

## Patterns in neurosurgical adverse events and proposed strategies for reduction

JUDITH M. WONG, M.D., M.P.H.,<sup>1-3</sup> ANGELA M. BADER, M.D., M.P.H.,<sup>1,2,4</sup>  
EDWARD R. LAWS, M.D.,<sup>3</sup> A. JOHN POPP, M.D.,<sup>3</sup> AND ATUL A. GAWANDE, M.D., M.P.H.<sup>1,2,5</sup>

<sup>1</sup>Department of Health Policy and Management, Harvard School of Public Health; <sup>2</sup>Center for Surgery and Public Health and Departments of <sup>3</sup>Neurosurgery, <sup>4</sup>Anesthesiology, Perioperative and Pain Medicine, and <sup>5</sup>Surgery, Brigham and Women's Hospital, Boston, Massachusetts

Neurosurgery is a high-risk specialty currently undertaking the pursuit of systematic approaches to reducing risk and to measuring and improving outcomes. The authors performed a review of patterns and frequencies of adverse events in neurosurgery as background for future efforts directed at the improvement of quality and safety in neurosurgery.

They found 6 categories of contributory factors in neurosurgical adverse events, categorizing the events as influenced by issues in surgical technique, perioperative medical management, use of and adherence to protocols, preoperative optimization, technology, and communication. There was a wide distribution of reported occurrence rates for many of the adverse events, in part due to the absence of definitive literature in this area and to the lack of standardized reporting systems.

On the basis of their analysis, the authors identified 5 priority recommendations for improving outcomes for neurosurgical patients at a population level: 1) development and implementation of a national registry for outcome data and monitoring; 2) full integration of the WHO Surgical Safety Checklist into the operating room workflow, which improves fundamental aspects of surgical care such as adherence to antibiotic protocols and communication within surgical teams; and 3–5) activity by neurosurgical societies to drive increased standardization for the safety of specialized equipment used by neurosurgeons (3), more widespread regionalization and/or subspecialization (4), and establishment of data-driven guidelines and protocols (5). The fraction of adverse events that might be avoided if proposed strategies to improve practice and decrease variability are fully adopted remains to be determined. The authors hope that this consolidation of what is currently known and practiced in neurosurgery, the application of relevant advances in other fields, and attention to proposed strategies will serve as a basis for informed and concerted efforts to improve outcomes and patient safety in neurosurgery.

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**KEY WORDS** • surgical safety • adverse events • perioperative care

NEUROSURGERY is a high-risk surgical specialty and has begun to pursue systematic approaches to measuring and improving outcomes for the national neurosurgical population. In the other 4 papers in this series,<sup>63–66</sup> we review the current evidence in 4 distinct areas of neurosurgery concerning the frequency of adverse events in practice and the state of knowledge about how to improve them. Here we describe the patterns revealed

from analysis of these data, describe current safety practices in other medical fields, including other surgical specialties, and propose strategies for similar advances in improving safety for neurosurgery. These strategies include process and outcomes monitoring, regionalization and subspecialization, development and dissemination of evidence-based guidelines and protocols, and equipment standardization. We also advocate universal adoption of the WHO Surgical Safety Checklist. Strategic design and development must be followed by a robust systems evaluation and implementation process. We hope this consolidation of what is currently known and practiced in neurosurgery, combined with advances in other fields, will serve as a basis for informed and concerted efforts to improve outcomes and patient safety in neurosurgery.

*Abbreviations used in this paper:* CMS = Centers for Medicare & Medicaid Services; N<sup>2</sup>QOD = National Neurosurgery Quality and Outcomes Database; NSQIP = National Surgical Quality Improvement Program; SAGES = Society of American Gastrointestinal and Endoscopic Surgeons; STS = Society of Thoracic Surgeons; WHO = World Health Organization.

### Patterns of Neurosurgical Adverse Events

We identified the most common neurosurgical adverse events from existing studies.<sup>63–66</sup> Spine surgery deserves special attention given its breadth; elements of our review are included here, but a separate focused review is needed to address all important issues for the field. Many of the events uncovered by our review are multifactorial; for example, cerebral infarct often complicates cerebrovascular care and can be attributed to the severity of the underlying disease and its sequelae, the quality of critical care management, and the quality of surgical technique. The goal of our review, however, is to provide a broad analysis to guide design of quality and safety initiatives along the entire chain of care, to improve outcomes for neurosurgical patients in advanced health systems.

Table 1 categorizes the adverse events by likely contributing factors, aside from patient condition. We hypothesize that this analysis of contributing factors will aid in the identification of interventions designed to reduce adverse event occurrence. Patterns of occurrence and prevention vary from discipline to discipline. Nonetheless, some common patterns of opportunity for strategic intervention emerged.

### Strategy 1: Process and Outcomes Monitoring

Until recently, there has been a universal absence of outcomes monitoring and accessible databases in neurosurgery—tools that have been essential to quality improvement in other fields. The American College of Surgeons oversees the National Surgical Quality Improvement Program (NSQIP), which began as the National Veterans Administration Surgical Risk Study in 1991 and evolved into NSQIP in 1994 to collect outcomes data from general and vascular surgery (<http://site.acsnsqip.org>). Many studies have analyzed information from this database,<sup>33</sup> and it is also used to benchmark quality improvement. Figure 1 shows an example of how these data may be used for such a purpose. Since its establishment in 1989, the Society of Thoracic Surgeons (STS) National Database has been a major source of outcomes data for adult cardiac, general thoracic, and congenital cardiac surgery. Not only is it useful for clinical research, but it also serves as a source of professional information for improving outcomes.<sup>19</sup> Similarly, the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) collects outcome data for gastrointestinal and endoscopic surgery (<http://www.sages.org>). Their database has also been the basis for several studies and collaborative programs.<sup>32</sup> Outside the US, Swedish national registries, such as the National Inpatient Register<sup>29,30</sup> and Epilepsy Surgery Register,<sup>41,48</sup> have provided data for many national outcome studies.

The American Association of Neurological Surgeons has recently announced the formation of the NeuroPoint Alliance. Included in this initiative is the launch of the National Neurosurgery Quality and Outcomes Database (N<sup>2</sup>QOD), a national data registry with an infrastructure and reporting system similar to that of the STS National Database; it also includes such details as patient satisfac-

tion scores and disability scores (<http://www.neuropoint.org>). If the project fulfills its goals, it will have similar capabilities to those of NSQIP, the STS National Database, and the SAGES database in the coming years. It has the potential to supply consistent, detailed, prospectively collected national neurosurgical data for future study, with an advantage over the aforementioned national databases in that the data will be specific to neurosurgical practice and its inherent risks and complications, allowing also for neurosurgery-specific risk stratification. Currently, N<sup>2</sup>QOD is focusing primarily on the lumbar spine with data collected from a small number of participating sites. As it expands, it will need to encompass more hospitals under a more formalized structure, including data managers at each institution, biannual risk-stratified reporting back to participating institutions, and consistent quality assurance. The NeuroPoint Alliance will also financially support more clinical trials to further enhance the benefits of national data reporting.

### Strategy 2: Regionalization and Subspecialization

In our review, the quality of surgical technique appeared to be the most common contributing factor (Table 1). We found 2 to 4 events for each discipline reflecting unique technical nuances. Some of these events are avoidable, while others are not. Strategies to minimize adverse events resulting from variations in surgical technique include regionalization and subspecialization, as well as volume thresholds and/or Centers of Excellence. There has already been substantial progress in subspecialization and informal development of Centers of Excellence in neurosurgery.

Data from cardiothoracic<sup>27,67</sup> and general surgery<sup>24</sup> suggest a significant difference in surgical outcome related to the surgeon's or hospital's volume. There also is observational data from a national database suggesting the same influence of volume on outcome for craniotomy for tumor resection,<sup>14,16</sup> as well as a beneficial effect of subspecialization and higher surgeon and hospital volumes in carotid endarterectomies.<sup>25,26</sup> The LeapFrog Universal Adoption initiative<sup>31,35</sup> encourages evidence-based hospital referral using the advantages of a wider patient referral base, public recognition when certain standards are met, and financial incentives through large-corporation insurance buyers.<sup>37</sup> Observational studies in certain high-risk procedures show that hospitals that are LeapFrog compliant with regard to hospital volume have significantly lower mortality rates.<sup>7,58</sup> Similarly, programs to formally certify centers of excellence and/or set surgeon- or hospital-level volume standards should be considered in neurosurgical practice. There is already substantial movement toward appropriate referral and regionalization, particularly for the highly technical disciplines of open cerebrovascular, endovascular, and skull-base neurosurgery.

In other surgical specialties, much of the centralization process has occurred through shifts in reimbursement. For example, CMS is using performance measures to help determine reimbursement.<sup>8</sup> This paradigm will only work, however, if the quality indicators are tightly linked to clinical outcomes.<sup>61</sup> The specialty of bariatric

TABLE 1: Adverse events categorized by likely contributing factors\*

Factor Category	Type of Surgery				
	Endovascular	Open Cerebrovascular	Shunt	Spine	Tumor
AEs related in part to surgical technique	thromboembolic events, access-related complications, intraprocedural rupture, failure to treat lesion	intraop rupture, incomplete obliteration, major vessel occlusion	intraabdominal complications, ICH	hardware-related complications, new deficit, hematoma, unintended durotomy	benign tumor recurrence, new/worsened deficit, CSF leak, postop hematoma
AEs related to periop medical management	thromboembolic events, groin-site hematoma, CIN	hemorrhage-related hyperglycemia, salt-wasting syndromes, new infarct, periop Sz	periop Sz	respiratory events, hardware-related complications, cardiac complications	postop peritumoral edema, postop Sz
AEs related to nonadherence to protocol	thromboembolic events, groin-site hematoma, CIN, radiation-induced effects	none known	infection	venous thromboembolism, wound infection, wrong-level surgery	venous thromboembolism, wound infection
AEs affected by preop optimization	thromboembolic events, groin-site hematoma, CIN	none known	none known	respiratory events, cardiac events	medical complications
AEs related to technology	radiation-induced effects	incomplete obliteration of target lesion, major vessel occlusion	valvular/mechanical dysfunction	hardware-related complications	WSS
AEs related to communication	none known	WSS	none known	none known	WSS

\* Likely contributing factors other than patient condition. Abbreviations: AE = adverse event; CIN = contrast-induced nephropathy; ICH = intracerebral hemorrhage; Sz = seizure; WSS = wrong-site surgery.

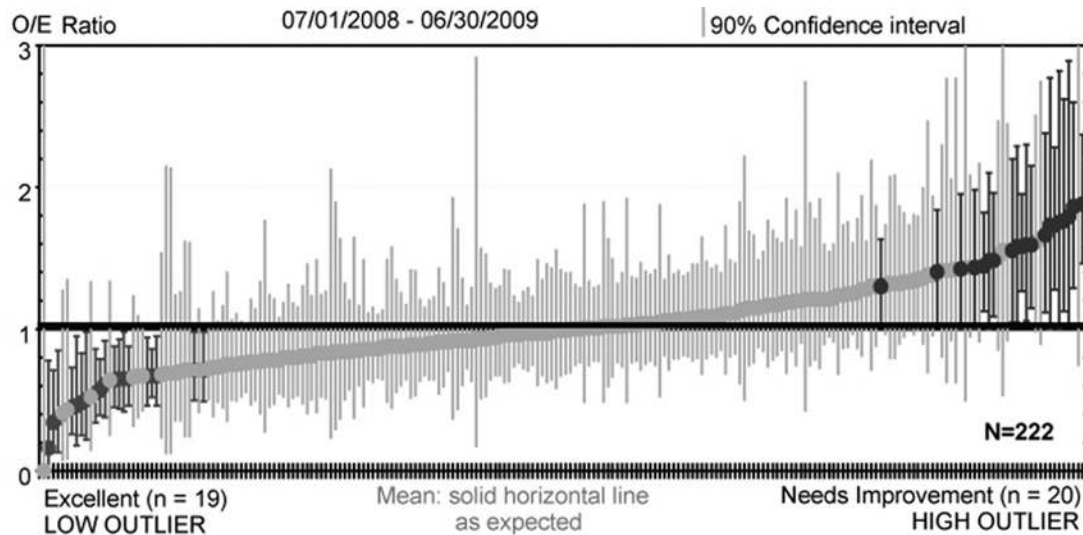


Fig. 1. Overall nonmultispecialty 30-day mortality of observed vs expected ratios for participating NSQIP hospitals. Each vertical line represents the confidence interval (CI) of one hospital. The CI lines of hospitals with significantly better outcomes are entirely below the mean (solid horizontal line); the CI lines of hospitals with significantly worse outcomes are entirely above the mean. Confidence interval = 90%, NSQIP = National Surgical Quality Improvement Program; O/E = observed vs expected. Reprinted from *The Permanente Journal* 16(1), Fuchshuber et al., The power of the National Surgical Quality Improvement Program—achieving a zero pneumonia rate in general surgery patients, 39–45, copyright 2012, with permission from The Permanente Press ([www.thepermanentejournal.org](http://www.thepermanentejournal.org)).

surgery uses not only surgeon volume thresholds but also structural measures including credentialing, consultant availability, and availability of bariatric equipment; these measures are used by the American Society for Metabolic and Bariatric Surgery and the American College of Surgeons to designate a Center of Excellence, a designation that is now required by CMS.<sup>24</sup> At times, centralization is technology-driven, as demonstrated by the rapid shift in robot-assisted laparoscopic prostatectomy to high-volume centers over just a few years.<sup>52</sup>

One of the main disadvantages is an increase in patient travel burden.<sup>24,52,61</sup> For this reason, many (including LeapFrog affiliates) advocate exemption of hospitals in rural areas. Additionally, there is concern that increased referral may lead to busier or overburdened tertiary care centers, leading to worse outcomes that may counteract the benefits of high volume.<sup>39,61</sup>

In other specialties, there are other techniques in development, including simulation<sup>15,34,51,68</sup> and supervised technical practice,<sup>6,20</sup> even for more senior surgeons. Although these appear promising in preliminary experience, the long-term clinical benefits have yet to be determined. Neurosurgery is beginning to embrace these ideas with the Society for Neurological Surgeons Boot Camp designed for upcoming interns (<http://www.societyns.org/BootCamp/BootCampCourses.asp>).

### Strategy 3: Guidelines and Protocols

Decreasing clinical and technical variability reduces the potential for error, but there remains tension between standardization of practice and allowance for personal practice variation. Nonetheless, adherence to well-designed guidelines and protocols has been a highly effective strategy in numerous other fields.<sup>1,53,55,57</sup> Further-

more, a significant range of neurosurgical adverse events involve complications that can likely be reduced with better adherence to established standards of perioperative medical management and/or evidence-based protocols (Table 1). Postoperatively, for example, a significant portion of cerebrovascular adverse events might be reducible with adherence to intensive care unit guidelines for subarachnoid hemorrhage, including insulin therapy,<sup>57</sup> and management of vasospasm<sup>5</sup> and salt-wasting syndromes.<sup>38,50</sup> Occurrence of spine-related adverse events may be reduced with consistent early postoperative mobilization when possible,<sup>36</sup> careful delineation of postoperative activity restrictions and bracing, and diligent pulmonary care.<sup>43</sup> The medical and cardiac literature has already demonstrated significant benefit from periprocedural guidelines designed to minimize the risk of contrast-induced nephropathy<sup>44</sup> in endovascular procedures.

Similarly, protocols targeting adequate preoperative optimization should be of benefit.<sup>22</sup> A fraction of the adverse events shown in Table 1 can likely be eliminated with appropriate preoperative optimization, although it remains unknown exactly what proportion of patients undergoing elective or emergent neurosurgical procedures have not undergone appropriate medical clearance. The Joint Commission mandates an appropriate preoperative assessment, including surgical history and physical examination completed within 30 days prior to the procedure, anesthesia assessment, nursing assessment, signed anesthesia and surgical consent, and appropriate preoperative testing.

We noticed that in the intraoperative setting there are many opportunities to further develop specific checklists or protocols for other neurosurgery procedures. In shunt placement procedures, substantial reductions in postoperative infection have been attained by the use of strict pro-

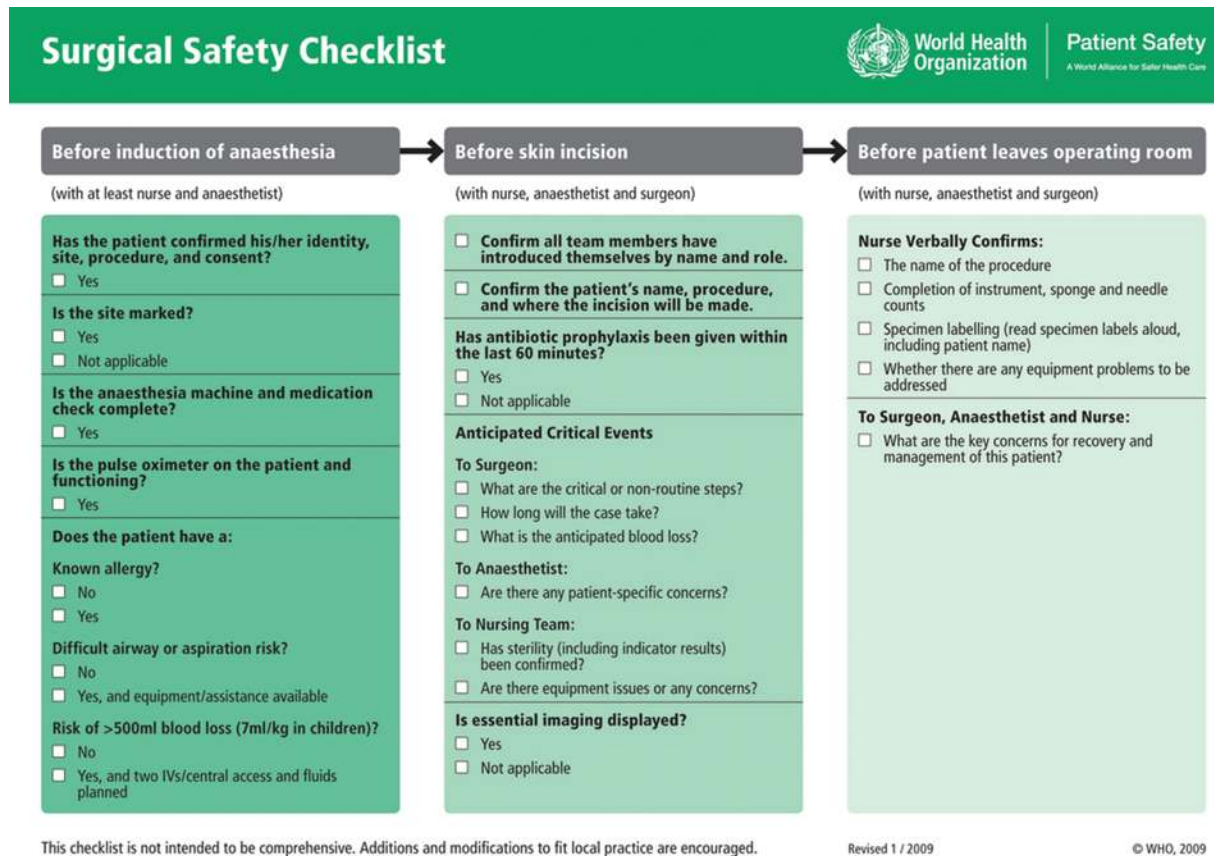


Fig. 2. The WHO Surgical Safety Checklist. Reprinted with permission from the World Health Organization.

ocols.<sup>9,21,47</sup> Additionally, the topic of wrong-level spine surgery deserves special attention. Unlike wrong-site surgery—which can be attributed to communication errors and, in a small fraction of cases, to errors in imaging labels—wrong-level spine surgery results from the similarity of anatomical features at different vertebral levels. Avoidance requires careful correlation between fluoroscopic images and preoperative MRI or CT, rather than the less challenging identification of the correct side of surgery that can be confirmed by a conscious patient. A number of initiatives already exist to address wrong-level spine surgery; for example, the North American Spine Society refined the original “Sign Your Site”<sup>3</sup> advisory by the American Academy of Orthopedic Surgeons into a more comprehensive guideline involving intraoperative fluoroscopy in addition to the already mandated preoperative site marking: “Sign, Mark, and X-Ray.”<sup>42,62</sup> This issue lends itself to a specific checklist item.

Previously, there have been successful efforts within neurosurgery for such practice. The American Brain Trauma Foundation has developed a set of guidelines for operative intervention in the setting of trauma, with special attention to the quality of evidence supporting each standard, guideline, or option (<http://site.acsnsqip.org>). In addition, the Joint Guidelines Committee, a standing subcommittee of the American Association of Neurological Surgeons and the Congress of Neurological Surgeons, was founded to evaluate clinical practice guidelines related to neurosurgery. Members undergo training in evidence-

based medicine and in the evaluation of clinical practice guidelines. Guideline topics include cervical spine injury, concussion, and severe traumatic brain injury.<sup>13</sup>

#### Strategy 4: Equipment Standardization

Table 1 presents a small number of adverse events partially attributable to technology and/or hardware. Variability applies not only to the clinical practice of surgery as described earlier, but to the technologies employed as well. Global standardization of spine hardware and CSF shunts, when possible, may help to reduce variability and thus the chance of human error. Evidence in other fields suggests benefit from equipment standardization. The American Society of Anesthesiologists has established a committee on equipment and standards<sup>4</sup> that facilitates open and formal communication between clinicians and manufacturers to address concerns before they become issues, and to create safety specifications<sup>11,12</sup> that have led to substantial redesign of anesthesia machines and other equipment. They have been able to forge these relationships without receipt of formal consultant fees, thus maintaining the integrity of the interaction.

#### Strategy 5: Implementation of the WHO Surgical Safety Checklist

Finally, a recurrent contributing factor found in our

review is communication failure (Table 1). Among surgical protocols, the WHO Surgical Safety Checklist has demonstrated significant reductions in complications across a broad range of surgical specialties and settings in independent studies (Fig. 2). This 19-item checklist was shown in 2 large prospective, multicenter trials to significantly decrease surgical complications and mortality.<sup>17,28</sup> It facilitates essential team communication, and it has proven useful in a number of uncontrolled studies, improving adherence to fundamental aspects of surgical care including prophylactic antibiotic treatment<sup>59</sup> and venous thromboembolism prophylaxis.<sup>56</sup>

Checklist development, as first devised by the aviation industry and mirrored in the development of the WHO checklist, follows a prespecified 5-step process: content and format, timing, trial and feedback, formal testing and evaluation, and local modification. These steps have been described previously.<sup>60</sup> The content and format involve compiling the known safety practices regarding the targeted safety issue into a background document. Using this document, a checklist is drafted, with specific items meant to be simple checks rather than algorithms. Expert consensus is used to modify the checklist content. Timing refers to identification of appropriate pause points within the workflow to maximize efficacy and efficiency. Once the checklist has been drafted, it is tested in a surgical setting and modified in response to specific feedback, based on the Plan-Do-Study-Act (PDSA) quality control model used in other fields including industry and mathematics/statistics.<sup>18,49</sup> Formal testing and evaluation constitutes the final step in which the now-modified safety tool is rigorously evaluated in the clinical setting. After wide dissemination, local modification may then be used to tailor the intervention to a specific culture or workflow.

Implementation must be followed by diligent auditing and careful monitoring of checklist compliance, given the multiple barriers to checklist implementation and continued use.<sup>23</sup> We have previously described our group's experience with implementation of a version of the WHO checklist at our institution,<sup>54</sup> a process modeled after Pronovost's "Four E's": engage, educate, execute, evaluate.<sup>46</sup> This approach may be tailored to fit any given institution's culture and workflow. For example, some teams may prefer that the surgeon initiate the surgical briefing while others may prefer that other members of the surgical team do so. In our preliminary work with checklists designed to assist with management of operating room emergencies, the team leader is not always the same person; rather, he or she is verbally and explicitly designated by the team at the beginning of the emergency.<sup>69</sup>

A less tangible benefit of the WHO checklist is incorporation of teamwork by beginning with team member introductions. This step encourages individuals to introduce themselves by their first name, thus beginning to flatten the hierarchy traditionally present in the surgical team. The WHO website [www.projectcheck.org](http://www.projectcheck.org) presents a number of videos demonstrating proper and improper checklist use and teamwork dynamics (<http://www.safe-surgery2015.org/south-carolina-checklist-videos.html>). Checklist briefing has been shown in uncontrolled studies to increase adherence to improved practices such as pro-

phylactic antibiotic treatment and venous thromboembolism prophylaxis;<sup>45</sup> a subsequent study by the same group showed that the implementation of team-based training reduces complications and mortality.<sup>40</sup> Such tools and programs that specifically address teamwork will likely enhance the benefits of other safety interventions similar to the WHO checklist. Endorsement and concerted effort by neurosurgical societies to support implementation have a significant chance of being highly beneficial.

## Conclusions

Adoption of policies in support of these recommendations is a potentially powerful starting point, but effective implementation is required for success. Population-wide improvement in surgery has generally required multicenter collaboration, bringing together surgeons, other clinicians involved in surgical care, and hospital leaders for targeted projects with regular monitoring of progress (<http://www.scha.org/transform>).<sup>2,10</sup>

The implementation process often requires specific training of dedicated personnel in order to be successful. As the neurosurgery community moves toward adopting quality improvement policies, it will require increasing resources and dedicated safety champions to implement the programs and tools. Such consolidated, concerted movement will be needed if population-wide change is to occur. We all share this responsibility for enacting change.

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*Address correspondence to:* Atul A. Gawande, M.D., M.P.H., Department of Surgery, Brigham and Women's Hospital, 75 Francis Street, Boston, Massachusetts 02115. email: agawande@partners.org.