Clinical Validation of Medical Simulation: A tale of two simulators-lessons learned
MICCAI 2003 Tutorial

Col. Mark W. Bowyer, MD, FACS
Associate Professor of Surgery
Surgical Director
National Capital Area Medical Simulation Center
Uniformed Services University
Bethesda, MD


SIMULATION WILL BE READY FOR PRIME TIME ONLY WHEN PROPOONENTS CAN SHOW THAT CLINICALLY USEFUL LEARNING RESULTS FROM SIMULATOR USE!!

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Face Validity

- The ability of the simulator to accurately provide a training/testing environment to measure knowledge skills and abilities
- Does it do what it is supposed to do?

Convergent Validity

- The degree in which the simulation experience is similar to real life.
- Does the simulator create an authentic and realistic experience.

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Learning a New Language

- Face Validity
- Content Validity
- Predictive Validity
- Construct Validity
- Concurrent Validity

- Reliability
- Test-test Reliability
- Inter-Rater Reliability
- Convergent Validity
Content Validity

- Does the simulator accurately measure the same KSA’s as the current “gold standards”

Predictive Validity

- Can the simulator accurately predict proficiency in the real world.
- Will they perform as advertised?

Construct Validity

- Does the simulator actually measure the skill level?
- Can you show a difference between a novice and an expert?
- Seeks agreement between theory and practice.

Criterion Validity

- Will the use of the simulator help develop the skills needed to meet the criteria.
- ie will training on a simulator result in competence in real world application?

Reliability

- Consistency, Repeatability, and reproducibility of performance and skills while using the simulator.

Test-retest reliability

- Can the student maintain the skill over time/retesting?
Inter-rater reliability

- Will the evaluators “see the same thing” when evaluating the subjects performance.

Designing a validation Study for simulation

- Need clear (unambiguous) definition of what constitutes error and success for the procedure.
- Need high inter-rater reliability

Questions

- Can Simulator training provide an equal or better training experience than what is currently available?
- How do incorporate appropriate simulators into curricula?

Choice of procedure for simulation

- Common procedure
- High stakes
  - Consequences severe if done wrong
  - Time sensitive
- Limited opportunity for training

Chest Tube Placement

Necessary And Life Saving Skill

How are Medical Students Taught to Insert Chest Tubes

- Standard Curriculum (USUHS)
  - Place 1 CT on Pig as MS3
  - Place 1 CT on Goat as MS4 (ATLS)
- Very Rare for student to place tube on human during clinical rotation
Validation

- Will Simulator training provide an equal or better training experience than what is currently available?
- Study designed to compare Virgil to Pig for teaching Medical students to insert a chest tube

Design

- IRB approval
- 20 third Year medical students starting surgery rotation
- All True novices – never seen one, never done one
- Knowledge & Perception questionnaire given
- Randomly divided into two groups of ten

Group 1 – Virgil Trained

- 10 Medical Students taught in standardized fashion (technique reviewed and corrections made as needed) to insert a chest tube on Virgil

Group 2 – Pig Trained

- 10 Medical Students taught in standardized fashion (technique reviewed and corrections made as needed) to insert a chest tube in an anesthetized pig

Testing on Virgil

- After Initial Training, both groups place CT in Virgil twice without coaching or instruction
- Time for chest tube insertion, proximity to organs, and complications recorded
**Evaluation by “experts”**

- On separate day as part of normal curriculum all students insert CT into a Pig
- Instead of teaching the skill, faculty assigned to each table and blinded to teaching method silently evaluate performance without correction
- Students given final knowledge & perception questionnaire

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**Test of Chest Tube Knowledge**

- [Graph showing bar chart with percent (%) vs. groups (Both Groups, Virgil Group, Pig Group).](#)
- *P* = .11, *P* < 0.003, *P* < 0.002

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**Faculty Evaluation – The Student Is Able to Discuss:**

- [Bar chart showing equipment needed, landmarks & indications, complications.](#)
- Virgil Trained vs. Pig Trained

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**Faculty Evaluation – The Students Technique & Overall Performance**

- [Bar chart showing technique and overall performance.](#)
- Virgil Trained vs. Pig Trained

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**Summary of Results**

- Basic CT Knowledge improved in both groups (> Virgil)
- Students Comfort level improved significantly in both groups
- **VIRGIL HAS GOOD FACE VALIDITY**
- Also has excellent Convergent Validity – realistic experience

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**Summary of Results cont**

- No faculty rated difference between groups for understanding of equipment, landmarks, indications, or complications (Content Validity)
- Faculty eval of technique & overall performance did not differ between groups (Content Validity)
Summary of Results Cont

- 75% of students felt capable of inserting CT in austere environment after limited training
- Time for chest tube insertion on Virgil decreased with practice and did not differ from “experts” after second testing attempt (Construct Validity)

Conclusion

- In this study, Virgil was at least equivalent to the Pig for training Medical students to insert a chest tube.

SimPL Validation Study Design

- 40 Third Year Medical Students who were all true novices (never done one, never seen one)
- Randomly divided into two groups of twenty

SimPL vs. Pig for teaching DPL

Pig Group (n=20) trained to do DPL on a pig
**Simulation for Medical Training – MICCAI 2003**

**DPL Validation Study**

**Design (Cont)**
- Both groups “tested” on ATLS® “standard” Trauma Mannequin

**Performance on Mannequin**
evaluated and scored by two trauma surgeons blinded to initial mode of training.

**Faculty Evaluation:**

<table>
<thead>
<tr>
<th>Site Selection</th>
<th>Seldinger Technique</th>
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<tr>
<td><em>P&lt; .0001</em></td>
<td><em>P&lt; .002</em></td>
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**Summary of Results DPL Validation Study**
- Knowledge increased significantly in both groups over baseline (p <.0001)
  - Good Content, Face, & Convergent Validity
- Students self reported level of comfort increased in both groups (p<.0001) but more so in the Simulator trained group (p<0.01)

**Summary of Results DPL Validation Study – Cont.**
- Students who trained on the Simulator had significantly increased performance on site selection (p<0.0001) and understanding of the Seldinger technique (p<0.002)
- Evaluators had greater faith in ability of Simulator trained students to perform procedure after training (90% vs 60%)
- There was good Inter-Rater Reliability
Lessons Learned

- Many of our “gold standards” are not validated
- There are no widely established standards for validation of medical simulators (need for VMAS)
- IRB’s not familiar with validation

Thank You!