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Assessment and validation of a low-cost ultrasound-guided suprapubic catheter insertion training (USCIT) model

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Assessment and validation of a low-cost ultrasound-guided suprapubic catheter insertion training (USCIT) model

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A Research Report submitted to the Faculty of Health of the University of the Witwatersrand, Johannesburg, in partial fulfillment of the requirements for the degree of Master of Medicine in Emergency Medicine

Johannesburg, 2019

Contents **Page**

Declaration i

Dedication ii

Acknowledgements iii

Submission format of this research iv

Manusrcipt 1 1- 23

Manuscript 2 24 - 48

Appendix 1: Research Protocol 49 - 65

Appendix 2: Ethics clearance certificate 66

Appendix 3: Article 1 - Journal Reprint PDF 67

Appendix 4: Article 2 - Confirmation of manuscript acceptance for publication 68

Appendix 5: Turn-it-in report 69

DECLARATION

I, James Nonde, hereby declare that this research report is my own work and has not been submitted or presented for any other degree or professional qualification at this or any other Institute. This research was undertaken in the Division of Emergency Medicine, University of the Witwatersrand, Johannesburg.

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Signature of Supervisor 2:  Date: 15/07/19

DEDICATION

This research is dedicated to: My Lord, the Creator, the sustainer, the All Knowing

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I would like to express my sincere gratitude to:

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My supervisors, Prof Abdullah Ebrahim Laher and Prof Ahmed Adam for their continual assistance, time, patience, dedication, motivation and guidance.

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Submission Format

1st part "a published article" of the original work

2nd part "an article in press "a systematic review on the topic

MANUSCRIPT 1

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Contents	Page
Manuscript title and authors	2 - 4
Conflict of interest, key words, funding and author contribution	4 - 5
Agreement by co-authors	6
Abstract	7
Main text introduction	8 - 9
Materials and methods	9 - 14
Figure 1: Construction of US-SCIT model	11
Figure 2: Images of SPC insertion using the US-SCIT	12
Results	12 - 15
Comment	15 - 20
Potential limitations	20
Conclusion	21
References	22 - 23

MANUSCRIPT TITLE

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CONFLICTS OF INTEREST

The authors hereby certify that this submission is not under publication consideration elsewhere and is free from any conflict of interest

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AUTHOR CONTRIBUTIONS

JN: Guarantor of the manuscript and responsible for the integrity of the data and the accuracy of the data analysis; data collection, statistical analysis and interpretation of the data; and drafting, writing, review and incorporating co-author feedback, revision, and final approval of the submission.

AA: Contributed to the concept and design, analysis and interpretation of the data, and the drafting, writing, review, revision and approval of the manuscript, corresponding author.

AL: Contributed to the concept and design, analysis and interpretation of the data, and the drafting, writing, review, revision and approval of the manuscript.

AGREEMENT BY CO-AUTHORS

By signing this declaration, the co-authors listed below agree the use of the article by the student as part of his Research Report.

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ABSTRACT

Objectives: To validate the newly designed ultrasound-guided suprapubic catheter insertion trainer (USSCIT) model against the real-life experience by enrolling participants with prior confidence in the technique of US-guided suprapubic catheter (SPC) insertion.

Methods: The US-SCIT was self-constructed from common disposables and equipment found in the emergency department. A validation questionnaire was completed by all participants after SPC insertion on the US-SCIT model.

Results: Fifty participants enrolled in the study. Each participant had reported confidence in the SPC insertion technique, prior to participation in this study. There were 13 "super-users" (>65 previous successful real life SPC insertions) in the study. The total material cost per US-SCIT unit was 1.71 USD. The US-SCIT's value in understanding the principals of US-guided SPC insertion had a mean score of 8.86 (standard deviation [SD] 1.03), whereas its value in simulating contextual anatomy had a mean score of 8.26 (SD 1.48). The mean score of the model's ability to provide realistic sensory feedback was 8.12 (SD 1.78), whereas that of realism of initial urine outflow was 9.06 (SD 1.20). Simulation with the model compared well with real life SPC insertion, with a mean score of 8.30 (SD1.48).

Conclusion: The US-SCIT model performed well in various spheres developed to assess its ability to simulate real-life SPC insertion. We are confident that this low- cost, validated, US compatible SPC trainer, constructed from common material present in the ED, will be a valuable learning asset to trainees across the globe.

INTRODUCTION

"There is no excuse today for the surgeon to learn on the patient".[1]

Almost a century later and this statement still holds true for training and simulation in both elective and emergent urologic conditions. Among the acute conditions in urology, acute urine retention (AUR) is a common presentation to the emergency department (ED), with an estimated, once-off, incidence of 10% among men in their 70s.[2] AUR is a medical emergency requiring emergent relief and it is not uncommon for urethral catheterization to either fail or be contraindicated. Thus, suprapubic catheter (SPC) insertion is a fundamental skill that needs to be efficiently performed in the ED.

SPC insertion is considered to be a relatively safe procedure, as the full bladder has a tendency to displace bowel away from the anterior part of the lower abdominal cavity. Despite this, the risk of bowel injury is estimated to be up to 2.4% with an associated mortality rate of 1.8%.[3] These complications have led to increased advocacy for the incorporation of ultrasound (US) imaging to limit iatrogenic injury to interposed loops of bowel. In light of this, US has been listed as a vital component in the British Association of Urological Surgeons SPC insertion guidelines.[4] The value of US has been further demonstrated in a study where the use of a sonar device, resulted in successful SPC insertion in 23 of 24 patients in whom blind insertion had originally failed.[5]

In the ED, SPC insertions are frequently required to be performed under emergency circumstances or during awkward times of the shift, leaving little or no chance to teach first-time performers. Thus, it is imperative to incorporate simulation training in the curriculum for

teaching of this vital skill.[6] Like any other simulator, an ideal SPC insertion model must fulfill a number of predetermined criteria. It must constitute a very close contextual anatomical resemblance to the real-life specimen and provide sensory feedback that replicates an actual clinical scenario. These properties would allow the trainee to easily translate the performance of the skill from a simulated model into real-life SPC insertion.[7]

A number of models have been developed with varying costs and aesthetics. However, the majority are not US compatible. We hence designed and developed the ultrasound guided suprapubic catheter insertion trainer (US-SCIT).

We aimed to validate the US-SCIT model against the real-life experience, by enrolling participants who reported prior confidence in the technique of US-guided SPC insertion.

MATERIALS AND METHODS

US-SCIT Model Construction

Using everyday items commonly found in the ED, construction of the US-SCIT was performed as follows (average time for construction from beginning was 8 minutes):

(1) Consumables or items required

These included: a standard surgical glove, waterproof Leukoplast Sleek tape, a used (empty) 1liter intravenous fluid infusion bag, a used (empty) glove or tissue box, paper towel, a black dust bin (refuse) plastic bag, a cervical spine immobilizer (trauma head blocks), and a linen saver (optional). For the procedure, a US scanning device with a curvilinear low frequency US transducer, US gel, and an SPC set (including needle for aspiration) were also required for SPC insertion (Fig. 1A).

(2) The distended "bladder"

To construct the distended "bladder", the 4 fingers of a size 7.5 latex surgical glove were tied together into 1 knot. This was followed by a single knot, to tie off the wrist end of the glove. The distal 1-2 cm of the "thumb" of the glove was then cut off to allow the glove to be filled with approximately 700 ml of tap water. The "thumb" opening was thereafter tied off with a double knot to seal off the distended "bladder" (Fig. 1B). Two strips of 5.0 cm × 7.5 cm of waterproof Leukoplast Sleek were finally applied to reinforce the anterior surface of the newly constructed "bladder" (Fig. 1C).

(3) Structural supports

The "bladder" was then inserted into a used (empty) glove or tissue box, via the side opening (on 1 side) and pulled into position via the other side opening (on the opposite end) of the box, so as to position the anterior part of the bladder directly underneath the oval aperture situated at the top end of the box. Finally, both ends of the box were stuffed with crumpled paper towel to keep the bladder in place (Fig. 1D). Both ends of the box were thereafter sealed with Leukoplast Sleek tape.

(4) Fascia and rectus muscle

Both ends of a used 1liter saline or Ringer's lactate intravenous fluid bag were cut off to let out any air or residual fluid. The bag was then tightly strapped over the oval aperture of the glove box with sleek tape (Fig. 1E).

(5) Symphysis pubis

The model was placed between trauma head blocks and strapped down firmly for stability (Fig. 1F).

(6) Skin and masking of internal contents

The entire unit was placed in a black refuse bag so as to limit visual bias (Fig. 2).

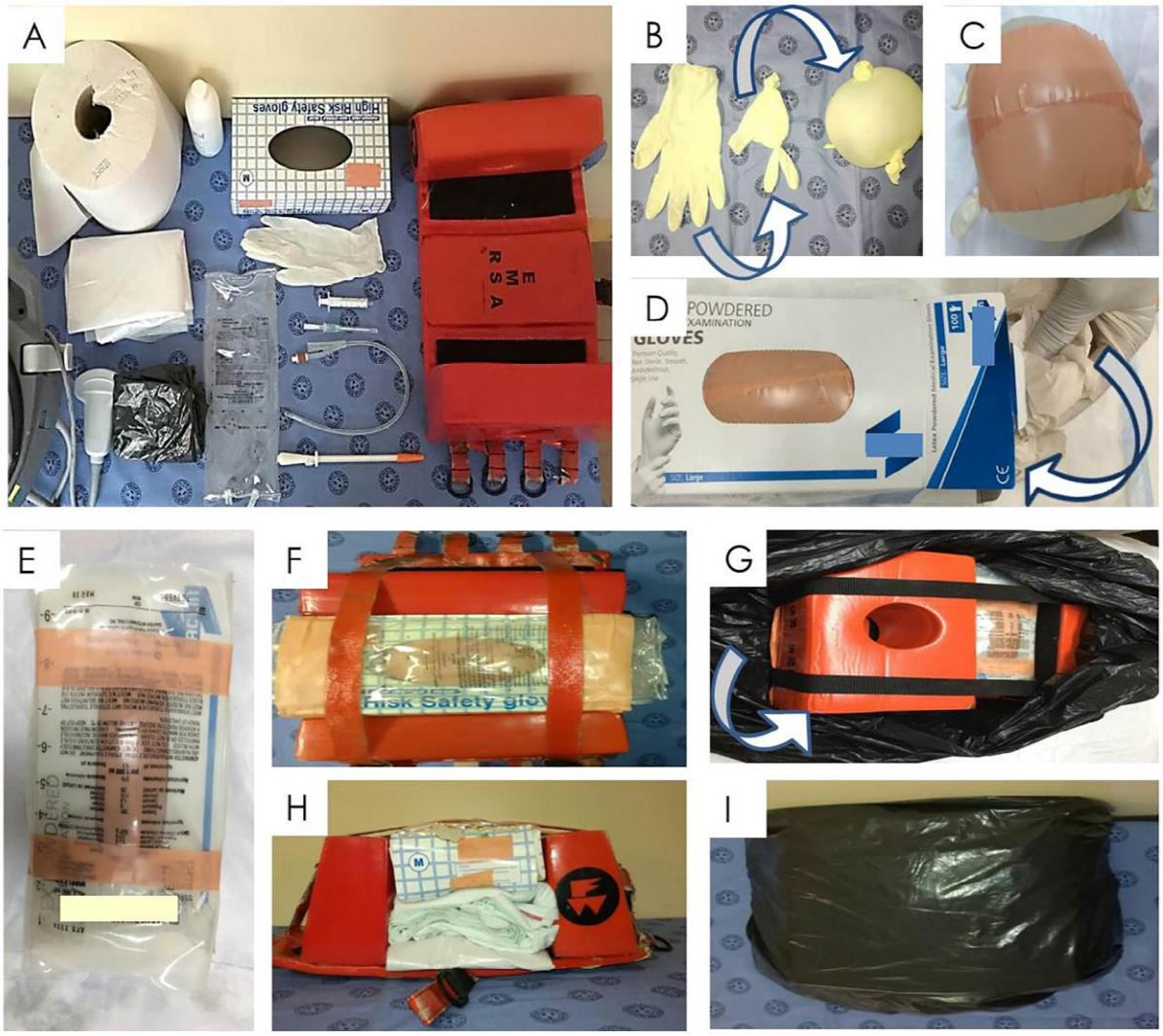


Figure 1. Construction of the ultrasound-guided suprapubic catheter insertion trainer (US-SCIT) model. (A) Items required to construct the US-SCIT model (B) and (C) constructing the "distended bladder". (D) The "bladder" is placed into the used glove box through the side opening and paper towel is stuffed on either side of the box. (E) A used intravenous fluid infusion bag is secured and taped over the glove box. (F) Model secured between trauma head blocks. (G) The unit is placed in a black dustbin (refuse) plastic bag. (H) (Optional step): If the height is a concern due to a discrepancy between the used box and the trauma head blocks, linen

savers, or linen can be folded up and used to elevate the level of the superficial structures. (I) US-SCIT model ready for simulation.

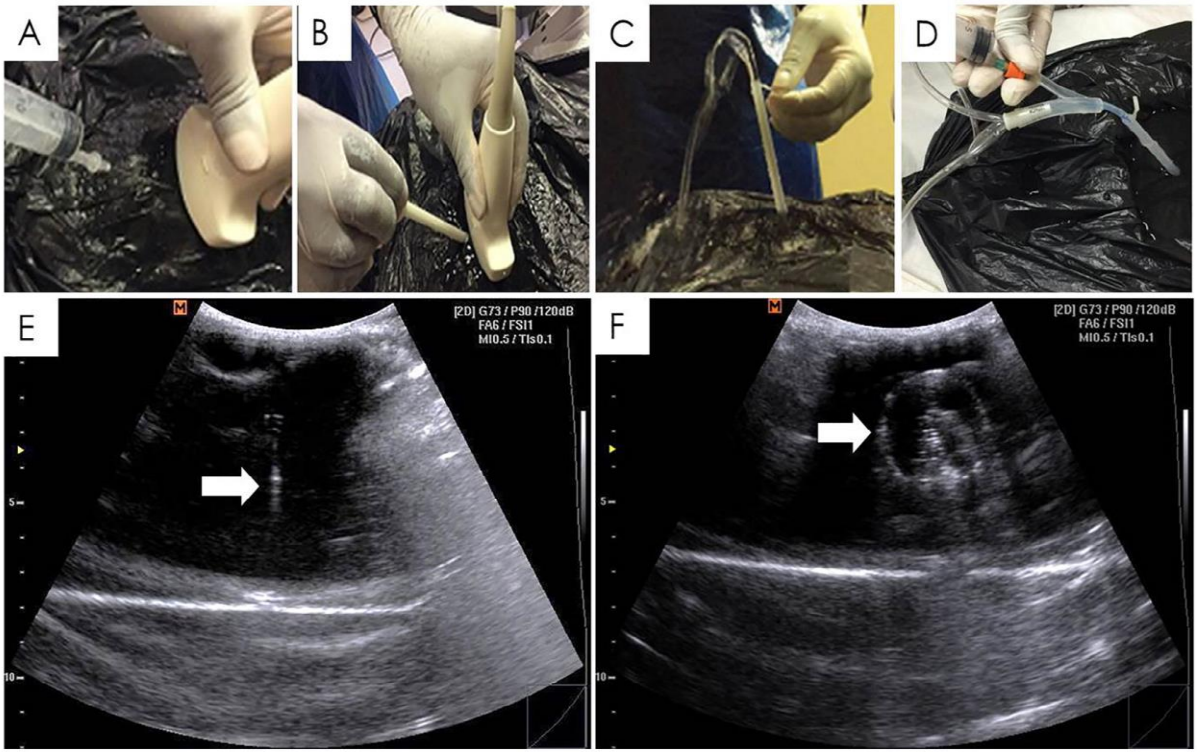


Figure 2. Images of the suprapubic catheter insertion simulation using the ultrasound-guided suprapubic catheter insertion trainer. (A) Needle aspiration (cf Fig. 2E). (B) Trocar insertion; (C) a strong "urine" stream is seen after trocar withdrawal. (D) Catheter balloon is inflated, while confirming placement with ultrasound (US) (cf Fig. 2F). (E) US image of the needle tip (arrow) seen within the bladder (cf Fig. 2A). (F) US image of the inflated suprapubic catheter balloon (arrow) within the "bladder" (cf Fig. 2D).

Validation of the US-SCIT Model

The US-SCIT model was subjected to validation by medical doctors that had reported prior confidence in the technique of US-guided SPC insertion and had previously performed at least

one real-life insertion efficiently. An expert, "super-user" was defined as a participant who had previously placed more than 65 SPCs.[8] An ultrasound device (Samsung Medison Sonoacer R3) with a CN2-8, 3.5-6 MHz curvilinear US probe, was used to perform the SPC insertion.

Participants were blinded to the components of the US-SCIT model, and the steps taken in the construction of the model. Participants were first asked to locate the "distended bladder" under US guidance and confirm presence of "urine" by aspirating with an 18G Smiths medical IV radiopaque JELCO attached to a 20 ml syringe. Participants thereafter proceeded with SPC insertion (Lawrence Add-a-Cath SPC trocar introducer size 16Fr [Femcare-Nikomed, Hampshire, UK]) transverse technique.[9] Upon removal of the trocar, as the "urine" gushed out through the sheath, a size 16Fr 2-way silicon Foley catheter (Akacia Medical, Isando, Kempton Park, South Africa) with an empty 2000 ml urine bag preconnected to the catheter outlet was inserted into the "bladder" via the sheath. The catheter balloon was inflated with 10-15 ml of tap water, and the sheath was removed from the model. Successful catheter placement was confirmed by US prior to allowing for complete emptying of the "bladder" and observing for "urine" flow into the catheter bag.

After completion of SPC insertion, each participant was asked to rate various components of the simulation by completing a 10-point questionnaire (Appendix S1). The various categories assessed were each scored out of a possible 10 points with zero 0 being "no value" to 10 being "greatest value" score.

Every study participant utilized a "new" US-SCIT model during their participation. Local institutional ethics clearance was obtained (Certificate No M170610) prior to commencement of the study.

RESULTS

The distribution of the 50 study participants included 14 consultants, 20 registrars, and 16 medical officers attached to various clinical disciplines, with most (19 of 50) from within the field of Urology. Study participants included medical officers (Urology = 8) (Emergency Medicine = 4) (General Surgery = 4), registrars (Urology = 4) (Emergency Medicine = 10) (General Surgery =5) (Chemical Pathology = 1), and consultants (Urology = 7) (Emergency Medicine = 3) (General Surgery = 3) (Orthopedics = 1).

The median number of previous successful real life SPC insertions for the entire group of fifty participants was 20. Twenty-four (48.0%) participants had successfully placed more than 20 real life SPCs and a total of 13 (26.0%) participants were experts or "super users".[8] The median number of previous successful real-life insertions for the "super users" was 100.

All participants successfully inserted the SPC using the US-SCIT on first attempt. The model scored a mean of more than 8.00 in 9 out of the 10 performance categories that were assessed by all the study participants, whereas the mean scores were 8.00 or higher in 8 out of the same 10 characteristics in the "super user" cohort. The US-SCIT model's "ability to improve confidence to perform SPC insertion" had a mean score 8.98 (SD 1.04), while the highest ratings were observed in the "realism of initial urine outflow" (mean 9.06, SD 1.20). Most of the participants agreed that "the addition of US made a difference" in adding value to the technique of SPC

insertion. The lowest score was a mean of 7.23 (SD 2.17) in the "super user" cohort for the "realism of resistance to force of trocar advancement". The "value of US in SPC insertion" was reaffirmed with a mean score of 9.62 (SD 0.65) among the "super users". Mean and SD rating scores of the model's performance characteristics are tabulated in Table 1.

The average time taken to construct the complete US-SCIT unit, from the beginning was under 8 minutes. The estimated total material cost for constructing each US-SCIT model was 1.71 USD. Details of the materials and their cost are outlined in Table 2.

Table 1. Participants' mean scores for the US-SCIT model.

Features Assessed	All study participants (n=50)		'Super User' cohort (n=13/50)	
	MEAN	**SD**	**MEAN**	**SD**
1. Value of US-SCIT in understanding US-guided SPC insertion	8.86	1.03	8.54	1.20
2. Value of US-SCIT in simulating contextual anatomy	8.26	1.48	8.00	1.63
3. Provision of realistic sensory/tactile feedback	8.12	1.78	7.77	1.64
4. Realism of resistance to force of trocar advancement	7.78	2.02	7.23	2.17
5. Overall rate of US-SCIT simulation compared to real life SPC insertion	8.30	1.48	8.08	1.50
6. Model's ability to improve confidence to perform SPCs insertion.	8.98	1.04	8.69	1.32
7. Realism of initial urine outflow	9.06	1.20	8.87	0.93
8. Value to participants scope of practice	8.84	1.41	8.08	1.89
9. Value of Ultrasound in SPC insertion	9.58	0.76	9.62	0.65
10. Does the addition of Ultrasound make any difference?	9.28	0.90	9.31	0.75

SD, standard deviation; SPC, suprapubic catheter; US-SCIT, ultrasound-guided suprapubic catheter insertion trainer

Table 2. Material cost breakdown, for each US-SCIT model unit

Component	**Material**	**Cost (USD)**
Distended Bladder	Latex 7.5 Surgical glove (each)	0.11
	Waterproof Leukoplast® Sleek 50mm X 150mm	1.24
Structural Supports	Paper Towel 2-ply 26cm X 11m x 3 sheets	0.14
	Empty (used) Gloves/tissue box	0.00
Sheath, Fascial layer	Empty (used) 1Litre Saline or Ringer's Lactate intravenous fluid bag	0.00
Skin	Black (Dust bin) refuse plastic bag (each)	0.22
Total Cost		**1.71**

COMMENT

Fundamental surgical and procedural skills have are practiced and reinforced via apprenticeship, or situated learning. This often meant practicing while placing patients at unnecessary risk of injury or complication. Simulation training provides realistic environments in which skills can be acquired and practiced repeatedly without the associated patient risk.[10] There is growing interest in simulation teaching in Urology with the continued development and validation of various simulation teaching methods.[11,12]

Previous Validated SPC Trainer Models

The UroEmerge model (2008), is an SPC trainer that utilizes a filled 3-liter irrigation bag with 2 tourniquet constrictions applied to create the distended bladder. This is housed in a plastic trainer box. The abdominal closure pad (Limbs & Things, Bristol, UK) is used to simulate the sheath, skin, and superficial fat pad. This model allowed juniors to train and perform SPC insertions.[13]

A more easy to reproduce "Lunch-box" trainer model (2013) that makes use of a party balloon covered with Mefix tape (Molnlycke Health Care, Gothenburg, Sweden) and housed in a plastic "lunch box" like container has also been described. Household sponges and Transpore layers are used to simulate abdominal wall resistance. Their study reported an estimated cost per trainee of 16.27 USD.[14]

Later, the UCH Bladder Manikin (2014) was developed, which is a trainer composed of foam, placed between 2 layers of leather, with a water-filled glove to simulate the "distended bladder". This model was constructed for use in a resource constrained setting and allows for both open

and percutaneous SPC insertion. This trainer is housed in a wooden box, which allows for multiple attempts, since 9 separate compartments where demarcated within 1 trainer box.[15]

Another low cost, anatomically correct SPC insertion simulator (2015) was developed by the Centre for Education in Medicine (Chicago, USA), utilizing urethane foam with resin glue to simulate the bony pelvis and silicone rubber with a Luer lock to maintain bladder distention. The total cost of this model was reported as 31.28 USD, although the authors mention that certain components may be reused.[8]

During the recent, United Kingdom's first 5-day intensive boot camp, the "emergency urological" SPC insertion station utilized the Advanced Male Catheterization Trainer model (Limbs & Things).[16] Like all the previously listed models, this trainer is not ultrasound compatible. Participant feedback from attendees at the boot camp, listed the SPC training station as "too simple". This response may also be explained by the skill level of the attendees assessed. The online listed cost for this SPC trainer (Limbs & Things) was 2564 USD.[16,17]

The importance of utilizing US guidance for SPC insertion, has become established in practice guidelines.[4] To incorporate this vital adjunct of SPC insertion, the first US compatible SPC trainer, the VesEcho training system (2017) was developed. This model, which was validated by 13 residents, consists of a water balloon (bladder) and nonrebreather masks (rectus fascia) that is housed within a replica of a pelvic model composed of a mixture of gelatin, psyllium, and water. The cost of this model was estimated at 60 USD.[18]

In comparison with the only other previous validated US compatible trainer (the VasEcho training system), the cost factor has been drastically improved with the construction of the US-SCIT model.

Furthermore, the validation of the US-SCIT was performed by 50 participants with 13 "super users", while validation of the VasEcho training system was observed during the participation of 13 participating urology residents. The components required for the US-SCIT model, are easily attainable and the process of production is not as time consuming as that of the VasEcho training system.[18]

Practical Aspects of SPC Insertion

Besides AUR, other indications for SPC insertion include; chronic urinary retention, neurological disease, urinary incontinence, postoperative care, urethral trauma, palliative use, and for urodynamic investigation.[4]

The algorithm performed at our center adheres to the British Association of Urological Surgeons SPC insertion algorithm, where questions answered within the treatment ladder include the history of previous lower abdominal surgery, a palpable bladder, and the presence of a distended bladder on US assessment.[4]

The contraindications for SPC insertion include: carcinoma of the bladder, anticoagulation or antiplatelet treatment, abdominal wall sepsis, and the presence of a femoro-femoral crossover graft.[4]

Technical Aspects in the Construction of the USSCIT Model

Prior to participant enrolment in this study, 25 US-SCIT models were tested and refined by the authors (JN, AA, and AEL). The following points on the construction aspects were observed:

(1) Filling the glove from the wrist end allowed for the entry of air bubbles and dead space which impacts on the quality of the US image generated. We therefore advocate filling the glove from the cut "thumb" end and tying the remaining fingers into a knot.

(2) The use of powdered gloves provides a more realistic bladder image on US. This is due to the powder closely resembling "sediment" that may be found within the bladder.

(3) Under-filling the glove does not allow for the urine stream jet when removing the trocar. We therefore recommend filling the glove with at least 600- 700 ml of water.

(4) Glove or tissue boxes with openings on either short side allow for easier passage of paper towel and the distended "bladder".

(5) Double bladder shadowing may be observed at increased depth settings if too much US gel is applied or if a tight seal is not present between the intravenous fluid bag layers.

(6) An echogenic needle tip enhances needle visibility on the US-SCIT.

(7) The empty (used) fluid bag utilized may allow for a tighter seal if the bottom edges of the bags are cut open, as the intravenous drug port may allow for air space between the "sheath".

(8) The layers above the "bladder" are to be compressed as close as possible to the anterior "bladder". This is achieved by taping (strapping) down the layers on both sides of the US-SCIT model, as displayed in Figure 1E. This important step avoids "dry coupling" between the layers and thus avoids obscurities in the resultant image.

(9) Correct application of the Leukoplast Sleek tape involves covering the anterior "bladder" surface, after it has been filled and tied, so any anterior point of access is possible without the "bladder" "popping" with needle aspiration.

(10) Dust bin (refuse) bags can be reused more than once, as the SPC incision site is only a 1 to 2 cm wide.

(11) The Lawrence Add-a-Cath SPC trocar introducer (Femcare-Nikomed, UK) can be reused multiple times, if the sheath is not torn during the insertion process. This will also save in the future training and service costs.

(12) To produce a more realistic color of "urine", 5 ml of Povidone-Iodine solution may be added to the "bladder", prior to adding tap water.[12]

Potential Limitations

The cost of the cervical-spine immobilizer (estimated at 60 USD) was not included in the total cost, as it can be returned for its original intended clinical use after simulation training. The Lawrence Add-a-Cath sheath cost was also not considered, as this component may be reused multiple times in simulation sessions. However, certain previous models described earlier have incorporated this cost into their model construction costs.

This study was not aimed at comparing the various SPC trainers available but has now successfully validated the novel US-SCIT model, which can be utilized in resource constrained environments.

Further, the time required to construct the US-SCIT model may be longer during the initial stages. This potential constraint must be factored in, when preparing for larger training simulation sessions.

CONCLUSION

SPC insertion training should incorporate the use of validated, affordable, and US compatible models that offer trainees an experience that closely resemble real-life insertion. The US-SCIT model received great reviews by the participants as seen from the median scores that were achieved. The materials required to construct the US-SCIT model are generally available in any basic ED unit, and can be constructed from beginning to end, in less than 8 minutes. We are confident that this affordable, easy to construct and now validated trainer model would add value to the simulation of this fundamental skill in all environments, including resource limited and regional centers, across the world.

REFERENCES

1. Mayo WJ. Medical education for the general practitioner. *JAMA*. 1927;88:1377-1379.

2. Marshal JR, Brian AEBJ. An evidence-based approach to emergency department management of acute urinary retention. *Emerg Med Pract*. 2014;16:PMID: 24804332.

3. Ahluwalia RS, Johal N, Kouriefs C, et al. The surgical risk of suprapubic catheter insertion and long-term sequelae. *Ann R Coll Surg Engl*. 2006;88:210-213. doi:10.1308/003588406X95101.

4. Harrison SCW, Lawrence WT, Morley R, Pearce I, Taylor J. British Association of Urological Surgeons' Suprapubic catheter practice guidelines. *BJU Int*. 2011;107:77-85. doi:10.1111/j.1464-410X.2010.09762.x.

5. Røhl L, Rasmussen OS. Ultrasound-guided percutaneous suprapubic cystostomy. *Eur J Ultrasound*. 1997;6:57-61.

6. Rashid P, Gianduzzo TRJ. Urology technical and non-technical skills development: the emerging role of simulation. *BJU Int*. 2016;117:9- 16. doi:10.1111/bju.13259.

7. Prystowsky JB, Regehr G, Rogers DA, Loan JP, Hiemenz LL, Smith KM. A virtual reality model for intravenous catheter placement. *Am J Surg*. 1999;177:171-175.

8. Singal A, Halverson A, Rooney DM, Davis LM, Kielb SJ. A validated low-cost training model for suprapubic catheter insertion. *Urology*. 2015;85:23-26. doi:10.1016/j.urology.2014.08.024.

9. Jacob P, Rai BP, Todd AW. Suprapubic catheter insertion using an ultrasound-guided technique and literature review. *BJU Int*. 2012;110:779-784. doi:10.1111/j.1464-410X.2011.10882.x.

10. De Montbrun SL, Macrae H. Simulation in Surgical Education. *Clin Colon Rectal Surg*. 2012;25:156-165. doi:10.1055/s-0032-1322553.

11. Schout BMA, Hendrikx AJM, Scherpbier AJJA, Bemelmans BLH. Update on training models in endourology: a qualitative systematic review of the literature between January 1980 and April 2008. *Eur Urol*. 2008;54:1247-1261. doi:10.1016/j.eururo.2008.06.036.

12. Brunckhorst O, Volpe A, van der Poel H, Mottrie A, Ahmed K, Catto J. Training, simulation, the learning curve, and how to reduce complications in Urology. *Eur Urol Focus*. 2016;2:10-18. doi:10.1016/j.euf.2016.02.004.

13. Shergill IS, Shaikh T, Arya M, Junaid I. A training model for suprapubic catheter insertion: the UroEmergeTM suprapubic catheter model. *Urology*. 2008;72:196-197.

14. Hossack T, Chris B, Beer J, Thompson G. A cost-effective, easily reproducible, suprapubic catheter insertion simulation training model. *Urology*. 2013;82:955-958. doi:10.1016/j.urology.2013.06.013.

15. Adebayo SA, Chibuzo IN, Takure AO, Okeke LI, Shittu OB. The UCH bladder manikin - A locally designed teaching aid for suprapubic catheterization in low-resource countries. *Afr J Urol*. 2015;21:262-265. doi:10.1016/j.afju.2014.10.006.

16. Biyani CS, Hanchanale V, Rajpal S, et al. First urology simulation boot camp in the United Kingdom. *Afr J Urol*. 2017;23:258-267. doi:10.1016/j.afju.2017.03.002.

17. Limbs & Things. Available at: https://www.limbsandthings.com/au/our-products/details/advanced-male-catheterization-trainer Accessed 10 December 2017.

18. Palvolgyi R, Lee A, Ramirez F, Durbin B. VesEcho training system: suprapubic catheterization under ultrasound guidance. *Urol Pract*. 2017;doi:10.1016/j.urpr.2017.01.003.

MANUSCRIPT 2

THE WORLD OF VALIDATED SUPRAPUBIC CATHETER INSERTION SIMULATION TRAINERS: FROM 'HEAD-BLOCKS' TO 'LUNCH BOXES': A SYSTEMATIC REVIEW

This manuscript has been accepted for publication (in press) in the following peer reviewed journal that is indexed in PubMed & Scopus: Current Urology. ***Journal Cite Score 0.9*** (Appendix 4).

CONTENTS **PAGE**

Manuscript title and authors	26 - 27
Conflict of interest, key words, funding	27
Author contributions	28
Agreement by co-authors	29
Abstract	30
Manuscript main text introduction	31 - 32
Materials and methods	32 - 34
CASP tool	34
Results	34 - 39
Study flow diagram	35
Summary of literature included	37 - 39
Discussion	40 - 45
Conclusion	45 – 46
Ethics statement	46
References	46 - 48

MANUSCRIPT TITLE

The world of validated suprapubic catheter insertion simulation trainers: from 'head-blocks' to 'lunch boxes': a systematic review.

RUNNING TITLE

Suprapubic catheter insertion simulation trainers - a review.

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Systematic Review

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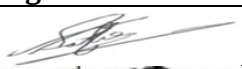
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ABSTRACT

Purpose: Various suprapubic catheter (SPC) insertion simulators have been described to aid in the training of this fundamental skill. The purpose of this review is to evaluate and critically appraise all validated simulators.

Methods: The PubMed, Web of Science, Cochrane Library, SCOPUS, British Medical Journal (BMJ) and the Embase databases were searched (March 2018), using key search terms *"suprapubic trainer", "suprapubic model", "suprapubic simulation"* and *"suprapubic simulator"*.

Results: A total of 196 articles were identified; 117 unrelated, 53 animal studies and 20 duplicates. Only 6 articles met the inclusion criteria for this review. The median number of participants per study was 30.5. Material costs ranged from 1.71 to 60 United States Dollars (USD) per model. Only 2 studies incorporated the use of ultrasound (US).

Conclusion: Despite validated SPC insertion models being a much-needed learning resource, only few have been described – mostly for low resource environments. There exists a general lack of guidelines on model validation processes. There is need to develop, appropriately validate and integrate models into training curriculum.

INTRODUCTION

Percutaneous suprapubic catheter (SPC) insertion is a vital skill that urologists and emergency department (ED) physicians need to perform proficiently to avoid the morbidity and mortality that may arise from its insertion [1, 2]. Indications for SPC placement include urethral injuries, urethral strictures, bladder neck masses, benign prostatic hyperplasia (BPH) and occasionally, prostate cancer [1]. The absence of an easily palpable or ultrasonographically localised distended urine bladder is an absolute contraindication to SPC insertion [1, 2].

Training in invasive surgical procedures continues to shift from the Sir William Halsted apprenticeship model of 'see one, do one, teach one' to that of simulation based medical education (SBME) permitting the safe repetitive practice of skills or procedures [2, 3]. This is aimed at ensuring that trainees have adequate time to perform and perfect a skill before it can be performed on real-life subjects [4]. SBME avoids aggravating patients' safety by preventing patient exposure to the risks of the early part of the surgical learning curve, a period during which more surgical 'errors' are known to occur [2,5].

SPC insertion is a relatively common procedure in the ED. Its complications include post-insertion gross haematuria (2-16%), post-obstruction diuresis (0.5-52%), post-bladder emptying hypotension, sepsis and intra-abdominal visceral injury [6]. SPC associated iatrogenic bowel injury is estimated to be at 2.4% to 2.7% with a 30-day mortality rate of 1.8% [7, 8].

The use of real-time ultrasound (US) is associated with a lower risk of visceral injury compared to blind insertions. Evidence from studies and case reports supports the appropriate integration of US in both training curriculum and real-life insertions so as to help localise the distended urinary

bladder and avoid inadvertent visceral injury [4, 9, 10]. A successful SBME program requires the development and use of models that are supported by validation studies with good evidence [11].

Models with varying degrees of validities, costs, and bona fide anatomy mimicking abilities have been described. An ideal surgical simulator is one that provides realistic experience and feedback that closely mimic real-life experiences [12].

Validity is a measure of the extent to which a simulator delivers a task it is meant to achieve [13]. A validation process can be subjective and, or objective. Subjective studies involve face, content, expert and referent types of validity which are mainly opinions of study participants. Objective studies aim to assess discriminative, construct and criterion ('concurrent' and 'predictive') validity [11]. Face validity examines the realism of a model while content validity evaluates its suitability for use as a training tool. Construct validity determines simulator's ability to differentiate the experienced (experts) from novice performers. Criterion validity assesses the validity of a new model in comparison with that of the old. There are two types of criterion validities; concurrent and predictive. Concurrent measures the degree to which a simulator agrees with the characteristics of the "gold standard" while predictive validity determines the model's ability to predict future performance. [13].

This review aimed at evaluating and critically appraising all the currently published and validated SPC insertion simulators.

MATERIALS AND METHODS

Search Strategy

A search strategy was developed and performed using an electronic database search. The PubMed, Web of Science, Cochrane Library, SCOPUS, British Medical Journal (BMJ) and the Embase databases were searched (March 2018). The following search terms; *'suprapubic catheter trainer', 'suprapubic catheter model', 'suprapubic catheter simulation'* and *'suprapubic catheter simulator'* were used. The citations of the papers generated by the search were also analyzed for any additional articles. Language restriction was not applied to this review.

Study Selection/Eligibility Criteria

Studies considered for inclusion met the following criteria: (i) the studies were clinical publications, (ii) full text articles, and (iii) studies provided details regarding positive versus negative findings. All published studies relating to the topic were eligible for inclusion. In the review process, animal studies/models were excluded.

Data Extraction and Methodological Quality Evaluation

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P) Guidelines were adhered to during the review [14]. After the search, authors collectively assessed the articles for the inclusion criteria. Selected studies were ranked for quality and relevance using the Critical Appraisal Skills Program (CASP tool) (Table 1) [15].

Table 1: Details of CASP tool used to assess the studies included for review

	QUESTIONS	AUTHORS					
		Shergil et al.[17]	Hossack et al.[18]	Olapade-Olaopa et al.[19]	Singal et al.[20]	Palvogyi et al.[21]	Nonde et al.[22]
1	Did the study address a clearly focused issue?	Y	Y	Y	Y	Y	Y
2	Was the cohort recruited in an acceptable way?	CT	CT	CT	CT	CT	CT
3	Was the exposure accurately measured to minimize bias?	CT	CT	CT	CT	CT	CT
4	Was the outcome accurately measured to minimize bias?	Y	CT	Y	Y	CT	Y
5a	Have the authors listed all confounding factors?	N	N	N	N	N	N
5b	Have the authors taken account of all the confounding factors?	N	N	N	N	N	N
6a	Was the follow-up complete enough?	CT	CT	CT	CT	CT	CT
6b	Was the follow-up long enough?	Y	N	Y	N	CT	N
7	Do you believe the results?	Y	Y	Y	Y	Y	Y
8	Can the results be applied to a local population?	Y	Y	Y	Y	Y	Y
9	Do the results of the study fit with other available evidence?	Y	Y	Y	Y	Y	Y

Y=Yes; N=No; CT= Cannot Tell

Relevant studies were assessed based on: participant numbers, participants' qualifications, prior SPC insertion/s, US compatibility, model/material cost, cost per use, construction time, expertise and materials required for model construction (Table 2). Conflicting entries, disagreements and differences were resolved by consensus amongst all reviewers.

RESULTS

Search

The search yielded 196 articles, represented as follows; BMJ best practice (7), Cochrane Database of Systematic Reviews (2), EMBASE (2), PubMed (45), Scopus (82), and the Web of Science (58) articles. The articles were screened for both duplicates and content. A total of 190 articles were excluded: 20 duplicates, 117 non-related articles and 53 animal studies. The

researchers independently reviewed the remaining 6 articles that were included in the review (Fig. 1).

Participant Characteristics

The number of study participants ranged from 13 to 50 (median 30.5) per study. Four of the six studies (66.7%) did not specify the participants' prior experience in SPC insertion [17 - 21]. In general, a greater number of participants had little to no prior experience. 'Expert assessors'(defined by >65 prior real life successful SPC insertions) accounted for 19.35% and 26% in Singal's and Nonde's studies respectively, thereby making an overall expert participation rate of only 10.27% [17-22].

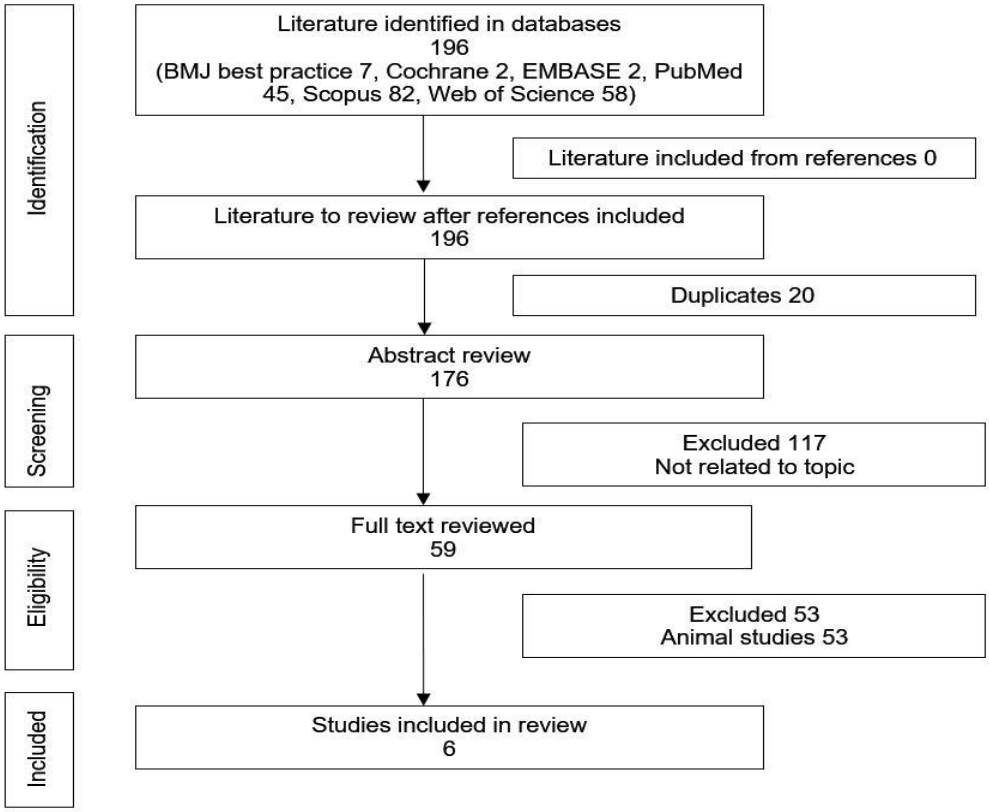


Fig. 1: Study flow diagram.

Model Construction Requirements

The materials required were common household materials and/or those found in most EDs. Some materials needed some sort of expert handling (Table 2). Some models were constructible from scratch within a few minutes while others require pre-made parts [17-22].

Model Costs

The cost of individual elements, as well as the number of times they may be reused, determined the overall estimated material cost. Some researchers clearly stated the costs while others simply overlooked it. The target market for most of the described models was tailored for low income settings [17-22].

US Compatibility

The use of US to guide SPC insertion was only assessed in two recent studies [21, 22].

Validity Assessed

All studies assessed face, content, expert and/or referent types of validity which were opinions the participants [17- 22].

Table 2: Summary of Literature included

Manuscript Title	**A Training Model for Suprapubic Catheter Insertion: The UroEmerge™ Suprapubic Catheter Model**	**A Cost-effective, Easily Reproducible, Suprapubic Catheter Insertion Simulation Training Model**	**The UCH bladder manikin – A locally designed teaching aid for suprapubic catheterization in low-resource countries**	**A Validated Low-cost Training Model for Suprapubic Catheter Insertion**	**VesEcho Training System: Suprapubic Catheterization under Ultrasound Guidance**	**Validation of a low cost, disposable, ultrasound-guided suprapubic catheter insertion trainer**
Corresponding Figure	Figure. 2	Figure. 3	Figure. 4	Figure. 5	Not Applicable	Figure. 6a & b
Author (Ref)	Shergil et al., 2008.[17]	Hosack et al., 2013.[18]	Olapade-Olaopa et al., 2015.[19]	Singal et al., 2015.[20]	Palvolgyi et al., 2017.[21]	Nonde et al., 2018.[22]
Region	UK	Australia	Nigeria	USA	USA	South Africa
Name of Model	The UroEmerge	Not Specified	UCH bladder manikin	Not Specified	VesEcho Training System	US-SCIT
Principle of Invention	To describe a simple model developed to teach junior doctors SPC insertion in a safe and reliable manner.	To develop an SPC model and assess its influence on a trainee's confidence in SPC insertion.	To describe the development of the manikin and assesses its usefulness in teaching SPC insertion.	To describe an anatomically correct simulator for use in SPC insertion training.	To develop a novel, cost- effective, sonographically accurate SPC insertion model.	To validate a low cost, disposable, ultrasound-guided SPC insertion trainer.
Construction Elements Required	3L bag of irrigation fluid, 10ml Povidone-Iodine, 2 tourniquets, clear plastic container, abdominal open and closure pad.	Party balloon filled with water, Mefix® tape, 2 sponges, Transpore®, plastic container with clip lid.	Wooden box (with base and lid), foam, leather, Perspex, water filled gloves.	Urethane foam, resin glue, molded liquid plastic parts, silicone rubber bladder, intravenous tubing, leur lock, gel wax, silicone rubber.	Water balloon, non-rebreather masks, gelatinous mold (gelatin, psyllium, and water), pelvic bone replica, interposed sheets	Surgical glove, Leukoplast® Sleek tape, empty 1litre intravenous infusion bag, glove/tissue box, paper towel, refuse liner, cervical spine immobilizer (trauma head blocks), linen saver
Construction Time	Not Specified	Not Specified	Not Specified	Not Specified	Not Specified	8 minutes
Expertise Required	None	None	carpentry skills	None	Gelatinous molding	None
Target Market	Junior doctors	Doctors(schools/work shops)	Low-resource countries.	Training institutions	Training institutions	Resource constrained environments
Validation	36 participants	30 participants	25 participants	31 participants	13 participants	50 participants
Participants' Qualifications	Not Specified	Surgical residents / Unaccredited surgical registrars	18 non-urological surgical residents, 7(physicians/gynecologists)	25 general surgeons, 6 expert Urologists	Urology residents	Not Specified

Participants' Prior Successful SPC Insertion	Not Specified	Not Specified	Not Specified	None for the 25 General Surgeons, 6 experts: >65 SPC	Not Specified	20 SPCs as median for the group, 13 experts: >65 SPC
Model's US Compatibility	Not Specified	Not Specified	Not Specified	Not Specified	Yes	Yes
Total Cost	Not Specified	16.27AUD per trainee	Not Specified	31.28USD	60.00USD	1.71USD
Cost Per Use	Not Specified	2.67AUD	Not Specified	Not specified	Not Specified	Not Specified
Model Assessments	<u>Candidates Ability to Perform SPC</u> Pre-course: Mean 3.14, SD 0.6. Immediate post-course: Mean 4.48 SD 0.7. Six weeks post course: Mean 4.48 SD 0.7, Three months post course: Mean 3.89.	<u>Realism; bladder anatomy:</u> 24/25 candidates scored it the highest possible score <u>Ability in helping Understand SPC insertion:</u> 25 candidates scored the model the highest possible rating. <u>Ability to increase confidence in SPC insertion:</u> 23 of candidates scored it the highest possible rating.	<u>Participants' Assessment</u> Participants' feedback: Model was an effective training too and that it enhanced their ability to perform SPC.	<u>Assessment by 25 general surgeons:</u> Ability to perform procedure: Mean 4.1 Value as testing / training model: Mean 4.1 Life-like feel: Mean 3.4 <u>Assessment by 6 Expert users:</u> Physical attributes: Mean 3.9 Realism of experience: Mean 4.3 Value as training tool: Mean 4.5 Value as testing tool: Mean 3.8 Relevance to practice: Mean 4.0	<u>Realism of Anatomy</u> All 13 Participants Anatomic landmarks: Mean 4.2, SD 0.6 US Image: Mean 4.3, SD 0.6 4 Junior Residents Anatomic Landmarks: Mean 4.7, SD 0.6 US Image: Mean 4.3, SD 0.6 9 Senior Residents Anatomic Landmarks: Mean 4.1, SD 0.6 US Image: Mean 4.4, SD 0.5 <u>Value as Training Tool</u> All participants: Mean 4.7, SD 0.5 4 Junior Residents Mean 4.7, SD 0.6 9 Senior Residents Mean 4.7, SD 0.5	<u>Contextual Anatomy</u> All 50 Participants: Mean 8.26, SD 1.48 13 Experts: Mean 8.00, SD 1.63 <u>Realism; Sensory / Tactile feedback</u> All 50 participants: Mean 8.12, SD 1.78 13 experts: Mean: 7.77, SD 1.64 <u>Value; understanding US-guided SPC insertion</u> All 50 Participants: Mean 8.86, SD 1.03 13 Experts: Mean 8.54, SD 1.20 <u>Realism; Initial Urine Outflow</u> All 50 Participants: Mean 9.06, SD 1.20 13 Experts: Mean 8.87, SD 0.93 <u>Realism of Resistance to Force of Trocar Advancement</u> All 50 Participants: Mean 7.78, SD 2.02

						13 Experts: Mean 7.23, SD 2.17 <u>Value to Participant's Scope of Practice</u> All 50 participants: Mean 8.84, SD 1.41 13 Experts: Mean 8.08, SD 1.89 <u>Overall Rate of Simulation with Model Compared Real-life Insertions</u> All 50 participants: Mean 8.30, SD1.48 13 experts: Mean 8.08, SD 1.50
Author's Conclusions	Model increase ability to perform SPC insertion initially, however, over time their ability decreased.	Low cost model, reasonable bladder representation, improved confidence and understanding SPC insertion principles. Small study and biased. .	An effective low-cost SPC insertion teaching aid easily manufactured and recommended for low-resource countries.	Useful tool with a bladder that could sustain 10-15 SPC insertions, skin and fat layers could withstand 50-75 SPC procedures.	A cost effective, US compatible teaching tool, can withstand up to 10 SPC insertions, great participants' reviews and satisfaction.	A low cost, US compatible, easy and quick to make from ED items, great participants' reviews, for use in resource limited and regional centers.

KEY: SPC=Suprapubic catheter; AUD=Australian Dollar; USD=United States Dollar

DISCUSSION

Simulation training has been a main feature of the aviation industry as part of the prerequisites for pilots to be certified safe to fly [16]. Taking a leaf out of this approach, the field of medicine continues to embrace and integrate the use of SBME. The development, validation and appropriate curricular integration of SPC insertion training models are a great example of this ever-expanding endeavor.

At the time of this review six models had been described and validated [17-22]. There was a general lack of consensus guidelines on how validation studies should be conducted. Standardized definition of terms such as an 'expert user' and their appropriateness to assess the models remains debatable. The six studies mainly explored face and content validities which were subjective participants' thoughts about the models. None of the studies explored the criteria that would objectively determine the true effect of a prospective model on the surgical learning curve [17-22].

Validated Simulator Models reviewed

The **UroEmerge™** (Fig. 2) increased participants' ability to perform SPC insertion initially. However, over time participatns' ability appeared to wane at three months post-course [17]. This model was the first ever (in the reviewed literature) to be described. It had a higher number of participants but neither their level of training nor prior successful real-life SPC insertions was specified. Validation was by blind technique and confirmation of correct placement was by exposing the bladder at the end of the procedure. The model's US compatibility and costs were unspecified.

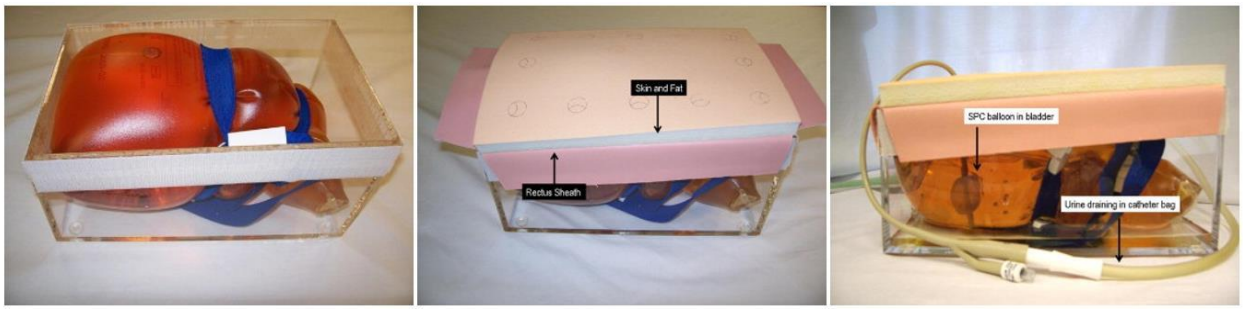


Fig. 2: The **UroEmerge™** Suprapubic Catheter Model, Construction images (cf with Table 2) (Image reproduced with courtesy of publisher: Elsevier, with permission certificate number: 4302050717055, date of certificate: Mar 04, 2018).

Hossack's '**lunch-box'** model (Fig. 3) was cost effective and easily reproducible. It had an initial running cost of 16.27USD per trainee. Two of its major components were reusable making consecutive runs cheaper [18]. It had the advantage of pre-prepared components enabling rapid resetting of units thus needing only one consultant to manage the entire course. However, validation was also by blind technique which is no longer recommended.

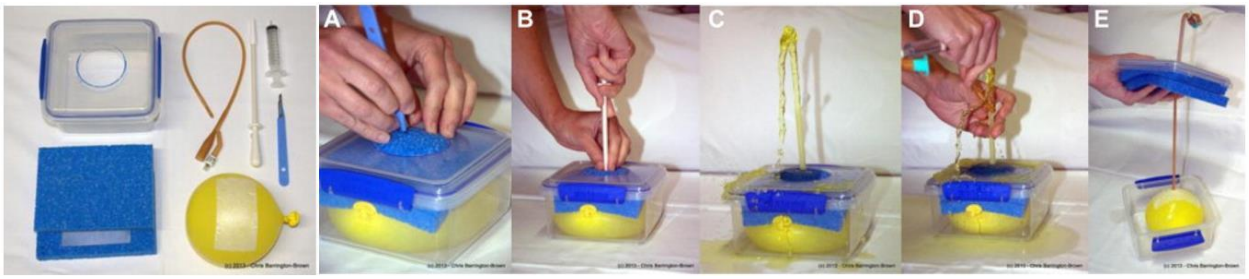


Fig. 3a-e: The **Hosack et al**. Suprapubic Catheter Insertion Simulation Training Model Construction and simulation images (cf with Table 2) (Image reproduced with courtesy of publisher: Elsevier, with permission certificate number: 4302051291270, date of certificate: Mar 04, 2018).

The **Bladder manikin** (Fig. 4) was an effective-low-cost aid in teaching SPC insertion [19]. This model required manufacturing prior to use. Validation was also by blind technique with unspecified participants' level of experience. The model's US compatibility and cost implications were unspecified.

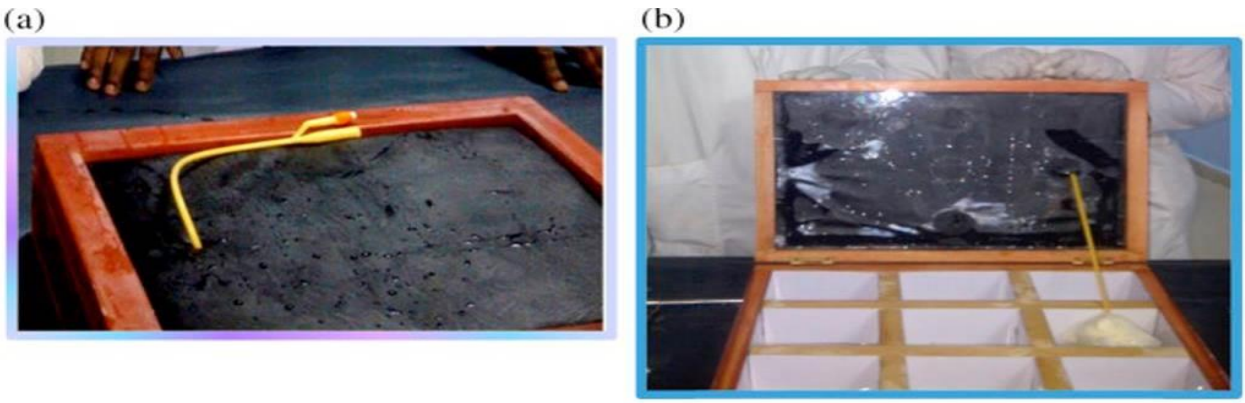


Fig. 4a-b: The **UCH bladder manikin** simulation images (cf with Table 2) (Image reproduced with courtesy of Creative Commons License: CC BY-NC-ND 4.0, available at: https://creativecommons.org/licenses/by-nc-nd/4.0/#).

Singal's model (Fig. 5) was evaluated by 25 general surgeons and 6 'experts'. The initial material cost was 31.28USD. The 25 general surgeons had no prior SPC experience [20]. The model's US compatibility was unspecified, and validation was by blind technique.

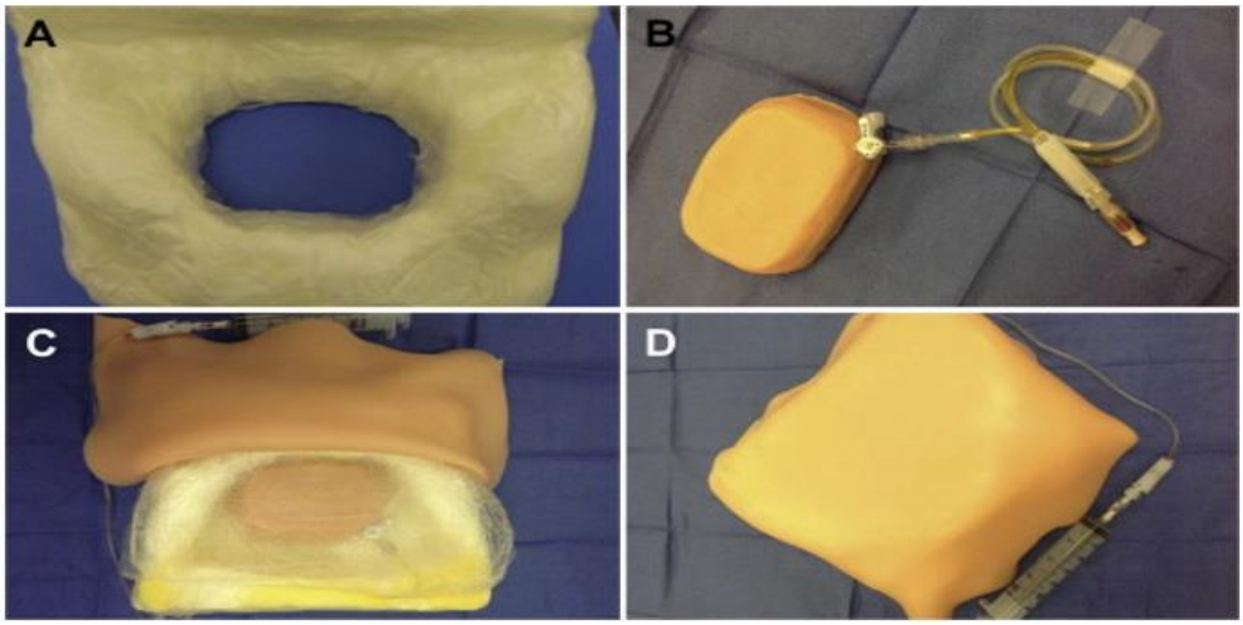


Fig. 5a-d: The **Singal et al.** Training Model for Suprapubic Catheter Insertion, construction images (cf with Table 2) (Image reproduced with courtesy of publisher: Elsevier, with permission certificate number: 4302060520603, date of certificate: Mar 04, 2018).

At 60.0USD material cost, the **VesEcho Training System** was the most costly and had fewer numbers of evaluators. However, the model could withstand multiple needle punctures and be reused up to 10 times [21]. Further, it was US compatible and appeared to have the well-defined sonographic image display. Confirmation of correct catheter placement was by visualization of intravesical trocar needle tip by US.

The **US-SCIT** (Fig. 6a and b) had the highest number of overall participants, is US compatible and the lowest material cost. It could be made from using materials found in most basic EDs within a short time [22]. However, the 1.71USD cost did not include that of the head blocks which formed part of the entire unit. Like the **VesEcho training system**, confirmation of correct placement was by real-time ultrasonographic visualization of both the intravesical trocar needle tip and the inflated catheter balloon.

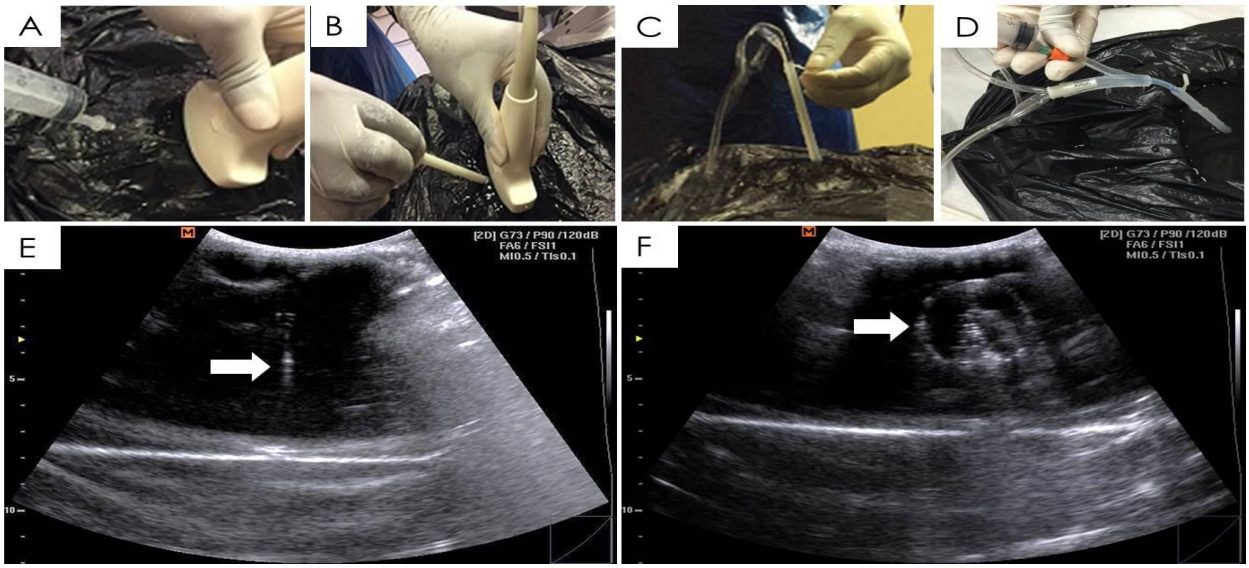


Fig. 6A: a-i Construction outline pictures of the Ultrasound-guided Suprapubic Catheter Insertion Trainer **(US-SCIT)** model (Image reproduced with courtesy of publisher: Elsevier, with permission certificate number: 4302061109913, date of certificate: Mar 04, 2018).

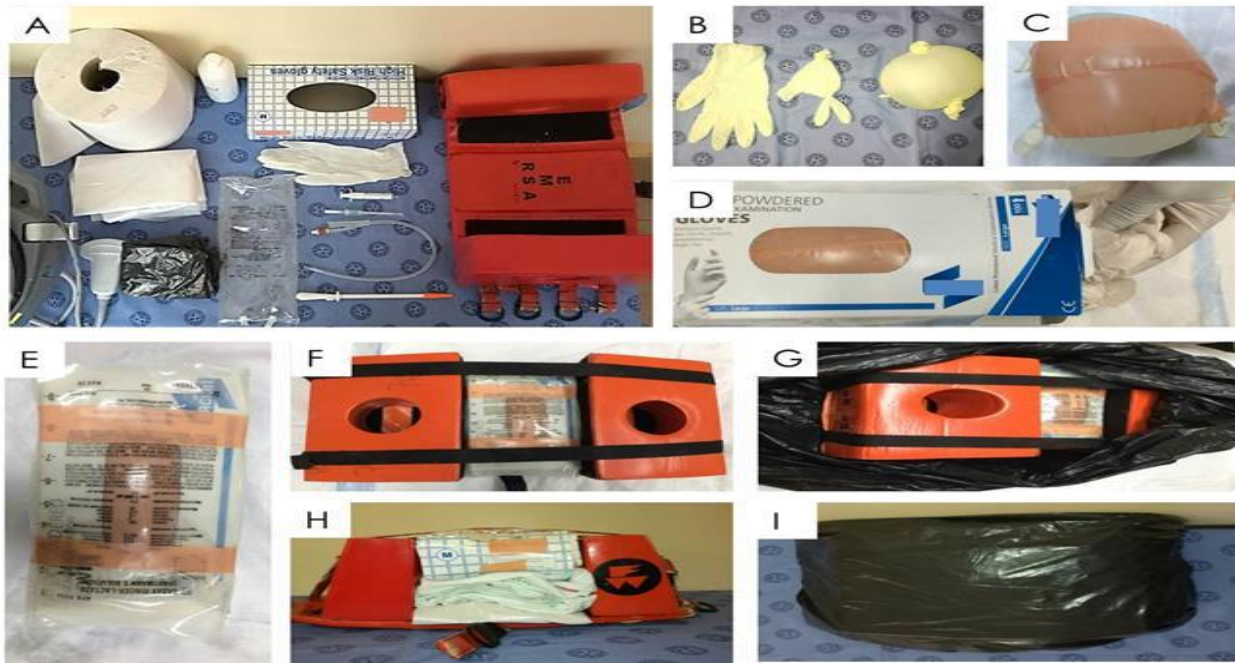


Fig. 6B: a-f Corresponding Ultrasound images of the Ultrasound-guided Suprapubic Catheter Insertion Trainer **(US-SCIT)** in use (Image reproduced with courtesy of publisher: Elsevier, with permission certificate number: 4302061109913, date of certificate: Mar 04, 2018).

SBME in Urological Training

Although, the optimal learning curve to achieve competence and proficiency in urological procedures may vary between individuals, a minimum case number for proficiency should be established by the relevant authorizing agencies [23]. There is a trend for the teaching of various surgical and procedural skills to move away from the operating room, to a controlled simulated laboratory environment [24, 25]. Centralized simulation programs that seek to assist with the technical and non-technical aspects of urological training are feasible to improve overall outcomes and patient safety [26]. Among the fundamentals of establishing a simulation program, the concept of the 'P's of the marketing mix must be considered, this includes; the place, people, pounds, products, program and positioning [27]. The 'pounds' factor pertains to costing of the actual simulation, a factor emphasized in the low-cost models [26].

CONCLUSION

There is general paucity of development and validation of models utilized in the training of SPC insertion. At present, the various SPC simulators assessed within this review are a reasonable teaching adjunct which can be implemented in (training) academic centers. Though SBME may not be the total replacement for the real-life patient-doctor interaction, it is a safe and efficient way to impart proficiency in fundamental surgical skills.

Developers of new SPC models must take into consideration the cost implications for their respective target market and the benefit of incorporating the use of US compatibility models in this scenario.

The use of SPC simulators would contribute to a successful SBME program, which in turn needs to be incorporated into the training curriculum for both Urology and ED trainees across the globe.

STATEMENT OF ETHICS

Institutional Ethics clearance was obtained from the University of the Witwatersrand Human Research Ethics Committee (Medical), Johannesburg, South Africa (Wits HREC-Medical-Clearance Certificate No. M170610).

REFERENCES

1. Ramos-Fernandez MR, Medero-Colon R, Mendez-Carreno L, et al. Critical urologic skills and procedures in the emergency department. Emerg Med Clin North Am. 2013; 31: 237-60.
2. Preece R, et al. The current role of simulation in urological training. Cent. European. J. Urol. 2015; 68: 207-211.
3. Robinson AJ, Miller G, Rukin N, et al. Simulation in urological training: Where are we in 2017; JCU 2017; 10: 548-556.
4. Harrison SCW, Lawrence WT, Morley R, Pearce I, Taylor J. British Association of Urological Surgeons' Suprapubic catheter practice guidelines. BJU Int. DOI:10.1111/j.1464-410X.2010.09762.x.
5. Brewin J, Ahmed K, Challacombe B, et al. An update and review of simulation in urological training. IJS 2014; 12: 103-1108.
6. Nyman MA, Schwwenk NM, Silverster MD. Management of Urinary Retention: Rapid Versus Gradual Decompression and Risk of Complications. Mayo clinic procedures. DOI.org/10.4065/72.10.951.

7. Ahluwalia RS, Johal N, Kouriefs C, et al. The surgical risk of suprapubic catheter insertion and long-term sequelae. Ann. R. Coll. Surg. Engl. DOI:10.1308/003588406X95101.
8. Sheriff MK, Foley S, McFarlane J, et al. Long-term suprapubic catheterisatiion: clinical outcome and satisfaction survey. Spinal Cord. 1998; 36: 171-6.
9. Jacob P, Rai BP, Todd AW, et al. Suprapubic catheter insertion using an ultrasound-guided technique and literature review. BJU. Int. DOI:10.1111/j.1464-410X.2011.10882.x.
10. Shah PN, Chaskar VP, Rathod P, Komawar A, Gadpale B. Need of Ultrasound in Emergency Department for Suprapubic Catheterization. Int. J. Anesthetic. Anesthesiol. DOI.org/10.23937/2377-4630/1/3/1014.
11. Schout BMA, Hendrikx AJM, Scheele F. Bemelmans BLH, Scherpbier AJJA. Validation and implementation of surgical simulators: a critical review of present, past, and future. Surgical Endoscopy. DOI:10.1007/s00464-009-0634-9.
12. Prystowsky JB, Regehr G, Rogers DA, et al. A virtual reality model for intravenous catheter placement. Am. J. Surg. 1999; 177: 171-175.
13. McDougall EM, et al. Validation of surgical simulators. J. Endourol. 2017; 21: 244–247.
14. Moher D, Shamseer L, Clarke M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. Systematic Reviews. DOI:10.1186/2046-4053-4-1.
15. Critical Appraisal Skills Programme. CASP Checklist 2018. Available online at: www.casp-uk.net. Accessed on 1st April, 2018.
16. Rosen KR, et al. The history of medical simulation. J. Crit. Care. 2008; 23: 157–66.
17. Shergill IS, Shaikh T, Arya M, Junaid I, et al. A training model for suprapubic catheter insertion: the UroEmergeTM suprapubic catheter model. Urology. 2008; 72: 196-197.

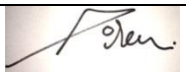
18. Hossack T, Chris B, Beer J, Thompson G. A cost-effective, easily reproducible, suprapubic catheter insertion simulation training model. Urology. DOI:10.1016/j.urology.2013.06.013.
19. Adebayo SA, Chibuzo IN, Takure AO, Okeke LI, Shittu OB. The UCH bladder manikin-A locally designed teaching aid for suprapubic catheterization in low-resource countries. Afr. J. Urol. DOI:10.1016/j.afju.2014.10.006.
20. Singal A, Halverson A, Rooney DM, Davis LM, Kielb SJ. A validated low-cost training model for suprapubic catheter insertion. Urology. DOI:10.1016/j.urology.2014.08.024.
21. Palvolgyi R, Lee A, Ramirez F, Durbin B. VesEcho training system: suprapubic catheterization under ultrasound guidance. Urol. Pract. DOI:10.1016/j.urpr.2017.01.003.
22. Nonde J, Adam A, Laher AE. Validation of a low cost, disposable, and Ultrasound-guided Sprapubic catheter Insertion Trainer. Urology. DOI:10.1016/i.urology.2018.02.013.
23. Abboudi H, Khan MS, Guru KA, et al. Learning curves for urological procedures: a systematic review. BJU. Int. 2014; 114: 617–29.
24. De Montbrun SL, Macrae H, et al. Simulation in Surgical Education. Clin. Colon. Rectal. Surg. 2012; 25: 156–165.
25. Schout BMA, Hendrikx AJM, Scherpbier AJJA, Bemelmans BLH, et al. Update on Training Models in Endourology: A Qualitative Systematic Review of the Literature between January 1980 and April 2008. *Eur. Urol.* 2008; 54: 1247–61.
26. Shamim Khan M, Ahmed K, Gavazzi A, et al. Development and implementation of centralized simulation training: evaluation of feasibility, acceptability and construct validity. BJU. *Int.* 2013; 111: 518–23.
27. Ahmed K, Amer T, Challacombe B, Jaye P. How to develop a simulation programme in urology. BJU. *Int*. DOI:10.1111/j.1464-410X.2011.010420.x.

APPENDICES

APPENDIX 1: RESEARCH PROTOCOL

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

FACULTY OF HEALTH SCIENCES

CANDIDATE'S SURNAME: Nonde	FIRST NAME/S: James		STUDENT NUMBER: 1259718
CURRENT QUALIFICATIONS: MBChB			
TEL: Nil	CELL: 0840238540	E-MAIL: nondej@gmail.com	FAX: Nil
DEGREE FOR WHICH PROTOCOL IS BEING SUBMITTED: MMed (Emergency Medicine)			
PART-TIME OR FULL-TIME: Full-Time			
FIRST REGISTERED FOR THIS DEGREE:	TERM: July		YEAR: 2015
DEPARTMENT: Emergency Medicine			
TITLE OF PROPOSED RESEARCH: Assessment and validation of a low cost ultrasound-guided suprapubic catheter insertion training (US-SCIT) model			
CANDIDATE'S SIGNATURE:			DATE:
SUPERVISOR 1 (NAME & SURNAME): Prof Abdullah Laher			% Supervision: 50%
SUPERVISOR'S QUALIFICATIONS: MBBCh, MMed, FCEM, Cert Critical Care, EDIC, DipPEC, DCH, DipAllergy			
SUPERVISOR'S DEPARTMENT: Emergency Medicine			
SUPERVISOR'S ADDRESS / TEL / E-MAIL: Cell: 0848402508 / E-mail: abdullahlaher@msn.com			
SUPERVISOR 2 (NAME & SURNAME): Prof Ahmed Adam			% Supervision: 50%
SUPERVISOR'S QUALIFICATIONS: MBBCh, Dip PEC (SA) MMed, FCUrol			
SUPERVISOR'S DEPARTMENT: Urology			
SUPERVISOR'S ADDRESS / TEL / E-MAIL: Cell: 0723252955 / E-mail: aadam81@gmail.com			
SYNOPSIS OF RESEARCH: This research is aimed at conducting validation of a newly locally developed low-cost suprapubic catheter insertion trainer and assess its appropriateness of being used as training tool. It will be a quantitative descriptive survey with a questionnaire administered to participants (target group of fifty; medical officers, registrars and consultants with prior experience in real life SPC insertions) after successful completion of simulations with the model. Simulations will be conducted in the simulations laboratory of the Division of Emergency Medicine. It is in partial fulfilment of Master of Medicine; Emergency Medicine. The results will be submitted for international journal publication.			
ETHICS APPROVED: YES	IF YES SUPPLY ETHICS CLEARANCE No: M170610		
As supervisor, I confirm that I have read the protocol which has been submitted for assessment.			
SIGNATURE OF SUPERVISOR/S:			
SIGNATURE PG OFFICE STAFF ……..	REGISTERED: YES / NO	STAMP	

INTRODUCTION

The urinary bladder is a distensile muscular organ that serves as temporal storage for urine. Its contractile detrusor muscle enables complete expulsion of urine at socially convenient times [1,2]. Located in the pelvis, the bladder receives urine from the kidney via the ureters thereby enabling normal excretory function of the kidneys. Acute and/or chronic bladder outlet obstruction (BOO) can result from numerous functional and anatomic etiologies [3]. Most patients with acute BOO are men and benign prostatic enlargement (BPE) is by far the commonest cause [4]. In males, the risk increases with age and about 10% of men in their 70s and 33% of those in their 80s report at least one episode of acute urine retention. Acute BOO presents with severe bladder pain and can potentially lead to acute kidney injury (AKI) if not urgently relieved [5]. Hence, it is a medical emergency requiring emergent bladder decompression.

Catheters have been used to drain urinary bladders for over 3500 years [6]. Bladder decompression can be achieved by either transurethral or suprapubic catheter (SPC) insertion. The transurethral approach is preferred for its perceived less invasiveness and lower incidence of procedure related complications. However, it has been associated with a higher rate of urinary tract infection and surveys have shown that most patients prefer SPC for various reasons [7,8]. In addition, urethral catheters have been cited as a cause of urethral strictures in as much as 45% of cases [9]. With failed transurethral catheterization, as well as in the presence of a contraindication such as urethral trauma, SPC insertion is the immediate rescue emergence department (ED) procedure that needs to be performed.

SPC insertion is thus a critical skill required for both urologists and ED clinicians. Since a fully distended bladder tends to displace bowel from the anterior aspect of the lower

abdominal cavity, the procedure is considered to be relatively safe. In spite of this, the risk of bowel injury is estimated to be up to 2.4% with a mortality rate of 1.8% [10]. This has led to increasing advocacy for the utilization of real time Ultrasound Scan (US) to identify the distended bladder and any interposed loops of bowel. Real time US helps guide trocar insertion and reduces the risk of inadvertent iatrogenic bowel injury. In recognition of the higher incidence of adverse outcomes associated with blind insertions, the incorporation of real time US guidance during SPC insertion is a fundamental part of the British Association of Urological Surgeons (BAUS) guidelines [11]. The value of US was also demonstrated in a study where US-guided SPC insertion had a complication-free first pass success of 100% cases and more than 95% in another study of patients in whom blind insertion had originally failed in the ED [12,13].

Most real life SPC insertions occur under emergent settings often at awkward hours thereby availing very little chance to teach first-time performers. This has prompted the world of simulation medicine to develop and validate models that can be used to train both under- and post- graduate trainees under controlled environments with ample time to practice freely. To limit the morbidity and mortality associated with this procedure, the BAUS further recommends that real life insertions be performed by individuals that have acquired appropriate competencies [11]. This calls for all doctors involved in the management patients with acute urinary retentions to acquire some form of training and practice prior to their first real life insertions. This is achievable with evidence-based development and validations of readily available training models that enhance skill acquisition with appropriate repetitive practice.

Like any other ideal training model, a SPC insertion simulator must fulfill a number of criteria. The model must closely approximate the real-life conditions and provide accurate sensory feedback. To ensure that all trainees are offered an opportunity to practice, it is essential to have multiple copies of the model to enable rapid scene and model resetting for smooth progression of simulations. Overall, the model must be cost effective and efficiently achieve the intended objective [14]. A number of SPC insertion trainer models have been described over the years with variant aesthetics and costs. Some are low cost while others may be perceived as financially unviable for resource constrained environments. Most of the few available models are not US compatible and thus fail shot of the BAUS level 3 of evidence recommendation [11].

A literature search using PubMed, the Cochrane Library, Web of Science, Scopus and Google Scholar databases for English-Language articles published between January 1980 and April 2008, showed that there was growing interest in simulation models in Urology. However, validation studies were few in number or of low evidence levels [15]. Another recent systemic review of MEDLINE®, Embase® and the Cochrane data bases for the English articles describing urological simulators and/or validations of these models, between 1990 and 2015 was conducted. It also confirmed that there had been exponential growth in the development of urology simulation models. Unfortunately, validation studies with high level of evidence demonstrating transferability of skills were very few. Out of the 91 validation studies in the review, only one received a level 1 recommendation [16].

The *U*ltrasound-guided *S*upra-pubic *C*atheter *I*nsertion *T*rainer (USCIT) model has been designed as a low cost US-guided SPC insertion trainer. It may be constructed from every day ED consumables making it potentially cost effective. This would be advantageous as it

would allow rapid cycling of units during training- a critical requirement of an ideal model. The model was presented as a poster at the 34th World Congress on Endourology (WCE); Cape Town; November 2016. This survey will assess and validate the USCIT regarding its appropriateness for use as a training model.

STUDY AIM

To conduct an assessment and validation study of the USCIT model.

STUDY OBJECTIVES

- To conduct SPC insertion simulation with USCIT
- To administer a questionnaire to all participants post-simulation.
- To assess the validity of the USCIT against the experience of the participants experienced in SPC insertions.
- To determine how realistic the USCIT is as a training model.
- To demonstrate the cost effectiveness of the USCIT.

METHODOLOGY

Study design

This will be a quantitative descriptive validation survey. It will engage the use of a questionnaire (appendix I) administered to participants after having taken part in the SPC insertion simulation using the USCIT. To assess the value of the model in different aspects, the participants will score the model out of ten possible points for each carefully structured question.

Study population

The target population will be consultants, registrars and medical officers that are experienced in US-guided SPC insertions. They will be targeted because of their involvement in the day to day management of patients presenting to the ED with acute urine retention requiring emergent rescue with SPC insertion.

Study site

This study will be conducted at the simulation laboratory, Faculty of Health Sciences, University of the Witwatersrand.

Inclusion criteria

- Participants must be experienced in US-guided SPC insertions.
- Participants must consent to participate in the study

Exclusion criteria

- Incomplete simulations will be excluded from the study.
- Inexperience with US-guided SPC insertions.

Sample size

Previous studies of SPC insertion have involved sample sizes ranging from twenty-four [13], twenty-five [17][14] and thirty-six [6]. This study will aim at a convenient sample size of fifty participants.

Data collection

- Data collection will commence after permission is obtained from the Dean of the Faculty of Health Sciences, University of the Witwatersrand (Wits) as well as ethical approval from the Human Research Ethics Committee (HREC) of Wits.
- In preparation for data collection, twenty USCIT models will be constructed a day prior.
- The principal researcher and supervisors will ensure strict uniformity of models during preparation.
- Prior arrangements will also be made to loan three ultrasound devices each with a curvilinear ultrasound probe from various suppliers of the service.
- The USCIT model will be constructed from everyday ED consumables. These are: a surgical glove, surgical adhesive tape (sleek), paper towel, an empty intravenous fluid vacolitre bag, an empty box of non-sterile gloves, a black dustbin bag, a set cervical spine immobilizer (head blocks) and tap water. In addition, the primary investigator will also acquire the following for each model; a linen saver (for absorption of excess spillage or water), a 10ml syringe (for inflation of the catheter balloon), a suprapubic-catheter set (re-usable) and ultrasound gel.
- The procedure will be as follows: First, the medial four fingers of a surgical glove will be tied together in one knot. Then a double knot will be made to tie the open proximal (wrist) end of the glove. Thereafter, the distal two centimeters of the thumb part will be trimmed off and the glove filled with approximately 700ml of municipal water by placing the open end of the thumb part around the sprout of a tap. A knot will then be tied to seal the open end of the thumb. Finally, strips surgical adhesive tape (sleek) will be applied on the anterior aspect of the bladder (the water-filled glove) to prevent it from bursting during the insertion of the SPC trocar. Sleek tape remains adherent to

the bladder (glove), even when wet. It also provides realistic resistance to trocar advancement. At this point, the bladder should appear as shown in Figure 1.

- The bladder will then be placed into an empty box of gloves through the side opening. Pieces of paper towel will be stuffed on either side of the bladder to hold it firmly in place. An empty intravenous fluid (vacolitre) bag will be strapped over the top of the box to simulate the skin of the anterior lower abdominal wall. At this point, the model will appear as shown in Figure 2.

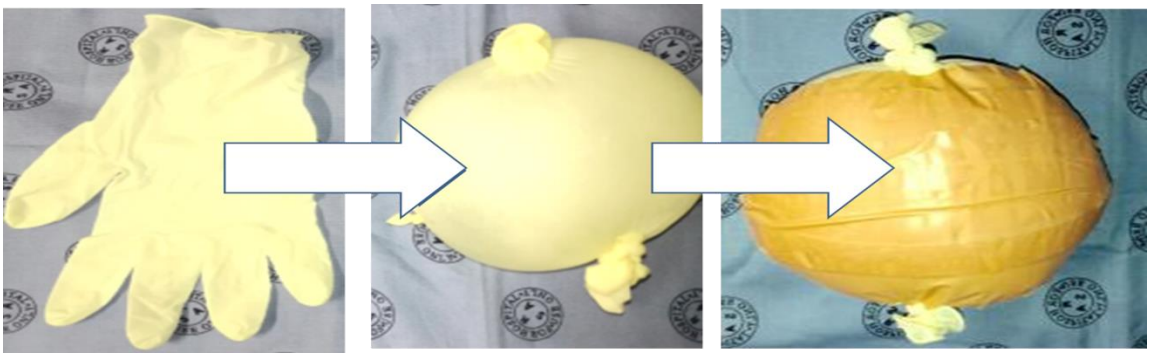


Figure 1: Bladder construction

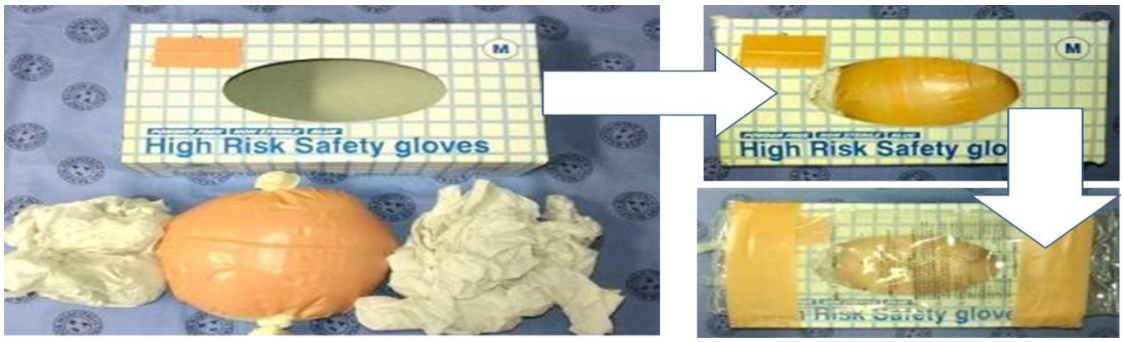


Figure 2: Bladder placed into an empty box of gloves, paper towel stuffed-in and empty vacolitre strapped on with sleek.

- This will then be placed and strapped between head blocks (cervical spine immobilizer) to simulate the bony pelvis in which the bladder lies as shown in Figure 3a.

- The unit will then be placed into a black dustbin plastic bag to limit bias as shown in Figure 3b.
- Consultants, registrars and medical officers from the departments Urology, General Surgery and EM will be approached to participate in the simulation during breaks or at the end of academic meetings. A junior person will be identified to do the recruitment of the MOs and/or registrars deemed subordinate to the researcher.
- Participants will be given a study information sheet (appendix VII) and briefed on procedure particulars. The technique will also be demonstrated to all participants.
- Participants will be asked to perform the assessment on the SPC trainer/s in isolation, to avoid any observer bias.
- Participants will use a suprapubic catheter and trocar and insertions will be done under real time US guidance using a lower frequency (3.5-6 MHz) curve-linear probe as would be in real life SPC insertions for greater depth penetration.
- After insertion, the catheter balloon will be inflated with 10ml of water to secure it. The unit will be re-scanned to confirm placement.
- After completion of the simulations, individual participants will be asked to complete the questionnaire (appendix I).
- Participants will NOT be remunerated for their time.

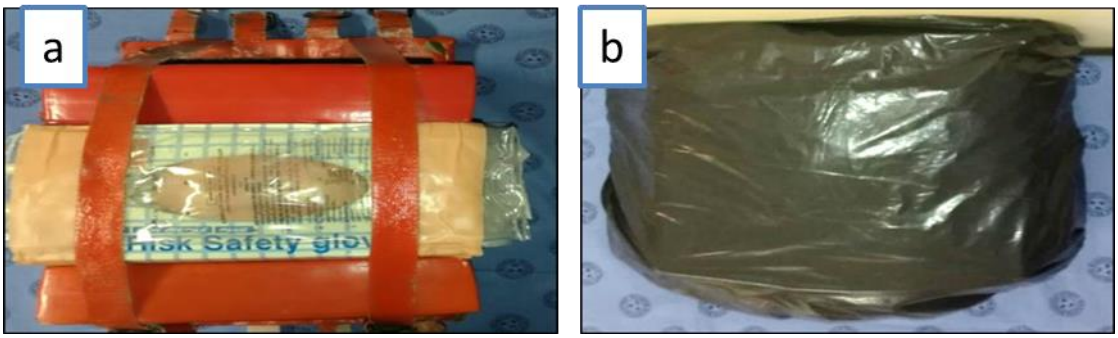


Figure 3: a) unit placed between head blocks, **b)** USCIT placed in black refuse bag

DATA ANALYSIS

The data will be of descriptive nature with an out of ten scoring system to assess the different attributes of both models. All data from the data collection sheets will be entered into an electronic data spread sheet for analysis (Microsoft® Excel®). STATA ® version12 software will be used to perform all statistical analyses. Tables, graphs, histograms, bar charts and pie charts will be used to describe data where appropriate. The mean, median standard deviation (SD) for each attribute of the model will also be determined.

ETHICS AND PERMISSIONS

Ethical clearance to conduct this research will be sought from the Wits Human Research Ethics Committee (HREC- medical). Further permissions to host the seminars will be obtained from the Dean of the Faculty of Health Sciences, Head of Division Emergency medicine and Head of Department of Urology.

TIMING

The projected schedule of activities is as outlined in Table 1.

Table 1: Schedule of activities

	Feb 2017	Mar	Apr	May -Jun	Jul- Aug	Sep- Oct	Nov	Dec	Jan 2018
Literature review									
Preparing protocol									
Protocol submission									
Protocol assessment									
Ethics clearance									
Data collection									
Data analysis									
Writing up: report									
Report submission:									
Publication									

FUNDING

The research will be self-funded, and the budget is as estimated in the Table 3. Consumables such as the empty boxes of non-sterile gloves and empty vacolitres will be collected free of charge from the ED as they are normally disposable.

Table 2: Estimated budget

ITEM	Unit Price	Total Estimate
Transport	R 1,400.00	R1,400.00
Stationary and Printing/Photocopying	R 1020.00	R 920.00
Empty boxes of non-sterile gloves	R 0.00	R 0.00
Sleek tape	R 5.00	R 50.00
Toweling paper	R 33	R 100.00
Empty vacolitres	R 0.00	R 0.00
Silicon catheter x 5	R 50.00	R 250.00
10ml syringe x 5	R 2.00	R 10.00
US gel	R 20.00	R 40.00
Linen saver x 100	R 5.00	R 500.00
Black plastic bin liner bags	R 1.00	R 100.00
Surgical gloves 50pairs/box	R 250.00	R 250.00
Non-sterile gloves 1000/box	R 50.00	R 100.00
Trocar	R 100.00	R 500.00
Head blocks (to be borrowed)	R 799.95	-
Sonar machine (to be borrowed)	R variable	-
Total		**R 4500.00**

PROBLEMS AND LIMITATIONS

This project is expected to progress smoothly. Incomplete questionnaires may limit data collection. However, this is not considered a major limitation in this study as most of the questions will be in a “mark the appropriate score” format.

REFERENCES

1. Bladder A. HHS Public Access. 2017;119:57–62.

2. Andersson K, Arner A. Urinary Bladder Contraction and Relaxation : Physiology and Pathophysiology. 2018;935–86.

3. Dmochowski RR. Bladder Outlet Obstruction : Etiology and Evaluation. 2005;7:3–13.

4. Selius BA, Subedi R. Urinary Retention in Adults: Diagnosis and Initial Management. 2008;

5. John R Marshal, Brian A EBJ. An Evidence-Based Approach To Emergency Department Management Of Acute Urinary Retention. Emerg. Med. Pract. 2014;16.

6. Mohammed A, Khan A, Shergill IS, Gujral SS. A new model for suprapubic catheterization: the MediPlus Seldinger suprapubic catheter. Expert Rev. Med. Devices. Taylor & Francis; 2008;5:705–7.

7. Chan SP, Tan GWL, Ho CK. Is Transurethral Catheterisation the Ideal Method of Bladder Drainage? A Survey of Patient Satisfaction With Indwelling Transurethral Urinary Catheters. Asian J. Surg. Asian Surgical Association; 2010;33:31–6.

8. Healy EF, Walsh CA. Bladder Catheterization for Gynecologic. 2012;120:678–87.

9. Tritschler S, Roosen A, Füllhase C, Stief CG, Rübben H. Urethral Stricture : Etiology , Investigation and Treatments. 2013;110:220–6.

10. Ahluwalia RS, Johal N, Kouriefs C, Kooiman G, Montgomery BSI, Plail RO, et al. The surgical risk of suprapubic catheter insertion and long-term sequelae. 2006;210–3.

11. Harrison SCW, Lawrence WT, Morley R, Pearce I, Taylor J. suprapubic catheter practice guidelines. 2010;77–85.

12. Aguilera PA, Choi T, Durham BA. Ultrasound-guided suprapubic cystostomy catheter placement in the emergency department. J. Emerg. Med. Elsevier; 2004;26:319–21.

13. Røhl L, Rasmussen OS. Ultrasound-guided percutaneous suprapubic cystostomy.

1997;6:57–61.

14. Hossack T, Chris B, Beer J, Thompson G. A Cost-effective, Easily Reproducible, Suprapubic Catheter Insertion Simulation Training Model. Urology. 2013;82:955–8.

15. Schout BMA, Hendrikx AJM, Scherpbier AJJA, Bemelmans BLH. Update on Training Models in Endourology : A Qualitative Systematic Review of the Literature between January 1980 and. 2008;54:1247–61.

16. Aydin A, Shafi AMA, Khan MS, Dasgupta P, Ahmed K. Review Article Current Status of Simulation and Training Models in Urological Surgery : A Systematic Review. J. Urol. Elsevier; 2016;196:312–20.

17. Singal A, Halverson A, Rooney DM, Davis LM, Kielb SJ. Suprapubic Catheter Insertion. Urology. Elsevier Inc.; 2015;85:23–6.

QUESTIONNAIRE / DATA COLLECTION SHEET

***U*ltrasound-guided *S*uprapubic *C*atheter *I*nsertion *T*raining (USCIT) model questionnaire**

Level of Training: [MO] [Reg] [Consultant] **Dept**: [EM] [GenSurg] [Uro]

Number of Successful SPCs previously inserted: [ ]

No	QUESTION	Score from 0(NO value) to 10 (GREAT value)
Q.1	How valuable was the USCIT model in understanding the principles of US-guided SPC insertion?	[0] [1] [2] [3] [4] [5] [6] [7] [8] [9] [10] …….
Q.2	How valuable was the USCIT model in simulating bladder anatomy?	[0] [1] [2] [3] [4] [5] [6] [7] [8] [9] [10] ……
Q.3	Does the USCIT model provide realistic sensory and tactile feedback during SPC insertion?	[0] [1] [2] [3] [4] [5] [6] [7] [8] [9] [10] …….
Q.4	Does the USCIT model provide realistic resistance to force of trocar advancement?	[0] [1] [2] [3] [4] [5] [6] [7] [8] [9] [10] ……
Q.5	How would you grade the overall performance of the USCIT model in simulating real life SPC insertion?	[0] [1] [2] [3] [4] [5] [6] [7] [8] [9] [10] …….
Q.6	Does USCIT model improve confidence in SPC insertion?	[0] [1] [2] [3] [4] [5] [6] [7] [8] [9] [10] …….
Q.7	How realistic was the initial urine outflow from the supra pubic trocar?	[0] [1] [2] [3] [4] [5] [6] [7] [8] [9] [10] ……
Q.8	Does the USCIT model add any value to your practice?	[0] [1] [2] [3] [4] [5] [6] [7] [8] [9] [10] ……
Q.9	Is Ultrasound of value in SPC insertion?	[0] [1] [2] [3] [4] [5] [6] [7] [8] [9] [10] ……
Q10	Does it make a difference in the SPC insertion simulation?	[0] [1] [2] [3] [4] [5] [6] [7] [8] [9] [10] …….

Note: 1. Short comments may be written on the dotted lines.
2. SPC: suprapubic catheter.

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LETTER TO THE DEAN OF FACULTY OF HEALTH SCIENCES AND HOD'S OF DIVISION OF EMERGENCY MEDICINE AND DEPARTMENT OF UROLOGY

Dear Professor / Doctor/ Sir/ Madam,

Re: **Permission to Conduct a Master of Medicine (MMed) Research at the Faculty of Health Sciences, University of the Witwatersrand**

Above subject matter refers.

My name is Dr James Nonde. I am a second year Emergency Medicine (EM) registrar at the Division of Emergency Medicine of the University of the Witwatersrand, faculty of health sciences. This research is a requirement for obtaining my Master of Medicine (MMed) degree.

My survey will be a validation study of a low-cost *U*ltrasound-guided *S*uprapubic *C*atheter *I*nsertion *T*rainer (USCIT) model. It will involve a questionnaire administered to my target population who will be medical officers, registrars and consultants from the divisions of Emergency Medicine, Urology and General Surgery after conducting a simulation using the model.

If granted permission, the simulations will be conducted during breaks or at the end of departmental / division's academic meetings in the simulation laboratory located at the medical school premises. There will be no risks to patients as they are not part of the participants and there will be no expense to the university or participants.

Once approved, data collection is expected to last two months. All expenses will be borne by me.

Yours Sincerely,

_____ _____

Dr J Nonde (Researcher) Date

I …… (Dean of Faculty of Health Sciences) hereby grant / do not grant permission to Dr J Nonde to carry out the research study as outlined above, pending ethics approval.

Remarks

……

……

_____ _____

Dean of Faculty of Health Sciences Date

(Name _____)

I …… (HOD Emergency Medicine) hereby grant / do not grant permission to Dr J Nonde to carry out the research study as outlined above, pending ethics approval.

Remarks
……
……

_____ _____
HOD Emergency Medicine Date

(Name _____)

I …… (HOD Urology) hereby grant / do not grant permission to Dr J Nonde to carry out the research study as outlined above, pending ethics approval.

Remarks
……
……

_____ _____
HOD Urology Date
(Name _____)

PARTICIPANTS INFORMATION SHEET/ CONSENT

The Validation of an *U*ltrasound-guided *S*uprapubic *C*atheter *I*nsertion *T*rainer (USCIT)
Ethics Clearance Certificate No: MP 170610

1. **Background and aims of the study**

This research aims to validate the USCIT by conducting simulations with the model. The study is funded by the primary researcher.

2. **Why have I been invited to take part?**

You have been invited because you are involved in the management of patients presenting to the ED with urine retention requiring emergent suprapubic catheterization.

3. **Do I have to take part?**

No. You can ask questions about the study before deciding whether or not to participate and you may freely withdraw yourself/data from the study at any time.

4. **What will happen in the study?**

You will be asked to perform a SPC insertion simulation using the USCIT model. Thereafter you'll assess the models on a specifically designed questionnaire. The entire procedure and completion of the questionnaire is expected to take 20 minutes maximum.

5. **Expenses and payments.**

There will be no payments for taking part in this research.

6. **What happens to the data provided?**

Data will be collected anonymously, and any personal information stored confidentially.

7. **Will the research be published?**

The research results may be published both locally and internationally.

8. **Who do I contact if I have concerns about the study?**

For any concerns and clarifications please contact the researcher and/or the supervisors listed below, or the Ethics Committee; University of the Witwatersrand.

Further information and contact details

Researcher: James Nonde email address: nondej@gmail.com phone: +27840238540
Department: Division of Emergency Medicine, University of the Witwatersrand
Supervisors: **1. Dr Abdullah Laher** **2. Dr Ahmed Adam**
Email: **abdullahlaher@msn.com** **aadam81@gmail.com**

PARTICIPANT'S CONSENT

I,_____, do hereby consent to take part in the study.

EMAIL:_____SIGN:_____DATE:_____

APPENDIX 2: ETHICS CLEARANCE CERTIFICATE

R14/49 Dr J Nonde

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M170610

NAME: (Principal Investigator)	Dr J Nonde
DEPARTMENT:	School of Clinical Medicine Department of Emergency Medicine Medical School
PROJECT TITLE:	The assessment and validation of a low cost ultrasound-guided supra-pubic catheter insertion simulation training (USCIT) model
DATE CONSIDERED:	30/06/2017
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Drs A Laher and A Adam
APPROVED BY:	Professor CB Penny, Co-Chairperson, HREC (Medical)
DATE OF APPROVAL:	28/09/2017

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on 3rd floor, Phillip V Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.
I/We fully understand the conditions under which I am/we are authorised to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated from the research protocol as approved, I/we undertake to resubmit to the Committee. **I agree to submit a yearly progress report**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. in this case, the study was initially reviewed in **June** and will therefore be due in the month of **June** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature _____ Date _____

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

APPENDIX 3: ARTICLE 1 – JOURNAL REPRINT PDF

https://doi.org/10.1016/j.urology.2018.02.013

Please see attached PDF

APPENDIX 4: ARTICLE 2 – CONFIRMATION OF MANUSCRIPT ACCEPTANCE FOR PUBLICATION

From: <editorialoffice@karger.com>

Date: Fri, Sep 14, 2018 at 9:13 AM

Current Urology

Ms No.: 201808004

Title: The world of validated suprapubic catheter insertion simulation trainers: from 'head-blocks' to 'lunch boxes': a systematic review.

Dear Prof. Adam,

Thank you for submitting your manuscript to Current Urology. We are pleased to inform you that it has now been accepted for publication in Current Urology and is scheduled to appear in one of the next issues of the journal. We hope that you will continue to support Current Urology in the future.

With kind regards,

Editorial Office

Current Urology

e-mail: xiaoleifang@sdu.edu.cn

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Tel. +86-531-85875737

https://xpresstrackcloud.net/karger/xpresstrack/submissions/author_login.cfm?jid=161

APPENDIX 5: TURN-IT-IN REPORT

1259718:Nonde,_Turn-it-in.docx

ORIGINALITY REPORT

6%	2%	6%	1%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	Allen, Michael, Karen Mann, Cathy Kells, Suzanne Ferrier, Nicolette O'Connor, and Paul MacDonald. "Cardiology grand rounds: effect of videoconferencing on educational value", Journal of Telemedicine and Telecare, 2007. Publication	1%
2	James Nonde, Ahmed Adam, Abdullah Ebrahim Laher. "Validation of a Low Cost, Disposable, and Ultrasound-guided Suprapubic Catheter Insertion Trainer", Urology, 2018 Publication	1%
3	academic.oup.com Internet Source	1%
4	www.iaslc.org Internet Source	1%
5	The Nurse Practitioner in Urology, 2016. Publication	1%
6	Singal, Ashima, Amy Halverson, Deborah M. Rooney, Lauren M. Davis, and Stephanie J. Kielb. "A Validated Low-cost Training Model for	<1%