Creating A Generalizable Checklist For The Construction Of A Coronary Anastomosis Using A Delphi Approach

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THESIS

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LIST OF ABBREVIATIONS

CTS	Cardiothoracic Surgery
MCQ	Multiple Choice Questions
OSATS	Objective Structured Assessment of Technical Skills
CAB	Coronary Artery Bypass
GRS	Global Rating Scales
JCTSE	Joint Council on Thoracic Surgical Education
IMA	Inferior Mesenteric Artery

SUMMARY

A checklist for a complex technical skill in cardiothoracic surgery can be produced using a Delphi method and engaging clearly defined experts from across the US. However, there is considerable variability among experts. Over 70% of the items experts independently believed to be mandatory for the performance of a technically proficient coronary anastomosis were unable to be accepted by the group into the final consensus list of items. In fact, when queried about an item they had themselves initially suggested, in the context of all the other items submitted by the other experts, many faculty were unwilling to identify the item as mandatory. These findings severely question the ability of any small local group of surgeons from creating a checklist that includes all the relevant items for a comprehensive checklist. Locally developed checklists will contain significant gaps (missed items) or non-mandatory items when examined by a more geographically diverse population of surgeons. These findings therefore threaten the generalizability of any locally produced checklist if used outside the location of origin.

I. BACKGROUND

Like all surgical disciplines, education in Cardiothoracic Surgery (CTS) requires the trainee to acquire both cognitive and motor skills. While assessment of cognitive skills is addressed with a number of tools well suited to their evaluation (e.g., MCQ examinations), motor skills have very few assessment tools currently in use. Despite an essential need to ensure that CTS trainees are competent in these procedures, assessment of surgical skills in general remains in its infancy with poor reliability and validity at the higher levels of training(1). Currently utilized methods include written and oral examinations, operative log books, operative time, direct observation, and morbidity and mortality data(2,3,4). Unfortunately, each of these tools possesses modest evidence of validity at best and operative logs, the most commonly implemented tool, have very poor validity(2,4,5). Direct observation, the next most commonly employed method, suffers from poor reliability, poor compliance, and inaccuracy(6,7). Considering the dominant role that technical skills play in CTS and the significant risk for medical errors when performed erroneously, the use of operative logs and direct observation as the sole methods of establishing competency in CTS procedures is a gaping problem that must be addressed.

In an attempt to address this gap, new tools for many procedures have been developed including checklists, objective structured assessments of technical skills (OSATS), dexterity analysis systems, virtual reality simulators, bench models, and error scoring systems(2,8,9,10,11). Bench models, virtual simulators, and OSATS are reliable but have varying degrees of validity evidence, are limited in their application to only some skills, are resource intensive, and, especially for OSATS, require several staff surgeons to observe the performance. Dexterity analysis systems require additional resources but provide objective data. Unfortunately, important outcome measures are missed by many of these tools as the majority have been developed for basic surgical skills. The tools available for advanced open surgical skills, the dominant skill in CTS, are scarce.

The most common procedure in CTS is coronary artery bypass surgery. A key component of that procedure is the construction of a coronary artery bypass (CAB) anastomosis. This involves exposing and creating an incision in the side of a coronary artery, preparing a segment of the patient's vein or artery from another site to serve as a bypass, constructing the anastomosis (i.e., the attachment of the open end of the vein or artery to the side of the coronary artery), performing any testing of the anastomosis to ensure patency and finally managing and directing any surgical assistants. Roughly 400,000 CAB surgeries are done annually in the United States alone(12). Considering that each CAB surgery requires an average of three anastomoses, roughly 1.2 million anastomoses are performed annually. Naturally, this technical skill has been the focus of many efforts at technical skill assessment in CTS. In addition to its frequency, the procedure is also short in duration and can be easily simulated with both high and low fidelity simulators. All these aspects make CAB an ideal procedure for assessment tool development.

Direct observation of surgical skills, the method commonly employed, suffers from all the deficiencies seen when applied to surgical skills. Checklists and behaviorally anchored global assessments, originally created for OSATS(13), have been adapted for CTS to improve the reliability and validity of direct observations of simulation exercises. These instruments have bee

developed and evaluated both in the simulated environment(14,15) as well as early attempts in assessing live operations(16). Reznick et al developed the OSATS tool which included both a checklist and a global rating scale. The majority of instruments adapted for use in CTS simply used the global rating component of the original OSATS tool and frequently dismissed the checklist component(17).

In general, work with checklists specific to CAB has been limited. This may stem from earlier work using global rating scales (GRS) and checklists in OSATS. When checklists were compared to GRS the latter was found to provide better inter-station reliability, better construct validity, and better concurrent validity. Also, there was no evidence that when added to GRS they improved the reliability or validity of GRS alone(18,19). These and similar data have likely contributed to the limited interest in developing checklists for procedural assessment. However, as identified in the systematic review by Ahmed and colleagues, while current available GRS and checklists may have known-groups validity evidence between junior and senior trainees, all observational assessments tools lack reliability and validity at the specialist or higher trainee level(1). This "ceiling effect" has been attributed to the simulation models(14) as well as the assessment tools themselves. However, in assessment of live surgery, the lack of a model implies that any observed ceiling effect must be attributable to the assessment tool itself. Therefore, there is a need for increased sensitivity in these instruments. It is possible that improved checklists may provide increased sensitivity.

One explanation for the limited sensitivity among existing checklists may be secondary to the variability that exists between institutions regarding the specific steps employed. Highly complex procedures can be performed in a variety of ways with similar outcomes. This may lead to a checklist, developed at one institution, which is populated with some items that detract from the overall sensitivity of the instrument. When such an instrument is applied at differing institutions validity will suffer. Therefore, any improvement in a checklist must also ensure that the instrument will be generalizable. The items included must be accepted by a broad population of experts to identify the key generalizable steps and exclude those steps that are "expert' or "site" specific. Unfortunately, the majority of checklists and GRS that have been developed lack broad participation(13).

Therefore, there is a need for a more reliable, valid tool to assess CAB anastomosis. The tool should be detailed enough to overcome the celling effect seen with existing tools. Finally, the tool should include input from a broad population of experts to maximize the generalizability of the tool among differing training programs. We hypothesized that a consensus building exercise that includes input from a randomly selected broad pool of clearly defined experts will produce a checklist that could addresses these three needs. We intend to explore three specific elements of this hypothesis. First, is this approach feasible? Second, what is the degree of variability that exists between experts with regards to the items that eventually reach consensus? Finally, are there any features that will help predict which items will reach consensus and guide future checklist item development?

II. METHODS

A. Selection of a Consensus Building Technique

Selection of a consensus building exercise was based on two criteria. First, the technique employed must address the wide variation that exists between experts on just what steps are felt to be essential to the procedure. There is a wide variation in techniques employed during construction of a coronary anastomosis that are specific to a surgeon and where they received their training. Many are potentially *stylistic* only and have limited impact on the outcome of the procedure (author's personal experience) while some items are consistent between surgeons and are core to the procedure. Therefore, any consensus technique used should be able to eliminate the stylistic non-impactful steps while preserving the key shared steps between experts. Second, any technique used should account for the nature of cardiothoracic surgery training and the personalities of those involved. Training in cardiothoracic surgery in the past (and still to some degree in the present) was heavily competitive and hierarchal(20). Additionally due to the small number of practicing cardiothoracic surgeons, especially those engaged in education, most surgeons are acquainted with one another. Therefore, any consensus technique used should limit or eliminate the impact of a particular expert's "personality" (e.g., extraversion, need for dominance) on the decisions of other experts.

Methods that allow anonymity between participants (Delphi Method(21)) would appear to have an advantage over other open group methods (Multi-Attribute Consensus Building(22) and Social Judgment Analysis(23)). Okoli and Pawlowski reviewed the Delphi methodology as a research tool and made specific recommendations, based on their review of the literature, on how to perform a rigorous Delphi method(24). They compared the Delphi method with social judgment analysis and found Delphi more desirable for the following reasons:

1. Delphi does not require the experts to meet physically, allowing more global access to experts
2. Delphi panel size requirements are modest, making the pool of experts queried manageable
3. Delphi is flexible in design, allowing any number of follow-up interviews

They did however highlight the need for a rigorous procedure for identifying the panel of experts, a critical requirement to the success of the Delphi method. The Multi-Attribute Consensus Building requires a comparison of two or more alternatives. Participants score the items and when a high degree of variability is noted, an open discussion is held between participants.

Delphi method has been used before in medical education. Robson and Rew published on the use of Delphi technique as a tool for collective decision making in oncology(25). While their focus was on the use of Delphi method to produce clinical management guidelines, they identified some practical limitations of this approach. First was the rapid change in medical knowledge. Even though the Delphi is a more economical approach than large face-to-face meetings of experts, it is still slow to adapt to change. Their greater concern centered on the selection and knowledge of the experts used for the consensus exercise. Like Okoli and Pawlawski they emphasized the importance of selecting a well-defined and knowledgeable field of experts.

A number of investigators have used Delphi to develop specific procedural checklists (26,27,28,29). Expert selection was commonly based on involvement in national societies, national leadership roles or on publication records. None of the studies mandated that experts were actively engaged in teaching although their criteria would certainly enrich their experts with teachers. An additional finding of these studies was that the initial lists of items for the checklist were created by the authors. This list was then distributed to the experts for the Delphi. The experts themselves were not used to identify the initial items to be included in the checklist although the items were adapted based on their feedback. Okoli and Pawlawski highlighted the need to use the experts to identify “factors of importance” in their example. This allows creation of a more comprehensive view and is referred to as “brainstorming” in their example.

B. Delphi Technique

1. Selection of Experts A total of 15 to 20 experts were sought for consensus building. This number is consistent with the recommended participant size when the panel consists of a homogeneous population of experts. A database of US experts involved in teaching coronary artery surgery was created. Criteria for expertise were based on three elements.

- Actively involved in performing coronary surgery
- Actively involved in teaching at an accredited CTS training program
- Board certified for a minimum of 10 years

A list of all current CTS educators in North America was obtained from the Joint Council on Thoracic Surgical Education (JCTSE). This list was filtered to include only those faculty with a clinical focus in coronary artery surgery. Clinical focus was based on their personal profile in CTSNet (cardiothoracic surgery network www.ctsnet.org) and other publically available surgeons’ profiles. The date of their initial Board certification was obtained from the annual report of the American Board of Medical Specialties and the American Board of Thoracic Surgery’s website. This data was used to further filter the list to only include surgeons in practice greater than 10 years. This final list (314 individuals) constituted the total North American sampled population of experts.

This list was randomized and surgeons were contacted individually. Contact was initiated in batches of 10. Each batch was given sufficient time to respond before moving to the next batch. In contrast to simply sending a request to all potential experts simultaneously this approach was selected for two reasons. First, to prevent too many individuals from agreeing to participate simultaneously. Second, to prevent a bias towards including those who simply respond quickly. Each individual was sent an email briefly describing the purpose of the project, how they were identified and requesting their participation. After 2 weeks any non-responders were assumed to have declined. Those who accepted were sent additional instructions. If additional participants were still needed, the next batch of 10 was contacted.

When an individual expressed interest they were asked to confirm if they were still actively teaching and routinely perform coronary work. Once affirmed the first step of the process was provided. The identity of any individual who was contacted was always kept anonymous during solicitation and throughout the Delphi.

The instructions sent to each participant is shown in Appendix A. The instructions were focused on four key elements. First, they clearly defined that the items the participants provided were “mandatory for the competent performance of a CAB anastomosis”. These are the steps that “just have to be there otherwise it will not be a safe and well-constructed anastomosis”. Second, the instructions defined what constituted a “CAB Anastomosis”, e.g., when it began and when it was completed. Next, instructions on how to construct a checklist item were provided including examples of well-constructed and poorly-constructed items. Finally, to help organize the items and remind experts to address all aspects of a CAB anastomosis, the procedure was divided into six sections.

1. Dissection of the target vessel
2. Creation of the arteriotomy
3. Preparation of the graft (vein or IMA)
4. Management of assistant(s)
5. Performance of the anastomosis
6. Testing or any additional manipulation of the graft

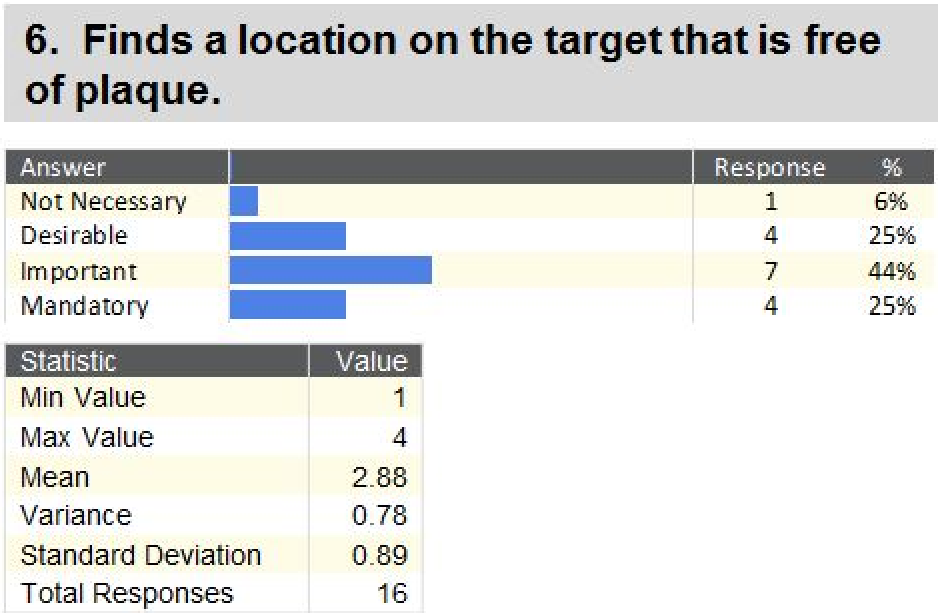
Experts were asked to provide as many items they felt were necessary for each section. Up to five reminders were sent to encourage submission of their initial self-created checklist. After the fifth reminder non-responders were assumed to have withdrawn.

2. Generation of an expert derived master item list Once all the items were received, they were collapsed into a master list. Items that had a similar focus were grouped. If grouping items required any significant change in the wording, the revised wording was sent back to the original author(s) to ensure that the true meaning of the item was preserved. The PI worked with each expert participant to ensure that all the items included in the master list reflected the original intent of that item as provided by the expert.
3. Consensus Building All surveys were constructed and distributed using survey software by Qualtrics (©2015 Qualtrics, LLC; Provo, Utah). Consensus was built using three rounds of surveys. A classic Delphi can include from 3-5 rounds although early work suggested four to be optimal(30). A fourth round was considered; however, considering the workload of the expert participants as active clinical cardiac surgeons, the fourth round was held in reserve to be used only if a significant number of items were added on the third round.

In round one, each participant received a survey with all the items contained in the master list. Each participant was asked to rank each item on a four point scale (1-Not Necessary, 2-Desirable, 3-Important, 4-Mandatory). Scales ranging between two and nine points have all been used in Delphis. We selected a four point scale as the descriptions of these approaches included clear definitions of consensus along with the description of the scale itself(31,32). Reminders were sent to ensure 100% completion of all the surveys. We deemed that an item attained positive consensus when 75% of experts ranked an item as mandatory 4. An item was discarded if none of the participants ranked the item as mandatory and the mean score was <2 (“Desirable”). All other items were advanced to round two.

In round two, any item that had not attained positive consensus or been discarded was sent to the participants. The participants were asked to rank each item using the same four point scale; however each item was also accompanied with descriptive data derived from round one. This included the minimum and maximum, mean, variance and the standard deviation of the data from round one. In addition, each item included a graph depicting the number of responses for each of the four possible ranks for that item (Figure 1). Finally, in addition to ranking the item using the four point scale, each item was also accompanied by a free text field allowing participants the opportunity to comment on that item. They were asked to use this field to advocate either for or against an item they felt strongly about. Again, all surveys were conducted anonymously. Reminders were sent to ensure 100% completion of all the surveys. Items that attained positive consensus were added to those that attained consensus in the first round. The remaining items were moved to round three.

An example of an item, with its accompanying data, sent to each participant during the 2nd or 3rd round of the Delphi



6. Finds a location on the target that is free of plaque.

Answer		Response	%
Not Necessary		1	6%
Desirable		4	25%
Important		7	44%
Mandatory		4	25%

Statistic	Value
Min Value	1
Max Value	4
Mean	2.88
Variance	0.78
Standard Deviation	0.89
Total Responses	16

Figure 1: Example of an item presented to a Delphi participant

In round three, the remaining items were again sent to all participants. The descriptive data and graphic representation of the responses from round two accompanied each item. In addition, any responses advocating for or against an item was included with that item. All of these comments were kept anonymous. Participants were informed of the criteria needed to reach a consensus and told that this was the last round of the survey. Any items that failed to attain positive consensus on this survey would be dropped. Reminders were sent to ensure 100% completion of all the surveys. The items that attained positive consensus were added to those from round one and two and together constituted the final checklist for the construction of a coronary anastomosis.

4. Analysis All responses from each round were analyzed using descriptive statistics. Comparisons were assessed using paired t-tests with the cutoff for statistical significance defined at $p < 0.05$.

III. RESULTS

A. Expert Participants A total of 100 faculty were contacted in just over 15 weeks. Four faculty revealed that they no longer were active in coronary surgery. Of the remaining 96 experts 25 (26%) agreed to participate and were provided with instructions. Generation of each participant's individual CAB anastomosis checklist took 22.6 weeks. Nine participants subsequently either withdrew or did not submit a checklist despite five reminders. This left 16 expert participants who provided individual CAB anastomosis checklist and proceeded to the Delphi. The demographics of the expert participants and the entire pool of experts are shown in Table I.

Table I

DEMOGRAPHICS OF THE NATIONAL EXPERT POPULATION AND THE DELPHI PARTICIPANTS

	Final Participants (n=16)		Expert Pool (n=314)	
Gender				
Male	15	94%	305	97%
Female	1	6%	9	3%
Geographic Distribution				
West	4	25%	50	16%
South	6	38%	82	26%
Midwest	3	19%	78	25%
North-east	2	13%	66	21%
Canada	1	6%	38	12%
Years of ABTS Certification				
Mean ± St Dev	20.1 ± 8.1 years		22.2 ± 9.2 years	
Median	20 years		21 years	
Range (Min:Max)	10:34 years		10:62 years	

B. Initial Master Item list Initial item generation by the participants required 1.6 ± 1.5 reminders. The time from the initial invitation to the provision of the item list was 31 ± 26 days (range 0 to 89 days). The total time to collect all 16 participants' checklists took 22.6 weeks.

The total number of items provided was 407. The average, standard deviation (±), median and range number of items submitted by each participant was 25 ± 10, 22, 11:48.

During the generation of the expert derived master list, it was noted that the "Performance of the Anastomosis" section of the CAB anastomosis contained items that were either very specific or more consistent with a general rule to be observed throughout the performance of the anastomosis. For example: "Toe sutures are placed as separate bites in the graft and the target" versus "Tissue handled gently to minimize tissue trauma". Therefore a new section was created titled "Anastomotic General Rules" to house the more general items pertaining to the performance of the anastomosis. The number of items suggested for each section and the final number after collapsing like-items together into a Master Item list is shown on Table II. The final number of unique items which constituted the Master Item List was 146. Of note was the rather consistent finding that 2/3rd of the items were duplicated by other participants in all the sections of the CAB anastomosis except for the "General Rules" section where only 1/3rd of items were duplicated by other participants.

Table II

TOTAL ITEMS SUBMITTED BY PARTICIPANTS AND FINAL NUMBERS AFTER MERGER OF LIKE ITEMS

Section	# Items Submitted by Participant			# Items prior to merging	Items following merger into a Master Item List	
	Mean	Median	Range		#	%
Dissection of Targets	3.6	3	1 to 8	57	17	30%
Creation of Arteriotomy	3.7	3	1 to 8	59	20	34%
Preparation of Conduit	4.5	4.5	0 to 9	72	28	39%
Management of Assistants	1.9	1	0 to 7	31	11	36%
Performance of Anastomosis	6.8	7	1 to 18	108	37	37%
General Rules	1.1	1	0 to 4	18	11	61%
Testing and Final Steps	3.9	4	0 to 8	62	19	31%
Total	**25.4**	**22**	**11 to 48**	**407**	**146**	**36%**

Overall, 63 (47%) of the 146 items in the Initial Master Item List were suggested by only one of the participants. Despite the expertise of the participants nearly half of the items in this Master List were not considered mandatory by the vast majority of the participants. In fact, just 30% of the items were suggested by 4 or more of the participants and none of the items were suggested by all the participants. The total distribution of items in the Initial Master Item List as a function of the number of participants who suggested those items is shown below (Figure 2).

The number of participants who submitted unique items in the final initial master item list

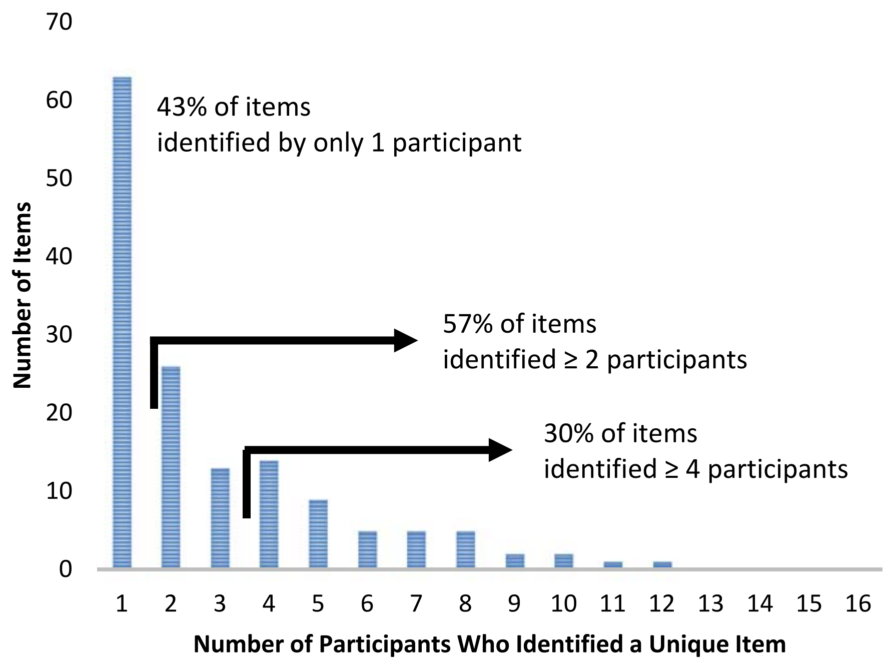


Figure 2: The number of participants who submitted each item in the Initial Master Item List

C. ***Final checklist Creation*** The Master Item list was used for the consensus building exercise. The results of each round of the Delphi are shown in Table III. Each round took roughly 10 weeks to collect all responses. After the 1st round there were 23 items that reached consensus (15.8% of the Master Item List) and 52 items (35.6%) that were dropped. This left 71 items available for the second round. After the 2nd round an additional 14 items reached consensus and 5 were dropped leaving 52 items for the 3rd round. Only 3 items reached consensus in the 3rd round so an additional round was not proposed.

Table III

NUMBERS OF ITEMS THAT REACHED CONSENSUS AFTER EACH ROUND

Section	Master List	Items that Reached Consensus			
		1st Round	2nd Round	3rd Round	Final Consensus
Dissection of Targets	17	4	2	1	7 (41%)
Creation of Arteriotomy	20	2	0	0	2 (2%)
Preparation of Conduit	28	7	3	1	11 (39%)
Management of Assistants	11	0	0	0	0 (0%)
Performance of Anastomosis	40	5	2	0	7 (18%)
General Rules	11	1	2	1	4 (36%)
Testing and Final Steps	19	4	5	0	9 (47%)
Total Items	146				
Total Items that Reached Consensus		23	14	3	40 (27%)

Of the original 146 unique items included in the Master Item List, only 40 (27%) were identified as mandatory items by consensus at the end of the 3 rounds of the Delphi exercise (Appendix B). The majority of the items that reached consensus were identified in the 1st and 2nd round (23 and 14 items respectively or 92.5%). Within each section of the CAB anastomosis the percentage of items reaching consensus varied widely. The section with the greatest consensus was "Testing and Final Steps" with 47% of the original 19 items reaching consensus. The section with the least consensus was "Management of Assistants" where none of the original 11 items reached consensus.

D. <u>Provision of Comments</u> One hundred and nineteen comments were provided during the 2nd round of the Delphi. Of the 71 items presented in the 2nd round, 56 (78.9%) received a comment. When a comment was provided the mean, standard deviation (±), median and range were 2.1 ± 1.2, 2 and 1:5. Of the 52 items that were included in the 3rd round, 40

(76.9%) items had at least one accompanying comment. The mean, standard deviation (±), median and range of comments provided were 2.2 ± 1.2, 2 and 1:5.

Looking specifically at the participants, the number of items that received comments per participant ranged from none to 31. Eleven participants (69%) commented on at least one item. Overall, each participant commented on an average of 7.4 ± 9.3 items or 10.4% of the items presented to them. Among the 11 who provided at least one comment the average number of items commented on was 10.7 ± 9.5 or 15.1% of the items presented to them.

The impact of the comments would be realized in the 3rd round of the Delphi. With only 3 items reaching consensus in the 3rd round the impact of the comments was unable to be ascertained.

E. *Prediction of Which Items Reach Consensus* When comparing items that reached a consensus with those that did not, the number of participants who suggested the item did not appear to predict its eventual inclusion in the final checklist. Items that reached a consensus were initially suggested by 3.2 ± 2.4 participants while items that did not reach consensus were initially suggested by 2.6 ± 2.4 participants (p=0.187). It was noted, however, that a number of participants who initially suggested an item did not rate it as a mandatory item during the Delphi. Reasons why they downgraded their significance of an item might include an inability to remember they had even suggested the item (many months transpired between some of the initial item lists provided by participants and the Delphi surveys) or they felt the item was no longer a mandatory item when viewed in the context of all the other items. We therefore examined the impact of loyalty of a participant to an item they originally suggested and that items ability to reach consensus. For items that reached consensus the number of participants who suggested that item and ranked it mandatory was 2.6 ± 2.0 while items that did not reach consensus had only 0.6 ± 1.0 loyal participants (p<0.001).

IV. DISCUSSION

At the outset of this study we hypothesized that a consensus building exercise could be applied to a generalizable sample of experts to produce a checklist addressing the construction of a CAB anastomosis. We were able to clearly defined a pool of experts across North America, identify and engage a sufficient sample of these experts, and have them complete a Delphi that produced a checklist of 40 items describing a CAB anastomosis. In addition, we were able to address our research questions that focused on feasibility, variability between experts and any clear predictors for item inclusion in a checklist.

The final product of this exercise was the production of a 40 item checklist that was created by 16 randomly selected experts across North America. While this is evidence of the feasibility of this approach, additional evidence is provided by the robust involvement of the participants throughout the exercise. While the overall response rate was only 17%, this project was considerably more involved than simply completing a survey. In fact, the initial response rate was 26%, a number much closer to many survey response rates. As these potential participants received more information on what the overall workload for the project would be, some withdrew. However, considering the workload of an active cardiothoracic surgeon in a teaching institution, the final engagement of 17% was more than expected. Perhaps more representative of the engagement, and hence feasibility, was the robust participation of those who agreed to participate. The high mean and median numbers of items suggested by participants suggested that they took the task seriously. The fact that there was significant overlap among the items suggested by participants (roughly 66% of items were repeatedly suggested by participants for all but one section) also reflects the high engagement of the participants. All the participants completed all three surveys with relatively limited prompting (only 1-2 reminders were ever needed). Finally, there was active provision of comments during the second round of the Delphi.

The variability between participants was demonstrated by the high rate of item rejection during the Delphi. After the final round, only 27% of the original 146 items were felt, by consensus, to be mandatory despite clear instructions that the participants only provide items that they deem mandatory to the construction of a safe CAB anastomosis. The variability was greater in some sections of the procedure than others. For example, there was much greater consensus with items pertaining to “Preparation of the Vein Graft”, where half the items suggested reached consensus. Alternatively none of the suggested items in the section pertaining to “Management of Assistants” reached consensus.

Unlike other reports utilizing a Delphi approach for checklist item development, our study differed in that all the initial items were created by the panel of experts, the expert panel was selected entirely at random (after applying a clearly defined criteria for expertise), and consensus was clearly defined. These efforts were employed to ensure that the final product would be generalizable across institutions. In the majority of other reports utilizing a Delphi the initial list of items are created by the authors or a select panel,(26,27,28,29,33) the participants are identified and invited by the authors(26,27,28), or no details are provided at all(34,35). Our use of experts from across North America revealed that the definition of what each surgeon considered a

mandatory step varies widely. Almost three out of every four items felt to be mandatory by at least one expert participant could not reach consensus by the entire group. This calls into question the generalizability of any locally developed checklist assessing a procedure. Even more concerning, this variability was uncovered using one of the most common procedures performed by cardiothoracic surgeons. Other procedures that are more complex and technically demanding (i.e., coronary endarterectomy, mitral valve repair, bronchial sleeve resection or esophagectomy) would be expected to show even greater variability.

Two potential sources for this variability could be postulated. The first source of variability may stem from the fact that some steps in a CAB anastomosis may need to be performed in a tight sequence. If one of these steps is rejected then the other steps in the sequence must also be rejected. This may have contributed to some of the variability in this study as evidenced by only 18% of the suggested items in "Performance of the Anastomosis" reaching consensus. This section is where the surgeons' actions would most conceivably be tightly sequenced. On the other hand, items from sections that required less tightly sequenced steps, such as "Anastomotic General Rules" and "Testing and Manipulation of the Graft", reached consensus at a higher rate. However, even if some sections of a CAB anastomosis require a sequence of steps the experts still could not agree on even one sequence. The seven items that reached consensus in "Performance of the Anastomosis" are very general in nature and are not describing a tight sequence of steps.

The second source of variability could be that Delphi participants are unaware of what constitutes an essential step in a CAB anastomosis. This could be due to inexperience or a lack of data. The lack of experience is unlikely as all the participants had at least 10 years of experience performing a CAB anastomosis. All would have a history of being able to create a CAB anastomosis with safety and reproducibility. The lack of data is a much more plausible explanation. Many steps to a procedure are based on a surgeon's prior training and the traditions and customs embedded within that training. Changing a technique that has been successful would carry some element of risk and therefore, as long as the surgical outcomes remain excellent, these traditions are not discarded. However, that same blind preservation of each step makes it difficult for a surgeon to distinguish which steps are mandatory and which are based on tradition and could be adapted. Theoretically, the Delphi would expose those items that are based on tradition and those that are more broadly accepted as necessary.

Evidence of that distinction between acceptance of an item due to tradition and acceptance due to an item's true importance was demonstrated by the predictors of an items proclivity to reach final consensus. If we hypothesize that items suggested by participants were always mandatory, then it would be logical to assume that items that were suggested by more participants should reach consensus. Additionally, since each participant was asked to suggest items they felt were mandatory those items should be consistently judged as mandatory by their authors during the Delphi. However, neither of these assumptions was validated. The frequency with which a particular item was suggested by the participants was not predictive of that item eventually reaching consensus. Also, not every participant who authored an item judged that item as mandatory during the Delphi. We can hypothesize that some participants, when they saw an item they authored in the context of the other items, revised their initial opinion of that item's value.

However, when they remained steadfast in their opinion of an item they authored the likelihood of that item reaching consensus was much greater.

Limitations of this study should be noted. The response rate among the randomly selected participants was very low. This was expected due to the significant effort required to provide an initial item list then to complete three lengthy surveys. However, there will be a bias towards surgeons willing to engage in this activity and perhaps a bias against very clinically active surgeons who simply did not have the time available to participate. Another limitation may have been survey fatigue. The engagement of each participant over the many months required to complete all the parts of the study may have affected their commitment. Some participants may have simply passed judgment on items solely off the prior survey data that accompanied each item. Classically, this is strength of the consensus building activity. If a participant has any reservations about the value of an item they should be swayed by the group's judgment and consensus will be reached. However, some participants may have been unwilling to dispute the group's judgment of an item not due to the presence of reservations but simply in an effort to complete the task or a perception that an additional survey would be needed if consensus was not reached. Certainly we can hypothesize that this took place with some participants but the use of a broad group of 16 participants should have minimized its impact. Additionally, the provision of comments in the second round by 69% of the participants suggests that these individuals were still actively engaged in the process.

In summary, our work has demonstrated that it is feasible to engage a broad coalition of randomly selected experts across a wide geographic area to produce a set of checklist items describing the mandatory steps in a complex procedure. The product created by this consensus building exercise also revealed a wide degree of variability among participants in terms of what items are mandatory. This high degree of variability calls into question the generalizability of locally developed checklist that does not engage a broad group of experts. Future work will examine the mechanics of the Delphi in greater detail trying to identify other factors that predict an item's ability to reach consensus, the number of participants needed to perform an effective Delphi and the difference in checklists created by a Delphi that utilizes group consensus versus those created by hierarchical or cognitive task analysis which use a limited number of experts. Additional work will focus on whether the checklist produced by this work can be used to assess trainees and faculty performing a CAB anastomosis.

V. APPENDICES

A. Appendix A

This email will explain the first step in the consensus building exercise. This initial step is where you provide your thoughts on just what elements need to be included in a checklist addressing a coronary anastomoses construction.

I have defined the beginning and end of a “CAB anastomosis” as follows:

- Begins with the initiation of dissection of the coronary artery
- Ends when all manipulation of the anastomosis is completed.
- These are “on pump” anastomoses only. (“off pump” is not addressed in this project)

You can list as many items you feel are required. It may be easier to do this over the course of a few days (keep a list and jot down a few items after each case). Each item should represent what you believe is a <u>key</u> step in the procedure (i.e. if that step were omitted the anastomosis would be compromised).

When you generate items please consider each of these Content Domains of constructing a coronary anastomosis and try to create items within each domain:

1. Dissection of the target vessel
2. Creation of the arteriotomy
3. Preparation of the graft (vein or IMA)
4. Management of assistant(s)
5. Performance of the anastomosis
6. Testing or any additional manipulation of the graft

If you have items that you cannot place in one of these Content Domains go ahead and include them anyway.

Finally, consider that we are building a checklist not a global rating scale. Global rating scale items allow the rater to provide a qualitative assessment. Checklist items are not “qualified”, they are either present or absent. An example of a global rating scale item would be “handles instruments properly” and the possible responses would be; “real bad”, “bad”, “okay”, “good” or “real good”. These sorts of items allow the rater to make a judgment.

A checklist item should require only a yes/no response. Therefore, each item you create must include enough detail to eliminate the need for any interpretation by a rater. An example of a poorly and properly written item is shown below:

Poorly constructed item “Needle enters the vessel wall properly”
Properly constructed item “Needle enters the coronary vessel wall perpendicularly >90% of the time”

APPENDEX A (continued)

Please don't avoid listing an item if you have trouble putting it in a checklist format. I am going to review all the items you send. If they are worded such that they allow rater interpretation I

may ask for some more information so we can revise the item to make it clearer. I will always have you approve the final wording to make sure I have captured exactly what you meant to assess.

When you have a final list just send it to me in an email or as any document (Excel, Word, etc…). I will try to gently remind you to get this done. This is the most time consuming component of the process. The rest of the process is simply a series of surveys to develop the consensus. I am putting together an honorarium to acknowledge your effort on this project. It is just a small reward for your effort.

Thanks so very much.

Ara Vaporciyan, MD, FACS
Professor and Chairman
Department of Thoracic and Cardiovascular Surgery

PS I included a copy of the approved protocol.

B. __Appendix B__

Final consensus derived 40-item checklist for CAB anastomosis construction

Dissection of Target Vessels	
1	Examines the surface of the arrested heart and evaluates the coronary anatomy
2	Heart positioned to allow clear and comfortable access to the target vessel
3	Locates the correct target vessel
4	Finds a location on the target distal to the most significant coronary stenosis
5	Differentiates between an coronary artery and a vein (i.e. might use cardioplegia to assist)
6	Can identify and expose intramyocardial target vessels
7	Can recognize inadvertent entry into the ventricle during dissection of intramyocardial vessels (and repair them)
Creation of Arteriotomy	
8	Enters the artery without injuring the back wall of the artery
9	If the back wall is injured the surgeon is able to repair it without compromising the vessel
Preparation of Vein Graft	
10	Vein is flushed to test for any leaks
11	No excessive pressure is used when distending the vein to check for leaks
12	Clips or ties any branches without stenosing or injuring the vein
13	All branches are ligated
14	The distal end of the vein is free of valves and varicosities
15	Maintains proper graft orientation
16	Ensures sufficient length of the graft to reach the aorta
Preparation of IMA Graft	
17	Divides IMA after heparinization
18	Clears fascia around the distal end of the IMA
19	Ensures the IMA is of adequate length to reach the target vessel
20	Visually ensures adequate flow in the IMA by releasing the clamp/bulldog
Performance of the Anastomosis	
21	The intima of the coronary vessel should never be grasped
22	Intima of the vessels is seen during placement of each of the sutures
23	All bites are full thickness
24	The back wall of the target vessel is never included in a stitch
25	Gentle tension is used when pulling the suture through
26	Ties gently but securely without purse stringing or tearing the coronary
27	Ties knot without breaking it
Anastomotic General Rules	
28	Tissue handled gently to minimize trauma.
29	Curve of the needle is followed to minimize trauma and the size of the needle holes
30	Always visualizes the intima during needle placement
31	Can judge how to load the needle with the proper angle for the various steps of the anastomosis
Testing or Manipulation of Graft	

APPENDIX B (continued)

32	Ensures that the flow is unobstructed
33	Examines the anastomosis for leaks during injection.
34	Evaluates IMA anastomosis (patency and presence of leaks) by unclamping the IMA
35	Does not compromise lumen when repairing a leak
36	Can differentiate between needle hole bleeding versus an anastomotic leak that requires repair
37	Measures the graft length to the aorta and cuts it
38	Ensures there are no twists in the graft as it is positioned to the aorta
39	Secures the IMA to the epicardium with interrupted sutures
40	Can appropriately identify an anastomosis that needs to be redone

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