All That Glitters Is Not a Golden Recommendation

Richard C. Prielipp, MD, MBA, FCCM,* and Douglas B. Coursin, MD, FCCP†

History is replete with examples where the actions of well-intentioned regulators focused on solving 1 problem inadvertently created a new quandary. For example, concern over the evils of alcohol consumption led to the 18th Amendment to the U.S. Constitution and Prohibition. However, temperance leaders likely never foresaw the disastrous increases in organized crime related to the illegal production and distribution of alcohol or the increased reliance of the government on personal income taxes to replace revenue lost from taxes on alcoholic beverages.[1] The "law of unintended consequences"[2] is a cautionary axiom that any intervention in a complex system is likely to create unknown, and often undesirable, consequences. This fundamental wisdom[1] serves as a warning against the unwitting and arrogant belief that experts can reliably predict the magnitude and diversity of consequences from proposed changes to a system. Medical leaders should heed this axiom as well.

In our clinical anesthesia and critical care practices, we have seen the results of unintended consequences recently with well-intentioned health care directors and regulators mandating sweeping changes to clinical care paradigms based on a "breakthrough" outcome study or studies often initiated by a single, simple intervention reporting extraordinary results. Therefore, we highlight 3 examples where the rapid and near-universal application of breakthrough research findings has significantly affected perioperative care algorithms. These 3 mandates focused on the broad application of perioperative β-blockade for patients undergoing noncardiac surgery; the universal application of tight glycemic control (TGC) in adult critical care patients; and the proliferation of mandatory checklists in medical care. In all 3 examples, changes were instituted on the basis of positive but limited or even flawed research data. In addition, the mandates were enacted with the promise to rapidly increase positive outcomes (or limit negative ones), and therefore, compliance was often enforced via audits, peer review, and even threats to staff credentials via censure. In these 3 examples, we also illustrate that the unanticipated consequences associated with premature adoption of initial research findings takes years to be recognized, acknowledged, and corrected. Our message is not antiguidelines or the denigration of efforts to institute quality improvements. It is to caution practitioners and regulators about rushing to judgment with institution of rigid policies based on insufficient or even inaccurate data. Furthermore, it is to call for real-time review of outcomes after initiation of new protocols, so that unexpected and potentially deleterious consequences are identified and addressed rapidly.

IMPLEMENTATION OF (INTENSE) β-ADRENERGIC BLOCKADE IN NONCARDIAC SURGICAL PATIENTS

In the late 1990s, new guidelines based largely on the work by Poldermans et al.[3] and Mangano et al.[4] enthusiastically called for the widespread initiation of β-adrenergic-blocking drugs (i.e., β-blockers) in patients undergoing noncardiac surgery. Indeed, the Agency for Healthcare Research and Quality embraced β-blockers as 1 of its key initiatives in its heralded analysis *Making Health Care Safer*.[5] But were these recommendations truly evidence based? Were surgical patients well served by rigorous application of these new guidelines?

First, both studies by Mangano et al. and Poldermans et al. lacked validated background work identifying the etiology of perioperative myocardial infarction (MI). Rather, it was assumed that perioperative myocardial infarction was the same entity as "ambulatory MIs" and would respond to β-blockers in a manner similar to Q-wave infarctions. Second, these 2 key trials were underpowered (with study populations of only 100–200 patients) and they lacked allocation concealment and a data analysis plan. Both studies were conducted at a single center. The statistical results were either fragile or arguably even implausible.

Specific criticisms of the study by Poldermans et al. include the lack of blinding for patients, physicians, and data collectors; the very low enrollment rate of only 8% of screened patients; and the fact the trial was terminated early (increasing the risk of a positive result due to chance alone). Moreover, as we now know, many of the works by Poldermans have come under scrutiny because Erasmus Medical Center in Rotterdam dismissed Professor D. Poldermans on November 16, 2011, due to violations of academic integrity.[6]

Some of the methodologies in the study by Mangano et al.[4] also puzzled clinicians. First, there were important imbalances in baseline variables between the 2 study groups. The randomization algorithm did not account for acute β-blocker withdrawal, which we know occurred in 8 chronically treated patients randomized to the control group. Moreover, only adverse events that occurred after hospital discharge were included in the publication by Mangano et al. Indeed, if the 4 atenolol-treated patients and 2 control patients who died during hospitalization are included in the analysis, the study loses statistical significance.

A few investigators voiced concern early on. Devereaux et al.[7] conducted a meta-analysis of all β-blocker studies up to 2005 and could not find statistical significance to favor the use of β-blockers in the "at-risk" population. The PeriOperative ISchemia Evaluation (POISE) trial was thus designed to provide a powerful statistical and clinical examination of the β-blocker question by comparing the effect of metoprolol versus placebo on major cardiovascular

From the *Department of Anesthesiology, University of Minnesota School of Medicine, Minneapolis, Minnesota; and †Departments of Anesthesiology and Medicine, University of Wisconsin School of Medicine and Public Health, Madison, Wisconsin.

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Address correspondence to Richard C. Prielipp, MD, MBA, FCCM, Department of Anesthesiology, University of Minnesota School of Medicine, B515 Mayo Medical Building, MMC 294, 420 Delaware St. SE, Minneapolis, MN 55455. Address e-mail to prielipp@umn.edu.

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events in patients having noncardiac surgery.[8] More than 8000 patients were analyzed in the treatment and control groups, and the results were published in 2008. From this research, we learned that metoprolol controlled release was associated with a significant reduction in the primary composite end point (cardiovascular death, nonfatal MI, or cardiac arrest) driven by the reduction in nonfatal MIs, but not in cardiovascular death alone. However, metoprolol controlled release also resulted in an increase in all-cause mortality, strokes, and clinically significant hypotension.[8] Commentary about the POISE-1 results ensued immediately, as authors considered alternative strategies that might increase the safety of β-blockers in the perioperative periods.[9] Suggestions included using smaller dose of β-blockers,[9] invoking a longer period of time in the preoperative period to slowly titrate drug therapy over 2 weeks or longer,[10] or titrating metoprolol to avoid postoperative tachycardia caused by perioperative events.[9] However, even these suggestions were extrapolated beyond evidence supported by randomized controlled trials in surgical patients.

Therefore, 17 years after the initial enthusiastic recommendations to embrace implementation of β-blockers in known or suspected at-risk noncardiac surgical patients, the latest joint statement of the American College of Cardiology/American Heart Association/European Society of Cardiology opines, "Whether β-blockers in perioperative care are *protective, safe, or harmful* continues to be a subject of debate." In addition, these specialty societies now suggest "the initiation of β-blockers in patients who undergo noncardiac surgery should *not* be considered routine."[11] Other authors assert that the societies and guideline bodies should retract without delay their previous recommendations as based on "fictitious data."[12] Clearly, the rush to mandate a simple answer to this complex question produced European and United States β-blocker guidelines in the 1990s that were premature and an insufficient substitute for physician judgment and experience involving complex medical decision making.[13]

A host of challenges in developing guidelines have been recently outlined including quality of grading of data, disclosure of conflicts of interest, the issue of competing guidelines, and the age of guidelines.[14–17] Two subtle but potentially major issues in guideline creation continue to be unrecognized biases of the guidelines' authors and unwitting influence of "experts" and their opinions. Recent commentaries by the Institute of Medicine and others outline recommendations to limit such influence and enhance the transparency of writing committees.[14–17] It is also clear that these guidelines failed to account for many important perioperative factors that potentially may modify the benefits and risks of β-blockers in this population, including the duration of therapy,[18] the timing of initiation of therapy, the type of β-blocker[19] (today, atenolol, and bisoprolol are used increasingly and may be associated with better protection against the deleterious effects of β-blockers than reported with metoprolol), the β_1-selectivity of the drug therapy, CYP2D6 metabolism profile of the individuals, the likelihood of intraoperative anemia,[20] and an accurate assessment of the cardiac risk of individual patients such as the presence of diabetes and other comorbidities. Indeed, the decision to initiate β-blocker therapy in this patient population is not so simple or safe at all.[11–13,21,22]

TGC IN CRITICALLY ILL PATIENTS

In 2001, Van den Berghe et al.[23] from the University of Leuven, Belgium, published a single-center trial in 1548 adult intensive care unit (ICU) patients, who were predominantly postoperative cardiothoracic surgical patients. The investigators compared a TGC protocol (goal glucose within the normal range, 80–110 mg/dL [4.4–6.1 mmol/L]) using continuous infusion of insulin with a "conventional" group (glucose goal of 180–200 mg/dL [10–11 mmol/L]). Although both groups received insulin as an infusion, the treatment triggers and target goals were different, with the results strikingly in favor of the TGC group. The positive findings included marked reduction in mortality, development of bloodstream infections, acute renal failure requiring renal replacement therapy, critical illness polyneuropathy, requirements for red blood cell transfusions, duration of mechanical ventilation, and ICU stay.[23] Despite these very positive results, in 2005, Bellomo and Egi as well as others highlighted the inadequate sample size to ensure all baseline characteristics were randomly distributed, the lack of study blinding, no or limited allocation concealment, predominance of a single type of postoperative surgical patient (rendering any conclusions not generalizable), use of an atypical postoperative glucose administration regime, atypical nutritional support postoperatively (frequently consisting of total parenteral nutrition), very high postoperative mortality rate for the cardiac surgical patients, and finally what they termed a biologically implausible improvement in patient outcome solely secondary to a modest reduction in glucose levels (50 mg/dL [3.1 mmol/L]) in the first Leuven study.[24] They went on to state "a reasonable conclusion for the same study might have been that administration of excessive intravenous glucose without strong attempts to control its consequences increases mortality in critically ill surgical patients." The authors called for caution in broadly applying the results of this study into clinical practice and asked that interested parties await the results of the much larger, ongoing, multicenter, multinational Normoglycemia in Intensive Care Evaluation and Surviving Using Glucose Algorithm Regulation (NICE-SUGAR) trial in a heterogeneous, adult medical and surgical critically ill population.[24]

Nonetheless, the intense insulin approach reported by Van den Berghe group was rapidly and broadly accepted by various surgical and critical care societies, embraced by regulatory bodies, and enthusiastically applied in ICUs worldwide with the goal being to normalize glucose levels (80–110 mg/dL [4.4–6.1 mmol/L]). Moreover, these findings were frequently embraced in the non-ICU setting without further investigation. One editorialist referred to it as the study that launched 1000 protocols.[25] Notably in 2006, the Leuven group was unable to reproduce their findings in a follow-up study confined to medical ICU patients.[26]

The NICE-SUGAR trial included 6104 patients and the results were reported in 2009.[27] This remains the largest clinical trial performed in adult critically ill patients. It called into question the benefit of routine application of TGC and raised concerns over the potential deleterious effect of

hypoglycemia in critically ill patients, in particular, those who received intense insulin therapy. In contradistinction to previous studies, the NICE-SUGAR investigators found that TGC was associated with an increased 90-day mortality in the intensely treated patients, no difference between outcome in medical versus surgical patients, and no change in the development of acute renal failure, duration of mechanical ventilation, or ICU stay. In a follow-up analysis of NICE-SUGAR,[28] the excessive mortality in the study occurred most commonly in patients who had hypoglycemia (blood glucose <70 mg/dL [3.9 mmol/L]) and distributive shock. Whether there is a cause and effect impact of hypoglycemia on outcome remains unknown and is under investigation.

After the results of NICE-SUGAR were reported, both experts and specialty societies[29–31] retreated from their previous recommendations and now advise the maintenance of glucose in the range of 110 to 180 mg/dL (6.1–10 mmol/L), far less risky than the previous goals of 80 to 110 mg/dL (4.4–6.1 mmol/L). Although it is clear that the NICE-SUGAR study showed that a conventional insulin treatment algorithm is better than an intensive insulin protocol, we believe that multiple covariables must be appreciated and balanced to identify the appropriate therapeutic glucose goals and formulate a safe therapeutic plan. For all ICU patients, this includes the balance of nutrition and insulin simultaneously. Important cofactors include method, frequency, and accuracy of glucose monitoring; the elements of the insulin titration algorithm in use for each subset of patients; baseline requirements for insulin or insulin resistance; and recognition of patients with stress-induced dysglycemia (i.e., hyperglycemia, hypoglycemia, or marked variability in glucose levels during critical illness).[32] Recent data call into question the difference in outcomes for patients with diabetes who develop hyperglycemia during a critical illness versus those without diabetes who have similar stress-induced levels of hyperglycemia. Interestingly, those with known diabetes appear to tolerate high and low glucose concentrations better than those with similar glucose levels who do not have diabetes.[33]

CHECKLISTS

We know that adverse events in hospitalized patients are common and system flaws are a major contributor to these errors. Moreover, failure analysis concludes that up to 50% of these errors are probably avoidable.[34] Checklists are now widely touted to address some of these system issues and thereby prevent avoidable errors. Dr. Atul Gawande, an expert on the utility of checklists, has opined: "We (humans) are built for novelty and excitement, not for careful attention to detail."[35] These sentiments resonated with a number of hospital leaders, and thus, the application of the checklist concept has blossomed over the past decade. Indeed, an informal audit of the PubMed search tool highlights the growth of publications with the terms "checklists and safety" from just 22 citations in 2003 compared to 215 publications 10 years later in 2013.

But in actual clinical studies, the introduction of a medical checklist has been found to be beneficial,[36–38] lacking in benefit,[39] or potentially even harmful,[40] and can even have a negative impact on team function.[41] One of the best known checklists is the standardized 19-item patient safety checklist for surgery from the World Health Organization[37] (Fig. 1). This algorithm has worldwide acceptance and acclaim, which is why the medical community was startled recently to learn that its (or a local customized form of it) mandatory implementation in all 133 surgical hospitals in Ontario, Canada, was not associated with significant reductions in either operative mortality or complications.[39] This recent finding from Ontario is particularly significant because many of the early checklist reports were limited by methodology including observational methods only, a small number of study sites, or inadequate measures of outcomes effectiveness.[40,41] In addition, it appears to confirm previous findings that a checklist does not change outcomes in hospitals that are already compliant and therefore have low rates of complications. Thus, it is appropriate to reflect on how checklists work and how they can falter.

So, is the checklist concept flawed, misapplied, or poorly implemented? We argue that all 3 failure factors may be involved in current medical applications. We have experienced frustration in the overly zealous application of checklists as the first recommendation to solve all current ills in perioperative patient safety. In our view, the simplicity of the checklist is 1 of its greatest strengths and weaknesses. Too often, we have seen committees and administrators leap to the introduction of a simple new form with a series of "tick boxes" (i.e., a checklist) as a quick, inexpensive, and verifiable solution to a recent adverse event of the patient. Then the temptation is to propagate this methodology to every new complication, adverse event, machine defect, drug administration error, or communication lapse that can easily be addressed by another checklist. Indeed, the perception by some clinicians of the current rush to the checklist solution to address all ills often generates an "us versus them" dynamic between administrative directors and clinicians at the bedside. Thus, although the checklist concept has utility in many instances such as crisis resource management situations, it requires thoughtful and selective application in the right situation and for the right reasons.

In addition, checklists require careful planning, construction, focus, and expertise for proper implementation. There are a host of possible pitfalls. The top 10 reasons for problems are noted below:

1. Checklists are an inadequate substitute when the real need is for additional education, training, simulation, resources, and enhanced communication. These later elements are more challenging, time consuming, and costly than a tick-box form. A checklist should never be a substitute when the actual need is for improved education and understanding.
2. Checklists do not fix flaws in the organizational culture but are more often a reflection of its shortcomings. For instance, a core communication problem in the operating rooms cannot simply be addressed by the mere action of checking that all operating room members introduce themselves at the beginning of an operation. In this situation, the checklist provides an opportunity for improved communication to occur but certainly does not by itself change the culture or assure better interpersonal understanding of the challenges ahead.

3. The burgeoning use of checklists may be an attempt to address too many issues, thus producing documents that are needlessly complex. For instance, there are only 7 steps in the landing protocol checklist for pilots landing 1 of our most sophisticated aircraft, the Boeing 777-300 (Table 1). Checklists must be focused and brief.
4. Checklists can be distracting and have the potential to interfere with other key responsibilities at critical times. Moreover, if various team members display discrepant adoption of the checklist concept, or have difficulty adapting to a change of life-long work habits, the checklist may antagonize some team members and serves to accentuate traditional hierarchy gradients.[41]
5. Gaming the system is universal. "Work-arounds" are notorious hospital-based strategies that evolve during time periods of high acuity, production pressure, and multitasking. Introduction of new tasks, e.g., "another checklist to fill out" may be seen as more busy work if the rationale for the new procedure is inadequate.
6. Too many checklists produce fatigue. Then, providers may complete these forms without actually performing the actions. The concept loses relevance and team members become disenfranchised by the extra tasks. To paraphrase a colleague: "The more uncommon the event, the more likely it is to change policy (and produce a new checklist)."[a]
7. Checklists may paradoxically reduce vigilance. Indeed, we believe that the normal sequence of events is that existing clinician vigilance leads to a user-generated checklist. Examples abound in anesthesiology. For instance, many anesthesiologists have a mental checklist before separation from cardiopulmonary bypass, a checklist of equipment and drugs needed for transport to and from the ICU, or a "start-up" safety check before initiating a rapid sequence induction. Excessive reliance on a mandated external checklist can incorrectly lessen the perceived personal level of engagement and responsibility for an issue. Essentially, some providers conclude "the 'system' will protect me and the patient now, so I don't have to pay much attention."
8. Implementation takes time; it is not an overnight solution. Sustained leadership, commitment, and ongoing verification are required. Training must be robust and just as comprehensive for new employees as when the checklist was initiated.
9. Team members need regular, transparent feedback on the process. To stay engaged, individuals must see results of their efforts. Is the checklist really making a difference and improving safety? If so, the data should be readily evident and communicated.
10. Implementing a new checklist is challenging, and physicians and nurses often need additional time and training in construction and implementation.[42] The benefit of checklists will only be realized when they are properly designed and tested. Most current hospital administrators and clinical providers have little experience with assessing and managing human factors related to checklist development, implementation, and efficacy. Therefore professional expertise may be required in formulating a meaningful and focused checklist to address an issue embedded in a complex system. A mechanism must be implemented to ensure that critical actions are observed and verified. Proper implementation strategies are critical to achieving positive long-term results.[43]

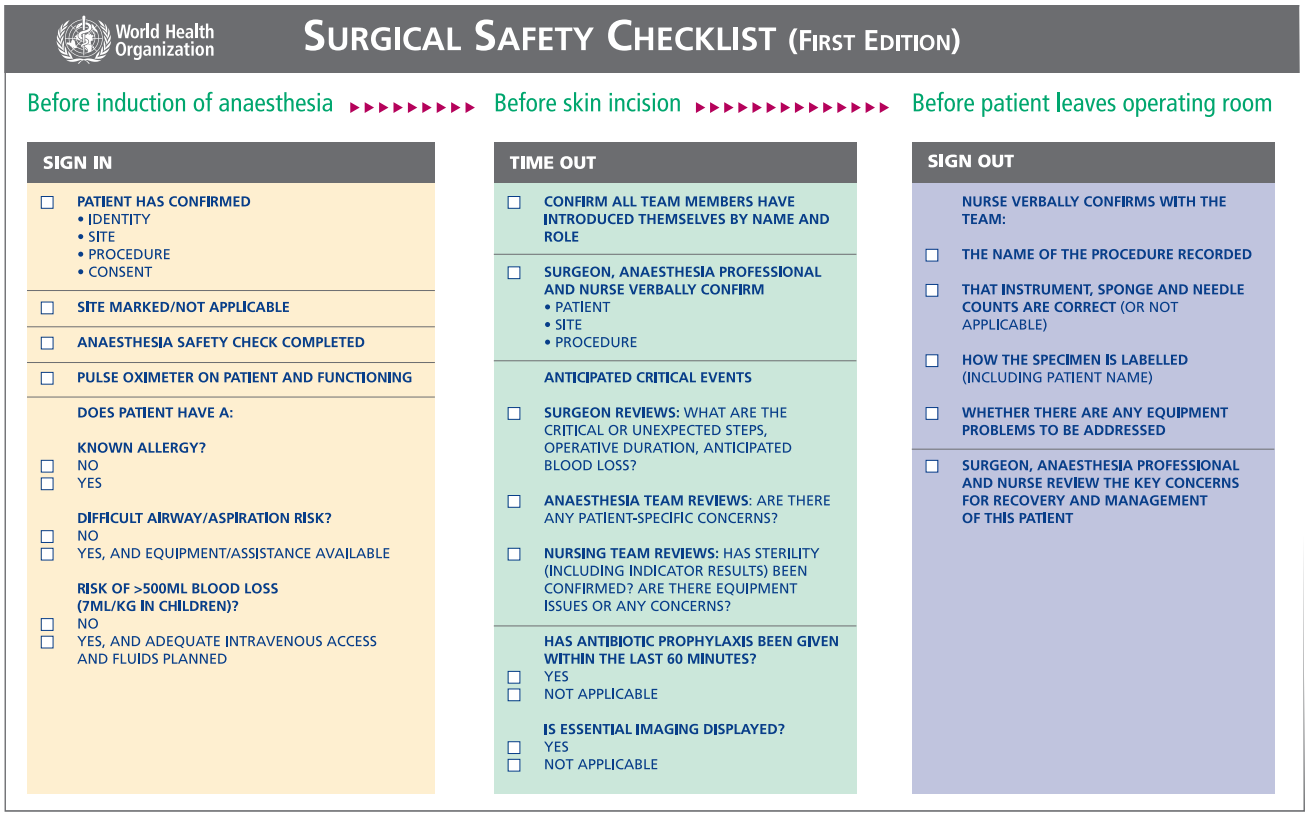
[a]Steven C. Hall, MD, with permission June 22, 2014, parentheses our additional wording.

CONCLUSIONS

The earnest desire of clinicians to improve the outcome of perioperative patients and the critically ill cared for in complex hospital systems may explain the enthusiastic uptake of new evidence into medical practice. However, we must also acknowledge that medicine is replete with examples where that enthusiasm and haste generate best-practice guidelines that resulted in initiatives that were later proven to harm patients or to increase cost of providing care without improving outcomes. Authors, editors, and health care practitioners must constantly be wary and diligent in assessing the ongoing impact of new and established initiatives on their population of patients. In addition, the transparency and quality of guidelines may be evaluated by use of the Grades of Recommendation Assessment, Development, and Evaluation (GRADE) system. However, Kavanagh[44] correctly notes the paradox that although GRADE has evolved through the evidence-based medicine movement, there is no evidence that GRADE itself is reliable.

So, what lessons do we draw from the 3 perioperative clinical scenarios noted above? First is the realization that quality improvement is not simple, swift, or inexpensive. The actions, highlighted in the initiatives we reviewed, were specifically motivated by a desire to apply a quick, easy, globally applicable fix to complex perioperative problems. Unfortunately, those fixes proved problematic, as assessed by clinical experience and follow-up studies. The goals of decreasing postoperative cardiovascular morbidity after noncardiac surgery or to diminish renal failure in cardiac surgery patients after cardiopulmonary bypass are clearly laudable, but in our view, the simplicity of a TGC solution lured leaders to rush adoption and implementation of new practices before sufficient scientific and medical confirmation. Compounding the potential adverse effect to patients was a "herd mentality," pushing both facilities and perioperative leaders to adopt new practices lest they get left behind. Thus, in diverse scenarios, hospital after hospital has quickly adopted the latest quality improvement trend out of fear of losing ground, being perceived as out-of-date, or even losing market share to a competitor. Insufficient time and effort have been dedicated to thoughtfully assessing the scientific vigor of the new recommendations vis-à-vis specific patient populations within a particular medical center or service line.

Second, we should humbly acknowledge that a large volume of current scientific publication findings might simply be wrong.[45–47] The probability that a research claim is true depends on a host of factors, including study power and bias, the number of similar studies on the same question, the magnitude of the effect size, the flexibility or inconsistency in study design, the vigor of



World Health Organization

SURGICAL SAFETY CHECKLIST (FIRST EDITION)

Before induction of anaesthesia ▸▸▸▸▸▸▸▸▸ Before skin incision ▸▸▸▸▸▸▸▸▸▸▸▸▸ Before patient leaves operating room

SIGN IN

- ☐ PATIENT HAS CONFIRMED
  - IDENTITY
  - SITE
  - PROCEDURE
  - CONSENT
- ☐ SITE MARKED/NOT APPLICABLE
- ☐ ANAESTHESIA SAFETY CHECK COMPLETED
- ☐ PULSE OXIMETER ON PATIENT AND FUNCTIONING
- DOES PATIENT HAVE A:

KNOWN ALLERGY?
☐ NO
☐ YES

DIFFICULT AIRWAY/ASPIRATION RISK?
☐ NO
☐ YES, AND EQUIPMENT/ASSISTANCE AVAILABLE

RISK OF >500ML BLOOD LOSS (7ML/KG IN CHILDREN)?
☐ NO
☐ YES, AND ADEQUATE INTRAVENOUS ACCESS AND FLUIDS PLANNED

TIME OUT

- ☐ CONFIRM ALL TEAM MEMBERS HAVE INTRODUCED THEMSELVES BY NAME AND ROLE
- ☐ SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE VERBALLY CONFIRM
  - PATIENT
  - SITE
  - PROCEDURE

ANTICIPATED CRITICAL EVENTS

- ☐ SURGEON REVIEWS: WHAT ARE THE CRITICAL OR UNEXPECTED STEPS, OPERATIVE DURATION, ANTICIPATED BLOOD LOSS?
- ☐ ANAESTHESIA TEAM REVIEWS: ARE THERE ANY PATIENT-SPECIFIC CONCERNS?
- ☐ NURSING TEAM REVIEWS: HAS STERILITY (INCLUDING INDICATOR RESULTS) BEEN CONFIRMED? ARE THERE EQUIPMENT ISSUES OR ANY CONCERNS?

HAS ANTIBIOTIC PROPHYLAXIS BEEN GIVEN WITHIN THE LAST 60 MINUTES?
☐ YES
☐ NOT APPLICABLE

IS ESSENTIAL IMAGING DISPLAYED?
☐ YES
☐ NOT APPLICABLE

SIGN OUT

NURSE VERBALLY CONFIRMS WITH THE TEAM:

- ☐ THE NAME OF THE PROCEDURE RECORDED
- ☐ THAT INSTRUMENT, SPONGE AND NEEDLE COUNTS ARE CORRECT (OR NOT APPLICABLE)
- ☐ HOW THE SPECIMEN IS LABELLED (INCLUDING PATIENT NAME)
- ☐ WHETHER THERE ARE ANY EQUIPMENT PROBLEMS TO BE ADDRESSED
- ☐ SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE REVIEW THE KEY CONCERNS FOR RECOVERY AND MANAGEMENT OF THIS PATIENT

THIS CHECKLIST IS NOT INTENDED TO BE COMPREHENSIVE. ADDITIONS AND MODIFICATIONS TO FIT LOCAL PRACTICE ARE ENCOURAGED.

Figure 1. Based on the WHO Surgical Safety Checklist. Available at: http://whqlibdoc.who.int/publications/2009/9789241598590_eng_Checklist.pdf. © World Health Organization 2009 All rights reserved.

Table 1. Landing Procedure Checklist for a Modern Boeing 777 Jet Aircraft

Landing checklist for Boeing 777-300 Atlantic Sun Airways CAT C Pilot Procedures	
Landing gear	Check down
AutoPilot	Off
Landing speed	150 KIAS[a]
After touchdown	Apply reverse thrust
	At 60 KIAS: cancel reverse thrust
Spoilers	Verify extended
Brakes	As required
Autobrake	Off

[a]KIAS = knots indicated airspeed.

outcome definitions and analytical methods, the potential for a Hawthorne effect, and even the financial or academic interests of the study team.[45,48,49] Publication bias is also widely recognized with negative results now accounting for only 14% of published articles, down from 30% in past years.[45,48,49]

Third, we call for real-time transparent review of new initiatives and protocols so that unexpected and potentially deleterious outcomes are more rapidly identified and addressed. Furthermore, equal effort should be made in limiting or reversing flawed guidelines as was expended in initiating them. Patients cannot afford to be subjects of deleterious guidelines that are in effect for years without adequate documentation and detailed analysis of effect.

Fourth, when unexpected findings are identified after release of guidelines, concerted efforts must be made and resources applied to identify the root cause of unintended consequences, whether major morbid or mortal events. Initiatives like guidelines and checklists cannot be chiseled in stone. They must be reviewed, challenged, and updated regularly as new data and therapies present.[16,50,51] Although challenging, every effort must be made to limit bias on the part of guideline development groups.

In closing, the law of unintended consequences appears to apply equally well to the medical sciences as the social sciences. Good intentions do not equate to sound policy. Medical guidelines remain vulnerable to potentially deleterious unintended adverse effects despite the very best of intentions.[47] We must remain open to change but be sanguine about our interpretation of single studies or data that appear intuitively to be better than biological laws would predict. The 3 examples noted here illustrate how rapid incorporation of inadequately tested algorithms can impact tens of thousands of patients with unforeseen consequences. Unfortunately, some patients unquestionably suffered serious, and in some cases even fatal, adverse events when suggested guidelines became de facto practice mandates. Decision makers should also note the significant time and resources required to revisit and ultimately correct premature, erroneous recommendations. Processes of care, as quality measures, should only be instituted after documentation of high quality and reproducible evidence.

DISCLOSURES

Name: Richard C. Prielipp, MD, MBA, FCCM.
Contributions: This author cocreated the concept, outline, and core content of the article and cowrote the manuscript.
Attestation: Richard C. Prielipp has approved the final manuscript and he attests to the integrity of the content in the original and referenced material.
Conflicts of Interest: Richard C. Prielipp is a member of the Executive Committee of Anesthesia Patient Safety Foundation (APSF), and on the Board of Directors of that Foundation.
Name: Douglas B. Coursin, MD, FCCP.
Contributions: This author cocreated the concept, outline, and core content of the article and cowrote the manuscript.
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