Design and Evaluation of a Low-Cost Speculum Examination Training Model

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Introduction: Learning how to perform a speculum examination is a key component of the medical student curriculum, yet there is a paucity of data on the validity of available speculum examination models. This purpose of this study is to design, evaluate, and improve a low-cost speculum examination model.

Methods: A speculum examination training model was created using low-cost or recycled materials from other simulators. A total of 54 medical students, residents, and faculty in the obstetrics and gynecology department of a single academic institution performed speculum examinations on the model. Each participant completed a survey to provide qualitative and quantitative data. Using this feedback from participants, adjustments were made to the model and a similar survey was repeated with a total of 35 medical students and residents.

Results: The first iteration of the model was viewed positively by most participants. Eighty-three percent gave the model either a very realistic or realistic rating. Ninety-four percent thought the model was very useful or useful teaching device. There were few significant differences in quantitative data based on experience level. Qualitative feedback yielded generally positive remarks with areas for improvement. The second iteration of the model was successful in differentiating between novice and skilled participants: residents were significantly better at identifying cervical position compared with students. Eighty-nine percent of participants thought the model was very useful or useful, whereas 49% thought the model was very realistic or realistic.

Discussion: The first iteration of the model demonstrated realism and usefulness; however, it lacked construct validity. Participant feedback yielded several helpful suggestions to improve the model. The second and final iteration of the model differentiated between novice and skilled participants at the cost of realism. This low-cost model is a useful tool to aid in teaching the speculum examination. Further development and study of the model could lead to a valid tool to evaluate speculum examination skills.

Key Words: Simulation, simulator, speculum, low-cost, pelvic examination, speculum examination, obstetrics, gynecology, task-trainer.

Simulation is an ideal way to teach medical procedures that would be dangerous or uncomfortable to practice on patients.1–3 The female pelvic examination is a core skill for the practicing physician that is well suited to simulation training.4–6 Previous work in validating gynecologic examination models has focused on discerning abnormal pelvic anatomy through bimanual examination.7,8 A literature review was unable to find any validated models teaching the speculum component of a female pelvic examination.

In addition to lack of literature-based validation, currently available pelvic simulators are expensive and not easily transportable. Pelvic examination simulators available for purchase from commercial brands cost US $500 to $3000.9–11 After years of wear and tear by trainees, these commercial simulators can be difficult to repair or replace because of cost concerns. Furthermore, these simulators tend to have vaginal walls, which remain open and separated at rest. This does not represent a realistic simulation, because the purpose of the speculum is to gain access to the cervix by separating closely approximated vaginal walls that cover and conceal the cervix at rest. The purpose of this study was to design and evaluate a pelvic model that improved upon the design of conventional pelvic models by recreating the vagina as potential space, which realistically conceals the cervix, and did so at lower cost than currently available models with materials commonly found in a simulation laboratory.

The evaluation of this model would be performed through several domains. First, did the model exhibit realism by representing what it is intending to represent? Second, did the model exhibit usefulness by teaching what it is intending to teach? And third, did the model exhibit construct validity by being able to differentiate users based on their level of experience and skill with speculum examinations?

METHODS

Construction of the Model

The simulator was constructed to mimic the vagina and cervix of a nulliparous patient. It consists of the following seven main components: the cervix, vagina, vulva, an inflatable plastic tube to stabilize the vagina, a foam block to stabilize the
cervix, a 1-L bag of saline to distribute weight on top of the vaginal canal, and a plastic box as a base.

We used an opaque 3-gal storage box large enough to house the simulator. The box needs to be approximately 30 cm long by 25 cm wide by 20 cm tall. A 3-gal Rubbermaid roughneck storage box was sufficient (Amazon, US $9). It is large enough to contain all of the components, but small enough to carry. The lid allows for easy access to the simulator. The opacity of the box hides the inner workings of the simulator from the participant. A 10-cm-diameter hole was cut from one of the small sides of the box using wire cutters.

Simulated skin was sewn together to construct the vaginal canal. Any simulated skin, no more than 7 mm thick and produced from a silicone-like product, can be used for the vaginal canal. A remnant piece of skin from a retired simulator part such as a patient simulator mannequin chest skin is best suited for this component. A 16 cm by 12 cm rectangle of simulated skin produced by protoCAD (La Plata, MD) was sewn on its longest edges to create a tube (Fig. 1).

To create the cervix, we used a recycled cervix from a Surgical Female Pelvic Trainer Uterus produced by Limbs & Things (Bristol, UK). The cervix was inserted into one end of the vaginal canal and secured with a zip tie (Fig. 2). As an alternative, simulated skin can be wrapped around a pill bottle, secured, a marker used to identify the external ostium, and then inserted into the vaginal canal and secured.

The opposite end of the vaginal canal was sewn to another 20 cm by 16 cm segment of simulated skin with a small, narrow opening cut from the center (Fig. 3). This served to simulate the vulva and to hide the contents of the box from the learner.

To stabilize the cervix, a block of foam with a small hole for the cervix to rest was placed inside the box. The foam was large enough to occupy half of the box furthest away from the hole cut in the box. The cervix was inserted into the hole in the foam, and the vulvar skin was pulled through the hole in the box. The vulva was secured to the box with two screws (Fig. 4).

An inflatable plastic tube was inflated and wrapped around the vaginal canal inside the box. This inflatable serves to distribute weight and create pressure around all sides of the vaginal canal. An inflatable armband intended for swimming can be slid onto the vaginal canal before securing the vulva to serve this purpose (Amazon, US $5) (Fig. 5).
A 1-L bag of saline was placed on top of the inflatable to put weight around the vaginal canal (Fig. 6).

The box was then closed, obscuring the learner’s view of simulator and completing its construction (Fig. 7).

Several adjustments were made to the model following feedback from the first group of study participants.

First, the cervix was removed and small beads of varying colors were added to the cervix at 10, 2, and 6 o’clock positions with light-colored thread (Fig. 8). This is to ensure that trainees visualize the entire cervix by identifying the colors of beads that they see during the examination. The cervix was placed back into the simulator.

Additional vulva was added to the front of the box by stapling a 12 cm by 12 cm square of simulated skin around the vaginal opening. A blade was used to create a 5-cm vertical incision in the new vulva (Fig. 9). This allows the learner to mimic the separation of the labia to insert the speculum (Fig. 10).

In clinical practice, cervices are in many different positions. Thus, a second model was created with the cervix in an anterior position as opposed to mid-position. This was accomplished by creating a small 2-cm-diameter hole in the anterior vaginal canal and carefully inserting the cervix so that the simulated skin of the canal was snug around the cervix. The cervix was then sewed to the vaginal canal and cut down in size so that it did not obstruct the inflatable tube. The end of the vaginal canal was sewn together to create a blind end (Fig. 11).
Study Design

The first iteration of the model was tested on a convenience sample of third-year medical students, residents, and practicing gynecologists in the obstetrics and gynecology department at a single institution between September and November 2015. Participants were recruited through in-person requests during the course of usual clinical and educational activities. Nine participants were used to pilot the proper orientation of the model and lighting, and their data were not included. Participants were excluded from participation if they had previous experience with this simulator or assisted in the design of the model.

The study protocol was approved by the Georgetown University Institutional Review Board. After voluntary consent, participants were given a headlight, speculum, and lubricant and were asked to find the cervix. To assess construct validity, a research assistant used a timer to record how long in seconds each participant needed to find the cervix. Participants filled out a survey after using the model, which asked whether the participants believed the model was realistic and useful and whether they would recommend it for trainees. The survey
also asked whether they thought the model was more difficult, less difficult, or just as difficult as a real patient examination. Demographic information such as age, sex, and level of training was collected. The survey also asked participants for general comments about the model.

After analysis of survey results from the first part of the study, adjustments were made to the model based on both quantitative data and general comments from participants. Updates to the model were intended to address inadequacies identified by participants.

The second iteration of the model was tested on a convenience sample of third-year medical students and residents between July and November 2016. If a participant had previous experience with the adjusted version of the simulator or assisted in the design of the new model, they were excluded. Participants were not excluded if they had used the first iteration of the model.

The updated study protocol was approved by the Georgetown University Institutional Review Board. After voluntary consent, participants were given a headlight, speculum, and lubricant and were asked to perform a speculum examination on each model in a specified order: mid-position cervix first, anterior position cervix second. For each model, they were asked to identify the colors of beads present on the cervix as well as the position of the cervix. A research assistant used a stopwatch to record how long it took the participant to complete all the tasks on each model. Construct validity was assessed by comparing the level of training and experience with speculum examinations of participants to speed and accuracy of examination on the simulators. Participants filled out a similar survey regarding their opinions of the model.

RESULTS
A total of 53 subjects completed the first portion of the study: 10 attending physicians, 1 nurse practitioner, 23 residents, and 19 third-year medical students. The attending physicians and nurse practitioner were included in the same group for...
statistical analysis. Results are summarized in Fig. 12. Eighty-three percent of the participants gave the model either a very realistic or realistic rating. A stronger majority, 94%, thought the model was a very useful or useful teaching device. There were no significant differences in these answers based on experience level. When compared with a patient examination, no participants surveyed indicated that finding the cervix on the model was more difficult. Thirty-one percent of participants found the model to be similar in difficulty to a real patient examination, whereas 67% of participants found it to be easier. One medical student responded, “don’t know.” The average time to find the cervix for each group is shown in Table 1. The difference between the resident mean time to find the cervix and the other two groups was statistically significant. There was no statistically significant difference in time to find the cervix between attendings and medical students. Qualitative analysis revealed generally positive feedback with constructive notes for adjustments to improve the model (Table 2).

After changes were made to the model as described in our methods, a total of 35 subjects completed the second part of the study: 8 residents and 27 medical students participated. Results are summarized in Figure 13. Sixty-two percent of residents and 44% of medical students thought the adjusted models were very realistic or realistic. Seven medical students responded, “don’t know.” Eighty-nine percent of participants thought the simulators were very useful or useful teaching devices.

<table>
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<tr>
<th>TABLE 1</th>
<th>Mean Time to Cervix by Group, Initial Model</th>
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<tr>
<td></td>
<td>Total</td>
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<tr>
<td>n</td>
<td>53</td>
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<td>Mean time (seconds)</td>
<td>6.98</td>
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Difference reached statistical significance ($P < 0.05$) in comparison of residents with students and residents to attendings. No significant difference was found between attendings and students.
devices. A total of 28.6% of participants found it similar in difficulty to a real patient examination, 45.7% found it to be easier, and 9% found it to be harder. Six medical students responded, “don’t know.” Residents were significantly better at both the speed, which they completed the tasks, and at correctly identifying cervical position compared with students (Tables 3, 4). There were no statistically significant differences in the ability of students and residents to correctly identify bead colors on the cervix.

CONCLUSIONS

Our final low-cost speculum examination training model was found to be useful by medical professionals in training. The primary novelty of this model is that it has flexible vaginal walls, which conceal the cervix, recreating a more accurate and challenging simulation of female anatomy than conventional models. Another advantage of this model is ease of construction and low cost. By using recycled simulator parts and materials commonly found in a simulation laboratory, this model was created for less than US $25. Commercially available simulators recreate the female pelvic anatomy for bimanual and speculum examination practice a much higher cost. The model weighs less than 10 lbs and can be easily transported, a feature that is conducive to conducting training in different learning environments outside of the traditional simulation laboratory. It requires minimal adjustment between training sessions. Maintenance is also minimal, and in the event of damage, parts can be easily replaced at little cost.

Our final speculum examination model was designed on the basis of analysis of survey data from the first iteration of the model. Most participants found the initial model to be both realistic and useful. However, most participants rated the model as easier or much easier in difficulty compared with a real patient examination. On average, participants completed the examination in less than 10 seconds, regardless of their skill level. Comments from participants echoed these data with multiple remarks describing the model as “too easy.” Our design changes focused on increasing the model’s difficulty to both improve realism and achieve ability to differentiate between novice and skilled learners. By adding beads to multiple locations around the cervix and creating a second model with the cervix in the anterior position, this requires the participant to maneuver the speculum appropriately to visualize the beads on the cervix as well as identify cervical position.

Realism and usefulness of the simulator were supported by the data in the first part of the study. Following design changes to the simulator, differentiation between novice and skilled participants was gained at the expense of realism. Residents were both significantly faster at completing the tasks and more accurate in identifying the position of the cervix in the final model compared with medical students. Although most participants rated the model as very useful or useful, less than half rated the model as very realistic or realistic. Compared with the first iteration of the model, a greater percentage of participants found the model to be similar in difficulty compared with a real patient examination.

The data collected suggest the first iteration of the model may be useful for acquisition of proper speculum examination skills; its realism may be useful for medical students to learn and practice skills before a patient examination. In contrast, results from the second iteration suggest that this model may be better suited as a summative evaluation tool after additional refinements to differentiate between novice and skilled learners. Efforts to refine the model will be focused on combining the qualities of both models to create a both realistic and useful teaching and evaluation tool.

Another future direction for modification would be to address other speculum examination teaching points, such as avoidance of the sensitive urethra during speculum entry and exit. Although not used for this study, we have experimented with a pressure sensor at the margin of the anterior introitus, which would cause a red light to light up indicating too much contact with the urethral area.

One of the strengths of the study was a relatively high sample size. However, there was the limitation of a relatively narrow field of participation at a single institution. Future research would be warranted to see whether a similar model could be replicated at other institutions and evaluated by other professionals. These professionals could include nurses, midwives, and physicians in other specialties who commonly use a speculum such as emergency medicine and family practice.

REFERENCES


