AMERICAN COLLEGE OF SURGEONS • DIVISION OF EDUCATION
ACCREDITED EDUCATION INSTITUTES®
ENHANCING PATIENT SAFETY THROUGH SIMULATION

AMERICAN COLLEGE OF SURGEONS | DIVISION OF EDUCATION
Blended Surgical Education and Training for Life

GUIDELINES FOR SIMULATION DEVELOPMENT

A SET OF RECOMMENDATIONS FOR PREFERRED CHARACTERISTICS OF SURGICAL SIMULATION

DEVELOPED BY THE TECHNOLOGY AND SIMULATION COMMITTEE
OF THE ACCREDITED EDUCATION INSTITUTE CONSORTIUM

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A. TARGET AUDIENCE FOR THIS GUIDELINE

AEI Member: Make use of guideline in discussions and decision making of use of simulator at an AEI.

Simulation Developer: Make use of guideline as a basis for understanding key components/ embodiments that ACS AEI members look to see identified or included in a surgical simulation that might be deployed at an Accredited Education Institute.

B. INTENT OF GUIDELINE

These guidelines seek to ensure that simulator hardware/software devices, deployment plans, and supporting educational content are specifically tied to surgically relevant educational/curricular goals. The related goal is to avoid what might be a worthy engineering exercise that becomes a developmental "dead end" for want of users. These guidelines are intended to apply to team, cognitive, mechanical, mixed reality, virtual reality, and immersive reality simulation or simulators. The ACS AEI T&S Committee recommends good stewardship and thereby looks for value in the simulator.

Disclaimer: These Guidelines for Simulation Development represent the opinions of the contributing authors and are not the official policy or position of the American College of Surgeons.

C. CONSIDERATIONS

1. Needs or Opportunities Assessment:

Considerations to address: What is the initial or current need or gap addressed by the simulator? What analysis process was used to make this determination?

a. Replacement:
At a very basic level the simulator may replace a live patient for training, or at an advanced level, replace current options that are more expensive, less realistic, more hazardous to replace, or ethically less favorable. What technology or teaching method does this simulator replace?

b. Educational Objectives:
It is understood that simulators typically have an intended use. For frame of reference, what educational objective(s) was the simulator originally designed to address?

c. Curricular Needs:
What curricular needs were identified that could be addressed by the simulator?

d. Sentinel Events:
Were there any known sentinel events that led to the development of the simulator?

e. Cost:
What is the initial cost of the simulator? What recurrent costs are associated with the simulator?

f. Is simulation the most effective education/training method from a cost perspective?

g. Is one particular simulator more cost-effective than the alternatives?

h. What is the expected functional life of the simulator?

2. Surgical Clinical Relevance:

Considerations to address: Does the simulator demonstrate relevance to a surgical clinical or educational problem?

a. Fidelity—"How Real":
How would you define the fidelity of the system? See #6 below (Face and Content Validity). Can the developer suggest the connection between fidelity of the simulator and the intended learner level?

b. Potential Impact:
Does it meet pressing educational needs? If so, what is the size/composition of the impacted learner base? Is it relevant to the ACS, to health care quality, or to the clinical education process in a broad or narrow way?

c. Improve Patient Safety, Care Efficiency, and Quality:
The simulator MUST have an application that relates directly or indirectly to improved patient safety, or increased health care efficiency and/or quality.

3. Educational Effectiveness

a. Performance Metrics:
This may be via embedded software—as with computerized systems, or as with mechanical systems—a suggested list of metrics that can be collected.

Simulator should measure performance or allow users/participants to be assessed by a process appropriate to the simulation (e.g., video analysis of patient simulator session).

Capability to measure and characterize an expert referent standard of performance where relevant.

b. Data Accessibility:
When possible, the simulator would need to provide simple access to learner and performance data/metrics Preferred: Exportability (for immersive VR/Cognative/VR) and Trendability. Are any educational data standards used for data transferability?

c. Tutoring & Feedback:
When possible, tutoring and feedback systems would be a great addition to any simulation system.

d. Configurability/Authoring:
When possible, the simulator user must be able to configure, reconfigure, and potentially author changes within the specifications of the simulator.

e. Capacity for Regionalization:
The capacity for or inclusion of various languages and diversity related components/design would be valued.

f. Identification of Transfer-of-Learning Issues:
Is there an imposed learning curve? We look to see a minimal learning curve (as opposed to the real world), further, we look for positive transfer and a minimization of zero or negative transfer.

4. Device Specification

a. Software Escrow:
For any system that includes software, we recommend that, at minimum, part of the "users agreement" include agreement that in an event the company should be unable to provide support for a simulator, that the software code and documentation be made available to the user or simulator owner, or even being made available as open source.

b. Sustainability:
What is the anticipated live cycle of the simulator and how does it fit in with existing simulator offerings? What happens when simulator gets phased out and is no longer supported?

c. Backward & Forward Compatibility:
When at all possible it is recommended that design account for forward and backward compatibility. When possible, the B/F compatibility should be defined.

d. Scalability:
When at all possible, it is recommended that design account for scalability, i.e., the system is capable of expansion in function. When possible, the state of scalability should be defined.

e. Flexibility/Configurability:
When at all possible, it is recommended that the design account for Flexibility/Configurability, i.e., the system is capable of being user configured and potentially configured beyond the intended use (but within the design specifications). Does the user license account for such flexibility?

f. Ergonomic Risk Factors (HF):
Systems must, when not mimicking real systems, minimize ergonomic risk to the user to a level less than actual performance or without imposing ergonomic/kinematic risk.

g. Environmental Consideration:
Systems should be as "green" and minimally environmentally impactful. What are some of the power/environment requirements to maximize simulator?

h. User Safety:
The Simulator/simulation should be as safe as possible to both user and patient.

i. Encourage Interoperability:
The ASC/AEI strongly encourages that all simulators, when possible, be designed to have inherent interoperability, either with other simulators in function or in data transfer/automation. Use of data exchange standards is considered and/or used wherever applicable appropriately.

5. Accessibility

Consideration to address: How to get the device into use and to many in the lab or to location.

a. Scalability
(see above)

b. Regionalization
(see above)

c. Value/Cost Analysis:
We strongly urge the designer to perform or have estimated value/cost analysis completed that considers the end user's perspective

d. Portability:
Power and network connectivity (tethered vs. wireless)

e. Security:
Data, physical storage, key/password control

f. Inventory support:
Consumables, compatibility with other simulators/equipment

6. Validation

a. What Is Being Validated?

b. Hardware Is Used in High-Quality Educational Experience:
It is recommended that when possible that the simulator is used in a high quality educational experience.

c. Face, Content, Construct, Concurrent, Congruent, Predictive Validity:
What degrees of validity have or are being validated/ associated with the simulator and for what specific use of the simulator?

7. Factors of impact:

Considerations to address: Do any additional embodiments apply to simulator?

a. Features Useful to Customers
How are requests of features collected by customers? What kind of user testing does and/or has the simulator been through?

b. Expectations for Various Technologies
Are there any expectations (e.g., infrastructure) and/ or prerequisites for the use or acquisition of other technology to support simulator that's not provided by simulation provider?

D. CONTACT INFORMATION FOR FEEDBACK

Please contact at the American College of Surgeons for any feedback:

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