Brandon Wojcik | Surgery at MGH | R PGY 3

Title: Implementation of a novel surgical service to safely enhance general surgery resident operative autonomy: An analysis of patient outcomes and satisfaction

PI Information:

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RESEARCH NARRATIVE

Description of problem to be addressed: Brief Research Summary: The Massachusetts General Hospital (MGH) general surgery residency program sought to enhance resident operative autonomy by creating a surgical service that addressed barriers to resident entrustment in the operating room. Barriers included attending surgeon supervision regulations, informed consent, case complexity, and efficiency.1,2 The novel rotation included both an inpatient service run by a chief resident that led a third-year resident through cases and a minor surgery outpatient clinic run by the third-year resident. During inpatient operations, residents began the case alone, with the attending immediately available and scrubbing for the critical portion, unless difficulty of the case prompted earlier involvement. Attending and resident involvement was explained to the patient by the attending surgeon prior to the procedure. The service was piloted for ten months and was ranked very highly by residents. Resident-provided care in the outpatient minor surgery clinic was previously analyzed by our group (unfunded research) and showed non-inferior outcomes compared to attending controls. We now seek to analyze the inpatient cohort. This study has been approved by the MGH Institutional Review Board. We hypothesize that increased resident operative autonomy does not increase perioperative complications or decrease patient satisfaction within the confines of this strategically designed service. We hope to inform other programs of this service by publishing our local results. We ultimately hope to use this data to gain additional funding to run a multi-institutional trial, the results of which may significantly impact the the structure of surgical education in the United States.

Preliminary Data: The first ten months of the outpatient procedures have been analyzed. A total of 404 procedures were performed; 110 in the resident clinic and 294 in the attending clinic. Procedures included soft tissue mass excision (n=268), abscess incision & drainage (n=66), skin lesion excision (n=34), skin tag removal (n=15), lymph node excision (n=6), and wound debridement (n=1). Patient demographics were similar between groups, but those seen in the resident clinic were more likely to have a Charlson Comorbidity Index \( \geq 3 \) (50.9% vs 38.8%; \( p = 0.028 \)). Thirty day post-operative complications measured included infection, seroma, hematoma, wound dehiscence, or wound debridement. There was no difference in the incidence of having a complication within thirty days between the resident and attending groups by univariate (3.64% vs 2.72%, \( p=0.63 \)) and multivariate analysis. This data has been accepted for oral presentation at the Association of Program Directors Surgical Education Week in April 2016.

Brief Literature Review: General surgery residency training has evolved to align with changes in work hour restrictions, supervision regulations, and reimbursement practices. These changes have culminated in graduating residents feeling inadequately prepared to operate when beginning fellowship or independent practice.1 Lack of operative autonomy, which increases resident self-confidence, is a contributing factor.2-3 This training deficit is a nationwide phenomenon and led to the American College of Surgeons creating a “Transition to Practice Program in General Surgery” with the goal of “obtaining an autonomous experience in broad-based general surgery.” There are no studies, to the best of our knowledge, that have changed the structure of a surgical services to increase resident operative autonomy or evaluate its impact on patient outcomes.
Patient outcomes when a resident is involved in the surgery has been assessed in a select number of studies in Urology, Orthopedic Surgery and Breast Surgical Oncology. These studies demonstrate that having a resident involved increased operative time, but did not change perioperative outcomes. However, these studies are very limited in that they do not measure the level of operative autonomy achieved by the resident, which is likely inferior to that obtained by the residents in our study. For example, residents in the aforementioned studies were not noted to be leading junior residents through cases and beginning without the attending surgeon. Specific aims 1 and 3 will address these knowledge gaps. In terms of patient satisfaction, a multi-center survey demonstrated that the public is more receptive to resident involvement in surgery than faculty or administrators predicted. This data may be extrapolated to support our hypothesis that patient informed consent to increased autonomous resident involvement would not impact the satisfaction of the care that they receive. This will be the focus of Specific Aim 2.


Hypothesis: We hypothesize that increased resident operative autonomy leads to increased resident confidence in performing operations, but does not increase perioperative complications or decrease patient satisfaction within the confines of this strategically designed service. We plan to achieve our study goals by focusing on three specific aims described below. Specific Aims:

1. Determine the direct effect of increased resident operative autonomy on patient outcomes compared to both institutional and national control cohorts. During its pilot period from September 2014 to June 2015, there were 133 major inpatient operations performed on the increased operative autonomy inpatient service. We will retrospectively gather data regarding these patients from the pilot year and perform a prospective observational study during the upcoming one-year trial period. Inpatient control cohorts with procedures performed by the same attending surgeons using our standard surgical services will be identified for institutional controls. National control cohorts for operations that did not have resident involvement will be extracted from the National Surgical Quality Improvement Program (NSQIP) and the Nationwide Inpatient Sample (NIS). Outpatient control cohorts will include procedures performed during the study period by a single attending surgeon with no resident involvement. Patients will be matched by demographics, co-morbidities, and procedure type. Perioperative complications, length of stay, readmission and operative time will be compared between groups. We predict that perioperative complications and length of stay will not differ between groups, but expect operative times to be longer for resident-lead operations.

2. Quantitatively assess patient satisfaction by conducting nationally validated satisfaction surveys. Patient satisfaction is increasingly emphasized in all aspects of medicine. We will utilize an established operative satisfaction tool, the Consumer Assessment of Healthcare Providers and Systems surgical care survey (S-CAHPS). The survey will be administered by mail or telephone to the pilot study patients and as part of the follow-up appointment during the prospective study period. Results will be compared to national benchmarks using the S-CAHPS database. This will provide direct evidence of how patient awareness of increased resident autonomy impacts patient satisfaction. We do not anticipate patient satisfaction to be significantly decreased compared to national data.

3. Quantitatively assess the impact of the study service on resident operative autonomy and self-confidence. Residents will be asked to take entrance and exit surveys to validate the degree of operative autonomy they receive and to assess their self-confidence in performing and leading junior residents through cases following their rotation on the study service. We anticipate results to show both increased operative autonomy during their time on the service and increased confidence in their ability to perform basic general surgery operations upon completing the service.
**Population to be studied:** We anticipate a total of 350 adult inpatients and 250 adult outpatients greater than age 18. There will be no patients selected for based on sex or ethnicity. We expect the patient’s health status to be American Society of Anesthesia Physical Classification System III or less. Patients will be admitted to the increased resident autonomy service at the discretion of the attending surgeon. The care received by the patient, type of operation, and attending surgeon present during the operation will not differ from if they were admitted to the standard surgical service. There is minimal human risk as the attending surgeon is immediately available during the case and scrubbed for the critical portion of the case. There are no changes to the usual regulations regarding resident involvement in cases, just the actual level of autonomy that is given. The degree of surgical resident autonomy per case is decided by the attending surgeon based on the patient factors and demonstrated experience level of the resident. We are performing a prospective observational study of the usual course of care and as this is not giving alternative/artificial treatment.

**Description of intervention or study design:** Increased Resident Autonomy Service: The proposed study has MGH IRB approval. The service was piloted from September 2014 to June 2015, during which time 133 major inpatient operations were performed. The same time period will be utilized each year. The service will continue to function as previously described. A fifth-year chief resident and a third year resident will rotate onto the service for a one-month period. Appropriate patients will be admitted by emergency department consultation, inpatient consultation or clinic and staffed with an attending surgeon. The chief resident will run the service, lead the junior resident through inpatient operations, and discuss patient care and decision to operate with the attending surgeon. The third-year resident will be the surgeon junior and handle inpatient care responsibilities. The third year resident will staff the resident run minor surgery clinic once weekly, at which time cases will be discussed with an attending running a simultaneous clinic, but that will not be involved with the actual procedure. Residents will begin inpatient cases alone, with the attending immediately available and scrubbing for the critical portion, unless difficulty prompts earlier involvement. The service will have its own block time, but also may book urgent cases on the waitlist. Operative times will not affect the historic time of the attending surgeon. Patients are informed of the respective roles of the surgeon and residents and consent for the procedure is obtained using standard institutional consent.

Patient Satisfaction Survey Administration: A research assistant that has not previously been involved in the care of the study patients will be trained to conduct the patient satisfaction survey. A packet will be mailed to the patient containing a letter recalling their specific surgical admission, a copy of the S-CAHPS3, and patient information sheet. They will have the option of completing the survey and returning it in a business reply envelope. If this is not received within 4 weeks, the assistant will contact the patient to answer any questions and offer a telephone-based survey. Results will be analyzed as previously published and compared to national standards. The S-CAHPS has been validated for patients completing up to one year out from their surgery, therefore a subset analysis of patient’s completing the survey over this period of time will be performed to ensure no confounding from increased duration. We do not anticipate that patient’s will have decreased satisfaction compared to national standards. Resident Quantitative Survey Analysis: We have worked with our collaborators from the Codman Center for Clinical Effectiveness in Surgery (CCCES) with expertise in survey methodology to design resident entrance and exit surveys. They will validate the degree of operative autonomy residents receive and assess confidence in performing and leading junior residents through cases. The surveys are administered electronically to residents two weeks prior to their rotation and upon completion. This was already initiated at the start of the year. We anticipate that a comparison of the entrance and exit surveys will show increased self-confidence in performing a number of specified surgical operations.

Data Extraction: Patient demographics, co-morbidities, operative details, thirty-day complications, and follow-up time will be obtained using coding software to query an institutional patient database (Research Patient Data Registry (RPDR)). Queried results will be confirmed with a manual review of the electronic medical record. This two-stage method will provide the most accurate data and was used during our outpatient analysis. Based on our preliminary outpatient data, we hypothesize that increased resident autonomy will not impact thirty-day patient outcomes.

Data Analysis: Data will be processed with the assistance of the Codman Center for Clinical Effectiveness. Univariate tests, using χ2 test, t test, and Fisher exact test, will be performed to examine differences in the complication rates, re-admission, operative times, and length of stay. Multivariate analyses will be conducted to assess these same outcomes, controlling for age, sex, race, and Charlson-Comorbidity Index. Statistical analysis will be performed using Stata statistical software (StataCorp LP), with statistical significance set at p ≤ .05.

**Description of comparison group (if relevant):** For the inpatient group, institutional controls that were admitted to the regular surgical service during the same time period will be identified and matched by demographics, co-morbidities, operation, and attending surgeon. A national control cohort will be obtained using NSQIP/NIS, removing cases that involved a resident. In terms of the
outpatient cohort, procedures performed in the attending minor surgery clinic during the study period will serve as the control cohort. The patient satisfaction survey will be compared to national data.

**Outcome variable to be used to determine efficacy of intervention (if relevant):** The primary outcome variable to determine efficacy will be 30-day post-operative complications according to NSQIP criteria (e.g. wound infection, bleeding, readmission, etc.). Secondary outcomes include patient satisfaction ratings, operative time, and six-month delayed complications for select procedures.

**Power analysis to determine feasibility (when relevant):** A power analysis was performed to show an equivalence of 2.5% for our primary outcome, perioperative complication rate. We estimated a minor perioperative complication rate of 2.5%, which we estimated to be the average rate of surgical site infection following our most common laparoscopic procedures. Using this data, our study has a power of 0.186. This is significantly underpowered when compared to the standard 0.8. However, working backward we found that we would require a sample size of over 13,000 patients to achieve a power of 0.8. Given the low complication rates in surgery and that we are attempting an EQUIVALENCE study and not a SUPERIORITY study, it is extremely difficult to achieve a sample size of this magnitude. We argue that by disclosing our power we convey the limitations of the study and mitigate the impact of Type II error. Additionally, the quantitative analysis of patient outcomes is only one aspect of this multi-faceted study. It is imperative that this study be conducted to lead to future larger-scale studies and multiple institutions in an attempt to gain increased power.

**Timeline:** This study will encompass patients from September 2014 thru February 2017. We will immediately begin coding, identifying control cohorts, and extracting patient outcomes data. The outcomes analysis and survey will be performed immediately for all patients that have reached the 30th post-operative day. Our analysis will be updated every four months. The resident survey has already been initiated and will continue during the study period. Our data completion will stop with patients operated on during Late November/Early December 2016 to provide adequate time to assess 30-day outcomes and perform satisfaction surveys in preparation for the final report to be submitted to the COE.

**HIPPA compliant/IRB status:** The protocol is HIPAA compliant. The protocol has been submitted for IRB.

**Clarification if needed:** IRB Approved 9/1/2015: 2015P001836/MGH

**Any relevant experiences and/or publications in this area:** I am a general surgery resident in two years of dedicated research time from 6/2015-6/2017. I have multiple publications in both basic science and clinical research. I served on this service and have been involved in many discussions with our program leadership regarding increasing operative autonomy. I am involved in resident education on a daily basis and also responsible for implementation of our monthly journal club. I oversaw the outpatient cohort analysis (unfunded research). This was accepted for a podium presentation at the Surgical Education Week led by the Association of Program Directors in Surgery. I plan to dedicate 25% of my protected research time to the proposed project. I will serve as project leader overseeing all aspects of its design, implementation, and analysis. I will also provide direct supervision and mentorship to the research assistant that will assist in conducting patient satisfaction surveys as they have had no direct involvement with patient care (limiting any bias).

**BUDGET**

**Budget:**

- Research Assistant Salary: $1,920 * $12/hour for 5 hours weekly for a total of 8 months A compensated undergraduate or medical student research assistant will assist with the administration, transcription and analysis of the patient satisfaction survey. It is important to have the surveys administered by a researcher that has not in any way been involved in direct patient care to help prevent administration bias. The research assistant will also assist in patient outcome data extraction and analysis. Dr. Wojcik will provide direct supervision and mentorship.

- Patient Satisfaction Survey Costs:
  - Copy Costs: $195
  - Postage: $350.00
  - Business-Reply Envelope Postage: $175 This will pay for the compilation of 350 patient satisfaction survey packets which will include a letter, the survey, and reply envelopes. Postage to send is calculated at $1.00 per packet.
  - We estimate that a maximum of 175 patients will return the survey by mail, which will cost $175. We will use business-reply envelopes to prevent wasted money on postage.
Statistician Consulting Fees: $360.00  6 hours at $60/hour during the final stages of our analysis.  Basic statistical assistant may be provided by Dr. Chang or Dr. Petrusa.

Total: $3,000

Disclosure of other funding sources: This grant would be sole source of funding.

LETTERS OF SUPPORT

Program Director: Dr. John T. Mullen
Received?: yes

Project Mentor: Dr. Roy Phitayakorn, MD, MHPE (MEd), FACS - General/Endocrine Surgery Attending; Director of Surgical Education Research; Surgical Lead, Strategic Initiatives and Operations at the Massachusetts General Hospital Learning Laboratory
Received?: yes

Why did you select this mentor? How are they going to support you in this endeavor?: Dr. Phitayakorn was an easy selection for me to serve as a faculty mentor on this project.  He is the director of the Massachusetts General Hospital Office of Surgical Education Research.  He has created and coordinated multiple surgical education projects including high-stakes simulation based operating room training.  He has mentored many of my predecessors during residency in conducting successful surgical education research.  He is involved locally and nationally with surgical education.  He was the most junior invited faculty member for the ACS Surgeons as Educators Course and serves on the Education Committee of the Association for Academic Surgery and the Association for Surgical Education.  Finally, he was a driving force of Baker 7 along with Dr. Mullen.  I cannot think of a better mentor to help see that this project is conducted successfully.

COE INFORMATION

Previous COE involvement: I have not previously been involved with the Centers of Expertise.  I have not previously applied for funding.

Previous COE funding: I have not previously applied for funding from the Centers of Expertise.