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Assessing the Usability of a Task-Shifting Device for Inserting Subcutaneous Contraceptive Implants for Use in Low-Income Countries

Women in low- and middle-income countries (LMICs) have limited access to long-acting contraceptives. Access to long-acting contraceptives, such as subcutaneous contraceptive implants, could be increased by task-shifting implant administration from advanced to minimally trained healthcare providers. The objective of this study was to investigate the usability of a task-shifting device for administering subcutaneous contraceptive implants. Healthcare providers (n = 128) from multiple health centers in Ethiopia were trained to administer implants on an arm simulator with the traditional method and a method using the device. Participants were observed while inserting implants into the arm simulator, and procedural error rates were calculated. Observations were analyzed using an iterative inductive coding methodology. For the device-assisted method, minimally trained healthcare providers had larger procedural error rates than other professions (p = 0.002). For the traditional method, physicians had larger procedural error rates than nurses and midwives (p = 0.03). Several procedural errors were identified such as participants inserting and removing the trocar and plunger completely or inserting and/or removing the trocar too far or not enough. These findings reinforce the importance of performing formative usability testing during the early phases of a medical device design process, considering users' mental models, and avoiding assumptions about healthcare providers' abilities. [DOI: 10.1115/1.4046092]

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Introduction

Women, particularly in low- and middle-income countries (LMICs), have limited access to contraceptive options. Sedgh et al. [1] estimates that 225 million women worldwide have unmet contraceptive needs. Meeting these needs can enable women to achieve their fertility aspirations and also is an important step in attaining broader social and economic development goals, particularly in LMICs [1]. A key challenge to meeting these needs is the lack of advanced skilled healthcare providers in LMICs—particularly in rural, under-served settings—limiting access to long-acting contraceptive options, especially options that are dependent on advanced skilled healthcare providers for initiation and discontinuation [2]. Therefore, long-acting contraceptive options in these settings require an easy and safe administration method that can be performed by minimally trained skilled healthcare providers, such as community health workers also referred to as health-extension workers (HEWs) in Ethiopia. Additionally, international organizations and ministries of health aim to increase access to long-acting contraceptive options that have high efficacy, require minimal training, and safely space pregnancies [3–5]. These aims can be met by using subcutaneous contraceptive implants, which consist of one to two small polymer rods and provide contraceptive protection for three to five years [6]. These implants have several advantages including effectiveness, convenience, discreetness, and suitability for nearly all women and family planning intentions (e.g., spacing, limiting) [6].

Although access to implants is increasing, several barriers remain. Barriers include a lack of information, familial and societal opposition, cost, and a large proportion of women living in rural, under-served settings often far from healthcare facilities and providers in LMICs [7,8]. Seventy percent of populations in low-income countries, about 1.5 billion women, live in these settings [9]. Currently, implants must be administered by advanced skilled healthcare providers due to the risk of complications such as deep administrations, hematomas, and infections [10,11]. Additionally, women often need to travel to healthcare centers with more advanced skilled healthcare providers to have deep administrations removed. This need for advanced skilled healthcare providers frequently prevents HEWs, who are often the most accessible healthcare providers in these settings, from administering implants; currently, the World Health Organization (WHO) recommends that HEWs only provide implants in the context of research or with additional training. Additional research and training to improve the ease of use and safety of administering implants could improve access [12].

Improving the ease of use and safety of administering implants can support the shift of the task to minimally trained skilled healthcare providers. Task-shifting is defined as "the allocation of tasks in health-system delivery to the least costly health worker capable of doing the task reliably" [13]. Task-shifting can increase access to long-acting contraceptive options. Several examples show task-shifting being used to improve access to health services—in Ghana, diagnosis and treatment of common disorders have been task-shifted from physicians to medical assistants; in Bangladesh and Thailand, tubal ligation has been task-shifted from physicians to nurses; and in Uganda, contraceptive injections have been task-shifted from nurses to community health workers [13,14]. Task-shifting has several advantages including increasing access to health services; alleviating workforce shortages; increasing the available time of advanced skilled healthcare providers to administer other services; standardizing the quality of health services across providers with varying skills; and increasing productivity [2,14]. Task-shifting devices aim to facilitate task-shifting by improving quality and consistency and reducing training requirements. This study approaches the challenge of increasing access to implants from a medical device-development perspective—developing a task-shifting device that enables task-shifting implant administration to HEWs by improving the accuracy of administrations.

Stakeholders including medical doctors, nurse-midwives, biomedical engineers and technicians, public-health staff, and others rank ease of use and safety of use as the most important characteristics to consider in task-shifting devices [15]. Therefore, the usability of the task-shifting device must be thoroughly evaluated through human-factors engineering, a field that focuses on "the application of knowledge about human capabilities…and limitations in the design and development of…devices" [16]. Usability testing, an important method of human factors engineering, is used to reveal issues that can affect safety and efficacy by conducting tests with end users [16]. Several examples show that usability testing reveals errors in the use of medical devices—a control knob for oxygen, which changes flow rates discretely but rotates continuously, causing a patient to become hypoxic; defibrillators, which have poor paddle placement and poorly labeled controls, inhibiting safe use; and infusion pumps, which have obstructed displays, delivering incorrect amounts of medication [17]. Several examples also show that usability testing improves safety and efficacy, specifically in glucometers, infusion pumps, and telemedicine systems [18–20]. The objective of this study was to investigate usability issues and insights for a task-shifting device for subcutaneous contraceptive implants to improve its safety, efficacy, and implementation.

Methods

After a needs assessment was conducted at St. Paul's Hospital in Ethiopia in 2013, the need for a task-shifting device to assist healthcare providers with the administration of contraceptive implants was identified. A task-shifting device was developed to address this need, and, since 2013, several iterations of design and testing were completed [21].

The device consisted of a single body of plastic with a clip (A) on the top to attach the device to a sphygmomanometer, an insertion site (B) at the front to accurately position the trocar (C) at the desired depth, and a cavity (E) on the bottom to control the displacement of tissue (Fig. 1). The device acted like a template, guiding healthcare providers in administering implants accurately [21]. The current version of the device can only be used once. However, a reusable version could be designed to support autoclaving or chemical sterilization between uses.

To use the device, a healthcare provider clipped the device to a sphygmomanometer, wrapped the sphygmomanometer around a patient's arm, and inflated it to 50 mmHg, causing the patient's tissue to rise into the cavity of the device. Then, the healthcare provider inserted a trocar, containing the implant, into the insertion site, administering the implant at an accurate depth (Fig. 2).

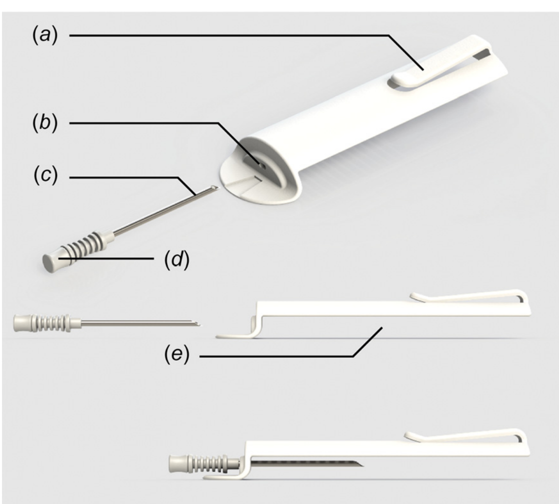

Fig. 1 The task-shifting device developed to assist healthcare providers with the administration of implants: (*a*) clip, (*b*) insertion site, (*c*) trocar, (*d*) plunger, and (*e*) cavity

If a healthcare provider administered a two-rod implant, then a version of the device with a "V"-shaped insertion site was used. The "V"-shaped insertion site enabled the healthcare provider to insert the trocar twice and administer two rods, one on each side of the "V."

This study was reviewed and determined to qualify for exempt status by the University of Michigan and the University of Gondar institutional review boards. Participants were recruited in person from the University of Gondar Hospital in Gondar, Ethiopia and St. Paul's Hospital and its surrounding clinics in Addis Ababa, Ethiopia. Participants provided verbal informed consent, completed a demographic questionnaire, and were compensated 100 birr (US$4.25) for their participation.

Participant ($n = 128$) demographics were gathered and are shown in Table 1. Based on the data about participants' number of years of implant experience, HEWs and students were considered minimally trained participants, and nurses, midwives, and physicians were considered skilled participants.

Participants were trained to administer Jadelle® (Bayer AG, Leverkusen, Germany), an implant, with the existing method (i.e., traditional method) and a method using the task-shifting device (i.e., device-assisted method) on an arm simulator. The traditional method is shown in an FDA document [11]. The device-assisted method is shown in Fig. 2. Both methods used a Jadelle® trocar to administer simulated Jadelle® implants. Therefore, for each administration, two implants were inserted. A diagram of the arm simulator is shown in Fig. 3.

After being trained on one method, participants completed a minimum of three administrations, completing more administrations using the same method if time permitted (3.98 ± 1.26 administrations, ±SD). Participants then completed a similar protocol using the other method. For each administration, several procedural steps were given a pass criterion, and whether the participant passed or failed each step was recorded. For each administration, researchers recorded qualitative observations in notebooks or spreadsheets.

Analysis

Analysis included both quantitative and qualitative methods. Quantitative analysis enabled comparisons of error rates. Qualitative analysis enabled identification of emergent themes that could not have been predicted prior to analysis [22,23].

The quantitative analysis included assessing procedural error rate, which was calculated as the percent of procedural steps that a participant performed incorrectly as shown in Eq. (1). These errors were aggregated for each end-user group. Each procedural step was also identified as a binary or nonbinary step. Binary steps included steps that had primarily two outcomes. For example, "kept plunger still when removing trocar" was a binary step because the participant either did or did not keep the plunger still. Nonbinary steps included steps that had a range of outcomes. For example, "inserted trocar to the correct position" was a nonbinary step because the participant could insert the trocar over a range of distances. Two-sample t-tests were performed and significance was defined by p-values less than 0.05.

$$\text{procedural error rate} = \frac{\#\text{ of steps performed incorrectly}}{\#\text{ of steps}} \tag{1}$$

All qualitative observations were de-identified and split into analytical units so that each unit represented a distinct observation. In total, 1867 observations were identified for analysis. Observations were analyzed using an iterative, inductive coding methodology following guidelines established for thematic analysis of open-ended data [24]. Observations were read and grouped based upon similar emergent themes; continuous comparisons among the observations were performed to identify the similarities

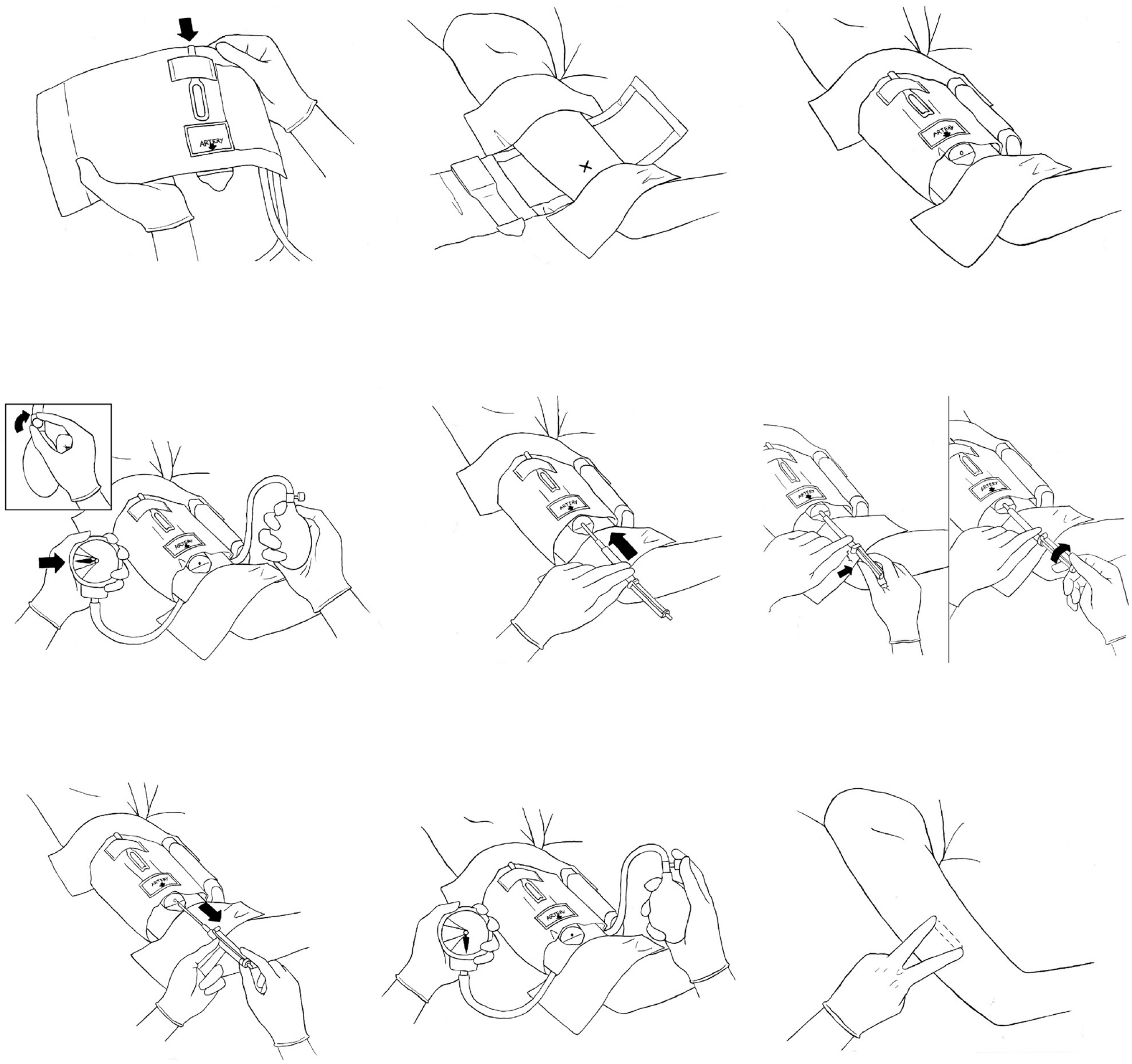

Fig. 2 The process to use the device: (1) Clip the device to the sphygmomanometer with clip aligned with the artery arrow. (2) Wrap the sphygmomanometer snugly around the arm, placing the device on top of the identified insertion site. (3) Twist the sphygmomanometer valve knob completely clockwise. Use the bulb to inflate the sphygmomanometer to the specific pressure. (4) Use the applicator to insert the needle into the insertion site and apply force to pierce through the skin until the needle is fully inserted into the site. (5) Break the seal of applicator by pressing the obturator support. Turn the obturator 90 deg in either direction. (6) While holding the obturator fixed in place, fully retract the cannula. (7) Deflate the sphygmomanometer by twisting the valve knob completely counterclockwise. Remove the cuff and the device. (8) Verify that the implant is in the skin.

Table 1 Participant demographics including participants' genders, professions, and years of contraceptive implant experience

	n	Male	Female	Contraceptive implant experience (Yr ± SD)
All	128	37	91	0.89 ± 2.09
Profession				
HEWs	54			0.17 ± 0.60
Medical students	19			0.01 ± 0.03
Nurses or midwives	38			1.86 ± 2.81
Physicians	12			2.58 ± 3.31

and differences [25–27]. The process was repeated until themes ceased to change. This led to the identification of 38 themes.

Results

The average procedural error rates for participants using the device-assisted and traditional methods are shown in Figs. 4 and 5, respectively. Generally, procedural error rates for the device-assisted method were greater than with the traditional method ($p = 0.0002$). The additional results presented below focus on comparisons among professions and steps for each method as comparisons between methods were confounded by variables such as previous duration and degree of exposure to the traditional method.

For the device-assisted method, HEWs had larger procedural error rates than other professions ($p = 0.002$, HEWs compared to

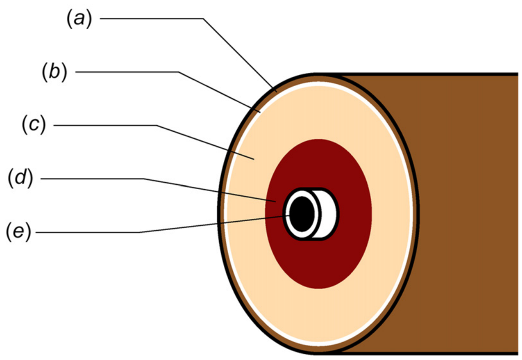

Fig. 3 The arm simulator: (*a*) epidermis and dermis tissue, Ecoflex® (Smooth-On, Inc., Macungie, PA) silicone (thickness = 1.5 mm); (*b*) connective tissue, cotton; (*c*) subcutaneous tissue, Ecoflex® silicone and Slacker® (thickness = 10 mm); (*d*) muscle tissue, Ecoflex® silicone (thickness = 30 mm); and (*e*) bone, polyvinyl chloride

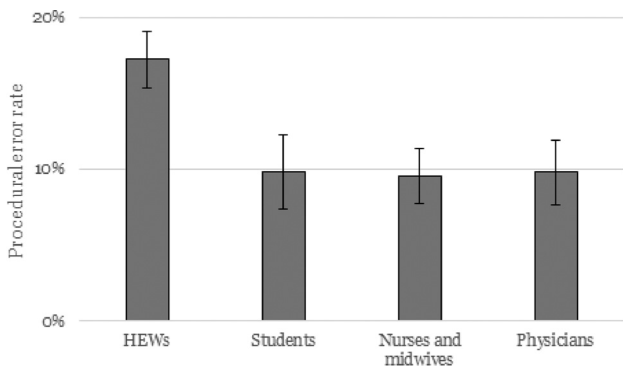

Fig. 4 Average procedural error rates for participants using the device-assisted method

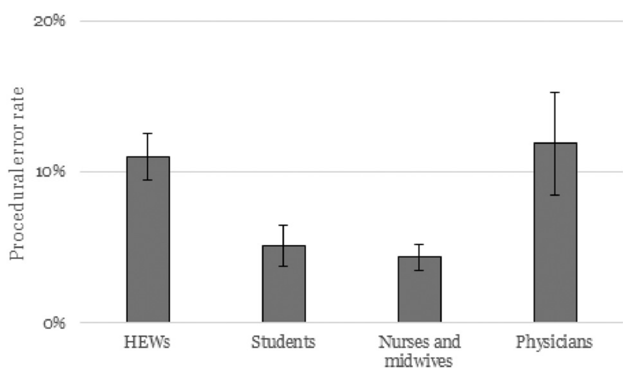

Fig. 5 Average procedural error rates for participants using the traditional method

nurses and midwives). For the traditional method, physicians had larger procedural error rates than nurses and midwives ($p = 0.03$).

Average procedural error rates for HEWs and nurses and midwives by step are shown in Fig. 6 (binary steps are labeled). Generally, nonbinary steps had larger procedural error rates than binary steps.

Table 2 shows the frequencies of the thematic groups developed from observations for the device-assisted and traditional methods. Thematic groups 1 and 6 represent the most frequently observed behaviors for the traditional and device-assisted methods, respectively. Thematic groups 2–6 had large differences between the device-assisted and traditional methods.

Discussion

This study revealed key insights into the design of, training for, and implementation of a task-shifting device for subcutaneous contraceptive implants. Specifically, this study revealed opportunities for the task-shifting device to facilitate task-shifting and considerations for designing and implementing the task-shifting device.

Often, nonbinary steps were more error prone than binary steps. For example, the nonbinary step, during which users were instructed to insert and remove the trocar a specific distance (thematic groups 1 and 6), was more error prone than the binary step, during which users were instructed to switch sides between the first and second implant to form a "V" shape (thematic group 8). Studies of other medical devices showed similar results and identified the importance of avoiding nonbinary steps [18,19]. These findings suggest that nonbinary steps require more attention during training or should be avoided altogether when designing task-shifting devices. A task-shifting device used for nonsurgical circumcision in adult males leverages binary steps, presumably to simplify its operation and minimize use errors [28].

Frequently, participants modified nonbinary steps; these modifications were often informed by prior experiences. For example, participants inserted the trocar completely (thematic group 1)—an action that was more analogous to common procedures, such as injections—instead of inserting the trocar to specific distances. This finding suggests that task-shifting devices may improve existing procedures if modifications are made to address challenges associated with the execution of nonbinary steps. For example, a nonbinary step associated with the existing traditional method is the production of a "V" shape between implants with a 30 deg angle (thematic group 8). The device was designed with a "V"-shaped insertion site, enabling users to accurately create a 30 deg "V" shape, reducing the number of errors associated with the "V" shape (thematic group 8).

Although task-shifting devices could reduce errors in nonbinary steps, the consequences of such designs should be fully explored. From the previous example, the small diameter of the insertion site improved "V"-shape accuracy because it constrained the side-to-side movement of the trocar. However, the small diameter had the unintended consequence of increasing the difficulty of insertion and removal because the small diameter negatively affected the insertion and removal of the trocar, and subsequently the placement of the implantation.

Similarly, assumptions about users' previous experience should not be made. For example, users were assumed to have experience using sphygmomanometers. However, in reality, participants often did not have experience with sphygmomanometers. Consequently, the use of the sphygmomanometer with the device increased the number of new steps, thereby increasing the difficulty of learning the device-assisted method. Research in healthcare information devices, medical devices, and home healthcare identified similar challenges when users' experiences were assumed [18–20,29,30]. Assumptions, particularly about previous experience, should be validated before being used to inform the design of task-shifting devices.

The increased number of steps in the device-assisted method could explain the frequency of certain errors. The high number of steps caused errors such as forgetting procedural steps (thematic group 2), repeating steps too many or too few times (thematic group 7), and inaccurately completing procedural steps in general (Fig. 2). Studies of other medical devices emphasized the importance of minimizing the number of steps [18–20]. Future design changes and training protocols focused on the incorporation of feedback could potentially mitigate these errors. For example, the most frequently forgotten procedural step was inflating the cuff. The lack of feedback during the performance of this procedural step may have contributed to this use error. Designing a feedback system, such as an auditory click, or training an additional step, such as squeezing the cuff to check for inflation, could potentially

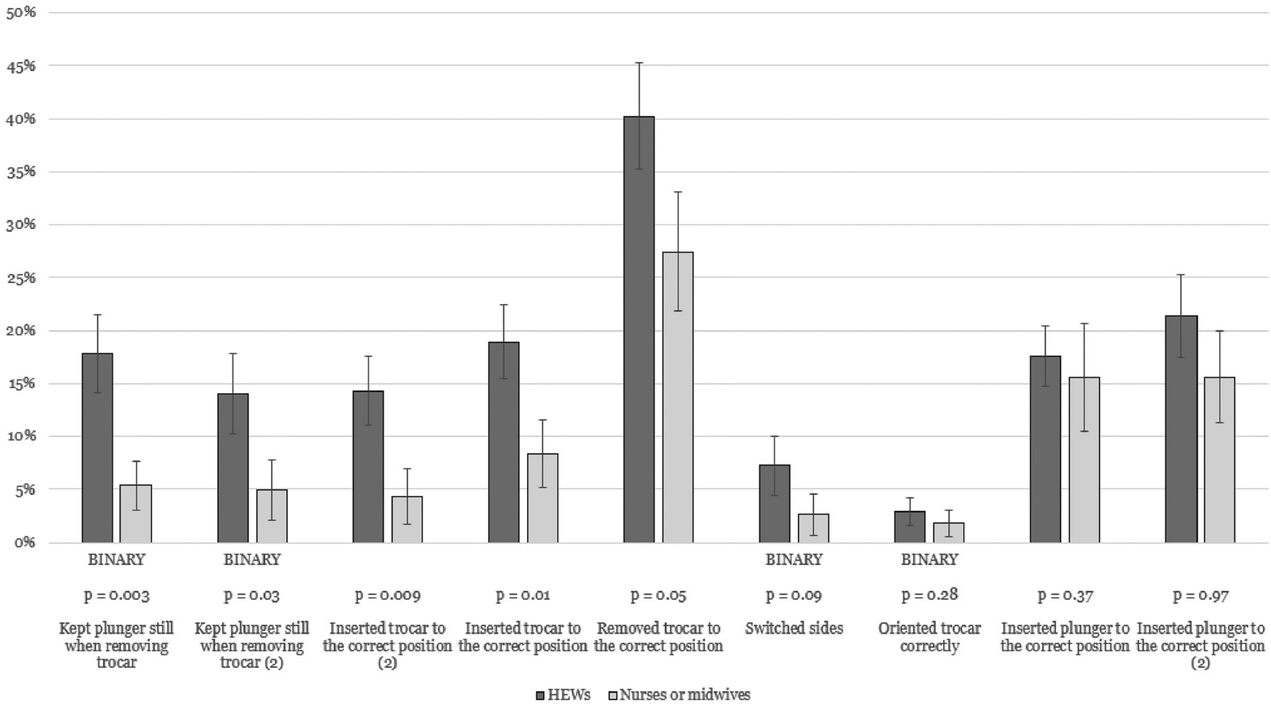

Fig. 6 Average procedural error rates for HEWs and nurses and midwives by step for the device-assisted method. (2) Indicates that the step was performed for the second implant. Steps are sorted by the differences in procedural error rates between HEWs and nurses/midwives; differences in procedural error rates decrease from left to right.

Table 2 Frequencies of thematic groups for the device and traditional methods

#	Description	Frequency of observations: Device	Frequency of observations: Traditional
Device-assisted and traditional methods			
1	Participants inserted and removed the trocar and plunger completely instead of to specific marks.	130	127
2	Participants forgot and skipped steps during the procedure. Participants most commonly forgot to inflate the sphygmomanometer.	77	6
3	Participants struggled to position their hands. Participants most commonly placed their hands on the sphygmomanometer, which could reduce its accuracy.	120	1
4	Participants struggled to keep the plunger still while removing the trocar.	32	65
5	Participants struggled to insert and remove the trocar smoothly because the insertion site was tight. Participants twisted and wiggled the trocar to compensate.	145	22
6	Participants inserted and removed the trocar too far, past the mark on the trocar, or not enough, before the mark on the trocar.	256	116
7	Participants completed steps too many or too few times.	31	16
8	For the device-assisted method, participants struggled to switch sides to create a "V" shape. For the traditional method, participants created "V" shapes of variable size.	30	34
Device-assisted method only			
9	Participants struggled to wrap and orient the sphygmomanometer.	45	n/a
10	Participants used existing traditional procedures instead of the device-assisted procedure.	44	n/a
Traditional method only			
11	Participants stretched the skin variable amounts before trocar insertion.	n/a	50
12	Participants tented the skin too much or not enough.	n/a	80

lessen the likelihood of these types of errors. Studies of other medical devices suggested that feedback was an effective method for improving usability [19,29,30].

Gaps in users' mental models may also have contributed to forgotten procedural steps. A mental model is a user's understanding of how something works [18]. Studies of other medical devices showed that gaps in mental models decrease usability [18,30]. During training, additional emphasis should be given to procedural steps that could represent a gap in users' mental models. For example, participants were instructed not to place their hand on the sphygmomanometer, as doing so could affect the accuracy of the sphygmomanometer. However, participants may not have understood how placing their hand on the sphygmomanometer could affect its accuracy (thematic group 3). This gap may have made placing a hand on the sphygmomanometer seems harmless, leading to error.

If training is used as an approach to reduce errors, such as errors resulting from nonbinary steps, a large number of procedural steps, and/or gaps in users' mental models, HEWs may require more training and practice than other types of healthcare providers. HEWs had a larger procedural error rate compared to other groups for the device-assisted and traditional methods. For the device-assisted method, nurses and midwives performed significantly better than HEWs on several steps: specifically, device-assisted method steps with equivalent traditional method steps, i.e., steps that nurses and midwives would theoretically have more experience performing. Students were expected to perform as well as HEWs, as both groups were minimally trained. However, students performed better than HEWs. The students in this study were medical students, who may have had more experience learning and executing new procedures, which may have contributed to this difference.

Furthermore, physicians' procedural error rates when using the traditional method were similar to HEWs' procedural error rates when using the device-assisted method. The physicians' high procedural error rates may have resulted from their infrequent a administration of implants. These higher procedural error rates were particularly noticeable for the traditional method, during which physicians inaccurately inserted the trocar (physicians had the least accurate insertions among all groups). This finding suggests that task-shifting devices may also improve the administration of implants for advanced skilled healthcare providers, as improved ease of use and safety could possibly reduce the need for frequent practice.

Several changes to the device have been made to address the usability challenges uncovered from this study. For example, the device was redesigned to enable users to insert the full length of the trocar to administer the implant instead of partially inserting the trocar to a specific position, eliminating one nonbinary step during administration. The diameter and smoothness of the insertion site was increased to improve the insertion and removal of the trocar. Visual guides on the front of the device were added, and a clear version of the device was created to improve both the feedback to the user and the user's mental model.

Limitations of the study include the investigation of a single task-shifting device coupled with a single task-shifting procedure involving participants from a single public healthcare system. Beyond the years of contraceptive implant experience, detailed information about the study population such as previous experience with sphygmomanometers was not collected. Additionally, this study was performed using a simulated human arm. Lastly, although the observation and interview protocols were standardized, differences in observation and interview styles of the researchers may have contributed to differences in results.

Conclusion

Task-shifting is increasingly being leveraged as a method for improving access to health services in under-served settings [31,32]. However, task-shifting the administration of long-acting reversible contraceptives such as implants remains limited due to challenges in training and implementation [32,33]. A task-shifting device could reduce these training and implementation barriers. However, for a task-shifting device to be successfully implemented, its ease of use and safety must be evaluated as these characteristics are ranked as most important among stakeholders [15].

Our findings reveal key insights into the design and implementation of task-shifting devices to improve ease of use and safety. Specifically, engineers and designers involved in the creation of task-shifting devices focused on improving access to health services in rural, under-served settings should consider designing devices that leverage binary steps and minimize the number of steps required for operation. Additionally, they should avoid assumptions about healthcare providers' prior knowledge. Implementers of task-shifting programs may also consider evaluating the use of task-shifting devices based on these criteria. Additionally, by focusing training on nonbinary steps and healthcare providers' mental models, implementers may improve the use of task-shifting devices in task-shifting programs.

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Nomenclature

HEW = health-extension worker
LMIC = low- and middle-income country
SD = standard deviation
p = probability value of a statistical test

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