## RESEARCH



# Nursing and midwifery simulation training with a newly developed low-cost high-fidelity placenta simulator: a collaboration between Italy and Ethiopia

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## Abstract

**Background** Simulation training provides safe environment for skill acquisition and retention. This study addresses a critical challenge in Africa – umbilical cord and placenta management after childbirth – aiming to bridge theoretical learning with practical experiences through simulation. We realized a new low-cost high-fidelity simulator of placenta and umbilical cord. We conducted a needs-based training course for nursing and midwifery students at St. Luke Hospital of Wolisso, Ethiopia, to validate our new simulator and compare its acceptability and teaching effectiveness with other two simulators (conventional low-fidelity model and human placenta).

**Methods** We surveyed St. Luke Hospital medical experts to obtain their feedback on the new simulator's face, content, and usability. We carried out a simulation training course for 67 students who received theoretical lectures and simulation courses being divided into three groups according to the simulator used. We assessed the simulators' user acceptability using the Technology Acceptance Model (TAM) and compared the final objective evaluations by tutors between groups.

**Results** Experts confirmed the new simulator's fidelity, material quality, and usability. Students training on the new simulator demonstrated higher objective scores and perceived it as more useful and user-friendly compared to human placenta, while there was no difference between conventional simulator and human placenta in the TAM items.

**Conclusion** We validated a new high-fidelity simulator developed by the Sant'Anna School of Advanced Studies in Pisa, Italy, using the TAM scale and robust statistical methods, thanks to a successful collaboration with St. Luke's Hospital in a simulation training course where students achieved higher objective scores and perceived the simulator

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as more useful and easier to use than a real human placenta, suggesting significant educational benefits and potential for future research.

Keywords Placenta, Umbilical cord, Simulation, Training, Midwifery, Nursing, Ethiopia

#### Introduction

Simulation training is a valuable tool in healthcare education, enabling safe skill acquisition, practice, and knowledge retention [1, 2]. Recent advances in African higher education have seen the successful implementation of physical simulation [3], boosting confidence and satisfaction among medical students [4, 5]. This study addresses a crucial aspect of healthcare, i.e. the management of the umbilical cord and placenta after childbirth.

Umbilical cord care and placenta management after childbirth are crucial for preventing infections, promoting healing, and ensuring the well-being of both the mother and newborn. Proper management reduces the risk of complications like hemorrhage and infection, which are significant causes of maternal and neonatal mortality. However, many healthcare providers, especially in low-resource settings, lack adequate training in these areas, leading to inconsistent practices and poor outcomes. Improved education and training are essential to standardize care, enhance safety, and reduce preventable deaths related to childbirth [6, 7].

Umbilical cord care and placenta management after childbirth are a matter of particular significance in the African context, especially due to a substantial lack of related education. Recent research confirmed the relevance of this issue, highlighting the prevalence of unsafe cord-care practices and low maternal knowledge of interventions such as chlorhexidine gel in Africa, which contribute to neonatal sepsis and mortality [8, 9].

Simulation training bridges classroom learning and real-world clinical experiences, offering benefits such as enhanced patient safety, error prevention, replicable case scenarios, increased confidence, and collaborative team training [10–12]. Simulation training in Africa offers valuable opportunities for improving healthcare skills and emergency response through realistic practice. It can adapt to various resource levels, from basic to advanced models. However, challenges include financial constraints, inadequate infrastructure, and a shortage of trained personnel. Effective implementation requires culturally relevant scenarios and integration with existing education systems. Despite these obstacles, simulation training holds promise for significantly enhancing healthcare education and worker preparedness across the continent [13].

In fact, while questions have arisen about the feasibility of integrating medical simulation into African healthcare systems, pioneering efforts have yielded positive outcomes among medical students and trainers [4, 14, 15]. The establishment of a simulation center in Rwanda exemplifies the untapped potential of medical simulations in Africa [16–18].

Financial constraints, personnel shortages, and technological limitations, such as inadequate power supply and limited Internet access, have hindered the growth of healthcare simulation. Addressing these challenges necessitates the development of methodologies that actively engage local resources and technologies to ensure the sustainability of training initiatives [15]. Additionally, effective training must align with a patientcentered and realistic approach [14], thereby requiring careful consideration of socio-cultural factors and their influence on the learning and teaching process.

Therefore, this work was designed to organize and implement a needs-based training course on umbilical cord care and placenta management after childbirth at the St. Luke Catholic Hospital and College of Wolisso, Ethiopia. This study involved both permanent staff and students, offering insights into the integration of such training into future educational curricula. The initiative underscored the importance of aligning training efforts with local context and resources while harnessing the transformative potential of simulation training to address critical healthcare challenges in Africa.

Prior literature has already demonstrated successful outcomes using low-fidelity manikins in various African settings, despite recognizing low-cost high-fidelity models as the most promising technical solution [12, 14, 17]. Low-fidelity simulators are simple, low-cost tools used to teach basic skills or procedures, offering a simplified view of real-world situations while lacking dynamic interaction. They are ideal for beginners. In contrast, high-fidelity simulators are devices that present a faithful replication of the anatomy, tissues biomechanical properties, and physiological behavior in relation to the clinical task it is intended to teach [19]. A low-cost high-fidelity simulator is a device possibly able to retain all the features of the high-fidelity simulators while keeping the final selling price affordable even for low resources setting.

Currently, the market provides low fidelity-simulators of the umbilical cord and placenta, which offer a poor replication of the anatomy and biomechanical properties of real tissues. The materials and design solutions adopted result in devices with limited abilities in providing comprehensive and quality training. Additionally, only part of clinical procedures can be effectively trained with them [20]. Recent literature solutions solved the low-fidelity issue with biohybrid simulators. These devices combine commercial simulators with pieces of the real umbilical cord [21, 22]. They provide higher fidelity though their applicability is limited by the risk of biological contamination and availability of the human tissue.

For these reasons, the development of a new synthetic simulator at high-fidelity and low-cost of umbilical cord and placenta was deemed necessary. After validating the new simulator's face, content, and usability by conducting expert surveys, we carried out the abovementioned training course to investigate and compare the acceptability and teaching effectiveness of our new high-fidelity simulator with a commercial low-fidelity simulator and the actual human placenta.

#### Methods

#### Validation of the new high-fidelity simulator

The development of the new low-cost, high-fidelity simulator began with an initial collaboration between Sant'Anna School researchers and healthcare professionals from St. Luke's Hospital. This collaboration led to the creation and local validation of a preliminary lowfidelity simulator of the placenta and umbilical cord at St. Luke's Hospital, as discussed in a prior short communication [23]. These early findings, along with subsequent Page 3 of 12

online meetings, informed the design and realization of the new simulator presented here. To validate the newly developed high-fidelity simulator, expert surveys were conducted prior to the simulation-based training course. Anonymous paper surveys were administered to experts in nursing, gynecology, midwifery, and neonatology at St. Luke's Hospital, assessing the simulator's face validity, content validity, and usability. The surveys utilized modified face, content, and usability measures, with responses recorded on a 1-to-5 Likert scale (from "strongly disagree" to "strongly agree"). Only the experts' specialties were collected, with their informed consent. Results are presented descriptively, highlighting the new simulator's key features (Supplementary Appendix S1).

## Characteristics of the newly developed high-fidelity simulator

The new high-fidelity simulator (Fig. 1) accurately reproduces the anatomical structures necessary to teach and train umbilical cord care and placenta management. The replicated umbilical cord consisted of two structures: a disposable and a reusable part. The disposable part was made of uncolored Ecoflex 0010 silicone (Ecoflex series, Smooth-On, USA) in a cylindrical shape with three through-holes aligned with the symmetry axis replicating



**Fig. 1** High fidelity umbilical cord and placenta simulator realized by the BioRobotics Institute of the Sant'Anna School. *Legend*. On the left: the simulator main components and maternal side of the placenta are visible. During the training, the simulator was connected to a commercial neonatal manikin (Newborn Anne, Laerdal, Norway) commonly used by St. Luke College that better resembled an Ethiopian neonate improving the suspension of disbelief. On the right: a portion of the reusable part of the umbilical cord and the neonatal side of the placenta are visible

the umbilical vein and two umbilical arteries. This part is cut during the procedure and can be used a maximum of five times. The disposable part was connected to a commercial neonatal manikin and the reusable part through two ad hoc connectors 3D printed in PETG material (RS PRO, RS Components, UK). The reusable part, made of colored Ecoflex 0010, reproduces the umbilical vessels arranged helically as in the healthy real umbilical cord, and it ends with the placenta. The disposable part of the umbilical cord was wrapped with white soft tulle fabric, while the vessels in the reusable part were made from shoelaces coated in colored silicone.

The placenta replicates the superficial vessels on the neonatal side and the 20 lobes on the maternal side and is made by colored Ecoflex 0010 silicone. Neonatal and maternal membranes were fabricated by coating a white soft tulle fabric with Ecoflex 0010 silicone and then, glued to the placental main body. One lobe and the maternal membrane can be easily detached and attached to simulate different pathological scenarios thanks to multiple hook-and-loop fasteners. The colors, materials, and sizes were carefully selected by means of literature data and real umbilical cord pictures to accurately reflect the visual and biomechanical properties of real tissues.

## Acceptability and teaching effectiveness of the new highfidelity simulator

#### Study setting

The study was conducted at St. Luke Catholic Hospital and College of Nursing and Midwifery, Wolisso, Ethiopia. Ethiopia has made significant strides in improving healthcare access and outcomes over recent decades, but it still faces substantial hurdles. The national healthcare infrastructure is primarily public, with the government playing a central role in providing services, particularly in rural areas where most of the population resides. Key challenges include a shortage of healthcare professionals, limited infrastructure, and insufficient resources. Many rural areas lack adequate health facilities, and the ratio of healthcare workers to the population is low, which affects service delivery. Maternal and child health, infectious diseases like malaria and tuberculosis, and malnutrition remain major public health concerns [24, 25].

St. Luke Hospital is a non-profit referral facility located in Wolisso, the capital of southwestern Shoa in the Oromiya region [26, 27]. It is run by the Ethiopian Government, the Ethiopian Catholic Church, and the NGO CUAMM - Doctors for Africa. It serves a population of approximately 1.25 million residents, in conjunction with 80 other healthcare facilities [28]. This private institution, accredited by the Oromiya public health system, functions as the referral center for three primary hospitals in the Southwest Shoa Zone – Ameya, Bantu, and Tullu Bolo [29]. The hospital is equipped with a maternity waiting home to accommodate pregnant women from distant areas with potentially high-risk pregnancies. The hospital plays a vital role in maternal and neonatal care as testified by the high number of deliveries performed every year (around 4,300 in 2017).

#### Study design

We prospectively collected data during the simulationbased training course. Two researchers from Sant'Anna School of Advanced Studies, Pisa, Italy (specifically, the authors S. M. and A. F.) visited St. Luke Hospital and College to organize this training course with nursing and midwifery college students. The researchers brought with them the new high-fidelity simulator of the umbilical cord and placenta, previously described. A research collaboration agreement was signed between the two Institutions to implement the training course.

#### The training course

On Day 1, the St. Luke college teachers (namely, the authors S. T., M. T., and M. W.) gave face-to-face theoretical lectures on umbilical cord management and placenta care to their nursing and midwifery students (n=67). The teaching materials normally used by university teachers during lectures were employed. A first questionnaire was administered to the students, to collect their baseline characteristics (Supplementary Appendix S2). Considering the high number of attendees, we split them into two subgroups of equal numerosity, one in the morning and one in the afternoon.

On Day 2, hands-on training activities were carried out by using three different simulators: group (A) a standard low-fidelity commercial simulator owned by the St. Luke College (GHDE&MD company); group (B) the new highfidelity simulator developed by Sant'Anna School; and group (C) a real placenta with still attached the maternal portion of the umbilical cord (Supplementary Appendix S3). Accordingly, attendees were randomly divided into three homogeneous groups of 22 (group A), 23 (group B), and 22 (group C) students, respectively. The randomization process was carried out by making each student pick a number from 1 to 67 from a closed box. Each group was given simulation lessons separately using the assigned simulator and in the same fashion by all three college teachers who were always present throughout the course. The college teachers showed to the attendees how to manage three different clinical scenarios: regular placenta and umbilical cord; placenta with a missing lobe and regular umbilical cord and placenta membranes; placenta with a missing membrane and regular umbilical cord and placenta lobes. Then, each student performed a practical simulation by replicating the three scenarios.

On Days 3–4, participants were involved in evaluation sessions to test the effectiveness of the training.

The attendees were divided into small subgroups of 2-3 people (21 of 3 people, 2 of 2 people). All the students in the same group did the practical session with the same simulator. One of the three scenarios was assigned randomly to each subgroup. All subgroup members had to work together and recognize the scenario, perform the actions they had learned during the training, and explain what they were doing. The attendees' performance was objectively evaluated by the teachers through a quantitative evaluation sheet (Supplementary Appendix S4). This evaluation sheet filled by the teachers aimed to quantitatively assess the skills acquired by the students during the hands-on sessions and provide a comparison between groups A, B and C, and thus, define which simulator brought to the best learning outcomes. The Mann-Whitney U test was used to explore between-group differences in the final scores given by tutors.

The evaluation session lasted a maximum of 20 min. After the simulation, the attendees were required to fill out in 10 minutes a second questionnaire, which included the items of the TAM scale (Technology Acceptance Model, Supplementary Appendix S5), as well as a pre/post evaluation test about the topics taught during the course (Supplementary Appendix S6). This pre/post evaluation test was designed to assess the proficiency gained by the students during the entire training course using true/false questions. The same Pre/post evaluation test was filled by the students both before starting the simulation training course and at the end of it. Then, the final scores were compared using the Student's t test for paired samples to verify that the scores in the post questionnaire were significantly higher than those in the pre questionnaire.

Throughout the course, breaks and refreshments were scheduled, to give the students time to rest.

#### Participants and ethics

The participants of this study were the 2nd year students enrolled in the College's Nursing and Midwifery Training program, with no previous experience in the topics taught during the training course. The course participation was on voluntary basis, free of charge and there was no economical compensation for attendants. No exclusion criteria were applied, but data from students who did not complete the course were not considered. No respondents' details or contact data that might allow tracing back the participant's identity (e.g., name, surname, date of birth, place of birth, email address, etc.) were collected. All survey data were anonymized using a unique identification numeric code (a number from 1 to 67) for each respondent that allowed the responses to the first and second questionnaires to be jointly analyzed.

The study was carried out in compliance with the Declaration of Helsinki and the Italian law on privacy

101/2018, which is aligned with the European GDPR 2016/679. Participants were fully informed of all possible risks they might face during the study, could opt out of the study at any time, and enrolled only after providing informed consent. The study protocol was approved by the Ethics Committees of both St. Luke College Hospital (resolution n. 0469/2023) and Sant'Anna School of Advanced Studies (resolution n. 14/2023).

#### Assessment

Using the validated TAM as the main theoretical framework, we developed the second questionnaire exploring these four dimensions: Perceived Usefulness (PU), Perceived Ease-of-Use (PEU), Behavioural Intention (BI), and Fidelity of the Simulator (FS) [30, 31]. The questionnaire was administered on Days 3–4 at the end of the evaluation sessions. The items were modified according to the characteristics of Sant'Anna simulators and were categorized as 1-to-7 Likert scales (from "extremely disagree" to "extremely agree").

First, we used Mann-Whitney's U test to investigate the differences in the scores of TAM items for placenta vs. standard simulator, standard simulator vs. new simulator, and placenta vs. new simulator. We also analyzed the between-group differences in the objective quantitative scores provided by teachers at the end of the evaluation session. Then, we ran a partial least squares structural equation model [32, 33] (PLS-SEM) to test both the associations between the TAM items and the respective dimensions considered as latent variables (measurement model) and the following cause-effect relationships (structural model):  $H_1$ ) FS has a positive effect on PU;  $H_2$ ) PEU has a positive effect on PU;  $H_3$ ) PU has a positive effect on BI;  $H_4$ ) FS has a positive effect on PEU.

We also performed a PLS-SEM-based multigroup analysis to understand whether the associations between the items and dimensions, as well as the cause-effect association paths, differed significantly among the three study groups. Then, using the latent variables created by the model for all dimensions (PU, PEU, BI, FS), we ran quantile regression models adjusted for participants' baseline characteristics to test the difference in each dimension for groups A and B as compared with group C taken as reference.

Statistical analyses were performed using Stata Software version 17.0 (Stata-Corp, LLC, College Station, Texas, USA). Statistical significance was set at a p-value < 0.05.

### Results

#### Validation of the new high-fidelity simulator

Expert surveys involved 37 health professionals, specifically 12 midwives, 15 nurses, 1 gynecologist, 1 neonatologist, and 8 other professionals (Supplementary Table

Baseline characteristics	Total (n=67)	A) Standard simulator (n = 22)	B) New simulator (n=23)	C) Human placenta (n=22)	<i>p</i> -value
Age, median (IQR)	21.0 (20.0, 22.0)	20.5 (20.0, 22.0)	21.0 (20.0, 22.0)	21.0 (20.0, 22.0)	0.83
Sex, n (%)					0.57
Male	18 (26.9%)	5 (22.7%)	8 (day34.8%)	5 (22.7%)	
Female	49 (73.1%)	17 (77.3%)	15 (65.2%)	17 (77.3%)	
Civil status, n (%)					0.37
With partner	3 (4.5%)	1 (4.5%)	2 (8.7%)	0 (0.0%)	
Without partner	64 (95.5%)	21 (95.5%)	21 (91.3%)	22 (100.0%)	
University faculty, n (%)					0.53
Midwifery	34 (50.7%)	12 (54.5%)	13 (56.5%)	9 (40.9%)	
Nursing	33 (49.3%)	10 (45.5%)	10 (43.5%)	13 (59.1%)	
Previous hands-on activities, n (%)					0.25
Yes	16 (23.9%)	4 (18.2%)	4 (17.4%)	8 (36.4%)	
No	51 (76.1%)	18 (81.8%)	19 (82.6%)	14 (63.6%)	
Economic status, n (%)					0.53
Very good	3 (4.5%)	0 (0.0%)	1 (4.3%)	2 (9.1%)	
Good	25 (37.3%)	9 (40.9%)	10 (43.5%)	6 (27.3%)	
Not good	39 (58.2%)	13 (59.1%)	12 (52.2%)	14 (63.6%)	
Previous work activities, n (%)					0.24
Yes	5 (7.5%)	0 (0.0%)	3 (13.0%)	2 (9.1%)	
No	62 (92.5%)	22 (100.0%)	20 (87.0%)	20 (90.9%)	
Previous university studies, n (%)					0.35
Yes	4 (6.0%)	2 (9.1%)	2 (8.7%)	0 (0.0%)	
No	63 (94.0%)	20 (90.9%)	21 (91.3%)	22 (100.0%)	
Interest in participating in the course, n (%)					0.35
Yes	66 (98.5%)	22 (100.0%)	23 (100.0%)	21 (95.5%)	
No	1 (1.5%)	0 (0.0%)	0 (0.0%)	1 (4.5%)	
Satisfaction with face-to-face lessons, n (%)					0.37
Very satisfied	64 (95.5%)	21 (95.5%)	21 (91.3%)	22 (100.0%)	
Quite satisfied	3 (4.5%)	1 (4.5%)	2 (8.7%)	0 (0.0%)	

#### Table 1 Baseline characteristics of the study population

To describe the participant baseline characteristics obtained from the first questionnaire, we reported continuous variables as median and interquartile range (IQR), and categorical variables as counts and proportions (%). To test the non-significant difference between the three study groups in the sociodemographic data, we used the Kruskal-Wallis and the  $\chi^2$  tests, respectively.

Student's t test p-value

S1). Results from surveys indicated that, on 1-to-5 Likert scales, the overall impression of the simulator was good (mean score 4.38), with high fidelity of the anatomic structures (4.38), materials (4.24), and visual appearance (4.43). Experts agreed that all the simulation steps could be performed using the new simulator (4.24), which was also perceived as useful for teaching purposes (4.59) and easy to be used (4.59).

#### Acceptability and teaching effectiveness of the new highfidelity simulator

We enrolled 67 participant students. As shown in Table 1, the median age was 21 years, and the predominant sex was female (73%). 95% of the participants lived without a partner, and 58% of them declared not to have a good economic status. Half of the participants were midwifery students, and half were nursing students. Most students had been involved in no previous hands-on activities, work activities, or other university studies. Most students were interested in participating in the course and

 Table 2
 Pre-post difference in the Pre/post evaluation test

scoles				
Score true/false	Mean	95% CI		
Pre (Day 1)	4,7	4,4 to 4,9		
Post (Days 3–4)	8,4	8,2 to 8,6		
Difference pre-post	-3,7	-4 to -3,5		

satisfied with the face-to-face lectures. There was no difference in the baseline characteristics between the three study groups.

< 0.001

The Pre/post evaluation test scores were significantly higher after the simulation training course (Table 2). In the pre-evaluation test, the mean score was 4.7 over a total of 10 points. In the post-evaluation test, the mean score almost doubled reaching 8.4/10. Furthermore, The TAM item scores PU1, PU2, PU4, PEU2, and PEU3 were significantly higher in the group B than in the group C (Table 3). The item score PEU3 was also higher in the group B than in the group A, while there was no

 Table 3
 Difference in TAM (Technology Acceptance Model)

 items between the new simulator (group B) and the real human placenta (group C)

TAM items	Human placenta (n=22)	New simulator (n=23)	<i>p</i> -value (Mann- Whitney test)
PU1, median (IQR)	6.0 (5.0, 6.0)	7.0 (6.0, 7.0)	0.006
PU2, median (IQR)	6.0 (6.0, 7.0)	7.0 (6.0, 7.0)	0.038
PU3, median (IQR)	6.0 (6.0, 7.0)	7.0 (6.0, 7.0)	0.130
PU4, median (IQR)	6.0 (6.0, 6.0)	7.0 (6.0, 7.0)	0.026
PU5, median (IQR)	7.0 (6.0, 7.0)	7.0 (6.0, 7.0)	0.880
PEU1, median (IQR)	6.0 (6.0, 7.0)	7.0 (6.0, 7.0)	0.058
PEU2, median (IQR)	6.0 (5.0, 6.0)	6.0 (6.0, 7.0)	0.006
PEU3, median (IQR)	6.0 (6.0, 6.0)	7.0 (6.0, 7.0)	< 0.001
PEU4, median (IQR)	6.0 (6.0, 6.0)	6.0 (6.0, 7.0)	0.200
PEU5, median (IQR)	6.0 (5.0, 7.0)	7.0 (6.0, 7.0)	0.053
BI1, median (IQR)	7.0 (6.0, 7.0)	7.0 (7.0, 7.0)	0.130
BI2, median (IQR)	6.0 (6.0, 7.0)	6.0 (6.0, 7.0)	0.380
FS1, median (IQR)	6.0 (6.0, 7.0)	6.0 (6.0, 7.0)	0.260
FS2, median (IQR)	6.0 (6.0, 7.0)	7.0 (6.0, 7.0)	0.080
FS3, median (IQR)	6.0 (5.0, 7.0)	6.0 (6.0, 7.0)	0.170

The median scores of each item of the TAM scale belonging to the four dimensions (Perceived Usefulness, Perceived Ease of Use, Behavioral Intention, Fidelity of the Simulator) were compared between the human placenta simulation group and the new simulator group by using the Mann-Whitney U test. Bold values indicate statistically significant p-values.

**Table 4** Between-group differences in the objective final scores aiven by tutors

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	C) Human placenta	A) Standard simulator	<i>p</i> - value
	n=22	n=22	
Final score by tutors, median (IQR)	7.0 (6.0, 9.0)	8.5 (3.0, 10.0)	0.94
	C) Human placenta	B) New simulator	<i>p-</i> value
	n=22	n=23	
Final score by tutors, median (IQR)	7.0 (6.0, 9.0)	11.0 (8.0, 11.5)	< 0.001
	A) Standard simulator	B) New simulator	<i>p-</i> value
	n=22	n=23	
Final score by tutors, median (IQR)	8.5 (3.0, 10.0)	11.0 (8.0, 11.5)	< 0.001

The Mann-Whitney U test was used to explore between-group differences in the final scores given by tutors. Please, see Supplementary Appendix S4 for further information on sheet used for the objective evaluation by tutors

significant difference between the group A and the group C (Supplementary Tables S2-S3).

The median final objective scores given by college teachers were statistically higher in group B compared to the scores obtained by group A and C (Table 4). On the contrary, there was no statistically significant difference between the scores obtained by groups A and C. Specifically, the group who worked with the standard simulator (A) got a mean final score of 8.5, the group that used the real placenta (C) received a mean final score of 7, while the group using the new simulator (B) reached a mean final score of 11.

The measurement model showed that the loadings of all TAM items (except PU1 and PEU1) were above the recommended value of 0.7 (Table 5). All values of composite reliability and Cronbach's alpha were higher than 0.7, and rho\_A values were between composite reliability and Cronbach's alpha. The average variance extracted (AVE) values exceeded the recommended threshold (0.5). We also assessed discriminant validity using the Fornell-Larcker criterion (Supplementary Table S5). Multigroup analysis showed no significant differences in factor loadings of TAM items between the three study groups.

The association paths were tested in the structural model (Fig. 2, Supplementary Table S6) by using a bootstrapping procedure. All hypothesized positive paths were significantly supported by the model's results (p-value < 0.05). Multigroup analysis revealed no significant differences between the study groups in the association paths. Furthermore, adjusted quantile regression models showed that the two latent variables PU and PEU (computed by the PLS-SEM) were significantly higher in the group B than in the group C, while there was no difference between the group A and the group C (Fig. 3, Supplementary Tables S7-S8).

## Discussion

#### Main findings

Our study describes the realization and validation with Ethiopian experts of a new low-cost high-fidelity simulator together with the implementation of a simulation course on placenta and umbilical cord management delivered to midwifery and nursing students at St. Luke's College, Ethiopia. Experts confirmed the new high-fidelity simulator's fidelity, material quality, and usability. The simulation course ensured adequate preparation of the attendees, as evidenced by the results obtained in the evaluation session. The course enabled students to comprehensively train all the steps of umbilical cord care and placenta management in an immersive setting. Attendees had the opportunity to appraise placental and umbilical weight, encumbrance, and consistency, and to thoroughly examine their main features to understand how to distinguish between a healthy and a pathological placenta.

Furthermore, the final objective evaluation given by the tutor, along with the results from the pre/post training questionnaires, demonstrated the educational effectiveness of the simulation and the teaching methods employed. All students successfully completed the training course and passed the final exam. The new simulator outperformed the other two, highlighting the value of a low-cost, high-fidelity simulator in resource-limited settings, as previously demonstrated in the literature [23,

Latent variable	Indicator variable	Loading	Cron- bach's alpha (CA)	Composite reliability (CR)	rho_A	Average variance extracted	Std simulator vs. placenta (p) *	New simu- lator vs. placenta (p) *
Usefulness	PU1	0.581					0.454	0.293
	PU2	0.866					0.338	0.345
	PU3	0.741	0.798	0.862	0.820	0.560	0.171	0.612
	PU4	0.824					0.157	0.404
	PU5	0.695					0.247	0.128
Ease-of-Use	PEU1	0.531					0.612	0.097
	PEU2	0.802					0.728	0.169
	PEU3	0.702	0.773	0.844	0.822	0.528	0.418	0.602
	PEU4	0.777					0.323	0.138
	PEU5	0.866					0.902	0.316
Behavioural	BI1	0.833	0.583	0.827	0.583	0.705	0.393	0.704
Intention	BI2	0.846					0.222	0.153
Fidelity of the Simulator	FS1	0.851					0.300	0.497
	FS2	0.819	0.792	0.878	0.796	0.706	0.179	0.317
	FS3	0.851					0.261	0.443
Reference values	for validity	>0.7	>0.7	>0.7	CA <rho_a<cr< td=""><td>&gt; 0.5</td><td>* <i>p</i>-values from mul<sup>:</sup> analysis</td><td>tigroup</td></rho_a<cr<>	> 0.5	* <i>p</i> -values from mul <sup>:</sup> analysis	tigroup
Average R-square	d = 52.1%							

#### Table 5 Measurement model: factor loadings

Absolute Goodness-of-Fit = 55.8%

Relative Goodness-of-Fit = 93.5%

The loadings of all TAM items (except PU1 and PEU1) were >0.7 confirming that all items successfully linked to the corresponding latent dimension. The model fitting was confirmed by all values of composite reliability and Cronbach's alpha > 0.7, and by rho A values between composite reliability and Cronbach's alpha. The average variance extracted (AVE) values exceeded the recommended threshold (0.5). Multigroup analysis showed no between-group significant differences in factor loadings of TAM items

34]. Employing local facilitators and hands-on activities allowed all the student to acquire and retain new knowledge and be able to obtain positive results in the pre/post questionnaire. This result is particularly significant and was achieved through the combined approach of introducing new concepts using teaching strategies already familiar to the students, along with the use of simulators. The students' familiarity with the tutors and teaching methods fostered a comfortable and engaging learning environment, encouraging active participation and facilitating the internalization of new knowledge. In addition, the simulator-based training, conducted individually and in small groups, required students to immediately apply theoretical concepts to practical skills in a safe, non-judgmental setting.

At the same time, our study sought to compare the acceptability of a new technology, that is the new highfidelity simulator developed by Scuola Sant'Anna, with a standard low-cost simulator and a real human placenta. The results of the PLS-SEM model validated the use of the TAM scale to assess the user acceptability of the three analyzed simulators. The association paths did not differ among the three study groups, making our results consistent across the entire study population. In addition, the results of the TAM scale showed that the new high-fidelity simulator was perceived by students as more useful and easier to be used than the real human placenta. The behavioral intention variable did not differ between the new simulator and the real placenta. In contrast, there were no significant differences between the standard simulator and placenta for the four items of the TAM scale.

#### Limitations

This study has some limitations. First, our results are not generalizable because the study was conducted in a single center. Second, our results may have been influenced by confounding factors that we did not consider. For example, although there were no differences among the three groups, the randomization process may have led to the formation of groups that differed in characteristics that we did not consider, partly because the sample size did not allow more than 6-7 variables to be included in the regression models. Third, the evaluation session was conducted by all three groups with the new high-fidelity simulator; therefore, students who had done the training with that simulator may have been advantaged. However, this choice was dictated by the need to use a simulator that would allow to perform several times all the required steps and tasks without lacking fidelity and avoiding the important issues related to the use of biological tissues such as the real placenta.



Fig. 2 Testing the hypotheses of the structural model. *Legend*. PU: Perceived Usefulness; PEU: Perceived Ease of Use; BI: Behavioral Intention; FS: Fidelity of the Simulator; R2: R-squared; H1-H2-H3: hypotheses 1-2-3. Note: \* p < 0.05; \*\* p < 0.01; \*\*\*p < 0.001

The new simulator is primarily composed of silicone, an unexpensive and sustainable material derived from silica. This material is highly stable and does not undergo degradation. It is also non-toxic to aquatic or soil organisms and can be recycled, making it an environmentally friendly option. As a result of these considerations, the reusable part of the simulator may be utilized for an extended period, whereas the disposable part can be easily disposed without contributing to a significant environmental impact. Despite its capacity to be exploited up to five times prior to depletion, the utilization of a disposable component diminishes the long-term sustainability of the entire simulator. The scarcity of silicone in African countries necessitates a supply chain from a developed country, which can result in expensive products. This phenomenon, already documented by relevant literature, underlines the need to explore alternative solutions using local resources and sustainable by the African market. Moreover, in many parts of Africa, high temperatures and limited access to clean water pose significant challenges for maintaining and properly cleaning medical equipment. These environmental factors can impact the effectiveness of sanitation procedures, potentially leading to equipment contamination and increased risk of infections. Addressing these challenges requires innovative solutions and adaptations to ensure the safe and effective use of medical tools and simulation devices in such conditions.

#### Implications

Sant'Anna new simulator is the first example in the literature of a high-fidelity simulator of the umbilical cord and placenta, which enables to teach and repeat all the steps necessary for the management of these organs after delivery. To date, the current market offers only low-fidelity umbilical cord and placenta simulators, which, albeit inexpensive and reusable, do not allow all the required steps and tasks to be performed. Also, they present a poor replication of the anatomy and biomechanical properties of the human organs. On the other hand, the high-quality teaching ensured during the course was previously achievable only through direct exposure of the students to real human organs, which inevitably entailed biological risk.

The implementation of the Sant'Anna new high-fidelity simulator allowed for the teaching and training to be conducted in a biohazard and chemical-risk free environment, as the device boasts a high level of fidelity and the utilized materials classified as safe for skin contact. Highfidelity low-cost simulators are considered a valuable



Technology Acceptance Model (TAM)

Fig. 3 Quantile regression models for the TAM items. Leaend. The latent variables for the four dimensions generated by the partial least squares structural equation model (PLS-SEM) were used as dependent variables. The models were adjusted by age, sex, faculty, reported economic status, and previous involvement in hands-on training activities (see Supplementary Tables S7-S8)

option for medical training in low-income countries. These simulators guide quality teaching and training, which are essential for the development of critical skills that can enhance patient outcomes and healthcare level.

The production costs of the disposable part of the new Sant'Anna simulator are not low. In principle, this is a challenge inherent with the sustainability of such equipment, and substantially questions if it can be of general interest. On the other hand, its reusable part can ensure long-term use and can be easily interfaced with low cost and local solutions, e.g., rubber tubes. Indeed, the simulator was left at St. Luke College to teach future students as per the collaboration agreement signed with Sant'Anna School. This experience should encourage collaborations between institutions that can produce high-fidelity, longterm reusable simulators, with or without replaceable parts, and institutions in low-income countries that could benefit from them. As a matter of facts, our study demonstrated that the new simulator provided at least comparable preparedness to that provided by the other two simulators, while also being perceived as more useful and easier to use by students. Preparedness, in the context of simulation-based training, refers to the degree to which an individual or group is equipped with the knowledge, skills, and confidence necessary to perform tasks or face real-world challenges [35]. In training environments, simulators play a critical role in fostering preparedness by replicating real-world conditions in a controlled, risk-free setting, as already described in the literature [36]. In our study, the new simulator, which was shown to provide at least comparable preparedness to that of the other two simulators, likely achieved this by offering realistic scenarios that allowed students to practice and refine their skills in a way that closely mirrors real-world conditions.

At the same time, we must recognize that the new simulator, while providing higher final scores in the objective evaluation by tutors, did not demonstrate higher acceptability than the standard low-cost simulator. Probably, in similar contexts, students perceive a commercial and a high-fidelity simulators as equally useful and easy-ofuse. However, Sant'Anna simulator offers the advantage of performing cord clamping and cutting via a replaceable part. It also shows students the correct anatomy of the placenta in a risk-free environment and two different pathological conditions, differently from other simulators. Training with this simulator could provide students with greater efficiency and lower risks when they first encounter a real clinical situation.

#### Conclusion

We successfully tested the new high-fidelity simulator for umbilical cord care and afterbirth placenta management, developed by the Sant'Anna School team, employing the tool described by Maglio et al. [23] and the TAM scale alongside robust statistical methods. The validation process not only confirmed the effectiveness of the simulator but also highlighted the fruitful collaboration between Sant'Anna School and St. Luke's College in organizing a comprehensive simulation training course for local students. The course was designed to align with the rigorous teaching standards of St. Luke's College, ensuring that the training provided met the highest educational benchmarks.

Our findings revealed that students who trained with the new simulator achieved significantly higher objective scores during the evaluation sessions compared to those who practiced with the real human placenta. Furthermore, the students reported that the simulator was both more useful and easier to use than the real placenta, underscoring the simulator's practical value in an educational setting. These results suggest that integrating highfidelity simulators into medical training can substantially enhance learning outcomes, offering a more effective and accessible alternative to traditional methods.

The success of this initiative highlights the potential for further research and development in simulation-based education, particularly in medical and healthcare training. The positive student feedback and improved performance metrics indicate that such simulators could play a crucial role in advancing medical education, ultimately contributing to better-prepared healthcare professionals. Our study lays the groundwork for future exploration into the broader applications of high-fidelity simulators, advocating for their adoption in various educational contexts to improve training efficacy and student engagement. Finally, yet importantly, it would be interesting to replicate this study within the framework of Basic Emergency Obstetric and Newborn Care (BEmONC) as integrated into Ethiopian healthcare education. BEmONC programs are crucial for improving maternal and neonatal health outcomes in low-resource settings by providing essential emergency care for pregnant women and newborns. Exploring the effectiveness of high-fidelity simulators in this context could offer valuable insights into how advanced simulation tools impact the training and preparedness of healthcare professionals dealing with obstetric and neonatal emergencies.

#### Abbreviations

TAM	Technology Acceptance Model
NGO	Non-governative organization
CUAMM	Collegio Universitario Aspiranti Medici Missionari
MeS	Management and Health
PU	Perceived Usefulness
PEU	Perceived Ease-of-Use
BI	Behavioural Intention
FS	And Fidelity of the Simulator
PLS-SEM	Partial least squares structural equation model
BEmONC	Basic Emergency Obstetric and Newborn Care

#### **Supplementary Information**

The online version contains supplementary material available at https://doi. org/10.1186/s12909-024-06152-0.

Supplementary Material 1

#### Author contributions

A.F. and S.M. equally contributed as first authors to conceptualizing and designing the study; collecting and managing data and performing statistical analyses; writing the first draft of the manuscript; reading, reviewing and editing the manuscript. S.Ta, M.T., and M.W. contributed to designing the study; collecting data; reading, reviewing and editing the manuscript. I.C. contributed to conceptualizing and designing the study; interpreting data; reading, reviewing and designing the study; interpreting data; reading, reviewing and editing the manuscript. F.M. and E.F. contributed to conceptualizing the study; interpreting data; reading, reviewing and editing the manuscript. S.To., M.V., A.M. equally contributed to conceptualizing and designing the study; interpreting data; reading, reviewing and editing the manuscript. S.To., M.V., A.M. equally contributed to conceptualizing the manuscript.

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#### Data availability

The data that support the findings of this study are available from the corresponding author upon reasonable request.

#### Declarations

#### Ethics approval and consent to participate

Participants were fully informed of all possible risks they might face during the study, could opt out of the study at any time, and enrolled only after providing informed consent. The study protocol was approved by the Ethics Committees of both St. Luke College Hospital (resolution n. 0469/2023) and Sant'Anna School of Advanced Studies (resolution n. 14/2023).

#### **Consent for publication**

Consent for publication was obtained from the study participants, who provided their consent for publication when they signed the informed consent for participation in the study.

#### **Competing interests**

The authors declare no competing interests.

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