statement. Raine et al\(^3\) assessed the sexual and contraceptive behaviors of young women aged 15 to 24 years who were randomly assigned to 1 of 3 EC-access groups: advance provision (with 3 packs of EC), pharmacy access, or clinic access (control group). Those in the advance-provision group were almost twice as likely to use EC as those in the clinic-access group at the 6-month follow-up. The advance-provision group did not have significantly higher frequency of unprotected intercourse compared with the clinic-access group. No other differences in contraceptive or condom use or other sexual behaviors by group were found. At the 6-month follow-up, 8\% of the young women in the study had become pregnant, and 12\% had acquired a sexually transmitted infection. There were no reductions in pregnancies or increases in sexually transmitted infections by group (advance provision, pharmacy access, or clinic access).

It is my understanding that the American Academy of Pediatrics will soon be publishing a pamphlet on EC for adolescents. This is a sorely needed resource for the pediatrician in practice, and I look forward to its availability.

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In Reply.—

The American Academy of Pediatrics (AAP) Committee on Adolescence welcomes Dr Gold’s letter and the opportunity to correct the dose and product recommendations of readily available emergency contraceptive (EC) products. Although the position paper\(^1\) was current at the time it was written and approved by the AAP, she is correct in noting that the availability of products has changed. 

Drs Stanford and Mikolajczyk identify several additional references that selectively address the lack of evidence for reductions in abortion rates for populations for which EC is available. However, whether populat-

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Perceived Increase in Mortality After Process and Policy Changes Implemented With Computerized Physician Order Entry

To the Editor.—

We read the article by Han et al\(^1\) with great interest. The authors of this study concluded that the implementation of computerized physician order entry (CPOE) in a pediatric critical care unit was associated with an unanticipated increase in mortality in children admitted via interfacility transport over a 5-month period. Although we acknowledge a growing concern that information technology that was intended to improve clinical care may actually facilitate certain types of errors,\(^2,3\) we are concerned that the authors’ conclusion is not justified by their data.

The authors describe several critical policy changes that were implemented concurrently with CPOE, each of which could account for an increased risk of mortality in these critically ill children. First, all medications (including antibiotics and vasoactive agents) were removed from the critical care units and housed in the central pharmacy. Second, order entry was not allowed until after a transported patient had physically arrived to the hospital and was registered into the system. Finally, the pharmacy could not receive medication orders until they were activated by the patient’s nurse. These all are major workflow changes that likely increased medication turnaround time for transferred patients. None of these changes were necessitated by CPOE implementation; in fact, the authors state that the second policy was recti-
fied later, although they did not clarify whether it was done before or after the study period ended.

The authors also describe 2 critical deficiencies that are reflective of inadequate preparation for implementation of an electronic medical chart, not of CPOE per se. First was the lack of bandwidth capacity on their wireless network. This infrastructure deficiency likely contributed to decreased face-to-face interactions between the nurse and the physician when orders were being entered and highlights the important concept that CPOE is not a replacement for verbal communication. Second, the authors state in their methods section that “no ICU-specific order sets had been programmed at the time of CPOE implementation but instead were developed over time after CPOE implementation.” In a consensus statement on successful CPOE implementation, Ash et al wrote that “order sets . . . must be developed, reviewed, and maintained for personal and/or departmental usage.” In fact, the authors later acknowledge in their discussion section that “ongoing development of preprogrammed order sets has helped to reduce some of the upfront time cost of order entry,” but again, it is not clear whether this effort was made before or after the study period ended.

In summary, we believe that inadequate preparation for CPOE implementation, highlighted by inappropriate policy and process changes, insufficient infrastructure, and lack of critical care order sets, contributed substantially to the increased mortality rate reported by Han et al. We applaud the authors for highlighting the importance of careful workflow redesign in CPOE implementation, particularly in the intensive care environment, but we caution other readers not to dismiss the importance of CPOE as a tool to help prevent medical errors and enhance patient safety. Indeed, other authors from the same institution have demonstrated a hospital-wide decrease in harmful adverse drug events, and other studies have described decreased medical errors in both a PICU and an NICU with successful CPOE implementation.

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to the Editor—

The article by Han et al reports a “direct association” between increased mortality rate and the implementation of a commercial computerized physician order entry (CPOE) system in a tertiary care PICU. The Children’s Hospital of Pittsburgh (CHP) investigators observed a significant increase in raw mortality and in severity-adjusted mortality rates. The investigators concluded that the problems they encountered were unanticipated and embedded in the CPOE system rather than being a result of choices in how this technology was adopted. Problems specifically mentioned were the inability to preregister patients, additional time needed to enter orders, the need for a second physician devoted solely to entering orders, nurses spending too much time at the computer and away from the bedside, delays in administration of critical medications, premature termination of standing medication orders, mistiming of medication administration, and using a generic platform in a highly specialized setting.

Many of the implementation strategies used by the CHP in their PICU have been identified previously as problematic, including (1) absence of active and meaningful involvement by critical care physicians in system design, decision-support tools, and implementation strategies, (2) use of an adult-based general medical ward platform not designed/redesigned for the organization’s needs or the requirements of critical care practitioners, (3) a training period for clinicians ending a full 3 months before implementation rather than using just-in-time training, (4) absence of order sets (widely regarded as the single most important factor for enabling physician workflow), and (5) adoption of a slow and inefficient platform with inadequate performance during peak periods. In addition, decisions to move from a
decentralized to a centralized pharmacy and acceptance of a CPOE platform that did not allow simultaneous users to enter/review medications were counterintuitive in a busy critical care unit. Furthermore, it seems that computer terminals were not optimally placed or were immobile and insufficient in number to allow nurses to carry on their work at the bedside, thus interfering with patient care.

Between April and December 2002, the Cincinnati Children’s Hospital Medical Center (CCHMC) implemented CPOE throughout the institution. CCHMC is a 423-bed facility with 1045 physicians and 1750 nurses. The PICU has a capacity of 25 beds and an average daily census of 18 children. The CPOE application is part of a larger integrating clinical information system, the core applications of which include a Web-based portal, CPOE, clinical documentation, and a data repository (Invision; Siemens Medical Solutions, Malvern, PA). These core applications interface with other hospital-based information systems including radiology PACS, laboratory, pharmacy, admissions, and dietary. The CPOE platform is linked to numerous intranet- and Internet-based resources and clinical decision-support tools such as medication dose-range checking, hospital policies, the medication formulary, a discharge summary system, and an Internet search engine. The CPOE system is accessed through fixed and wireless workstations throughout the institution. Each week, 30 000 orders are generated through the system, 90% of which are entered directly into the computer by physicians or advance practice nurses.

Our experience with implementing CPOE in a PICU setting was quite different from that noted by Han et al. Critical care physicians, nurses, and respiratory therapists were heavily involved in our CPOE system design before implementation. Pediatric-specific information (including critical care order sets, pathways for the entry of continuous infusions, and critical care–specific medication dose-range checking) was developed by critical care clinicians and incorporated into the system well in advance of implementation. Workflow incompatibility with the CPOE system was analyzed and deficiencies corrected in advance of implementation. The system was implemented in a stepwise fashion, with entry into the critical care unit only after a successful pilot in a medical unit. Live user support was offered 24 hours/day, 7 days/week, until no longer needed. Ongoing feedback was not only accepted, but was solicited. Other important issues such as optimal workstation (fixed and wireless) numbers and location and standardized nomenclature (ie, centigrade versus Fahrenheit) were addressed before implementation.

Unlike CHP, the CCHMC did not observe a rise in mortality rates in its critical care unit after implementing CPOE. In fact, the raw mortality rate has declined, and the severity-adjusted mortality ratio has remained stable (Fig 1).

The CHP is to be congratulated for adopting an important technology and persevering despite important challenges in their critical care setting. The pediatric community will benefit from the lessons they have learned. The study confirms the importance of having a well-supported plan for adopting and implementing CPOE. Our experience at the CCHMC validates the notion that CPOE can be implemented successfully with numerous benefits and without an adverse impact on mortality rates.

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To the Editor.—

Han et al describe a retrospective study in which the mortality rate for interfacility transfers into an ICU was compared before and after implementation of a computerized provider order entry (CPOE) system. The authors found that the mortality rate increased from 2.8% (30 deaths of 1394 patient transfers during 13 months) before CPOE implementation to 6.6% (36 deaths of 548
transfers during 5 months) after. The authors conclude that the increased mortality was associated directly with modifications in standard clinical processes, including the following changes: (1) not allowing order communication until the patient was physically present and registered in the admitting system; (2) relocating medication dispensing to a central (rather than a satellite) pharmacy; (3) increasing the physical separation of nursing and physician staff during the time that orders were generated; (4) implementing computerized order entry; and (5) system-wide provider role changes to support the CPOE system.

Perhaps the most important lesson from this study is that there exists an intimate association between care-delivery processes and health information technology. Any shift in the methods used to manage patient care (such as implementing and using a CPOE system) is associated with significant changes in clinical workflows, communication among providers, and distribution of responsibilities. Decades of research in medical informatics have underscored the importance of this observation, a message that was not lost on the authors. In this study, they note that the increased unadjusted mortality may reflect problems with the process of change, including the extremely rapid implementation plan adopted by their organization. The authors describe other major changes in workflow and patient care processes that occurred coincident with the CPOE system implementation. For example, their institution changed its policies to prohibit providers from entering patient orders before the patient had physically arrived and had been registered. This change was not a function of the CPOE system but rather of how the institution chose to implement it. The authors list other similar workflow changes that occurred coincident with the CPOE system implementation, such as the elimination of bedside stocks of critical drugs, resulting in the need to request these drugs when needed from a remote pharmacy.

The authors’ findings merit additional scrutiny because, as they noted, there are numerous limitations to the study’s design. The primary study outcome, mortality rates, naturally change over time with trends that are associated with significant changes in clinical workflows, communication among providers, and seasonal variations in disease. In a pre-post single-crossover design, as this study used, there is no way to disentangle trends associated with time from the effects of the CPOE system-implementation process. In cases such as this, investigators must aggressively adjust for all possible measured confounders, taking pains to identify and include all that might reflect changes occurring over calendar time, including seasonal effects, primary diagnoses, a large number of comorbidities, staffing levels, and any changes in care-delivery and hospital-workflow processes. This limitation is amplified by the concern that many of the statistical methods used in this study have known problems that can invalidate apparently significant statistical associations. For observational studies such as this one, in which the number of deaths is limited, the preferred method for adjusting for confounding is propensity score analysis. The propensity model should include all measured confounders regardless of whether they are statistically significant. A more rigorous approach that pays attention to identifying and including all known confounders in an appropriate statistical analysis might influence the outcomes observed in this study. It is also important to realize the very unique population of critically ill children in this study. Interfacility transfers occur under a variety of conditions. Mortality in this group may be a result of factors including suboptimal diagnosis and management at the transferring site, delays in transfer, problems during transit, and other factors remote from the study site.

Implementing health information technology such as CPOE and electronic health record systems is a complex process. In the commentary that accompanied the article by Han et al, Gesteland et al emphasized this lesson: “Deploying a sophisticated clinical-applications platform including CPOE in 6 days is an audacious task and leaves little margin for error in adapting highly evolved work processes to the new environment.” There exist well-established approaches to enabling high-risk organizational change. Untoward effects have been well described when the process is not performed appropriately. Additional studies need to be designed and conducted to understand whether there are unique implications of process change in ICU and other acute care environments and to determine how pediatric health care affects these implications. However, as noted recently by the Institute of Medicine, the preponderance of evidence to date strongly suggests that CPOE systems can reduce medication-related errors of commission and may be useful for improving compliance with errors of omission. Readers of the article by Han et al should not abort plans to implement CPOE systems under the belief that CPOE itself can increase harm; rather, they should proceed with implementations cautiously, applying the lessons about systems implementation learned and published by others. In this regard, a more appropriate title for the article might have emphasized that any increase in observed mortality at the authors’ institution was associated with the process of implementing change rather than with the CPOE system itself.

All systems designed to deliver health care, computerized or not, will fail at certain points. The process for implementing new systems should be designed to identify potential failures and to assure that they do not result in sentinel or catastrophic events. Key steps in the implementation of CPOE systems, for example, should include detailed flowcharted analyses of current and proposed workflow processes, failure analyses con-
ducted throughout the design and implementation process, usability testing in a controlled environment, and a stepwise rollout in which each subsequent institutional unit learns from challenges experienced by the previous unit. Pertinent system evaluations should supplement classic technical software and hardware analyses with human-interface and human-interaction testing. There also should be extensive end-user testing in realistic situations that takes place with a “frozen” software design. Finally, there must be well-designed “break-the-glass” functionality that allows users to do what they think is best for the patient even when the computer system does not allow it (eg, writing orders before a critically ill patient is registered in the hospital).22

The CPOE system-implementation process described by Han et al did not incorporate steps or elements known to ensure system dependability and usability. For example, CPOE systems commonly include tools designed to improve safety and time efficiency, such as “order sets.”23 Order sets allow providers to select and order multiple related items such as medications and diagnostics tests with only a few mouse clicks or keystrokes. According to the authors, their institution chose an implementation approach that did not include order sets, although the commercially available system they implemented offered the ability to construct them. The authors also describe unforeseen technical problems that occurred during the rapid implementation process (eg, overloaded wireless networks that slowed down CPOE systems). Technical problems such as these should have been evident in testing that typically takes place before system implementation.

Over the past 5 years, numerous investigators have outlined case studies documenting successful and failed CPOE implementations.14,24 Many successful implementations have received the Nicholas E. Davies award (these case studies are available at www.himss.org/ASP/daviesAward.asp). Fortunately, there now exists enough shared and published experience with CPOE implementation that each institution should not need to rediscover problems that others have found. However, with the increasing demand for technology infrastructure in medicine, there continues to be an insufficient number of individuals trained in biomedical informatics to provide consultation. Efforts such as the American Medical Informatics Association’s 10 × 10 program and the National Library of Medicine’s short course in medical informatics, fellowship training programs, and career development grants all promise to improve the penetration of informatics knowledge in the pediatric workforce.

Awards such as the Davies award recognize best practices for CPOE and electronic health record system implementation. Ongoing efforts by the Certification Commission for Health Information Technology (CCHIT) are designed to inform purchasers about the quality of commercial systems. These nationally visible products and programs add to the knowledge that can be applied to CPOE and electronic health record system implementation.

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In Reply.—

We appreciate the insightful comments of Longhurst et al, Jacobs et al, and Rosenbloom et al in response to our study findings. They all emphasize the critical importance of careful planning and preparation for successful computerized provider order entry (CPOE) implementation. We wholeheartedly agree. However, these authors also assert that our observations probably resulted from inadequate planning or foresight exercised by the CPOE project team at the Children’s Hospital of Pittsburgh (CHP). Although we cannot, ourselves, refute this assertion, we note that members of CHP’s CPOE project team seemed to have been well aware of the many potential pitfalls that can impede successful CPOE implementation.1 The report by Upperman et al,1 which described in great detail how CPOE was introduced at CHP, suggests that considerable thought and effort went into our institution’s adoption of CPOE technology. This endeavor was rewarded, in fact, with a significant reduction in harmful adverse drug events.2 In this regard we ask, had we not performed our independent investigation specifically examining mortality outcomes, would anyone have questioned the adequacy of the preparations made at CHP? Clearly, debating the potential merits and shortcomings of various CPOE implementation strategies is important and necessary, but we submit that this debate must first proceed with a uniform definition of success. Because the mandate for widespread implementation of CPOE throughout all US hospitals stems from the promise that this technology will save patient lives, we further submit that the realization of this promise should serve as the “gold-standard” definition of success.

Longhurst et al, Jacobs et al, and Rosenbloom et al also seem to make a clear distinction between CPOE and the implementation process, implying that our observation resulted entirely from faulty implementation and not from CPOE technology, itself. Although we acknowledge this possibility in our article, we find it extremely difficult to separate one element from the other. A CPOE system does not operate in isolation, and its proper functioning requires its seamless integration into a strong and dynamic health information technology (HIT) infrastructure. In its broadest sense, implementation encompasses not only solving potential clinical workflow problems but also building this HIT infrastructure, resolving systems-integration glitches, and overcoming machine-human–interface obstacles. Although CPOE, itself, may not be to blame for undesired patient outcomes, a well-designed, well-programmed, user-friendly CPOE software architecture constructed “from the ground up” with a clear understanding of how clinicians think and operate in real-life situations can only serve to facilitate the implementation process. Conversely, a general, minimally modifiable, clinically awkward CPOE platform may require considerable creative efforts to “retrofit” this technology into operational form. Although CPOE, itself, may not be at fault for network problems related to ever-present threats from Internet worms and viruses, the vulnerability or resilience of a specific CPOE platform and its HIT infrastructure to properly function during periods of attack and after firewalls and other network security upgrades have been installed seem to be considerations intrinsic to the adoption of this technology.

Rosenbloom et al caution careful interpretation of our data because of inherent limitations of study design and raise questions regarding the statistical approach used. We have openly acknowledged and enumerated our study’s limitations and share in their sentiment to cau-
tiously interpret our data. We remain unclear, however, how our results might be invalid, because we have performed a well-accepted method of regression analysis. Still, to appease their criticism of our approach, we have subsequently performed a propensity score analysis as requested. Propensity scores were generated with CPOE as the dependent variable and with all of the variables listed in Table 1 of our article, except for Pediatric Risk of Mortality (PRISM) score, as independent variables. The propensity scores were then recorded into deciles, and a logistic-regression model was fitted using CPOE, decile group, and the interaction between CPOE and decile group as predictors of mortality. The interaction between CPOE and decile group was not found to be significant and was subsequently dropped from the model. Results then indicated that CPOE was significantly associated with increased odds of mortality (odds ratio [OR]: 2.420; 95% confidence interval [CI]: 1.508–3.883). The addition of PRISM score into this regression model continued to demonstrate increased odds of mortality (OR: 3.130; 95% CI: 1.848–5.302).

We applaud Jacob et al for continuing to monitor mortality outcomes (a practice we strongly support) after CPOE implementation at their institution. We find it very reassuring that they observed no increase in PICU mortality after using a different implementation strategy (and different CPOE platform). The CPOE project team at Cincinnati Children’s Hospital Medical Center should be commended for their diligence and their particular attention devoted to tackling the unique challenges of the PICU environment. On the other hand, if we are permitted to briefly play “devil’s advocate,” it seems that severity-of-illness–adjusted mortality rates did not substantially improve after CPOE implementation, either. As fellow pediatric intensivists, Jacobs et al should be well aware of the excitement after the publication of the adult clinical trials of drotrecogin alpha for severe sepsis that showed significant improvements in survival.1 In contrast, the pediatric clinical trials were terminated recently because similar survival benefits could not be demonstrated among children. Although drotrecogin alpha has received Food and Drug Administration approval as a treatment for adults with severe sepsis, this approved indication has not been extended to the pediatric population.

We wish to make it clear that despite our unexpected study results, we continue to believe that CPOE holds great promise as a tool to improve patient care and save lives, and we reject any proposal that calls to abandon this important technology. At the same time, the excellent points made by Longhurst et al, Jacobs et al, and Rosenbloom et al reinforce our impression that the very complexity of CPOE technology and its implementation requires a thorough, organized, systems approach to adequately address their many concerns and may be best resolved through carefully designed, multicenter trials supported by the National Institutes of Health and/or Food and Drug Administration. If the HIT community finds this suggestion unfeasible or unreasonable because of the unique nature of computer/software technology, another approach may be to examine how the aviation industry, long considered a model industry for maintaining high safety standards, has addressed the incorporation of these technologies into its field. We note that Federal Aviation Administration oversight ensures the mission-critical reliability of any new computer-related device or software throughout all US airport control towers. Alternatively, an independent self-governance HIT body analogous to the American Board of Pediatrics, for example, might provide another means to certify the proper deployment of CPOE.

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Failure to Thrive as Distinct From Child Neglect

To the Editor.—

As pediatricians and psychologists who have conducted research involving children with failure to thrive (FTT) and/or treated literally thousands of children with FTT, we wish to share our concerns regarding the report “Failure to Thrive as a Manifestation of Child Neglect”1 from the American Academy of Pediatrics (AAP) Com-