



First Milestone Report

Fundamentals of Robotic Surgery: Consensus Conference on Outcomes Measures

Conducted by:

Minimally Invasive Robotics Association* Florida Hospital Nicholson Center**

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Florida Hospital Nicholson Center Celebration, Florida December 12-13, 2011

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Foreword

Similar to the evolution of laparoscopic surgery and the Fundamentals of Laparoscopic Surgery (FLS), robotic surgery has been established as an essential procedural approach in surgery and shows every sign of continuing its adoption of more diverse surgical procedures and specialties. It has been clear to the leaders in surgery that there is a need for the creation of a unified approach and standard for basic training in robotic surgery skills principles, to be referred to as the Fundamentals of Robotic Surgery (FRS).

There are current efforts to develop a core curriculum for certifying robotic surgeons; however, this is a fragmented effort, with different approaches and outcomes measures. This has resulted in conflicting, competing and redundant training and assessment tools for robotic surgery. In addition, these have generally lacked the financial resources necessary to carry the project to completion at a national level. The Minimally Invasive Robotic Association (MIRA) has received a substantial industry educational grant to fund a project to create the FRS through the full life cycle of curriculum development, from initial outcomes measures through final validation study. Florida Hospital has also received a Department of Defense grant which is partially dedicated to the creation of FRS and which will be working collaboratively with MIRA on this project.

The joint effort is being carried out with the involvement of key stakeholders from appropriate surgery specialty boards, societies and national certification bodies such as the Accreditation Council of Graduate Medical Education – (ACGME), via their Residency Review Committees – (RRC) – as well as the American Association Gynecologic Laparoscopy (AAGL), American Urologic Association (AUA), the Department of Defense and the Veterans Administration. The scope of the project includes a comprehensive curriculum development process based upon established needs assessment, adult educational principles, appropriate validation study design and application toward certification to the appropriate authorities.

The deliverable from this effort will be a validated curriculum called FRS (similar to FLS), that is based upon the integrated effort of the various stakeholders' stated needs, that will be scientifically stringent enough to meet the criteria of high stakes testing and evaluation, and be acceptable to certification authorities across multiple specialties.

This report contains the results of the first of three workshops that are being conducted to pursue this goal. The first workshop focused on defining the outcomes that must be measured to be able to provide a certification in fundamental robotic surgery.

Executive Summary

FRS Mission Statement:

"Create and develop a validated multi-specialty, technical skills competency based curriculum for surgeons to safely and efficiently perform basic robotic-assisted surgery."

Purpose: On 12-13 December, 2011 the Fundamentals of Robotic Surgery (FRS) Consensus Conference (FRSCC#1) on Outcomes Measures convened an international body of leaders in robotic surgery to define the skills necessary to begin the process of creating a certifiable curriculum and testing method in robotic surgery.

Goals: To identify the outcomes that must be measured to certify that a surgeon has the most basic of cognitive and psychomotor technical skills for robotic surgery. These outcomes are organized as a list of tasks that a surgeon must be able to perform successfully, a list of the most common errors associated with each task, and the metrics that will be used to measure competency in that task.

Objectives: To develop a list of skills, tasks and errors critical to the performance of robotic surgery, and identify quantitative outcome metrics that accurately measure performance.

Scope: Material developed under FRS in this work focused on measuring the most basic skills that a surgeon must possess in order to perform robotic surgery. Although some of these skills require a background of general surgical knowledge, most measures of competency in FRS were technical (both cognitive and psychomotor) skills specifically required and essential to robotic surgery.

The scope was limited to actions performed by the surgeon in preparing, performing, and after finishing a robotic procedure as well as the more common errors in each of these areas. The actions of the entire surgical team were not part of this evaluation, though team leadership and performance were recognized as critical. The surgeon's role within that team was included.

Methodology: The Consensus Conference was conducted during a 2 day period using a modified Delphi methodology. The participants consisted of subject matter experts from 14 different surgical specialties that use robotic surgery, as well as representatives from a number of the certifying surgical specialty boards and surgical education societies, and included participation by the civilian, the Department of Defense and the Veterans Administration (VA) sectors. Many of the participants are members of the American College of Surgeons – Accredited Education Institutes (ACS-AEI) and of the Alliance of Surgical Specialties for Education and Training (ASSET). After the evaluation of existing materials and curricula, a task deconstruction was performed to identify the tasks, subtasks and errors that need to be measured. A matrix was then created that matched metrics to the tasks, skills and errors.

Following the conference, a second round classic Delphi anonymous rating was used to ensure concurrence, to prioritize the ranking of the tasks and to eliminate low-scoring tasks.

Results: The results provide a matrix of specific robotic surgery tasks that are matched to their common errors, a description of the desired outcome and the quantitative metrics that support those outcomes. These tasks are the core material that will be presented at this meeting.

Future Directions: The measures that are the results this conference will be utilized as the requirements for metrics that must be incorporated into the curriculum development at the FRSCC#2 Curriculum Development conference. Following the completed curriculum, there will be a FRSCC#3 Validation Study Design conference, the design of which will be utilized in the multi-institution Validation Study.

Upon completion, the validated curriculum will be transitioned to the Fundamentals of Laparoscopic Surgery Committee of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) / American College of Surgeons (ACS) to develop the high-stakes testing and evaluation and eventually submitted to appropriate certifying boards for consideration of adoption.

Introduction and Summary of Formal Presentations

The conference began with definitions (Appendix 1) to accurately and unambiguously define the terminology, followed by background presentations on the state of robotics training and curriculum from selected experts. The purpose was to put the conference into the context of the current state of the art, to avoid duplication where possible, and to stimulate discussion based upon existing knowledge. Presentations of the following lectures are included in Appendices (App):

App 2. History and Definitions

App 3. Task Deconstruction

App 4. ISI Standard Curriculum

App 5. UT Curriculum

Richard Satava, MD, FACS, University of Washington Mika Sinanan, MD PhD FACS, University of Washington Henry Lin, Intuitive Surgical Inc.

Danny Scott, MD FACS,

University of Texas (UT) Southwestern

Methodology

There have been previous efforts to define a fundamental curriculum in robotic surgery, but these have generally been carried out within a single organization and validated for use only within that organization. The goal of this effort is to arrive at outcome measures, a curriculum, and validation results which will be accepted by the entire community and which can be accredited by surgical boards as means of credentialing surgeons for robotic surgery.

To accomplish this, we began by ensuring that this project would be free of bias from any single organization. The funding which supports this work is free of any influencing effects by medical providers, equipment manufacturers, or other entities which have a financial interest in the outcome of the work.

Invitations to participate in the consensus conferences were sent to the boards, professional societies, and associations which represent practitioners and regulators of robotic surgery. The organizers of this event invited the boards and societies to nominate a representative who could speak for them and their members. The organizations who were invited to send representatives are identified in Appendix 6, along with the names of the individuals whom they sent or who were selected as a good representative of that organization (Appendix 7).

The Fundamentals of Robotic Surgery will be developed through a series of at least three consensus conferences:

- 1. Outcomes Measures
- 2. Curriculum Development
- 3. Validation Study Design

This report is on the first of these conferences, the FRSCC#1, outcomes measures. During the conference, the group developed the template shown in Table 1 to capture the outcomes that must be measured in order to support credentialing in robotic surgery. The matrix aligns outcomes with specific tasks that must be mastered. This includes identifying errors in

performing the task, the outcome that must be achieved, and the metric by which that outcome will be measured.

The group developed the first list of tasks, errors, outcomes, and metrics by examining existing lists of robotic tasks and using one of those as a starting point for discussion and development. Specifically, the list which served as a beginning framework was that created and published by Daniel Scott, MD, from the University of Texas Southwestern (Appendix 5).

Table 1. Task List and Importance Rating Matrix

Task Name	Description	Errors	Outcomes	Metrics]	lmp	orta	ance	e Rating	
					1 2 3 4 Total				Rank	
									Score	Order

Through group discussion and relooking at task deconstruction for comparison to the reference list, decisions were made to modify Dr. Scott's reference list by adding new tasks, removing existing entries, and rewording or redefining existing entries. Upon arriving at a consensus on an accepted list of tasks, errors, outcomes, and metrics, the group then engaged in a modified Delphi technique for identifying the level of support that existed for each item on the list. The first round of voting was carried out in the open forum with participants indicating their opinion on the importance of the task on a 1 to 4 scale, where 1 = not important, 2 = somewhat important, 3 = important, and 4 = critically important. The votes were tallied into columns in the task matrix and a total score was computed by multiplying the scoring level by the number of votes at that level and summing across all levels.

Table 2. Rating Scale:

Rating/Points	Definition
1	Not Important
2	Somewhat Important
3	Important
4	Critically Important

Scoring Method: Total Score = $\sum (Rating * NumberOfVotes)$

The tasks were then rank ordered based on each of their Total Scores where a higher score results in a higher order in the ranking, where 1st is considered the highest rank. In the event of ties in the total score, the tasks received sequential places in the ranking. The purpose of this ranking is to clearly identify any tasks which are not strongly supported by the representatives. The order in which two tasks with equal scores are ranked relative to each other will not result in one task being eliminated while another with an identical score is retained.

After the conclusion of the conference, the task list matrix was edited, the scores compiled, and the ranking assigned. This information was then emailed to the members of the group for the next step in the Delphi Process. Each member then considered the compiled scores and rankings of the tasks in private, and submitted a new vote on the importance of each task. The second vote

was then compiled and the scores were examined to determine whether the second Delphi round significantly changed the total score and ranking for each task.

Tasks which received a total score below two standard deviations from the mean score were then tagged for elimination from the list. These tasks will not be included in the ongoing development of a curriculum or testing methods.

After the members of the conference arrived at an agreed upon list of tasks, errors, outcomes, and metrics, the results were sent to the Presidents or Executive Directors of each of the boards, societies, and associations represented. They were invited to review the results and to submit comments and recommendations for inclusion in this report. Their input was then incorporated into this report.

Finally, this report was submitted to the financial sponsors of the project as the official deliverable resulting from this portion of the work. The final report was also revised to meet publication requirements in a peer reviewed journal.

Results

Participants in the conference proposed specific tasks that should be included in the testing of competency in robotic surgery. Some of these items were drawn from the background presentations and others were introduced for the first time in this forum. Table 3 provides a list of all of the tasks that were proposed and supported by the members of the conference. The table also includes a brief description of the task, a list of errors that can occur when performing the task, outcomes that should be tested for competency in the task, and metrics that can be used to measure those outcomes.

Once this list of tasks had been established, the group was asked to assign each task an importance rating based on their experience. For the rating process, votes were taken only from practicing surgeons who felt that they had the necessary expertise and experience to rate these tasks. The list of surgeons who participated in the rating phase is given in Appendix 8.

The Total Score for each task was calculated using the algorithm given in the methodology section. Using this Total Score, each task was then assigned a rank order from highest importance to lowest based on the cumulative score in Table 3 (Table 5 contains the 2nd round Delphi Scores). A table containing all tasks, but ordered by rank is provided as Table 4 (Table 6 contains the rank ordered 2nd round Delphi Scores).

Table 3. FRS Task List and Importance Rating – 1st Round Voting

According to Sequential Occurrence During a Procedure

Task Name	Description	Errors	Outcomes	Metrics	Iı	Importance Rating						
					1	2	3	4	Total Score	Rank Order		
Pre-Op												
System settings	Setting up and adjusting console settings as needed during surgery	Improper console settings, Scope angle selections, Magnification setup, Motion speed/scaling	Appropriate console settings with minimal ongoing adjustments	Number of adjustments, correct console settings, checks settings, time	0	4	4	1	24	21		
Ergonomic positioning	Positioning of the surgeons torso, arms and feet.	Poor posture, elbow placement	Maintains appropriate posture and ergonomics throughout the operation and minimizes fatigue.	Work load, posture, muscle fatigue	0	3	6	0	24	22		
Docking	Surgeon guides OR nurse in positioning bedside robot and attaches arms to trocars	External collision, Misalignment, Bed movement post-docking	Appropriately docks robot in timely fashion with minimal adjustments.	Time to dock, adjustment, patient or instrument collision, robotic arm position, alignment	0	2	4	3	28	11		
Robotic trocars	Safe insertion technique.	Incorrect remote center, Trocar slippage, Spatial orientation, Blind insertion (2 nd and later), Organ injury, Access will mirror FLS	Appropriate trocar insertion and positioning relative to target and other trocars, without unintentional tissue contact. Maintaining positioning.	Time, tissue damage, number of adjustments, remote center placement, distance between trocars, trocar spatial relationship to target	0	1	6	2	28	12		
Operating Room (OR) set-up	Placing the bedside cart in the location where the operative field is most accessible	Incorrect support equipment placement, Breaking sterile field	Proper placement of equipment in a sterile and safe fashion	Breaks in sterile protocol, equipment placement, access and visualization for assistant, time, time to conversion, access/clearance to patient cart for rapid undocking	1	1	6	1	25	18		
Situation awareness	Awareness of the status and readiness of the people and equipment essential to the operation.	Unaware of Robot-Patient- Assistant –team state	Maintain awareness of the robotic, patient, and team status that is out of view.	Missed communication. Missed information. Missed changes in patient status and injuries, missed changes in robotic status	0	1	2	6	32	1		
Closed loop	Definitive	Communication	Actions match	Use of names, clarity	0	1	5	3	29	10		

Task Name	Description	Errors	Outcomes	Metrics	Iı					
					1	2	3	4	Total Score	Rank Order
communication	communication techniques between the members of the surgical team.	failure, Incorrect terminology	intent between team members. Use of names, individual responsibilities given, follow- up information provided.	of request, response time, call back requested and provided (TeamSTEPPS®)						
Respond to robot system error	Understand the robotic protocol	Protocol violation	Identifies correct troubleshooting algorithm and applies steps in a timely fashion to correct the error. Avert unnecessary conversion.	Protocol violations, algorithm identification and correct response, time	0	4	3	2	25	19
Intra-Op										
Energy sources	Activation and control of cautery or other energy sources	Mirror FLS errors, Pedal to instrument discordance, Activate energy before tissue contact, Unintentional energy activation, Unintentional energy arcing	Appropriate choice and use of energy sources with no collateral damage.	Collateral tissue damage (real time and delay contact), instrument and energy choice, activation without tissue contact, economy of energy use (air burns), pedal selection	0	2		3	28	13
Camera	Maneuvering the camera to obtain a suitable view	Not focused, Wrong distance to tissue, Inappropriate field of view, Disorientation on camera orientation, Inappropriate choice of camera angle, Camera contact with tissue	Maintains optimal imaging, including horizontal orientation, field-of-view, angle at all times.	Time, efficiency(clutching), sizing(magnification and field of view), horizontal orientation, camera tissue contact, control and manipulation, smoothness, scope angle selection	0	0	5	4	31	4
Clutching	Maintaining comfortable range of motion for manual controls	[Extension of Ergonomics] Loss of range- of-motion	Efficiently maintains full range of motion at all times, in an ergonomic manner.	Joystick collisions, joystick maintained within fly zone(establish what fly zone is), efficient control system usage(excessive clutching, wrong pedal)	0	0	5	4	31	5

Task Name	Description	Errors	Outcomes	Metrics	Importance Rating					
					1	2	3	4	Total Score	Rank Order
Instrument exchange	Changing out instruments used in the operation	Tissue collision during exchange, Non-visualized or memory- guided instrument insertion, Inserting or removing the wrong instrument	Efficient, accurate and safe instrument exchange without tissue collision.	Tissue damage, time, economy of motion, connection to energy source, coordination with assistant, instrument selection, recognition of instrument failure, proper instrument engagement to robotic arm and port, memory recognition, trouble shoot protocol	0	2	6	1	26	15
Foreign body management	Removal of all foreign bodies from the operating space.	Failure to confirm foreign body removal (needle, sponge, bulldog)	Safe, appropriate and confirmed foreign body removal	Instrument selection for removal, correct instrument, sponge and needle count, removal technique, immediate confirmation of removal	1	1	5	2	26	16
Multi-arm control	Activating the fourth arm through clutching and using it in the operation	Collision, Moving wrong arm	Efficient use of multi-arm control without collisions	Time and number of collisions	0	4	3	2	25	20
Eye-hand instrument coordination	Using the manual controls to accurately manipulate bedside instruments and perform tasks. Passing objects between the instruments.	Ineffective targeting	Efficient hand coordination and accurate and efficient movement of instruments	Time and economy of motion	0	0	4	5	32	2
Wrist articulation	Understanding and utilizing the full range of motion of the endowrist	Not using all degrees-of- freedom, Inadvertent trapping of tissue or suture	Uses all degrees of freedom appropriately	Time, dexterity and economy of motion	1	2	6	0	23	23
Atraumatic handling	Haptic comprehension. Using graspers to hold tissue or surgical material without crushing or tearing.	Traumatic handling, Tissue damage or hemorrhage	Manipulates tissue and surgical materials without damage	Metric-respect for tissue, Stress and strain indentation and deformation	0	0	5	4	31	6

Task Name	Description	Errors	Outcomes	Metrics	Iı	npo				
					1	2	3	4	Total Score	Rank Order
	Respect to tissue									
Dissection – fine & blunt (Traction/ counter- traction)	Using instruments to perform precise or blunt dissection of structures	Failure to identify correct tissue plane, Inadequate traction/counter- traction, Reversing blunt vs. fine	Performs dissection in appropriate planes with suitable traction/counter- traction and without collateral damage	Accuracy and damage to surrounding structures, distribution of force across tissue, time, & provides adequate exposure of target tissue	0	0	6	3	30	9
Cutting	Using the scissors to cut at a precise location	Cutting the wrong structure, Past-pointing, Inappropriate instruments	Accurate and efficient division of target structure without collateral damage	Accuracy, lack of tissue damage, timeliness	0	1	6	2	28	14
Needle driving	Accurate and efficient manipulation of the needle.	Tearing tissue, Troughing the needle, Needle scratching, Wrong angle on entry/exit, Adjacent organ injury, Needle damage, Needle positioning, Needle dropping, Holding out of field-of-view, Poor accuracy	Accurate and efficient placement of needle through targeted tissue, Following the curve of the needle, without associated tissue injury	Time, accuracy, tissue damage, material damage	0	0	4	5	32	3
Suture handling	Running and interrupted sutures (separate or combined)	Breaking suture, Fraying suture, Tissue tearing, Inadequate following, Poor tension, Inadequate tissue coaptation, Inadvertent locking	Appropriate handling of suture material without fraying, breakage, or tissue damage.	Tissue damage, time, accuracy, economy of motion, material damage	0	2	6	1	26	17
Knot tying	Exactness of the creation of a knot with suture.	Air knot, Knot slippage, Insecure knot, Inappropriate tail length, Bunny ears, Too tight,	Ties secure knots appropriately, accurately and efficiently without tissue damage	Time, economy of motion, tissue damage, material damage, knot location, air knot, knot security, protocol violation,	0	0	5	4	31	7

Task Name	Description	scription Errors Out	Outcomes	Outcomes Metrics			Importance Rating							
					1	2	3	4	Total Score	Rank Order				
		Tissue ischemia		appropriate tail length										
Clip applying	Accurate application of clips.	Cross-clipping, Short-clipping, Poor accuracy, Inadequate coaptation	Places the clips accurately, appropriately and securely without crossing and without leakage	Time, accuracy, crossed clips, clip damage, incomplete and ineffective clip placement	0	5	3	1	23	24				
Safety of Operative Field	Appropriate insertion and positioning of instruments.	Instrument collision with tissue outside of field-of-view	Effectively avoids instrument collision and damage with tissue outside of field of view	Instrument to tissue contact, tissue damage	0	2	1	6	31	8				
Post-Op														
Transition to bedside assist	Instrument removal	Tissue damage, Lack of port-site inspection	Safe and efficient removal of instruments and ports	Time, inspection of port sites, bleeding, tissue damage	0	8	1	0	19	25				
Undocking	Removal of robotic equipment from the trocars and patient	Undocking without instrument removal, Tissue damage	Safe and efficient undocking of cart in routine and emergency situations	Time, protocol violation, tissue damage, collisions	0	8	1	0	19	26				

Table 4. FRS Task List Rank Ordered by Total Score - 1st Round Voting

Task Name	Description	Errors	Outcomes	Metrics	Ir					
					1	2	3	4	Total Score	Rank Order
Situation awareness	Awareness of the status and readiness of the people and equipment essential to the operation.	Unaware of Robot-Patient- Assistant –team state	Maintain awareness of the robotic, patient, and team status that is out of view	Missed communication. Missed information. Missed changes in patient status and injuries, missed changes in robotic status	0	1	2	6	32	1
Eye-hand - instrument coordination	Using the manual controls to accurately manipulate bedside instruments and perform tasks. Passing objects between the instruments	Ineffective targeting	Efficient hand coordination and accurate and efficient movement of instruments	Time and economy of motion	0	0	4	5	32	2
Needle driving	Accurate and efficient manipulation of the needle	Tearing tissue, Troughing the needle, Needle scratching, Wrong angle on entry/exit, Adjacent organ injury, Needle damage, Needle positioning, Needle dropping, Holding out of field-of-view, Poor accuracy	Accurate and efficient placement of needle through targeted tissue, Following the curve of the needle, without associated tissue injury	Time, accuracy, tissue damage, material damage	0	0	4	5	32	3
Camera	Maneuvering the camera to obtain a suitable view	Not focused, Wrong distance to tissue, Inappropriate field of view, Disorientation on camera orientation, Inappropriate choice of camera angle, Camera contact with tissue	Maintains optimal imaging, including horizontal orientation, field-of-view, angle at all times	Time, efficiency(clutching), sizing(magnification and field of view), horizontal orientation, camera tissue contact, control and manipulation, smoothness, scope angle selection	0	0	5	4	31	4
Clutching	Maintaining comfortable	[Extension of Ergonomics]	Efficiently maintains full	Joystick collisions, joystick maintained	0	0	5	4	31	5

Task Name	Description	Errors	Outcomes	Metrics	Importance Rat			Importance Rating				
					1	2	3	4	Total Score	Rank Order		
	range of motion for manual controls	Loss of range- of-motion	range of motion at all times, in an ergonomic manner	within fly zone(establish what fly zone is), efficient control system usage(excessive clutching, wrong pedal)								
Atraumatic handling	Haptic comprehension. Using graspers to hold tissue or surgical material without crushing or tearing. Respect to tissue	Traumatic handling, Tissue damage or hemorrhage	Manipulates tissue and surgical materials without damage	Metric-respect for tissue Stress and strain indentation and deformation	0	0	5	4	31	6		
Knot tying	Exactness of the creation of a knot with suture	Air knot, Knot slippage, Insecure knot, Inappropriate tail length, Bunny ears, Too tight, Tissue ischemia	Ties secure knots appropriately, accurately and efficiently without tissue damage	Time, economy of motion, tissue damage, material damage, knot location, air knot, knot security, protocol violation, appropriate tail length	0	0	5	4	31	7		
Safety of Operative Field	Appropriate insertion and positioning of instruments.	Instrument collision with tissue outside of field-of-view	Effectively avoids instrument collision and damage with tissue outside of field of view	Instrument to tissue contact, tissue damage	0	2	1	6	31	8		
Dissection – fine & blunt (Traction/ counter- traction)	Using instruments to perform precise or blunt dissection of structures	Failure to identify correct tissue plane, Inadequate traction/countertraction, Reversing blunt vs. fine	Performs dissection in appropriate planes with suitable traction/counter- traction and without collateral damage	Accuracy and damage to surrounding structures, distribution of force across tissue, time,& provides adequate exposure of target tissue	0	0	6	3	30	9		
Closed loop communication	Definitive communication techniques between the members of the surgical team.	Communication failure, Incorrect terminology	Actions match intent between team members. Use of names, individual responsibilities given, follow-up information provided.	Use of names, clarity of request, response time, call back requested and provided (TeamSTEPPS®)	0	1	5	3	29	10		
Docking	Surgeon guides OR nurse in positioning	External collision, Misalignment,	Appropriately docks robot in timely fashion	Time to dock, adjustment, patient or instrument	0	2	4	3	28	11		

Task Name	Description	Errors	Outcomes	Metrics	Ir	npo				
					1	2	3	4	Total Score	Rank Order
	bedside robot and attaches arms to trocars	Bed movement post-docking	with minimal adjustments.	collision, robotic arm position, alignment						
Robotic trocars	Safe insertion technique.	Incorrect remote center, Trocar slippage, Spatial orientation, Blind insertion (2 nd and later), Organ injury, Access will mirror FLS	Appropriate trocar insertion and positioning relative to target and other trocars, without unintentional tissue contact. Maintaining positioning.	Time, tissue damage, number of adjustments, remote center placement, distance between trocars, trocar spatial relationship to target	0	1	6	2	28	12
Energy sources	Activation and control of cautery or other energy sources	Mirror FLS errors, Pedal to instrument discordance, Activate energy before tissue contact, Unintentional energy activation, Unintentional energy arcing	Appropriate choice and use of energy sources with no collateral damage.	Collateral tissue damage (real time and delay contact), instrument and energy choice, activation without tissue contact, economy of energy use (air burns), pedal selection	0	2	4	3	28	13
Cutting	Using the scissors to cut at a precise location	Cutting the wrong structure, Past-pointing, Inappropriate instruments	Accurate and efficient division of target structure without collateral damage	Accuracy, lack of tissue damage, timeliness	0	1	6	2	28	14
Instrument exchange	Changing out instruments used in the operation	Tissue collision during exchange, Non-visualized or memory- guided instrument insertion, Inserting or removing the wrong instrument	Efficient, accurate and safe instrument exchange without tissue collision.	Tissue damage, time, economy of motion, connection to energy source, coordination with assistant, instrument selection, recognition of instrument failure, proper instrument engagement to robotic arm and port, memory recognition, trouble shoot protocol	0	2	6	1	26	15
Foreign body management	Removal of all foreign bodies from the operating space.	Failure to confirm foreign body removal (needle, sponge, bulldog)	Safe, appropriate and confirmed foreign body removal	Instrument selection for removal, correct instrument, sponge and needle count, removal technique, immediate confirmation of removal	1	1	5	2	26	16

Task Name	Description	Errors	Outcomes	Metrics	Iı	npo				
					1	2	3	4	Total Score	Rank Order
Suture handling	Running and interrupted sutures (separate or combined)	Breaking suture, Fraying suture, Tissue tearing, Inadequate following, Poor tension, Inadequate tissue coaptation, Inadvertent locking	Appropriate handling of suture material without fraying, breakage, or tissue damage.	Tissue damage, time, accuracy, economy of motion, material damage	0	2	6	1	26	17
Operating Room (OR) set-up	Placing the bedside cart in the location where the operative field is most accessible	Incorrect support equipment placement, Breaking sterile field	Proper placement of equipment in a sterile and safe fashion	Breaks in sterile protocol, equipment placement, access and visualization for assistant, time, time to conversion, access/clearance to patient cart for rapid undocking	1	1	6	1	25	18
Respond to robot system error	Understand the robotic protocol.	Protocol violation	Identifies correct troubleshooting algorithm and applies steps in a timely fashion to correct the error. Avert unnecessary conversion.	Protocol violations, algorithm identification and correct response, time	0	4	3	2	25	19
Multi-arm control	Activating the fourth arm through clutching and using it in the operation	Collision, Moving wrong arm	Efficient use of multi-arm control without collisions	Time and number of collisions	0	4	3	2	25	20
System settings	Setting up and adjusting console settings as needed during surgery	Improper console settings, Scope angle selections, Magnification setup, Motion speed/scaling	Appropriate console settings with minimal ongoing adjustments	Number of adjustments, correct console settings, checks settings, time	0	4	4	1	24	21
Ergonomic positioning	Positioning of the surgeons torso, arms and feet.	Poor posture, elbow placement	Maintains appropriate posture and ergonomics throughout the operation and minimizes fatigue.	Work load, posture, muscle fatigue	0	3	6	0	24	22
Wrist articulation	Understanding and utilizing the full range	Not using all degrees-of-freedom,	Uses all degrees of freedom appropriately	Time, dexterity and economy of motion	1	2	6	0	23	23

Task Name	Description	Errors	Outcomes	Metrics	Iı					
					1	2	3	4	Total Score	Rank Order
	of motion of the endowrist	Inadvertent trapping of tissue or suture								
Clip applying	Accurate application of clips.	Cross-clipping, Short-clipping, Poor accuracy, Inadequate coaptation	Places the clips accurately and appropriately and securely without crossing and without leakage	Time, accuracy, crossed clips, clip damage, incomplete and ineffective clip placement	0	5	3	1	23	24
Transition to bedside assist	Instrument removal	Tissue damage, Lack of port-site inspection	Safe and efficient removal of instruments and ports	Time, inspection of port sites, bleeding, tissue damage	0	8	1	0	19	25
Undocking	Removal of robotic equipment from the trocars and patient.	Undocking without instrument removal, Tissue damage	Safe and efficient undocking of cart in routine and emergency situations	Time, protocol violation, tissue damage, collisions	0	8	1	0	19	26

2nd Round Delphi Results

Following the face-to-face conference, each of the voting members was asked to participate in a second round of voting following the Delphi Method of consensus building. The voting members received the original list and a rank ordered list of the tasks, along with a basic statistical analysis of the distribution of those scores. They were asked to vote again on the rating of each task to see if their knowledge of all scores and the ranking of the tasks would cause them to change their score. All of the members of the original group of nine surgeons returned their second round scores.

The PI's (Principal Investigators) indicated that tasks receiving a total score that is more than two standard deviations below the mean score would be recommended for removal from the list.

Table 5. FRS Task List and Importance Rating – 2nd Round Delphi Voting

According to Sequential Occurrence During a Procedure

Task Name	Description	Errors	Outcomes	Metrics	Iı	mpo	rtar	ice]	Rating	
									Total Score	Rank Order
Pre-Op										
System settings	Setting up and adjusting console settings as needed during surgery	Improper console settings, Scope angle selections, Magnification setup, Motion speed/scaling	Appropriate console settings with minimal ongoing adjustments	Number of adjustments, correct console settings, checks settings, time	0	2	6	1	26	20
Ergonomic positioning	Positioning of the surgeons torso, arms and feet.	Poor posture, elbow placement	Maintains appropriate posture and ergonomics throughout the operation and minimizes fatigue.	Work load, posture, muscle fatigue	0	1	8	0	26	19
Docking	Surgeon guides OR nurse in positioning bedside robot and attaches arms to trocars	External collision, Misalignment, Bed movement post-docking	Appropriately docks robot in timely fashion with minimal adjustments.	Time to dock, adjustment, patient or instrument collision, robotic arm position, alignment	0	1	3	5	31	10
Robotic trocars	Safe insertion technique.	Incorrect remote center, Trocar slippage, Spatial orientation, Blind insertion (2 nd and later), Organ injury, Access will mirror FLS	Appropriate trocar insertion and positioning relative to target and other trocars, without unintentional tissue contact. Maintaining positioning.	Time, tissue damage, number of adjustments, remote center placement, distance between trocars, trocar spatial relationship to target	0	2	4	3	28	16
Operating Room (OR) set-up	Placing the bedside cart in the location where the operative field is most accessible	Incorrect support equipment placement, Breaking sterile field	Proper placement of equipment in a sterile and safe fashion	Breaks in sterile protocol, equipment placement, access and visualization for assistant, time, time to conversion, access/clearance to patient cart for rapid undocking		3	6	0	24	22
Situation awareness	Awareness of the status and readiness of the people and equipment essential to the operation.	Unaware of Robot-Patient- Assistant –team state	Maintain awareness of the robotic, patient, and team status that is out of view.	Missed communication. Missed information. Missed changes in patient status and injuries, missed changes in robotic status	0	0	1	8	35	1
Closed loop communication	Definitive communication	Communication failure,	Actions match intent between	Use of names, clarity of request, response	0	0	5	4	31	9

Task Name	Description	Errors	Outcomes	Metrics	Iı	npo	rtai	ice l	Rating	
					1	2	3	4	Total Score	Rank Order
	techniques between the members of the surgical team.	Incorrect terminology	team members. Use of names, individual responsibilities given, follow- up information provided.	time, call back requested and provided (TeamSTEPPS®)						
Respond to robot system error	Understand the robotic protocol	Protocol violation	Identifies correct troubleshooting algorithm and applies steps in a timely fashion to correct the error. Avert unnecessary conversion.	Protocol violations, algorithm identification and correct response, time	1	2	5	1	24	23
Intra-Op										
Energy sources	Activation and control of cautery or other energy sources	Mirror FLS errors, Pedal to instrument discordance, Activate energy before tissue contact, Unintentional energy activation, Unintentional energy arcing	Appropriate choice and use of energy sources with no collateral damage.	Collateral tissue damage (real time and delay contact), instrument and energy choice, activation without tissue contact, economy of energy use (air burns), pedal selection	0	2	4	3	28	14
Camera	Maneuvering the camera to obtain a suitable view	Not focused, Wrong distance to tissue, Inappropriate field of view, Disorientation on camera orientation, Inappropriate choice of camera angle, Camera contact with tissue	Maintains optimal imaging, including horizontal orientation, field-of-view, angle at all times.	Time, efficiency(clutching), sizing(magnification and field of view), horizontal orientation, camera tissue contact, control and manipulation, smoothness, scope angle selection		0	4	5	32	6
Clutching	Maintaining comfortable range of motion for manual controls	[Extension of Ergonomics] Loss of range- of-motion	Efficiently maintains full range of motion at all times, in an ergonomic manner.	Joystick collisions, joystick maintained within fly zone(establish what fly zone is), efficient control system usage(excessive clutching, wrong pedal)	0	1	2	6	32	7
Instrument	Changing out	Tissue collision	Efficient,	Tissue damage, time,	0	0	7	2	29	12

Task Name	Description	Errors	Outcomes	Metrics	Importance Rating					
			1	2	3	4	Total Score	Rank Order		
exchange	used in the operation Non-visualized or memory-guided instrument insertion, Inserting or removing the wrong instrument Non-visualized or memory-guided collision. Inserting or removing the wrong instrument wrong instrument wrong instrument nemory recount of connection to source, coord with assistant instrument seriospic instrument far proper instrument are engagement to trouble shoot protocol		economy of motion, connection to energy source, coordination with assistant, instrument selection, recognition of instrument failure, proper instrument engagement to robotic arm and port, memory recognition, trouble shoot protocol							
Foreign body management	Removal of all foreign bodies from the operating space.	Failure to confirm foreign body removal (needle, sponge, bulldog)	Safe, appropriate and confirmed foreign body removal	Instrument selection for removal, correct instrument, sponge and needle count, removal technique, immediate confirmation of removal	1	1	3	4	28	15
Multi-arm control	Activating the fourth arm through clutching and using it in the operation	Collision, Moving wrong arm	Efficient use of multi-arm control without collisions	Time and number of collisions	0	3	4	2	26	21
Eye-hand instrument coordination	Using the manual controls to accurately manipulate bedside instruments and perform tasks. Passing objects between the instruments.	Ineffective targeting	Efficient hand coordination and accurate and efficient movement of instruments	Time and economy of motion		0	3	6	33	2
Wrist articulation	Understanding and utilizing the full range of motion of the endowrist	Not using all degrees-of- freedom, Inadvertent trapping of tissue or suture	Uses all degrees of freedom appropriately	Time, dexterity and economy of motion	0	2	5	2	27	18
Atraumatic handling	Haptic comprehension. Using graspers to hold tissue or surgical material without crushing or tearing. Respect to	Traumatic handling, Tissue damage or hemorrhage	Manipulates tissue and surgical materials without damage	Metric-respect for tissue, Stress and strain indentation and deformation	0	0	3	6	33	4

Task Name	Description	Errors	Outcomes	Metrics	Iı	npo	rtar	ice]	Rating	
					1	2	3	4	Total Score	Rank Order
Dissection – fine & blunt (Traction/ counter- traction)	Using instruments to perform precise or blunt dissection of	Failure to identify correct tissue plane, Inadequate traction/counter-	Performs dissection in appropriate planes with suitable	Accuracy and damage to surrounding structures, distribution of force	0	0	4	5	32	8
,	structures	traction, Reversing blunt vs. fine	traction/counter- traction and without collateral damage	across tissue, time, & provides adequate exposure of target tissue						
Cutting	Using the scissors to cut at a precise location	Cutting the wrong structure, Past-pointing, Inappropriate instruments	Accurate and efficient division of target structure without collateral damage	Accuracy, lack of tissue damage, timeliness	0	1	5	3	29	13
Needle driving	Accurate and efficient manipulation of the needle.	Tearing tissue, Troughing the needle, Needle scratching, Wrong angle on entry/exit, Adjacent organ injury, Needle damage, Needle positioning, Needle dropping, Holding out of field-of-view, Poor accuracy	Accurate and efficient placement of needle through targeted tissue, Following the curve of the needle, without associated tissue injury	Time, accuracy, tissue damage, material damage		0	3	6	33	3
Suture handling	Running and interrupted sutures (separate or combined)	Breaking suture, Fraying suture, Tissue tearing, Inadequate following, Poor tension, Inadequate tissue coaptation, Inadvertent locking	Appropriate handling of suture material without fraying, breakage, or tissue damage.	Tissue damage, time, accuracy, economy of motion, material damage		2	5	2	27	17
Knot tying	Exactness of the creation of a knot with suture.	Air knot, Knot slippage, Insecure knot, Inappropriate tail length, Bunny ears, Too tight, Tissue ischemia	Ties secure knots appropriately, accurately and efficiently without tissue damage	Time, economy of motion, tissue damage, material damage, knot location, air knot, knot security, protocol violation, appropriate tail	0	1	4	4	30	11

Task Name	Description	Errors	Outcomes	Metrics	Iı	mpo				
					1	2	3	4	Total Score	Rank Order
				length						
Clip applying	Accurate application of clips.	Cross-clipping, Short-clipping, Poor accuracy, Inadequate coaptation	Places the clips accurately, appropriately and securely without crossing and without leakage	Time, accuracy, crossed clips, clip damage, incomplete and ineffective clip placement	2	5	2	0	18	26
Safety of Operative Field	Appropriate insertion and positioning of instruments.	Instrument collision with tissue outside of field-of-view	iment Effectively Instrument to tissue contact, tissue coutside of instrument damage		0	1	2	6	32	5
Post-Op										
Transition to bedside assist	Instrument removal	Tissue damage, Lack of port-site inspection	Safe and efficient removal of instruments and ports	Time, inspection of port sites, bleeding, tissue damage	0	7	2	0	20	25
Undocking	Removal of robotic equipment from the trocars and patient	Undocking without instrument removal, Tissue damage	Safe and efficient undocking of cart in routine and emergency situations	Time, protocol violation, tissue damage, collisions	0	6	2	1	22	24

Table 6. FRS Task List Rank Ordered by Total Score - 2nd Round Delphi Voting

Task Name	Description	Errors	Outcomes	Metrics	Iı	mpo	rtai	ice]	Rating	
					1	2	3	4	Total Score	Rank Order
Situation awareness	Awareness of the status and readiness of the people and equipment essential to the operation.	Unaware of Robot-Patient- Assistant –team state	Maintain awareness of the robotic, patient, and team status that is out of view.	Missed communication. Missed information. Missed changes in patient status and injuries, missed changes in robotic status	0	0	1	8	35	1
Eye-hand instrument coordination	Using the manual controls to accurately manipulate bedside instruments and perform tasks. Passing objects between the instruments.	Ineffective targeting	Efficient hand coordination and accurate and efficient movement of instruments	Time and economy of motion	0	0	3	6	33	2
Needle driving			0	0	3	6	33	3		
Atraumatic handling	Haptic comprehension. Using graspers to hold tissue or surgical material without crushing or tearing. Respect to tissue	Traumatic handling, Tissue damage or hemorrhage	Manipulates tissue and surgical materials without damage	Metric-respect for tissue, Stress and strain indentation and deformation	0	0	3	6	33	4
Safety of Operative Field	Appropriate insertion and positioning of instruments.	Instrument collision with tissue outside of field-of-view	Effectively avoids instrument collision and	Instrument to tissue contact, tissue damage	0	1	2	6	32	5

Task Name	Description	Errors	Outcomes	Metrics	Iı	mpo	rtar	ice]	Rating	
					1	2	3	4	Total Score	Rank Order
			damage with tissue outside of field of view							
Camera	the camera to obtain a suitable view Inappropriate field of view, Disorientation on camera orientation, Inappropriate choice of camera angle, Camera contact with tissue Wrong distance to tissue, imaging, including and field of view), horizontal orientation, orientation, angle at all times. Wrong distance to tissue, imaging, including and field of view), horizontal orientation, camera tissue contact, control and manipulation, smoothness, scope angle selection		orientation, camera tissue contact, control and manipulation, smoothness, scope	0	0	4	5	32	6	
Clutching	Maintaining comfortable range of motion for manual controls	[Extension of Ergonomics] Loss of range- of-motion	Efficiently maintains full range of motion at all times, in an ergonomic manner.	joystick maintained within fly zone(establish what		1	2	6	32	7
Dissection – fine & blunt (Traction/ counter- traction)	Using instruments to perform precise or blunt dissection of structures	Failure to identify correct tissue plane, Inadequate traction/countertraction, Reversing blunt vs. fine	Performs dissection in appropriate planes with suitable traction/counter- traction and without collateral damage	Accuracy and damage to surrounding structures, distribution of force		0	4	5	32	8
Closed loop communication	Definitive communication techniques between the members of the surgical team.	Communication failure, Incorrect terminology	Actions match intent between team members. Use of names, individual responsibilities given, follow-up information provided.	Use of names, clarity of request, response time, call back requested and provided (TeamSTEPPS®)		0	5	4	31	9
Docking	OR nurse in positioning Misalignment, docks robot in positioning Misalignment, docks robot in do		or instrument collision, robotic arm	0	1	3	5	31	10	
Knot tying	Exactness of the creation of a knot with suture.	Air knot, Knot slippage, Insecure knot, Inappropriate tail length,	Ties secure knots appropriately, accurately and efficiently	Time, economy of motion, tissue damage, material damage, knot location, air knot,	0	1	4	4	30	11

Task Name	Description	Errors	Outcomes	Metrics	Iı	mpo	rtai	ice]	Rating	
					1	2	3	4	Total Score 29 28	Rank Order
		Bunny ears, Too tight, Tissue ischemia	without tissue damage	knot security, protocol violation, appropriate tail length						
Instrument exchange	Changing out instruments used in the operation	Tissue collision during exchange, Non-visualized or memory- guided instrument insertion, Inserting or removing the wrong instrument	Efficient, accurate and safe instrument exchange without tissue collision.	Tissue damage, time, economy of motion, connection to energy source, coordination with assistant, instrument selection, recognition of instrument failure, proper instrument engagement to robotic arm and port, memory recognition, trouble shoot protocol	0	0	7	2	29	12
Cutting	Using the scissors to cut at a precise location	Cutting the wrong structure, Past-pointing, Inappropriate instruments	Accurate and efficient division of target structure without collateral damage	Accuracy, lack of tissue damage, timeliness	0	1	5	3	29	13
Energy sources	Activation and control of cautery or other energy sources	ivation and trol of errors, choice and use tery or other rgy sources instrument discordance, Activate energy before tissue contact, Appropriate choice and use damage (real time and delay contact), instrument and energy choice, activation without tissue contact, economy of energy		damage (real time and delay contact), instrument and energy choice, activation without tissue contact, economy of energy use (air burns), pedal	0	2	4	3	28	14
Foreign body management	Removal of all foreign bodies from the operating space.	Failure to confirm foreign body removal (needle, sponge, bulldog)	Safe, appropriate and confirmed foreign body removal	Instrument selection for removal, correct instrument, sponge and needle count, removal technique, immediate confirmation of removal	1	1	3	4		15
Robotic trocars	Safe insertion technique.	Incorrect remote center, Trocar slippage, Spatial orientation, Blind insertion (2 nd and later), Organ injury, Access will	Appropriate trocar insertion and positioning relative to target and other trocars, without unintentional tissue contact. Maintaining	Time, tissue damage, number of adjustments, remote center placement, distance between trocars, trocar spatial relationship to target	0	2	4	3	28	16

Task Name	Description	Errors	Outcomes	Metrics	Iı	mpo	ortance Rating				
					1	2	3	4	Total Score	Rank Order	
Suture handling	Running and interrupted sutures (separate or combined)	mirror FLS Breaking suture, Fraying suture, Tissue tearing, Inadequate following, Poor tension, Inadequate tissue coaptation, Inadvertent locking	positioning. Appropriate handling of suture material without fraying, breakage, or tissue damage.	Tissue damage, time, accuracy, economy of motion, material damage	0	2	5	2	27	17	
Wrist articulation	Understanding and utilizing the full range of motion of the endowrist	Not using all degrees-of- freedom, Inadvertent trapping of tissue or suture	Uses all degrees of freedom appropriately	Time, dexterity and economy of motion	0	2	5	2	27	18	
Ergonomic positioning	Positioning of the surgeons torso, arms and feet.	Poor posture, elbow placement	Maintains appropriate posture and ergonomics throughout the operation and minimizes fatigue.	Work load, posture, muscle fatigue		1	8	0	26	19	
System settings	Setting up and adjusting console settings as needed during surgery	Improper console settings, Scope angle selections, Magnification setup, Motion speed/scaling	Appropriate console settings with minimal ongoing adjustments	Number of adjustments, correct console settings, checks settings, time		2	6	1	26	20	
Multi-arm control	Activating the fourth arm through clutching and using it in the operation	Collision, Moving wrong arm	Efficient use of multi-arm control without collisions	Time and number of collisions		3	4	2	26	21	
Operating Room (OR) set-up	Placing the bedside cart in the location where the operative field is most accessible	Incorrect support equipment placement, Breaking sterile field	Proper placement of equipment in a sterile and safe fashion	Breaks in sterile protocol, equipment placement, access and visualization for assistant, time, time to conversion, access/clearance to patient cart for rapid undocking		3	6	0	24	22	
Respond to robot system error	Understand the robotic protocol	Protocol violation	Identifies correct algorithm identification and algorithm and applies steps in every correct violations, algorithm identification and correct response, time		1	2	5	1	24	23	

Task Name	Description	Errors	Outcomes	Metrics	Importance Rating					
					1	2	3	4	Total Score	Rank Order
			a timely fashion to correct the error. Avert unnecessary conversion.							
Undocking	Removal of robotic equipment from the trocars and patient	Undocking without instrument removal, Tissue damage	Safe and efficient undocking of cart in routine and emergency situations	Time, protocol violation, tissue damage, collisions	0	6	2	1	22	24
Transition to bedside assist	Instrument removal	Tissue damage, Lack of port-site inspection	Safe and efficient removal of instruments and ports	Time, inspection of port sites, bleeding, tissue damage	0	7	2	0	20	25
Clip applying	Accurate application of clips.	Cross-clipping, Short-clipping, Poor accuracy, Inadequate coaptation	Places the clips accurately, appropriately and securely without crossing and without leakage	Time, accuracy, crossed clips, clip damage, incomplete and ineffective clip placement	2	5	2	0	18	26

This second round of voting drew the members to a more centralized position on all of the tasks in the table.

Task Removal

A basic statistical analysis of the total scores was performed to identify the mean, standard deviation, and lower threshold for the scores. Any task on the list which received a score lower than two standard deviations below the mean was recommended for deletion from the list. Based on the second round of Delphi scoring, one task was identified which met this criteria (Table 7). As a result of falling below the threshold, this task will not be included in future curriculum and testing materials developed through the consensus conference process.

Table 7. Tasks Removed Based on Low Scores

Task Name	Description			Imp	orta	ance Ratir	ıg
		1	2	3	4	Total Score	Rank Order
Clip applying	Accurate application of clips.	2	5	2	0	18	26 th

Threshold score to be included in the outcomes measures is 19.77.

Summary

This report describes the work of a consensus conference of surgeons and associated experts who were convened to develop the Fundamentals of Robotic Surgery. This, the first of three conferences of subject matter experts, focused on the identification of specific tasks, errors and metrics that should be the "critical outcomes measures" of a curriculum that will be developed and validated to meet the requirements for certification of a surgeon's basic cognitive and psychomotor technical skills in robotic surgery.

The group identified a number of tasks for which proficiency is required to perform robotic surgery. For each of these an associated definition was provided, common errors for the task were identified, outcomes measures were listed, and metrics for measuring proficiency were established.

The task lists that are recommended in this report were developed through a two stage Delphi process of achieving consensus. The tasks that remain in the list are all supported by the majority of the consensus group. Tasks which were proposed but did not receive sufficient support from the group will be omitted from future curriculum and testing development.

This report will be distributed to the sponsors of the event, the participants, and the leadership of the stakeholder organizations identified in the appendices. The contents of the report will be prepared for publication in a peer reviewed journal and for presentation at medical conferences.

Conclusions

The committee recommends that the list of robotic surgery tasks, errors and metrics that are identified in this document become the basis for the development of a robotic curriculum. This will be undertaken at a second consensus conference that will focus on the topic of curriculum development.

The tasks, errors, outcomes, and metrics, along with the curriculum to be developed in the future, will be validated through multi-site tests. The process of validation study design will be defined in a third consensus conference.

Finally, it is the goal of these consensus conference proceedings to create the curriculum and associated assessment tools necessary to meet the needs and expectations of those organizations that are responsible for training and certification in robotic surgery. Using the curriculum for training and assessment should result in a surgeon who has proficiency in basic robotic surgery skills and is capable of passing the requirements of high stakes testing and evaluation. This high stakes testing and evaluation would be conducted by an appropriate independent, objective and authoritative organization which will receive and adopt the use of the materials developed from this consensus process.

df, pg 10. (accessed 19 October, 2010)

Bibliography

- ______. To Err is Human: Building a Safer Health System. National Academy Press; Washington DC, November, 1999
 _____. Fundamentals of Laparoscopic Surgery. http://www.flsprogram.org/ Accessed 29 Dec, 2010
 _____. American Council on Graduate Medical Education (ACGME). Program Requirements for Graduate Medical Education in Surgery: Common Program Requirement, Effective: January 1, 2008, Section II D (2), 2009.
 http://www.acgme.org/acWebsite/downloads/RRC_progReq/440_general_surgery_01012008_u08102008.p
- Albani JM, Lee DI. Virtual reality-assisted robotic surgery simulation. J Endourol 2007; 21:285-287.
- 5 Albani JM. The role of robotics in surgery: a review. Mo Med 2007; 104:166-172.
- 6 Ali MR, Rasmussen J, BhaskerRao B. Teaching robotic surgery: a stepwise approach. Surg Endosc 2007; 21:912-915.
- American College of Surgeons Core Competencies (2009) http://www.facs.org/education/surged.html (accessed 19 October, 2010)
- 8 Amodeo A, Linares QA, Joseph JV et al. Robotic laparoscopic surgery: cost and training. Minerva Urol Nefrol 2009; 61:121-128.
- 9 Arnold P, Farrell MJ. Can virtual reality be used to measure and train surgical skills? Ergonomics 2002; 45:362-379.
- 10 Balasundaram I, Aggarwal R, Darzi A. Short-phase training on a virtual reality simulator improves technical performance in tele-robotic surgery. Int J Med Robot 2008; 4:139-145.
- 11 Benson AD, Kramer BA, Boehler M et al. Robot-assisted laparoscopic skills development: formal versus informal training. J Endourol 2010; 24:1351-1355.
- 12 Brown-Clerk B, Siu KC, Katsavelis D et al. Validating advanced robot-assisted laparoscopic training task in virtual reality. Stud Health Technol Inform 2008; 132:45-9.:45-49.
- 13 Brydges R, Kurahashi A, Brummer V et al. Developing criteria for proficiency-based training of surgical technical skills using simulation: changes in performances as a function of training year. J Am Coll Surg 2008; 206:205-211.
- 14 Cadeddu J, Herman M, Lepor H et al. Robotically speaking: Experts consider the current and future state of robotic surgery. Interview by Kevin D. Blanchet. BJU Int 2011; 108:ii-vii.
- 15 Chang L, Satava RM, Pellegrini CA et al. Robotic surgery: identifying the learning curve through objective measurement of skill. Surg Endosc 2003; 17:1744-1748.
- 16 De Ugarte DA, Etzioni DA, Gracia C et al. Robotic surgery and resident training. Surg Endosc 2003; 17:960-963.
- 17 Derossis AM, Fried GM, Abrahamowicz M, Sigman HH, Barkun JS, Meakins JL. Development of a model of evaluation and training of laparoscopic skills Am J Surg 175: 482-87, 1998
- 18 Doumerc N, Yuen C, Savdie R et al. Should experienced open prostatic surgeons convert to robotic surgery? The real learning curve for one surgeon over 3 years. BJU Int 2010; 106:378-384.
- 19 Fiedler MJ, Chen SJ, Judkins TN et al. Virtual reality for robotic laparoscopic surgical training. Stud Health Technol Inform 2007; 125:127-9.:127-129.
- 20 Flexner A. Medical Education in the United States and Canada: A Report to the Carnegie Foundation for the Advancement of Teaching (1910). Original document http://www.carnegiefoundation.org/files/elibrary/flexner_report.pdf (accessed 19 November, 2010).
- 21 Gamboa AJ, Santos RT, Sargent ER et al. Long-term impact of a robot assisted laparoscopic prostatectomy mini fellowship training program on postgraduate urological practice patterns. J Urol 2009; 181:778-782.
- 22 Gavazzi A, Bahsoun AN, Van HW et al. Face, content and construct validity of a virtual reality simulator for robotic surgery (SEP Robot). Ann R Coll Surg Engl 2011; 93:152-156.

- 23 Guru K, Menon M. How do we improve techniques in robotic surgery? J Urol 2011; 185:1186-1187.
- 24 Guru KA, Kuvshinoff BW, Pavlov-Shapiro S et al. Impact of robotics and laparoscopy on surgical skills: A comparative study. J Am Coll Surg 2007; 204:96-101.
- 25 Guzzo TJ, Gonzalgo ML. Robotic surgical training of the urologic oncologist. Urol Oncol 2009; 27:214-217.
- 26 Hanly EJ, Marohn MR, Bachman SL et al. Multiservice laparoscopic surgical training using the daVinci surgical system. Am J Surg 2004; 187:309-315.
- 27 Heemskerk J, van Gemert WG, de VJ et al. Learning curves of robot-assisted laparoscopic surgery compared with conventional laparoscopic surgery: an experimental study evaluating skill acquisition of robot-assisted laparoscopic tasks compared with conventional laparoscopic tasks in inexperienced users. Surg Laparosc Endosc Percutan Tech 2007; 17:171-174.
- 28 Hoznek A, Katz R, Gettman M et al. Laparoscopic and robotic surgical training in urology. Curr Urol Rep 2003; 4:130-137.
- 29 Hung AJ, Zehnder P, Patil MB et al. Face, content and construct validity of a novel robotic surgery simulator. J Urol 2011; 186:1019-1024.
- 30 Kahol K, Satava RM, Ferrara J, Smith ML. Effect of short-term pretrial practice on surgical proficiency in simulated environments: a randomized trial of the pere-operative warm-up" effect. .J Am Coll Surg. 2009 Feb;208(2):255-68.
- 31 Katsavelis D, Siu KC, Brown-Clerk B et al. Validated robotic laparoscopic surgical training in a virtual-reality environment. Surg Endosc 2009; 23:66-73.
- 32 Kaul S, Shah NL, Menon M. Learning curve using robotic surgery. Curr Urol Rep 2006; 7:125-129.
- 33 Kaushik D, High R, Clark CJ et al. Malfunction of the Da Vinci robotic system during robot-assisted laparoscopic prostatectomy: an international survey. J Endourol 2010; 24:571-575.
- 34 Kenney PA, Wszolek MF, Gould JJ et al. Face, content, and construct validity of dV-trainer, a novel virtual reality simulator for robotic surgery. Urology 2009; 73:1288-1292.
- 35 Kesavadas T, Stegemann A, Sathyaseelan G et al. Validation of Robotic Surgery Simulator (RoSS). Stud Health Technol Inform 2011; 163:274-6.:274-276.
- 36 Kwon EO, Bautista TC, Jung H et al. Impact of robotic training on surgical and pathologic outcomes during robot-assisted laparoscopic radical prostatectomy. Urology 2010; 76:363-368.
- 37 Kypson AP, Nifong LW, Chitwood WR, Jr. Robot-assisted surgery: training and re-training surgeons. Int J Med Robot 2004; 1:70-76.
- 38 Lee JY, Mucksavage P, Sundaram CP et al. Best practices for robotic surgery training and credentialing. J Urol 2011; 185:1191-1197.
- 39 Lendvay TS, Casale P, Sweet R et al. VR robotic surgery: randomized blinded study of the dV-Trainer robotic simulator. Stud Health Technol Inform 2008; 132:242-4.:242-244.
- 40 Lenihan JP, Jr., Kovanda C, Seshadri-Kreaden U. What is the learning curve for robotic assisted gynecologic surgery? J Minim Invasive Gynecol 2008; 15:589-594.
- 41 Lerner MA, Ayalew M, Peine WJ et al. Does training on a virtual reality robotic simulator improve performance on the da Vinci surgical system? J Endourol 2010; 24:467-472.
- 42 Lin DW, Romanelli JR, Kuhn JN et al. Computer-based laparoscopic and robotic surgical simulators: performance characteristics and perceptions of new users. Surg Endosc 2009; 23:209-214.
- 43 Marecik SJ, Chaudhry V, Jan A et al. A comparison of robotic, laparoscopic, and hand-sewn intestinal sutured anastomoses performed by residents. Am J Surg 2007; 193:349-355.
- 44 McDougall EM, Corica FA, Chou DS et al. Short-term impact of a robot-assisted laparoscopic prostatectomy 'mini-residency' experience on postgraduate urologists' practice patterns. Int J Med Robot 2006; 2:70-74.
- 45 Mukherjee M, Siu KC, Suh IH et al. A virtual reality training program for improvement of robotic surgical skills. Stud Health Technol Inform 2009; 142:210-4::210-214.
- 46 Narula VK, Watson WC, Davis SS et al. A computerized analysis of robotic versus laparoscopic task performance. Surg Endosc 2007; 21:2258-2261.

- 47 Obek C, Hubka M, Porter M et al. Robotic versus conventional laparoscopic skill acquisition: implications for training. J Endourol 2005; 19:1098-1103.
- 48 Patel HR, Linares A, Joseph JV. Robotic and laparoscopic surgery: cost and training. Surg Oncol 2009; 18:242-246.
- 49 Rashid TG, Kini M, Ind TE. Comparing the learning curve for robotically assisted and straight stick laparoscopic procedures in surgical novices. Int J Med Robot 2010; 6:306-310.
- 50 Resnick R, Regehr G, MacRae H, Martin J, McCulloch W. Testing technical skill via an innovative bench station examination. Am J Surg 173: 226-30, 1997
- 51 Satava R, Hunter AM. The surgical ensemble: choreography as a simulation and training tool . Surg Endosc: 2011 Sept 25(9), 3080-3086
- 52 Seymour NE, Gallagher AG, Roman SA, O'Brien MK, Bansal VK, Andersen D, Satava RM. Virtual Reality Training Improves Operating Room Performance: Results of a Randomized, Double-blinded Study. Ann Surg 236: 458-64, 2002
- 53 Stefanidis D, Heniford BT. The formula for a successful laparoscopic skills curriculum. Arch Surg 2009; 144:77-82.
- 54 Stefanidis D, Walters KC, Mostafavi A et al. What is the ideal interval between training sessions during proficiency-based laparoscopic simulator training? Am J Surg 2009; 197:126-129.
- 55 Suh IH, Siu KC, Mukherjee M et al. Consistency of performance of robot-assisted surgical tasks in virtual reality. Stud Health Technol Inform 2009; 142:369-73.:369-373.
- 56 Sun LW, Van MF, Schmid J et al. Advanced da Vinci Surgical System simulator for surgeon training and operation planning. Int J Med Robot 2007; 3:245-251.
- 57 Wilson EB. The evolution of robotic general surgery. Scand J Surg 2009; 98:125-129.
- 58 Zorn KC, Gautam G, Shalhav AL et al. Training, credentialing, proctoring and medicolegal risks of robotic urological surgery: recommendations of the society of urologic robotic surgeons. J Urol 2009; 182:1126-1132.

Appendix 1. Definitions

Consensus Conference. A dialogue between experts on a specific topic, which includes participation from interested parties outside of the field.

Curriculum. A set of courses and their content. A curriculum is prescriptive, and is based on a more general syllabus which merely specifies what topics must be understood and to what level to achieve a particular grade or standard.

Metric. A standard of measurement.

Outcomes Measure. A measure of the result of a system, relative to the aim. An outcome measure is used to measure the success of a system.

Robotic Surgery. A computer- and mechanically-assisted surgical procedure which enhances the human surgeon's ability to perform specific tasks.

Task. A usually assigned piece of work often to be finished within a certain time

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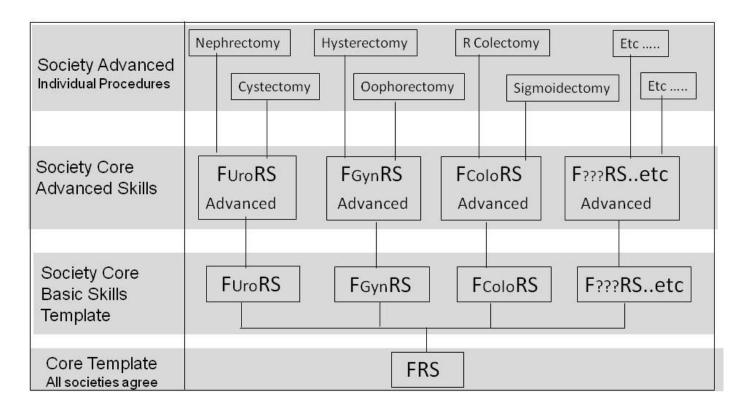
Appendix 2. History and Definitions, Richard Satava, MD, FACS

Full life cycle of curriculum development

The Metrics Drives the Process

	Curriculum Development								
	Outcomes & Metrics	Curriculum Development	Simulator Development	Validation Studies	Implement: Survey Training Certification	Issue Certification			
	Consensus Conference	Standard Curriculum Template	Engineering Physical Simulator	Standard Validation Template	Current Procedures	Issue Mandates And Certificates			
)	ABS SAGES ACS Specialty Societies	SAGES ACS Societies Academia	Industry with Academia Medical Input	ACS SAGES, Participating Societies	FLS SAGES/ACS	ABS			

Development of Curriculum from common template "Sweet* Tree"



^{*} Adapted from Rob Sweet, MD, Professor of Urology, University Minnesota, 2010

Example of skills classification from task deconstruction (laparoscopic cholecystectomy)

Methodology for identifying outcomes measures

	Task or subtask	Outcome Measurement	Quantitative or Qualitative metric	Common Error	Measurement Methodology
Cognitive Skills	Identify structures of Calot Triangle	Common Duct, Cystic Duct , cystic artery	Mustidentify all 3 structures	Not identifying all three structures	Question/answer Identify on image
Psychomotor Skills	Laparoscopic knot tying	Two throws, does not break, Knot tight	Surgeon knot first throw Second knot tight Total 4 knots Total time 2 min	Suture breaks Knot slips >0.5kg force applied Not surgeon knot Unable to complete in 2 minutes	Broken suture Grasp one end of suture, apply 0.5kg force (measured Time Observed or video
Team Training Skills	Position instrument ports	Communication between surgeon, assistant and nurse	Assistant receives trocar from nurse Assistant confirms site with surgeon	Trocar not available Assistant places port without confirmation from surgeon	Observe real time or though video analysis Unambiguously defined check list

Appendix 3. Task Deconstruction, Mika Sinanan, MD PhD FACS

Definition: Task Deconstruction

- Taking a complex process and breaking it down into constituent parts
- Reduction to meaningful components
 - Easily defined
 - Meaningful to trainee relevant to level of training and experience
 - e.g. bowel anastomosis
 - Two layer inverting anastomosis
 - » Inner running full thickness and outer running Lembert
 - · Align limbs of bowel and place anchoring sutures 180° apart
 - Place "Lembert" suture into the submucosa 5 mm from the stapled, closed end of the bowel to be anastomosed
 - Grasp needle with forceps and adjust needle orientation to the tip of the needle driver then secure with one click of the ratchet
 - Place fingers in the loops of the handle and point the instrument away from you in the right(or left for L-handed surgeons) hand

Essential Tasks: Abstracted from Training Materials

- Robot setup
 - Powering up, calibration
 - Video/camera calibration, focus, white balance
 - Surgeon master unit configuration
- Team orientation
 - Patient and procedure specific factors
 - Dual console agreements
- Patient preparation, positioning, protection
- Sterile field Draping
- Insufflation
- · Port marking and placement
- Docking
- · Camera navigation

- Instrumentation selection, exchange, and manipulation
 - Two handed manipulation
 - Endowrist
 - Dissection
 - Suturing and knot tying
- 3rd Arm
- Assistant surgeon's role
- Clutching and Instrument/camera control
- Energy Devices
 - Unipolar, bipolar cautery
 - Ultrasonic and bipolar tissue fusion
- Troubleshooting
 - Detection
 - Overriding vs. conversion

Appendix 4. ISI Standard Curriculum, Henry Lin

Intuitive Surgical da Vinci Clinical Training Pathway

The ultimate goal of the da Vinci Surgery Training Pathway is to develop a self-sufficient surgical team capable of performing da Vinci procedures with minimal support and instruction. The pathway is divided into four distinct phases.

Phase	Content	Trainer	
Introduction to da Vinci Surgery	Product Training	Intuitive Surgical	
Preparation and System Training			
III: Post System Training	Clinical Training	Independent Surgeons & Societies/Academic Institutions	
IV: Advanced Training	*		
Beyond the Pathway	Continuing Clinical Education	Independent Surgeons & Societies/ Academic Institutions	

	Support Tools and Technology		
Support	Online System Modules & Evaluation: da Vinci System set-up and functionality		
Tools	Online Procedure Modules & Evaluation: Narrated case videos		
	da Vinci Surgery Online Community: A secure social networking site providing access to the largest collection available of robotic surgery abstracts, over 1,000 hours of procedure videos and a range of supporting educational materials		
Technology*	Optional da Vinci _e Si ⁿ Dual Console: Real-time proctoring while sharing the same 3D surgical view da Vinci _e Skills Simulator***: Additional surgeon console practice via virtual experience Connect** for the da Vinci* Si** System**: Remote case observation and mentoring		

Phase Content Details

Phase	Time (hrs)	Content
1	1 2	Da Vinci System Test Drive Live da Vinci procedure observation
2	2 (min) 4 3-4 7	Online da Vinci system training modules and evaluation (80% pass) Two online procedure modules On-site system training at own hospital Off-site training at ISI training center
3	2 variable variable	Procedure dry run First procedure (proctored) and post-case debriefing Additional skills drills or simulator modules
4	14	Advanced training programs (surgeon led)

Skills Simulator Assessment Overview

Clinical Pathway	Phase	Skills Simulator exercises	Proficiency req	Anticipated total time
On-site Training	2	Camera Targeting 1 Peg Board 1 Thread the Rings Energy Switching 1	Yes	3-5 hours
Off-site Training	2	Peg Board 2 Camera Targeting 2 Suture Sponge 1 Energy Switching 1	Yes	30 minutes
Prior to first cases	3	Ringwalk 3 Ring and Rail 2 Suture Sponge 2 Energy Dissection 1	Yes	3-5 hours

Appendix 5. UT curriculum, Danny Scott, MD FACS

Developing a Comprehensive, Proficiency-Based Training Program for Robotic Surgery

University of Texas Southwestern Medical Center Robotic Training Curriculum Daniel J. Scott, MD

SURGERY

Introduction: Robotically-assisted surgery has become very popular for numerous surgical disciplines yet training practices remain variable with little to no validation. The purpose of this study was to develop a comprehensive, proficiency-based robotic training program.

Methods: A skill deconstruction list was generated by observation of robotic operations (n=10) and interviews with experts (n=6) from General Surgery, Urology, Obstetrics and Gynecology, and Otolaryngology. Available resources were used and other components were developed as needed to develop a comprehensive, proficiency-based curriculum to teach all deconstructed skills. Preliminary construct and content validity and curriculum feasibility were evaluated.

Results: The skill deconstruction list contained 23 items. Curricular components included an online tutorial, a $\frac{1}{2}$ day interactive session, and 9 inanimate exercises with objective metrics. Novice (546 \pm 26) and expert (923 \pm 60) inanimate composite scores were significantly different (p <0.001), supporting construct validity, and significant pre-test to post-test improvement was noted after successful training completion. All 23 deconstructed skills were rated as highly relevant (4.9 \pm 0.5, 5-point scale) and no skills were absent from the curriculum, supporting content validity.

Conclusions: These data suggest that this proficiency-based training curriculum comprehensively addresses the skills necessary to perform robotic operations with early construct and content validity and feasibility demonstrated. Further validation is encouraged.

Appendix 6. Organizations Invited to Send Representatives

American Association Gynecologic Laparoscopy (AAGL)

American College of Surgeons (ACS)

American Congress of OB-Gyn (ACOG)

American Urologic Association (AUA)

American Academy of Orthopedic Surgeons (AAOA)

American Assn of Thoracic Surgeons (AATS)

American Assn of Colo-Rectal Surgeons (ASCRS)

American Assn of Gynecologic Laparoscopists (AAGL)

Minimally Invasive Robotic Association (MIRA)

Society for Robotic Surgery (SRS)

Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)

American Board of Surgery (ABS)

Accreditation Council of Graduate Med Education (ACGME)

Association of Surgical Educators (ASE)

Residency Review Committee (RRC) – Surgery

Royal College of Surgeons-Ireland (RCSI)

Royal College of Surgeons-London (RCSL)

U.S. Department of Defense (DoD)

U.S. Department of Veterans Health Affairs (VHA)

Appendix 7. Conference Participants

Arnold Advincula, MD American Assn of Gynecologic Laparoscopists (AAGL) and

American Congress of Obstetricians and Gynecologists (ACOG)

Rajesh Aggarwal, MD Imperial College of London, Royal College of Surgeons

Mehran Anvari, MD Minimally Invasive Robotic Association (MIRA)

John Armstrong, MD USF Health, Center for Advanced Medical Learning and Simulation (CAMLS)

Adeena Bleich, BSC Management, FRS Conference Organizer

Paul Neary, MD Vice Dean of Surgical Training, Dublin Region, RCSI, Senior Lecturer RCSI, Senior

Lecturer Trinity College Dublin, Consulting Colorectal Surgeon

Wallace Judd, PhD Authentic Testing Corp.

Michael Koch, MD Professor and Chairman of Urology, Indiana University School of Medicine, Past

President American Board of Urology

Kevin Kunkler, MD Telemedicine and Advanced Technology Research Center (TATRC)/US Army

Medical Research and Material Command (USAMRMC), the Joint Program

Committee 1, and the University of Maryland School of Medicine

George Lewis, PhD Consultant to FRS Consensus Conference

Vipul Patel, MD Global Robotics Institute - Florida Hospital Celebration Health

COL Robert Rush, MD US Army Madigan Healthcare System

Richard Satava, MD Minimally Invasive Robotic Association (MIRA)

Danny Scott, MD Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)

Mika Sinanan, MD Institute for Simulation & Interprofessional Studies (ISIS), University of

Washington

Roger Smith, PhD Florida Hospital Nicholson Center

Dimitrios Stefanidis MD Carolinas HealthCare System, Association for Surgical Education

Chandru Sundaram, MD American Urological Association, Dept. of Urology, Indiana University

Robert Sweet,MD American Urological Association, Dept. of Urology, University of Minnesota

Edward Verrier, MD University of Washington, Joint Council on Thoracic Surgery Education

Appendix 8. Surgeons Voting on Task List and Importance Rating

List of Surgeons Voting – 1st Round and 2nd Round:

Total number of surgeons voting = 9.

- 1. Arnold Advincula, American Assn of Gynecologic Laparoscopists (AAGL) and American Congress of Obstetricians and Gynecologists (ACOG)
- 2. Michael Koch, Professor and Chairman of Urology, Indiana University School of Medicine, Past President American Board of Urology
- 3. Vipul Patel, Global Robotics Institute Florida Hospital Celebration Health
- 4. COL Robert Rush, US Army Madigan Healthcare System
- 5. Richard Satava, Minimally Invasive Robotic Association (MIRA)
- 6. Danny Scott, Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)
- 7. Dimitrios Stefanidis, Carolinas HealthCare System, Association for Surgical Education
- 8. Chandru Sundaram, American Urological Association, Dept. of Urology, Indiana University
- 9. Robert Sweet, American Urological Association, Dept. of Urology, University of Minnesota

Appendix 9. Invitation Letter





Esteemed Colleagues:

Similar to the evolution of laparoscopic surgery and the Fundamentals of Laparoscopic Surgery (FLS), robotic surgery has been established as an essential procedural approach in surgery and shows every sign of continuing its adoption of more diverse surgical procedures and specialties. It has been clear to the leaders in surgery that there is a need for the creation of a unified approach and standard for basic training in robotic surgery skills principles, to be referred to as the Fundamentals of Robotic Surgery (FRS).

There are current efforts to develop a core curriculum for certifying robotic surgeons; however, this is a fragmented effort, with different approaches and outcomes measures. This has resulted in conflicting, competing and redundant training and assessment tools for robotic surgery. In addition, these have generally lacked the financial resources necessary to carry the project to completion at a national level. The Minimally Invasive Robotic Association (MIRA) has been fortunate to receive a substantial industry educational grant to fund a project to create the FRS through the full life cycle of curriculum development, from initial outcomes measures through final validation study. Florida Hospital has also received a Department of Defense grant which is partially dedicated to the creation of FRS and which will be working collaboratively with MIRA on this project. We are Co-Principal Investigators for the combined grants to pursue the development of FRS, which is administered independently through the academic robotic surgery society MIRA and Florida Hospital. The key stakeholders involved will be appropriate surgery specialty boards, societies and national certification bodies such as the Accreditation Council of Graduate Medical Education – (ACGME) -through their Residency Review Committees – (RRC) – as well as the AAGL and AUA and the Department of Defense and the Veterans Administration. The scope of the project will include a comprehensive curriculum development process based upon established needs assessment, adult educational principles, appropriate validation study design and application toward certification to the appropriate authorities.

The desired deliverable from this effort would be a validated curriculum called FRS (similar to FLS), that is based upon the integrated effort of the various stakeholders stated needs, that will be scientifically stringent enough to meet the criteria of high stakes testing and evaluation, and be acceptable to certification authorities across multiple specialties. Given the rigor needed to insure broad acceptability upon completion that could meet the requirements for certification should a society, board, or certification authority so choose, it is essential to have your input to guide us through this process.

As the Co-PI's for these grants, we would like to invite you to serve in developing the outcomes measures for the Fundamentals of Robotic Surgery Project. We plan to address FRS development process through a series of at least three Consensus Conferences. The first will address the necessary Outcomes Measures that could meet the criteria for certification. We would like to hold this on December 12-13, 2011 in Orlando, Florida. The second Consensus Conference later will independently be on Curriculum Development, which will be based upon the previous conference's identified outcomes measures; this approach is taken to ensure total transparency and separation of establishment of outcomes measures from curriculum development so as to guarantee absolutely no real or perceived conflict of interest. The third consensus conference will be for the design of the Validation Study, to meet the most rigorous evaluation that would meet criteria for high stakes testing and evaluation.

In accepting this role with the FRS, your responsibilities would be those of any advisory board to a major research initiative, which would include actual participation at the annual project review meeting, quarterly teleconferences, and responses to ad hoc advice (written, email or telephonically). All incurred expenses will be covered by the grant and hotel accommodation information will be sent at a later date. Your benefit will be an opportunity to guide this new important initiative to create not only an essential educational, training and assessment curriculum, but also to help establish a unified approach (across specialties) to this new discipline of robotic surgery. This is a unique opportunity to begin breaking down the silos that have fractionalized robotic surgery and create a scientifically acceptable process for developing critical surgical curricula.

We would greatly appreciate your response indicating your acceptance or declination of this invitation by November 23, 2011. Please confirm your participation on the committee and attendance at the first consensus conference by emailing the FRS Project Director, Adeena Bleich at Adeena@bscmanage.com or by phone at 310.437.0555x141.

Respectfully,

Richard Satava, MD, Roger Smith, Ph.D. and Vipul Patel, MD

Co-Principal Investigators, FRS Project

Appendix 10. Agenda of Meeting (FRSCC#1)

Monday December 12

7:15am- Bus from Celebration Bohemian Hotel to Nicholson Center

7:15-8:00am- Breakfast & Registration

8:00-8: 10am- Welcome,

Monica Reed, MD – CEO Celebration Health

8:10-8: 20am- Objective of FRS Outcomes Conference

Roger Smith, PhD & Vip Patel, MD

8:20-8:30am Introductions & Admin Announcements

George Lewis, Facilitator

8:30-8:35 History and Definitions Rick Satava, MD, FACS

- Identify specific products that will be created during this event.
- Definitions: What will be measured? How will it be measured?

8:35-9:30- Skills tasks and subtasks analysis, and existing curricula

- Task Deconstruction Mika Sinanan, MD PhD FACS, University of Washington
- Current standard curriculum Henry Lin, Intuitive Surgical Inc.
- UT curriculum Danny Scott, MD FACS, University of Texas Southwestern

9:30-9:35am- Short Refresher Break

9:35-11:30am- Skills to be measured (all attendees)

George Lewis, Facilitator

- Pursue at consensus on the tasks/subtasks that need to be measured for certification.
- Concur on generally applicability across specialties
- Generate list of common errors affiliated with the tasks/subtasks

11:30am-1:00pm- LUNCH

11:30am-12:00pm Optional Tour of Nicholson Center

1:00-4:00pm- Breakout sessions

Group 1: Outcomes to be Measured, Rick Satava, Facilitator

• Performance, competence, patient safety, quality etc.

Group 2: Measurement Methods, George Lewis, Facilitator

• Quantitative, structured method, qualitative (Likert Scale, etc.), Global rating scale, other

4:00-4:05pm- Short Refresher Break

4:05-5:00pm- Integration review (all attendees), George Lewis, Facilitator

Group 1 Report: Outcomes to be Measured

Group 2 Report: Measurement Methods

Integration process of the two reports

5:30pm- Bus to Hotel

7:00-9:00pm- Group Dinner, Hosted by MIRA

Tuesday December 13

7:30am- Bus from Celebration Bohemian Hotel to Nicholson Center

7:45-8:30am- Breakfast & Registration (for any late arrivals)

8:30-10:00am- Review and follow-up discussion of Monday's work - George Lewis, Facilitator Integration of:

- Tasks/subtasks and errors revalidated
- Outcomes measures and methods reviewed
- Integration of Outcomes and their methodology

10:00am-10:05- Short Break

10:05am - 12:00pm- Final Integration - George Lewis, Facilitator

- Match specific skills to outcomes measures and methods
- Match specific errors to outcomes measures and methods
- First Delphi Scoring on Outcomes and Measurements

12:00-1:00pm- LUNCH

1:00-2:00pm- Wrap up Session and Next Steps

- Compile and review Consensus of Skills and Measurement Methods.
- Give assignments to specific members
- Call for delivery of products in 4 weeks
- Set dates and agenda for next meeting (propose: Feb 13-14, 2012)

2:00pm- Depart for Airport (Taxi pickup at Nicholson Center)

Appendix 11. FRS Background Paper

Fundamentals of Robotic Surgery (FRS) Outcomes Measures Consensus Conference Workshop 12-13 December, 2011

Richard M. Satava, MD, FACS

Introduction

The purpose of this workshop called Outcomes Measures Consensus Conference Workshop is to define the outcomes needed to develop (and then validate) a curriculum called the Fundamentals of Robotic Surgery (FRS). This curriculum is intended to be used as the very most basic curriculum to teach the skills necessary to use a robotic surgery platform safely, regardless of surgical specialty. While it is difficult to predict what newer platforms will emerge, the purpose is to be able to develop the cognitive, psychomotor and team training skills that would be appropriate for current and hopefully future robotic surgical platforms.

This first consensus conference will focus upon the "outcomes measures" which will drive the subsequent consensus conferences on "curriculum" and "validation". Most previous curricula on technical skills (which are supported by a simulator for psychomotor skills) have had the shortcoming of not being adopted by regulatory authorities; in the past, the metrics and content for the curriculum were developed by only one or two clinical experts, whose perspective focused entirely upon the skill/procedure to be taught, and not the larger needs for patient safety, which is one of the main concern for the regulatory authorities.

Over the past 2 decades, it has become apparent that engagement of the organizations with the appropriate authority for standards (ACGME, RRCs), training (e.g. societies of the American Board of Medical Specialties (ABMS)), and certification (respective surgical Boards and specialty Boards) are critical to the development of a curriculum that is meaningful and acceptable to all entities involved in the "full life cycle" of training. An example of one current model for such a full life-cycle curriculum (Appendix 1)* demonstrates that the initial step for any curriculum is to establish (preferably by a consensus conference such as this) the appropriate Outcomes Measures. It should be noted that this life cycle process requires that there be continuous long-term feedback from the Boards such that iterative improvement of the curriculum can be achieved over many years, referred to as the longitudinal maintenance of a curriculum over time. It is acknowledged that some of the Boards may or may not initially agree to require such a curriculum, however their input at this time is essential in order to insure that, if over time, any Board would want to reconsider and to require such a curriculum, that Board would have had input into the creation of such a curriculum. It is evident that participation by multiple specialties provides an essential broader perspective that could create a stronger curriculum, whether they are adopted now or in the future.

As noted above, some of the other steps in the curriculum development will also need a consensus conference, so the full life cycle was included to provide a perspective as to both where Outcomes Measures fit into the process, as well as to the critical importance of defining outcomes BEFORE developing a curriculum. This approach was inspired by the American Council on Graduate Medical Education (ACGME) and American Board of Medical Specialties (ABMS) establishing the 6 competencies before beginning the task of developing the educational and training curriculum that will be needed to teach the competencies.

It is noteworthy that the above ACGME competencies were developed to be inclusive of all medical specialties; in a similar fashion, this FRS curriculum is intended to serve most all surgical (and procedural)

specialties that use or have the future potential to perform robotic and computer assisted interventions. In addition, it is anticipated that, if created within a framework of a more comprehensive utilization, the process and perhaps curriculum template will be adopted by the participating specialties, to develop their own "specialty fundamentals of robotic surgery" (Appendix 2)*. This concept of an initial template upon which subsequent similar curricula can easily developed has been proposed by Dr. Robert Sweet (University of Minnesota) and is referred to as the 'Sweet Tree'. The advantages of such a concept of using a common template are twofold:

- 1. Across specialties, a common process would permit a more scholarly and scientifically valid way of performing *comparative analysis of outcomes for the same or similar procedures*. In addition, some of the most basic types of procedural skills (such as open, laparoscopic, flexible endoscopic, image guided, etc) can also be developed and adopted with a uniform methodology, as the FRS has the potential to do thus saving resources by eliminating the need for every society to develop their own variation of skills, and, in resulting in a 'de facto standard' that could be acceptable towards a more uniform way of developing curricula.
- 2. Within a specialty, such a common process would allow much easier development of subsequent more-complicated, specialty-specific curricula, as indicated by the Sweet Tree. And similar to above, it will be possible to conduct a more scientific validation of a *comparative analysis of the same procedure* using different techniques (such as robotic versus laparoscopic versus open surgery for example hysterectomy).

This methodology has been successfully executed within other non-medical simulation environments, and has lead to 'inter-operability' of curriculum development, validation, certification and resulted in saving time and resources by eliminating competition and redundancy.

This last point warrants emphasis, because simulation is new to healthcare, and much can be learned about simulation and curriculum development from the more than 80 years of experience in the aviation, military, nuclear, etc domains. While each of these domains is unique, it is the process and methodology that has allowed for a much more efficient development of training curricula.

It should also be emphasized that the above examples are NOT written in stone, and although they have proven to be effective in the past or other domains, it is most likely that variations from (or even possible disregard of) some of the examples are likely.

Goals

There are four specific goals of this Outcomes Measures Conference that will lead up to the definition of the metrics for the tasks of the FRS and the methods of measuring/acquiring the metrics so the subsequent Curriculum Conference will have the correct Outcomes Measures for which the curriculum must be designed.

- 1. <u>Define the tasks/subtasks that are to be measured using task analysis methods</u>

 The first goal is to do a task analysis and determine what the components are that need to be taught and assessed. This would include at least cognitive, psychomotor, and team training components
- 2. <u>Identify the outcomes measures which will be required by the curriculum and methods of measuring them</u>

The second goal is to determine what it is that needs to be measured (the What breakout workshop), For example, suggested critical outcomes measures might include patient safety, quality improvement, cognitive and psychomotor performance, team training, learning curve, etc. This will be the generic types of outcomes measures from the first workshop breakout session. At the same time, the other breakout session will determine the methods (the How) by which the metrics will be acquired. Will there need to be specific quantitative metrics, qualitative measurements (with Likert scale), the OSATS

method, global ratings, etc.? Other issues include whether review will be real time, saved video tape for later analysis for unambiguous errors, etc. Finally, can specific tasks be identified that will generate the outcomes measures that are required

- 3. <u>Integrate how and which process will be used to acquire the outcomes measures</u>
 The third goal will need to be an integration of the specific measure (ie psychomotor skill, team training, etc.) with the method(s) by which it will be measured (specifically for robotic surgery), for example psychomotor skills for knot tying can be quantitatively analyzed with physical objects and the OSATS or on the simulator that automatically collects the data. Perhaps team training will be evaluated using the well validated STEPPS methodology.
- 4. <u>Match the list of specific tasks/sub-tasks</u>, with the desired outcome measurements and how those measurements will be acquired

The fourth goal will take the previous goals (task analysis, outcomes measures and methods of measurement) and integrate them with specific measurements for the specific tasks/subtasks. The output of the final goal might look something like Appendix 3*.

Suggestions for other possible approaches are welcome. (* = reference Appendix 2 in this report)

Methodology

The Outcomes Measures Workshop will be a conventional modified Delphi method. This typical methodology consists of a facilitator who works with the participants (in each group and all together) to capture ideas/suggestions (usually on an easel) generated by the participants. The ideas are then analyzed for common groups/concepts, duplication, etc to produce a list of categories of critical items (objects, processes, measurements, etc). The individual categories are then prioritized (by value, rank-order, sequence, etc), either in a table, graph or narrative form. From each session workshop, a 'reporter' will be chosen from the group to summarize the results of the session to the group as a whole. This is an iterative process, which most educators are familiar with, however for the sake of having a common understanding of the conference approach, it was presented.

Deliverables

Report of the Outcomes Measures Workshop, to be made available for the next Curriculum Workshop of FRS, which specifically lists:

- 1. the suggested tasks/subtasks/errors/ for the FRS,
- 2. appropriate Outcomes needed to train, assess and certify the most fundamental skills in robotic surgery,
- 3. where possible, the suggested/preferred methods of measuring/acquiring the metrics
- 4. the actually quantitative/qualitative measure that need to be measured for the individual tasks/subtasks/errors that comprise the FRS

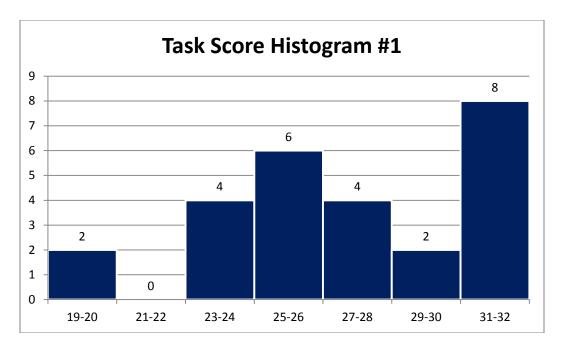
It is anticipated that the results of the Outcomes Measures Consensus Conference will be used by the Curriculum Consensus Conference, and will have iterative improvement by clinicians that will be attending that conference.

Appendix 12. Task List Score Statistics - 1st Round Voting

Based on 9 voting members.

Mean Score = 27.19 Standard Deviation = 3.82

Threshold = Two Standard Deviations Below the Mean: Score < 19.56



Appendix 13. Task List Score Statistics - 2nd Round Voting

Based on 9 voting members.

Mean Score = 28.31 Standard Deviation = 4.27

Threshold = Two Standard Deviations Below the Mean: Score < 19.77

