines was conducted and a model, locally appropriate for Saudi echocardiography laboratories and applicable in the current settings, was developed.**

Results: **The document specifies the organizational setting as well as the following categories of personnel: medical director, technical director, medical staff, and technical staff. The guideline team also examined aspects related to the facility and the facility safety policies and protocols. Examination and procedural issues for Adult transthoracic echocardiography including instrumentation, archiving media, examination interpretation and reports are also included as well as the required components for the Adult transthoracic echocardiography report. The last section of the guidelines focuses on Key Performance Indicators. A similar approach was taken regarding the Adult Stress Echocardiography, Transesophageal Echo, and monitoring of the patients during the procedures.**

Conclusion: **The development of the Saudi Echocardiography Guidelines and Standards is a basic requirement for accreditation and also mandatory to improve the quality and utilization of such an important investigation.**

Keywords: Saudi Arabian Society of Echocardiography, Accreditation, guidelines, Transthoracic, Transesophageal, Stress Echocardiography, Quality

1. Introduction

Echocardiography is a widely available diagnostic modality. In many instances, the echocardiography report will alter the clinical decision and treatment strategy. Evidence-based echocardiography-related guidelines will minimize reporting errors and acquisition, and reporting variability. Evidence indicates that the comprehensiveness of the study and the completeness of the report are improved in a facility after accreditation [1]. In addition to clinical benefits, laboratory accreditation indicates the compliance of the facility to the standards that will reflect in the training process of a sonographer and physician and improve research credibility. Compliance with standards can be assured via the accreditation program, which periodically assess compliance to standards and establishes self-assessment tools to ensure compliance. Intersocietal Accreditation

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* Corresponding author at. Department of cardiology, Ministry of National Guard health Affair, King Saud Bin Abdulaziz University for health sciences, COM-WR, King Abdullah International medical research center, Mail code 6599, P.O. Box 9515, Jeddah, 21423, Saudi Arabia.
E-mail addresses: akinsara@yahoo.com, kinsaraaj@ngha.med.sa (A. Jamal Kinsara).

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Commission (IAC) accredited facilities had more complete reports and better image quality compared to non-accredited facilities [2].

In 2011, the American Society of Echocardiography published Quality Echocardiography Laboratory Operation Recommendations [3], which sets quality standards and values for compliance. The IAC and the European Association of Cardiovascular Imaging (EACVI) also provide accreditation through setting standards and facility assessment. After a thorough review of the available international quality standards, it was found that the qualification requirements are mainly based on American and European training, which deprive many local laboratories from the benefits of accreditation. Subsequently, the Saudi Society of Echocardiography assembled an accreditation task force team, including practitioners with prior experience in the international accreditation process as well as worked in an internationally accredited echocardiography facility. The task force revised all available international standards and accreditation protocols and produced a Saudi Society of Echocardiography accreditation document (Table 1). The document takes in consideration locally accredited qualifications and training by the Saudi Commission for Health Specialties.

As shown in Table 1, there is no major discrepancy in terms of the equipment and facilities stated in the three guidelines. However, in terms of staffing, to

Abbreviation

ACLS	Advanced cardiac life support American College of Cardiology)
ARDMS	American Registry for Diagnostic Medical Sonography
AV	Aortic valve
BSE	British Society of Echocardiography
BLS	basic life support
CW	continuous wave
CCI	Cardiovascular Credentialing International
CRCS	Canadian Registered Cardiac Sonographer
COCATS	Core Curriculum Cardiology Training Statement (recommended by the
EACVI	European Association of Cardiovascular Imaging
EACVI	European Association of Cardiovascular Imaging
IAC	Intersocietal Accreditation Commission (North America)
KSA	Kingdom of Saudi Arabia
KPI	Key performance indicator
LV	left ventricle
MV	Mitral valve
NS	National Societies of Echocardiography (within the Europe)
NBE	National Board of Echocardiography (US)
NBE	American National Board of Echo
PV	Pulmonic valve
PW	pulsed Doppler
RV	right ventricular
SCFHS	Saudi Commission For Heath Specialties
SASE	Saudi Arabian Society of Echocardiography
SHA	Saudi heart association
TTE	transthoracic echocardiography
TEE	transesophageal echo
TV	Tricuspid valve

Table 1. Comparison of the criteria for accreditation of the echocardiography laboratories.

	IAC	EACVI	SASE
Medical Director	• Should be a licensed physician • NBE Testamur status and Practice experience OR • Level 2 or 3 COCATS training with practice experience OR • Cumulative practice experience	• EACVI certification OR • Recognized NS Certification OR • Level III training plus NBE certification	• Active SCFHS registration as consultant cardiology • NBE Diplomat status OR EACVI certification OR one-year fellowship of echo in an accredited program in the KSA • Ongoing practice experience
Technical Director	• Holding credentials and registration in ARDMS, OR CCI, OR CRCS	• Holding same qualification as that of the medical director	• Active SCFHS registration as cardiac technologist • Certification by ARDMS, CCI, EACVI, BSE OR • Bachelor degree in cardiac technology OR echo diploma from the KSA
Medical Staff	• Same qualification as of that of the medical director with less ongoing experience	• No specific qualification • Same as that of the medical director	• Active SCFHS registration as at least senior registrar • Ongoing practice experience
Technical Staff	• Same qualification as that of the technical director	• All medical and non-medical staff should have appropriated qualifications to do echocardiography	• Active SCFHS registration • Bachelor degree in cardiac technology OR echo diploma from the KSA
Facility	• Examination, reporting, and archiving area • Facility safety	• Examination, reporting, and archiving area • Facility safety	• Examination, reporting, and archiving area • Facility safety

have a more viable guideline, we made some modifications, based on the availability of local manpower. This consideration is in line with the North American guidelines in which a transthoracic echocardiography is mainly performed by qualified sonographers and not necessarily by physicians, as is the practice in most European countries.

Recently, many highly qualified echocardiography laboratories have been established in Saudi Arabia, which are eligible to train post-cardiology echocardiography fellows and sonographers similar to North America [3]. The training programs are approved and monitored by a council affiliated to the Saudi Commission for Health Specialties (SCFHS). SASE guidelines, therefore, facilitate the use of these graduates for medical and technical staffing of echo laboratories in the Kingdom.

2. Method

A review of available accreditation guidelines of North America and Europe was conducted and a model, appropriate for local Echocardiography Laboratories and applicable in the current setting, was developed.

3. Main finding

3.1. Definitions

Echocardiography facility: which located in one postal address, composed of at least one ultrasound machine, medical director and technical director and performing/or interpreting transthoracic echocardioghraphy (TTE). Also, this facility can perform stress and transesophageal echo (TEE).

The followings are areas for accreditation;

a) Adult TTE
b) Adult stress
c) Adult TEE

Fig. 1 summarize the different aspects that was addressed by this guideline.

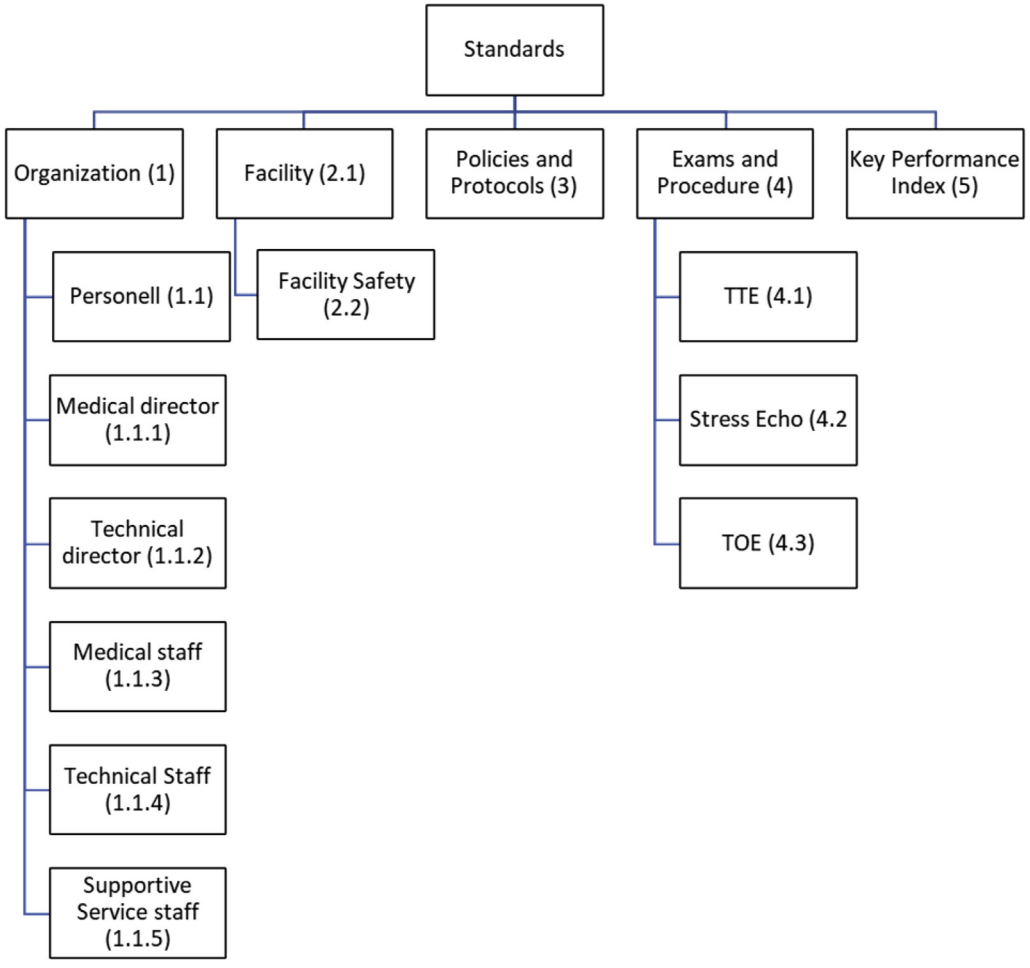

Fig. 1. Different areas of standards cover by the guidelines.

3.2. Part 1: Organization [4]

3.3.1. Personnel

3.3.1.1. Medical Director. The Medical director must meet the followings:

a) Active Saudi commission registration classification as consultant cardiology
b) Formal echo training Must be held:
   i. American National Board of Echo (NBE) with active Diplomat status OR
   . European Association of Cardiovascular Imaging accreditation in TTE, TEE, or Congenital heart disease.
   iii. One-year fellowship of echocardiography in an accredited training program in the Kingdom of Saudi Arabia.
c) Ongoing Practice Experience Requirements Performance/ interpretation of an average minimum number echocardiography examinations per year in the specialties for which the staff member is listed:
   i. TTE 300 examinations/year
   ii. TEE 50 examinations/year
   iii. Stress 50 examinations/year

Medical Director Responsibilities:

a) Supervising and ensuring the smooth flow of work in the lab
b) Managing patients complaints
c) Interpretation and performing studies in the facility
d) Provide teaching and guidance for the staff
e) Maintaining Quality standards and ensuring appropriateness of studies.

3.3.1.2. Technical Director. An appropriate technical director should be in the facility as a full-time job, and must meet the following:

a) Active Saudi commission registration as a cardiovascular technician/technologist.
b) Appropriate credential in echocardiography:
   i. Certification in adult echocardiography by ARDMS, CCI, EACVI, or British Society of Echocardiography Or
   ii. Bachelor's degree in cardiac technology with 2-year experience OR
   iii. Echocardiography diploma with 4-year experience

Technical Director Responsibilities:

a) Assumes responsibilities by medical director.
b) Supervise technical and support service staff.
c) Perform echocardiographic studies in the facility.
d) Work with a medical director, medical staff and technical staff to ensure high-quality patient care.
e) Active teaching of junior technical staff.
f) The daily technical operation of the facility (e.g., staff scheduling, patient scheduling, facility record keeping)

3.3.1.3. Medical Staff. The Medical staff must meet the followings:

a) Active Saudi commission registration and classification as at least cardiology senior registrar
b) Active BLS and ACLS
c) Ongoing practice experience performance/interpretation requirements of a minimum number of echocardiography examinations per year in the specialties for which the staff member is listed:
   i. TTE 150 examinations/year
   ii. TEE 50 examinations/year
   iii. Stress 25 examinations/year
   d) Should have certification or training in conscious sedation for TEE examination.
   e) In cardiac centers that have an accredited post cardiology echo fellowship program, fellows can perform and interpret the echo studies (TTE, TEE, stress echo) under the supervision of the medical director and based on the policy of medical facility and Saudi council training level.

Medical staff Responsibilities:

a) Interpretation and performance of studies in the lab.
b) Reports to the medical director.

3.3.1.4. Technical Staff. The technical staff must meet the followings:

a) Active Saudi commission registration as a cardiovascular technician/technologist.
b) Appropriate credentials in echocardiography:
   i. Bachelor's degree in cardiac technology with 1-year experience or
   ii. Echocardiography diploma with 2-year experience
c) Should have an active BLS certificate

Technical staff Responsibilities:

a) Perform studies in the facility
b) Reports to technical director

3.3.1.5. Supportive Service Staff. Enough supportive staff (nursing, transporter) should be in the facility to ensure a smooth workflow.

a) Sufficient number of nursing staff (1 staff in the small facility)
b) The medical director should ensure this number for best quality patient care

c) Should be trained in administering agitated saline and echo contrast agent.
d) Should be trained in all policies and procedures of echo lab.
e) Should have an active BLS certificate

3.3.2. Part 2.1: Facility

Reporting Area: Should have sufficient room to allow the physicians to interpret and report in an effective way.

Examination Area: Examinations must be performed in a setting providing patient and technical staff safety, comfort and privacy:

a) Patient privacy must be assured with the use of either appropriate curtains or doors.
b) A sink and antiseptic soap must be readily available and used for hand washing in accordance with the infection control policy of the facility.
c) Approximately 12 m^2 is recommended for a TTE examination room.
d) Bigger room provide for TEE and stress echo is required.

3.3.3. Facility Safety

Patient and employees Safety:

a) Patient and worker safety area unit ensured by written policies and procedures approved by the medical director.
b) Special echocardiographic procedures, like TEE and stress echocardiograms, create potential risks for the protection of the patient a cardiac monitor and fully associate equipped crash cart ought to be offered within the procedure space including:
   i. Crash cart equipped with a defibrillator, cardiac monitor.
   ii. Room equipped with a suction instrument, oxygen and infusion pump.
   iii. An antidote for medication used throughout the procedure.
c) Written policy within the facility to handle cardiac arrest ought to be in situ.
d) Well train personnel should cover these kinds of procedures with adequate credentials
e) Discharge policy from the facility after recovery from sedation.

3.3. Part 3: Policies and protocols

A qualified physician should interpret routine inpatient echocardiographic studies within twenty-four hours of completion of the examination. Outpatient studies should be interpreted within seventy-two hours. The report should accurately reflect the content and results of the study.

Policies and protocols are essential elements within the facility, raise the standard of patient care and workflow.

3.3.2. Policies

The following policies must be available:

i. Patient Confidentiality
ii. Patient Complaints
iii. Primary Source Verification
iv. Cardiac arrest
v. Conscious sedation
vi. Routine safety inspections and testing of all facility electrical instruments.
vii. Instrument cleaning
viii. Planned preventive maintenance
ix. Personnel safety policy (Ergonomics)
x. Preliminary and final reports
xi. Critical value reporting
xii. If contrast is used, there should be a written policy for the utilization of contrast agents.
xiii. Discharge policy from facility for recovery from sedation.

3.3.3. Protocols

The following protocols got to be available:

a) Adult TTE
b) Adult TEE
c) Adult stress
d) Key performance indicator (KPI)

3.4. Part 4: Examination and Procedure

3.4.1. Adult TTE

3.4.1.2. Patient preparation: Adequate patient preparation include the followings

i. Explanation of the procedure
ii. Positioning of the patient in the left lateral position
iii. Adequate study time (45 to 60 minutes).
iv. High, weight and blood pressure must be obtained before the examination.

3.4.1.3. Indications and Ordering Process

i. TTE is performed for acceptable indications.
ii. TTE orders to be checked for appropriateness.
iii. The ACC-ASE-EACVI appropriate use criteria documents pertaining to echocardiography should be available for review within the facility.

Verification of the Indication – A method ought to be in place within the facility for getting and recording the indication. Before a study is performed, the indication ought to be verified, and any further information needed to direct the examination ought to be obtained.

3.4.1.4. Definition of Procedure Types and Protocols

a) Complete Study: A complete imaging study is one that examines all the cardiac chambers and valves and the great vessels from multiple views, then uses the offered data to define any recognized abnormalities with complete Doppler study that examines every cardiac valve, and the atrial and

ventricular septa for antegrade and/or retrograde flow. Additionally, a complete Doppler study provides functional hemodynamic information.

b) Limited Study: A limited study is generally performed once the patient has undergone a complete recent examination and there is no clinical reason to suspect any changes outside the particular area of interest. A limited study typically examines a single area of the heart or answers a single clinical question.

c) Focused study: A targeted study that performed to evaluate cardiac pathophysiology at the point of care, by providers actively managing the patient.

d) Urgent cases schedule:
   i. Urgent cases ought to be done at the next available time
   ii. Urgent cases ought to be determined by the cardiologist
   iii. Outside normal working hours, a qualified person should be available for urgent and emergency cases.

3.4.1.5. Instrumentation. Cardiac Ultrasound Systems: Ultrasound instruments used for diagnostic studies should include hardware and software to perform:

i. 2-D imaging (the system must include harmonic capabilities); M-Mode imaging; Color flow imaging;
ii. Spectral display for pulsed (PW) and continuous wave (CW) Doppler and tissue Doppler imaging; A transducer dedicated to the performance of non-imaging continuous wave Doppler should be offered at each site.
iii. At least 2 imaging transducers, one of low frequency (2-2.5 MHz) and one of high frequency (3.5 MHz or higher); or a multi-frequency transducer specific to the adult patients.
iv. Monitor or other display methods of appropriate size and quality for observation and interpretation of all modalities;
v. Cardiac software analysis for 2D measurements, Pulse/continuous/tissue Doppler analysis. Stress echo, myocardial contrast and speckle tracking as per need.

3.4.1.6. Archiving media. Archiving should be done in digital storage: The number of cardiac cycles acquired should be enough to permit adequate review, usually one or more cycles are recommended.

An interpretation ought to be within the digital storage and be easily accessible for all hospital departments.

Examination Interpretation and Reports:

3.4.1.7. Components of the TTE. Complete Examination: Includes standard views from multiple planes including views of all cardiac structures and selected extra cardiac structures. These include, however, not limited to the above items and if any structure can't acquire, it will be labeled/documented.

Standard views should be obtained for complete study: [5].

a) Standard 2-D views:
   i. Parasternal long axis
   ii. Parasternal short axis at the level of the aortic valve, basal, mid and apical LV
   iii. RV inflow view
   iv. Apical: four-chamber/two/five and long-axis view
   v. Subcostal four-chamber view, short-axis view (when indicated)
   vi. Subcostal IVC/hepatic vein view
   vii. Suprasternal notch view

b) 2-D/3-D (as indicated) or M-Mode measurements of the left heart:
   i. End-diastole LV internal dimension and/or volume.
   ii. End-systole LV internal dimension and/or volume.
   iii. End-diastole LV poster basal free wall and septal thickness
   iv. End-systole LA volume index or LA dimension;
   v. End-diastole aortic root dimension and ascending aorta dimension.

c) 2-D/3-D (as indicated) exam ought to include comments on:
   i. LV size, ejection fraction
   ii. Assessing regional wall motion abnormalities and determine the type of diastolic function if any
   iii. RV size and function
   iv. RA/LA
   v. Valves: Mitral valve (MV), Aortic valve (AV), Tricuspid valve (TV) and Pulmonic valve (PV)
   vi. Pericardium
   vii. Aorta/Pulmonary artery.
   viii. Inferior Vena cava (IVC)

d) Standard Doppler flow evaluations: [6].
   i. Four cardiac valves – assessing individual valves for forward flow and regurgitation if present. Such regurgitation should be evaluated in at least two imaging planes with color Doppler;
   ii. Evaluation of peak and mean gradients and measure/calculate valve area in case of valve stenosis;
   iii. TR spectrum should always be sought with CW Doppler from multiple views for estimation of systolic RV pressure when tricuspid regurgitation is present; or other recommended methods.
   iv. Atrial and ventricular septa – color Doppler screening for defects;
   v. LV outflow tract velocity;
   vi. Velocity-time integral, in addition to pulmonary and hepatic vein flow.
   vii. For aortic stenosis, the systolic velocity should be evaluated from multiple transducer positions (e.g., apical, suprasternal and right parasternal). This must include interrogation from multiple views with a Pedoff Doppler transducer (at least one clear envelope should be obtained); and

viii. Diastolic Function analysis – LV diastolic function should be evaluated through a combination of PW and tissue Doppler techniques.
ix. Strain imaging is optional, however, preferred in chemotherapy patients

3.4.1.8. Adult TTE Report Components: [7]

i. Date of the study. Name and/or identifier of the facility
ii. Name and/or identifier of the patient/location.
iii. Date of birth, Gender Height, Weight, Body surface area and Vital signs of the patient
iv. Indication for the study/type.
v. Name or initials of the performing sonographer, ordering physician and reporting physician. The report must accurately reflect the content and results of the study. The report should include, but may not be limited to:

a) The measurements performed throughout the examination and/or interpretation
b) 2-D, 3-D and/or M-Mode numerical data for TTE should include, but not be limited to (except wherever technically unobtainable) items addressed in section 4.1.6 items B and C.
c) A report of the Doppler analysis should include, but not be limited to items addressed in section 4.1.6 item D.
d) Address other pathology as noted.

Summary of examination and its contents: Should include statements that:

i. Endorse the indication
ii. Quality of the study (Good, Fair, Suboptimal)
iii. Emphasize significant abnormal findings
iv. Comparison to the previous study if available

3.4.1.9. Recommendation for contrast use: [8]. In the case of the poor endocardial border, definition contrast is highly recommended.

3.4.2. Adult Stress Echocardiography [9]

Procedure Types:

i. Stress echo using treadmill exercise
ii. Stress echo using bicycle exercise (ergometry)
iii. Stress echo using supine bicycle exercise (ergometry)

3.5. Stress echo using pharmacological stress agents

Techniques: The followings should be observed:

i. Qualified physicians, technicians, and nurses are required to be present throughout stress testing.
ii. Proper placement of emergency equipment (crash cart and oxygen) such that they are simply accessible whenever needed.
iii. A clear explanation of the procedure including safety and risks. Obtain written consent
iv. Proper patient positioning. Appropriate ECG lead placement
v. For treadmill stress, post-stress images should be obtained within 60-90 seconds of peak stress (if images are obtained beyond ninety seconds it should be noted within the report)
vi. For pharmacologic echo, images should be obtained within the last sixty seconds of every stage
vii. Appropriate side by side image display. Avoidance of foreshortening
viii. If technically suboptimal, a contrast agent can be used. Avoidance of artifacts when using contrast.

Stress Echocardiogram Components: [10].

d) Treadmill Stress Echo:
i. Images should be obtained at baseline and immediately post-exercise. All LV segments must be visualized and compared side by side (baseline vs. peak exercise).
ii. The required views are parasternal long-axis view, parasternal short axis view (mid-level), apical four-chamber view, apical two-chamber view, and apical long axis (for ischemia evaluation).
b) **Bicycle Stress Echo**:
i. At a minimum, images must be obtained at baseline and immediately post-exercise preferably at peak.
ii. The required views are parasternal long-axis view, parasternal short axis view, apical four-chamber view and apical two-chamber view and apical long axis (for ischemia evaluation).
c) Pharmacologic Stress Echo:
i. Four stages of imaging are acquired: baseline, low, high dose and recovery stages
ii. The required views are parasternal long-axis view, parasternal short axis view, apical four-chamber view, apical two-chamber view and apical long-axis (for ischemia/viability evaluation)
d) **A Doppler stress echocardiogram** will assess flow velocities and gradient from the same site before, during and immediately after stress. Doppler stress might be utilized to evaluate diastolic filling pattern changes as well.

Patient Monitoring:

i. Patient must be connected to standard stress testing leads during the test.
ii. During the image acquisition phase and during the recovery phase of the examination, the vital signs of the patient must be periodically evaluated in accordance with the stress testing protocol.

3.5.1. TEE [11]

TEE Transducer:

i. TEE transducers must be those manufactured for the ultrasound system used by the facility.
ii. TEE transducers must incorporate multiplane imaging capabilities.

Training of the staff:

i. All performing physicians must be adequately trained and experienced to perform and interpret the study and hold active conscious sedation training.
ii. A documented competency for assisting sonographers and nurses should be available. The staffs had to be trained for assisting in conscious sedation and have periodic validation and written policies for invasive procedures.

Component of TEE:

i. Standard 2 and 4 chamber views;
ii. Short and long-axis views of AV with appropriate Doppler;
iii. Multiple imaging planes of MV with appropriate Doppler;
iv. Multiple imaging planes of TV with appropriate Doppler;
v. Longitudinal view of PV with appropriate Doppler;
vi. Multiple imaging planes of the RA, LA, and LA appendage with appropriate Doppler;
vii. In cases of suspected cardiac source of emboli, appropriate use of contrast methods to evaluate for the presence of intracardiac shunting;
viii. Multiple imaging planes of the atrial septum and foramen ovale with appropriate Doppler
ix. Imaging of the pulmonary veins with appropriate Doppler, when MR is present;
x. Gastric short axis and long axis views;
xi. Short axis views of the AA, DA and transverse arch of the aorta;
xii. Long axis views of the main pulmonary artery and proximal portions of the right and left pulmonary arteries;
xiii. Images of the inferior and superior vena cava;
xiv. Imaging of the pericardial space and pericardium.

Techniques:

i. Explain the Procedure for the patient or guardian. Preparing the patient for the test;
ii. Obtain the height, weight and blood pressure. Patient monitoring all throughout the examination
iii. Administration of anesthetic medication
iv. Transducer insertion; Optimization of equipment settings like gain and display;
v. Utilization/Optimization of appropriate Doppler technique and measurements;
vi. Following the facility designed protocol to perform a 2D/3D Doppler TEE that examine different image planes.

Monitoring the Patient:

i. During procedure, the vital sign should be obtained and recorded to ensure patient stability.
ii. Monitoring of the patient as are recommended by the standard TEE guidelines.
iii. After procedure, patient should be monitored according to the facility protocol for sufficient amount of time.
iv. Post procedure care should be written for patient.

3.6. Part 5: Key Performance Indicator (KPI) [1]

3.6.1. Key Performance Indicator (KPI)

Each facility should have written KPI to insure the quality of work in the lab and should take care of covering all quality aspect from:

i. Technical
ii. Interpretive
iii. Report completeness and timeliness

3.6.2. Unit Technical Meetings

At least 4 meetings should be held yearlyall staff should attend and during each meeting the results of technical aspects of KPI should be discussed with staff. Any issue or conflict will be handled in this meeting. Minutes of the meeting should be documented.

3.6.3. Unit Continuing Educational Meetings

It is highly recommended to have weekly or biweekly educational meetings to maintain standard level of knowledge in the field echocardiography by all medical staff. These meetings can be run by delivering lectures or presenting interesting cases by staff physicians or sonographers. Attendance of these meetings can be counted as CME hours if approved by the SASE Accreditation Committee. (These Echocardiography activities either related CME and Non CME activities).

4. Conclusion

In **conclusion**: This is the first guideline for echocardiographic examination in Saudi Arabia. An effort was made to incorporate the composition of the different health sectors as well as simplicity in the presentation. Guidelines and Standards are mandatory to improve the quality and utilization of such an important tool.

Authors' contribution

The SASE under the SHA has written this manuscript. Dr. Abdulhalim Kinsara, President of the SASE, and lead author of the manuscript, was actively involved in the conception and execution of this project. All authors have actively participated in recommendation generation, conducting the literature review, and contributing to the development,

review, and finalization of the manuscript. The board of the SHA approved the final manuscript.

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