Can a Log of Infusion Device Events Be Used to Understand Infusion Accidents?

Yuval Bitan, PhD and Mark E. Nunnally, MD

Objective: This study sought to determine whether infusion device event logs could support accident investigation.

Methods: An incident reporting database was searched for information about log file use in investigations. Log file data from devices in clinical use were downloaded and electronically searched for characteristics (signatures) matching specific function queries. Different programming sequences were simulated, and device logs were downloaded for analysis.

Results: Database reports mentioned difficulties resolving log file data to the incident report and used log file data to confirm programming failures. Log file search revealed that, aside from alarm types and times, the devices were unable to adequately satisfy functional queries. Different simulated programming scenarios could not be easily differentiated by log file analysis.

Conclusions: The device logs we studied collect data that are poorly suited to accident investigation. We conclude that infusion device logs cannot function as black boxes do in aviation accidents. Logs would be better applied to assist routine operations.

Key Words: patient safety, infusion devices, incident reporting, data recording, accident investigation

(*J Patient Saf* 2007;3:208–213)

If the ultimate goal of incident analysis is accident prevention, the challenge is to learn from each event. Accordingly, certain industries have sought ways to improve collection and interpretation of accident data. When the methods are successful, detailed investigations can be made from the data. However, collection, organization, and the ultimate interpretation of data are complex functions with design requirements that surface only after long evaluative processes.

As an example, commercial aviation developed and refined the "black box" to record detailed event data from aircraft functions and crew activities. Originally developed in the mid 1950s, this technology continues to evolve with investigator experience.[1] The black box includes a flight data recorder and cockpit voice recorder. The two record simultaneous complementary data to assist aviation accident investigations. Currently, devices in commercial aviation have evolved to track at least 88 variables for review[2] but can track up to 700.[3] This capability is the result of multiple improvements both in technology and insight into the information needed to understand the circumstances of an accident.[4] The records have become important elements in the investigation of commercial aviation accidents. They provide a context for review of the elaborate circumstances and latent problems that are common in complex system failure.[5]

Proven techniques and devices, such as the black box, might leverage previous success to a new domain. In medicine, accidents involving infusion devices occasionally lead to patient disability or death,[6] and there is a professional[7] and regulatory[8] interest in investigating their causes. Devices available today possess logs that record use activity. Given the role the black box has taken in aviation, similar technologies might work well in health care. Government[9] and industry[10] have considered existing device event logs as tools for accident investigation, and log files constitute an important part of event reporting in the device-incident database of Food and Drug Administration's Manufacturer and User Facility Device Experience Database (MAUDE).[11] Although modern aircraft and medical infusion devices both possess data recorders, their abilities to assist an accident investigation are very different because of the ways data are collected and used in each domain. Aviation investigations succeed because they uncover complex details. The experience with infusion device logs is less well characterized.

Our investigation is a functional analysis of 1 device log. Our previous investigations[12,13] have used videotaped simulations and incident reporting databases to characterize the way users interact with devices. We relied on some of these techniques and also a set of systematically produced questions about the use of event recorders to evaluate their ability to support accident investigations. By analyzing log contents and use and through simulation, we illustrate the shortcomings of a good idea misapplied to a new domain. We hypothesized that logs of modern infusion devices lack the design elements necessary to enhance accident investigation. Our goal was to describe what the logs can and cannot show and how these factors contribute or detract from accident investigation.

METHODS

This study was performed with a modern commercially available infusion device. All pumps had a standard basic software configuration. None of the devices was programmed with a drug library. Log file reports were taken from devices in use in a pediatric intensive care unit (PICU) at a teaching hospital in the United States. Simulations were performed under controlled conditions. Device logs were accessed

From the Department of Anesthesia and Critical Care, University of Chicago Medical Center, Chicago, Illinois.

Correspondence: Mark E. Nunnally, MD, Department of Anesthesia and Critical Care, University of Chicago Medical Center, 5841 South Maryland Ave, MC 4028, Chicago, IL 60637 (e-mail: mnunnall@dacc.uchicago.edu).

through a standard laptop personal computer connected with a cable and with software provided by the manufacturer. All simulated pump programming was performed by one of the authors and videotaped for review.

Log File Data

The log file data from 28 infusion pumps were studied. The pumps, in a PICU during August and September 2005, were used for a variety of infusion practices, including volumetric delivery of intravenous fluids and drugs, and weight-based drug delivery.

Queries were composed about the process of drug infusion. The goal of the queries was to understand the context and vulnerabilities of the infusion situation.[14] The infusion process was broken into 3 components: ordering, programming, and delivery. Each has its own specific vulnerabilities. Ordering is a "prepump" activity but should be accounted for during a functional analysis of the infusion process. Two queries concerned the ordering process: "What infusions were being delivered?" and "Did the infusions comply with written orders?" Programming translates what the user intends to do into a "language" the infusion device can understand. Logs cannot be expected to record users' intentions, but logs can capture detailed programming information. Our query for programming was, "How was the device programmed?" Delivery was analyzed by looking at the disposition of programs once they were run. A program may run to completion, be modified while running, or be stopped manually or by an alarm. Analysis starts with basic information, drug, dose, and rate before the clinical context is considered. Six of the questions ask for narrow facts about the infusions and explore contextual information. The remaining 2 questions were composed to address specific clinical concerns: response to alarms and piggyback (secondary) infusions, which have been the subject of previous research.[13,15] To extract the details from the log files, screening software was developed by one of the authors using Microsoft Visual Basic (Microsoft Corporation, Redmond, Wash) to track and record specific log entry characteristics (signatures) that supported the specific query. Many queries proved to be highly academic because they required contextual information not available in the device logs. The queries were as follows:

Question 1. What infusions were being delivered? A basic understanding of the purpose of an infusion is useful. The devices did not record drug names, but rates, volumes to be infused, and changes in infusions might provide useful information about the type of infusions that were delivered.

Question 2. Did the infusions comply with written orders? Ideally, in the event of an accident investigation, other sources of data are available. Information on orders and policies help describe the circumstances of an event. The device logs currently have no way to record this information.

Question 3. When were the infusions started? The total number of starts was identified, as were the total number of hours of drug delivery, using the timekeeping feature of the device logs.

Question 4. When were the infusions completed? The survival of a program to infusion completion could mark efficiency or relative patient stability. Alarm-associated stops suggest difficulties with tubing and setup, venous access, or programming.

Question 5. Why, if an infusion was not completed, did it stop? The disposition of all programs was sought to account for all infusion activities. These data represent the activities that deviate from a "natural" infusion disposition (setup to program to run to complete) and likely result from complex circumstances in the working environment that constantly degrade simple activities into less organized operations.

Question 6. How was the device programmed? Previous research[12] suggested variability in programming methods. Different users find their way to the correct program by different sequences of keystrokes. This variability is an artifact of the flexibility and complexity of the devices and suggests mechanisms causing failures. This question explores these possibilities in an accident investigation.

Question 7. Was an infusion drug changed? It is important to know what is connected to the infusion pump. Medication, tubing, splices, and even bag height play important roles in what comes out at the end of the pump cassette. The device is not capable of understanding these details, so this question is largely academic.

Question 8. When did the device alarm, and why? Alarms are a specific response to a set of circumstances. Although alarms themselves are easily quantified, the circumstances leading to their trigger are not. Alarm data mark interruptions and might suggest circumstances that contribute to the interruption.

Question 9. How was the problem that caused the alarm remedied? The answer to this question is not searchable in the logs, so it is largely academic.

Question 10. How many piggybacks were delivered? Previous research on piggybacks[10] highlighted the unique hazards that accompany this use of the pumps. Piggyback signatures were sought and accounted for.

Incident Report Analysis

The Food and Drug Administration keeps a database for adverse event reports involving medical devices. This database, MAUDE, is free on the Internet and includes reports for infusion devices.[11] We found 330 entries for the study device between March 22, 2005, and March 24, 2006. Reports were individually screened for the mention of the use of log or device history, and those reports were reviewed separately. All reviewed reports were for the same generation device as the one used in the PICU.

When investigating the MAUDE reports for log file data, it was important to characterize not just what the logs could show but, more importantly, what they could not. It was anticipated that log file data would be deficient in circumstantial information. Aside from tabulating the type of information available by comprehensive search and review, individual reports were analyzed in detail. Specifically, each report contains several accounts from different perspectives.

Each perspective takes into account not just expertise but reporting priorities. Some contain a user summary of events in which someone proximal to the incident gives a detailed event account. Manufacturer summaries provide an explanation of the reported behavior. Log file data are explained in the manufacturer summary. Reports were searched for details of the order of programming and for speculation about the way a wrong entry might have been made (e.g., a wrong key press or an incorrect calculation). The ways log file data were used to support an investigation illustrate how device logs contribute to the investigative process.

Simulated Programming Processes

Because the way a device is programmed to deliver an infusion can influence the evolution of a programming failure or adverse event, different calculation and programming methods were simulated. The order in which the pump acquired information was changed to reflect different ways to create the same infusion program, and the generated log files were compared.

Two different drug delivery tasks were simulated. For each, a calculation is required to convert dosing parameters into the common volumetric "language" of the device. The first programming objective was to deliver 1 liter of "normal saline" over 8 hours, requiring a rate calculation (125 mL/h). In the second, a "dopamine" concentration of 400 mg in 250 mL of solution was supposed to infuse at a rate of 3 μg/kg per minute in a 70-kg patient (rate = 7.94 mL/h). This step requires a rate calculation that takes into account drug concentration and patient body mass.

The infusion device permits different methods of programming in the same mode. Figure 1 demonstrates the interface screen for a volume over time infusion. In this type of program, the interface permits the entry of infusion rate, volume to be infused, and infusion duration. Entry of any 2 of the 3 parameters will result in device calculation of the last because they are interdependent. For the drug dosing example, total drug in the infusion bag, volume of solution, patient body mass, delivery rate, volume to be infused, and infusion rate can each be entered independently; when sufficient information is available, the pump can calculate the other variables. Each scenario was programmed under 2 different circumstances. In the first, the basic parameters were entered into the device, and the microprocessor was allowed to calculate the end infusion rate. For the second, the infusion rate was independently calculated and entered. After the simulations, the device infusion logs were compared to see if the different methods of programming were reflected in the electronic record.

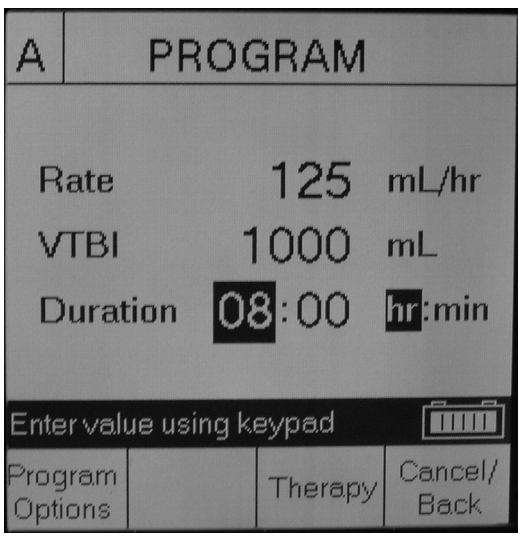

FIGURE 1. User interface screen for a volumetric infusion. Relevant variables are displayed.

RESULTS

Log File Data

The studied devices had no way of tracking compliance with orders (Question 2) nor whether a drug had been changed (Question 7) and could provide little data about corrective measures in the event of an alarm (Question 9). Furthermore, the devices tested logged only the end result of a programming sequence, not the individual keystrokes in the programming process or the pathways used by the programmer, so Question 6 was largely academic. The answers to the other queries are presented below:

Question 1. What infusions were being delivered? Because the devices studied did not have drug libraries, there was no way for the device to "know" what sort of drug was being infused. Of the programs identified, 602 were primary infusions, and 15 were piggybacks.

Question 3. When were the infusions started? The log files studied covered an average of 30 hours of pump operation, with a range of 5 to 63.5 hours. There were 617 program starts. Start times were recorded for each start.

Question 4. When were the infusions completed? Of the 617 infusion starts, 115 (18.6%) ran to completion as documented in the log files. An additional 430 infusions (69.7%) were stopped concurrent with alarms. The remaining programs were interrupted manually. In the case of the programs that ran to completion, all the pumps reverted to a low-flow state (keep volume open). For alarms and command stops, we could not reliably trace the circumstances of the stoppage nor understand the results of the stoppage.

Question 5. Why, if an infusion was not completed, did it stop? Contextual data related to new orders, changes in patient condition, and various working circumstances would enrich any analysis of these activities. The device logs record none of these data. There were few clues as to why the pumps were stopped.

Question 8. When did the device alarm, and why? Alarm data were very well logged in the devices. There were a total of 430 alarms in the 812 hours of pump infusion time, an average of an alarm every 1.89 hours. A breakdown of the types of alarms is provided in Table 1. "Distal occlusion" was the most common alarm [161 (37.4%)]. Aside from the specifications for alarm trigger, the situation-specific circumstances of the alarm were not available.

TABLE 1. Alarm Distribution from the Log Files of 28 Infusion Pumps in Clinical Service for Approximately 1 Month

Alarm Message		Description	No.
N186	Distal occlusion	Distal occlusion detected (peak detection algorithm)	161
N161	Line A VTBI complete	Line A volume to be infused (VTBI) has reached zero	105
N102	Infuser idle, 2 min	No fluid delivery or operator input for 2 min outside of line A or line B delivery screens	68
N232	Prox Air A, backprime	Air detected in proximal line	18
N183	Prox occl B at startup	Proximal occlusion detected on line B during backprime (when the device pumps to clear the cassette) (peak detection algorithm)	17
N188	Prox occl B/air	Proximal occlusion detected on line B (negative detection algorithm)	15
N251	Cassette test failure	Valve or cassette failed startup leak test	13
N160	Line B VTBI complete	Line A VTBI has reached zero and is not a piggyback	10
N250	Door open while pumping	Cassette holder opened while infusing	5
N101	No action alarm	No operator input for 2 minutes when delivery parameters have been entered or modified	4
N185	Prox occl A at startup	Proximal occlusion detected in line A during backprime (peak detection algorithm)	4
N231	Prox air B, backprime	Proximal air in line on line B	3
N180	Distal occlusion	Distal occlusion detected during cassette test (peak detection algorithm)	2
N233	Distal air	Cumulative distal air	2
N234	Distal air	Distal air bolus	2
N189	Prox occl B/air	Proximal occlusion detected on line B (peak detection algorithm)	1
TOTAL			430

Question 10. How many piggybacks were delivered? We found 61 piggyback starts in the device logs. Of these, 23 ran to completion (38%), and 38 did not. Of the completed piggybacks, in 13 cases, the pumps automatically reverted to a previous infusion program (57%), whereas 10 alarmed and reverted to a low flow infusion. There was no information about the type of piggyback.

Incident Report Analysis

Of the 330 MAUDE reports, there were 37 (11.2%) that made use of log file data. Of particular interest were data that provided useful clues about the cause of an incident and data use that was clearly attributive. In the case of the latter, there were several statements that appeared frequently. Most prevalent was the following statement: "delivered as programmed." This statement was in 18 reports (5.5%). Attributions of operator error, phrased as "result of operator error" or "probable…error" occurred in 12 cases (3.6%).

Reports frequently highlighted discrepancies between log data and user reports. Seven manufacturer summaries noted a difference between the log clock and actual time at the site of the event. For 2 incidents, the manufacturer merely asserted that the log data did not correlate with the account of the event, without providing further data. One discrepancy mentioned by the manufacturer included recorded use of a different infusion channel than that mentioned in the narrative. In 4 other cases, the memory buffer of the log had been overwritten because of use subsequent to the event, so there were no data to evaluate. Two reports showed discrepancies regarding alarms. In one, the user reported an alarm that subsequently did not appear in the device log. In the other, both the log file and user account mentioned an alarm, but the manufacturer was unable to simulate the alarm in question (the alarm was an "audio alarm failure" accompanying a delivery stoppage that also could not be replicated). Date discrepancies were found in 2 cases; in both, the manufacturer provided no further log data to help explain the incident.

```
10/31/06 16:00 STOP Delivery: A, VI= 0.1
10/31/06 16:00 Line A: Program: Stopped
10/31/06 16:00 Line A: Dose: 10.077
10/31/06 16:00 Line A: Duration: 13:17
10/31/06 16:00 Line A: Rate: 18.8, VTBI:250
10/31/06 16:00 Line A: Step 1
10/31/06 16:00 Patient Wt: 50.0 Kg
10/31/06 16:00 Drug A Conc: 400.0, Dil: 250.0
10/31/06 16:00 Drug A Conc Units: mg
10/31/06 16:00 Line A: Dose Units: mcg/kg/min, Max D.P.:6.0 PSI
10/31/06 16:00 Line A: Callback: No
10/31/06 16:00 Line A: Dose Calc therapy
10/31/06 16:00 Delivery Started

09/27/06 14:46 Line A Program: Stopped
09/27/06 14:46 Line A: Duration: 08:00
09/27/06 14:46 Line A: Rate: 125, VTBI:1000.0
09/27/06 14:46 Line A: Step 1
09/27/06 14:46 Line A: Dose Units: mL/hr, Max D.P.:6.0 PSI
09/27/06 14:46 Line A: Callback: No
09/27/06 14:46 Delivery Started
09/27/06 14:46 Line A: Start mL/hr delivery
09/27/06 14:46 Line A Program: Delivering
```

```
10/31/06 15:59 STOP Delivery: A, VI= 0.0
10/31/06 15:59 Line A: Program: Stopped
10/31/06 15:59 Line A: Dose: 10
10/31/06 15:59 Duration: 13:17
10/31/06 15:59 Rate: 18.8, VTBI:250
10/31/06 15:59 Line A: Step 1
10/31/06 15:59 Patient Wt: 50.0 Kg
10/31/06 15:59 Drug A Conc: 400.0, Dil: 250.0
10/31/06 15:59 Drug A Conc Units: mg
10/31/06 15:59 Line A: Dose Units: mcg/kg/min, Max D.P.:6.0 PSI
10/31/06 15:59 Line A: Callback: No
10/31/06 15:59 Line A: Dose Calc therapy
10/31/06 15:59 Delivery Started

09/27/06 14:46 Line A Program: Stopped
09/27/06 14:46 Line A: Duration: 08:00
09/27/06 14:46 Line A: Rate: 125, VTBI:1000.0
09/27/06 14:46 Line A: Step 1
09/27/06 14:46 Line A: Dose Units: mL/hr, Max D.P.:6.0 PSI
09/27/06 14:46 Line A: Callback: No
09/27/06 14:46 Delivery Started
09/27/06 14:46 Line A: Start mL/hr delivery
09/27/06 14:46 Line A Program: Delivering
```

FIGURE 2. Log file records of programming with 2 different sequences. In the left column, the final pump rate is calculated by the infusion device after the other variables are entered. In the right column, the rate is programmed instead of the last variable. Observable differences indicate different volumes infused (VI) and different decimal estimates of dose (<1% difference).

Simulated Programming Processes

The logs from the dopamine simulation are displayed in Figure 2. The logs showed the end result of the infusion that was delivered but provided no information on the programming process that led to it. The logs do not specify which data were entered and which were automatically calculated by the device. As a consequence, they reported almost identically for the 2 circumstances. It was not clear what the dependent and the independent variables were. The same is true for the logs for volumetric infusion (1 liter over 8 hours). There was no indication of how the infusion was conceived, configured, or calculated, not to mention any indication of what was going on at the same time the pump was programmed.

DISCUSSION

Infusion device logs are not black boxes for medication safety; they cannot be expected to be. Our functional analysis demonstrates that the event log studied is difficult to obtain, lacks essential contextual information, and is conceptually unsuited to fulfill the role for which it has been promoted. Flat and narrow facts are well recorded but do little to reproduce the details that would be helpful to an accident investigation.

This project looked at 1 device. There are several different brands and models of infusion devices in use today that make use of event logs. Comparing these models with each other or with an "ideal" log would extend and validate the findings published here. Unfortunately, an "ideal" model is not readily available. It is worth pointing out several key flaws to event logging that limit the technology's value for the purposes of accident investigation. Any "ideal" would need to overcome these shortcomings.

1. The device sees the world in a constrained fashion. Modern infusion devices offer users only a "keyhole" perspective of their complex programming pathways. Similarly, the logs of device events reflect the infusion situation through a constrained keyhole. The devices operate during periods of changing physiology, opposing priorities, and data overload. They perform a simple function, to pump fluid at a specific rate. The interface between this simple function and the complex world in which it occurs has 2 parts. One is the actual pump interface, responsible for translating a pumping rate into meaningful dose equations and relevant infusion limitations. The other is the human programmer who translates this function into a broader clinical context and maintains reliable operations under adverse circumstances. The infusion log has no way of gathering or processing the activities that operate at this interface. As a result, log data from an individual infusion device will be a sterile and myopic representation of a mundane process.
2. Device logs support "error" analysis. Logs capture technical information and alarms very well. A log reveals the rate at which a medication was pumped very reliably. Although not at all supportive of contextual analysis, these data point out exactly where something was "wrong," supporting an assertion of "error" often attributed to operators.[16–18] With the error assertion, discourse and investigation into contributing factors frequently end, retarding fuller understanding.
3. Event logs and subsequent accident analyses have been the responsibility of manufacturers. Manufacturers do not have the resources to do in-depth investigations of every alleged adverse event. They are interested parties and, therefore, cannot be expected to be objective assessors. What they can do is what this analysis has shown: logs support the reliability of devices and provide data to suggest that users misuse them. They support the contention that manufacturers must protect devices from unreliable users but do nothing to help solve difficulties with the device interface and workplace complexities.
4. Logs record what happened, not what did not. Previous research has demonstrated extensive programming activities that do not result in the final program.[12] In a study of routine tasks performed and videotaped, users made more than twice as many keystrokes to program the device than were necessary, an opportunity for failures in programming. Programming activities can be very different from the activities on the logs. The device log we studied does not show keystroke information. It does not provide information on aborted programs that could represent "near misses." Even if it did, it would not necessarily help explore the problems that practitioners struggle with to use these devices. Finding these problems requires techniques to evaluate cognition in a natural environment.[19–21]

In the case of the aviation black box, the simultaneous recording of multiple variables and cockpit conversations attests to the importance of parallel complementary data. The way aviation's flight data recorder and cockpit voice recorder work is not currently reproducible in the medical setting. Aviation recorders are integrated into the entire flight task; integration is not yet possible for infusion devices because they operate in a stand-alone mode. There is no single dashboard that integrates all data.[22] If, as with medical devices, the operations of 1 component of a plane, such as the landing gear or a passenger lavatory, were the only available data, one might find interesting clues about what was going on during an event but be challenged to determine the entire story.

What would an ideal event log look like? Given the concerns raised above, we suggest that the logs should be better suited to help users in real time, rather than support flawed retrospective analyses. They should be easy to access and read. They could help with activities like charting or pharmacy ordering. They could anticipate and provide useful reminders, like the need to check fluid levels or line status. Interestingly, traditional transportation black boxes are beginning to be used for routine operations. Modern flight recorders make use of data for maintenance queries.[4] Nautical navigation recorders are now configured to provide real-time display information and assist in routine reports and performance monitoring.[23] Above all, infusion device logs must integrate into high-order patient care activities without coupling complex processes, making multisystem failures more likely.[24] To our knowledge, no infusion device in current use has logs with this sort of capability.

Our data are rightfully subject to several criticisms. We base our conclusions on a detailed study of only 1 device. However, because all pumps are stand-alone devices, our findings and conclusions, especially regarding the lack of data integration, are likely pertinent to many different recording log systems. Our investigations did not consider additional features that are promoted to improve safe use, including drug libraries and dose limitation software, but we believe that these features still do nothing to satisfy the flaws we have discussed.

CONCLUSIONS

In conclusion, we have demonstrated that logs recording infusion device events can provide specifics about the history of infusions for a given device but do not provide data well suited to accident prevention. To improve safety, significant innovation is required that should be tested with real events. If their purpose is safety, device logs need to be rethought. Currently, the existing designs fulfill the needs of manufacturers while largely ignoring the complex operations of practitioners. A better purpose for these logs might be to facilitate operations and provide feedback to users.

REFERENCES

1. Australian Government, Department of Defense. Dave Warren—Inventor of the black box flight recorder. [Defense Science and Technology Organization Web site]. Available at: www.dsto.defence.gov.au/page/3383. Accessed November 17, 2006.
2. National Transportation and Safety Board. Cockpit Voice Recorders (CVR) and Flight Data Recorders (FDR). [NTSB Web site]. September 2004. Available at: www.ntsb.gov/aviation/CRV_FDR.htm. Accessed November 17, 2006.
3. Bonsor, K. How Black Boxes Work. [How Stuff Works Web site]. Available at: www.howstuffworks.com/black-box.htm. Accessed November 17, 2006.
4. History of Flight Recorders [L3 communications Web site]. Available at: http://www.l-3ar.com/html/history.html. Accessed November 17, 2006.
5. Crash of Eastern Airlines Flight 401. A burnt out light bulb leads to a major disaster. Available at: http://freshgasflow.com/flight401.htm. Accessed November 17, 2006.
6. Joint Commission on Accreditation of Healthcare Organizations (JCAHO). Sentinel Event Alert 15. Infusion Pumps: Preventing Future Adverse Events. [JCAHO Web site]. November 30, 2000. Available at: www.jointcommission.org/sentinelevents/sentineleventalert/sea_15.htm. Accessed November 17, 2006.
7. Samore MH, Evans RS, Lassen A, et al. Surveillance of medical device–related hazards and adverse events in hospitalized patients. *JAMA*. 2004;291:325–334.
8. Joint Commission on Accreditation of Healthcare Organizations. *Root Cause Analysis in Health Care: Tools and Techniques*, 3rd ed. Chicago: JCAHO; 2005.
9. Australian Government. *TGA News*. Issue 47, July 2005.
10. Squires M, Biesiada D, Fanizza R, et al. New approaches to improving patient safety: strategy, technology and funding. *Healthc Q*. 2005;8:120–122, 124.
11. Federal Drug Administration (FDA). MAUDE database. Available at: http://www.fda.gov/cdrh/maude.html. Accessed November 17, 2006.
12. Nunnally M, Nemeth C, Brunetti V, et al. Lost in Menuspace: user interactions with complex medical devices. Special Issue on Studies in Healthcare Technical Work. *IEEE Trans Syst Man Cybern*. 2004;34(part A):736–742.
13. Nunnally ME, Bitan Y. Time to get off this pig's back? The human factors aspects of the mismatch between device and real world knowledge in the health care environment. *J Patient Saf*. 2006;2:124–131.
14. Albolino S, Cook R. Making sense of risks: a field study in an intensive unit. In: Tartaglia R, Bagnara S, Bellandi T, Albolino S, eds. *Healthcare Systems Ergonomics and Patient Safety*. London: Taylor and Francis; 2005:208–214.
15. Meyer J, Bitan Y. Why better operators get worse warnings. *Hum Factors*. 2002;44:343–353.
16. Cook R, Woods D, Miller C. *Tale of Two Stories: Contrasting Views of Patient Safety (Report from a Workshop on Assembling the Scientific Basis for Progress on Patient Safety)*. Chicago, IL: National Patient Safety Foundation; 1998.
17. Cook R, Woods D. Operating at the sharp end: the complexity of human error. In: Bogner MS, ed. *Human Error in Medicine*. Hillsdale, NJ: Lawrence Erlbaum; 1994:255–310.
18. Woods DD, Cook RI. Nine steps to move forward from error. *Cogn Technol Work*. 2002;4:137–144.
19. Klein G. *Sources of Power How People Make Decisions*. Boston, MA: MIT Press; 1999.
20. Hutchins E. *Cognition in the Wild*. Boston, MA: MIT Press; 1995.
21. Barley SR, Orr JE, eds. *Between Craft and Science Technical Work in US Settings*. Ithaca, NY: Cornell University Press; 1997.
22. Egan M. Clinical dashboards impact on workflow, care quality, and patient safety. *Crit Care Nurs Q*. 2006;29:354–361.
23. Northrop Grumman, Sperry Marine. Maritime Voyage Date Recorder: NTSB Vehicle Recorder Topical Technical Symposium. June 4–5, 2003. Available at: http://www.ntsb.gov/Events/symp_vr_toptec/Presentations/Panel_1/marine_king.pdf. Accessed June 15, 2007.
24. Perrow C. *Normal Accidents: Living With High-Risk Technologies*. Princeton, NJ: Princeton University Press; 1999.