

## Preliminary Evaluation of ALL-SAFE Components

### Preliminary evidence relevant to test content

DM Rooney

#### 7.19.21

**Methods.** The first week of April 2021 a total of 9 participants evaluated the ALL-SAFE box trainer, and/or the ectopic pregnancy simulator. The sample consisted of 4 General Surgery attendings, 3 Obstetrics/Gynecology attendings, and 2 general surgery residents (1-PGY1, 1-PGY3). The group reported a range of |0,50|, M=9.4 (SD=17.8) laparoscopic ectopic pregnancies, and |20,1000|, M=415 (SD=387.8) laparoscopic cases.

Four participants evaluated the box trainer's ease of build, while all 9 evaluated the box trainer's characteristics, and the ectopic pregnancy simulator.

Data capture methods followed best practices identified by Cook et al [1,2]. Reporting evidence relevant to content validity followed practices identified by Gao et al [3], Orringer et al [4], and Hsiung et al [5].

#### Box Trainer Ease of Build (n=4)

The ALL-SAFE box trainer's ease of build was measured using 6 items, rated on true Likert scales ranging from 1 (Strongly Disagree) to 5 (Strongly Agree), and a seventh item to capture time required to build the box trainer. Means are reported in table below for each item.

No.	Item	Mean (SD)	Meet criteria? (≥3.0)
1.	Build instructions for the trainer box were easy to understand	4.50 (.58)	YES
2.	Materials required to build trainer box were easy to acquire	4.50 (.58)	YES
3.	Reproduced trainer box matched the intended design	4.50 (.58)	YES
4.	Trainer box is of adequately stable construction, overall	4.33 (.58)	YES
5.	Estimated time to build (minutes)	90 (42.4)	—

ACTIONS: Mean ratings were well over 3.0 (Agree) criteria, and there were no suggestions for improvement on the build instruction, so no action taken.

### Box Trainer Attributes (n=9)

The ALL-SAFE box trainer's attributes were measured using an additional 6 items, rated on true Likert scales ranging from 1 (Strongly Disagree) to 5 (Strongly Agree), and a seventh item to capture if participants were required to stabilize the finished box trainer. Suggestions for improvements were captured using a fill-in-the-black option. Means are reported in table below for each item.

No.	Item	Mean (SD)	Meet criteria? (≥3.0)
1.	The amount of light from window/cutouts allows for adequate visualization	3.25 (.50)	YES
2.	Trainer box dimensions provide a working space which adequately represents an average pelvic cavity	2.50 (.58)	NO
3.	Front camera placement provides a view adequately comparative to that of a 30° laparoscope	2.75 (.50)	NO
4.	Top camera placement provides a view adequately comparative to that of a 0° laparoscope	2.75 (.50)	NO
5.	The trocar site placement was flexible enough to allow comfortable instrument management	2.00 (.50)	NO
6.	Trainer box of adequately stable construction, overall	3.00 (.00)	YES
7.	During testing, were you required to take action to stabilize the trainer box on the table? (Scored Yes=1, No=0)	0.50 (.58)	—

Suggestions for improvement included “Need to readjust the port sites,” which targeted making the port sites bigger in size to allow instruments to slide through the sites with more ease as well as adjusting their placement. The box dimensions were elongated to create more realistic working space.

A final question which asked participants to rate current version of box trainer by selecting ONE statement below:

No.	Item	Raw (%)
1.	The ALL-SAFE Trainer Box requires <i>extensive</i> adjustments before it can be considered for use in salpingostomy training.	0 (0.0%)
2.	This simulation requires <i>minor</i> adjustments before it can be considered for use in salpingostomy training.	3 (33.3%)
3.	The ALL-SAFE Trainer Box can be used in training salpingostomy <i>as is</i> , but could be improved slightly	3 (33.3%)
4.	The ALL-SAFE Trainer Box can be used in salpingostomy training with no improvements made.	3 (33.3%)

Actions taken included:

- 1) Elongating the box to create more realistic working space

- 2) Increase scale of and modify placement of the “port holes” to better align with authentic surgical experience

### Ectopic Pregnancy Simulator (n=9)

The ALL-SAFE ectopic pregnancy was evaluated by 9 participants across 2 domains– ease of build and attributes. The simulator’s ease of build was measured via 2 items, while its characteristics were measured using an additional 11 items, rated on true Likert scales ranging from 1 (Strongly Disagree) to 5 (Strongly Agree), and a 14th item to capture time required to build the ectopic pregnancy simulator. Means are reported in table below for each item.

No.	Item	ALL 9 (n=9) Mean (SD)	Ob/Gyne (n=2) (SD)	Meet criteria? (≥3.0)
<b>Ease of Build</b>				
1.	Build instructions for the ectopic simulation were easy to understand	4.50 (0.58)	4.00 (0.00)	YES
2.	Materials required to build ectopic simulation were easy to acquire	4.50 (0.58)	4.00 (0.00)	YES
<b>Attributes</b>				
3.	The proportions of the simulated pelvic organs were appropriate to each other	4.14 (0.69)	3.5 (0.71)	YES
4.	The proportions of the simulated pelvic organs were appropriate to the size of the trainer box	3.17 (0.76)	4.0 (0.00)	YES
5.	The uterus, fallopian tubes, and ectopic pregnancy were uniquely identifiable	4.63 (0.52)	5.0 0 (.00)	YES
6.	The uterus, fallopian tubes, and ectopic pregnancy were located realistically in relation to one another	4.00 (1.10)	3.5 (2.12)	YES
7.	The fallopian tube could be retracted with similar force to reality	4.20 (0.45)	4.0 (0.00)	YES
9.	The tactility of the fallopian tube was realistic	3.33 (.82)	3.0 (1.41)	NO
10.	The tactility of the ectopic pregnancy was realistic	3.40 (1.52)	2.5 (2.12)	NO
11.	Amount of force required to evacuate the ectopic contents was realistic	3.80 (1.10)	3.0 (1.41)	NO
12.	The feeling of the fallopian tube (penrose drain) during cutting of salpingostomy was realistic	3.60 (1.14)	3.0 (1.41)	NO
13.	Reproduced ectopic simulation matched the intended design	4.29 (0.49)	4.5 (0.71)	YES
14.	Estimated time to build (minutes)	45 (21.21)	—	—

Suggestions for improvements targeted 2 primary areas:

- a) Ectopic pregnancy, with comments that included:

“Need to have something a bit more solid for the ectopic,” “Would suggest thicker substance such as playdoh to mimic clot/tissue of ectopic,”

b) Fallopian tube, with comments that included:

“Typically fallopian tube has more resistance than penrose, so penrose was easier to Cut,”

Favorable feedback included: “None - the feel of the trainer felt very conducive to educational simulation”

Actions taken included:

- 1) Change ectopic pregnancy contents from toothpaste to playdough recipe
- 2) No changes to fallopian tubes as no viable alternative to penrose drain that is low cost.

### Ability to Perform Tasks (n=8)

Six participants rated their personal ability to perform tasks associated with the laparoscopic management of ectopic pregnancy on the ALL-SAFE simulator and trainer box. Ability was measured via 5 items (tasks), rated on 5-point rating scales, scored from 1 (Too difficult to perform), 2 (Difficult to perform), 3 (Reasonably difficult to perform), 4 (Easy to perform), to 5 (Too easy to perform), with a “Don’t know” option provided. Means are reported in table below for each item.

No.	Item (Task)	All (n=6) Mean (SD)	Ob/Gyne (n=2) Mean (SD)	Meet criteria? (≥2.5*)
1.	Evaluate both fallopian tubes	3.86 (0.38)	3.50 (0.71)	YES
2.	Identify ectopic pregnancy site	3.75 (0.46)	3.50 (0.71)	YES
3.	Place suture ligature on fallopian tube	2.86 (0.90)	3.00 (1.41)	YES
4.	Complete 1-2cm longitudinal incision along ectopic pregnancy site opposite to mesosalpinx	3.50 (0.53)	3.50 (0.71)	YES
5.	Complete salpingostomy without injury to ovary	2.67 (0.82)	2.00 (0.00)	YES

\*Criteria for appropriateness does not follow criteria for other evidence. Variability across items (tasks) is expected and could be later used for expert/novice discrimination for items (tasks) considered more difficult by less experienced surgeons.

### Value/Relevance (n=8)

Value of the simulation was rated by 8 participants using a 4-point rating scale, scored as 1 (No value/relevance), 2 (Little value/relevance), 3 (Some value/relevance), and 4 (High value/relevance) with a “Don’t know” option provided. Means are reported in table below for each item.

No.	Item (Task)	All (n=8) Mean (SD)	Ob/Gyne (n=2) Mean (SD)	Meet criteria? (≥3.0)
1.	Value as a training tool	3.88 (0.35)	4.00 (0.00)	YES
2.	Value as a testing tool	3.57 (0.53)	3.00 (0.00)	YES

**REFERENCES**

1. Cook DA, Zendejas B, Hamstra SJ, Hatala R, Brydges R. What counts as validity evidence? Examples and prevalence in a systematic review of simulation-based assessment. *Adv Health Sci Educ Theory Pract*, 2014 May;19(2):233-50.
2. Cook DA, R, Zendejas B, SJ, Hatala R. Technology-enhanced simulation to assess health professionals: a systematic review of validity evidence, research methods, and reporting quality. *Acad Med*. 2013 Jun;88(6):872-83.
3. Gao RW, Rooney D, Harvey R, Malloy KM, VanKoevering KK. To Pack a Nose: High-Fidelity Epistaxis Simulation Using 3D Printing Technology. *Laryngoscope*, 2021 Jul;00:1-7.
4. Orringer MB, Hennigar D, Lin J, Rooney DM. A novel cervical esophagogastric anastomosis simulator. *J Thorac Cardiovasc Surg* 2020 Dec;160(6):1598-1607.
5. Hsiung GE, Schwab B, O'Brien EK, Gause CD, Hebal F, Barsness KA, Rooney DM. Preliminary Evaluation of a Novel Rigid Bronchoscopy Simulator. *J Laparoendosc Adv Surg Tech A*. 2017 Jul;27(7):737-743.