

# Patient willingness to allow hands-on training for post-graduate learning of new surgical techniques

Emily C. Rosenfeld<sup>1</sup>, Jennifer M. Wimberly<sup>1</sup>, Alana Christie<sup>1</sup>, Philippe E. Zimmern<sup>1\*</sup>

<sup>1</sup> University of Texas Southwestern Medical Center, Dallas, TX, USA

## Abstract

**Background:** This study assessed patient willingness to allow hands-on training from the surgeon of record to supplement the current ‘observership’ model when learning new techniques.

**Methods:** A survey was administered to patients in two separate outpatient settings, comprising three components: Rapid Estimate of Adult Literacy in Medicine- Short Form (REALM-SF), State Trait Anxiety Inventory form X2 (STAI-X2), and a specifically designed Observer Questionnaire (OQ) with free space for comments. The OQ included two questions of interest. Exclusion criteria were: sub-sixth grade reading level, non-English speakers, and pregnancy. Demographic data collected were: age, gender, and ethnicity.

**Results:** Ninety-nine patients (Location I) and 100 patients (Location II) met inclusion criteria with 91.9% of patients at Location I and 82% at Location II consenting to hands-on training. For current methods of training, responses were: 61% cadaver lab (A), 63% training video/reading material (B), 62% observation without direct contact (C), and 73% observation with direct trainee contact (D). Neither age ( $p=0.41$ ), ethnicity ( $p=0.95$ ), or gender ( $p=0.42$ ) significantly affected responses, nor did an occupational background in health care ( $p=0.55$ , surveyed in Location II only). REALM-SF and STAI-X2 scores did not significantly affect responses at either location. The majority of explanations cited for declining hands-on contact were unease due to history of past surgical complications.

**Conclusions:** Supplementing the current ‘observership’ model utilizing on the job training can be acceptable to the majority of patients given strict boundaries including informed patient consent, the surgeon of record remaining fully in charge, and the trainee surgeon having tested credentials.

**Citation:** Rosenfeld EC, Wimberly JM, Christie A, Zimmern PE (2016) Patient willingness to allow hands-on training for post-graduate learning of new surgical techniques. *Advances in Medical Ethics* 3:2. doi:10.12715/ame.2015.3.2

**Received:** June 18, 2015; **Accepted:** September 11, 2015; **Published:** February 26, 2016

**Copyright:** © 2015 Rosenfeld et al. This is an open access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

**Competing interests:** The authors have declared that no competing interests exist.

\* Email: philippe.zimmern@utsouthwestern.edu

## Introduction

New surgical techniques and technologies are developing at an increasingly rapid rate, especially in the field of female pelvic medicine and reconstructive surgery (FPMRS) [1]. The options for practicing surgeons to learn new techniques and technologies after completion of residency and fellowship are currently limited to instructional videos, reading material, cadaver labs, and observerships. Observership restricts the trainee surgeon to simply

watching the procedure without being able to scrub in and touch key anatomical landmarks. Though these observership restrictions may have initially been enacted to protect patients, the legal hurdles are now so difficult to overcome that they have become counterproductive. Currently, the only time surgeons from different institutions can operate together is after completing an extensive process of validation and obtaining credentials, typically one that is associated with a visiting professorship. Our inspiration to further investigate this seldom studied domain

Date: \_\_\_\_\_

stemmed from the widely publicized complications seen with vaginally placed mesh for prolapse repair, which led many to wonder if the relative lack of available hands-on training may have played a role in the process [2].

The goal of this study was to determine patient willingness to allow properly qualified surgeons to undergo hands-on learning under the supervision of the surgeon of record during his/her procedure. A secondary endpoint was to determine patient understanding of how surgeons learn new technologies and techniques after completion of their residency and/or fellowship. We hypothesized that patients would generally accept having an established surgeon, who is interested to learn from a mentor, to carry out their procedure, and that there was a poor understanding of how postgraduate surgeon training occurs. This study was not intended to explore the current proctor model, in which an expert observes a surgeon as they train in a new technology, nor was it intended to explore the simulator model used in robotics.

**Methods**

For the purpose of this study, we designed a survey with two questions (Fig. 1), which assessed patient understanding of current surgeon training (Fig. 1; Q1) and patient opinion concerning hands-on training (Fig. 1; Q2). After obtaining IRB approval at two separate institutions, the survey, written in English and using language at the sixth-grade reading level, was given to patients in two separate clinical locations over a three-month period (IRB number STU 052013-088, Pilot Study of Patient Acceptance in Allowing Surgeon Training of New Technologies ). Consent was verbal and voluntary.

Patients were all-comers, including postoperative, pre-operative, new and follow-up clinic visits. Location 1 was a county hospital that sees all general and subspecialty urology patients (Urology Clinic at Parkland Health and Hospital System), and Location 2 was a private practice clinic that sees female pelvic medicine and reconstructive surgery patients (Urology Clinic at Aston Center, University of Texas Southwestern).

**Q1. After completion of formal surgical training, also known as residency or fellowship, how do you think that surgeons learn to use new surgical techniques and technologies?**

Check all that apply.

- a) Cadaver lab (practicing on a deceased body that has been donated to science).
- b) Training video with reading material.
- c) Observation of a surgeon with NO direct contact allowed (the surgeon trainee may NOT participate in the surgery)
- d) Observation of a surgeon with direct contact allowed (the surgeon trainee MAY participate in surgery)

**Q2. If your surgeon asks permission to have another surgeon, with proper credentials, learn a new technique from him/her during your procedure by being able to not just observe but also to have gloves on to touch key anatomical landmarks, would you grant such permission as long as your surgeon remains in charge of the whole procedure?**

- a) Yes. Please list any concerns: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_
- b) No. Please briefly explain why: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

**Figure 1.** Surgical training questionnaire

Both are affiliated with the same medical school and residency program, and are based in a university setting. A third party administered the survey to consecutive patients at each location. Exclusion criteria were: non-English speakers, a reading level of lower than sixth grade, and pregnant females. Demographic data collected were: age, ethnicity and experience in the medical field (acquired for Location 2 only).

Two additional forms were administered to assess patient literacy levels and anxiety levels. Literacy was assessed utilizing the Rapid Estimate of Adult

Literacy in Medicine- Short Form (REALM-SF) [6]. This consists of seven medical terms, which the patient was asked to pronounce verbally. The maximum time taken to pronounce each word is designated at five seconds, for a total of 35 seconds for completion. If a word was mispronounced or not stated within five seconds, it was considered missed. The scores ranged from 0-7.

Anxiety was assessed utilizing the ‘Trait’ portion (Form X2) of the State Trait Anxiety Inventory (STAI-X2) [7]. This form consists of 20 questions intended to rate how anxious a patient generally feels; responses are on a scale including “almost never”, “sometimes”, “often”, and “always”. Scores ranged between 20 and 80. The total time to complete the questionnaire and additional forms averaged five minutes by design to encourage participation.

Descriptive statistics were done using means, ranges, frequencies, and percentages. Whether a value was predictive of a patient being willing to consent or not was analyzed using logistic regression, with location included as a controlling factor in the model. All statistical analyses were performed using SAS 9.3 for Windows (SAS Institute Inc., Cary, NC).

## Results

Between the months of July and September 2013, 199 patients were recruited for the study. Ninety-nine patients from Location 1 met the inclusion criteria, and 100 patients from Location 2. Patients were taken in consecutive order with no selection, and only a minority (<5%) refused to participate because of time constraints with other appointments or work-related issues. Thirteen patients from Location 1 did not answer question 1. Overall, 86.6% (161/186) of patients stated “yes” to the question of whether they would allow a surgeon to undertake hands-on training during their procedure. For the remainder of this discussion, these patients will be identified as “willing” patients. The 25 patients who responded with “no” to the question of allowing hands-on training will be identified as “non-willing”. Demographics, REALM-SF and STAI-X2 scores, and patient willingness are listed in Table 1.

**Table 1.** Patient demographics and test results

Patient characteristics	Location 1 (n=99)	Location 2 (n=100)	Total (n=199)
Mean age (range)	56.1 (27-90)	64.9 (25-93)	60.5 (25-93)
Male gender n/N (%)	77/99 (77.8)	3/100 (3.0)	80/199 (40.2)
Non-Hispanic ethnicity n/N (%)	88/98 (89.8)	93/100 (93.0)	181/198 (91.4)
REALM-SF score n/N (%)			
3	1/99 (1.0)	0/0 (0.0)	1/199 (0.5)
4	9/99 (9.1)	0/0 (0.0)	9/199 (4.5)
5	11/99 (11.1)	1/100 (1.0)	12/199 (6.0)
6	18/99 (18.2)	8/100 (8.0)	26/199 (13.1)
7	60/99 (60.6)	91/100 (91.0)	151/199 (75.9)
Mean STAI-X2 Score (range)	40.0 (20-68)	36.2 (22-58)	38.0 (20-68)
Consent to surgeon trainee n/N (%)	79/86 (91.9)	82/100 (82.0)	161/186 (86.6)

None of the demographic, REALM-SF or anxiety scores were predictive of response (Table 2). The mean age of patients who were willing and non-willing to allow hands-on training was within the same age range (60.2 versus 60.7 years). The majority of non-willing patients and willing patients were female (80% and 59.6%). In both groups, greater than 90% were of non-Hispanic ethnicity. Four percent of the non-willing patients and 8.1% of the willing patients had a REALM-SF score of 3, 4, or 5. Eight percent of the non-willing patients had a REALM-SF score of 6 compared to 13.7% of the willing patients. Eighty-eight percent of patients that were non-willing had a REALM-SF score of 7 compared to 78% of patients in the willing group. Interestingly, higher anxiety scores had slightly greater odds for being willing than lower anxiety scores (OR=1.03,  $p=0.3524$ ).

**Table 2.** Predictors of response for or against ‘hands-on’ training

Patient characteristics	Willing (N=161)	Non-willing (N=25)	Odds ratio (95% CI)	p-value
Mean Age (range)	60.7 (25–93)	60.2 (34–88)	1.01 (0.98, 1.04)	0.4079
Male gender n/N (%)	65/161 (40.4)	5/25 (20.0)	1.85 (0.41, 8.45)	0.4248
Non-Hispanic ethnicity n/N (%)	145/160 (90.6)	23/25 (92.0)	1.05 (0.22, 5.01)	0.9478
REALM-SF Score n/N (%)				
3	1/161 (0.6)	0/25 (0.0)	0.75 (0.31, 1.79)	0.5151
4	5/161 (3.1)	0/25 (0.0)		
5	7/161 (4.3)	1/25 (4.0)		
6	22/161 (13.7)	2/25 (8.0)		
7	126/161 (78.3)	22/25 (88.0)		
Mean STAI-X2 Score (range)	37.9 (20–68)	35.5 (24–57)	1.03 (0.97, 1.08)	0.3524

Regarding the question of how surgeons train before they utilize new surgical techniques, 72.7% of patients answered that they believed a surgeon could utilize observation of a surgeon with direct contact, (63.8% of patients from Location 1 and 81.9% of patients from Location 2). Answering “no” to this question was statistically significant in predicting the non-willing patient,  $p=0.0356$ . These results, as well as the results for the other questions, are displayed in Table 3.

Lastly, an occupational background in health care ( $p=0.55$ , surveyed in Location 2 only) had no impact on the response.

**Table 3.** Results of question 1 of the Observer Questionnaire, with regards to patient willingness to allow ‘hands-on’ training

Patient characteristics	Willing (N=161)	Non-Willing (N=25)	Odds ratio (95% CI)	p-value
Cadaver lab n/N (%)	98/159 (61.6)	15/25 (60.0)	1.06 (0.45, 2.54)	0.8888
Training video with written material n/N (%)	101/159 (63.5)	16/25 (64.0)	1.05 (0.43, 2.55)	0.9177
Observation of surgeon without direct contact n/N (%)	96/159 (60.4)	20/25 (80.0)	2.62 (0.93, 7.39)	0.0689
Observation of surgeon with direct contact n/N (%)	121/159 (76.1)	15/25 (60.0)	0.37 (0.15, 0.94)	0.0356

## Discussion

As suggested by the present study, most patients would agree if asked to consent to the presence of a trained surgeon who desired to learn a new procedure via hands-on training while under the responsibility of an established surgeon of record, during his/her procedure. Such a willingness to permit hands-on access was not affected by anxiety, demographic characteristics, or medical exposure, nor was it clearly associated with knowledge on how surgeons are trained for a new procedure. The majority of explanations for declining hands-on contact cited unease due to a history of past surgical complications.

An interesting feature of this study is that it goes beyond patient comfort with trainee involvement in surgical procedures. This pilot study investigates a new domain regarding the process by which an educated and practicing surgeon can train to learn a new surgical technique after completion of formal surgical training (residency and/or fellowship) and typically obtaining board certification.

This very problem of learning new surgical techniques may have played a crucial role in some of the unfortunate outcomes reported after transvaginal mesh placement, and for which two US Food and Drug Administration (FDA) notifications were issued in the recent past [3,4]. While many believe the problem may be multi-factorial, the problem of the mesh material itself, although not always tested thoroughly before its implementation in humans, cannot account for all the complications. Many experts believe the complication arose as a result of the lack of proper training, prompting specialty societies to recommend credentialing steps and FPMRS specialty certification being issued [5].

Taking all this information into account, one may therefore extrapolate that a surgeon who has completed his/her training (residency and/or specialized fellowship), has gained experience in practice, has an interest in a specialty field like FPMRS, and desires to learn a new technique from a surgeon mentor, would be well accepted by a patient [2].

A strength of this study is that the structured survey included a literacy and anxiety scale, which was administered by a third party in two clinical settings with differing socio-economic demographics; one a county hospital and the other a tertiary care center. Admittedly, our two questions were new and unvalidated since there were no instruments on which we could base our questions. However, they were tested first and were met with good patient understanding because of their simplicity and low reading age. Furthermore, because patients were de-identified, we could not review their medical records for additional information. Nevertheless, at one location we queried patients' prior exposure to the healthcare field to avoid that possible bias in their answers. The study originated from two urology practices with different patient populations, thus these findings are not necessarily applicable to other surgical sub-specialties. Clearly, a larger study can now be considered at multiple surgical centers, with a variety of patients of different ethnicities and surgical experience backgrounds to validate these early findings.

## Conclusions

This study investigated the willingness of patients to allow an already-trained surgeon to undertake hands-on training during a surgical procedure under the supervision of a surgeon mentor. The response was favorable, but an additional finding was that many patients believed hands-on training is already part of the training for learning new procedures.

## References

1. Chapple CR, Raz S, Brubaker L, Zimmern PE. Mesh sling in an era of uncertainty: lessons learned and the way forward. *Eur Urol*. 2013;64(4):525-9.
2. Zimmern PE. Re: Purely transvaginal/perineal management of complications from commercial prolapse kits using a new prostheses/grfts complication classification system: F. Firoozi, M. S. Ingber, C. K. Moore, S. P. Vasavada, R. R. Rackley and H. B. Goldman *J Urol* 2012; 187: 1674-9. *J Urol*. 2013;190(3):1141-2.
3. US Food and Drug Administration [Internet]. UPDATE on serious complications associated with transvaginal placement of surgical mesh for pelvic organ prolapse; 2011. Available from: <http://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm262435.htm>.
4. US Food and Drug Administration [Internet]. FDA public health notification: serious complications associated with transvaginal placement of surgical mesh in repair of pelvic organ prolapse and stress urinary incontinence; 2008. Available from: <http://www.fda.gov/medicaldevices/safety/alertsandnotices/publichealthnotifications/ucm061976.htm>.
5. American Urogynecologic Society's Guidelines Development Committee. Guidelines for providing privileges and credentials to physicians for transvaginal placement of surgical mesh for pelvic organ prolapse. *Female Pelvic Med Reconstr Surg*. 2012;18(4):194-7.
6. Davis, T.C. et al., Rapid estimate of adult literacy in medicine: a shortened screening instrument. *Fam Med*, 1993. 25(6): p 391-5.
7. Spielberger, C.D., R.L. Gorsuch, and R.E. Lushene, Manual for the State-Trait Anxiety Inventory. 1970, Palo Alto, CA: Consulting Psychologists Press.