Standards and Guidelines for Accreditation of High-Fidelity Extracorporeal Simulation Programs

Goal statement:

This accreditation process has been initiated by the American Society of ExtraCorporeal Technology and the American Academy of Cardiovascular Perfusion and further developed through a consortium of representatives from organizations within the extracorporeal circulation community. The goal of this collaboration is to assure the quality of the educational experience offered at centers earning this accreditation, and ultimately improve the care of patients dependent on extracorporeal clinical services. This proposed accreditation process for high-fidelity extracorporeal simulation programs is based upon the recognition process for simulation facilities from numerous other professions (SSIH.org (1), Anesthesia (2), Surgery (3) and others (4)) and a profession specific definition of High-fidelity Extracorporeal Simulation which is at the core of the standards. These accreditation Standards and Guidelines are the minimum standards of quality used in accrediting programs that offer experiential educational curricula related to clinical extracorporeal technologies.

Purpose and scope of the accreditation consortium

1. To recognize programs that demonstrate best-practices in high-fidelity extracorporeal simulation
2. To build a community of high-fidelity extracorporeal simulation institutions, faculty and researchers

Definitions:

High-Fidelity Extracorporeal Simulation:

High-fidelity extracorporeal circulation is conducted in a setting which closely resembles clinical practice and includes realistic environmental, physiologic, and technical elements. These elements are consistent with real life extracorporeal practice / techniques, critical patient conditions, and device malfunction. High-fidelity extracorporeal circulation simulation activities are based upon validated educational constructs that incorporate cognitive, psychomotor and affective domains and provide expert evaluation of both technical and non-technical skills. High-

fidelity extracorporeal simulation activity shall be delivered at a facility that is specifically accredited for extracorporeal circulation simulation.

Standard:

Standards are the minimum requirements to which an accredited program is held accountable.

Guidelines:

Guidelines are descriptions, examples, or recommendations that elaborate on the Standards. Guidelines are not required, but can assist with interpretation of the Standards.

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Standard 1: Sponsor

Standard 1.1: The sponsor must ensure that the provisions of these standards are met.

Standard 1.2: Sponsors are responsible for ensuring that the program has a written mission statement and clearly identified measurable goals for the high-fidelity extracorporeal simulation.

Guideline 1.1: Sponsors may be:

- A post-secondary academic institution accredited by a recognized institutional accrediting agency for the appropriate educational level
- A hospital, clinic or medical center accredited by a healthcare accrediting agency or equivalent
- Corporation engaged in the manufacture of medical devices relevant to the extracorporeal community
- A business engaged in skill training through high-fidelity simulation technologies

Standard 2: Personnel

Standard 2.1: The sponsor must appoint sufficient faculty, staff, and volunteers to ensure that program goals and outcomes are achieved. Program personnel must be identified and tasked with the following responsibilities as demonstrated through written job descriptions and demonstrated work product.

Standard 2.2 Director: The Director will be responsible for program administration, leadership and insuring that the simulation program meets the criteria outlined in this document.

Qualifications:

- Graduate degree in education, science or medicine
- Proficient in instructional methodology and curriculum design with qualifications in medical simulation instructional methods

Responsibilities:

- Responsible for the organization, administration, periodic review, continued development and general effectiveness of the program
- Responsible for the design, development, and implementation of high-fidelity extracorporeal simulation education modules
- Collaborate with the Clinical Expert to achieve high-fidelity representations of clinical practice

Standard 2.3 Clinical Expert: The clinical expert is responsible for ensuring that the simulated clinical environment, educational experiences and evaluation meet the requirements for high-fidelity extracorporeal simulation program accreditation.

Qualifications:

- For programs holding a specialty in CPB:
    - Five years and 250 CPB cases of clinical experience as a perfusionist
- For programs holding a specialty in ECLS:
    - 2000 bedside hours experience as an ECLS clinician
- Direct clinical experience with relevant aspects of patient care and extracorporeal technology and techniques
- Record of continuing education in extracorporeal technologies as demonstrated by maintenance of national certification, state licensure, participation or attendance at CEU granting professional conferences, hospital competency assessment programs or university based Perfusion curriculum

Responsibilities:

- Responsible for assuring that the high-fidelity extracorporeal simulation curriculum represents relevant clinical practice and standard best-practice techniques
- Collaborate with the Director to achieve high-fidelity representations of clinical practice

Standard 2.4 High-Fidelity Extracorporeal Simulation Facilitator: The Facilitator conducts simulation training that meets the requirements of the accreditation process for simulation centers in extracorporeal circulation.

Qualifications:

- Two years and 500 hours of bedside of professional experience as a perfusionist or ECLS clinician

- Record of continuing education in extracorporeal technologies as demonstrated by maintenance of national certification, participation or attendance at CEU granting professional conferences, hospital competency assessment programs or university based Perfusion curriculum
- Proficiency with all clinical and educational technologies used in the high-fidelity extracorporeal simulation modules that they teach
- Credentialed/certified as a simulation educator

Responsibilities:

- Responsible for working with program participants and facilitating the educational experiences designed by the Director and Clinical Expert including the briefing and debriefing as well as the simulated clinical scenario.
- Provide expert evaluation of participant's technical and non-technical performance in cognitive, psychomotor and affective domains

Standard 2.5 Support Staff: Technical support staff assist with simulation equipment maintenance, provide IT, biomedical and audiovisual support. Administrative support staff assist the Director, clinical experts and facilitator with organizational management.

There must be sufficient technical and administrative support staff assigned to the high-fidelity extracorporeal simulation program to ensure achievement of the program goals and outcomes.

Standard 2.6 Clinical Validation Panel : A panel of no less than 5 clinical content reviewers will validate simulated clinical experiences by assessing the environmental, technical, physiologic and clinical practice elements included in the high-fidelity extracorporeal simulation curriculum.

Qualifications:

- Current national certification, state license or ECMO / ECLS experience
- A minimum of 1000 documented hours first hand clinical experience in the area of specialty they are validating (CPB or ECLS)
- No relationship with the sponsoring institution which may constitute an unmanageable conflict of interest

Responsibilities:

- Independently witness, experience and perform the high-fidelity extracorporeal simulation scenarios offered by the sponsor
- Complete a survey which evaluates the fidelity of environmental, technical and physiologic elements
- Attest that, based on their expert opinion, these elements are (or are not)
    - Consistent with real life execution of extracorporeal practice / techniques, critical patient conditions, and device malfunction.
    - Skills used in the high-fidelity extracorporeal simulation environment are significantly similar to the skills used in the clinical arena
    - Performance in the high-fidelity extracorporeal simulation environment is predictive of performance in the clinical arena

Guideline 2.1: It is preferred that the Director complete a training program for simulation facilitators that is recognized by this accreditation body.

Guideline 2.2: It is preferred that the Director be equally qualified as a content reviewer.

Guideline 2.3: It is preferred that the Director have a Doctorate degree in a specialty related to education (teaching, learning, curriculum, assessment, medical simulation etc).

Guideline 2.4: It is preferred that the Clinical Expert hold a current national Perfusion certification, state Perfusion license or ECLS experience.

Guideline 2.5: It is preferred that the Clinical Expert's responsibilities for the sponsoring institution dedicate at least 10 % of their time to the high-fidelity extracorporeal simulation program.

Guideline 2.6: High-fidelity extracorporeal simulation programs may have different Clinical Experts for each recognized specialty.

Guideline 2.7: It is preferred that a Facilitator hold a current national Perfusion certification or state Perfusion license.

Guideline 2.8: It is preferred that a Facilitator complete a training program for simulation facilitators that is recognized by this accrediting body.

Guideline 2.9: Experts drawn from the Perfusion or ECLS community should have a variety of clinical experiences in order to ensure the diversity of the educational process.

Guideline 2.10: Programs are encouraged to include medical professionals who are experienced with the care of extracorporeal patients (physicians, nurses, allied health professionals) but not extracorporeal clinicians (Perfusionists and ECMO Specialists) on their Clinical Validation Panels. These individuals should be given a voice but not a vote when validating the environmental, technical and physiologic fidelity of the curriculum.

Standard 3: Facilities and Equipment

Standard 3.1: High-fidelity extracorporeal circulation is conducted in an environment which closely resembles and is consistent with real life extracorporeal clinical practice.

Standard 3.2: The technical (clinical) equipment used in high-fidelity extracorporeal simulation must function realistically and in a manner consistent with real life extracorporeal clinical practice replicating normal and failure conditions.

Standard 3.3: The patient simulator technologies used in high-fidelity extracorporeal simulation must realistically reproduce normal and critical human physiologic variables and respond predictable and appropriately to the technical interface in a manner consistent with real life extracorporeal practice.

Standard 3.4: The environmental, physiologic and technical elements included in the curriculum must be validated by a 80% majority consensus of the program's Validation Panel as being

consistent with real life extracorporeal clinical practice/techniques, critical patient conditions, and device malfunction.

Standard 3.5: Must have IT/AV technologies sufficient to support the educational goals of the program and provide feedback to participants.

Standard 3.6: Must have physical space sufficient to support the educational goals of the program and provide high-fidelity extracorporeal simulation.

Guideline 3.1: The AmSECT Clinical Practice Standards and Guidelines (5) and ELSO practice guidelines (6) should serve as the authoritative sources defining the necessary physiologic variable, technical abilities and parameters used in high-fidelity extracorporeal simulation.

Guideline 3.2: The ability to capture simultaneous video and audio streams and review of captured files with participants is strongly recommended.

Guideline 3.3: The ability to stream live AV to other rooms or to the internet for presentation and discussion with a wider participant group is strongly recommended.

Guideline 3.4: Simulation space should be greater than 500 SF.

Guideline 3.5: It is recommended that there be separate and adequate spaces for simulation, briefing and debriefing, lockers, etc.

Guideline 3.6: It is recommended that maximum number of learners in the simulation space not exceed five per scenario.

Standard 4: Curriculum

Standard 4.1: Simulation scenarios must be delivered by a high-fidelity extracorporeal simulation facilitator as defined in section 2.3 above.

Standard 4.2: High-fidelity extracorporeal simulation programs must have objectives for each scenario which identify the technical and non-technical skills that will be evaluated.

Standard 4.3: The technical and non-technical skills and clinical practice techniques modeled during high-fidelity extracorporeal simulation must be validated by an 80% majority consensus of the program's Validation Panel as:

- representative of the skills used in the clinical arena
- predictive of performance in the clinical arena

Guideline 4.1: The AmSECT Clinical Practice Standards and Guidelines (5) should serve as the authoritative source defining the necessary technical and non-technical skills that are included and evaluated in high-fidelity extracorporeal simulation scenarios.

Guideline 4.2: The ExtraCorporeal Life Support Organization practice guidelines (6) should serve as the authoritative source defining the necessary technical and non-technical skills that are included and evaluated in high-fidelity extracorporeal simulation scenarios.

Guideline 4.3: The learner's familiarity with the HFES equipment should be taken into consideration in scenario design, especially during high-stakes simulation and competency checks.

5. Program Evaluation and Improvement

Standard 5.1: Quality assurance and continuous quality improvement that includes participant and faculty feedback must be demonstrated for each educational program offered.

Guideline 5.1: The program will provide evidence of one major quality improvement project per year that follows the standard DMAIC or PDCA formats. The quality improvement project should focus on one of the program's scenarios.

6. Community Development

Standard 6.1: Each Program must demonstrate a continuous commitment to the development of the high-fidelity extracorporeal simulation community and consortium.

Guideline 6.1: Commitment to the high-fidelity extracorporeal simulation community/consortium may be demonstrated through

- Membership in medical simulation professional organizations
- Attendance at medical simulation continuing educational conferences
- Participation in the governance of medical simulation organizations and committees
- Presentation of original work at medical simulation and professional conferences
- Publication or original work in peer reviewed journals
- Local and regional interdisciplinary team training

7. Fair Practice and Confidentiality

Standard 7.1: All activities associated with the program, including participant recruitment, admission, participation and evaluation must be non-discriminatory and in accord with federal and state statutes, rules, and regulations.

Standard 7.2: All records of participation (AV files, assessment reports, curricular projects, other) are considered confidential.

Standard 7.3: The use of participants data for research purposes requires review by the sponsors and/or a collaborator's Institutional Review Board for Research on Human Subjects and may require informed consent by the participant.

Standard 7.4: The use, release or distribution of participants data for all purposes other than internal program quality improvement and research is strictly prohibited in the absence of a release form signed by the participant that specifically identifies the method and scope of use, release or distribution.

Standard 7.5 High-fidelity extracorporeal simulation programs must have a clear procedure for assuring the protection of the participants' personal data in relation to the restrictions assigned by the participant.

References

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2. Steadman RH. The American Society of Anesthesiologists' national endorsement program for simulation centers. Journal of Critical Care. 2008 Jun;23(2):203–6.

3. Sachdeva AK, Pellegrini CA, Johnson KA. Support for simulation-based surgical education through American College of Surgeons--accredited education institutes. World J Surg. 2008 Feb;32(2):196–207.

4. Fernandez R, Wang E, Vozenilek JA, Hayden E, McLaughlin S, Godwin SA, et al. Simulation center accreditation and programmatic benchmarks: a review for emergency medicine. Acad Emerg Med. 2010 Oct;17(10):1093–103.

5. American Society of ExtraCorporeal Technology Standards and Guidelines For Perfusion Practice [Internet]. 2013 ed. amsect.org. 2013 [cited 2014 Sep 25]. pp. 1–22. Available from: http://www.amsect.org/

6. Extracorporeal Life Support Organization Guideline for ECLS [Internet]. ELSO.org 2016 [cited Jan 2016]. Available from http://www.elso.org/