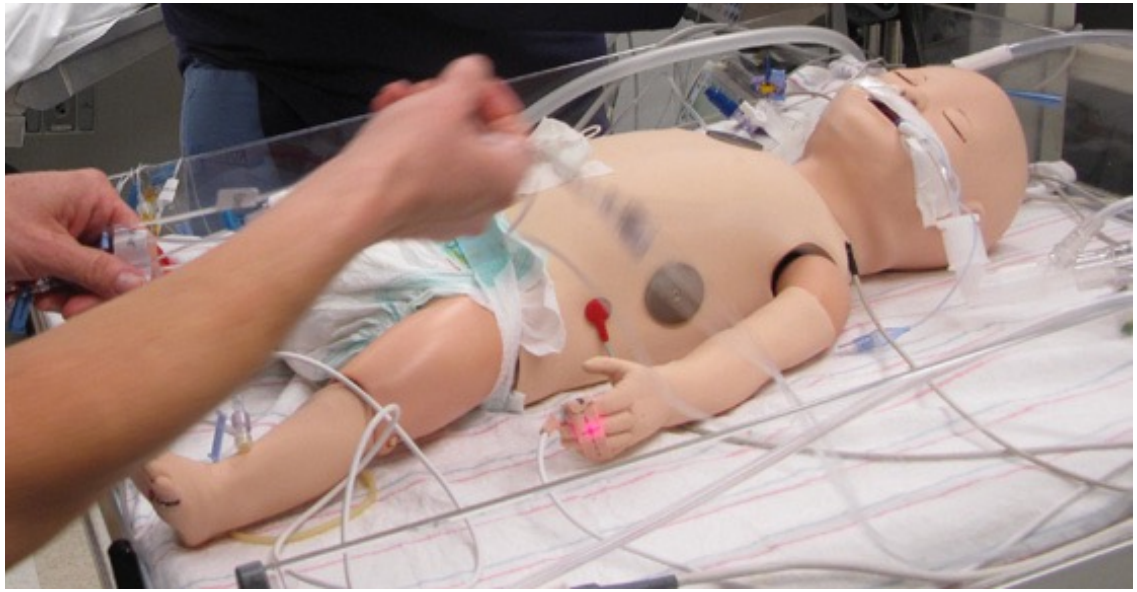
SIMULATION CENTERS: SELECTION AND TIPS FROM THE FIELD

Linda Pellegrino, Sr. Usability Specialist
Laurie Reed, Sr. Human Factors Engineer

What is a Medical Simulation Center?

Medical Simulation Centers mimic medical environments for the purpose of clinical training, medical device development, and evaluations.



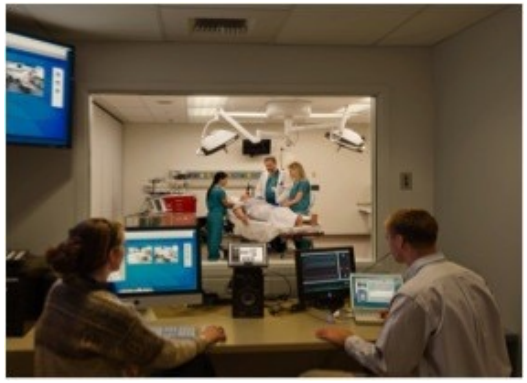
From the FDA Draft Guidance: *Applying Human Factors and Usability Engineering to Optimize Medical Device Design*

"Simulated use testing involves systematic collection of data from users (participants) using a device (or device component or system) in **realistic situations**."

"It is particularly important during validation testing to use a production version of the device, representative device users, actual use or simulated use in **an environment of appropriate realism**, and to address all aspects of intended use."

Types of Simulation Centers

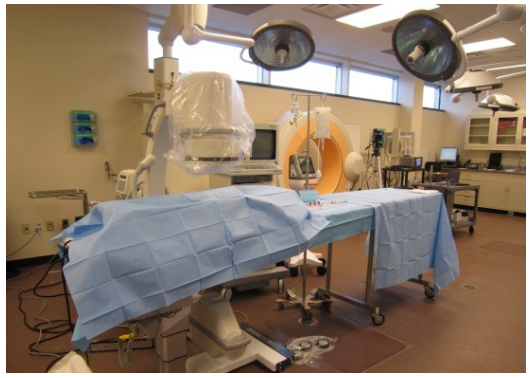
Hospital and University Simulation Centers
These centers are used for student courses and clinical training of hospital staff. Some centers are open to product development companies when not in use. They are typically more available during evenings and weekends.


University of Virginia School of Medicine

Commercial Simulation Centers
Commercial simulation centers are open to the public. Some centers offer very sophisticated mannequins and medical equipment. Animal labs are options if physiology is important to the simulation.


Center for Medical Simulation, Boston MA

Private Simulation Centers
Private simulation centers are operated by device manufacturers and are not typically open to the public.


Private Simulation Lab

WHEN TO USE SIMULATION CENTERS

When is it Beneficial to Test in a Simulated Environment?

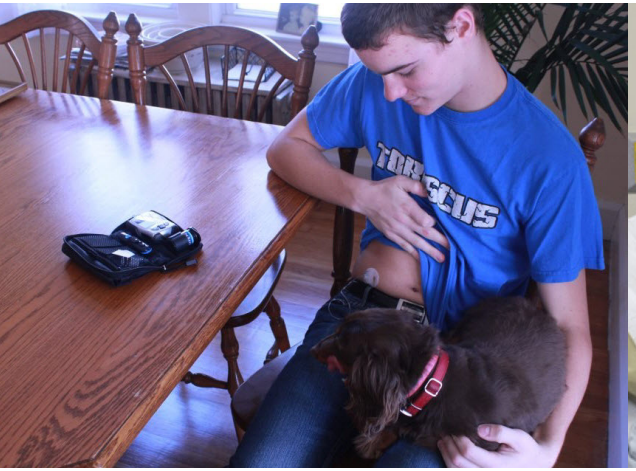
- When the effects of stress and distractions can influence the use of the device
- When extensive medical equipment is necessary in the use environment
- When the impact of motion on the use of the device may be evaluated (ambulance simulator)
- When an animal or wet model is needed to simulate the proper physiology or anatomy
- When medical mannequins can enhance the realism of the scenario
- When proper lighting and ambient sounds are important for gathering feedback about the effectiveness of the user interface

When is a Simulation Center Too Much?

- When the device does not need to interact with other medical devices
- When the device can be used in the field (defibrillator)
- When you are testing a consumer or home healthcare device (can be conducted in a research or home setting)
- When renting and transporting surrounding medical equipment is less costly than using a Sim Center
- When the clinical environment is less complex and more controlled (doctor's office)

When is a Simulation Center Not Enough?

- When patient behavior is an integral part of using the product, it is better to observe the patient in everyday life to capture all scenarios
- When you want to assess usability over time, a clinical trial may be more appropriate
- When home hazards or sterility requirements may impact the usability of the device, evaluate it in the actual home setting



TIPS FROM THE FIELD

Institutional Review Boards (IRB)

Is IRB approval necessary when conducting an evaluation in a simulation center?

- Whether or not IRB approval is required for usability tests is a debated topic
- According to the FDA's guidance for IRBs, clinical investigators, and study sponsors, one could conclude that many usability tests would fall into the "exempt" category
- However, potential patient risks must be evaluated carefully in making this decision. As with all research, including human subjects, the safety, privacy, and welfare of the participants must be protected
- Even if the study sponsor feels that IRB approval is not required, some simulation centers have their own internal IRBs, which mandate approval prior to using the facility
- The IRB approval process can be lengthy and time-consuming, so consider whether your study is eligible for expedited review

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Audio/Visual and Room Requirements

Consider whether the simulation center has the audio/visual capabilities required for your project:

- Can the video cameras adequately capture the detail needed, and are they manned?
- Are lapel microphones needed?
- Is any specialized recording equipment required, such as Morae for recording GUI screens, a camera inside the OR lamp for top-down views, or surgeon head-cams?

Determine if the observation area will accommodate your needs:

- Will the observers be able to hear what is happening in the other room and see what the cameras are capturing?
- Is the observation area truly sound-proof and one-way?

Assess the other spaces needed for the project:

- Check-in area for participant arrival
- Lobby or waiting area for decay of learning
- Additional conference rooms for IFU evaluations or post-test interviews

Staffing and Access

Determine whether the simulation center staff are available to:

- Assist with security badges or the check-in process
- Provide IT support throughout the study
- Assist in the set up of the test environment to ensure its realism
- Operate certain medical equipment during the study (i.e., cath lab fluoro)
- Operate the control room, cause interruptions, cue mannequins to speak
- Make copies, order and set up food/beverages

Consider when your team and participants will have access to the center:

- Do doors lock at a certain time?
- Is access to the Sim Center limited during evenings or weekends (elevators, badge access)?
- Is a locked area available for overnight storage of equipment and consumables?

Running a Pilot at the Center Beforehand

Never underestimate the importance of conducting a pilot prior to the session to:

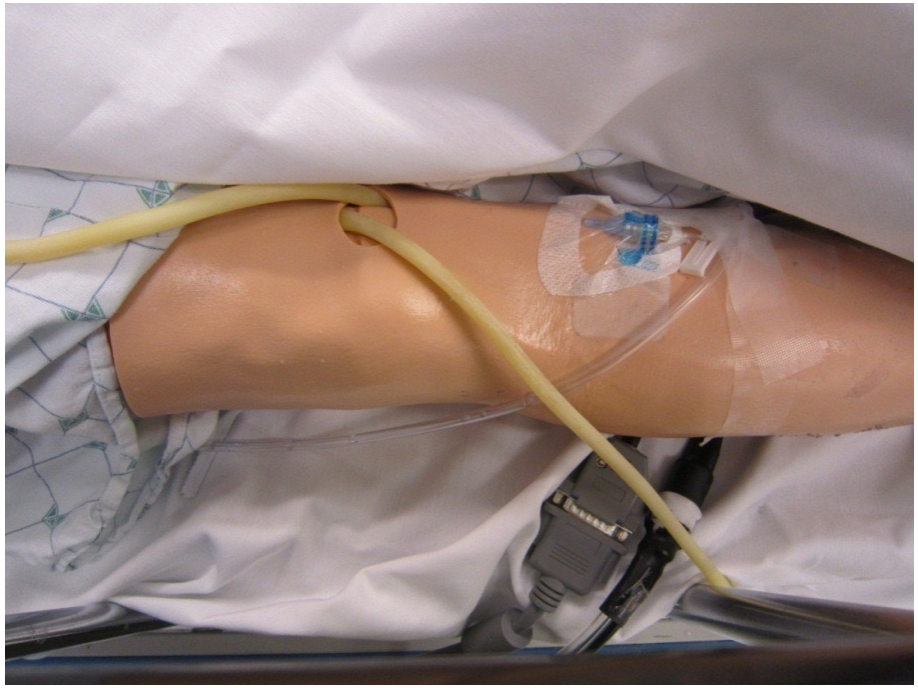
- Test participant directions to the facility
- Familiarize with the simulation center environment
- Verify the test setup
- Confirm that the center can supply all necessary equipment
- Test out your protocol and interview script, including the intended training
- Run through the various staff roles (who is resetting between sessions; who gives directions, greets participants, and handles consent forms; what items are you collecting afterward for inspection)
- Make necessary adjustments prior to the actual usability test

CASE STUDY

Product evaluation at a Simulation Center in Baltimore

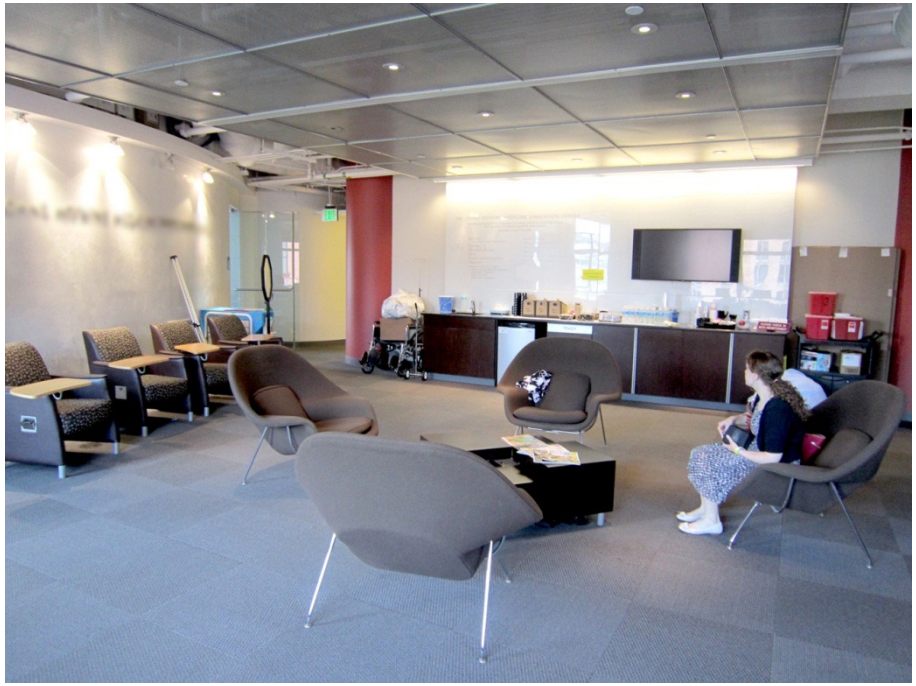
Purpose of the Evaluation

- This was a validation study of a device associated with pain management
- The objective was to validate that all of the use-related hazards were sufficiently mitigated
- Portions of the Instructions for Use were redesigned and being re-tested also



Why This Center Was Chosen

- The simulation center was chosen for its ability to simulate a labor and delivery environment, and pregnant medical mannequins were available
- The center provided access to clinical expertise in this specialty
- This was a very large study. There were sufficient hospitals in the geographical area to draw the necessary participants for the study
- The reception area was comfortable for learning decay wait times



How Using a Simulation Center Benefited This Study

- 100% of participants followed the aseptic protocol when using the device in a more realistic environment, compared to a previous test that was conducted in a research center
- Interacting with a pregnant mannequin motivated nurses to be behave more realistically. This led to fewer errors
- Simulating a worst-case scenario uncovered one nurse's unconventional use of the product

What Went Really Well

- Conducting a pilot at the center was critical to our success
- The center provided manned camera operators and people who knew the equipment well
- Plenty of extra rooms for IFU testing and post-session interviews
- There was enough equipment to simulate two L&D rooms, allowing us to run concurrent sessions and to shorten the duration of the evaluation significantly

Lessons Learned

- Due to classes being in session, the center was only available during evenings and weekends
- Access to the simulation center needed to be coordinated with facilities on the weekend
- We assumed all participant consent and verification information had been fully collected by the staff, but it had not
- We assumed the recruiters would be available to the participants during weekend sessions for directions, reschedules, and cancellations, but they were not

APPENDIX

Appendix A: Sample Listing of Simulation Centers

Bay State Simulation Center (MA)
Cincinnati Children's Hospital Simulation Center (OH)
Dartmouth-Hitchcock Medical Simulation Center (NH)
Duke University Human Simulation and Patient Safety Center (NC)
Harvard Center for Medical Simulation (MA)
Hunter College Bellevue School of Nursing (NY)
Johns Hopkins Medicine Simulation Center (MD)
MGH Knight Simulation Center (MA)
Michael S. Gordon Center for Research in Medical Education (FL)
Mt. Sinai Skills and Simulation Center (OH)
Penn State Hershey Simulation Center (PA)
Rhode Island Hospital Medical Simulation Center (RI)
Simulated Interactive Advanced Medical Education Center (NY)
SiTel/MedStar (DC)
Springfield Technical Community College SIMS Medical Center (MA)
Texas Tech University SimLife Center (TX)
Tulane University Center for Advanced Medical Simulation (LA)
UCSF Kanbar Center for Simulation, Clinical Skills and Telemedicine Education (CA)
University of Florida Center for Simulation, Education and Safety Research (FL)
University of Maryland School of Nursing CSL Lab (MD)
University of Michigan Clinical Simulation Center (MI)
University of Nebraska Clinical Simulation Lab (NE)
Vanderbilt University Center for Experimental Learning & Assessment (TN)
WakeMed Center for Innovative Learning (NC)
West Penn Allegheny Health System STAR Center (PA)

http://ssih.org/sim-center-directory

THANK YOU.

Business Center
12 Silver Lake Road
P.O. Box 1260
Hollis, NH 03049

Phone: 603 465-9800
Fax: 603 465-9801

Development Center
27 Proctor Hill Road
P.O. Box 1260
Hollis, NH 03049

Phone: 603 465-9800
Fax: 603 465-3287

Farm Cleveland Clinic
Global Cardiovascular
Innovation Center
10000 Cedar Avenue

Cleveland, OH 44106

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