

A Cervical Cancer Screening Trainer for Use in Low-Resource Settings

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Abstract – Each year, cervical cancer causes the death of over 275,000 women worldwide with eighty percent of these cases occurring in low or lower-middle income countries. Cervical cancer screening programs reduce cervical cancer occurrence by identifying and treating pre-cancerous cervical abnormalities before they develop to malignant stages. Standard methods of screening are inappropriate for use in low-resource settings and therefore screening is very limited. Based on a design ethnography study performed over a two-month period in Ghana, a need was identified for a low-fidelity model to assist in training healthcare providers to screen for cervical cancer using visual inspection with acetic acid. The design presented in this paper is a box trainer with a simulated vaginal cavity that allows a user to insert cervical images displayed on plastic tabs or cards from the Jhpiego Visual Inspection of the Cervix Flash Card Set[®]. A modular electronic feedback mechanism trains the user to properly complete the steps of the screening procedure and to track the successes of their diagnoses. This paper describes the need for a cervical cancer screening trainer, the process used to design a trainer to support visual inspection with acetic acid, and the results of prototyping and preliminary usability tests.

Index Terms – Cervical cancer screening, visual inspection with acetic acid, medical training, design ethnography, global health design

INTRODUCTION

Throughout the world, the burden of cervical cancer fatality is most prominent in low and lower-middle income countries (LMICs).¹ This is primarily due to a lack of infrastructure for traditional cervical cancer screening techniques.² Visual inspection of the cervix with acetic acid (VIA) is an effective low-cost method to screen for cervical cancer in women in LMICs, but it is not widely used.³ VIA requires experiential knowledge, which can be gained from performing the procedure in a clinical or simulated setting, in order to accurately diagnose precancerous cells. The lack of sustained use of the VIA in LMICs is due in large part to a lack of awareness and training of the method.⁴ The goal of this work was to address training shortcomings by developing and assessing a simulation based model to assist in training midwifery students, midwives, and other healthcare providers in LMICs to accurately screen for cervical cancer using VIA.

BACKGROUND

Cervical Cancer Screening

Each year, cervical cancer causes the death of 275,000 women worldwide.² Eighty percent of these cases occur in LMICs.³ Screening for cervical cancer has been shown to significantly reduce mortality, given that most cervical cancer cases caught in early stages are treatable. However, there is a lack of awareness of screening methods as well as healthcare providers trained to perform screenings in resource-limited settings.^{3,4,5}

The most commonly used Western method of the Pap smear is rarely performed in LMICs because of its cost and reliance on cytology.⁶ Alternative screening methods to cytology (Pap smear) include: colposcopy, visual inspection with acetic acid and magnification (VIAM), cervicography, HPV screening, and visual inspection with acetic acid (VIA). Colposcopy allows a healthcare provider to gain a magnified view of the patient's cervix using a colposcope, or specialized magnifying device.⁷ VIAM refers to the more general set of magnification screening tests under which colposcopy is classified. While some studies show no difference in outcomes for the two methods,⁸ further research is needed to confirm the advantages of one method over the other. Cervicography involves taking a photo of a magnified cervix and sending the image to a remote diagnostician,⁹ and has been used as both an adjunct¹⁰ and an alternative¹¹ method of cervical cancer screening. HPV screening involves testing a sample from the patient's cervix for human papillomavirus (HPV) and referring the patient to further treatment upon finding a positive result. Previous studies show that HPV screening is the most effective screening method to reduce the rates of cervical cancer,¹² but it also necessitates sophisticated screening equipment and therefore increased costs.

Visual inspection with acetic acid (VIA) is a low-cost and easy-to-perform cervical cancer screening method that immediately informs the healthcare provider of the patient's cervical abnormalities. The procedure was specifically designed for use in LMICs due to its reliance only on commonly found materials and training.¹³ The VIA is performed as follows: (1) a healthcare professional performs a standard pelvic examination and inserts a speculum into the patient's vaginal cavity, (2) the healthcare professional visually inspects the patient's cervix for any existing abnormalities and then applies acetic acid (or white table vinegar) to the cervix, (3) the healthcare professional visually inspects the cervix one minute after application of acetic acid for

any acetowhite lesions that may appear, signifying pre-cancerous cells, and (4) upon visualization of acetowhite lesions, the healthcare professional either refers the patient to specialized medical care or performs cryotherapy to remove the pre-cancerous cells.^{5,14}

One major drawback of VIA is that it cannot be used on post-menopausal women because the squamocolumnar junction is not visible to the naked eye. VIA is known to have a high false-positive rate in this population.⁵ However, there is some evidence that improved training may reduce this rate.¹⁵ A recent meta-analysis found VIA to have 80% sensitivity (consistent with previous measures at approximately 79% sensitivity) and 92% specificity (an increase from the previously measured 85% specificity) for early detection of cervical cancer.¹⁴ This meta-analysis also concluded that VIA is a more effective and cost-efficient alternative to cytology in LMICs.

Although designed specifically for use in low-resource settings, visual inspection with acetic acid is not widely used due to a lack of training, and therefore a lack of healthcare providers skilled in performing VIA. The VIA depends on experiential knowledge and the acetowhite lesions are often difficult to see or distinguish from other non-premalignant cervical abnormalities. Therefore, it is imperative that healthcare providers performing VIA screenings are sufficiently trained to recognize and interpret a wide variety of visual screening outcomes.⁵

Effects of Clinical Simulation on Training for Cervical Cancer Screening

Clinical simulators ranging in sophistication have been used in medical training for many years.^{16,22} Simulators vary based on their engineering or physical fidelity, as well as by their psychological and procedural or functional fidelity. Previous analyses of multiple simulators have shown that increases in simulator engineering fidelity lead to large increases in costs of materials and manufacturing, while leading to minimal improvements in trainee performance. Conversely, functional fidelity has proven extremely important in clinical simulator design in order to optimize “skill transfer” from simulated to actual patient interaction.¹⁷ Multiple studies have shown that high functional fidelity can be achieved with low engineering fidelity devices.^{18,19} Additionally, there have been successful low-cost simulator based training programs in multiple areas of medical training including trauma, maternal, and infant health.^{20,21}

One essential requirement to successfully screen for cervical cancer in LMICs is appropriate training programs directed towards healthcare providers. These programs help ensure proper implementation and high participation in the screening method.¹³ The Alliance for Cervical Cancer Prevention (ACCP) asserts, “training should be done in a clinical setting that resembles the service-delivery conditions at the program site.” The training should consist of a protocol that first includes simulation models followed by clinical practice with patients. Advantages of model-based clinical simulation are exposure to a range of clinical scenarios and the ability to practice an invasive procedure without putting a patient at risk.²²

Cervical Cancer Screening Training Technologies

A variety of existing simulation and educational methods are used in cervical examination and training applications. Jhpiego, a nonprofit organization focused on global health issues in LMICs, developed the Visual Inspection of the Cervix Flash Card Set[®] (flashcards). The flashcards (Figure 1) were created to supplement training, determine competency, and allow for self-review.²³ Jhpiego’s Atlas of Unaided Visual Inspection of the Cervix[®] is used as a reference in VIA screening and shows a variety of VIA screening outcomes with distinct clinical images.²⁴ Previous research supports the use of training with cervical images (i.e., Jhpiego flashcards) in

place of training with live patients. One study compared the assessment of cervical images taken after application of acetic acid by three different physicians. The researchers found a 67% level of agreement between the three physicians' assessment of 144 images.²⁵ The ACCP reviewed several cervical cancer screening training programs and identified that ideal training should be done with simulation models initially.¹³ By themselves, neither the atlas nor the flashcards offer human interaction, feedback, or a realistic clinical situation.

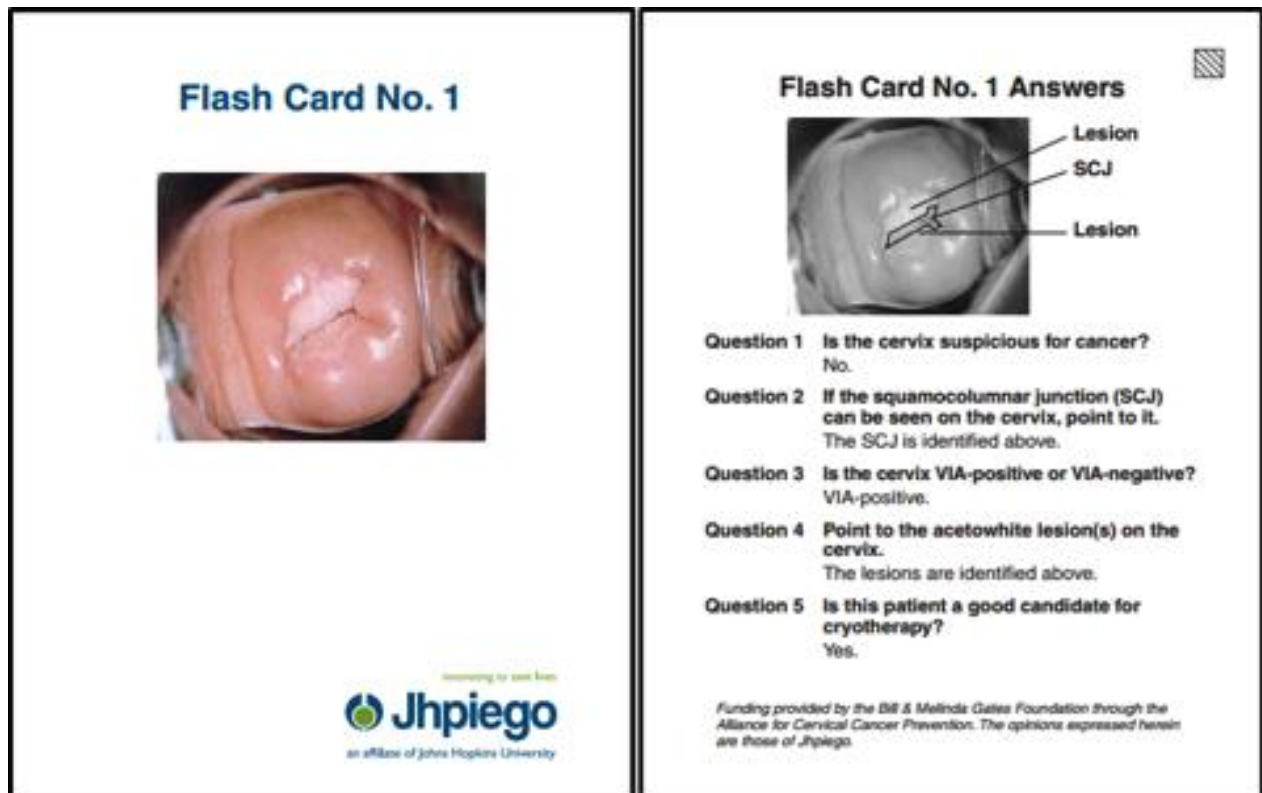


FIGURE 1
FRONT AND BACK OF A JHPIEGO FLASHCARD

Pelvic models are used to offer realistic clinical situations for students in a variety of medical training programs. The use of pelvic models to practice clinical examinations results in a decrease in the time necessary for trainees to reach performance competency by offering a humanistic experience and reducing stress.²⁶ Despite this, no pelvic models are currently intended for VIA training.

METHODS

Design Ethnography

A design ethnography study was performed during May and June of 2013, in the Upper East, Ashanti, and Greater Accra regions of Ghana to identify unmet women's health needs as part of the Global Health Design Specialization at the University of Michigan.²⁷ Design ethnography

techniques such as observations, interviews, and focus groups were used to gain a deep understanding of stakeholders' needs and cultural and social contexts in order to increase inform front-end design decisions.²⁸ Ghana was chosen as the site of interest due to a previously established 25-year partnership between the University of Michigan and teaching hospitals in Ghana.^{29,30} In Ghana, where cervical cancer is the number one cause of cancer-related death for women, less than 5% of women have been screened.³¹ There are limited organized efforts in Ghana to ensure that women are screened often and accurately for cervical cancer.³² Following the completion of the design ethnography study, the development of a training model to support midwives and other healthcare providers as they learn to screen for cervical cancer was pursued.

More than 80 stakeholders were contacted at 10 different health facilities across Ghana. Health facilities included teaching hospitals, district hospitals, medical school simulation centers, community health clinics, and government health facilities. Upon return to the University of Michigan, the design of the trainer was completed throughout a single semester capstone design course followed by a single semester independent design course. During these semesters, user requirements and engineering specifications were developed, several iterations of prototypes were manufactured, and preliminary evaluations of prototypes were performed.

User Requirements and Engineering Specifications

A ranked list of user requirements was developed taking into account: (1) design ethnography observation and interview results in Ghana, (2) interviews with healthcare professionals in the United States, and (3) supplemental literary research including benchmarking. Ranking was performed through team discussion and information source analysis to identify the impact and relative importance of each requirement. Ghanaian gynecologists, obstetricians, oncologists, midwives, and nurses were also asked to rank the list of user requirements, which served to validate the finalized rank ordering. The engineering specifications were developed with subject matter expert input, a wide-ranging literature review, and clinical observations. The user requirements and engineering specifications are shown in Table 1, organized by the importance of each requirement. Specific justification for each engineering specification is given in the following paragraph.

Benchmarking from a standard cervical model, the Jhpiego Visual Inspection of the Cervix Flash Card Set[®], and the Jhpiego Atlas of Unaided Visual Inspection of the Cervix[®] informed the development of several engineering specifications (1.2, 2.1, 2.3, 2.4).^{23,24, 33} According to stakeholders in Ghana, the current VIA training generally takes three months, but it was determined that the trainer should shorten the necessary training period (1.1). Clinical observations and interviews in Ghana informed the requirements ensuring the trainer's ability to match the VIA procedure and to signal the user's correct diagnosis (2.2, 2.5, 2.6, 4.1, 4.2, 5.2, 6.1). The trainer's ability to match the VIA procedure would also need to be realistic according to a group of trained users (2.7). To determine the anatomical dimensions necessary for the trainer, several human anatomy resources were referenced (3.1, 3.2, 3.3, 3.4).^{34,35} Durability requirements were determined jointly through a study by the Alliance for Cervical Cancer Prevention and an interview with an end-user (5.1, 5.3).¹³ To define ease of use, a study of the learning curve necessary to use a virtual reality medical trainer was referenced (6.2).³⁶ Portability, important for ensuring that Ghanaian midwives could easily transport the trainer by motorbike as they travel to rural clinics and smaller healthcare facilities, was defined by the ability of the trainer to fit in a typical backpack, while leaving room for other items (7.1, 7.2). Cost-

effectiveness of the trainer was difficult to quantify, as there are limited funds currently spent in Ghana on preventative healthcare. Clinical observations in family planning clinics provided information for the costs of high-fidelity trainers, but these amounts far exceeded what stakeholders deemed as appropriate for a low-fidelity trainer. Therefore, a reasonable, yet arbitrary price point was established as the constraint (8.1). Finally, interviews with multiple healthcare providers and officials in Ghana emphasized the desirability of domestic manufacturing to increase the likelihood of maintainability and cost-effectiveness of the trainer while serving to empower the community and the local economy (9.1).

TABLE 1
 USER REQUIREMENTS AND ENGINEERING SPECIFICATIONS

User Requirement	Engineering Specification
1 Support existing VIA training methods	1.1 < 3 months for a user to perform VIA accurately and independently 1.2 Must allow for the incorporation of Jhpiego flashcards
2 Simulate VIA screening method	2.1 ≥ 16 visibly distinct cervical screening outcomes 2.2 Change in cervix occurs 1 minute after application of acetic acid 2.3 Simulated vaginal opening must be 3.18 cm in diameter 2.4 Size of lesions must range from 0.00cm to 3.18 cm 2.5 Necessitates the use of a flashlight to accurately view cervical lesions during simulated inspection 2.6 Allows for application of acetic acid 2.7 Focus group score for realism of experience > 3
3 Maintain anatomical accuracy	3.1 Simulated skin UTS between 50-100 MPa, Young's Modulus ~ 0.6 MPa 3.2 Simulated vaginal opening ≥ 2.23 cm in length 3.3 Vaginal length ~ 8.25 cm 3.4 Simulated cervix ~2.50 cm long, cylindrical in shape
4 Signals correct diagnosis	4.1 Binary outcome: VIA negative or VIA positive 4.2 Confirms user waited 1 minute from application of acetic acid to inspection
5 Be durable	5.1 ≥ 5950 Uses 5.2 ≤ 3 elements of the trainer are consumable products 5.3 Power source lasts a minimum of 120 minutes
6 Be easy to use	6.1 No more than 1 operator required to operate 6.2 < 138 seconds for new user to learn to correctly operate the trainer
7 Be portable	7.1 ≤ 31.8 cm x 24.77 cm x 16.19 cm 7.2 ≤ 4.79 kg.
8 Be cost-effective	8.1 ≤ GHc50 to manufacture and distribute (~20 USD)
9 Be manufacturable in low and lower-middle income settings	9.1 Composed of materials available in low and lower-middle income settings

Concept Generation and Design Iteration

Over 50 concepts were generated using a variety of ideation methods, including team brainstorming and brainsketching,^{37,38} analogical thinking,³⁹ Design Heuristics,⁴⁰ and functional decomposition.⁴¹ These concepts were synthesized, iterated on, and down-selected through several phases of sketch modeling, CAD modeling, and physical prototyping. Multiple variants of the design were developed during two semesters of design based coursework. Remote and in-person feedback from stakeholders at the University of Michigan and healthcare centers in

Ghana was obtained at multiple points throughout the design process to confirm design decisions and inform redesign. Two exemplary iterations of prototyped concept solutions are described below along with the evaluation to inform subsequent redesign.

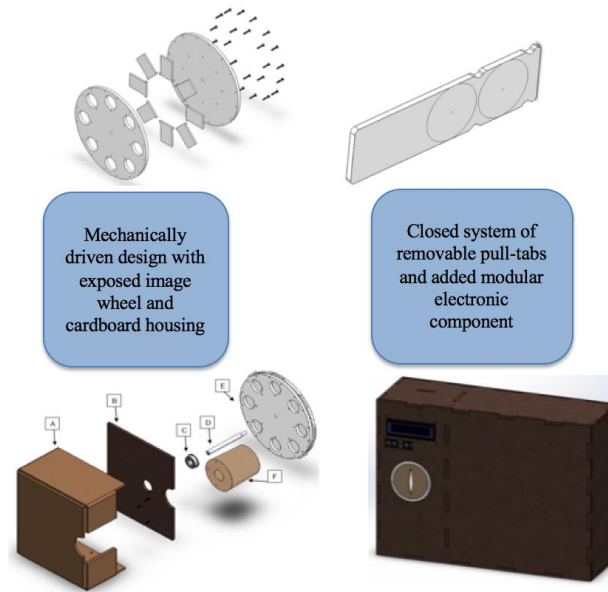


FIGURE 2
TWO SELECT PROTOTYPED DESIGN ITERATIONS
FROM LEFT TO RIGHT: "IMAGE WHEEL" "PULL-TAB"

An initial fully functional prototype, the "image wheel prototype" (Figure 2) featured a wheel with 16 different overlapping cervical images. The user would first see a pre-image of a cervix (before acetic acid was applied) and then would be able to pull a tab to reveal a post-image (after acetic acid was applied) of the same cervix. The image wheel also made possible the ability to randomize the cervical image a user would be tested on by spinning the image wheel. This prototype was initially assessed during a focus group held with eight midwifery students from the University of Michigan School of Nursing. Midwifery students used the trainer prototype and completed a survey on the model's physical attributes, realism of experience, ease of use, and functional fidelity. The survey responses resulted in a score of 3.38 out of 5 for realism of experience. Key themes from the focus group included the high procedural fidelity of inserting a speculum and viewing the 'cervix.' Design decisions for the vaginal canal feature were confirmed and are included as features in the refined concept solution described in detail below. This focus group also informed a redesign for the mechanism to view pre- and post- images of the cervix as well as and reselection of material to be used for the simulated labia.

TABLE 2
 SELECT PROTOTYPE ITERATIONS

Prototype Description	Evaluation	Select design changes informed by evaluation
“Image Wheel”	Focus group with University of Michigan midwifery students	Removal of the image-wheel and creation of multi-image pull-tabs
		Addition of modular electronic component
		Replacement of the simulated labia material
“Pull-tab”	Focus group with midwifery students and evaluation in Ghana	Replacement of silicon with latex foam for the simulated vaginal cavity
		Incorporation of Jhpeigo flashcards

Another exemplary prototype, the “pull-tab” prototype (Figure 2) featured removable multi-image pull-tabs and a modular electronic component. Each pull-tab contained a pre-image and post-image of the same cervix. These tabs are a feature of the refined prototype described below. This prototype was brought to Ghana in March 2014 to gain direct feedback from Ghanaian stakeholders including doctors, midwives, midwifery instructors, and midwifery students. Multiple design changes were informed by this evaluation trip including modifications to the electronic component and incorporation of Jhpeigo flashcards into the trainer. The resulting concept solution and subsequently referred to as the *Visualize* trainer, is described below.

VISUALIZE: A BOX TRAINER FOR VIA TRAINING

Visualize is a box trainer constructed of materials available in Ghana, including pressboard, PVC pipe, latex foam, and assorted hardware (Figures 3 and 4). The *Visualize* prototype includes a simulated vaginal cavity, made with PVC pipe and latex foam, which allows the user to insert a speculum. The user can either insert a Jhpeigo flashcard or a plastic tab with cervical images, both of which are visible by looking through the simulated vaginal cavity. An Arduino microcontroller and LCD screen provide an optional modular electronic feedback mechanism to guide the user through the steps of the VIA. The *Visualize* trainer opens from the back, revealing a storage compartment. Here, the user can store the speculum, sponge-holding forceps, tab set, and flashcard set. This storage compartment also provides the user with easy access to the battery for the Arduino and LCD screen module.

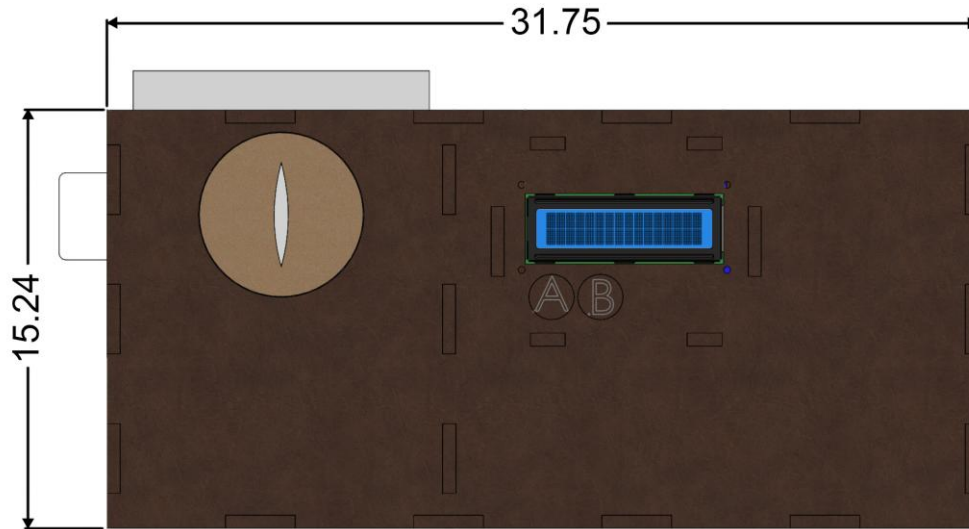


FIGURE 3
COMPUTER RENDERING OF *VISUALIZE*. DIMENSIONS ARE IN CENTIMETERS.

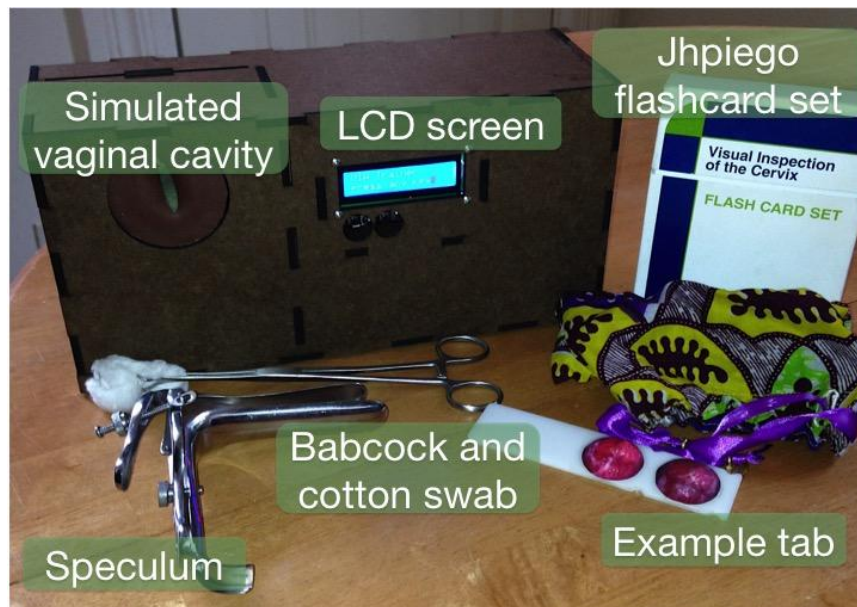


FIGURE 4
VISUALIZE COMPONENTS.

Figure 5 depicts *Visualize's* stages of use. The user can choose to either insert a Jhpiego flashcard or a customized tab. The Jhpiego flashcards show only an image of a cervix after application of acetic acid, but they provide more details about the diagnosis and describe 115 clinical scenarios. Eight multi-image laser cut tabs were created to display images of a cervix both (pre-image) before and after (post-image) application of acetic acid; hardboard or cardboard

could be used to display the images if a laser cutter is not accessible. An Arduino microcontroller and LCD screen provide optional modular electronic feedback to guide the user through the VIA procedure.

When using the tab method, the LCD screen prompts the user to select a specific numbered tab. The tab is then fully inserted into the opening on the left side of the box trainer. The user is then prompted via the LCD screen to insert the speculum, inspect the cervical pre-image, and use the sponge-holding forceps to apply acetic acid to 'cervix'. Next, the user starts a one-minute timer on the LCD screen. After one minute, the user is prompted to partially retract the tab in order to visualize the cervical post-image and make a diagnosis on whether or not the cervix pictured on the tab is pre-cancerous, cancerous, or neither. If the cervix is cancerous or pre-cancerous, the correct diagnosis is VIA positive. If the cervix is neither, the correct diagnosis is VIA negative. The user presses either VIA-positive (button A) or VIA-negative (button B). (Buttons are not shown in Figure 4). After the user makes his/her selection, the LCD screen displays the correct response. The simulator also has the ability to allow a user to complete ten different tabs presented in a random order, before outputting the results, e.g., "X out of 10 cervical images diagnosed correctly".

For the flashcard method, the user chooses a random flashcard to insert into the opening in the top of the box and then inserts a speculum into the simulated vaginal opening. Next the user visualizes the pictured cervix through the simulated vaginal opening and makes a diagnosis. After doing so, the user can check the correctness of his/her diagnosis by retracting the card and reviewing the information on the back. Note, the flashcard method does not utilize the modular electronic feedback system.



Tab Method.

1. Insert speculum
2. Push in tab, visualize pre-image.
3. Apply acetic acid.
4. Pull tab out tab, visualize post-image.



Jhpiego Flashcard Method.

1. Insert speculum.
2. Insert flashcard.
3. Visualize flashcard image.

FIGURE 5

STAGES OF USE, FOR BOTH THE “TAB METHOD” AND THE “JHPIEGO FLASHCARD METHOD”. AT THE BEGINNING OF THE TRAINING SESSION, THE USER CHOOSES WHICH OF THESE METHODS, BOTH EQUALLY VALID, TO CONDUCT.

PRELIMINARY EVALUATION

Preliminary evaluations of the *Visualize* design were driven by the engineering specifications outlined in Table I. Several specifications were met through design intent (1.2, 2.2, 2.3, 2.4, 2.6, 3.2, 3.3, 3.4, 4.1, 4.2, 5.2, 5.3, 6.1, 7.1, 7.2). For example, the LCD interface ensures that the user waits one minute after the test solution is applied because it does not allow the user to input a diagnosis until one minute has passed. Other specifications were formally tested. For example, anatomical accuracy of the vaginal cavity was evaluated through materials testing. To minimize cost and increase the likelihood of local manufacturability, a small materials fidelity test was performed with five University of Michigan Midwifery students. In this test, midwifery students compared the realism of seven materials (Figure 6), including silicone, which had been compression molded to meet the anatomical specifications of the vaginal cavity, and six inexpensive materials known to be locally available in Ghana. All studies involving human subjects were reviewed by the Institutional Review Board of the University of Michigan in Ann Arbor, Michigan, USA, which determined that it met US federal criteria for exemption, including not more than minimal risk to subjects.



FIGURE 6

SIMULATED VAGINAL CAVITIES USED FOR MATERIALS TESTING

TOP ROW FROM LEFT TO RIGHT: SILICONE, COTTON, RUBBER PLACEMAT, STYROFOAM

BOTTOM ROW FROM LEFT TO RIGHT: RUBBER LATTICE, FOAM PAPER, SPONGE

Midwifery students with varying levels of experience performing internal gynecological exams were asked to insert, expand, and remove a speculum into the different simulated vaginal cavities and rate how well the simulated vaginal cavity accurately represented the insertion, expansion, and removal of a speculum during an actual cervical exam. The midwifery students were asked to rate each simulated vaginal cavity on a scale of 1 (strongly disagree) to 5 (strongly agree) to determine the extent to which the materials realistically represented inserting, expanding, or removing a speculum in the vaginal cavity. As shown in Table 3, the test revealed that a low-cost sponge was most realistic.

As a result of this test, it was determined that it was not necessary to use silicone, a high-fidelity yet expensive material, to simulate the vaginal cavity. A similar materials test was performed in Ghana with a number of stakeholders with the addition of a simulated vaginal cavity made with latex foam, a locally available material with demonstrated similar properties to silicone and sponge. The feedback from Ghanaian stakeholders confirmed that latex foam was optimal for use and therefore was used in all future prototypes.

TABLE 3

MATERIALS FIDELITY TESTING RESULTS

($N = 5$, SCALE: 1 – STRONGLY DISAGREE THAT THE MATERIAL REALISTICALLY REPRESENTED INSERTING, EXPANDING, OR REMOVING A SPECULUM INTO, IN, OR FROM THE VAGINAL CAVITY, 5 – STRONGLY AGREE THAT THE MATERIAL REALISTICALLY REPRESENTED INSERTING, EXPANDING, OR REMOVING A SPECULUM INTO, IN, OR FROM THE VAGINAL CAVITY.)

Material	Inserting	Expanding	Removing
Rubber placemat	2.6	3.8	3.6
Cotton	2.6	2.8	3.4
Sponge	4.4	4.4	4.0
Foam paper	2.6	3.0	3.4
Rubber lattice	3.0	3.0	3.0
Styrofoam	3.25	3.0	3.0
Silicone	3.4	3.0	3.0

Prototype evaluation performed in Ghana allowed for research and feedback on the potential for the design to be manufactured locally in Ghana. Engineers at Kwame Nkrumah University of Science and Technology in Kumasi confirmed that microcontrollers are available to import and are appropriate for use in Ghana. Furthermore, interviewers informed that local artisans from nearby wood villages would be able to construct the trainer. All other materials were found to be locally available by visiting Central Market in Kumasi and speaking with local shop owners.

Several specifications were either not met or not fully evaluated (1.1, 2.7, 5.1, 6.2, 8.1). Specification 1.1 (<3 months for a user to perform VIA accurately and independently) requires longitudinal evaluation and therefore has not yet been addressed in the current work. Specification 2.7 (focus group score for realism of experience >3) has been preliminarily evaluated for the vaginal cavity as shown in Table 3, but additional work is needed to evaluate the specification for the trainer as a whole. Specification 5.1 (≥ 5950 uses) requires a more rigorous evaluation, as the trainer was only evaluated once for up to 600 uses. Specification 6.2 (< 138 seconds for new user to learn correctly operate trainer) was tested on a small sample of engineering students ($N=3$), and therefore requires a more rigorous evaluation with the target user in the intended implementation setting. Specification 8.1 (\leq GHc50 to manufacture and distribute (~20 USD)) was not met, as the modular electronic component significantly drove up the price of the trainer.

DISCUSSION

The *Visualize* prototype achieved the objective of creating a low-fidelity trainer to help teach Ghanaian midwives to screen for cervical cancer using visual inspection with acetic acid. There is currently no formal model-based cervical cancer screening training program in Ghana. Several

organizations have attempted to address the issue of cervical cancer detection and early treatment, but none through the lens of trainer-based education. The use of low-fidelity trainer has the potential to improve cervical cancer screening training and subsequently, cervical cancer detection in LMICs. In Ghana for example, VIA training, including simulation based learning, could be provided to midwifery students during their formal education and to practicing midwives through continuing professional development (e.g., workshop).

The selected concept solution leverages the advantages of both the tab and flashcard methods. By using *Visualize*, the user is able to practice the entire VIA procedure, including insertion of the speculum, application of acetic acid, and visualization of the change in the cervix, which would not be possible with only the flashcards. However, the user also benefits from the breadth of cervical situations presented in the Jhpiego flashcard set and is able to practice with a much larger set of possible outcomes.

Visualize's positive design attributes include its modular electronic component, its ability to provide a strong experiential experience, and its portability. The trainer's electronic component is completely modular, enabling the simulator to work as either an electromechanical or a purely mechanical system. This is beneficial for potential implementation in low and lower-middle income countries because the electronic component may further engage users and provides immediate feedback, but the trainer still remains fully functional in the absence or failure of the electronics. While the electronic component does add a significant cost to each trainer, stakeholders in Ghana expressed a strong interest in having a feedback system that allows for individual training and practice. Furthermore, *Visualize* provides the user with an opportunity to gain valuable experiential knowledge. It supports current cervical cancer screening theoretical education and enhances a midwife's ability to correctly perform and diagnose the outcome of a cervical cancer examination. *Visualize* also allows midwives to visualize an increased number of unique cervical cases than they would be able to observe on live patients. Additionally, *Visualize* can be easily transported by motorbike, a common mode of transportation for midwives working in rural areas of Ghana.

Visualize's design shortcomings include its relatively high cost and its lack of completed validation. The LCD component significantly increases the price of the trainer. As it stands, an individual prototype costs approximately 32 USD, exceeding the somewhat arbitrary price point of 20 USD by 12 USD. This price reflects the cost of materials only, and does not take into account the labor necessary to manufacture and distribute. Future work includes durability and time to proficiency evaluations.

The overarching goals of making VIA training more accessible throughout Ghana and encouraging screening proficiency for a large number of midwives informed the design process used to create *Visualize*. For example, a concept solution that augmented current training practices and educational models was intentionally pursued over a "blue-sky"/disruptive innovation for cervical cancer screening. While advantageous from a potential short-term implementation standpoint for Ghanaian midwives and midwifery programs, this approach was also advantageous from a student design project standpoint; simulator-based designs typically don't require regulatory approval and are more conducive to single-year design project budgets and timelines.⁴² The pursuit of an educational/training tool design versus a medical device design also facilitated active engagement among stakeholders, probably due to the increased likelihood that a student-based design solution in the simulation space was achievable within the relatively short timeframe.

Future work includes performing additional validation and usability studies and iterating on the design as needed. Prior to implementation, training strategies and curricula would need to be developed and assessed in collaboration with subject matter experts in Ghana.

CONCLUSION

The need for a tool to aid in training healthcare providers to accurately screen for cervical cancer in low and lower-middle income settings was established through a design ethnography study in Ghana. The trainer design described in this paper aimed to enhance, support, and add an experiential education component to the theoretical training currently being performed in Ghana. Cultural and clinical contexts were considered throughout the design process to increase the likelihood for adoption. Preliminary testing and feedback suggests that the concept solution could improve VIA training, but additional testing is required. Future work involves exploring the marketability of the concept and delivering prototypes to interested end-users in Ghana.

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REFERENCES

- ¹ Sankaranarayanan, Rengaswamy, You-lin Qiao, and Namory Keita. "The next steps in cervical screening." *Women's Health* 11.2 (2015): 201-212.
- ² Marc Arbyn et al. "Worldwide burden of cervical cancer in 2008." *Annals of oncology* 22.12 (2011): 2675-2686.
- ³ Jacqueline Sherris, Cristina Herdman, and Christopher Elias. "Beyond our borders: cervical cancer in the developing world." *Western Journal of Medicine* 175.4 (2001): 231.
- ⁴ Paul, Prama, et al. "Screen-and-treat approach to cervical cancer prevention using visual inspection with acetic acid and cryotherapy: experiences, perceptions, and beliefs from demonstration projects in Peru, Uganda, and Vietnam." *The oncologist* 18.12 (2013): 1278-1284.
- ⁵ "Global Guidance for Cervical Cancer Prevention and Control." *FIGO (International Federation for Gynecology and Obstetrics)* (2009)
- ⁶ Lynette Denny, Michael Quinn, and R Sankaranarayanan. "Screening for cervical cancer in developing countries." *Vaccine* 24 (2006): S71-S77.
- ⁷ "Colposcopy - directed biopsy." 2014. 31 Aug. 2015
<<https://www.nlm.nih.gov/medlineplus/ency/article/003913.htm> >
- ⁸ Winkler, Jennifer L., et al. "Is magnification necessary to confirm visual inspection of cervical abnormalities? A randomized trial in Peru." *Revista Panamericana de Salud Pública* 23.1 (2008): 1-6.
- ⁹ A. Staff "Cervicography: a new method for cervical cancer detection." *Am J Obstet Gynecol.* 1981 Apr; 139(7) 815-825. PMID: 7211987.
- ¹⁰ Ferris, D. G., et al. "Cervicography: adjunctive cervical cancer screening by primary care clinicians." *The Journal of family practice* 37.2 (1993): 158-164.
- ¹¹ Schneider, Diana L., et al. "Cervicography screening for cervical cancer among 8460 women in a high-risk population." *American journal of obstetrics and gynecology* 180.2 (1999): 290-298.
- ¹² Sankaranarayanan, Rengaswamy, et al. "HPV screening for cervical cancer in rural India." *New England Journal of Medicine* 360.14 (2009): 1385-1394.
- ¹³ Paul D. Blumenthal et al. "Training for cervical cancer prevention programs in low-resource settings: focus on visual inspection with acetic acid and cryotherapy." *International Journal of Gynecology & Obstetrics* 89 (2005): S30-S37.
- ¹⁴ Sauvaget, Catherine, et al. "Accuracy of visual inspection with acetic acid for cervical cancer screening." *International Journal of Gynecology & Obstetrics* 113.1 (2011): 14-24
- ¹⁵ El-Said Abdel-Hady, Mohamed Emam, Alaa Al-Gohary, Mostafa Hassan, Mohamed K Farag, Mohamed Abo-Elkheir. Screening for cervical carcinoma using visual inspection with acetic acid. *Int J Gynaecol Obstet.* 2006 May; 93(2):118-22.
- ¹⁶ Bradley, P. (2006). The history of simulation in medical education and possible future directions. *Medical education*, 40(3), 254-262.
- ¹⁷ Maran, N. J., and R. J. Glavin. "Low-to high-fidelity simulation—a continuum of medical education?." *Medical education* 37.s1 (2003): 22-28.
- ¹⁸ Pringle, K., Mackey, J. M., Modi, P., Janeway, H., Romero, T., Meynard, F., ... & Ruskis, J. (2015). A short trauma course for physicians in a resource-limited setting: is low-cost simulation effective?. *Injury*.
- ¹⁹ Hamstra, S. J., Brydges, R., Hatala, R., Zendejas, B., & Cook, D. A. (2014). Reconsidering fidelity in simulation-based training. *Academic Medicine*, 89(3), 387-392.

-
- ²⁰ Andreatta, P., Gans-Larty, F., Debpuur, D., Ofosu, A., & Perosky, J. (2011). Evaluation of simulation-based training on the ability of birth attendants to correctly perform bimanual compression as obstetric first aid. *International journal of nursing studies*, 48(10), 1275-1280.
- ²¹ Perosky, J., Richter, R., Rybak, O., Gans-Larty, F., Mensah, M. A., Danquah, A., ... & Marzano, D. (2011). A low-cost simulator for learning to manage postpartum hemorrhage in rural Africa. *Simulation in Healthcare*, 6(1), 42-47.
- ²² Steven A. McLaughlin, David Doezema, and David P. Sklar. "Human simulation in emergency medicine training: a model curriculum." *Academic Emergency Medicine* 9.11 (2002): 1310-1318.
- ²³ "Flash Card Set - IARC Screening Group." 2013. 20 Sep. 2013
<http://screening.iarc.fr/doc/cecip_flashcards.pdf>
- ²⁴ Paul D. Blumenthal and H. Sanghvi. "Atlas for Unaided Visual Inspection of the Cervix." *Baltimore, Maryland and Harare, Zimbabwe: JHPIEGO Corporation and University of Zimbabwe Medical School (1997)*.
- ²⁵ Sellors, J. W., Jeronimo, J., Sankaranarayanan, R., Wright, T. C., Howard, M., & Blumenthal, P. D. (2002). Assessment of the Cervix After Acetic Acid Wash: Inter-Rater Agreement Using Photographs. *Obstetrics & Gynecology*, 99(4), 635-640.
- ²⁶ "Forty Greatest Hits: Revolutionizing Training of Health Providers..." 20 May 2016
<<https://www.jhpiego.org/success-story/40-greatest-hits-revolutionizing-training-of-health-providers/>>
- ²⁷ Sienko, K. H., Effah Kaufmann, E., Musaaazi, M., Sabet Sarvestani, A., & Obed, S. (2014). Obstetrics-based clinical immersion of a multinational team of biomedical engineering students in Ghana. *International Journal of Obstetrics and Gynecology*, 127(2), 218-220.
- ²⁸ Salvador, T., Bell, G., & Anderson, K. (1999). Design ethnography. *Design Management Journal (Former Series)*, 10(4), 35-41.
- ²⁹ Anderson, F., Johnson, T. (2008). U-M Medicine: Long-term Partnerships in Ghana. *The Journal of the International Institute*, 15(2):11.
- ³⁰ "Ghana school names library after U-M Obgyn chair for devotion to global maternal health." 16.June.20013
<<https://medicine.umich.edu/medschool/about/news/ghana-school-names-library-after-u-m-obgyn-chair-devotion-global-maternal-health>>
- ³¹ William, M., Kuffour, G., Ekuadzi, E., Yeboah, M., ElDuah, M., & Tuffour, P. (2014). "Assessment of psychological barriers to cervical cancer screening among women in Kumasi, Ghana using a mixed methods approach." *African Health Sciences*, 13(4), 1054-1061.
- ³² R.M.K. Adanu. "Cervical cancer knowledge and screening in Accra." *Ghana Journal of Women's Health and Gender-Based Medicine* 11, no. 6 (2002): 487-488.
- ³³ "Eva Pelvic Exam Model with Case - Armstrong Medical Industries." 2008. 20 Sep. 2013
<<https://www.armstrongmedical.com/index.cfm/go/product.detail/sec/2/ssec/11/cat/42/fam/1964>>
- ³⁴ Henry Gray, *Anatomy of the Human Body* (1918), accessed 20 Sept. 2013, <<http://www.bartleby.com/107/>>
- ³⁵ Irene Chen "A Biomechanical Properties Overview of Skin and Muscle Tissue" 20 Sep. 2013
<http://www.meyersgroup.ucsd.edu/literature_reviews/2010/Literature%20Review_Chen.pdf>
- ³⁶ Sung Gu Kang et al. "A Study on the Learning Curve of the Robotic Virtual Reality Simulator." *Journal of Laparoendoscopic & Advanced Surgical Techniques* 22.5 (2012): 438-442.
- ³⁷ Alex Osborn, *Applied imagination: Principles and procedures of creative problem solving (Third Revised Edition)* (New York, NY: Charles Scribner's Sons, 1963).
- ³⁸ Arthur B. VanGundy, *Techniques of structured problem solving. (2nd ed.)* (New York: Van Nostrand Reinhold, 1988).

- ³⁹ Darren W. Dahl and Page Moreau. "The influence and value of analogical thinking during new product ideation." *Journal of Marketing Research*, 39(1) (2002): 47-60.
- ⁴⁰ "Design Heuristics: Strategies to Inspire Ideas." 2014. *Design Heuristics, LLC*. 11 Sep. 2014
<<http://www.designheuristics.com> >
- ⁴¹ Manikandan Mohan, Ying Chen, and Jami J. Shah. "Towards a framework for holistic ideation in conceptual design." In *ASME 2011 International Design Engineering Technical Conferences and Computers and Information in Engineering Conference*, (2011):661-672.
- ⁴² "Overview of Medical Device and their Regulatory Pathways." 2014. 18 Aug. 2014.
<<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm203018.htm> >