ORIGINAL CONTRIBUTION



Development and content validation of the checklist for assessing placement of a small-bore chest tube (CAPS) for small-bore chest tube placement

Majid Shafiq MD, MPH¹ | Stefani Russo MD² | Joshua Davis MD³ | Ronald Hall MD² | Jared Calhoun² | Edward Jasper MD² | Katherine Berg MD, MPH² | Dale Berg MD² | Emma C. O'Hagan MLIS, MPH⁴ | Lee Ann Riesenberg PhD, MS⁵

Correspondence

Majid Shafiq, Division of Pulmonary and Critical Care Medicine, Brigham and Women's Hospital, 75 Francis St., Boston, MA 02115, USA.

Email: mshafiq@bwh.harvard.edu

Abstract

Background: Small-bore chest tube (SBCT) placement via modified Seldinger technique is a commonly performed invasive procedure for treatment of pleural effusion and pneumothorax. When performed suboptimally, it may lead to serious complications. Validated checklists are central to teaching and assessing procedural skills and may result in improved health care quality. In this paper, we describe the development and content validation of a SBCT placement checklist.

Methods: A literature review across multiple medical databases and seminal textbooks was performed to identify all publications describing procedural steps involved in SBCT placement. No studies were identified that involved systematic development of a checklist for this purpose. After the first iteration of a comprehensive checklist (CAPS) based on literature review was developed, the modified Delphi technique involving a panel of nine multidisciplinary experts was used to modify it and establish its content validity.

Results: After four Delphi rounds, the mean expert-rated Likert score across all checklist items was 6.85 ± 0.68 (out of 7). The final, 31-item checklist had a high internal consistency (Cronbach's alpha = 0.846) with 95% of the responses (by nine experts across 31 checklist items) being a numerical score of 6 or 7.

Conclusions: This study reports the development and content validity of a comprehensive checklist for teaching and assessing SBCT placement. For purposes of demonstrating construct validity, this checklist should next be studied in the simulation and clinical setting.

INTRODUCTION

The insertion of small-bore chest tubes (SBCTs) involving the modified Seldinger technique is frequently performed by a variety of clinicians when treating pleural effusion, hemothorax, or pneumothorax. An SBCT may be the preferred type of chest tube in many of these instances because, compared to large-bore chest tubes (LBCTs), SBCTs have been associated with less patient discomfort. 1,2

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¹Division of Pulmonary and Critical Care Medicine, Brigham and Women's Hospital, Boston, Massachusetts, USA

²Rector Clinical Skills and Simulation Center, Thomas Jefferson University, Philadelphia, Pennsylvania, USA

³Department of Emergency Medicine, Vituity, and University of Kansas School of Medicine, Wichita, Kansas, USA

⁴UAB Libraries, University of Alabama at Birmingham, Birmingham, Alabama, USA

⁵Department of Anesthesiology and Perioperative Medicine, University of Alabama at Birmingham, Birmingham, Alabama, USA

Furthermore, according to one meta-analysis, SBCTs may also be associated with lower complication rates and shorter hospital length of stay in the setting of pneumothorax.³

SBCTs can nevertheless lead to several complications, with rates estimated from 5% to 15%, 4-6 particularly in cases of suboptimal insertion technique. These include infection; hemothorax, pneumothorax, and parenchymal lung injury; and injury to other organs including heart, diaphragm, and abdominal organs. SBCTs are also prone to clogging, kinking, and dislodgement, risks that may be mitigated through certain procedural techniques. A root cause analysis of two chest tube-related complications identified lack of familiarity with the procedural steps as a key area of weakness and identified key steps that were more prone to operator error. Other studies have also identified key procedural steps as being associated with either higher success rates (e.g., use of ultrasound) or lower complication rates (e.g., considerations when choosing the entry site). 10

The traditional paradigm of procedural skill teaching comprising "see one, do one, teach one" has largely been replaced with a competency-based framework that incorporates skills attainment, deliberate practice, and directed feedback. Procedural checklists, besides being a useful resource for teaching and learner assessment, have been shown to improve quality of health care and reduce complications. Haynes et al. ¹¹ demonstrated mortality reduction following the use of a surgical safety checklist in noncardiac surgery, while both Santos et al. ¹² and See et al. ¹³ showed that standardization of procedural steps involved in bedside pleural procedures can lower the risk of major procedural complications.

Previously, a group from Australia developed the TUBE-iCOMPT checklist for all chest tubes placed using either the modified Seldinger technique or blunt dissection. ¹⁴ To our knowledge, there have been no validated checklists specifically for the insertion of SBCTs using the modified Seldinger technique. In this study, we developed and established the content validity of a SBCT insertion checklist that employed the modified Seldinger technique.

METHODS

Study design and setting

This study was granted exemption by the Thomas Jefferson University's Institutional Review Board (IRB Control # 10 E.48). In this multistep study, we initially performed a thorough review of published literature, then developed an evidence-based draft checklist, and subsequently established its content validity through systematic expert feedback using the modified Delphi process.

Definition of SBCT

For purposes of this study, we defined SBCT as a chest tube sized ≤14 French that is placed using the modified Seldinger method.

Literature search and initial checklist development

A librarian (ECO) performed a comprehensive search of all published English-language articles between 1950 and February 17, 2020, that described procedural steps involved in SBCT placement. Databases searched included Embase, PubMed, Cochrane, and Scopus. Emtree terms included "drainage catheter," "checklist," and "protocol." Medical Subject Headings (MeSH) terms "chest tubes" and "checklist" were used in combination with keywords including "pigtail catheter," "chest tube," "Seldinger chest tube," and "small-bore chest tube" as well as "technique," "checklist," "best practice," "protocol," and various synonyms.

The literature review yielded 641 references. Three authors (MS, RH, and JD) reviewed all titles and abstracts (when available) for possible inclusion. Publications were included if they described procedural steps involved in SBCT placement, either in a narrative format or in the form of a checklist. Twenty-seven articles were selected and reviewed by the same authors for publication of a relevant checklist. The references of all obtained articles were reviewed for possible additional articles. Ultimately, 17 studies were utilized for checklist development (Figure 1). No studies were identified that described systematic development and validation of a checklist for SBCT.

In addition, 10 seminal textbooks in the fields of medicine, surgery, emergency medicine, interventional pulmonology, thoracic surgery, and interventional radiology were reviewed for checklists or descriptions of procedural steps involved in SBCT placement (Appendix S1). Seminal textbooks were identified by the study investigators as most notable in their respective fields on a subjective basis.

Based on techniques described in the literature search results, the authors developed a 32-item draft checklist, named Checklist for Assessing Placement of a SBCT (CAPS). Three authors (MS, RH, and JD) drafted the initial draft and presented it to the remainder of the study team, which reviewed and revised this draft for clarity.

Checklist validation using the modified Delphi process

The modified Delphi method, described in detail previously, was used to establish content validity of the SBCT insertion checklist. ¹⁵ Briefly, this entailed iterative consensus building among subject matter experts through multiple rounds of anonymized and pooled feedback on a series of draft checklists.

We identified nine experts in SBCT placement. Experts were nominated by the study investigators on the basis of their subjective reputation as strong clinicians in their fields with experience in performing and teaching this procedure. Experts were selected if they agreed to participate and met the a priori definition of "expert," which entailed having performed or supervised >20 SBCT placements as an independent practitioner, including at least five within the preceding year. This threshold of 20 procedures was chosen in line with postgraduate training standards set for this procedure by

ORIGINAL CONTRIBUTION 3 of 14

FIGURE 1 Process of identifying publications containing checklists or procedural steps used for SBCT placement. SBCT, small-bore chest tube.

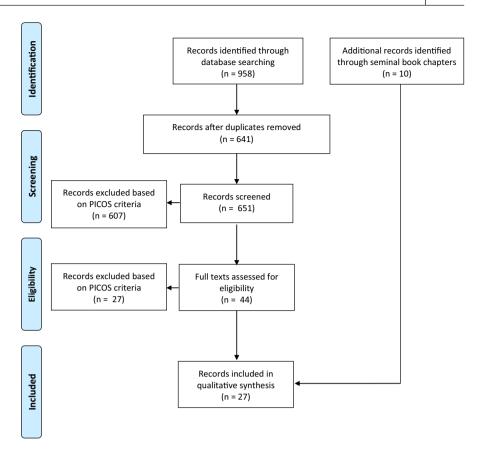


TABLE 1 Baseline characteristics of Delphi experts.

Reviewer	Area of clinical expertise	U.S. geographical region	Sex	Total SBCTs performed (lifetime)
1	Pulmonary and/or critical care	South	Male	325
2	Pulmonary and/or critical care	South	Female	200
3	Pulmonary and/or critical care	Midwest	Male	200
4	Pulmonary and/or critical care	West	Female	500
5	Emergency medicine	Northeast	Male	25
6	Emergency medicine	Northeast	Female	45
7	Thoracic surgery	Northeast	Male	125
8	Interventional radiology	Northeast	Male	50
9	Interventional radiology	Northeast	Male	150

Abbreviation: SBCT, small-bore chest tube.

a multisociety accreditation committee. ¹⁶ The nine experts represented diversity in specialty (interventional pulmonology, interventional radiology, emergency medicine, and thoracic surgery), institution/geographic location, and sex (Table 1). A diverse array of specialties was felt by the study investigators to be more likely in generating healthy debate and critique and less likely to result in confirmation bias as might be more likely among providers trained in the same way. The identities and specialties of other experts were kept confidential from each expert.

Next, the draft checklist was presented to the group of independent experts. In Round 1, experts were individually invited to rate

each checklist item on a 7-point Likert-type scale, where 1–3 represented "unimportant" steps, 4–6 represented "somewhat important" steps, and 7 represented a step that was mandatory for the procedure. Experts were allowed to insert free-text comments wherever deemed appropriate.

Items receiving a mean of <4 were removed from the checklist. The checklist was modified by the authors based on the value and distribution of scores as well as any free-text comments from the experts. The study team was blinded to the identity of the expert behind each comment; all communication with experts was performed by the Delphi checklist coordinator (JC) and all scores as

well as comments were deidentified before presentation to the study team. Experts were blinded to each other's identity and did not get to view other scores or comments before submitting their own.

In subsequent Delphi rounds, the modified checklist was sent back to the same blinded experts for repeat review and feedback. This process was continued until there was consensus (defined as mean of >6 on the 7-point scale) on all items, and there were no comments remaining unaddressed by the study team.

Statistical analysis

The average rating for each item was calculated using descriptive statistics. The internal consistency of the final checklist was determined using Cronbach's alpha. All statistics were performed using Microsoft Excel (Microsoft 365 Office version 2021).

RESULTS

The results of each Delphi round are illustrated in Table 2. In total, four Delphi rounds were carried out. Checklist items were added or modified based on aggregated Likert scores and in light of freetext comments. Experts were also asked to vote on certain specific aspects. These included the exact timing of preprocedural timeout and whether to perform skin incision or guidewire insertion first. With regard to timeout, six (67%) felt that it should be done immediately after obtaining consent, two (22%) felt that it should be done after washing hands and before opening the kit, and one (11%) felt that it should be done immediately before first incision/needle insertion.

Based on expert feedback, one item present in the original checklist (namely, identification of pleural effusion or pneumothorax via ultrasound or computed tomography [CT]) was removed from the final checklist to avoid redundancy; another item already referred to using ultrasound or CT to mark an appropriate site of entry. One other item (namely, sharps disposal) was merged into a preexisting separate item (namely, "cleans up"), whereas one item that was not present in the original version was added (namely, application of sterile drape following the skin prep).

In the first round of the Delphi process, the average score across all items was 6.42 ± 1.34 . This increased to 6.85 ± 0.68 at the end of the fourth and last Delphi round. In the first round, 247 of 288 responses (by nine experts across 32 checklist items) were a numerical score of 6 or 7, representing 85.7% of all responses. This percentage increased to 94.9% in the fourth round. Furthermore, in line with our a priori benchmark, the percentage of checklist items receiving a mean score of >6 increased from 25/32 (78%) in round 1 to 31/31 (100%) in round 4. Following the fourth Delphi round, a consensus checklist was adopted by the author team with unanimous approval. This final, 31-item

checklist (Table 2 and Appendix S2) had high internal consistency (Cronbach's alpha = 0.846).

DISCUSSION

We present CAPS—a comprehensive checklist for insertion of SBCTs using the modified Seldinger technique—and hope that it will not only serve as a useful formative assessment tool to aid learner education and feedback but also provide a means for summative assessment of procedural competence. Through a rigorous process, we have established this checklist's high content validity, which indicates the completeness with which it encompasses all aspects of SBCT insertion. This provides a strong foundation for investigating the checklist's construct validity next, which would reflect its ability to accurately assess a subject's performance when inserting an SBCT.

Previously, a group from Australia developed the TUBE-iCOMPT checklist for chest tube insertion. ¹⁴ The authors, evidently experts in chest tube insertion, developed this checklist for any chest tube placed using either the Seldinger technique (as is frequently done with SBCTs) or by blunt dissection (as more typical with LBCTs). To our knowledge, CAPS is the first procedural checklist on insertion of SBCTs using the modified Seldinger technique that was developed in a systematic, evidence-based manner and subsequently validated through generation of blinded, multidisciplinary expert consensus using the modified Delphi technique.

Notably, during the content validation phase, we found that more than one Delphi round was required to achieve expert consensus on the various aspects of the CAPS checklist. These included the list of steps to follow, the specific details pertaining to each item, and the optimal sequence of steps required for sound conduct of this procedure.

One major item of debate was the timing of the procedural timeout. We respected the expert majority in developing the final checklist; however, we acknowledge that local or institutional protocols may vary in this aspect. The Joint Commission's Universal Protocol also leaves some room for interpretation by requiring that the timeout take place before starting the invasive procedure or making the incision.¹⁷ In the operating room, a surgical timeout involves not just the surgeon but also the circulating nurse and other team members such as the anesthesiologist. There, the timeout is typically performed immediately before the surgeon makes the incision. A SBCT insertion, on the other hand, is more commonly performed outside of the operating room with a variable number of health care practitioners present in the room besides the proceduralist, if any at all. Therefore, depending on the urgency of the procedure and the availability of assistance, this timeout may potentially require some flexibility in terms of the specific timing (e.g., before the proceduralist washes their hands and dons sterile gloves). We suggest that, when administering this checklist, credit should be given for completing this task while allowing room for appropriate variability in terms of its exact timing.

TABLE 2 Results of each Delphi round.

	Delphi round 1	1	Delphi round 2		Delphi round 3		Delphi round 4	4	
Item number	Mean; median; SD	Modification	Mean; median; SD	Modification	Mean; median; SD	Modification	Mean; median; SD	Modification	Final version of item
1. Obtains informed consent	6.0 7.0 2.0	Added subtext: "Except in urgent cases"	6.88 7.0 0.314	Modified to "May not be possible in emergent cases"	6.77 7.0 0.682	N/A	6.77 7.00.628	N/A	1. Obtains informed consentMay not be possible in emergent cases
2. (Originally checklist item #3) Positions patient appropriately • Sits on edge of bed leaning forward with amms resting on a table with a pillow • Alternatively: lateral decubitus with operated side up • Alternatively: supine or semirecumbent (with ipsilateral hand behind or above head if planning lateral approach)	6.55 7.0 0.831	Added to text: "in a supported manner" Cut from first subtext: "with arms resting on a table with a pillow" Cut from third subtext: "(with ipsilateral hand behind or above head if planning lateral approach)" Added fourth subtext: "Alternatively: supine oblique, as when performing procedure under CT guidance"	6.88 7.0 0.314	Moved from Step #3 to Step #2 Modified first subtext to: "Sitting on edge of bed and leaning forward"	6.88 7.0 0.314	∢ Ž	6.77 7.0 0.628	∢ Z	2. Positions patient appropriately in a supported manner • Sitting on edge of bed and leaning forward • Alternatively: lateral decubitus with operated side up • Alternatively: supine or semirecumbent • Alternatively: supine or performing procedure under CT guidance
3. (Originally checklist item #4) Inspects chest wall	6.44 7.0 0.831	N/A	6.33 7.0 1.56	Moved from Step #4 to Step #3	6.77 7.0 0.682	A/N	6.55 7.0 0.831	N/A	3. Inspects chest wall
4B. (Originally checklist item #5) Identifies effusion or pneumothorax (as applicable) via ultrasound	5.44 6.0 2.006	Added to text: "or CT"	6.88 7.0 0.314	Moved from Step #5 to Step #4	0 % 0 0 0 0	Cut step from checklist			(Cut from final checklist) Identifies effusion or pneumothorax (as applicable) via ultrasound or CT
4. (Originally checklist item #6) Uses ultrasound as a guide to mark an appropriate site of entry • Ideally, an intercostal space one to two ribs below the upper level of fluid	5.55 6.0 1.892	Modified to "Using ultrasound or CT as a guide, marks an appropriate site of entry" Cut "Ideally, an intercostal space one to two ribs below the upper level of fluid"	6.44 7.0 0.955	Moved from Step #6 to Step #5	6.33 7.0 1.247	Moved from Step #5 to Step #4 Modified to "Using imaging (e.g., US or CT) as a guide"	6.44 7.0 1.571	₹ Z	4. Using imaging (e.g., US or CT) as a guide, marks an appropriate site of entry
5. (Originally checklist item #8) Opens kit	6.22 7.0 1.872	∀ /Z	7.0 7.0 0	Moved from Step #8 to Step #6, before step "Washes hands"	7.0 7.0 0	Moved from Step #6 to Step #5	7.0 7.0 0	N/A	5. Opens kit
6. (Originally checklist item #7) Washes hands	6.22 7.0 1.872	Z/A	7.0 7.0 0	Swapped positioning to come after step "Opens kit"	6.66 7.0 0.942	Moved from Step #7 to Step #6	6.66 7.0 0.942	∢ ∑	6. Washes hands (Continues)

TABLE 1 (Continued)

	Delphi round 1	1	Delphi round 2		Delphi round 3		Delphi round 4		
Item number	Mean; median; SD	Modification	Mean; median; SD	Modification	Mean; median; SD	Modification	Mean; median; SD	Modification	Final version of item
7. (Originally checklist item #9) Applies cap, mask, sterile gown	6.33 7.0 1.05	Modified to "Dons appropriate personal protective equipment"	7.0 7.0 0	Moved from Step #9 to Step #8	6.77 7.0 0.682	Moved from Step #8 to Step #7	6.88 7.0 0.314	Y/N	7. Dons appropriate personal protective equipment
8. (Originally checklist item #10) Applies sterile gloves	6.66 7.0 0.942	N/A	7.0 7.0 0	Moved from Step #10 to Step #9	7.0 7.0 0	Moved from Step #9 to Step #8	7.0 7.0 0	A/A	8. Applies sterile gloves
9. (Originally checklist item #11) Arranges material appropriately, including placing straightening catheter in pigtail	6.11 7.0 1.28 <i>6</i>	Ψ Z	0 0 0 %	Moved from Step #11 to Step #10 Modified to "Arranges materials appropriately, including placing internal stiffener into pigtail catheter"	6.88 7.0 0.314	Moved from Step #10 to Step #9	6.66 7.0 0.942	∀ Z	9. Arranges materials appropriately, including placing internal stiffener into pigtail catheter
10. (Originally checklist item #12) Preps over marked site and surrounding skin with chlorhexidine or appropriate alternative	6.77 7.0 0.628	N/A A	7.0 0 0	Moved from Step #12 to Step #11	7.0 7.0 0	Moved from Step #11 to Step #10	7.0 7.0 0	N/A	10. Preps over marked site and surrounding skin with chlorhexidine or appropriate alternative
11. (Item did not exist in initial checklist)	٧/ ٧	Created new item #13: "Applies sterile drape, leaving only the procedure site exposed"	7.0 7.0 0	Moved from Step #13 to Step #12	6.88 7.0 0.314	Moved from Step #12 to Step #11	7.0 7.0 0	Y /Z	11. Applies sterile drape, leaving only the procedure site exposed
 12. (Originally checklist item #2) Performs a preprocedure timeout immediately before procedure Including confirmation of: patient ID, procedure, and site by all members of team performing procedure. 	6.77 7.0 0.628	Posed question to experts: "Should the step above ("time out") be positioned as is or immediately after step 7 "Washes hands"?	0 % %	Moved from Step #2 to Step #13 Cut "doing procedure" Posed question to experts: "Should the step above ("time out") be positioned as-is? If not, after which step should it be placed?"	7.0 7.0 0	Moved from Step #13 to Step #12 Modified to "verification of patient ID" Added text "(including laterality)"	0 .	∀ /Z	 12. Performs a preprocedure time out immediately before procedure Including verification of patient ID, procedure, and site (including laterality) by all members of the team
Reconfirms that puncture site is on the superior aspect of lower rib of the selected intercostal space Must make puncture on top, never bottom of rib	6.33 7.0 1.247	Moved from Step #13 to Step #14	6.44 7.0 0.955	Modified to "Confirms that the marked entry site is immediately above the lower rib bordering the selected intercostal space"	6.22 7.0 1.314	Moved from Step #14 to Step #13	6.44 7 1.065	∀ /Z	13. Confirms that the marked entry site is immediately above the lower rib bordering the selected intercostal space

TABLE 1 (Continued)

	Delphi round 1	1	Delphi round 2		Delphi round 3		Delphi round 4	4	
Item number	Mean; median; SD	Modification	Mean; median; SD	Modification	Mean; median; SD Modification	Modification	Mean; median; SD	Modification	Final version of item
14. Injects lidocaine at site of procedure • Subcutaneous injection, 25-to 22-G needle, wheal formation, then deeper into skin, aspirating before each injection for evidence of blood or entry into pleura; when pleural fluid or air obtained, note depth, inject 2-3 mL more to anesthetize the parietal pleura	6.77 7.0 0.415	Moved from Step #14 to Step #15	7.0 7.0 0	Modified text to "Injects local anesthetic (for example, lidocaine) at the entry site." Modified subtext to three separate subtext points: "Using 25- to 22-G needle, creates a superficial wheal" "Then injects deeper into skin, aspirating before each injection for evidence of blood or entry into pleura" "When pleural fluid or air is obtained, notes depth, and injects additional 2-3 mL of anesthetic to anesthetice to anesthetice to anesthetical pleura"	6.66 7.0 0.942	Moved from Step #15 to Step #14 Changed subtext "injects additional 2-3 mL of anesthetic" to "injects additional anesthetic"	7.0 0 0	Added to subtext point 3: "pulls back needle slightly"	14. Injects local anesthetic (for example, lidocaine) at the entry site • Using a 25- to 22-G needle, creates a superficial wheal • Then injects deeper into skin, aspirating before each injection for evidence of blood or entry into pleura • When pleural fluid or air is obtained, notes depth, pulls back needle slightly, and injects additional anesthetic to anesthetize the parietal pleura

(Continues)

TABLE 1 (Continued)

	Delphi round 1	1	Delphi round 2		Delphi round 3		Delphi round 4	4	
Item number	Mean; median; SD	Modification	Mean; median; SD	Modification	Mean; median; SD	Modification	Mean; median; SD	Modification	Final version of item
15. After reconfirming position inmediately above the rib, uses appropriate blade to make a superficial skin incision that is parallel to the rib • Typically, a No. 11 blade is used. • Keep incision superficial, enabling entry of catheter through the epidemis without causing injury to soft tissues or running the risk of lacerating an intercostal vessel	6.77 7.0 0.628	Moved from Step #15 to Step #16	0 0 0	Modified second subtext to "Keeps incision superficial, enabling entry of catheter through the epidermis without causing injury to deeper structures"	6.66 7.0 0.942	Moved from Step #16 to Step #15	0 0 0	₹ Z	15. After reconfirming positioning immediately above the rib, uses appropriate blade to make a superficial skin incision that is parallel to the rib Typically, a No. 11 blade is used Keeps incision superficial, enabling entry of catheter through the epidermis without causing injury to deeper structures
16. Attaches appropriate sized syringe to large hollow bore needle hub (typically, an 18-G needle is used) and after reconfirming position immediately above the rib, introduces needle through the incision site	6.22 7.0 1.474	Moved from Step #16 to Step #17 Added subtext "If using real-time imaging guidance, use of a syringe may be omitted"	6.66 7.0 0.94	Modified text to "Attaches appropriately sized syringe to the hub of a large hollow-bore needle"	6.66 7.0 0.942	Moved from Step #17 to Step #16	6.33 7.0 1.885	₹ Z	16. Attaches appropriately sized syringe to the hub of a large hollow-bore needle (typically, an 18-G needle is used) and after reconfirming position immediately above the rib, introduces needle through the incision site I fusing real-time imaging guidance, use of a syringe may be omitted
17. While inserting needle, continuously aspirates syringe to immediately recognize fluid or air return from pleural space	6.0 7.0 2.0	Moved from Step #17 to Step #18 Added subtext "If using real-time imaging guidance, this step may be omitted"	6.66 7.0 0.94	∀ ∕Z	6.88 7.0 0.314	Moved from Step #18 to Step #17	7.0 0 0	∢ Z	17. While inserting needle, continuously aspirates syringe in order to immediately recognize fluid or air return from pleural space If using real-time imaging guidance, this step may be omitted

TABLE 1 (Continued)

	Delphi round 1	Ţ	Delphi round 2		Delphi round 3		Delphi round 4	4	
Item number	Mean; median; SD	Modification	Mean; median; SD	Modification	Mean; median; SD	Modification	Mean; median; SD	Modification	Final version of item
Removes syringe from needle hub while carefully maintaining position of needle Once syringe removed, places gloved thumb over hub of needle	6.0 7.0 2.0	Moved from Step #18 to Step #19 Posed question to experts: "Should the subtext pertaining to 'places gloved thumb overhub of needle' be kept or removed?" Added subtext "If using real-time imaging guidance, use of a syringe may be omitted"	6.55 7.0 0.955	Cut subtext "Once syringe removed, places gloved thumb over hub of needle"	7.0 0 0	Moved from Step #19 to Step #18	7.0 0 0	∀\X	 18. Removes syringe from needle hub while carefully maintaining position of needle I fusing real-time imaging guidance, use of a syringe may be omitted
19. Threads guidewire through hollow-bore needle • The guidewire should be inserted approximately twice the distance from the skin to pleural space. This can be estimated as twice the length of the inserted portion of the needle • Placing guidewire too superficially or too deeply should be avoided • If resistance to guidewire insertion met, stops and reconfirms placement of needle • If resistance to guidewire insertion met, stops and reconfirms placement of needle	6.44 7.0 1.065	Moved from Step #19 to Step #20 Modified first subtext to "The guidewire should be inserted at least several centimeters beyond the tip of the needle" Cut second subtext	2 2 2 0 0	Modified text to "Threads guidewire through the hollow- bore needle" Modified second subtext to "If resistance to guidewire insertion is encountered, stops and reconfirms placement of needle"	0 0 0 0	Moved from Step #19 #19	7. 0 0 0 0 0	₹ Z	19. Threads guidewire through the hollow-bore needle • The guidewire should be inserted at least several centimeters beyond the tip of the needle • If resistance to guidewire insertion is encountered, stops and reconfirms placement of needle
20. While continuously holding guidewire, removes hollow-bore needle from site	7.0 7.0 0	Moved from Step #20 to Step #21	7.0 7.0 0	Modified text to "While continuously holding guidewire, removes hollow-bore needle"	7.0 7.0 0	Moved from Step #21 to Step #20	7.0 7.0 0	N/A	20. While continuously holding guidewire, removes hollowbore needle

(Continues)

TABLE 1 (Continued)

Item number	Delphi round 1 Mean; median; SD		Delphi round 2 Mean; median; SD	Modification	Delphi round 3 Mean; median; SD	Modification	Delphi round 4 Mean; median; SD	4 Modification	Final version of item
6.33 7.0 1.563	m	Moved from Step #21 to Step #22 Modified text to "While continuously holding guidewire, inserts dilator over guidewire until an abrupt loss of resistance (i.e. 'give') is felt." Added subtext "Subsequently, using small back and forth movement (racking) of the guidewire, confirms that it is freely moving and not kinked."	6.55 7.0 0.955	Modified text to "While continuously holding guidewire, inserts dilator over guidewire" Added subtext "The appropriate depth of dilator placement may be determined using the previously noted depth in Step 15 and/or when an abrupt loss of resistance (i.e., 'give') is felt"	6.88 7.0 0.314	Moved from Step #22 to Step #21	6.88 7.0 0.314	∢ Ž	21. While continuously holding guidewire. • The appropriate depth of dilator placement may be determined using the previously noted depth in Step 15 and/or when an abrupt loss of resistance (i.e., "give") is felt • Subsequently, using small back and forth movement (racking) of the guidewire, confirms that it is freely moving and not kinked
6.88 7.0 0.314	8	Moved from Step #22 to Step #23	6.88 7.0 0.314	N/A	6.88 7.0 0.314	Moved from Step #23 to Step #22	6.88 7.0 0.314	N/A	22. While continuously holding guidewire, removes dilator
6.88 7.0 0.314	6.88 7.0 0.314	Moved from Step #23 to Step #24 Added subtext "Keeps inserting until the tip is inside the pleura, then advances only the pigtail and not the straightening catheter"	70 0 0	Modified text "straightening catheter" to "internal stiffener" Modified subtext "inserting" to "advancing"	6.33 7.0 1.885	Moved from Step #24 to Step #23	0 0 0	Κ/X	23. While continuously holding guidewire, inserts pigtail catheter (with internal stiffener in place) over the guidewire, stopping if any resistance is noticed. • Keeps advancing until the tip is inside the pleura, then advances only the pigtail and not the internal stiffener
6.87 7.0 0.33	6.875 7.0 0.330	Moved from Step #24 to Step #25 Modified text to "Removes the guidewire, and then, removes the straightening catheter" Posed question to experts: Should the text pertaining to "while placing finger/thumb tip over exposed hub" be kept or removed?"	7.0 0 0	Modified text "straightening catheter" to "internal stiffener"	7. O O O	Moved from Step #25 to Step #24	6.33 7.0 1.247	4 /X	24. Removes the guidewire and then removes the internal stiffener

TABLE 1 (Continued)

	Delphi round 1	1	Delphi round 2		Delphi round 3		Delphi round 4	4	
Item number	Mean; median; SD	Modification	Mean; median; SD	Modification	Mean; median; SD	Modification	Mean; median; SD	Modification	Final version of item
25. (Originally checklist item #26) Attaches catheter tubing to chest drain tubing and secures tightly via twisting motion. • Attaches chest drain to suction or leaves it on water seal as desired	0 0 0	Moved from Step #26 to Step #27	7.0 0 0	Moved from Step #27 to Step #26	7.0 0 0	#26 to Step #25 to Step #25 Modified first subtext "as desired" to "as appropriate" Added second subtext "Alternatively, attaches catheter tubing to a Heimlich valve"	7.0 0 0	Υ	25. Attaches catheter tubing to chest drain tubing and secures tightly via twisting motion. • Attaches chest drain to suction or leaves it on water seal as appropriate • Alternatively, attaches catheter tubing to a Heimlich valve
26. (Originally checklist item #27) Secures chest tube in place using either a sterile suture or alternate device	6.77 7.0 0.628	Moved from Step #27 to Step #28	6.66 7.0 0.666	Moved from Step #28 to Step #27	0 0 0 0 0 0 0	Moved from Step #27 to Step #26	7.0 7.0 0	X A	26. Secures chest tube in place using either a sterile suture or alternate device
27. (Originally checklist item #25) Obtains a small amount of fluid for diagnostic workup if indicated, using the side/flushing port and a syringe (e.g., 60-mL syringe)	6.44 7.0 6.684 0.684	Moved from Step #25 to Step #26 Modified text to "Obtains fluid for diagnostic workup if indicated, using the side/flushing port (if available) and a syringe" Should the above step take place as is, after the next step "Attaches catheter tubing to chest drain tubing and secures tightly via twisting motion," OR after the following step: "Secures chest tube in place using either a sterile suture or alternate device?"	6.66 7.0 0.942	Moved from Step #26 to Step #28 Modified text to "Obtains fluid for diagnostic workup if indicated, using the side/flushing port and a syringe (e.g., 60-mL syringe)"	0 % 0 0	Moved from Step #28 to Step #27	0 0 0	∀ X	27. Obtains fluid for diagnostic workup if indicated, using the side/flushing port and a syringe (e.g., 60-mL syringe)

TABLE 1 (Continued)

		he	leans up" opriately)	rps	te	e catheter imaging
	of item	Places a dressing at tl	item #29 "C sharps appr	eans up Disposes of sharps appropriately	rocedure no	Confirms appropriate cathete positioning via chest imaging
	Final version of item	28. Places a dressing at the catheter entry site	Merged into item #29 "Cleans up" (Disposes of sharps appropriately)	29. Cleans up Dispo appro appro	30. Writes procedure note	31. Confirms appropriate catheter positioning via chest imaging
	Modification					
nnd 4		Υ Σ		N/N	A/A	A/N
Delphi round 4	Mean; median; SD	7.0 7.0 0		7.0 7.0 0	6.77	6.77 7.0 0.628
	Modification	Moved from Step #29 to Step #28 Modified to "Places a dressing at the catheter entry site"	Merged into item #29 "Cleans up"	Moved from Step #31 to Step #29 Added subtext "Disposes of sharps appropriately"	Moved from Step #32 to Step #30	Moved from Step #33 to Step #31
Delphi round 3	Mean; median; SD	6.88 7.0 0.314	7.0 7.0 0	6.33 7.0 1.885	7.0 7.0 0	7.0 7.0 0
	Modification	۷ ک	N/A	∀ ∕Z	Modified to "Writes procedure note"	٧/ ٧
round 2	lian; SD					
Delphi rou	Mean; median; SD	6.77 7.0 0.628	7.0 7.0 0	6.88 7.0 0.314	7.0 7.0 0	6.77 7.0 0.628
	Modification	Moved from Step #28 to Step #29 Modified to "Places a dressing over the catheter entry site"	Moved from Step #29 to Step #30	Moved from Step #30 to Step #31	Moved from Step #31 to Step #32	Moved from Step #32 to Step #33 Modified to "Confirms appropriate catheter positioning via chest imaging"
Delphi round 1	Mean; median; SD	6.22 6.0 0.785	6.88 7.0 0.314	6.22 7.0 1.872	6.22 7.0 1.872	5.88 7.0 1.852
	Item number	28. Places a clear dressing over the catheter entry site	28B. (Originally checklist item #29) Disposes of sharps appropriately	29. (Originally checklist item #30) Cleans up	30. (Originally checklist item #31) Writes procedure note in appropriate space	31. (Originally checklist item #32) Orders a chest radiograph and interprets it

ORIGINAL CONTRIBUTION 13 of 14

Another variability in practice noted in our study was what qualified as appropriate personal protective equipment (PPE) for this procedure. This could conceivably vary depending on institutional policies. After the same was pointed out by the experts, we modified the checklist to include a more generic descriptor, "dons appropriate PPE."

Similarly, expert consensus was to avoid prescribing an ideal site of entry relative to level of pleural fluid (i.e., one or two intercostal spaces below the upper level of fluid) as has been commonly prescribed for pleural fluid drainage. Experts reported variable practice and lack of evidence to support such a recommendation. On the other hand, there was broad consensus on using imaging guidance as opposed to anatomic landmarks to choose the entry site, as is currently expected as the standard of care. This was therefore incorporated into the final version of the checklist and would apply equally to all institutions, specialties, and practitioners.

Some experts recommended performing the scalpel incision prior to guidewire insertion; others noted that it could be performed after the guidewire was inserted. The rationale given for the former technique was to avoid accidentally cutting the guidewire. In the final Delphi round, there was broad consensus in favor of the former approach.

LIMITATIONS

This study has several limitations. Intrinsic bias among experts is possible. However, this possibility was minimized by presenting a literature-based checklist as the starting instrument, selecting exerts from a wide range of institutions and across different specialties (Table 1) and using blinding during the modified Delphi process. While we did involve a diverse set of experts in terms of geography and training, it is possible that this checklist may not be generalizable to all settings. This checklist was designed keeping the novice learner in mind; experts may choose to depart from specific checklist items in certain situations. While this study demonstrates robust content validity of the new checklist, it does not inform the checklist's construct validity which would require further investigation involving subjects with varying levels of training and skill. Such a study would be expected to generate a cutoff (in terms of number of items correctly performed) correlating with each degree of performance or skill (e.g., novice, intermediate, expert, etc.). Finally, the feasibility of administering this 31-item checklist (Appendix S2) would also require careful investigation, particularly at the bedside where the time it takes to be administered may have a greater bearing on its usability than in the simulation setting.

CONCLUSIONS

We report the first steps toward the development and validation of a comprehensive checklist for small-bore chest tube insertion using the modified Seldinger technique. This checklist will likely be of use in formative training and summative assessment and as a quality improvement/quality assurance tool, though the same remains to be investigated. Our study provides content validity evidence for the checklist for assessing placement of a small-bore chest tube checklist. Evidence of construct validity should be investigated next, including an examination of its performance in both simulated and real-life clinical environments and its ability to discriminate proceduralists based on level of training and skill.

AUTHOR CONTRIBUTIONS

Majid Shafiq, Katherine Berg, Dale Berg, and Lee Ann Riesenberg conceived and designed the study. Majid Shafiq, Joshua Davis, Ronald Hall, Edward Jasper, and Emma C. O'Hagan were involved in literature review and initial development of the checklist. Majid Shafiq, Stefani Russo, Joshua Davis, Ronald Hall, Jared Calhoun, Edward Jasper, and Lee Ann Riesenberg were involved in checklist modification during the Delphi process. Majid Shafiq drafted the manuscript, and all authors contributed substantially to its revision. All authors take responsibility for the paper as a whole.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

ORCID

Majid Shafiq https://orcid.org/0000-0001-7971-3350

Joshua Davis https://orcid.org/0000-0002-6096-2856

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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