

Multi-Institutional Evaluation of a Sinus Surgery Checklist

Zachary M. Soler, MD, MSc; David A. Poetker, MD, MA; Luke Rudmik, MD; Alkis J. Psaltis, MD, PhD;
John D. Clinger, MD; Jess C. Mace, MPH; Timothy L. Smith, MD, MPH

Objectives/Hypothesis: To examine the frequency of safe surgical practices specific to endoscopic sinus surgery (ESS) before and after implementation of a checklist at four institutions across North America.

Study Design: Prospective, multi-institutional, observational study.

Methods: Consecutive surgeries were observed at four institutions before ($n = 100$) and after ($n = 100$) implementation of the ESS Checklist. A passive observer documented whether 10 specific tasks were performed by the surgical team during the course of each case. The frequency with which each item was performed was tabulated, and differences across institutions were evaluated using the Pearson χ^2 test. Improvement in the frequency of each single item between pre- and postintervention time periods was assessed by the McNemar χ^2 test.

Results: Successful performance of all 10 tasks in the prechecklist period was not observed for any ESS case at any of the four study sites. As might be expected, performance of any individual task was highly variable, ranging from 14% to 95%. After implementation of the ESS Checklist, successful performance of all 10 tasks during an individual surgery increased from 0% to 87% across all institutions, a change that was highly significant ($P < .001$). Significant increases in the performance of individual tasks was observed for nine of 10 items across all institutions ($P \leq .031$ for all).

Conclusions: Significant heterogeneity exists with regard to performance of specific tasks aimed at minimizing error during ESS. Utilization of the ESS Checklist standardized practice across four institutions and significantly increased the likelihood that individual safety tasks were performed during the course of sinus surgery.

Key Words: Checklist, sinusitis, medical errors, operating rooms, safety, health care evaluation mechanisms.

Level of Evidence: 2C

Laryngoscope, 122:2132–2136, 2012

INTRODUCTION

Endoscopic sinus surgery (ESS) is one of the most common surgical procedures performed by otolaryngologists.¹ Although safely accomplished in the majority of instances, surgical errors during ESS may lead to major complications given the close proximity of the paranasal sinuses to the orbit and skull base. A recent review of a nationwide database of 62,823 patients undergoing ESS indicated a major complication rate of 1.0%, with hemor-

rhage requiring transfusion, cerebrospinal fluid leak, and orbital damage as the most frequent adverse events.² This reality is reflected in US malpractice litigation, wherein rhinology claims represent 70% of the total indemnity compensation for otolaryngology lawsuits, with sinusitis being the most common diagnosis.³

Surgical checklists represent a systems-based approach to decrease the frequency of avoidable surgical errors. A wealth of evidence documents the ability of generic checklists to enhance basic surgical practices, such as routine delivery of preoperative antibiotics.^{4,5} These checklists have also been shown to assist in the reduction of adverse outcomes, including infection rates and perioperative mortality.^{6,7} We recently developed and proposed a surgical checklist, specific to ESS, with the objective of minimizing avoidable surgical errors (Fig. 1). The ESS Checklist supplements existing generic surgical checklists with items felt critical to performing safe ESS based on published literature.⁸ The goal of the current study was to examine the frequency of ESS-specific safe surgical practices before and after implementation of the ESS Checklist at four institutions across North America.

MATERIALS AND METHODS

Consecutive endoscopic sinus surgeries ($n = 100$) were observed at four institutions across North America (Medical University of South Carolina, Medical College of Wisconsin, University of Calgary, and Oregon Health and Science

From the Division of Rhinology and Sinus Surgery, Department of Otolaryngology–Head and Neck Surgery, Medical University of South Carolina, Charleston, South Carolina, U.S.A. (Z.M.S., A.J.P.); Department of Otolaryngology and Communication Sciences, Medical College of Wisconsin, Milwaukee, Wisconsin, U.S.A. (D.A.P.); Division of Otolaryngology–Head and Neck Surgery, Department of Surgery, University of Calgary, Calgary, Alberta, Canada (L.R.); and Division of Rhinology and Sinus Surgery, Oregon Sinus Center, Department of Otolaryngology–Head and Neck Surgery, Oregon Health and Science University, Portland, Oregon, U.S.A. (J.D.C., J.C.M., T.L.S.).

Editor's Note: This Manuscript was accepted for publication April 25, 2012.

J.C.M. and T.L.S. both receive grant funding from the National Institute on Deafness and Other Communication Disorders, one of the National Institutes of Health (Bethesda, MD). T.L.S. is a consultant for IntersectENT (Palo Alto, CA), a position unassociated with any part of this investigation.

The authors have no other funding, financial relationships, or conflicts of interest to disclose.

Send correspondence to Timothy L. Smith, MD, MPH, Division of Rhinology, Oregon Sinus Center, Department of Otolaryngology–Head and Neck Surgery, Oregon Health and Science University, 3181 SW Sam Jackson Park Road, PV-01, Portland, OR 97239. E-mail: smitthim@ohsu.edu

DOI: 10.1002/lary.23437

Step 1: Preparation [Surgeon(s) Only]	Timing: Prior to Intubation
* Lead Surgeon Reviews (Assisting Surgeon(s) Confirm)	
☐ Correct CT/MRI displayed in room (patient, date, sidedness) ☐ Image guidance in room, proper scan uploaded, correct views available (if necessary for case) ☐ Important anatomic variations identified and discussed among surgical team (skull base erosion, dehiscent lamina papyracea, Onodi cell, etc)	
Step 2: Pause/Time-Out [Full Operative Team]	Timing: Prior to Instrumentation
Review/Confirm Roles Vary by Institution	
☐ Complete standardized surgical checklist - WHO-equivalent (site, procedure, antibiotics, etc) - Exact organization expected to vary by institution	
* Surgeon Reviews (Anesthesia, Nursing, and Tech Teams Confirm)	
☐ Topical epinephrine/cocaine/oxymentazoline stained and labeled appropriately ☐ Injectable anesthetic labeled and left unstained ☐ Suction cautery/bipolar immediately available in room ☐ Hemostatic materials immediately available in room ☐ Method of specimen collection (sidedness, microdebrider trap, fresh/formalin)	
Step 3: Completion [Surgeon, Nursing, Tech]	Timing: Prior to Extubation
* Surgeon Reviews (Nursing and Tech Teams Confirm)	
☐ Pledget count correct ☐ Documentation of materials left in situ (stents, spacers, packing) ☐ Specimen properly collected, labeled, and sent to pathology	

Fig. 1. The Endoscopic Sinus Surgery Checklist. ESS, endoscopic sinus surgery; CT = computed tomography; MRI = magnetic resonance imaging; WHO = World Health Organization. Image reproduced from: Soler ZM, Smith TL. Endoscopic sinus surgery checklist. *Laryngoscope* 2012;122:137–139.

University). In each case, ESS was being performed for an indication of acute or chronic rhinosinusitis. A passive observer at each tertiary care center documented whether 10 individual, specific tasks were performed by the surgical team during the course of each surgical case (Table I). These tasks were associated with potentially avoidable errors that could result in perioperative complications during ESS. The primary surgeon and perioperative team were blinded to the study occurrence and unaware that the performance of particular perioperative tasks was being evaluated and recorded.

The ESS Checklist was then formally implemented at each institution as a quality improvement measure. The specific method of implementation was allowed to vary across institutions, but included at least a formal presentation of the ESS Checklist to otolaryngology surgeons at either the divisional or departmental level. Surgeons performing sinus surgery at each institution agreed to utilize the ESS Checklist for all future cases. Because the ESS Checklist is surgeon-led and supplements rather than replaces existing generic surgical checklists, no attempt was made to formally discuss the checklist with other members of the surgical team. The ESS Checklist was not considered a standard procedure by administration at any particular hospital or operating room.

An additional 100 ESS cases were then observed across the same four institutions, and performance of the ESS-specific safe surgical practices was recorded. Once again, the primary surgeon and surgical team at each site were unaware that they were being observed and that performance of these specific tasks was being recorded. Study protocol was approved by institutional review board.

All pre- and post-ESS Checklist data was deidentified, compiled, and analyzed using commercially available statistical software (SPSS v.19.0, SPSS Inc., Chicago, IL). The frequency with which each single task was performed in the prechecklist period was tabulated using 2×4 contingency tables, and differences across institutions were evaluated using the Pearson χ^2 test. The frequency with which all 10 tasks were performed during a single surgery was dichotomized (yes/no) and compared across institutions. The same analyses were completed for the postchecklist time period. Improvement in the frequency of each single item between pre- and postintervention time periods was assessed by McNemar's χ^2 test, using exact two-tailed

binomial probabilities for correlated proportions. Additionally, improvement in the frequency with which all 10 tasks were performed during a single surgery was assessed using the same procedures. A P value $<.05$ was considered statistically significant for all tests.

RESULTS

Prechecklist Time Period

During the prechecklist time period, data were collected from 100 consecutive ESS procedures observed equally over four institutions. Successful performance of all 10 tasks was not observed for any ESS case at any of the four study sites. Thus, because completion of all 10 items was considered success, the baseline success rate was 0% at each institution (0/25) and 0% (0/100) overall.

As might be expected, performance of any individual, specific task was highly variable. Proper display of imaging was the most commonly performed task and occurred in 95 of 100 cases (range, 92%–100%), with no difference seen across institutions ($P = .510$). Proper labeling of injectable local anesthetic was also commonly performed, ranging from 84% to 100% across institutions ($P = .053$). The least commonly performed task was discussing the use of topical vasoconstrictor with the anesthesiologist. In only 14 of 100 cases did the surgeon notify the anesthesiologist prior to placing pledgets soaked in epinephrine intranasally, with most instances occurring at a single institution. The frequency with which notification occurred differed significantly between institutions (0%–44%; $P < .001$). Staining of topical, concentrated vasoconstricting agents has been advocated as a safety measure to prevent inadvertent injection, which can cause tachycardia, myocardial

TABLE I.
Safe Surgical Practices Observed During Each Endoscopic Sinus Surgery.

Individual ESS Items	Response
Q1. Was the correct CT scan (hard film, computer, or image guidance device) displayed in OR at the start of case?	Yes/no
Q2. Did surgical team verbally review among themselves important anatomic variations at start of case?	Yes/no
Q3. Was topical vasoconstrictor labeled appropriately?	Yes/no
Q4. Was topical vasoconstrictor stained/dyed?	Yes/no
Q5. Did surgeon discuss the use of topical vasoconstrictor with anesthesia team?	Yes/no
Q6. Was injectable anesthetic labeled appropriately?	Yes/no
Q7. Did surgeon discuss the use of injectable local anesthetic with anesthesia team?	Yes/no
Q8. Did surgeon state whether specimens were to be collected and the manner in which that would occur (microdebrider trap, etc.)?	Yes/no
Q9. Was suction monopolar cautery on field at the start of case?	Yes/no
Q10. Did surgeon confirm proper pledget count at end of case?	Yes/no

ESS = endoscopic sinus surgery; Q = question; CT = computed tomography; OR = operating room.

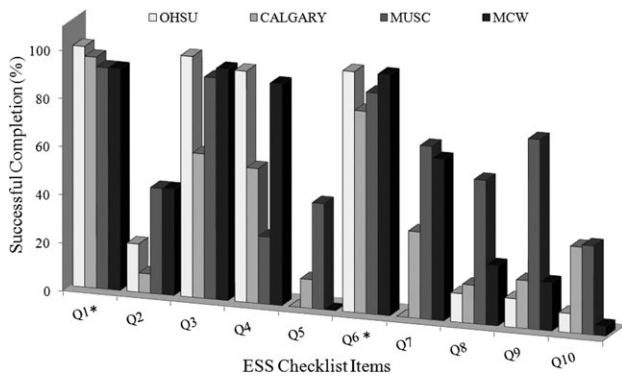


Fig. 2. Safe surgical practices across all study institutions before Endoscopic Sinus Surgery (ESS) Checklist implementation. Differences between study institutions were statistically different for all checklist items ($P < .050$) *except for item #1 ($P = .510$) and item #6 ($P = .053$). OHSU = Oregon Health and Science University; Calgary = University of Calgary; MUSC = Medical University of South Carolina; MCW = Medical College of Wisconsin; Q = question.

infarction, and stroke.⁹ The prevalence of staining vasoconstrictors varied across institutions, ranging from 28% to 96%, a statistically significant variation in practice ($P < .001$). It is commonly thought that sinonasal anatomic variations can predispose to complications during ESS if not properly identified and factored into the operative plan.¹⁰ Verbal review of anatomic variations occurred in only 29 of 100 cases, with significant variation across institutions (range, 8%–44%; $P = .008$). Similar variation was seen across institutions for the performance of the remaining specific safety items ($P < .004$) as detailed in Figure 2.

Postchecklist Time Period

Data were available from 100 consecutive ESS procedures after implementation of the ESS Checklist, equally spread across four institutions. Successful

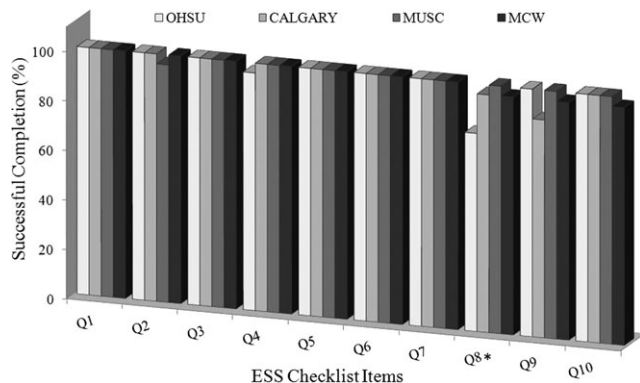


Fig. 3. Safe surgical practices across all study institutions after Endoscopic Sinus Surgery (ESS) Checklist implementation. Differences between study institutions were statistically similar for all checklist items ($P > .050$) *except for item #8 ($P = .032$). OHSU = Oregon Health and Science University; Calgary = University of Calgary; MUSC = Medical University of South Carolina; MCW = Medical College of Wisconsin; Q = question.

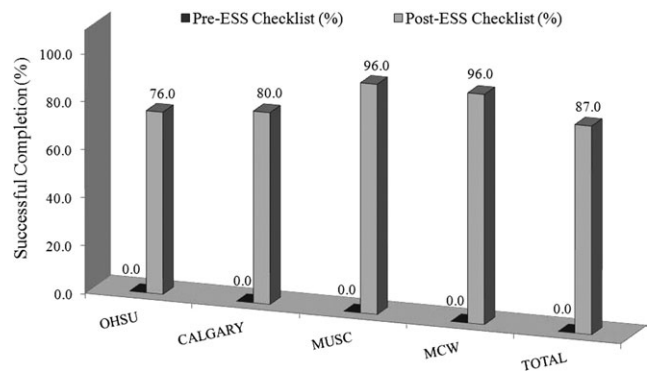


Fig. 4. Percentage of successful completion of all Endoscopic Sinus Surgery (ESS) Checklist-related safety tasks during sinus surgery for all four study institutions. Differences between pre- and postchecklist implementation are statistically significant for all sites ($P < .001$). OHSU = Oregon Health and Science University; Calgary = University of Calgary; MUSC = Medical University of South Carolina; MCW = Medical College of Wisconsin.

completion of all 10 safe surgical tasks improved to 87% of 100 procedures. At individual institutions, comprehensive performance of all tasks ranged from 76% to 96%, and this variation was of borderline statistical significance ($P = .062$).

The frequency with which individual tasks were performed was much less variable in the postchecklist time period (Fig. 3). A number of tasks were performed 100% of the time across all institutions, including proper display of imaging, labeling of topical vasoconstrictor, labeling of injectable local anesthetic, and notification of the anesthesiologist prior to applying topical vasoconstrictor or injecting local anesthetic. Important items such as staining of topical vasoconstrictor, verbal review of anatomic variations, and confirmation of proper pledget count occurred in 99 of 100 cases. A discussion regarding whether specimens were to be collected was the task least likely to be performed (91%), and this varied significantly across institutions (range, 80%–100%; $P = .032$).

Pre- Versus Postchecklist Comparison

After implementation of the ESS Checklist, successful performance of all 10 tasks during an individual surgery increased from 0% to 87% across all institutions, a change that was highly significant ($P < .001$). Each individual institution observed similar improvements after implementation of the checklist (Fig. 4; $P < .001$ for all).

Differences between the pre- and postchecklist time periods for all study sites are shown in Figure 5 and Table II. Significant increases in the performance of individual tasks was observed for nine of 10 items across all institutions ($P \leq .031$ for all). This includes highly significant increases in the frequency with which topical vasoconstrictors were stained, labeled, and discussed with the anesthesiologist. The verbal review of important anatomic variations also increased across all studies from 29% to 99% ($P < .001$). The increase in verbal review of anatomic variations was observed at all

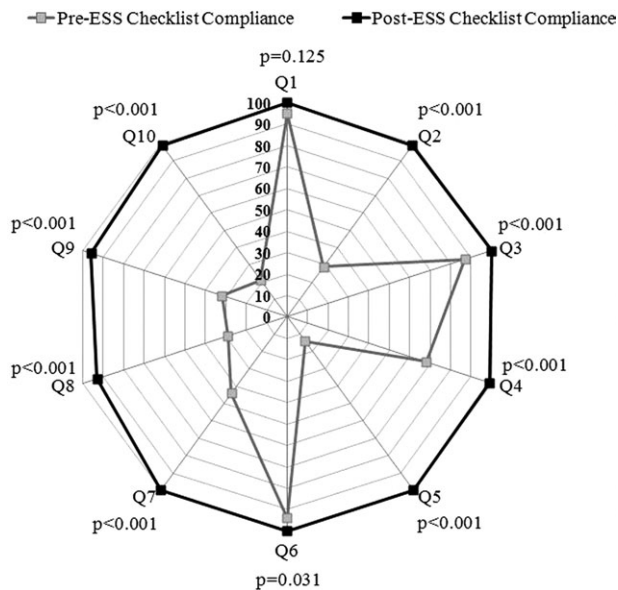


Fig. 5. Comparison of the frequency (%) of successful compliance with 10 endoscopic sinus surgery (ESS)-specific checklist items, across all study institutions, before and after the introduction of the ESS Checklist described in Table I. Significance levels are reported for each pre- and postintervention comparison. Q= question.

four individual study institutions ($P < .001$ for all). Although the display of imaging prior to the start of surgery increased from 95% to 100%, this difference was not significant ($P = .125$).

DISCUSSION

A number of specific practices have been advocated to help minimize errors that might occur during ESS, including correct display of radiographic imaging, identification of anatomic abnormalities, and proper labeling and staining of topical vasoconstrictors. These specific surgical practices are typically adopted by surgeons as means of minimizing error based on their prior training and personal experience. This study demonstrates that significant differences exist across institutions in North

America with respect to these practices and that tasks are rarely universally performed. The adoption and use of the ESS Checklist served to standardize practice across institutions and led to significant increases in the performance of nearly every task.

The finding that specific practices varied across institutions is not unexpected. Surgical teams at these four institutions are diverse with respect to educational background and experience. Some practices were likely already part of particular institutions' operative routines prior to the ESS Checklist, whereas others were not. Surprisingly, lapses in performance occurred even if a particular practice was already an accepted standard at an institution. The staining of topical vasoconstrictors is a noteworthy example. At two institutions, this technique was already considered an essential part of the surgical routine, and the expectation was that it would be performed for every case. However, in three of 50 cases the epinephrine was never stained. A root cause analysis revealed that in most instances the procedure occurred after hours. It should not be surprising that standardized routines can be disrupted during unusual situations, such as operating at night, in an unusual room, or with operative assistants unfamiliar with the particular surgeon's customs or ESS in general. This suggests that the ESS Checklist may have particular value when ESS is being performed in emergency situations or in less familiar environments.

Checklists are powerful tools because they standardize important practices across institutions and increase the likelihood that these practices occur during any particular case. Even the simplest surgical procedure requires an inordinate amount of planning, decision making, and coordination among team members. The surgeon, in particular, must perform a myriad of specific tasks during ESS, and it should not be surprising that oversights may occur. In this study, adoption of the ESS Checklist standardized safe surgical practices across four institutions and dramatically increased the frequency with which nearly all individual safety tasks were performed. Despite considerable increases across all items, the checklist did not result in 100% compliance at any institution. The inability to

TABLE II.
Successful Completion of All Endoscopic Sinus Surgery Items Across All Study Institutions.

Item	Prechecklist	Postchecklist	P
Q1. Proper imaging display	95%	100%	.125
Q2. Discuss anatomic variation	29%	99%	<.001
Q3. Labeled topical vasoconstrictor	87%	100%	<.001
Q4. Stained/dyed topical vasoconstrictor	68%	99%	<.001
Q5. Discuss topical vasoconstrictor with anesthesia	14%	100%	<.001
Q6. Labeled injectable anesthetic	94%	100%	.031
Q7. Discuss use of injectable local anesthesia	44%	100%	<.001
Q8. Statement of specimen collection	29%	93%	<.001
Q9. Suction monopolar cautery	32%	96%	<.001
Q10. Confirmation of pledget count	21%	99%	<.001

Q = question.

achieve 100% compliance underscores the complex demands of the operating room and imperfection of human pursuits, including use of tools such as the ESS Checklist.

The overall goal of the ESS Checklist is to reduce errors and minimize avoidable complications related to ESS. Although the checklist increased performance of tasks that may avoid errors, this study provides no direct evidence that the checklist actually reduces complications. We purposefully did not examine complications as an outcome of this study given the unrealistic demands of sample size. Assuming that the major complication rate for ESS is 1.0% and that adoption of the ESS Checklist can reduce this rate to 0.5% (a 50% reduction), a total of 9,300 operative cases would be necessary to demonstrate a statistically significant difference at $\alpha = .05$ and $\beta = .8$, a study size that is likely not feasible to enroll prospectively. Despite the lack of direct evidence, there is sufficient reason to believe that utilization of the ESS Checklist might reduce complications. Other studies examining generic checklists have demonstrated an improvement in actual end-outcomes, such as infection rates and perioperative mortality.⁵⁻⁷ Although none of the tasks covered in the ESS Checklist is proven to reduce complications, each item addresses ESS-specific errors highlighted in the literature, based on either previous study or expert opinion.⁹⁻¹² Individual practitioners are also encouraged to modify the checklist, incorporating unique steps (such as specialized equipment or medications) that they feel are critical aspects of their surgical approach and could predispose to error. For example, surgeons operating alone would probably elect to review anatomic abnormalities in a nonverbal fashion. The more relevant the checklist is to a specific surgeon, the greater the buy-in, and ultimately the greater the overall efficacy.¹³

This study has several important strengths and limitations. The inclusion of four institutions across North America adds robustness to the findings, given the diversity of surgeons, operating room staff, and existing medical center policies. The fact that the surgical teams were unaware they were under observation minimizes the Hawthorne effect, whereby participants in a study often improve or modify their behavior because they know they are being studied.¹⁴ Although multiple statistical tests were performed as part of the analysis of these data, most outcomes were highly significant and easily survive multiple comparisons testing, minimizing the likelihood that our findings represent false positives. However, each institution observed in this study is an academic tertiary medical center, and it remains unclear whether findings can be extrapolated to the community setting, where less day-to-day variation in experience

and operating staff may exist. Although dramatic improvements were seen after implementing the ESS Checklist, these outcomes should be considered relatively short-term findings, as only 25 cases were observed at each institution in the postchecklist period. It remains possible that utilization of the checklist could diminish over time if enthusiasm wanes, resulting in decreased performance of individual tasks. We certainly acknowledge that this possibility is real and future actions may be required to ensure that checklist utilization remains strong.

CONCLUSION

Significant heterogeneity exists with regard to performance of specific tasks aimed at minimizing error during ESS. Utilization of the ESS Checklist standardized practice across four institutions and significantly increased the likelihood that individual safety tasks were performed during the course of sinus surgery. The adoption of an ESS-specific checklist may be able to reduce complications related to sinus surgery, but causation will be difficult to prove given the large sample size necessary.

BIBLIOGRAPHY

1. Bhattacharyya N. Ambulatory sinus and nasal surgery in the United States: demographics and perioperative outcomes. *Laryngoscope* 2010; 120:635-638.
2. Ramakrishnam VR, Kingdom TT, Nayak JV, Hwang PH, Orlandi RR. Nationwide incidence of major complications in endoscopic sinus surgery. *Int Forum Allergy Rhinol* 2012;2:34-39.
3. Dawson DE, Kraus EM. Medical malpractice and rhinology. *Am J Rhinol* 2007;21:584-590.
4. Helmio P, Blomgren K, Takala A, Pauniah SL, Takala RS, Ikonen TS. Towards better patient safety: WHO Surgical Safety Checklist in otorhinolaryngology. *Clin Otolaryngol* 2011;36:242-247.
5. Weiser TG, Haynes AB, Dziekan G, et al. Effect of a 19-item surgical safety checklist during urgent operations in a global patient population. *Ann Surg* 2010;251:976-980.
6. Haynes AB, Weiser TG, Berry WR, et al. A surgical safety checklist to reduce morbidity and mortality in a global population. *N Engl J Med* 2009;360:491-499.
7. Van Klei WA, Hoff RG, van Aarnhem EE, et al. Effects of the introduction of the WHO "surgical safety checklist" on in-hospital mortality: a cohort study. *Ann Surg* 2012;255:44-49.
8. Soler ZM, Smith TL. Endoscopic sinus surgery checklist. *Laryngoscope* 2012;122:137-139.
9. Shah RK, Hoy E, Roberson DW, et al. Errors with concentrated epinephrine in otolaryngology. *Laryngoscope* 2008;118:1928-1930.
10. Nouraei SA, Elisay AR, Dimarco A, et al. Variations in paranasal sinus anatomy: implications for the pathophysiology of chronic rhinosinusitis and safety of endoscopic sinus surgery. *J Otolaryngol Head Neck Surg* 2009;38:32-37.
11. Shah RK, Nussenbaum B, Kienstra et al. Wrong-site sinus surgery in otolaryngology. *Otolaryngol Head Neck Surg* 2010;143:37-41.
12. Shah RK, Kentala E, Healy GB, Roberson DW. Classification and consequences of errors in otolaryngology. *Laryngoscope* 2004;114:1322-1335.
13. Weiser TG, Haynes AB, Lashoher A, et al. Perspectives in quality: designing the WHO Surgical Safety Checklist. *Int J Qual Health Care* 2010; 22:365-370.
14. Kennedy MT, Ong JC, Mitra A, Harty JA, Reidy D, Dolan M. The use of weekly departmental review of all orthopaedic intra-operative radiographs in order to improve quality, due to standardized peer expectations and the "Hawthorne effect." *Surgeon* In press.