By Barry P. Chaiken, MD, FHIMSS

Transparency: For All Eyes Only

One early morning in September 1982, a 12-year-old girl awoke in her home in the outskirts of Chicago with moderate cold symptoms. Her loving parents prepared a tall glass of water and one Extra Strength Tylenol® capsule for her to take before sending her back to bed. A few hours later, Mr. and Mrs. Kellerman awoke to find their daughter Mary critically ill on the bathroom floor. Her parents rushed her to the hospital, and she died a short time later.

That same day, Adam Janus of Arlington Heights died unexpectedly in that same hospital. Soon afterward, his brother Stanley and wife Theresa died after gathering to mourn and taking pills from the same bottle used by Adam. Both Paula Prince and Mary Reiner from the Chicagoland area died under similar conditions. Fortunately, investigators discovered the Tylenol link and began broadcasting urgent advisories. Chicagoland police even drove through neighborhoods issuing warnings over loudspeakers.

Analysis of the facts of the case quickly pointed to product tampering as the cause of the poisonings. Wikipedia describes the events of the case as follows:

> As the tampered bottles came from different factories, and the seven deaths had all occurred in the Chicago area, the possibility of sabotage during production was ruled out. Instead, the culprit was believed to have entered various supermarkets and drug stores over a period of weeks, pilfered packages of Tylenol from the shelves, adulterated their contents with solid cyanide compound at another location, and then replaced the bottles. In addition to the five bottles which led to the victims' deaths, three other tampered bottles were discovered. Johnson & Johnson, the parent company of McNeil, distributed warnings to hospitals and distributors and halted Tylenol production and advertising. On October 5, 1982, it issued a nationwide recall of Tylenol products; an estimated 31 million bottles were in circulation, with a retail value of over US$100 million. The company also advertised in the national media for individuals not to consume any products that contained Tylenol. When it was determined that only capsules were tampered with, they offered to exchange all Tylenol capsules already purchased by the public with solid tablets.

Response to a Crisis

Public relations experts often describe the response of Johnson & Johnson to this crisis as the gold standard on how companies should act when confronted with the competing interests of public safety and company profits. At the time of the tampering, Tylenol saw its market share of over-the-counter pain medications drop from 38% to 8%. In less than a year, its market share rebounded to pre-event levels, a move credited to Johnson & Johnson's prompt, aggressive, and credible response to the crisis. Initially, Johnson & Johnson changed its packaging to include a triple seal. After tampering events in subsequent years,

Only by embracing a high level of transparency was Johnson & Johnson able to weather their catastrophic Tylenol event.

Johnson & Johnson, as well as other companies, abandoned the capsule for the tamper proof caplet formulation. Only by embracing a high level of transparency—honest, informative, and timely communication with the public—was Johnson & Johnson able to weather their catastrophic Tylenol event, rebuild its trust with the public, and over time, innovate to introduce the caplet, a safer drug delivery formulation.

As healthcare deploys information technology in an effort to make care delivery safer and less expensive, provider organizations and vendors must consider the inevitable—an error in embedded clinical content (e.g., clinical decision support algorithms), software deployment, or application coding leading to a catastrophic patient outcome.

Reviewing research by Ash et al. (2007) that evaluated the impact of provider order entry on care, it is reasonable to assume that bad outcomes have already occurred and continue to occur, caused by problems with the implementation and use of clinical IT systems. Yet as we race to deploy these systems, few provider and vendor organizations embrace active forums and related processes that can identify and analyze these errors, develop corrective actions to prevent their reoccurrence,

and formulate a means to communicate the findings to other organizations in an effort to prevent a repeat of events.

Currently provider organizations struggle with transparency issues associated with medical errors. What is to be disclosed? How is it done? What are the risks to the organization or its providers? What about malpractice liability? The industry is working through these issues by embracing greater honesty and open communication, but the acceptance of full transparency among provider organizations advances slowly.

These issues only become more challenging through the complexity imposed by clinical health IT systems. In addition, these systems collect more data, more accurately, and allow for better identification of errors and the events that lead up to them. Our industry now faces an increasing problem of how to address these errors. In the near future, the mounting pressures imposed by patients, payers, and government will force this issue into the forefront, requiring an effective response by both provider organizations and HIT vendors.

Learning from Errors

As more clinical HIT systems facilitate the care of more patients, the risk grows that a system error will generate a poor outcome in multiple facilities using that system. In turn, it is likely that such a system error will injure numerous patients before being identified as the source of the problem. Without a means to share experiences, a facility that corrects a problem internally has little chance of transferring that knowledge to other organizations. Therefore, lessons learned have little if any chance of actively being shared on a timely basis to prevent future injuries. Each organization is left on its own to learn through trial and error, benefiting little if any from the challenges overcome by similar organizations.

Both provider and vendor organizations need to establish event repositories that document errors and near misses. Rather than focus narrowly on the single event, the error must also be looked at in the context of the entire clinical IT system including the workflow, interfaces, and embedded clinical content. These events can then be shared with the vendor to develop evidence-based best practices from these lessons learned. The accrued database of events then provides a basis for how best to implement technology. This then can be shared with both existing and future clients.

Without a means to share experiences, a facility that corrects a problem internally has little chance of transferring that knowledge to other organizations.

Only a strong relationship among provider organizations and their vendors can achieve this. Vendor organizations must empower their clinical leadership (e.g., CMO, CNO) to stand firm against product designs that have the potential to do harm. These clinical leaders, similar to chief safety officers in manufacturing plants, must put the safety of patients first, just the way senior management of Johnson & Johnson put its customers' safety first. Vendor organizations can then work to modify their products to address workflow issues that may lead to errors. In addition, clinical content can be changed to reflect best practices.

As in the Tylenol case described above, honest transparency need not destroy an organization. Effective communication, collaboration with partners, and a focus on continuous improvement leads to a stronger and more successful organization. In addition, we achieve the added benefit of making care safer. PSQH

Barry Chaiken *is the chief medical officer of DocsNetwork, Ltd. and a member of the Editorial Advisory Board for* Patient Safety & Quality Healthcare. *With more than 20 years of experience in medical research, epidemiology, clinical information technology, and patient safety, Chaiken is board certified in general preventive medicine and public health and is a fellow, board member, and chair-elect of HIMSS. As founder of DocsNetwork, Ltd., he has worked on quality improvement studies and clinical investigations for the National Institutes of Health, Framingham Heart Study, and Boston University Medical School. Chaiken also serves as an adjunct assistant professor in the Department of Public Health and Family Medicine at Tufts University School of Medicine. He may be contacted at bchaiken@docsnetwork.com.*

References

1982 Chicago Tylenol murders. (2008, September 29). In *Wikipedia, The Free Encyclopedia.* Retrieved 18:25, September 30, 2008, from http://en.wikipedia.org/w/index.php?title=1982_Chicago_Tylenol_murders&oldid=241814668

Ash, J. S., Sittig, D. F., Poon, E. G., Guappone, K., Campbell, E., Dykstra, R. H. (2007). The extent and importance of unintended consequences related to computerized provider order entry. *JAMIA, 14,* 415-423.

Further Reading

Chaiken, B. P. (2001). Enhancing patient safety with clinically intelligent physician order entry. *Nursing Economics, 19*(3), 119-120.

Chaiken, B. P. (2001). Evidence-based medicine: A tool at the point of care. *Nursing Economics, 19*(5), 234-235.

Chaiken, B. P. (2002). Clinical decision support: Success through smart deployment. *Journal of Quality Health Care, 1*(4).

Chaiken, B. P. (2007). Healthcare IT solutions. In K. H. Cohn & D. E. Hough (Eds.), *The Business of Healthcare, Vol. 3, Improving systems of care.* Westport, CT: Praeger, 119–141.

Chaiken, B. P. (2007). Revolutionary HIT: Cure for insanity. *Patient Safety and Quality Healthcare, 4*(6), 10-11.

Chaiken, B. P., & Holmquest, D. L. (2002). Patient Safety: Modifying Processes to Eliminate Medical Errors. *Journal of Quality Health Care, 1*(2): 20-23.

Effective crisis management: The Tylenol crisis 1982. Available at http://iml.jou.ufl.edu/projects/Fall02/Susi/tylenol.htm