What Are the Effects of Introducing the WHO "Surgical Safety Checklist" on In-Hospital Mortality?

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The term *evidence-based medicine* was first coined by Sackett and colleagues[1] as "the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients." The key to practicing evidence-based medicine is applying the best current knowledge to decisions in individual patients. Medical knowledge is continually and rapidly expanding, and it is impossible for an individual clinician to read all the medical literature. For clinicians to practice evidence-based medicine, they must have the skills to read and interpret the medical literature so that they can determine the validity, reliability, credibility, and utility of individual articles. These skills are known as critical appraisal skills. Generally, critical appraisal requires that the clinician have some knowledge of biostatistics, clinical epidemiology, decision analysis, and economics as well as clinical knowledge.

The Canadian Association of General Surgeons (CAGS) and the American College of Surgeons (ACS) jointly sponsor a program titled, "Evidence-Based Reviews in Surgery" (EBRS), supported by an educational grant from Ethicon Inc and Ethicon Endo Surgery Inc. The primary objective of this initiative is to help practicing surgeons improve their critical appraisal skills. During the academic year, 8 clinical articles are chosen for review and discussion. They are selected not only for their clinical relevance to general surgeons, but also because they cover a spectrum of issues important to surgeons; for example, causation or risk factors for disease, natural history or prognosis of disease, how to quantify disease (measurement issues), diagnostic tests and the diagnosis of disease, and the effectiveness of treatment. Both methodologic and clinical reviews of the article are performed by experts in the relevant areas and posted on the EBRS website. A listserve discussion is held, where participants can discuss the monthly article. Fellows and candidates of the College can access Evidence-Based Reviews in Surgery through the American College of Surgeons website (www.facs.org). All journal articles and reviews are available electronically through the website. Currently we have a library of 50 articles and reviews, which can be accessed at any time. Each October, a new set of articles will be available each month until May. Surgeons who participate in the current (modules) packages can receive CME credits by completing a series of multiple choice questions. Additional information about EBRS is on the ACS Website or by email to the administrator, Marg McKenzie at mmckenzie@mtsinai.on.ca.

In addition to making the reviews available through the ACS and CAGS Websites, 4 of the reviews are published in condensed versions in the *Canadian Journal of Surgery*, 4 in the *Journal of the American College of Surgeons*, and 4 in *Diseases of Colon and Rectum* each year.

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SELECTED ARTICLE

Effects of the Introduction of the WHO "Surgical Safety Checklist" on In-Hospital Mortality

van Klei WA, Hoff RG, van Aarnhem EEHL, et al. Ann Surg 2012;255:44–49.

Question: What is the effect of implementation of the World Health Organization (WHO) surgical checklist on in-hospital 30-day mortality and the impact on compliance?

Study Design: Retrospective cohort study using before-after design to identify groups of patients exposed to the WHO surgical checklist.

Patients: There were 25,513 patients who were or were not exposed to the surgical checklist.

Setting: University Hospital in the Netherlands.

Data Sources: Hospital administrative data and electronic patient records.

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Main Outcomes: In-hospital mortality within 30 days of surgery.

Results: The absolute 30-day mortality rates before and after the checklist implementation were 3.13% and 2.85% (odds ratio [OR] 0.91, 95% CI 0.78 to 1.05), respectively, on univariate analysis. However, after adjustment for baseline variables, mortality was significantly decreased (OR 0.85, 95% CI 0.73 to 0.98). The effect of compliance on outcomes was significantly related to outcomes with ORs of 0.44 (95% CI, 0.28 to 0.70), 1.09 (95% CI, 0.78 to 1.52), and 1.16 (95% CI, 0.86 to 1.56) for completed, partially completed, and non-completed checklists, respectively.

Conclusions: Implementation of the WHO surgical checklist reduced in hospital 30-day mortality. Although the impact on outcome was smaller than previously reported, the effect depended crucially upon checklist compliance.

Commentary: The introduction of checklists to medical practice was adapted from experiences in aviation, when a plane crash in 1935 was attributed to overwhelming complexity, and a pilot's checklist was developed to streamline processes associated with routine functioning of the new aircraft.[1] Since that time, checklists have become more common in medicine, and have been associated with improved clinical outcomes. In one example, significant reductions in catheter-related blood stream infections in the ICU have been attributed to the introduction of a checklist.[2,3]

The introduction of checklists to operating room practice has been an international effort, spearheaded by the World Health Organization (WHO). Participating institutions adopting this practice reported their outcomes in 2009[4] and represented the spectrum of WHO regions and therefore a variety of resource and socioeconomic environments. The significant findings were a reduction in major complications, from 11% to 7%, and a reduction in in-hospital death within 30 days, from 1.5% to 0.8%. When centers were stratified into high and low income, the reduction in complications remained significant at all sites; the significant reduction in deaths persisted for lower income sites only. The death rate in high income sites was 0.9% prechecklist and 0.6% postchecklist.

In this study, the authors demonstrated that important reductions in mortality also may be achievable in large academic medical centers in high income countries. More than 25,000 surgical patients were included in this before-after retrospective cohort study from a single institution in the Netherlands. Mortality decreased from 3.13% to 2.85%. The results were achieved despite a lack of full compliance, and remained true when controlling for predetermined confounders. Importantly for organizations adopting the surgical checklists, the improvements were positively associated with greater compliance.

The study design, a before-after cohort study, is an important consideration when interpreting the results because it is subject to biases that might not have been seen in randomized controlled trials. In this trial design, confounders may be present (such as differences in patient populations), and might contribute to observed differences between the groups in ways for which we cannot control or account. In addition, technologic progress or the experience of the people who work in the environment could bias the results. As a health center/surgical team gains experience, it may be possible that outcomes will improve with time. Therefore, the second arm of a before-after design might do better, but it would not be due to the intervention. A retrospective before-after design has the potential confounder of reporting bias, in which medical records may not be as accurately kept for issues specific to the intervention before the intervention. There might also be a Hawthorne effect, ie, the effect may not be due to the checklist itself but behavior is changed because there is a focus on the perioperative team or because compliance with the checklist is being recorded.

The conclusion made by the authors attributes the change in perioperative outcomes to the checklist. The challenge of association is the difficulty parsing correlation and causation. Generally, we can determine causation only in experimental studies (ie, randomized controlled trials in the clinical world) because we control for all factors and confounders besides the intervention. So if a difference is observed, we can be fairly confident that it is due to the intervention. In nonexperimental or observational studies such as this study, we can only conclude that there is an association. Because of the retrospective nature of this study, it is possible that nonquantifiable or unidentified confounders may have caused or been partially responsible for the observed differences. Although the lower perioperative mortality may be correlated with implementation of a checklist, it is more difficult to prove that it was caused by the checklist.

There are at least 3 possible mechanisms by which a checklist could work: the actual content of the checklist could uncover unrecognized problems before actual patient harm occurs; adoption of a checklist could lead to an increased awareness of patient safety issues and engender a culture of patient safety; or completing a checklist could encourage communication between team members so salient pieces of information specific to each case are transmitted. In fact, all 3 of these are likely occurring simultaneously at least to some degree, and they all may have an effect on the outcomes associated with implementation of a check list.

Adopting a major change in practice is difficult.[5,6] This study has demonstrated that the adoption of the WHO checklist by the University of Netherland's health care system has been a success. Obstacles and resistance to change are well described by Mahajan[7] with respect to the NHS experience. These are not unique and include anxiety of unfamiliarity, overcoming staff hierarchy and authority, impact on logistics and efficiency, requirement for duplication, and relevance. Improving patient safety through significant changes in process requires not only adoption of checklists but organizations and leadership that prioritize safety and create a culture that value these initiatives. Identifying and supporting key leaders are also fundamental for the task. Ongoing communication, positive feedback, and delivery of key messages are critical to the change process.

So the question is—how should this study affect clinical care or policy? This study is important in that it further validates the finding that checklists save lives. For this reason, we should continue what we are doing: disseminating and adopting surgical checklists in whichever format is most conducive to a specific environment. But unfortunately, we are really no closer to understanding how checklists work or identifying the optimal content, length, and format as a result of this work.

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