Annals of Surgery
DOI: 10.1097/SLA.0000000000004531

Expert Consensus Recommendations for Robotic Surgery Credentialing

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Sources of Funding
No funding was received in support of this project.

Robotic Credentialing Recommendations

Mini Abstract

Existing robotic credentialing institutional policies are highly variable and inadequate to ensure surgeon proficiency. To address this gap, a consensus conference of robotic experts was convened to develop credentialing criteria for robotic surgery that promote surgeon proficiency which are presented in this study.

Structured Abstract

Objective

To define criteria for robotic credentialing using expert consensus.

Background

A recent review of institutional robotic credentialing policies identified significant variability and determined current policies are largely inadequate to ensure surgeon proficiency and may threaten patient safety.

Methods

28 national robotic surgery experts were invited to participate in a consensus conference. After review of available institutional policies and discussion, the group developed a 91 proposed criteria. Using a modified Delphi process the experts were asked to indicate their agreement with the proposed criteria in three electronic survey rounds after the conference. Criteria that achieved 80% or more in agreement (consensus) in all rounds were included in the final list.

Results

All experts agreed that there is a need for standardized robotic surgery credentialing criteria across institutions that promote surgeon proficiency. 49 items reached consensus in the first round, 19 in the second, and 8 in the third for a total of 76 final items. Experts agreed that privileges should be granted based on video review of surgical performance and attainment of clearly defined objective proficiency benchmarks. Parameters for ongoing outcome monitoring were determined and recommendations for technical skills training, proctoring, and performance assessment were defined.

Conclusions

Using a systematic approach, detailed credentialing criteria for robotic surgery were defined. Implementation of these criteria uniformly across institutions will promote proficiency of robotic surgeons and has the potential to positively impact patient outcomes.

This is the author's manuscript of the work published in final form as:

Stefanidis, D., Huffman, E. M., Collins, J. W., Martino, M. A., Satava, R. M., & Levy, J. S. (2020). Expert Consensus Recommendations for Robotic Surgery Credentialing. Annals of Surgery. https://doi.org/10.1097/SLA.0000000000004531

INTRODUCTION

Robotic surgery has seen exponential growth since its introduction into clinical practice after the first robotic system received United States (US) Food and Drug Administration (FDA) approval in the year 2000.[1] In 2019 alone, approximately 1,229,000 surgical procedures were performed worldwide using the most commonly available robotic system today, an increase of 18% over the prior year.[2] Independent studies have confirmed this upward trend in robotic surgery use across a broad range of common surgical procedures and have cautioned that the ongoing diffusion of this relatively new technology should be monitored so that it does not lead to diminished patient safety.[3, 4] Indeed, prior studies have suggested there may be an increased risk for patient complications during the introduction of new technology, including robotic surgery, though this remains to be identified in prospective trials.[5-7]

To ensure safe surgical practice and safe introduction of new technologies, the Joint Commission requires institutions to have specific credentialing policies the development of which, however, is the responsibility of the institution.[8] In 2013, the US FDA conducted a small-scale survey of 11 surgeons which revealed a lack of standardization in the credentialing processes at their respective institutions.[9] Specialty societies have suggested relevant guidelines to address gaps and lack of standardization in robotic surgery privileging and credentialing, however, none of these are uniform and the current uptake of such guidelines by hospital credentialing committees is unknown.[10-14] Further, existing guidelines tend to be specialty specific, which may limit their generalizability.

Indeed, in a recent review of a representative sample of 42 US hospital credentialing policies by our group, we identified significant variability in credentialing policies for robotic surgery.[15] Importantly, existing credentialing policies were deemed inadequate to ensure surgeon proficiency and the development and implementation of standardized credentialing guidelines was recommended to optimize patient safety and outcomes.[15] There are legal implications from the lack of a standardized approach, and it is therefore not surprising that recent lawsuits have argued that institutional robotic surgery credentialing processes are not sufficient to ensure patient safety.[16]

As a response to this existing lack of standardization for credentialing in robotic surgery that may threaten patient safety the Institute for Surgical Excellence (ISE) convened a consensus conference of experts from multiple disciplines to develop credentialing guidelines for robotic surgery using a systematic methodology. In this paper we report expert consensus derived criteria for robotic credentialing focused on ensuring surgeon proficiency and patient safety.

METHODS

A steering group consisting of ISE members was formed to define criteria for robotic credentialing that would ensure surgeon proficiency and optimize patient outcomes. PubMed and the gray literature were searched by the steering group for proposed robotic surgery credentialing criteria. The steering group also evaluated robotic surgery credentialing policies from 42 US institutions,[15] and organized a consensus conference of a multidisciplinary expert panel in person to review the available evidence and propose optimal criteria for

credentialing. Following the conference an online Delphi process was used to obtain expert consensus on credentialing criteria.

Expert consensus conference

The steering group invited a total of 8 surgical societies representing specialties that use robotic surgery and 45 individuals to the in-person consensus conference. Participants were selected in consultation with participating surgical organizations based on their reputation and experience with robotic surgery, contributions to the literature, and interest or prior work in robotic credentialing. Participants consisted of 28 key opinion leading expert robotic surgeons (27 from the US and 1 European representative), 2 non-physician society representatives, 3 government agency representatives, 9 robotic manufacturing or related industry representatives, 1 lawyer, and 2 ISE staff members (see table, supplemental digital content 1 , http://links.lww.com/SLA/C665). The 8 surgical societies represented at the meeting included the American College of Surgeons, American Urological Association, American College of Obstetricians and Gynecologists, Society of Thoracic Surgeons, Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), AAGL, Society of Robotic Surgery, and Clinical Robotic Surgery Association.

A modified nominal group technique was used to obtain group opinions during the conference. Participants were sent the goals of the conference ahead of time and were asked to consider optimal credentialing criteria to propose at the meeting. During the meeting the results of the survey of 42 institutional credentialing policies for robotic surgery[15] were presented along with a variety of comprehensive and innovative credentialing policies chosen by the steering group from 7 panelist institutions. In addition, the definitions of a proctor and preceptor were presented and agreed upon as published previously.[17] After these presentations and a brief Q&A session, participants were divided into three breakout groups tasked to discuss and define credentialing criteria on the following topics:

Group 1: Prerequisite Education and Training Qualifications

Group 2: Assessing the Surgeon's Performance - Quantitative Metrics

Group 3: Ongoing Monitoring and Surveillance

Participants of these groups were asked to record their individual ideas for credentialing criteria that would ensure surgeon proficiency in robotic surgery and maximize patient safety, and the facilitator then asked each participant to state a single idea to the group in a 'round robin' fashion. The results of the generated list were then discussed among the group and the item list finalized.

The larger group reconvened after the breakout sessions and representatives presented the key elements of their discussion to the entire group for feedback. Finally, the groups' discussions were summarized, and a first draft of the Delphi survey was generated.

Delphi process

Following the consensus conference, the Delphi methodology was employed to gain expert consensus of the credentialing criteria proposed and drafted during the in-person meeting. The Delphi methodology refers to a systematic process of collecting, evaluating, and tabulating expert opinion on a specific topic. The principal features of a Delphi process include: (1) anonymity (through the use of anonymous, self-administered questionnaires); (2)

iteration (through completion of questionnaires over a series of rounds); (3) controlled feedback; and (4) statistical aggregation of the group response. A particular benefit of this approach is that it can sample the opinion of a group of experts without being overwhelmed by overly influential individuals and can be controlled by appropriate feedback and modification to drive findings toward a group consensus.[18]

An internet survey (Google Forms, Mountain View, CA) was generated and sent to the 28 expert surgeon members of the panel. Supplementary file 1 , http://links.lww.com/SLA/C666 shows a full list of the survey questions. Panelists were asked to indicate their agreement or disagreement with the proposed criteria established during the in-person meeting. The results of this initial electronic survey were analyzed and questions in which there was ≥80% agreement or disagreement were removed from the next round of the survey. Repeated iterations of anonymous voting continued over three rounds, where an individual's vote in the next round was informed by knowledge of the entire group's results in the previous round. Responders had the option of proposing new credentialing criteria during all rounds. New criteria were added to the following round and were voted upon along with the other questions. Outcomes of the e-consensus at each round were displayed as histograms so the result could be reflected on before selecting a response in the next round. To be included in the final list of credentialing criteria each survey item had to have reached group consensus (80% agreement) by the end of the 3 survey rounds. Items which did not reach consensus were excluded from the final recommendations of this paper.

RESULTS

95 questions were submitted to the expert panel on round 1 of the Delphi process (see table, Supplemental Digital Content 2 , http://links.lww.com/SLA/C666, which contains the full list of questions). Of those, 53 (55.7%) reached consensus after this first round. After questions that achieved consensus were removed (including questions that achieved <20% consensus), and 3 new proposed questions were added, 39 questions were sent to the panelists for round 2 of the Delphi process. Of those, 19 (48.7%) reached consensus after this round. 20 questions that did not reach consensus plus 1 new question were sent back to the panel for the final round. Of those, 8 (38.1%) reached 80% consensus and another 4 had >70% agreement. In total, 76/91 (83.5%) questions achieved 80% consensus at the end of the three rounds of the Delphi process.

All panelists agreed that there is a need for a separate credentialing process in robotic surgery. The panel provided a unanimous recommendation that a common credentialing pathway for basic robotic surgery skills should be created across all specialties that use robotic surgery. Further, 83% of panelists agreed that it would also be beneficial to have a separate but common pathway for credentialing for advanced robotic surgery procedures across specialties. Table 1 lists the panel's recommendations for initial robotic credentialing criteria. Panelists agreed that surgeons seeking robotic surgery privileges should be board-eligible in their specialty if recent graduates or have a chair support letter if already practicing or moving from a different institution. The panel suggested that, independent of the stage in their career, surgeons should have cognitive and technical training in basic robotic surgery before they apply for initial privileges. Further, they recommended that surgeons have

documented cognitive, technical, and non-technical training in specialty specific robotic procedures for which they are interested in obtaining privileges.

For technical skills specifically, the panel recommended a proficiency-based training paradigm with documentation of proficiency using objective metrics or performance. Such training should be developed by independent surgical education organizations and should not be left to device manufacturers. The panel agreed that surgeons should receive device specific training sponsored by the respective manufacturers, including usage of the device and related instrumentation, which should ensure the acquisition of proficiency by surgeons interested in using their devices.

Before applying for privileges, the surgeon should have observed the robotic procedures for which he/she is interested in obtaining credentials. Importantly, the panel opined that once these criteria have been met, the surgeon's initial robotic OR cases should receive special attention. Specifically, the initial cases should be performed under the guidance of a preceptor who is qualified and experienced in robotic surgery. While the panel felt that the preceptor should be present for the initial cases, they also agreed that part of preceptorship could be accomplished via remote presence if necessary. Under the guidance of their experienced preceptor, the surgeon seeking privileges should first participate in cases as first assistant and once proficient in that role (as judged by the preceptor) should serve as primary surgeon with the preceptor as assistant. Once deemed proficient by the preceptor and by an independent proctor, the surgeon should then be allowed to practice robotic surgery independently. There was consensus that the proctor should be a different individual from the preceptor and should not be picked by industry. Once independent practice commences, the surgeon's initial cases should be monitored through random audit of operative videos by independent experts and supplemented by chart review as needed. The panel left the decision for the frequency of such monitoring to the individual institution.

In regard to maintenance of privileges, the panel recommended a number of outcome parameters to be monitored once initial privileges have been obtained (Table 2). Importantly, the panel recommended that acceptable/expected performance criteria be developed for each of these outcomes that should trigger an audit of surgeon performance if not achieved. In addition, random performance audits via video review of operative performance at predetermined intervals were recommended.

The panel also achieved consensus on a number of other items related to credentialing in robotic surgery (Table 3). Importantly, the panel recommended that an independent national robotic outcome database be developed that should be funded both by surgeons and industry.

Table 1. Panel's recommendations for credentialing requirements (% agreement and round in which consensus was achieved). * Preceptorship can be in person in the OR or remote through telementoring.

Table 2. Proposed requirements for maintenance of privileges (% agreement and round in which consensus was achieved). These parameters should be monitored after initial credentialing and have expected/acceptable performance criteria set; if such criteria are not

met a surgeon performance audit should automatically be triggered; random audits of surgeon should also be routinely performed.

Table 3. Additional panel recommendations related to credentialing (% agreement and round in which consensus was achieved). * National specialty societies should select proctors reached 74.1% agreement.

DISCUSSION

Concerns have been raised about the technical proficiency of surgeons engaging in the use of robotic surgery technology and the resulting impact on operative safety.[6, 7] Appropriate credentialing in robotic surgery that ensures that cognitive, technical, and non-technical proficiency has been acquired by surgeons pursuing privileges in robotic surgery should alleviate such concerns and bolster patient safety. Unfortunately, evidence from a representative sample of US institutions demonstrated that existing credentialing policies are highly variable and inadequate to ensure robotic surgery proficiency.[15] It was therefore our group's intention in this project to develop robust, standardized credentialing criteria for robotic surgery rooted in the best available practices and evidence that can be uniformly applied across disciplines that use robotic devices. To accomplish this aim, we recruited a multi-disciplinary panel of expert robotic surgeons and followed a systematic approach of expert consensus building to develop credentialing criteria for robotic surgery.

These criteria are rooted in best education practices and evidence regarding skill acquisition which require that proficiency is demonstrated by surgeons seeking privileges. Specifically, the proposed criteria require that surgeons first demonstrate proficient use of robotic surgery and robotic devices outside the operating room followed by demonstration of proficiency in the OR in the assistant role and later as primary surgeon. Our panel also recommended that objective metrics be used to benchmark proficient robotic surgeon performance; this is an important requirement for the definition of proficiency. These metrics should be transparent to enable integration into hospital e-learning platforms, simulation model development, and enable sustained deliberate practice.[19] Surgical performance metrics also need to be transparent to enable comparison with developing automated performance metrics and promising evidence has emerged for the use of automated performance metrics for this purpose as also proposed by the panel.[20-22] In regard to training until proficiency has been achieved, or to correct any identified skill deficiencies, the panel recommended reliance on simulation. Indeed, numerous papers have demonstrated the value of simulation training for surgical skill acquisition and have proposed proficiency-based curricula as the optimal training paradigm.[23-26] Along those lines, our group recently proposed the Fundamentals of Robotic Surgery (FRS), a proficiency-progression based curriculum for robust acquisition of basic robotic surgery skills.[27] This curriculum includes a cognitive assessment of knowledge around robotic surgery, a simulated model for robust and objective assessment of psychomotor robotic skill, and assessments of teamwork. Further, the FRS simulated tasks have associated benchmarks of expert performance that can be used not only for training but also for assessment and credentialing decisions.[27]

The proposed criteria go beyond technical proficiency, however, requiring that cognitive knowledge and nontechnical skills relevant to robotic surgery be acquired before

commencement of individual robotic practice. Additionally, the proposed criteria go a step further by suggesting that credentialing criteria for the whole robotic surgery team be developed and required for privileging. While specific criteria for team credentialing were not proposed as the panel consisted mainly of surgeons, these could be developed by similar expert panels involving other disciplines in the future.

The proposed criteria also exemplify the importance of procedural video review for credentialing. Numerous studies support the use of video assessment for performance review.[28-30] Given that video-based assessments of surgeon skill have been shown to be associated with patient outcomes, they are uniquely suited to also be used as part of the credentialing process.[31] Indeed, SAGES has incorporated anchoring procedures for each of the performance levels of its masters program that will be assessed based on video review.[32] In the context of credentialing, video-based assessments are advantageous over direct observation as they allow for asynchronous and remote performance evaluation by an independent entity. Indeed, given the subjective nature of human assessments it is impossible to avoid multiple existing biases during such assessments that decrease their reliability when assessments are provided by surgeons who are not blinded to the performer.[33, 34] Blinded assessments thus are likely to provide a more objective assessment of surgeon performance and should be considered for credentialing purposes. However, a challenge for institutions could be the identification of independent expert raters. Nevertheless, reliable platforms exist today that enable blinded video ratings such as the C-SATS program that relies on crowd sourced assessments of surgeon performance.[35] Crowd sourced assessments have been shown to have similar reliability to that of expert raters, are easy to obtain, and are already used for credentialing and coaching purposes at some of the panelist's institutions.[36-38]

The panel further advocates that the initial experience of the surgeon with robotic surgery should be carefully monitored and include review of patient outcomes to ensure safe introduction of this new technology. Patient outcome monitoring is employed currently by a number of credentialing committees in the United States as part of Ongoing Professional Practice Evaluation (OPPE) that supports the feasibility of this recommendation.[39] Nevertheless, there is lack of standardization and suboptimal incorporation of this mechanism across institutions. Importantly the panel also recommended that a national database of robotic surgery outcomes be developed that will help better define appropriate outcomes and less frequent complications of robotic surgery that may otherwise be difficult to detect and correct; this is expected to further benefit patients. Given the comprehensive nature and robustness of the proposed criteria, we believe that were they to be implemented widely a noticeable improvement in robotic surgery outcomes would become evident.

There are several areas where our proposed criteria differ from prior relevant recommendations. The most important difference is that they emphasize the demonstration of proficient surgeon performance rather than propose a specific number of cases that should have been performed as is typical of existing recommendations and institutional policies.[10-14, 40,41] This is supported by our current knowledge that case numbers are known poor surrogates of performance.[42] Our criteria go also a step further by promoting proficiency-based progression requiring surgeons to demonstrate adequate knowledge first, proficient performance on a simulator next, followed by proficient performance as a first assistant in the operating room and finally as the primary surgeon. In each of these steps the robotic surgeon

is required to demonstrate proficient performance before progressing to the next step. Our criteria also provide specific recommendations for ongoing surgeon performance evaluation and define the outcomes that need to be monitored which have not been included in prior recommendations. Further, they better clarify the roles of the preceptor and proctor in the credentialing process, the role of industry and the hospital, and advocate for similar criteria for other members of the robotic team. Our criteria strongly support objective performance evaluation and benchmarking via operative case video review or simulator-based assessment as described above. Finally, our criteria are not specialty specific as is the case in most existing recommendations and are meant to apply to all surgical specialties that use the robot.

While the criteria presented here were derived from expert opinion and were informed by existing evidence, they are not evidence based in the strictest sense of the word. To be evidence-based these criteria should have been applied to institutional credentialing and their impact on surgeon performance and patient outcomes been assessed. Unfortunately, such direct evidence does not currently exist in the literature, but the authors of this paper argue that it should be generated through well designed, high quality research studies. In the absence of such evidence we have to rely on expert opinion that is collected in a systematic fashion similar to the method applied in this project to guide the field. Another limitation is that even though some of our expert panelists were members of their institutional credentialing committees, we did not deliberately include in our panel leaders of such committees nor C-suite hospital administrators and other regulatory bodies that could have led to different recommendations. Nevertheless, we wanted the credentialing criteria to be relevant to robotic surgeons and their patients which led us to select experts in the field. In addition, our panel did not specifically address the feasibility and cost of the proposed criteria which some may find challenging to implement. However, the majority of the proposed criteria have already been successfully implemented in various institutions where our experts practice. Further, the panel recommended that costs associated with surgeon credentialing in robotic surgery should be supported by hospitals and industry partners alike. In addition, the panel recommended that surgeons themselves, along with device manufacturers, should support the development of the suggested robotic surgery outcome database. Finally, while we could have developed credentialing criteria based on our literature review and steering group opinion and subjected them to the Delphi process with our expert panel without bringing them together, we chose to use a combination of the nominal group and Delphi techniques.[43,44] This approach allowed us to benefit from the panel's wisdom in developing the initial Delphi survey during the in-person conference and the benefits of anonymity of the Delphi process during consensus development. In our opinion, this approach strengthened the results of our study.

In conclusion, detailed credentialing criteria for robotic surgery were defined by expert robotic surgeons using a systematic approach. Implementation of these criteria uniformly across institutions may ensure proficiency of robotic surgeons and has the potential to positively impact patient outcomes

ACKNOWLEDGEMENTS

We would like to acknowledge and thank the participants of the Credentialing Consensus Conference:

Steven Knych, MD; Ajit Sachdeva, MD; Phil Shadduck, MD; Patrice Gabler Blair, MPH; Steven Schwaitzberg, MD; Michael Awad, MD; Vip Patel, MD; Farid Garagazloo, MD; Roberto Bergamaschi, MD, PhD; Mireille Truong, MD ; Ranjan Sudan, MD; Seth Rosen, MD; Mario Leitao, MD; Anthony Antonacci, MD; Jay Redan, MD; John Lenihan, MD; Jennifer Stevenson; Dorian Korz, MD; Ghulam Abbas, MD; Richard Feins, MD; Ahmed Ghazi, MD; Amanda Fader, MD; Andrew Hung, MD; Lawrence Kong, MD; Robert Poston, MD; Ketan K. Badani, MD; Andrew Yoo, MD MS; Art Sedrokian, MD, PhD; Bill Kennedy, JD; Joe Taylor; Guy Laplante; Daniel Oh, MD; Shilpa Mehendale; Sundeep Master; Cindy Domecus; Jason Shields; Chris Canter; Mark Slack, MD; Lynn Hatcher; Keith Nahigian.

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Table 1

Initial Credentialing Requirements	% Agreement	Round
Board eligibility or specialty certification	90.0%	1
Chair support letter	82.6%	2
Basic cognitive training in robotic surgery	100.0%	1
Cognitive training on specific robotic device for which requesting privileges	96.7%	1
Specialty specific cognitive training on robotic surgery	91.3%	2
Basic robotic technical skills training	100.0%	1
Robotic device specific technical training	100.0%	1
Specialty specific skills training on robotic procedures	83.3%	1
Specialty specific non-technical skills training in robotic surgery	91.3%	2
OR observation of procedure specific cases for which requesting privileges	90.0%	1
Initial cases preceptored/ proctored (both basic and advanced) *	93.3%	1
Initial cases performed with experienced co-surgeon with surgeon seeking privileges in an assistant role until proficiency demonstrated. Subsequent cases performed as primary surgeon with co-surgeon in assistant role again until proficiency demonstrated	86.7%	1
Review of first several cases performed by an independent expert	93.3%	1
Random audit of initial cases via video and chart review	80.0%	1
Objective procedure-specific performance benchmarks met/ proficiency demonstrated outside the OR	100.0%	1

Table 2

Maintenance of Privileges Requirements	% Agreement	Round
Annual robotic case volume	90.0%	1
Complication rates	96.7%	1
Estimated blood loss	92.6%	3
Operative time and total room time	83.3%	1
Return to the OR	93.3%	1
Conversion rate to open surgery	86.7%	1
Readmission rates	86.7%	1
Operative costs	85.2%	3

Table 3

Additional Recommendations	% Agreement	Round
Simulation should be used if performance concerns arise after review: both for assessment and training	90.0%	1
Separate credentialing for basic and advanced robotic procedures	91.3%	2
Proficiency should be demonstrated in basic cases first before advanced privileges approved	83.3%	1
Digital media policy should exist in all institutions to allow for video review of performance as an ongoing assessment tool	90.0%	1
A dedicated Robotic Steering/Program committee should be required at each institution; they should be responsible both for the credentialing of surgeons and the OR team	86.7%	1
Random performance audits can be done via video review of surgeon's procedures	93.3%	1
Video review should be done by independent entity	90.0%	1
Assessment of proficiency should be done by procedural video review and using objective metrics	100.0%	1
A national independent database for robotic surgery outcomes should be created	83.3%	1
Surgeons should share the cost of development and maintenance of this database	82.6%	2
Industry should share the cost of development and maintenance of this database	87.0%	2
Industry should share the cost of ensuring surgeon proficiency	82.6%	2
Hospitals should share the cost of ensuring surgeon proficiency	82.6%	2
Instrument tracking (automated performance metrics) is beneficial for assessing surgeon proficiency; eye tracking is not	95.7%	2
Objective proficiency metrics should be developed for each procedure and standardized to be applicable to all robotic platforms	93.3%	1
The OR team besides the surgeon should also participate in credentialing for participation in robotic procedures	83.3%	1
Evaluation of surgeon performance by an independent evaluator using OSATS is appropriate	80.0%	1
Preceptors should be different than proctors	92.6%	3
Preceptors/ proctors should be able to participate in procedures if needed for training and patient safety reasons	90.0%	1
Industry should not select proctors *	93.3%	1
Proctors should be specialty specific	90.0%	1
Proctors should be independent	95.7%	2
Specialty specific procedure training should not be developed by device makers	90.0%	1
Device training should be developed by device makers	86.7%	1
Device training developed by industry should be peer reviewed by specialty societies	95.7%	2
Advanced training should be developed by non-profit education organizations	80.0%	1