CLINICAL ARTICLE

Design and evaluation of a subcutaneous contraceptive implant training simulator

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Keywords

Community health nurses; Contraceptive implant; Family planning; Ghana; Implanon; Nexplanon; Novice; Simulation

Synopsis:

Novices trained with the implant insertion simulator were able to perform error-free simulated insertions more accurately and quickly compared with the current mode of training.

ABSTRACT

Objective: To design and fabricate a subcutaneous contraceptive implant insertion simulator, and to characterize the performance of nursing students trained with and without the simulator.

Method: A cross-sectional study was conducted on nursing students in Ghana who had no previous training in the insertion of contraceptive implants. They were given standardized training in insertion of implants from 25 April to 26 April, 2016, and then randomly assigned to an intervention or control group. The control group watched insertions of live implants while the intervention group practiced using the simulator. Local materials were used to fabricate the simulator. The performance of both groups was assessed after the training.

Results: The participants consisted of 50 nursing students. Those in the intervention group were more likely to: insert the implant accurately (95.2% vs 78.4%, $P<0.001$); take less time to complete an insertion (mean of 33.6 seconds vs 42.2 seconds, $P<0.001$); and commit fewer errors (1.9 vs 2.5, $P=0.005$) compared to the control group. In addition, participants rated the simulator high on 11/11 of the product requirements with the teaching (93.2%), learning (91.4%), and skill acquisition (88.6%) requirements being the highest rated.

Conclusion: A low-cost, locally fabricated simulator is an effective tool for augmenting the current training protocol by improving insertion skills of contraceptive implants.

1 INTRODUCTION

In Ghana, there is an unmet demand for family-planning services. In the 2014 Ghana Demographic and Health Survey, 29.9% of married women had unmet needs for family planning services. In addition, only 26.7% of currently married women used contraception: 22.2% used modern methods, with the three most popular modern methods being injectables (8.0%), implants (5.2%), and pill (4.7%) [1]. Contraceptive implants are a very effective, long-acting, reversible family-planning method with the potential to contribute to the family-planning needs of most women [2]. They prevent pregnancy for up to 3–5 years after administration with no regular action by the user and no routine clinical follow-up required [3,4]. Implants are reported to have high rates of continuation and client satisfaction among users in recent years [5,6]. Contraceptive implants offer promising opportunities for addressing the high and growing unmet need for modern contraceptives in sub-Saharan Africa [5]. Currently, three main types of implants (Jadelle, Sino-implant, and Implanon/Nexplanon) are being used in Ghana. Jadelle and Sino-implant are composed of two thin, flexible rods, each containing 75 mg levonorgestrel and are currently labeled for five years of use. Implanon, and its latest version Nexplanon, is a single-rod, hormonal implant that contains etonogestrel and is labeled for three years of use [7].

A key factor contributing to the low usage of modern methods, particularly implants, is a shortage of trained staff, particularly those skilled in providing contraceptive insertion services [8-10]. Insertion of implants requires skilled staff; if not properly inserted, implants can cause pain, vary in their effectiveness, and lead to difficult removal frequently requiring surgical interventions with the possibility of additional complications [11]. A recent WHO review of the evidence on the safety of the insertion and removal of implants concluded that auxiliary nurses could deliver implant services with targeted monitoring and evaluation [12]. Some studies have also shown that community health nurses (CHNs) can indeed administer contraceptive implants, suggesting that if more CHNs are trained to provide contraceptive implant services, coupled with the creation of demand, the use of implants may increase [8,13].

However, training CHNs remains a major challenge in Ghana as the current mode of training is primarily conducted through lectures, videos, and observations of clinical experts performing insertion of implants. This approach lacks the opportunity for trainees to gain proficiency through practice. We hypothesized that a simulator-based training curriculum, when compared to video-based exposure to methods of insertion, would improve insertion skills in novices and improve confidence of providers.

The aim of the present study was to develop and assess a subcutaneous contraceptive implant insertion simulator for training healthcare workers to appropriately insert contraceptive implants. The results of this research are expected to contribute to increased access to long-term contraceptive products/services for women through improved training of healthcare workers.

2 MATERIALS AND METHODS

The project was a cross-sectional study and was divided into three phases: design; development; and evaluation of the simulator.

In the design phase, physicians, nurses, midwives, and engineers from the University of Michigan and University of Ghana were consulted to develop the product requirements and engineering specifications for the simulator between December 2014 and January 2015. Healthcare personnel provided critical information, including a detailed understanding of the procedural steps required for performing proper insertion of contraceptive implants, and identified the key anatomical features required to properly simulate the procedure. The product requirements (Table 1) were defined and prioritized based on the input from these professionals as well as from the literature [14]. After determining the requirements, functional decomposition was performed and design concepts were generated [15].

The concepts were assessed based on their ability to satisfy the product requirements, and three distinct concepts were selected for further assessment. Ethical approval (exempt status) was obtained from the University of Michigan Institutional Review Board (IRB) in February 2015 to solicit feedback from clinical experts to inform iterations to the design of the final simulator.

Forty-one clinical experts from the Korle Bu Teaching Hospital in Accra, Ghana assessed mock-ups of the three selected concepts for their suitability in August 2015. Two of the concepts (17 and 16 clinicians ranked them the highest, respectively) were preferred over the third concept. Based on the results of the initial assessment, the prototype with the highest score (subsequently referred to as the simulator) was fabricated (Fig. 1) using materials that were locally produced in Ghana (PVC pipe, latex foam, cotton, and leather) and was used for formal evaluation to enable the trainee to learn the entire process of implant insertion. The process is briefly described as follows: the "patient" is asked to lie on her back with her arm resting on an arm support; the implant insertion package is opened; the insertion site is cleaned with antiseptic; the optimal insertion site is determined; local anesthetics are applied; the implant is then inserted.

The simulator included a semi-hollow, cylindrical, PVC base to mimic bone and a piece of cloth for firmly securing it to the arm of the patient (person to receive the implant) during testing or training, to enable the trainee to more accurately replicate typical interactions with the patient and practice the steps outlined above.
Figure 2 provides an illustration of the study design used to evaluate the simulator. Fifty community health nursing students in their second year of training, and with no previous training in the insertion of contraceptive implants, were selected from the CHNs training school in Winneba, in the Central Region of Ghana. The sample size was calculated based on the ability to detect a difference of 30.0% in the accuracy of insertion between the control and intervention groups at a power of 80.0%. The study was approved by the Ghana Health Service Ethics Review Committee and participants gave written

informed consent before the training. Participants were trained in the processes and steps of Implanon insertion using the current method of training, including lectures and standardized training videos. After the training, participants were randomly assigned to an intervention or control group equally. Participants were assigned serial numbers from 1 to 50 and the Microsoft Excel RANDBETWEEN function was used to generate 25 random numbers between 1 and 50 to form the intervention group, with the balance of the participants forming the control group. The control group observed actual insertions of implants in the clinical setting (six insertions) performed by midwives (standard method currently in use) while the intervention group practiced insertions of Implanon using the simulator (five insertions each), without watching the midwives perform actual insertions. The accuracy and duration of each insertion were measured. The accuracy of the insertion was assessed by two midwives via visual inspection using the scale in Table 2. Insertion underneath the skin or within the fat layer (code 2 or 3) were considered accurate. Time to complete the insertion was measured in seconds from start to finish using a stopwatch. The performance of both groups was then assessed after the training using the MERCK model of Implanon insertion training [16]. The accuracy of insertion, duration of insertion, and number of errors committed were assessed for each insertion.

After the training and the performance assessment were completed, all participants and 23 clinical experts with knowledge and experience of inserting contraceptive implants tested and evaluated the simulator on 11 key requirements: (1) anatomic fidelity; (2) procedural fidelity; (3) ability to allow the user to gain proficiency; (4) provision of feedback to the user; (5) ease of use (setup); (6) ability to facilitate acquisition of insertion skills; (7) usefulness in teaching implant insertion; (8) usefulness in learning implant insertion; (9) enhancement of confidence of the trainee; (10) provision of realistic practice opportunities; and (11) ease of insertion of implants. They scored each requirement using a Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). In addition, they provided comments about the simulator and responses to several open-ended questions focused on first impressions, specific training problems the simulator would address, comparison with other methods of training to insert implants, and the main advantages of the simulator. Thematic coding was used to analyze the open-ended questions (Table 5). Stata MP Version 13 was used to analyze the quantitative data. χ^2 analysis was used to test the association between the groups and the ratings of the various requirements of the simulator, while a t-test was used to test the performance between the intervention and control groups at a significance level of 95%.

3 RESULTS

Table 3 shows the performance of the participants after the assessment. Overall, the number of accurate insertions by all participants was 217 (86.8%), while the mean time taken to complete an insertion was 37.9 seconds and the mean number of errors committed was 2.20. There were significant associations between the groups and the accuracy, duration of insertion, and number of errors committed. The participants in the intervention group were more likely to: insert the implant accurately (119 [95.2%] of all the insertions by the intervention group were accurate compared to 98 [78.4%] for the control group, $P<0.001$); take less time to complete an insertion (mean time of 33.6 seconds for intervention group compared to 42.2 seconds for control group, $P<0.001$); and commit fewer errors (mean number of errors committed was 1.9 compared to 2.5 for the control group, $P=0.005$) (Table 3).

Fifty-four (75.0%) of the participants (20 [80.0%] in the intervention group, 17 [68.0%] in the control group, and 17 [77.0%] health professionals) agreed that the simulator was anatomically realistic. Additionally, more than 57 (80.0%) participants agreed that the simulator was useful for teaching, learning, and acquisition of skills (Fig. 3). Overall, the average rating of the simulator for the intervention group was 4.1 (out of a maximum of 5) compared to 4.3 for the control group and 4.2 for the health professionals. There were no significant differences in the ratings of the requirements of the simulator by participants with the exception of the requirement that the simulator should provide feedback to the user (mean rating of 4.3 for intervention and control groups, and 3.7 for health professionals, $P=0.038$) as shown in Table 4.

Regarding their first impressions about the simulator, several of the participants commented on its potential for enhancing practice and the realistic look and feel of the simulator (Table 5). The most prevalent themes raised included “looks and feels like human arm” and “enhances the practice of insertion.” The following comment from a participant illustrates this finding: “*It is designed just like the human arm so it makes practice easy*” (a nurse). There were a few critiques of the simulator as well; for example, a student said, “*My first impression of the simulator was that it is too soft and enhances insertion errors*.”

Most participants said the simulator would address the challenge of not having adequate practice before inserting implants in humans and would also address the anxiety that learners may face while performing real insertions. Comments from respondents that illustrate this finding include: “*the simulator would prevent any insertion injury, since one has been practicing with the simulator*” (a student); and “*help build the confidence of the health practitioner who do this insertion and prevent error in inserting the implant on a real human skin*” (a student).

When asked how this simulator compares to other methods of training to insert implants, most participants said that the simulator was very useful and provided a practical opportunity to trainees. They described the simulator-based learning as very useful and easy to use (e.g. “*Practicing with the simulator is more helpful than you watching a video or watching someone doing it for you to see*” [a student]).

On the main advantages provided by this simulator, most respondents said it improves insertion skills, makes practice of insertion easier, and enhances confidence. A student respondent stated, “*It gives you the chance to do the inserting even without a human being. It is more or less like a human body so if you are able to do correct insertion on it, then you can do likewise on the human being*”.

Participants recommended that the simulator should be used in the training schools: “*It should be made and used in the training schools to enable students to practice and* *know how to insert implants … It should be done such that every student can own one*" (a nurse).

4 DISCUSSION

This study sought to design, develop, and assess a low-cost, high-fidelity simulator made from local materials for the training of nursing students, and other health professionals, on the insertion of contraceptive implants. The results show that the participants trained with the simulator were more likely to insert the implant accurately, take less time to complete an insertion, and commit fewer errors compared to those trained without the simulator. In addition, participants rated the simulator high on all of the product requirements.

The results of the assessment of the participants' performance show that the intervention group performed better in all areas (accuracy of insertion, duration of insertion, and number of errors committed), suggesting that the simulator would be a useful tool for training nursing students and other healthcare workers in performing insertion of implants. Similar results from simulators developed for learning to manage postpartum hemorrhage [14], surgical training [17], and breast examination [18] have also shown positive effects. Simulation-based learning, a method where an environment similar to the real context is created for the trainee to learn the skills required, enables learners to practice extensively and gain experience in a safe, non-threatening environment and has been shown to yield positive results [19,20].

The high rating of the simulator by health professionals and students also provides evidence to support the use of this simulator for training healthcare workers on the insertion of contraceptive implants. The findings in this study mirror similar ratings assigned to other low-cost simulators developed with local materials [14]. Consistent with results from similar work carried out in Ghana [14], the healthcare professionals with experience in the insertion of implants and the nursing students found the simulator to be realistic and particularly useful for teaching, learning, and the acquisition of skills. In contrast, the current mode of training does not provide students with the opportunity to practice before they undertake insertion of implants in the field. Tools for practicing such insertions are not readily available, particularly for nursing students in training; thus, they only learn through lectures and training videos, and from observing clinical experts when they are working at health facilities. Opportunities for students to practice before performing the insertion of implants on humans are mostly non-existent. This simulator therefore provides the opportunity for students to gain enough practice not only in the act of insertion but also the entire process of inserting implants. It may also boost the confidence of trainees and reduce any anxiety that they may have in the process of inserting implants. This simulator adds to the growing body of evidence that simulator-based training has the potential to help healthcare workers acquire the skills needed to perform various activities [11,19,21,22].

One limitation of this study is that the intervention group was not asked to also observe actual insertions of implants in the clinical setting (a component of the current standard training procedure) before practicing with the simulator. It is possible that the inclusion of that additional training component may have further improved the performance of the intervention group.

Author contributions

SKKD developed the concept for the study and was responsible for the study design, analysis and writing of the manuscript. EEK was responsible for the study design and revision of the manuscript. DM was responsible for the study design and revision of the manuscript. MD was responsible for the study design and revision of the manuscript. CKA was responsible for the literature review and revision of the manuscript. KHS developed the concept for the study and was responsible for the study design and revision of the manuscript. All authors approved the final version of the manuscript.

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Conflicts of interest

The authors have no conflicts of interest.

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Figure legends

Figure 1. Sample of the simulator.

Figure 2. Study design.

Figure 3. Overall rating of the simulator.

Table 1. Product requirements.

Priority	Product requirements
1	Be anatomically correct
2	Allow user to gain proficiency of insertion process
3	Provide user and trainer with knowledge of results
4	Be safe
5	Be producible in resource-limited setting
6	Be easy to use by both trainer and trainee
7	Be low cost
8	Be reusable
9	Allow simulation of insertion of major implants used in Ghana
10	Be portable
11	Allow user to gain proficiency with implant removal procedures

Table 2. Accuracy of insertion scale.

Code	Type of insertion
0	False/no insertion
1	Insertion within the skin
2	Insertion underneath the skin and partially in the fat layer
3	Insertion in the fat layer
4	Insertion in the muscle layer

Table 3. Performance assessment scores.

	Intervention group	**Control group**	**All groups**	***P* value**
Accuracy of insertion, n (%)	119 (95.2)	98 (78.4)	217 (86.8)	<0.001
Insertion time, $\bar{x}$ (SD)	33.62 (1.20)	42.24 (1.99)	37.93 (1.19)	<0.001
Number of errors committed, $\bar{x}$ (SD)	1.93 (0.11)	2.48 (0.16)	2.20 (0.10)	0.005

Table 4. Simulator ratings.

Requirement	**Intervention group (n=25)**	**Control group (n=25)**	**Health professionals (n=23)**	**All participants**	***P* value**
	$\bar{x}$ (SD)	**$\bar{x}$ (SD)**	**$\bar{x}$ (SD)**	**$\bar{x}$ (SD)**	
Anatomical fidelity	3.88 (0.13)	3.56 (0.16)	3.73 (0.18)	3.72 (0.09)	0.348
Procedural fidelity	3.88 (0.19)	4.08 (0.17)	4.08 (0.13)	4.00 (0.10)	0.673
Allow user to gain proficiency	4.12 (0.17)	4.24 (0.20)	3.95 (0.21)	4.11 (0.11)	0.588
Provide feedback to user	4.28 (0.19)	4.28 (0.09)	3.69 (0.23)	4.10 (0.11)	0.038[a]
Ease of use (setup)	4.08 (0.22)	4.32 (0.19)	4.26 (0.18)	4.22 (0.11)	0.662
Facilitate acquisition of insertion skills	4.12 (0.19)	4.38 (0.12)	4.10 (0.19)	4.20 (0.10)	0.430
Useful in teaching insertion of **implant**s	4.36 (0.19)	4.48 (0.12)	4.47 (0.12)	4.44 (0.08)	0.806
Useful in learning insertion of **implant**s	4.52 (0.14)	4.63 (0.12)	4.57 (0.15)	4.57 (0.08)	0.856

Enhancing confidence of the trainee	4.24 (0.20)	4.48 (0.12)	4.26 (0.21)	4.33 (0.10)	0.577
Provide realistic practice opportunities	4.04 (0.21)	4.24 (0.17)	4.30 (0.16)	4.19 (0.10)	0.571
Easy to insert implant	4.00 (0.19)	4.16 (0.15)	4.52 (0.15)	4.22 (0.10)	0.088
Average rating of simulator	4.14 (0.13)	4.26 (0.08)	4.22 (0.13)	4.20 (0.56)	

[a] significant

Table 5. Themes generated.

Category	**Themes**	**n (%)**
First impressions	Enhances practice	15 (20.3)
	Looks and feels like the natural human body	14 (18.9)
	Simulator will be very helpful	9 (12.2)
	Simulator does not look or feel real	5 (6.8)
	Difficult to penetrate with needle	3 (4.1)
Problems simulator would help address	Enhances practice and confidence and removes fear	22 (29.7)
	Helpful in teaching insertion	15 (20.3)
	Simulator not real enough	6 (8.1)
Comparison to other methods of training to insert implants	Allows for more practice	21 (28.4)
	Easy to use	20 (27.0)
	Enhances teaching / learning of insertion skills	16 (21.6)
	Simulator is better than other teaching methods	12 (16.2)
	Simulator looks and feels like human arm	9 (12.2)
Main advantages of the simulator	Enhances insertion skills training /teaching	37 (50.0)
	Simulator is easy to use	22 (29.7)
	Builds up confidence	16 (21.6)
	Allows for practice	12 (16.2)
General comments	Enhances teaching and learning of insertion	24 (32.4)
	Encourages constant practice and builds confidence	18 (24.3)
	Improves insertion skills	16 (21.6)
	Simulator needs more improvements	7 (9.5)

Figure 1. Sample of the simulator

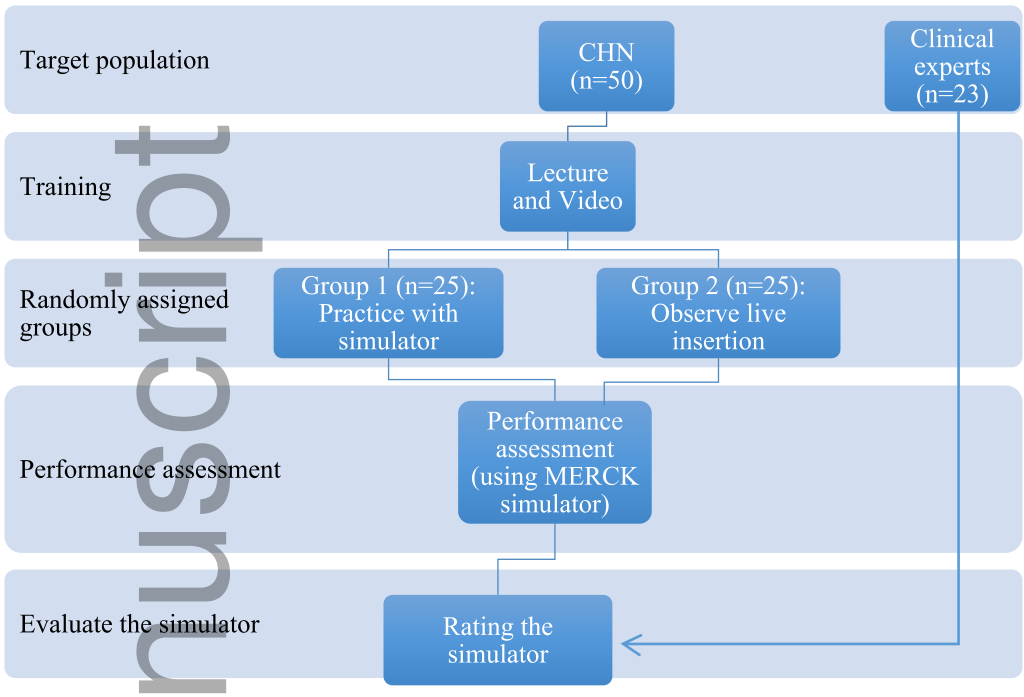

Figure 2. Study design

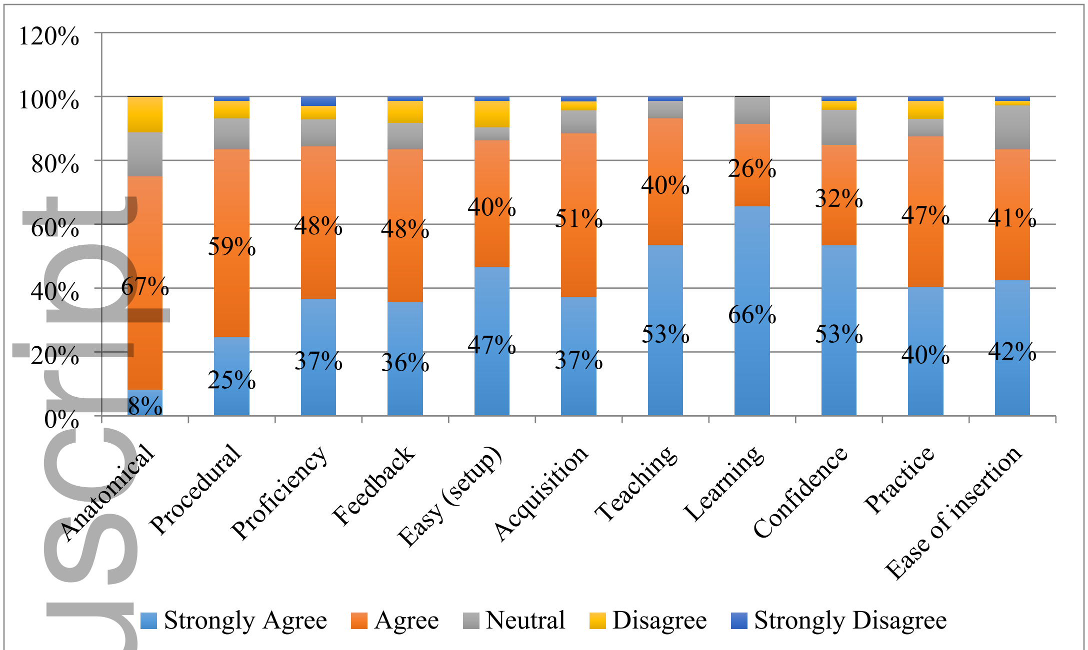

Figure 3. Overall rating of the simulator