it seems likely that dietary constituents, not too surprisingly, can influence the immune system and intermediary metabolism, our knowledge of the mechanisms at play are, at present, rudimentary. Data from the ongoing multicenter Trial to Reduce IDDM in the Genetically at Risk (TRIGR; ClinicalTrials.gov number, NCT00179777) should help clarify whether hydrolyzed casein formula exerts a protective effect against the risk of type 1 diabetes.

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Strategies for Improving Surgical Quality — Checklists and Beyond

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Long standard in the safety-conscious aviation industry, checklists are now being promoted aggressively in the medical literature and popular press.1-3 Almost all U.S. hospitals mandate simple preoperative “time-outs” to minimize the risk of egregious mistakes, such as operating on the wrong site or the wrong patient. Recently, however, many hospitals have started implementing more comprehensive checklist procedures for the operating room, aimed at increasing compliance with practices known to reduce complications and enhancing teamwork. Last year, a large international study supported by the World Health Organization (WHO) reported that such checklists cut surgical morbidity and mortality almost in half.4

Nonetheless, findings from the WHO study left some unconvinced about the true effectiveness of surgical checklists.5 First, the preintervention–postintervention study failed to control for confounding factors, including the concurrent implementation of outcomes measurement and feedback. The “surgical Hawthorne effect” — which has it that outcomes tend to improve rapidly when surgeons know they are being evaluated — is widely recognized. Second, the study's operating room checklist consisted primarily of common-sense items and processes of care that seemed unrelated to the most common serious complications of surgery. It was implausible to some people that improved compliance with these practices could lead to such drastic reductions in morbidity and mortality. Finally, compliance of the eight study hospitals with the checklists had no bearing on the extent of improvement in outcomes. Overall compliance with processes of care on the checklists improved negligibly even in the two hospitals with the greatest reductions in morbidity and mortality. Conversely, the two hospitals with the greatest increase in compliance showed no change in outcomes.

The study in this issue of the Journal by de Vries and colleagues should quiet the skeptics. The authors evaluated the effects of a comprehensive surgical checklist intervention in six regional and tertiary care centers in the Netherlands.6 In contrast with the more narrow operating room checklist evaluated in the WHO study, this intervention involved 11 distinct checklists applied during different phases of preoperative, intraoperative, and postoperative care, completed by
surgeons, anesthesiologists, nurses, and other staff. The nearly 100 items on the checklists address the availability of imaging information, equipment and materials, patient and operative-site verification, communication of postoperative instructions between caregivers, and discharge instructions. Outcomes improved substantially as a result of this intervention. The proportion of patients with one or more complications fell from 15.4 to 10.6%. Mortality dropped from 1.5 to 0.8%.

In avoiding pitfalls associated with the former study, the current report makes a particularly persuasive case for the effectiveness of checklists. First, it included hospitals that had already been tracking their surgical outcomes with the same detailed registry for many years, so the results cannot be attributed to the effects of performance feedback. Second, the study documented a strongly positive relationship between checklist compliance and outcomes. Patients with incomplete checklists had significantly more complications than those for whom checklists were more fully completed. Finally, and perhaps most important, the study included a control group. At five similar hospitals that did not implement the checklist intervention, morbidity and mortality were unchanged during the study period.

This study also provides insights into why checklists work in the first place. A common assumption is that they work for surgeons as they do for pilots, by helping surgical teams avoid simple oversights and mistakes, such as failing to have blood available for a high-risk patient. If that assumption were correct, one would expect checklists to be most effective in avoiding complications directly related to processes of care specified on the checklists — for example, the number of surgical-site infections would decline as more patients received preoperative antibiotics. In this study, however, rates declined for essentially every type of postoperative complication. Much of this improvement could be attributable to more effective communication and hand-offs between different types of providers, an explicit goal of the multidisciplinary checklist used in this study. Surprisingly, rates of bleeding and anastomotic leak — technical problems that occur primarily at the hands of the operating surgeon — dropped to the same extent as other types of complications. The mechanisms underlying such improvement are unclear, but checklists could play a role by reducing unnecessary distractions in the operating room. Together, the findings of this study suggest that the indirect effects of implementing checklists may be much more important than their specific content.

The durability of improvements achieved by means of surgical checklists remains an important question. Outcomes were assessed for only 3 months after implementation in the current study and for only 6 months in the WHO study. Studies of electronic-reminder systems indicate that “alert fatigue” often develops in physicians and nurses, who gradually begin to ignore warnings. It is thus conceivable that the benefits of surgical checklists could wane over time as they lose their novelty and become a perfunctory component of care. It is also unclear what makes for an optimal surgical checklist. The Surgical Patient Safety System (SURPASS) used in the current study involved all aspects of surgical care from admission to discharge and requires that 11 forms be completed and documented by numerous providers. Although it is not clear whether similar benefits would have been achieved with fewer items, it is worth noting that the WHO study achieved similar reductions in morbidity and mortality with a much simpler checklist focused on the operating room alone.

Although some questions remain, surgical checklists should be considered a priority for providers, payers, and policymakers. According to the results documented in both major studies, checklists could avert tens of thousands of surgical deaths and hundreds of thousands of serious complications every year in the United States. The Joint Commission is positioned to accelerate the adoption of surgical checklists. Payers could provide incentives for the use of checklists through their pay-for-performance programs instead of continuing to focus on hospital compliance with a small number of specific processes of care.

Of course, checklists are not the final step toward optimizing surgical quality. For example, they will not eliminate the variation in the surgeon’s inherent skill and the proficiency conferred by procedure volume and experience. In addition, although checklists may be useful in enhancing the implementation of processes of care that have been proved effective, they will not
identify what those best practices are. Rigorous, population-level outcomes measurement and collaborative quality improvement will be essential to clinical innovation and the development of optimal delivery systems for surgical care. In the meantime, checklists seem to have crossed the threshold from good idea to standard of care.

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