Editorial

The Checklist: Recognize Limits, but Harness Its Power

A checklist can be many things, as simple as "a list of items required, things to be done, or points to be considered, used as a reminder,"[1] or, according to the Agency for Healthcare Research and Quality, "an algorithmic listing of actions to be performed in a given clinical setting, the goal being to ensure that no step will be forgotten."[2] Since the Institute of Medicine's scathing report on medical error,[3] checklists have gained substantial attention, owing to reports of their pivotal role in driving the success of numerous patient safety initiatives. Greater notoriety naturally precipitates greater scrutiny, however, so both the promise as well as the limitations of checklists need acknowledgement. This editorial will consider the often heralded and sometimes belittled checklist for its general benefits, potential utility, and range of evidence attesting to its value in quality and safety improvement.

General Benefits of Checklists

What is it about checklists that suggests they can be helpful to patient care? Some of the general benefits of checklists are identified in Table 1. The overriding virtues of this device may be its provision of clarity, order, and efficiency.

Usefulness of Checklists in Patient Care

The notion of harnessing the potential of checklists in patient care is virtually always ascribed to borrowing from high risk, high reliability organizations in fields such as aviation or nuclear power management,[4] where complex and potentially hazardous operations need to be executed with a near zero tolerance for failures.[5] In high reliability organizations, checklists have served as a "cornerstone of safety management ... for nearly a century."[5(p53)] Although their use in health care is more recent, performance-based checklists are familiar to any health care professional

Table 1 Benefits of checklists

Benefit	Trial (n=61)
Reminders	Minimizes omission, or commission errors or oversights owing to memory lapses, distractions, interruptions
Clarification	Specifies the relevant who, what, why, when, where, how
Consistency	Standardizes all steps of a process or procedure so all practitioners complete them in the same manner
Order	Specifies the sequence in which an activity is to be completed
Precision	Minimizes unintended/varying interpretations or ambiguity
Efficiency	Succinctly summarizes a lot of information or complex procedures
Straightforward	Easy to understand
Easy to use, practical	Facilitates user acceptance, utility
Limited to essentials	Saves time, effort
Evidence based	Necessary for validity, reliability, credibility

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certified in cardiopulmonary resuscitation Basic Life Support by the American Heart Association within the past 5 decades.[6]

Today's younger generation of critical care nurses likely encountered extensive series of clinical checklists at onboarding, when competency-based education and orientation programs guided their initial development, augmented by competency assessment programs. Baby Boomer nurses had to await introduction of competency-based education,[7,8] competency-based orientation,[9] and competency assessment[10,11] concepts into critical care instruction in the 1980s and thereafter before performance-based checklists became commonplace for staff nurse and preceptor development.[12,13] As these references suggest, I have had a longstanding affinity for the pragmatic value of checklists.

Two physicians who appear to share my bias toward checklists are Dr Gawande and Dr Pronovost. In *The New Yorker,* Dr Gawande related a story of how a critical care physician, Dr Provonost, drafted a 5-item checklist for preventing central venous catheter (CVC) infections at Johns Hopkins Hospital in 2001 and then asked his intensive care unit nurses to document whether physicians completed each step. Finding steps skipped in more than one-third of insertions, Dr Provonost secured administrative approval for nurses to stop physicians who skipped steps and to inquire daily whether CVCs could be removed. Over the next year, the 10-day central catheter infection rate dropped from 11% to 0%, with only 2 infections over the next 15 months.[14] Dr Gawande went on to write *The Checklist Manifesto.*[15] Dr Pronovost spearheaded stunning achievements in preventing infection throughout Michigan and worldwide.[16]

Evidence on the Usefulness of Checklists

Existing literature related to the effectiveness of checklists in preventing infection and improving patient safety and other aspects of health care includes an array of outcomes. This section provides an overview of each category of outcomes with offered explanations for each.

Positive Outcomes

A small sample of the large volume of research evidence reporting significant beneficial outcomes from employing checklists to improve patient care and safety is summarized in Table 2. In patient safety, Pronovost's landmark success preventing CVC infection throughout Michigan[16] ignited international impetus in using checklists for other aspects of care, most notably in the Surgical Safety Checklist of the World Health Organization (WHO).[18,19] A reasonable takeaway from this checklist is the verified potential that such a device offers in saving lives and minimizing life-threatening morbidity.

When checklists are effective, at least part of the credit is owed to their design. In much the same way that designing instructional programs requires knowing the content and the learner, strategies for effective checklist design require knowing the task and the user (Table 3).

Negligible or No Differences in Outcomes

A number of studies were not able to replicate Pronovost's central line–associated bloodstream infection (CLABSI) prevention[16] or the WHO Surgical Safety Checklist success,[18] finding negligible or no differences in targeted outcomes and, occasionally, negative associations. The most often cited failure to replicate CLABSI prevention[16] is the "Matching Michigan" initiative in the United Kingdom, involving more than 200 intensive care units over a 2-year period.[34] A number of explanations have been offered for these contrasting findings, including that the UK version was not a true replica, but varied in many ways such as numerous sites with low compliance, particularly among senior physician staff,[35] a problem highlighted in other studies reporting no effects.[22,36]

For the WHO checklist, the dramatic reductions in both operative mortality and complication rates achieved by Haynes et al[18] were not replicated in Ontario, Canada, where more than 101 acute care hospitals and 200 000 surgical procedures were examined following mandated use of that checklist.[37] One explanation offered for those results related to a recurring culprit: despite the mandate, actual compliance varied within and among institutions.[37]

In 2015, a dual disappointment was reported when a different research group in Michigan, using a surgical checklist modeled after that of Pronovost , found no improvements in infections, complications, or mortality among nearly 65 000 general surgery patients in 29 hospitals.[38]

Inconsistent Outcomes

Inconsistent findings were revealed in studies in which checklists were and were not associated with significant differences in outcomes of interest. For example, in a Netherlands study,[24] improvements in operative

Table 2 Evidence for the usefulness of checklists

Source	Findings
Pronovost et al,[16] 2006	The "Keystone ICU Project": 103 Michigan ICUs in 77 hospitals participated in a statewide initiative to reduce CLABSI by instituting a checklist of 5 bundled evidence-based prevention strategies, local leadership, and team collaboration. The median CLABSI rate per 1000 catheter days decreased from 2.7 infections at baseline to 0 at 3 months after implementation and the mean rate fell from 7.7 to 1.4 at up to 18 months, reflecting a 66% sustained reduction in infection rates.
Pronovost et al,[17] 2010	Follow-up to the Pronovost 2006 study, reporting that the dramatic CLABSI prevention improvement was sustained for 36 months.
Haynes et al,[18] 2009	Introduction of the WHO Surgical Safety Checklist was associated with striking postoperative outcomes in 8 hospitals in 8 international cities, representing a variety of economies and cultures. The rate of death declined from 1.5% before checklist introduction to 0.8% after introduction. Inpatient complication rates decreased from 11% of patients before to 7% after the checklist was introduced.
Mackenzie et al,[19] 2009 de Vries et al,[20] 2010 Thomassen et al,[21] 2010 Mayo et al,[22] 2011 van Klei et al,[23] 2012 Bliss et al,[24] 2012 Thomassen et al,[25] 2014	Studies reporting success using the WHO Surgical Safety Checklist[26]
Basoor et al,[27] 2013	A checklist was developed to reduce heart failure readmissions by documenting medications, dose titration, counseling, and follow-up discharge instructions. Sample and control groups were randomly selected. More patients in the checklist group were taking ordered medications (40 of 48 vs 23 of 48); dose titration more common in checklist group (4 of 48 vs 21 of 48). Both 30-day and 6-month readmissions were lower in the checklist group.
Gladstone et al,[28] 2015	Developed and validated a "DOAC Monitoring Checklist" for patients with atrial fibrillation receiving direct oral anticoagulants to prevent stroke. Checklist distills hundreds of published clinical trial findings, recommendations, monographs, research results, and expert opinion into a practical single page worksheet.
Haynes et al,[29] 2017	14 hospitals voluntarily completed the WHO Surgical Safety Checklist program. Postoperative risk-adjusted 30-day mortality at hospitals using the checklist fell (3.38% in 2010 to 2.84% in 2013) compared to rising from 3.5% in 2010 to 3.71% in 2013 at 44 nonparticipating hospitals, reflecting a 22% difference between groups.
Woods-Hill et al,[30] 2017	A quality improvement initiative with more than 2200 pediatric ICU patients was successful in decreasing the number of blood cultures (46% reduction) and central venous catheter cultures (from 1321 [73.1%] before to 389 [39.5%] after), without increasing mortality, readmission, or episodes of suspected infection or septic shock.
Lashoher et al,[31] 2017	35 researchers investigated whether implementing the WHO Trauma Care Checklist would improve care for trauma patients in low-, middle-, and high-income countries. Data from 1641 patients before and 1781 after implementation showed that the checklist was associated with statistically significant improvement in 18 of 19 process measures.
Kerner et al,[32] 2017	Investigators developed 3 checklists (prehospital care, ACS, acute asthma/COPD). Documentation of patients' history (preexisting diseases, medication, allergies), diagnostic measures (oxygen saturation, auscultation), and basic treatments (oxygen, intravenous access) increased significantly. ACS subanalysis showed a significant increase in use of 12-lead ECG, oxygen, aspirin, heparin, β-blockers, and morphine. For COPD, use of oxygen and inhalative and intravenous β2-mimetics increased significantly. Checklists appear to help improve adherence to prehospital emergency treatment guidelines.

Abbreviations: ACS, acute coronary syndrome; CLABSI, central line–associated bloodstream infection; COPD, chronic obstructive pulmonary disease; ECG, electrocardiogram; ICU, intensive care unit; WHO, World Health Organization.

mortality were demonstrated only in patients for whom the WHO surgical checklist was fully completed; no improvements were found when the checklist was partially or not completed.

A recent systematic review of 25 WHO Surgical Safety Checklist studies found that complication rates were measured in only 20 studies, were decreased in 10, but increased in 1. Of the 18 studies that examined

Table 3 Guidelines for effective checklist design

Category	Guidelines
Knowing the task[33]	Analyze the task to extract essential components Explicitly identify subtasks that could be overlooked Require a value or status of an item (eg, heart rate 88/bpm) rather than just a checkoff that it was measured Avoid conflicting physical demands of the task with checklist completion (eg, if task requires sterile or clean object handling or use of both hands, user not able to manage checklist simultaneously unless pauses are introduced) Create separate checklists to cover different scenarios, when appropriate (eg, to cover aspects unique to pediatric or neonatal patients versus adults) Present task requirements based on how it is actually performed, rather than to an ideal theoretical performance
Additional considerations related to the task	Targeted to performance where the expected behaviors can be readily identified in a stepwise manner Appropriately targeted to schematic (rather than attentional) behaviors. According to the Agency for Healthcare Research & Quality Patient Safety Network website, checklists are most appropriate for schematic behaviors, which can be completed in a nearly reflex, automatic manner. Fatigue, distractions, or lack of concentration may cause errors (called slips). Checklists are an elegant yet simple means of reducing slips, which represent the majority of health care errors.[2] Attentional behavior demands active problem solving and deliberate planning. Errors (called mistakes) arise from a lack of knowledge, experience, or instruction, which checklists cannot provide.[2]
Knowing the user[33]	To ensure good communication and collaboration Follow basic usability guidelines such as using clear, readable fonts; avoiding all caps, including generous white space to minimize visual clutter, increasing visual contrast between printed words and their background, using familiar and unambiguous language in a consistent manner Assign tasks/subtasks to specific roles (distinguish physician vs nurse responsibilities) to avoid diffusion of responsibility or erroneous assumptions regarding assignments Pilot test every iteration of a checklist with actual users in realistic scenarios (time limits, pressure, distractions, interruptions) comparable to real life execution
Optimize the interplay between the checklist and user	Checklist is readily available when and where user needs it[15] Clear, unambiguous, precise phrasing to minimize varying or erroneous user interpretations Specify the manner and order in which performance needs to occur[5] Visual presentation is clear, easy to see, read, and document Length no longer than necessary[5] Each inclusion is evidence based (gold standard) so users can have confidence in its validity, reliability, and currency[16] End users have opportunity to tailor checklist to local practices to maximize ownership[16] Consensus on inclusions among stakeholders/end users[16]

operative mortality, rates decreased in 4, increased in 1, and decreased only in developing nations.[39]

Negative Outcomes

In addition to the negative findings just noted,[39] an earlier randomized trial reported a higher surgical site infection rate (45%) in the extended arm of the study versus 24% in the standard arm ($P = .003$).[40] So how do we reconcile such contrasting findings related to the effectiveness of checklists?

Accounting for Variability in Findings

Employing checklists in safety and quality improvement programs involves much more than just a good checklist. This may be most readily apparent by using the Pronovost study.[16] The checklist in that study actually comprised a bundle of 5 evidence-based actions to prevent CLABSI infections[41]:

1. Proper hand hygiene
2. Chlorhexidine skin antisepsis
3. Maximal sterile barriers during insertion
4. Subclavian (versus femoral) preferred insertion site
5. Daily check to discontinue unnecessary central catheters

This safety program always required full compliance with all 5 elements, as well as creation of an environment conducive to continual improvement that the research team characterized as a "culture of safety" that recognizes sociocultural features of how organizations operate and people function best within them. Without the culture of safety, the checklist is not effective. One particularly insightful enumeration of those sociocultural prerequisites

is summarized in Table 4, with a reminder that it took 9 months of arduous preplanning in Michigan before launching the checklist.[42] These elements simultaneously created a foundation upon which the checklist can be embedded for support and circumvented barriers that could have negated the effectiveness of the checklist.

When these culture of safety considerations are included in the equation, the reasons why many safety programs involving checklists were/are not successful can be more readily understood. Analysis of the Matching Michigan study revealed marked differences in implementation and attention to sociocultural features (consensus-building, leadership support, revising local practices did not happen at many sites).[35] Absent attention to those sociocultural necessities, the work culture does not translate checklist expectations into work performance standards,[42] and neither staff nor their work unit makes the investment needed to achieve successful outcomes.[43] Lack of buy in, particularly among senior physicians, remains an obstacle to success of these programs.[44]

Other analyses of WHO surgical checklist reports implemented across hospitals in England reinforce the pivotal role that specific cultural factors play in program success. Some are painfully clear and direct: If staff do not correctly, completely, or consistently use the checklist, its value is nullified and the program is destined for disappointing outcomes.[36,45] Similarly, when surgical staff at participating UK hospitals were asked about barriers to implementing this checklist, the barrier most often identified was active resistance of senior clinicians.[46] Other obstacles were imposing the checklist without introduction, training or support to staff; finding it poorly worded, redundant, or time-consuming; and neglecting to integrate it into existing procedures.[46] Conversely, facilitators' suggestions to improve implementation echoed many culture of safety requisites: enabling staff to tailor the checklist to local procedures; providing staff education, data feedback, and logistical support (supplies, products); supporting leadership; and instilling accountability.[46]

Another suggestion noteworthy when high compliance rates are reported yet no differences are found was incorporating direct observation of compliance. In a study with checklist compliance documented at 100%, observers identified that on average, hospital staff completed only 4 of WHO's 13 requirements.[47]

Table 4 "Culture of safety" sociocultural prerequisites for safety checklist program effectiveness[42]

Creation of social networks with a shared sense of mission and mutual cooperation to complete the designated interventions

Before intensive care units (ICUs) were allowed to participate in the intervention, each hospital had to create and maintain a culture of safety in their ICUs via the following:

- Assign a senior executive to work with participating ICUs via monthly meetings with staff to listen and solve problems
- Identify ICU physician and nurse team leaders
- Provide team leaders with instruction in safety science and each intervention
- Team leaders provide instruction to colleagues on safety and study components
- Team leaders use conference calls and meetings to remain in touch with study leaders and one another
- Infection control practitioners collect, calculate, and report infection rates to ICU staff
- Solicit caregiver feedback on results of their efforts
- A flash of role-reversal: empower nurses to stop central venous catheter insertions if guidelines are not followed

Lessons Learned

Health care facilities that use checklists to improve patient safety and quality of care need to recognize that checklists by themselves do not improve care, but when they identify a series of evidence-based strategies, they can be employed as tools to support practices among staff individually and collectively committed to making them work. Just as the sociocultural landscape can foster improved program practices, however, it is equally capable of thwarting and undermining them at any and all stages of their life.

Developing a great checklist and expecting it to improve care is much like having healthy seedlings and expecting them to bear fruit; neither will thrive without first preparing its foundation for growth; nurturing and supporting its progress with others; removing predators that could choke its development; and monitoring its fruit at the right times.

Closing

No one ever improved patient care just by making check marks on a piece of paper or tablet, but a well-designed checklist in a supportive environment with committed practitioners can save lives, prevent complications,

and improve safety. In addition to noting the compendium of checklists now offered by the Joint Commission[48] and American Hospital Association[49] toward that goal, please do not forget the bonus from using checklists in clinical decision support mentioned in my February editorial[50]: the virtual elimination of implicit bias such as that associated with gender or race. Providing improved and safer care to all patients, rather than just to some—wouldn't that be a welcomed serendipitous finding! CCN

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Editor

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