AHRQ TEAM TRAINING GRANT
FINAL PROGRESS REPORT

Project Title: **Evaluating the Impact of Simulated Team Training on Patient Safety**

Principal Investigator: Daniel J. Scott

Team Members:
Rajiv Gala (Co-Investigator)
John Forestner (Co-Investigator)
Ravi Bhoja (Co-Investigator)
Girish Joshi (Co-Investigator)
Nancy Gardner (Research Nurse)
Linda Hynan (Biostatician)
Abu Minhajuddin (Biostatistician)
Lisa Hollett (Skills Lab Coordinator)
Seifu Tesfay (Skills Lab Coordinator)
Deborah Hogg (Research Associate)
Christopher Olukoga (Research Fellow)
Antonio Castellvi (Research Fellow)

Organization:
The University of Texas Southwestern Medical Center at Dallas
Southwestern Center for Minimally Invasive Surgery
Departments of Surgery, Gynecology, and Anesthesiology

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Report Components (4-20 pages maximum, including a title page and all components listed below). (4 pages minimum)

1. **Structured Abstract** (max 200 words)

(Include the following 5 elements: Purpose; Scope; Methods: Results; Key Words.)

Purpose: The purpose of this study was to evaluate the role of team training using previously validated bench model simulations and real-life simulations in a virtual OR environment and to determine the effect of training on patient safety.

Scope: This study involved OR teams composed of surgeons, gynecologists, anesthesiologists, nurses, and scrub techs with performance measurement during laparoscopic cholecystectomies and tubal ligations.

Methods: Training outside of the OR involved proficiency-based curricula using bench model simulations for team members. Over a 4-week period, teams were then randomized to undergo virtual OR training focusing on patient safety, best practices, and communication skills or to a control group that did not receive team training. Both controls and trained teams were observed during designated actual operations, and performance was measured using a variety of instruments.

Results: Trainees successfully completed the bench training components, as expected. We successfully enrolled 41 teams in the real operating room assessments (pre and post tests), with 22 teams randomized to the virtual OR simulated team training exercises. Twenty-five additional individual participants underwent assessment in the virtual OR environment as part of a construct validity trial. Preliminary data are very encouraging that both the bench and the team training simulations were effective. Analyses are currently underway to examine the inter-rater reliability of various rating tools, overall patient safety and compliance with best practices data, and between-group differences.

Key Words: Team Training, Communication, Patient Safety, Simulation

2. **Purpose** (objectives of study)

The purpose of this study was to evaluate the role of team training using previously validated bench model simulations and real-life simulations in a virtual OR environment and to determine the effect of training on patient safety.

Aims:

1. Validate a multidisciplinary, proficiency-based simulation curriculum, incorporating skills training, cognitive material, and team training based on best practices guidelines and expert-derived performance standards with mandatory remediation for all members of the operative team that can be implemented prior to contact with human patients.
2. Generate benchmarks for acceptable performance in the clinical setting for all members of the operative team with regard to best practices guidelines and surgeon performance.
3. Assess patient safety outcomes in the context of clinical care with respect to individual and team performance.
4. Create a culture of safety by increasing vigilance and prevention of adverse events and outcomes through continual monitoring, identification of threats to patient safety, and systematic implementation of preventive training regarding newly identified hazards.
5. Assess the cost effectiveness of team training in the context of medical school residency and hospital staff training programs.
6. Use the ambulatory surgical setting as a model to better understand risks and injuries and to focus efforts to further reduce them, such that these lessons may subsequently be applied to the inpatient surgical setting.
7. Use individual and team training curricula for surgery, gynecology, and anesthesia residents as a model to better understand methods to assess competency that can subsequently be applied to practicing physicians in numerous specialties at both academic and community hospitals.
8. Disseminate the results of this study to organized surgical, gynecologic, anesthesia, nursing, and other healthcare organizations through publications, conferences, committees, and internet distribution.

3. **Scope** (background, context, setting, participants, incidence, prevalence)

Preventable and often life-threatening complications occur in a significant percentage of all operations performed in the U.S. each year. As reported by the Institute of Medicine in 1999, as many as 98,000 deaths per year may be attributed to medial errors, many of which are preventable.[1] Zhan and Miller (2003) reported in the Journal of the American Medical Association that postoperative complications accounted for up to 22% of preventable deaths.[2] Surgical adverse events (2% of admissions in Colorado and Utah) accounted for 2/3 of all adverse events and 1 of 8 hospital deaths in a recent retrospective study.[3] According to prospectively collected data at the University of Michigan, complications may occur in nearly 13% of cases.[4] Preventable healthcare-related injuries cost the economy from $17 to $29 billion annually, of which half are healthcare costs.[1] In a large teaching hospital, errors in healthcare have been estimated to cost more than $5 million per year.[5] Complications related to surgery triple the length of stay and increase costs by over 600%.[4] Many of these factors are system related, in that sufficient checks and balances are not in place in many healthcare environments.[6] It is clear that evidence-based practice recommendations with redundant safeguards can improve surgical care. For example, the National Surgical Quality Improvement Program (NSQIP) resulted in a 27% reduction in surgery-related mortality and a 45% reduction in morbidity within the VA system.[7-8] Systematic institutional implementation remains the key to such widespread success.[9]

Ambulatory surgery, though simple in that patients get to leave the hospital sooner, creates unique circumstances related to increasingly complex operations being performed in the outpatient setting, as driven by evolutions in minimally invasive surgical techniques, improvements in anesthesia, and changes in reimbursement. Ambulatory procedures have undergone tremendous growth that will likely continue; from 1980 to 1995, although inpatient operations remained relatively constant at about 17 million per year, outpatient surgeries increased dramatically from 3 to 27 million operations.[10] In fact, over 77% of all medical procedures are now performed in ambulatory settings.[11] Moreover, this system is relatively complex and prone to medical errors, with few mechanisms in place to ensure patient safety; these factors make ambulatory surgery a prime target for outcomes research related to workflow and safety.[12]

Medical error, a lack of adherence to best practices, poor communication, and suboptimal individual and team performance are all threats to patient safety in the operating room environment. This study was designed to address patient safety issues in the OR by enrolling teams of operating room personnel in a randomized fashion to novel simulation-based training. This study targeted 2 high-volume ambulatory surgery procedures, laparoscopic cholecystectomy and laparoscopic tubal ligation, at a large county hospital (Parkland Memorial Hospital, Dallas, Texas).

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7. Khuri SF, Daley J, Henderson W, Hur K, Demakis J, Aust JB, Chong V, Fabri PJ, Gibbs, JO, Grover F, Hammermeister K, Irvin G, McDonald G, Passaro Jr E, Phillips L, Scamman F, Spencer J, Stremple JF, and the Participants in the National VA Surgical Quality Improvement Program. The Department of Veterans Affairs' NSQIP. The first national, validated, outcome-based, risk-adjusted, and peer-controlled program for the measurement and enhancement of the quality of surgical care. Ann Surg 1998;228:491-507.

8. Khuri SF, Daley J, Henderson WG. The comparative assessment and improvement of quality of surgical care in the Department of Veterans Affairs. Arch Surgery 2002;137:20-27.

9. Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Evidence Report/Technology Assessment: Number 43. AHRQ Publication No. 01-E058, July 2001. Agency for Healthcare Research and Quality, Rockville, MD. http://www.ahrq.gov/clinic/ptsafety/

10. Kozak L, McCarthy E, Pokras R. Changing patterns of surgical care in the United States 1980-1995. Health Care Financing Review 1999;21:31-49.

11. Hall M, Lawrence L. Ambulatory surgery in the United States. Vital Health Statistics 1998;300:1-16.

12. Hammons T, Piland NF, Small SD, Hatlie MJ, Burstin, HR. Conference Synthesis: Research Agenda for Ambulatory Patient Safety. December 2001. Grant No. R13-HS10106. Agency for Healthcare Research and Quality, Rockville, MD. http://www.ahrq.gov/about/cpcr/ptsafety/

4. **Methods** (study design, data sources/collection, interventions, measures, limitations)

   This study was designed according to CRAWL/WALK/RUN designations for components of training and assessment.

   CRAWL PHASE: According to well-developed curricula at the UT Southwestern Medical Center, training outside of the OR involved proficiency-based curricula using bench model simulations for team members. Surgeons (PGY1-2) and gynecologists (PGY1-4) underwent training using validated open knot-tying and suturing models (12 tasks) followed by laparoscopic exercises (12 tasks) along with cognitive video-based training regarding operative strategies, equipment and patient troubleshooting, and patient safety issues. Performance data using validated metrics were collected. The Fundamentals of Laparoscopic Surgery (FLS) program was used, and all participants reached a sufficiently high level of performance to meet the certification criteria for this program. Anesthesiologists (CA1) underwent bench training on mannequin simulators using 9 scenarios: Elective Intubation, Rapid Sequence Intubation, Hypovolemia Induction, Coronary Artery Disease/Congestive Heart Failure Induction, Apnea During Sedation, Wall Gas Failure, Circuit Hole Failure, Pre-Oxygenation, and Esophageal Intubation. Circulating nurses and scrub techs underwent standard routine inservice training regarding laparoscopic equipment. This bench training outside of the operating room was considered the *CRAWL PHASE*.

   WALK PHASE: Over a 4-week period, teams were randomized to undergo virtual OR training focusing on patient safety, best practices, and communication skills or to a control group, which did not receive team training. Teams consisted of a surgeon or gynecologist, an anesthesiologist, a circulating nurse, and a scrub tech. A series of training exercises was developed and refined for use in the virtual OR simulation lab. This simulation experience was immersive and aimed to create a high-fidelity environment, replicating the look and feel of an actual operating room. The team members individually underwent proctored role-playing simulations immediately before and after the team exercise to vocalize appropriate patient preparation steps and to delineate adherence to best practices. The team then underwent a 20-minute exercise consisting of 3 scenarios introduced by a standardized script, conducted without interruption, allowing the team to interact and troubleshoot patient and equipment problems that developed. The simulation used a Laerdal mannequin that replicated patient physiology, a laparoscopic box trainer equipped with a porcine cadaveric cholecystectomy or tubal ligation model, and real operating room equipment. Team and individual performances were recorded using the Safety Standards Compliance Checklist (SSCC), Scenario Rating Scales (SRS), OSATS Global Rating Scale, LOSA Behavioral Markers Rating Scale, Operating Room Communication Assessment (ORCA), NASA TLX Workload Rating Scale, Team Communication Survey (TCS), and Face Validity & Educational Benefit (FVEB) survey. After completion of the exercise as well as the individual post-exercise role play, a formal debriefing was held with all team members and all proctors.

A secondary study in the virtual OR environment was undertaken to assess the validity of metrics used to assess surgeon performance in this environment. This study was aimed to determine construct validity of the rating instruments that the investigators deemed most useful, including the SRS, LOSA, ORCA, TLX, and FVEB. Expert (faculty level) and novice (PGY1-2) participants were enrolled and underwent the team training simulation, conducted with scripted confederates for the non-surgeon team members. Multiple raters completed the evaluation so that inter-rater reliability data could be analyzed.

RUN PHASE: During the same 4-week period as the WALK PHASE, both controls and trained teams were observed during designated actual operations. Efforts were made to keep the same individuals assigned to the same teams throughout the 4-week period. These procedures consisted of laparoscopic cholecystectomy or tubal ligation, depending on surgeon vs. gynecologist participation. The standard operating room activities were monitored by direct observation by the study nurse and team, and individual performances were tracked using the Safety Standards Compliance Checklist (SSCC), OSATS Global Rating Scale, Global Operative Assessment of Laparoscopic Skills (GOALS), LOSA Behavioral Markers Rating Scale, Operating Room Communication Assessment (ORCA), NASA TLX Workload Rating Scale, and Team Communication Survey (TCS). An additional observer also rated 13 selected cases to generate inter-rater reliability data.

LIMITATIONS:

CRAWL PHASE: Metrics were not applied to anesthesiologists in bench training sessions, and data collection was not feasible. Circulating nurses and scrub techs early in the study underwent additional training outside of routine inservice training, but these additional sessions had to be discontinued due to scheduling problems, given nursing personnel work obligations.

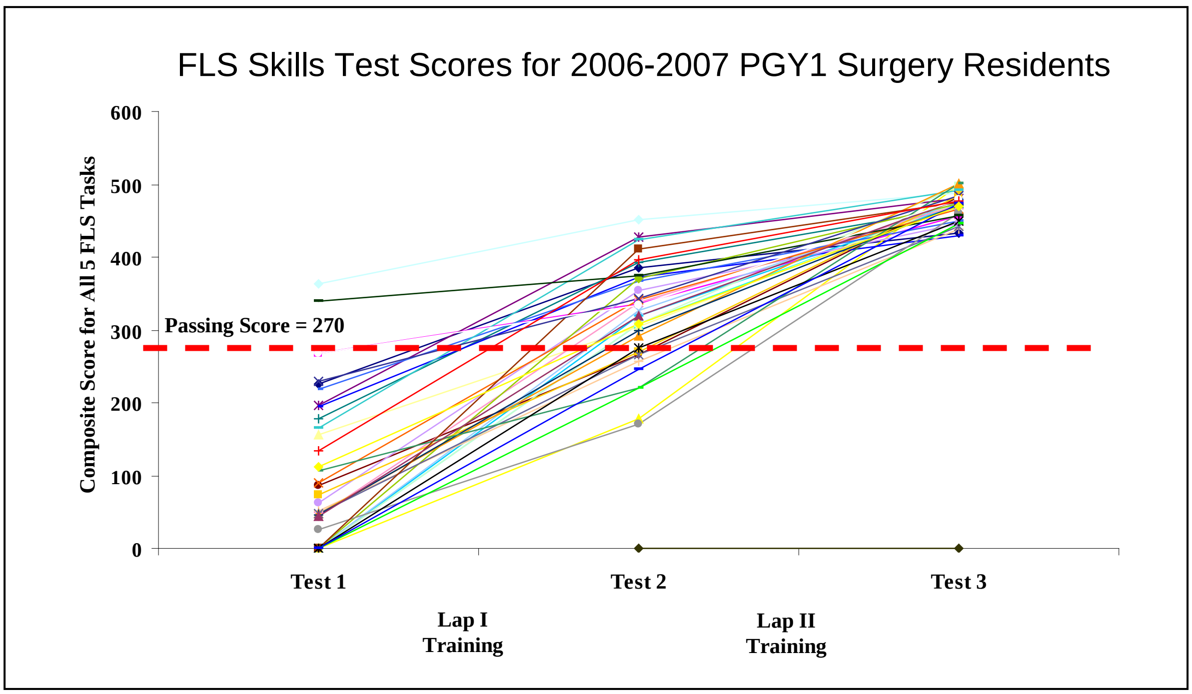
WALK PHASE: Early in the study, we conducted an interactive seminar that was attended by team members at a separate time from their virtual OR training; however, due to scheduling issues, this additional session proved unfeasible and was discontinued. We also faced numerous hurdles concerning scheduling and successfully arranging for all team members to attend the designated virtual OR training sessions.

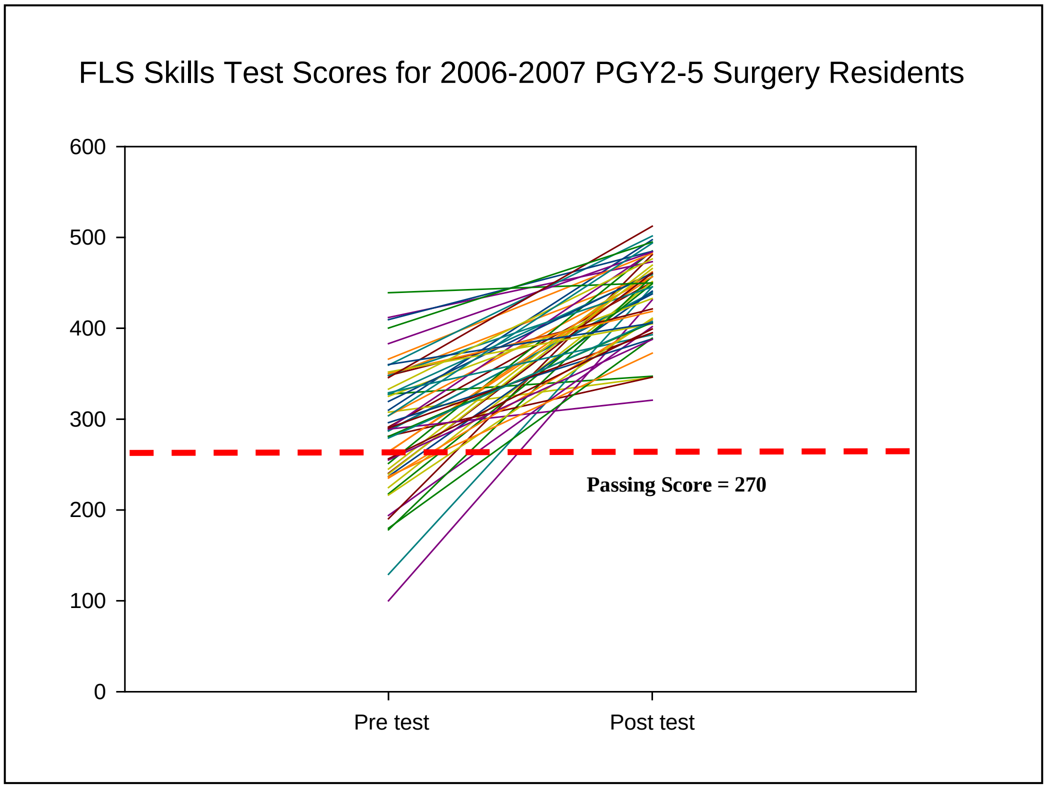
RUN PHASE: Logistics regarding scheduling issues was our biggest hurdle in this area, with difficulties encountered regarding patient cancellations and availability issues for trainees.

5. **Results** (principal findings, outcomes, discussion, conclusions, significance, implications)

CRAWL PHASE:

Over the 2-year grant period, 37 PGY1 surgery residents per year were enrolled in the following curricula: 1) open knot-tying and suturing, 2) Lap I basic skills, 3) Lap II basic skills, 4) Cognitive Lap Chole Video curriculum, and 5) FLS Cognitive curriculum. In Year 1, all but 1 trainee (excused by the program director for personal reasons) completed the curricula as planned. All trainees achieved sufficient skill levels to meet or exceed the pass rate criteria for the FLS certification examination. All trainees also met the 75% minimum passing score threshold established for the cognitive components. Data for the FLS curricular component were compared for PGY1 (n=36) vs. PGY2-5 (n=54) levels, and skill retention at 1 year was also analyzed. For 44 PGY2-5 residents available for assessment during Year 2 of this study, skill retention was 96% at the 1-year follow-up. Similar positive results were obtained for gynecology residents, and data for these subjects are under review and compilation.





WALK PHASE:

Much development and refinement work were needed, even on an ongoing basis during the first 6 months of the study. During this time period, our 3 initially developed scenarios were implemented during the team training exercises in the virtual OR. The implementation style was that of on-the-fly teaching, with stop and start of the scenarios to afford teaching opportunities consistent with a tutorial methodology. We received very good feedback according to the FVEB survey from the trainees, supporting the excellent educational benefit and high degree of realism of the simulation.

However, after discussion with other experts in the field and review of our initial experience, we opted to change the implementation methodology of the virtual OR exercise to a continuous format with no interruptions. This implementation method was designed to allow the team to fully interact in an immersive environment, rely independently on each other without input from the proctors, and allow for more robust means of assessment. Our subsequent feedback according to the FVEB survey data was also positive but slightly less supportive of the educational benefit from the trainees' viewpoints. Accordingly, we took specific steps to expand the debriefing session as an opportunity to strengthen the teaching components of this experience. These efforts were again supported with high FVEB survey ratings. Thus, this final format was the ultimate steady-state version of the team training exercise in the virtual OR environment and was used during the second year of the study.

The 3 scenarios developed were 1) Symptomatic Bradycardia – shortly after insufflation, the patient becomes bradycardic and hypotensive, and 4 mandatory treatments must be rendered by the team: desufflation, atropine, epinephrine, and IV fluids; 2) Loss of Visualization – the image on the monitor becomes quite dim, and equipment must be checked and replaced by the team; and 3) Hypercarbia – the patient becomes hypercarbic with increased peak inspiratory pressures, and 4 mandatory treatments must be rendered by the team: desufflation, checking breath sounds, increasing minute ventilation, and administering a paralytic agent. An objective scoring system was developed for each scenario (SRS), as was a maximum time allotment.

In their final format, the 3 scenarios proved robust and reproducible. After a 20-minute orientation and script reading, the exercise itself took about 20 minutes, along with 20 minutes each for the pre- and post-exercise individual role plays plus 40 minutes for the debriefing session. Thus, teams consistently completed the virtual OR training with 1 iteration within a 2-hour period. Although we had originally aimed to have 2 back-to-back sessions conducted within the 2-hour period, this proved unfeasible given the time requirements for a single iteration.

We found that the rating tools that we had researched prior to study implementation regarding communication seemed to inadequately capture the data on each team member. Thus, we developed the Operating Room Communication Assessment (ORCA) after numerous investigator meetings, pilot implementations, and iterative refinements. This rating tool was finalized and used in a steady-state format (included in Appendix A, attached as a separate file) for the final year of the study. Data regarding inter-rater reliability of this as well as the other tools used in the virtual OR environment are currently being analyzed.

Over the 2-year study period, we successfully trained 22 teams that were randomized to the Walk Phase. In our sub-study investigating construct validity, we additionally enrolled 15 residents and 10 faculty who were assessed in this environment. Using the modified surgeon-only format, we submitted this entire exercise, consisting of the 3 scenarios and the rating scales, to the American College of Surgeons (ACS)/Association of Program Directors in Surgery (APDS) for Phase III of the National Skills Curriculum. Modules of this curriculum are made available to other institutions, free of charge, though the ACS website (listed as "Laparoscopic Troubleshooting," http://www.facs.org/education/surgicalskills.html). Phase III is expected for release in spring 2009; hence, widespread distribution will be facilitated. The scenario descriptions and rating scales in the surgeon-only format are included in Appendix B, attached as a separate file.

Data from the virtual OR simulation derived from the overall study (the 22 teams in the WALK PHASE training arm) as well as the Construct Validity study (the 25 sessions including novices and faculty) are currently being analyzed and are planned for publication in 2009. From a logistical standpoint, we clearly learned that, in comparison to our bench simulations, team training simulations require a large amount of personnel resources. On average, 4-5 proctors were in attendance for each session. Additionally, gathering full teams of 4 trainees from different disciplines (i.e., surgery or gynecology, anesthesiology, nursing, and OR techs) was quite difficult and required tremendous planning and support from the various services. With full teams enrolled, at least 4 proctors were needed to facilitate individual role plays, with at least 2 proctors being available during the virtual OR scenarios. For surgeon-only sessions, successfully enrolling participants was significantly easier, because only 1 trainee was needed per time slot; however, at least 4 proctors were needed to provide scripted confederates in addition to proctors conducting the simulation.

RUN PHASE:

Our biggest hurdle concerning this phase of the study was logistics. Often, patients would cancel at the last minute, or a trainee would become unavailable on very short notice due to clinical service needs, emergencies, schedule changes, etc. Thus, our enrollment was less than expected, despite concerted efforts by our team to maximize participation. Nonetheless, we successfully enrolled 41 teams over the 2-year study period who were observed during actual cases before and after being randomized either to the virtual OR training or to the control group.

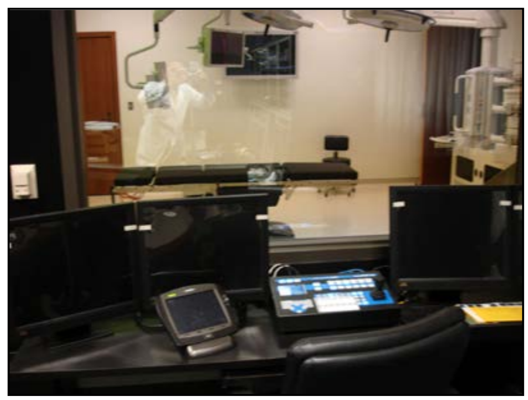
Overall, these sessions were very well accepted by the OR personnel, and we expect that there will be minimal bias skewing our observations from outcomes that would have been seen from nonobserved cases. We specifically tracked data regarding patient safety and best practices, including SCIP measures, using the Safety Standards Compliance Checklist (SSCC). Preliminary review seems relatively positive on the whole. For both trained and control groups, it is startling how little information regarding some aspects of relevant patient information is conveyed either during the time-out period or thereafter. A detailed analysis aiming to identify overall compliance with safety standards and best practices, as well as between-group differences, is currently underway. We are also in the process of analyzing data regarding surgeon performance (OSATS, GOALS), team and individual communication and leadership performance (LOSA, ORCA, TCS), and individual workload (NASA TLX). Additionally, data regarding inter-rater reliability are being analyzed from 13 sessions for which paired (study nurse and faculty-level research fellow) data are available.

CONCLUSIONS, SIGNIFICANCE, IMPLICATIONS

Over the course of this 2-year study, our team of investigators learned a great deal regarding the difficulties and the benefits of simulation-based team training. Our research team is confident that our efforts have been well spent. Given the fact that the virtual OR team training exercise that we developed is specifically geared to patient safety issues that arise everyday during actual operations, the continued use of this type of training both here at UT Southwestern Medical Center as well as at other institutions will undoubtedly have a significant postive impact. Our expectation is that our data may show some positive elements of support for this theory, which, after implementing our study, seems apparent from a gestalt viewpoint. Although our virtual OR simulation is now quite robust, we still fully expect that we may need to further refine some of our methods.

In particular, tools for assessment are still lacking, as evidenced by our team's need to create our own Operating Room Communication Assessment (ORCA) instrument. We fully expect that we will need to continue developing this and similar instruments, drawing from work others are doing in the field and maintaining a multidisciplinary approach to team training simulation activities. Until the assessment tools are validated and widely available in a mature state, proving the value of simulation in this context will remain difficult.

Even with the current limitations, our team is very excited both with the progress we have made and that significant momentum is gaining at a national level to adopt and disseminate team training activities. As mentioned above, much of the work that this grant fostered will soon be made available to other institutions free of charge through the ACS/APDS Phase III National Skills Curriculum. Moreover, through the work of other research teams, we will be able to adopt and implement team training curricula regarding other domains, such as rare event crises in the OR, trauma and ER scenarios, minimization of medical error, and the like. Our center has just completed construction of a new dedicated virtual OR, such that we can continue our efforts in this field; the figures below show this brand-new environment fully equipped with state-of-the-art operative, anesthesia, and monitoring equipment.



The implications for this work are profound. As we have proven in the past and again in this study, teaching trainees outside of the operating room using simulation is effective at providing them with skills and knowledge in a safe environment with no risk to actual patients. As we and others amass data supporting the expansion of simulation into formal structured team training exercises, routine implementation will be fostered nationally and patient safety will be enhanced.

We are grateful for the opportunities that this grant from AHRQ has afforded our team. Thank you.

6. **List of Publications and Products** (bibliography of published works and electronic resources from study---use AHRQ citation style for reference lists)

Journals

1. Scott DJ. Patient safety, competency, and the future of surgical simulation. *Simulation in Healthcare* 2006;1:164-70.
2. Scott DJ, Goova MT, Tesfay ST. A cost-effective proficiency-based knot-tying and suturing curriculum for residency programs. *J Surg Res* 2007 141:7-15.
3. Ritter EM, Scott DJ. Design of a proficiency-based skills training curriculum for the Fundamentals of Laparoscopic Surgery. *Surg Innov* 2007 14(2):107-12.
4. Scott DJ, Dunnington GL. The new ACS/APDS skills curriculum: moving the learning curve out of the operating room. *J Gastrointest Surg* 2008 12(2):213-21.
5. Goova MT, Hollett LA, Tesfay ST, Gala RB, Puzziferri N, Kehdy FJ, Scott DJ. Implementation, construct validity, and benefit of a proficiency-based knot-tying and suturing curriculum. *J Surg Educ* 2008 65(4):309-15.
6. Scott DJ, Ritter EM, Tesfay ST, Pimentel EA, Nagji A, Fried GM. 100% FLS Technical skills certification pass rate following proficiency-based training. *Surg Endosc* 2008 22(3):1887-93.
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8. Scott DJ. Proficiency-based training for surgical skills. *Sem Colon Rectal Surg* 2008 19:72-80.

Books

None

Scientific and Technical Reports

None

Grant or Contract Reports

None

Dissertations and Theses

None

Conference Proceedings

None

Electronic Resources and Nonprint Data

1. Scott DJ. Laparoscopic Troubleshooting Module. In: Dunnington G (editor). Association of Program Directors in Surgery (APDS)/American College of Surgeons

(ACS) National Surgical Skills Curriculum Phase III (in press, http://www.facs.org/education/surgicalskills.html).