

# Development and validation of a performance assessment checklist for insertion of an intra-uterine device (IUD)

Stephanie Mignot<sup>1,2</sup>, Anne-Charlotte Berthome<sup>1</sup>, Marion Andre<sup>1</sup>, Cyril Breque<sup>3</sup>, Jean-Pierre Richer<sup>3,4</sup>, Daniel Aiham Ghazali<sup>3,5,6</sup> , Denis Oriot<sup>3,7</sup>

<sup>1</sup>Department of General Practice, Faculty of Medicine, University of Poitiers, France

<sup>2</sup>Department of Gynecology and Obstetrics, University Hospital, Poitiers, France

<sup>3</sup>ABS Lab, Simulation Laboratory, Faculty of Medicine, Poitiers, France

<sup>4</sup>Department of GI Surgery, University Hospital, Poitiers, France

<sup>5</sup>Emergency Department and EMS, University Hospital of Amiens, Amiens, France

<sup>6</sup>MUSE (Emergency Medicine, Simulation and Education in Emergency Medicine) Unit Research, University Hospital of Amiens, France

<sup>7</sup>Pediatric Emergency Department, University Hospital, Poitiers, France

## ABSTRACT

**Objectives:** The World Health Organization (WHO) supports increasing the availability and acceptability of long-acting reversible contraception including intra-uterine device (IUD), but its insertion includes certain risks (uterine perforation). The objective was to develop and validate an IUD insertion performance assessment checklist.

**Material and methods:** This prospective study took place in hospitals and simulation center of the Poitou-Charentes region, France. The checklist content reached consensus among 10 experts solicited by a Delphi method. A modified gynecologic mannequin Zoe (Gaumard<sup>®</sup>) was used for simulations. Psychometric testing included 30 multi-professional participants for internal consistency and reliability between two independent observers, and 27 residents for assessment of score evolution over time and reliability. Cronbach alpha (CA) and intraclass coefficient (ICC) were used. Progression of performance was carried out using ANOVA for repeated measures. The data collected were used to plot receiver operating characteristic (ROC) curves for the score values and the area under the curve (AUC) was determined.

**Results:** The checklist included 27 items (2 sections, total score = 27). Psychometric testing showed CA = 0.79, ICC = 0.99, and good clinical relevance. The checklist is discriminative, showing a significant increase in performance scores when the simulations were repeated ( $F = 77.6$ ,  $p < 0.0001$ ). ROC curve [AUC: 0.792 (95% CI: 0.71–0.89);  $p < 0.0001$ ] revealed the best score cutoff predictive of 100% sensitivity, *i.e.*, true positive rate or success rate. Performance score was highly correlated to success rate. The cut-off score guaranteeing successful IUD insertion was 22/27.

**Conclusions:** This coherent and reproducible checklist for IUD insertion provide an objective assessment of the procedure during SBT, with the aim of obtaining a score  $\geq 22/27$ .

**Keywords:** IUD; contraception; assessment checklist; performance; uterine perforation; simulation-based education

Ginekologia Polska 2023; 94, 11: 874–882

## INTRODUCTION

The intra-uterine device (IUD) is the first long-acting contraception method used by women in the world [1]. The World Health Organization supports increasing the availability and acceptability of the use of long-acting reversible contraceptives (IUD and implants), inserted if possible, by midwives, general practitioners, and gynecologists [2]. The insertion of an IUD is a procedure that is not without risks,

expulsion, malpositioning, and uterine perforation [3]. Uterine perforation is rare, but it may cause serious problems, including bleeding, bowel or bladder perforation, and fistula formation. Many risk factors were suggested, including inexperience of the inserter and inappropriate technique during the IUD insertion [3]. There exists a correlation between lack of training and occurrence of uterine perforation: the onset of perforation is linked to the clinical inexperience

Corresponding author:

Daniel Aiham Ghazali

Emergency Department and EMS, Amiens Academic Hospital, 1 Rond-Point du Professeur Christian Cabrol Cabrol, 80000 Amiens, France

e-mail: aiham@hotmail.com

Received: 30.10.2022 Accepted: 19.12.2022 Early publication date: 4.04.2023

This article is available in open access under Creative Commons Attribution-Non-Commercial-No Derivatives 4.0 International (CC BY-NC-ND 4.0) license, allowing to download articles and share them with others as long as they credit the authors and the publisher, but without permission to change them in any way or use them commercially.

of the practitioner and nearly 2/3 of perforations occur during the first 25 IUD insertions of a practitioner [4–6]. Being trained in IUD insertion and feeling self-confident in this procedure are the two most widely identified factors conducive to supporting IUD as a means of contraception during a consultation [7].

The American nonprofit organization, Jhpiego, listed in its training program the different steps of learning how to perform an IUD insertion [8]. Nevertheless, only a few studies have reported on the benefits of simulation-based training (SBT) in terms of performance during IUD insertion training using a validated checklist. Most of them used only self-assessment of satisfaction of trained learners [9, 10]. Nippita used a specific checklist for IUD insertion from the training resource package of family planning and demonstrated the benefits of repetition of simulations regardless of the model used [11]. However, the checklist was not psychometrically tested for validity and reliability evidence. Psychometric analysis ensures that the checklist scores accurately reflect the construct it is intended to measure, *i.e.*, the ability to perform the procedure [12]. Therefore, the primary objective of this study was to provide validity and reliability evidence for the Jhpiego IUD insertion performance assessment checklist enriched by other items for objective evaluation. Secondary objectives were: 1 — to determine the predictive cut-off score for successful IUD insertion in simulation setting; 2 — to analyze the satisfaction of trainees.

## MATERIAL AND METHODS

### Study design

This prospective, multi-site, non-randomized study took place in different hospitals of the Poitou-Charentes region (1.8 10<sup>6</sup> inhabitants, France) (Niort, La Rochelle, Rochefort) and the ABS Lab (Anatomy Biomechanics Simulation Laboratory) of the Faculty of Medicine of Poitiers, for a duration of two years from September 3, 2018 to September 3, 2020.

The ABS Lab has an agreement from the Regional Health Agency of Poitou-Charentes for research on healthy volunteers. IRB approval was obtained from the Research Board of the Faculty of Medicine under the number # 2018-04-DO.

All participants signed an informed consent form. Results were kept anonymous.

### Creation of the instrument

The checklist was created following INSPIRE guidelines for developing checklists for simulation-based education and simulation-based assessments [12].

#### Contents

Based on the analysis of comprehensive literature review conducted using the Ovid MEDLINE and PubMed databases, many evaluation tools for IUD exist [13]. Our choice was

directed using a checklist for a two-handed technique of insertion of IUD, currently used in Europe. Among the available checklists, the Jhpiego checklist was chosen because it was concise and complete compared to others [8]. It was enriched by some items from the IUD Levonorgestrel (Mirena®) leaflet to implement missing items for “good practice of IUD insertion” (Bayer HealthCare France, Mirena® 52 mg (20 micrograms/24 hours), intrauterine device) [14]. This Mirena® IUD was chosen because its placement procedure was similar to those of the majority of IUDs. It was more convenient for the simulation model used, *i.e.*, with a wide cervix, as Mirena® IUD is wider than copper IUDs.

The Jhpiego checklist is divided into two sections: preparation of the equipment for IUD insertion, and IUD insertion technique *per se*. This checklist contains several items that were considered inappropriate for teaching in the French setting (*i.e.*, ask the woman to wash herself, to empty her bladder, remove the speculum after IUD insertion, *etc.*). Furthermore, a reformulation of some items was necessary for clarification, with less ambiguity.

A Delphi method was carried out to reach a consensus to determine the required steps of the IUD insertion procedure [15]. Our aim was to recruit 10 experts. Inclusion criteria were to be general practitioners (with competence in gynecology) and gynecologists, inserting at least one IUD per week for at least five years. Recruited experts were then contacted by e-mail giving information about the study and sending them the first questionnaire if they consented to participate. Anonymity of answers was respected, each expert receiving a personal e-mail with no knowledge of the other experts' answers.

Among the 18 French experts chosen, 10 agreed to participate in the study. There were 5 gynecologists, and 5 general practitioners for whom IUD insertion is a frequent procedure in their medical practice. The checklist was then sent to these experts, asking them to rank the importance of each item to successful performance of the task and to avoid the immediate risk of perforation during IUD insertion by using a 7-point Likert scale according to INSPIRE guidelines with free comments [12]. The mean score for each item was calculated. For the next round, Items with a mean rating of 1 to 3 (*i.e.*, not important) were removed from the checklist. Some questions were modified with more precise/accurate definitions according to some experts' remarks. This process aimed to continue until all experts agreed on the checklist items (*i.e.*, all items have an average score  $\geq 4$ ), and no additional revisions are needed, based on the experts' comments [12]. Two rounds were carried out to obtain a consensus.

Within the initial checklist, 10 items were deleted (check for the absence of bleeding, insertion of the speculum, removal of the speculum, removal of the Pozzi forceps...), three were rephrased (hand washing became hand

disinfection) and modified through the Delphi process. The final checklist assigned the same weight to each item, but three items specifically denoted success of insertion: intrauterine position of the IUD, not protruding into the cervix, and correct deployment of the IUD in the uterine cavity (no twisting or pushing against the wall). Because the technical procedures for inserting an IUD are relatively simple, it was more appropriate to evaluate participants by a yes/no choice for each item rather than using a multiple-choice scale. The checklist is presented on Table S1.

### *Response process*

Pilot testing of the checklist was carried out in a simulation setting similar to the one in which we planned to apply it. The response process was tested during an assessment of 10 participants (2 gynecologists, 7 general practitioners, and 1 midwife). Two independent observers who were certified for Gynecology and Obstetrics performed assessment. Sources of errors in transcription of the score and discordance among observers were identified (more than 10% discordance on item score). If necessary, they led to modifications of the checklist (rephrasing aimed at a more precise description of items) to end up with the definitive version. The final version of the IUD insertion performance assessment checklist included 27 items divided into two sections: seven items dealt with the search for contraindications of IUD in the history of the patient, and 20 items assessed the technical aspect of IUD use (equipment set-up, respect of hygiene, technical aspects of insertion) (Tab. S1).

## **Psychometric testing**

### *Participants and simulation setting*

Comparison of scores at different training times was conducted with two other populations of participants: 1/the first (sample A) included experienced practitioners who inserted at least one IUD per month and medical residents who had no practice of IUD insertion. This sample was used to analyze internal consistency and inter-observer reproducibility; 2/the second (sample B) included medical residents from the 1<sup>st</sup> to 3<sup>rd</sup> year. These participants were novices, had inserted between 1 and 10 IUDs during their residency, and in a very irregular manner depending on their rotation. Sample B was used to assess evolution of performance scores over time. Each participant was given three attempts at IUD insertion during one hour under direct supervision, called simulation 1 (S1), simulation 2 (S2) and simulation 3 (S3). Each attempt was interspersed with a debriefing and the instructions remained the same.

For all participants, a video was displayed to show the insertion of a copper IUD and a Levonorgestrel IUD (Mirena® or Jaydess®) on a mannequin prior to the simulation. Moreover, a briefing was given to the participants explaining the

anatomy of the mannequin and the equipment available to perform the procedure. Each participant was then given time for hands-on procedures to perform vaginal touch and insert a speculum in the mannequin under supervision.

During simulation, the participants were asked to insert an IUD on the model without supervision. They had their performance assessed using the final version of the checklist. Success rate was assessed during three attempts at IUD insertion with direct supervision. Since the procedures for inserting an IUD are simple, there seemed little point in repeating the insertion more than three times in a single session; this was confirmed during the period when the feasibility of the protocol was tested. The intrauterine position of the IUD was videotaped using a fibroscopic camera inserted in the wall of the uterus of the mannequin (Fig. S1). The three insertion attempts were filmed with an external camera and timed with a stopwatch. The time between IUD placement in the insertion tube and display of the IUD in the uterine cavity had to be inferior to five minutes for the IUD insertion to be considered as a success (the insertion leaflet recommends not to leave the IUD more than five minutes inside the insertion tube) [14]. The three simulations were successively performed on the same day, each of them followed by a good-judgment debriefing [16].

The primary outcome was the performance assessment score established on the checklist. Secondary outcomes were success rate (IUD not in the uterine cervix, correct display of IUD in uterine cavity), and insertion time less than five minutes. These criteria were assessed after each of the three tries. Other outcomes were concordance between assessment by direct observation and on video.

All the participants assessed the benefit of SBT in IUD insertion by filling out the satisfaction questionnaire at the end of the sessions.

### *Model*

The model used for simulation sessions was the gynecologic mannequin Zoe (Gaumard®). This task-trainer is made up of a female abdomen and pelvis, with an anteverted uterus (8 cm height). This model was modified in our laboratory, the objective being to observe the placement of the IUD inside the uterine cavity by a small cut of the uterine wall and insertion of a fibroscopic camera. It made it possible to evaluate the correct performance of hysteroscopy and to check the position of the IUD (Suppl. Fig. 1). This choice was made because the model was not suitable for ultrasound monitoring of IUD insertion.

The simulation environment was standardized; all participants from the various hospitals came to the simulation lab for testing. The IUD inserted in the model was the Mirena® IUD.

### Observers

The same two trained observers assessed performance for all simulations. All simulations were videotaped. Videos were anonymized and reviewed by the two observers in random order.

### Statistics

Analysis was performed with Statview version 4.5 (SAS Institute Inc., Cary, NC). The number of required participants was determined to analyze internal consistency and inter-observer reproducibility in sample A, and to analyze performance in sample B. Based on a previous simulation study with similar design that aimed at developing a performance checklist [17]. The number of required simulations was at least 22 for sample A and 26 for sample B. Kolmogorov-Smirnov test was used to check normal distribution for assessed measures. Continuous variables were described as mean (SD) or median and 1<sup>st</sup> and 3<sup>rd</sup> quartile (Q1; Q3). Categorical variables were described as numbers and percentage (%). Internal consistency of the checklist was analyzed by the Cronbach alpha coefficient. Inter-observer reproducibility was analyzed by the intra-class coefficient (ICC), comparison of means, and linear regression analysis (Spearman coefficient and R<sup>2</sup>). F-test was used to compare variance of scores of observers 1 and 2. Performance of participants was assessed at three different times (S1, S2, and S3). The evolution of performance scores was analyzed, using an ANOVA for repeated measures. In case of statistically significant results, the Scheffe Post hoc test was pre-specified to explore differences between multiple means while controlling the experiment-wise error rate. Performance scores were compared at different times using a Student t-test. Success rate was expressed as percentage. A p value < 0.05 was considered significant. The data collected were

used to plot receiver operating characteristic (ROC) curves for the score values. The area under the curve (AUC) as well as the sensitivity, specificity and likelihood ratios were determined for different score thresholds.

## RESULTS

### General findings

The final version of the checklist included 27 items distributed in four sections: patient history, pre-insertion procedure steps, preparation of IUD, and insertion. All in all, 57 participants carried out 111 simulations (Tab. 1). In sample A, 30 participants carried out 30 simulations. This sample included 19 experienced practitioners (*i.e.*, at least 1 IUD per month): 5 gynecologists, 6 midwives, and 8 general practitioners. This sample also included 11 medical students who had no practice of IUD insertion. Median age was 36 (25; 39) and sex ratio was 9 (30%) males and 21 (70%) females. In sample B, 27 participants carried out 81 simulations. This sample included 27 medical residents from 1<sup>st</sup> year (n = 9), 2<sup>nd</sup> year (n = 12), and 3<sup>rd</sup> year (n = 6). These participants were novices (*i.e.*, fewer than 10 IUDs during their residency). Median age was 26 (25; 27) and sex ratio was 10 (37%) males and 21 (63%) females.

### Validity analysis

Validity analysis was carried out on sample A. Twenty-seven residents performed an IUD insertion in simulation and were assessed by the checklist. Internal consistency of the checklist gave a Cronbach alpha coefficient of 0.79 (Tab. 1).

The checklist is discriminative, showing a significant increase in performance scores when the simulations were repeated ( $F = 77.6, p < 0.0001$ ). The Scheffe post-hoc test showed a difference between S1 and S2 ( $p < 0.0001$ ). All the subsection scores increased between S1 and S2 ( $p < 0.0001$ ).

**Table 1.** Psychometric testing process for validity evidence of the modified JHPIEGO checklist

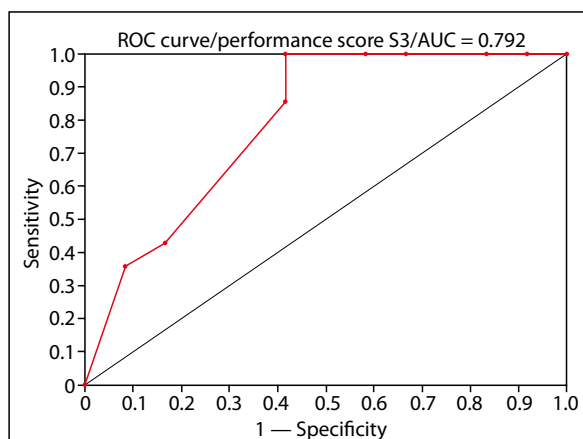
	Population tested	Assessment	Variables	Results
<b>Sample A</b>	30 multi-professional (GP, MW, GO, PGY)	30 simulations and 90 checklists filled out by 2 independent observers + 1 video reviewer	Internal consistency: CA (tested on 3 observations played 90 times) Reliability: ICC, comparison of means, comparison of variances, R <sup>2</sup>	CA = 0.79 ICC = 0.99 Means: O1 video vs O1 direct vision vs O2 video = NS F-test = NS R <sup>2</sup> = 0.90
<b>Sample B</b>	27 general medicine residents	81 simulations and 162 checklists filled out by 1 observer + 1 video reviewer	Evolution of performance scores over time during 3 simulation sessions Reliability: ICC, comparison of means, comparison of variances, R <sup>2</sup>	p < 0.0001 R <sup>2</sup> = 0.99 ICC = 0.99
<b>Total</b>	57 participants	111 simulations		

Sample A included multi-professional participants for internal consistency and reliability analysis; sample B included residents to assess score evolution over time and reliability. CA — Cronbach alpha; GO — gynecologist obstetrician; GP — general practitioner; ICC — intra-class coefficient; MW — midwife; NS — not significant; O1 — observer 1; O2 — observer 2; PGY — post-graduate year (resident); R<sup>2</sup> — square of correlation coefficient

**Table 2.** Evolution over time of intra-uterine device (IUD) insertion performance scores (n = 27)

	S1	S2	S3	ANOVA (F)	p value	Scheffe post-hoc test (p value)
Past-history score /7	3.58 ± 1.24	5.73 ± 1.04	6.19 ± 0.90	64.6	< 0.0001	Difference between S1 and S2: p < 0.0001
IUD insertion score /20	12.73 ± 2.74	17.19 ± 2.81	17.92 ± 2.33	38.4	< 0.0001	Difference between S1 and S2: p < 0.0001
Total performance score /27	16.31 ± 3.53	22.92 ± 3.24	24.11 ± 2.70	77.6	< 0.0001	Difference between S1 and S2: p < 0.0001

Scores are given as mean ± SD; S1 — first simulation; S2 — second simulation; S3 — third simulation; Analysis of the score evolution over time used an ANOVA for repeated measures and a Scheffe post-hoc test in case of significance



**Figure 1.** Receiver operating characteristic (ROC) curve for the performance score at S3 (n = 27); AUC — area under the curve

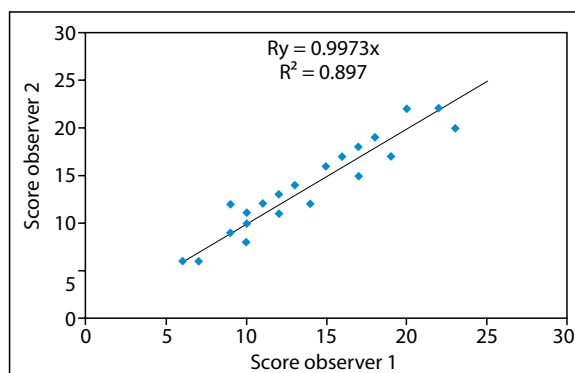
All results are given in Table 2. Success rate was 19% for S1, 46% for S2 and 53.8% for S3. The success rate significantly increased between S1 and S2 (p = 0.04).

Receiver operating characteristic (ROC) curve [AUC: 0.792 (95% CI: 0.71–0.89); p < 0.0001] revealed the best score cutoff predictive of 100% sensitivity, *i.e.*, true positive rate or success rate on this model during IUD insertion (Fig. 1). The point maximizing the positive likelihood ratio is the point of 100% sensitivity and the best ratio between sensitivity and specificity, corresponding to a score of 22/27. This finding reflected a very strong correlation between 'success' and 'process' (score on the checklist) of IUD insertion for a score  $\geq 22/27$ .

### Reliability analysis

Reliability analysis was performed on sample A and sample B (Tab. 1). There was no difference between the mean scores of observers 1 and 2 (p = 0.47) or between the mean scores of direct observation and observation of video, carried out by observer 1 (p = 0.99). Comparison of variances of means between the two observers did not find any significant difference (p = 0.94).

There was a very strong correlation between the scores of the two observers: ICC = 0.99 for sample A and B, which



**Figure 2.** Sample A, correlation between mean scores of observer 1 and observer 2 (n = 30)

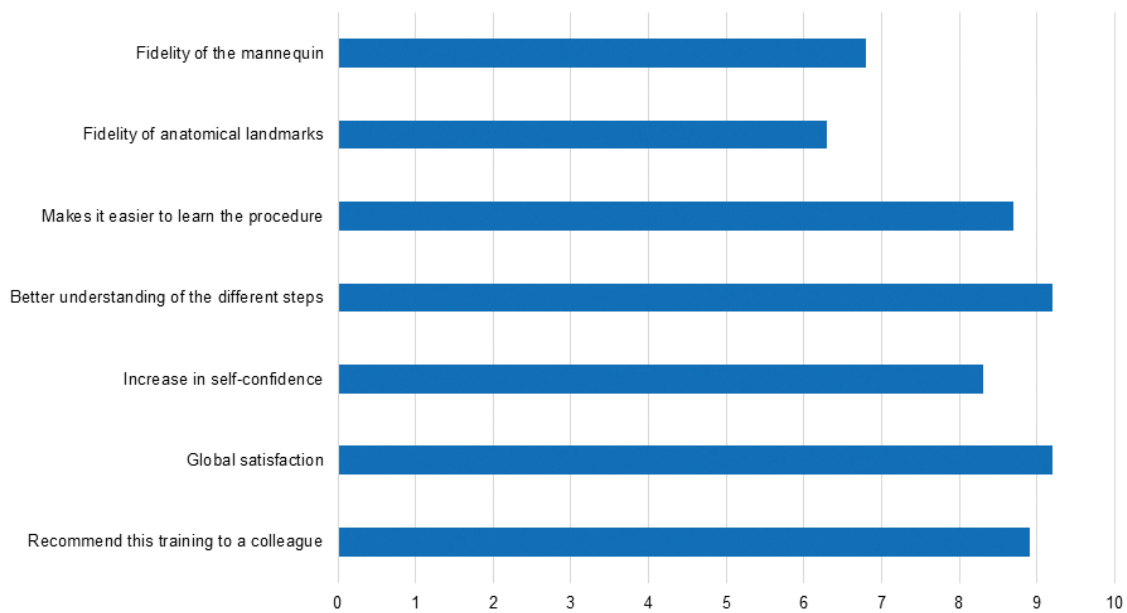
represented particularly high inter-observer reproducibility (Tab. 1). In linear regression there was a strong correlation with Spearman coefficient of 0.99 and  $R^2 = 0.90$  for sample A (Fig. 2). Linear regression showed a very strong correlation for sample B with  $R^2 = 0.99$ .

The participants considered the mannequin realistic. The vaginal cavity was often considered too smooth with a cervix that was too easy to find. Although not questioned, the presence of the intrauterine camera was greatly appreciated. Participants were very satisfied with their participation in this simulation session (Fig. 3).

## DISCUSSION

### Main results

The existing Jhpiego checklist for evaluation of an IUD insertion performance was redesigned and assessed. It was used as an assessment instrument during SBT on a task-trainer. The final version of the checklist included 27 items divided into two sections with a total score of 27. Psychometric testing showed excellent reliability and good internal consistency. To our knowledge, there currently exists no other adjustable tool with psychometric tests showing validity and reliability designed to assess clinical performance during IUD insertion. Furthermore, performance score was highly correlated to success rate of the procedure. Performance assessment with this instrument was easy to apply and well-accepted.



**Figure 3.** Answers to the satisfaction questionnaire (n = 57)

### Instrument development and psychometric properties (validity & reliability)

Creating a checklist with strong initial evidence of validity ensures that the steps for performing the procedure are valid, accurate, and comprehensive [12]. The use of this valid and reliable checklist allowed an objective evaluation of the performance in simulation before considering performance of the procedure in a clinical situation. A major improvement of performance scores was found between S1 and S2 in the present study. It could be explained by the benefit of debriefing between each try. This specific reflection time allowed participants to express their feelings, to analyze and correct their performance gaps, and it represented an essential step of the simulation sessions [18], providing safe clinical care and new knowledge [19]. Otherwise, improvement in performance scores could be partially explained by rapidly cycled deliberate practice between simulation assessments [20]: the participant repeats a task until reaching mastery level; along with feedback to close performance gaps, this constitutes an active learning technique [20]. Nevertheless, a memory effect, especially in the past-history section of the performance score, may have explained this improvement.

### Use of the instrument

Although some studies comparing simulation to classical teaching methods have not found it beneficial [20], other studies have, and implementation of simulation in curriculum has increased residents' performances [21]. As a result, the French National Gynecologist and Obstetri-

cians College recommended the completion of traditional teaching by SBT to improve performance of procedures [22]. The present study determined a cut-off score guaranteeing 100% success of insertion of the IUD in a simulation setting. Although the situation in simulation may differ from the clinical situation, from an ethical point of view, the determination of such a score makes it possible to have a minimum pedagogical objective to reach based on metric analysis before considering the real clinical situation.

Intra-uterine device insertion simulation-based education could also be implemented in initial education of different health care providers. It could furthermore be used for reassessment of professionals' competence in continuous medical education. The low cost of the task-trainer and the minimal equipment required to perform the procedure render this tool usable for teaching in low-income countries, even if the anatomical landmarks could be improved. The checklist could be enriched as practices evolve regarding the placement of IUDs, the evolution of these devices, and the modification of recommendations regarding screening for sexually transmitted infections.

### Limitations

The present study is not without limitations. The first limitation involved the task-trainer (as revealed on the questionnaire). The anatomical structures of the mannequin presented technical limitations: the cervix was relatively near the entry of the vagina, favoring IUD placement, which is not the case in clinical practice. The hard plastic of the model offered strong resistance to its manipulation and made it necessary to



pull back the insertion tube to replace the IUD inside the cervix, subsequently overestimating this event and decreasing in parallel the success rate. The second limitation involved complication of IUD insertion. While perforation is often assumed to occur at insertion, the phenomenon of late migration of the IUD out of an intra-uterine location is well-recognized as potentially leading to unintended pregnancy. Future research should look for factors that may predict late migration of IUDs from the uterus. For this purpose, the use of the present checklist in clinical situations could be considered. Finally, limitations concerning generalization of the use of the checklist exist. The checklist was tested with a copper IUD, excluding the multiload and LNG52 copper IUD and other models of IUD that were not available in France. Moreover, the checklist is related to the “two handed” inserter used in Europe, as opposed to the “single-handed” inserter in use in the USA and Canada. It would be interesting to test the checklist in these application conditions to improve its applicability to the later settings.

## CONCLUSIONS

This designed and tested, valid and reproducible checklist for IUD insertion provides an objective assessment of the procedure during SBT. According to the results, it is suggested to use this assessment checklist during simulation sessions, with the aim of obtaining a score  $\geq 22/27$  — a performance level guaranteeing success in simulation setting — prior to clinical practice. Future studies should focus on assessment of the impact of simulation practice on real-life IUD insertions.

### Article information and declarations

#### Data availability statement

All data analyzed during this study are included in the manuscript and supplemental files. Materials described in the manuscript, including all relevant raw data, are freely available to any scientist wishing to use them for non-commercial purposes, without breaching participant confidentiality. For more details, please contact the corresponding author.

#### Ethics statement

Research has been performed in accordance with the Declaration of Helsinki. IRB agreement was obtained from the Research Board of the Faculty of Medicine under the number # 2018-04-DO. Participants consented to participate, and “informed consent” was obtained from all subjects. Participants consented to the publication of de-identified data and individual details. The manuscript does not contain individual images or videos.

#### Author contributions

Contributions of authors: SM supervised the study, provided educational support for the simulation sessions, re-

viewed and completed the text; ACB and MA carried out the simulation sessions, collected and analyzed the data, analyzed the literature, and wrote the text; CB modified the Zoe mannequin (GaumardR) to obtain an intra-uterine assessment of IUD placement; JPR reviewed the text and made suggestions for the discussion; DAG: was responsible of the methodology; DO had the idea for this research and designed the study. DAG and DO drafted the manuscript, and all authors contributed substantially to its revision. All authors read and approved the final manuscript.

#### Funding

None declared. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

#### Acknowledgments

The authors would like to thank the experts who participated in the nominal group and all the medical students who participated to the simulation sessions. The authors would like to thank Jeffrey Arsham, an American scientific translator, for having reviewed the English language text.

#### Conflict of interest

None of the authors have any financial conflicts of interest in connection with the work to disclose.

#### REFERENCES

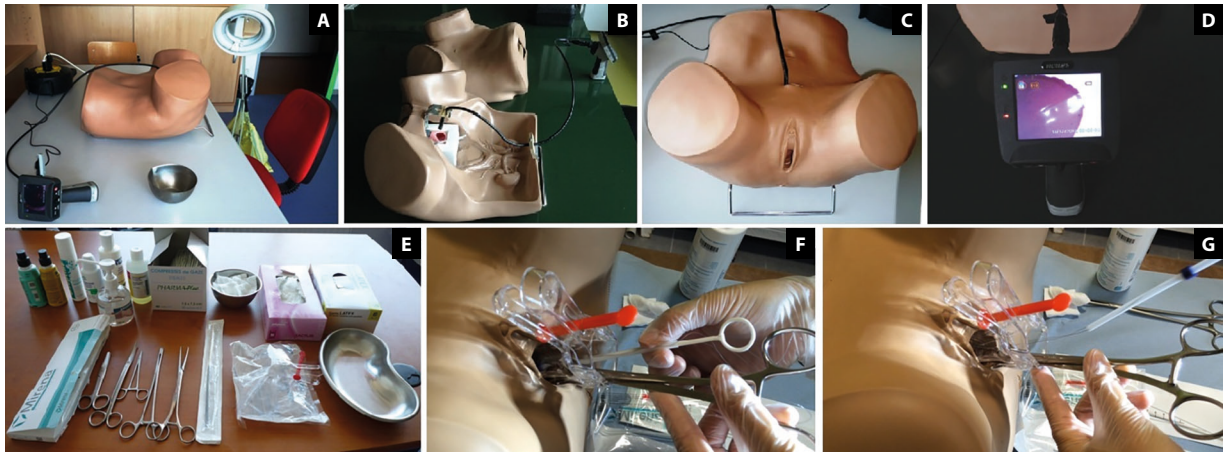
- d'Arcangues C. Worldwide use of intrauterine devices for contraception. *Contraception*. 2007; 75(6 Suppl): S2–S7, doi: [10.1016/j.contraception.2006.12.024](https://doi.org/10.1016/j.contraception.2006.12.024), indexed in Pubmed: 17531612.
- WHO. Strategies to increase use of long-acting and permanent contraception 2012. [https://assets.publishing.service.gov.uk/media/57a08a6ded915d3cfd00076c/WHO\\_RHR\\_HRP\\_12.20\\_eng.pdf](https://assets.publishing.service.gov.uk/media/57a08a6ded915d3cfd00076c/WHO_RHR_HRP_12.20_eng.pdf) (28.10.2022).
- Sun X, Xue M, Deng X, et al. Clinical characteristic and intraoperative findings of uterine perforation patients in using of intrauterine devices (IUDs). *Gynecol Surg*. 2018; 15(1): 3, doi: [10.1186/s10397-017-1032-2](https://doi.org/10.1186/s10397-017-1032-2), indexed in Pubmed: 29386988.
- Caliskan E, Oztürk N, Dilbaz BO, et al. Analysis of risk factors associated with uterine perforation by intrauterine devices. *Eur J Contracept Reprod Health Care*. 2003; 8(3): 150–155, indexed in Pubmed: 14667326.
- Harrison-Woolrych M, Ashton J, Coulter D. Uterine perforation on intrauterine device insertion: is the incidence higher than previously reported? *Contraception*. 2003; 67(1): 53–56, doi: [10.1016/s0010-7824\(02\)00417-1](https://doi.org/10.1016/s0010-7824(02)00417-1), indexed in Pubmed: 12521659.
- Dubuisson JB, Mugnier E. Acceptability of the levonorgestrel-releasing intrauterine system after discontinuation of previous contraception: results of a French clinical study in women aged 35 to 45 years. *Contraception*. 2002; 66(2): 121–128, doi: [10.1016/s0010-7824\(02\)00329-3](https://doi.org/10.1016/s0010-7824(02)00329-3), indexed in Pubmed: 12204786.
- Moreau C, Bohet A, Hassoun D, et al. FECOND group. IUD use in France: women's and physician's perspectives. *Contraception*. 2014; 89(1): 9–16, doi: [10.1016/j.contraception.2013.10.003](https://doi.org/10.1016/j.contraception.2013.10.003), indexed in Pubmed: 24239330.
- Jhpiego Corporation, affiliated with The Johns Hopkins University. Providing long-acting reversible contraception (LARC). Course notebook for learners. Jhpiego Corporation, Brown's Wharf, Baltimore, Maryland, USA. 2015. [https://pdf.usaid.gov/pdf\\_docs/PA00W8C9.pdf](https://pdf.usaid.gov/pdf_docs/PA00W8C9.pdf) (28.10.2022).
- McBain L, Pullon S, Garrett S, et al. Genital examination training: assessing the effectiveness of an integrated female and male teaching programme. *BMC Med Educ*. 2016; 16(1): 299, doi: [10.1186/s12909-016-0822-y](https://doi.org/10.1186/s12909-016-0822-y), indexed in Pubmed: 27876033.

10. Hiraoka M, Kamikawa G, McCartin R, et al. A pilot structured resident orientation curriculum improves the confidence of incoming first-year obstetrics and gynecology residents. *Hawaii J Med Public Health*. 2013; 72(11): 387–390, indexed in Pubmed: 24251084.
11. Nippita S, Haviland MJ, Voit SF, et al. Randomized trial of high- and low-fidelity simulation to teach intrauterine contraception placement. *Am J Obstet Gynecol*. 2018; 218(2): 258.e1–258.e11, doi: [10.1016/j.ajog.2017.11.553](https://doi.org/10.1016/j.ajog.2017.11.553), indexed in Pubmed: 29138033.
12. Sawyer TL, White ML et al. INSPIRE Procedural Checklists Development and Validation Instructions. <https://inspiresim.org/annual-report/downloadable-documents/> (28.10.2022).
13. TRP Training Resource Package for Family Planning. Intrauterine Devices (IUDs). <https://www.fptraining.org/training/18/sessions> (28.10.2022).
14. Mirena 20 micrograms/24 hours intrauterine delivery system. The electronic medicines compendium (emc). Last updated 5 Jan 2021. <https://www.medicines.org.uk/emc/product/1132/smpc#gref> (28.10.2022).
15. McMillan SS, King M, Tully MP. How to use the nominal group and Delphi techniques. *Int J Clin Pharm*. 2016; 38(3): 655–662, doi: [10.1007/s11096-016-0257-x](https://doi.org/10.1007/s11096-016-0257-x), indexed in Pubmed: 26846316.
16. Bowe SN, Johnson K, Puscas L. Facilitation and debriefing in simulation education. *Otolaryngol Clin North Am*. 2017; 50(5): 989–1001, doi: [10.1016/j.otc.2017.05.009](https://doi.org/10.1016/j.otc.2017.05.009), indexed in Pubmed: 28822579.
17. Ghazali DA, Delaire C, Blottiaux E, et al. Development of a performance assessment scale for simulated dispatcher-assisted cardiopulmonary resuscitation (telephone-cpr): a multi-center randomized simulation-based clinical trial. *Prehosp Disaster Med*. 2021; 36(5): 561–569, doi: [10.1017/S1049023X21000716](https://doi.org/10.1017/S1049023X21000716), indexed in Pubmed: 34296667.
18. Weinger MB, Banerjee A, Burden AR, et al. Simulation-based assessment of the management of critical events by board-certified anesthesiologists. *Anesthesiology*. 2017; 127(3): 475–489, doi: [10.1097/ALN.0000000000001739](https://doi.org/10.1097/ALN.0000000000001739), indexed in Pubmed: 28671903.
19. McGaghie WC, Issenberg SB, Cohen ER, et al. Does simulation-based medical education with deliberate practice yield better results than traditional clinical education? A meta-analytic comparative review of the evidence. *Acad Med*. 2011; 86(6): 706–711, doi: [10.1097/ACM.0b013e318217e119](https://doi.org/10.1097/ACM.0b013e318217e119), indexed in Pubmed: 21512370.
20. Gordon JA, Shaffer DW, Raemer DB, et al. A randomized controlled trial of simulation-based teaching versus traditional instruction in medicine: a pilot study among clinical medical students. *Adv Health Sci Educ Theory Pract*. 2006; 11(1): 33–39, doi: [10.1007/s10459-004-7346-7](https://doi.org/10.1007/s10459-004-7346-7), indexed in Pubmed: 16583282.
21. Steadman RH, Coates WC, Huang YM, et al. Simulation-based training is superior to problem-based learning for the acquisition of critical assessment and management skills. *Crit Care Med*. 2006; 34(1): 151–157, doi: [10.1097/01.ccm.0000190619.42013.94](https://doi.org/10.1097/01.ccm.0000190619.42013.94), indexed in Pubmed: 16374169.
22. <http://http://www.cngof.net/Journees-CNGOF/MAJ-GO/RPC/extraction-instrumentale-2008.pdf>. <http://http://www.cngof.net/Journees-CNGOF/MAJ-GO/RPC/extraction-instrumentale-2008.pdf> (28.10.2022).

## SUPPLEMENTARY MATERIAL

Table S1. Intra-uterine device (IUD) insertion performance assessment checklist, obtained after Delphi method and response process		
<b>1. Past history</b>		
Assess the risk of ongoing pregnancy (last period date or contraceptive or recent BHCg measurement)	Yes	No
Ask for the time elapsed since the most recent childbirth	Yes	No
Ask about ongoing breastfeeding	Yes	No
Inquire about gynecologic past-history	Yes	No
Ask if previous gynecologic infections	Yes	No
Search for risk factors of sexually transmitted infections	Yes	No
Propose to the patient a screening for Chlamydia trachomatis	Yes	No
<b>2. Pre-insertion steps</b>		
Has chosen all the pieces of equipment required for IUD insertion	Yes	No
Handwashing with hydro-alcoholic solution for at least 20 seconds	Yes	No
Performs a vaginal touch and determines height and position of uterus	Yes	No
Puts clean gloves on	Yes	No
Cleans cervix orifice and vaginal walls	Yes	No
Utilizes a specific solution for cleaning (dermic Proviodyne or vaginal Proviodyne)	Yes	No
Catches cervix with a Pozzi clamp	Yes	No
Applies moderate pull back on the Pozzi clamp	Yes	No
Performs a hysteroscopy by inserting the tube until the uterine fundus (video control)	Yes	No
Finds a uterine height between 7 and 9 cm (read on the hysteroscope)	Yes	No
<b>3. Preparation of the IUD</b>		
Opens the tip of the wrapping allowing sterile manipulations of the IUD through the wrapping	Yes	No
Inserts the IUD in the distal opening of the insertion tube by pulling back on threads	Yes	No
Extremities of lateral arms of IUD slightly exceed (1 mm) the distal extremity of the insertion tube	Yes	No
Position the rear of the blue ring at a distance to the distal extremity of the insertion tube equivalent to those found at hysteroscopy with its large transversal axis in the same plane as the one for display of IUD lateral arms	Yes	No
<b>4. IUD insertion</b>		
Introduces the assembly (insertion tube-IUD-pusher) in the cervical canal until the blue ring is touching the exocervix	Yes	No
Stabilizes the pusher and pulls back the insertion tube until disappearance of the pusher's smooth part (at the beginning of the grooved portion)	Yes	No
Pushes in bloc the whole assembly (insertion tube-IUD-pusher) until the blue ring is still touching the exocervix	Yes	No
Stabilizes the pusher and pulls back the insertion tube until the pusher ring (by going over the grooved portion)	Yes	No
Removes in two steps the pusher, and then the insertion tube	Yes	No
Cuts the threads at 2 cm ± 0.5 cm from the exocervix	Yes	No
Total score: .../27		





**Figure S1.** Modified gynecologic mannequin Zoe (Gaumard<sup>®</sup>) to observe the placement of the IUD inside the uterine cavity using a fibroscopic camera; **A.** Gynecologic mannequin Zoe (Gaumard<sup>®</sup>); **B, C.** Small cut of the uterine wall and insertion of a fibroscopic camera; **D.** Visualization of the uterine cavity; **E.** equipment required for IUD insertion; **F.** IUD insertion in the cervical canal; **G.** Remove of the pusher and then the insertion tube in two steps