Surveillance of Medical Device–Related Hazards and Adverse Events in Hospitalized Patients

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Context Although adverse drug events have been extensively evaluated by computer-based surveillance, medical device errors have no comparable surveillance techniques.

Objectives To determine whether computer-based surveillance can reliably identify medical device–related hazards (no known harm to patient) and adverse medical device events (AMDEs; patient experienced harm) and to compare alternative methods of detection of device-related problems.

Design, Setting, and Participants This descriptive study was conducted from January through September 2000 at a 520-bed tertiary teaching institution in the United States with experience in using computer tools to detect and prevent adverse drug events. All 20 441 regular and short-stay patients (excluding obstetric and newborn patients) were included.

Main Outcome Measures Medical device events as detected by computer-based flags, telemetry problem checklists, *International Classification of Diseases, Ninth Revision (ICD-9)* discharge code (which could include AMDEs present at admission), clinical engineering work logs, and patient survey results were compared with each other and with routine voluntary incident reports to determine frequencies, proportions, positive predictive values, and incidence rates by each technique.

Results Of the 7059 flags triggered, 552 (7.8%) indicate a device-related hazard or AMDE. The estimated 9-month incidence rates (number per 1000 admissions [95% confidence intervals]) for AMDEs were 1.6 (0.9-2.5) for incident reports, 27.7 (24.9-30.7) for computer flags, and 64.6 (60.4-69.1) for *ICD-9* discharge codes. Few of these events were detected by more than 1 surveillance method, giving an overall incidence of AMDE detected by at least 1 of these methods of 83.7 per 1000 (95% confidence interval, 78.8-88.6) admissions. The positive predictive value of computer flags for detecting device-related hazards and AMDEs ranged from 0% to 38%.

Conclusions More intensive surveillance methods yielded higher rates of medical device problems than found with traditional voluntary reporting, with little overlap between methods. Several detection methods had low efficiency in detecting AMDEs. The high rate of AMDEs suggests that AMDEs are an important patient safety issue, but additional research is necessary to identify optimal AMDE detection strategies.

JAMA. 2004;291:325-334 www.jama.com

ADVERSE DRUG EVENTS HAVE BEEN studied extensively,[1-7] but the computer-based techniques used to detect adverse drug events have not been used to identify medical device events. Although the US Food and Drug Administration's mandatory and voluntary medical device reporting programs have played an essential role in identifying specific hazards associated with individual types of devices,[8-13] they are limited by underreporting and the absence of denominator data. The diverse array of types of medical devices and comparable variety in potential problems associated with these devices[11,14-21] create challenges for the development and implementation of comprehensive surveillance programs. Human factors are more important than for drugs because devices have to be operated by a person,[22-24] and proper use depends on optimal design and instructions.[25-28]

For editorial comment see p 367.

Because surveillance of adverse drug events was facilitated by the application of computer-rule–based methods for screening and detection,[5,29,30] we hypothesized that computer-based surveillance could facilitate recognition of

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device events. To test this hypothesis, we conducted a pilot study of an electronic-flag–based system to detect device use problems that operated within the computerized patient record in the way that the computerized adverse drug event monitor does. Our primary objective was to measure the positive predictive value (PPV) of the electronic rules and to estimate the incidence of problems associated with devices identified by computer-based surveillance compared with postdischarge *International Classification of Diseases, Ninth Revision (ICD-9)* codes and the existing hospital incident event-reporting system. Secondary methods of detecting problems associated with devices were also evaluated in a pilot fashion: a prospective checklist system for telemetry-related problems, a postdischarge patient satisfaction survey, and a review of the clinical engineering logs.

METHODS

Study Site

The main part of the study was conducted from January to September 2000 at a 520-bed tertiary teaching institution in the United States with experience in using computer tools to detect and prevent adverse drug events. The study was approved by the hospital's institutional review board. The target patient population comprised all hospitalized patients, excluding obstetric and newborn patients. Short-stay patients were expected to be discharged within a day of admission and included patients undergoing same-day surgery. The hospital's electronic medical record, Health Evaluation through Logical Processing (HELP), consists of an integrated clinical database and a frame-based medical decision system. Approximately 1300 terminals throughout the hospital facilitate routine clinical use. Other systems that interface with HELP include the Medical Information Bus,[31,32] pharmacy, billing, laboratory, electrocardiography, medical records, digital radiology, and a collection of local area networks used by a variety of departments for local research and departmental management functions.

Definitions

Problems associated with devices were classified as device-related hazards or adverse medical device events (AMDEs) according to whether patient harm had occurred. Device-related hazards were events that had the potential to cause harm but manifested none, including a device malfunctioning or failing to perform as intended; problems in how a device was used, including misdiagnoses; failure to recognize and act on information from monitoring devices; and improper treatment. Examples were misplacement of a nasogastric tube in the esophagus in the absence of overt clinical consequences, failure of the cardiac monitor to initiate an alarm for an episode of unsustained ventricular tachycardia, false reading of oxygen saturation from a pulse oximeter, and malposition or clotting of a central venous catheter.

AMDEs were defined as any patient harm caused by device-related medical or surgical management rather than the patient's illness. Bleeding and infections associated with surgery were considered device-related only if they were associated with a specific device. A failed device that had to be replaced, if an invasive procedure that carried risk of harm to the patient was necessary to replace it, was considered an AMDE. Examples of AMDEs included electrocautery-device–induced burn; catheter-related bloodstream infection; failure to promptly detect asystole because of monitor failure; misprogramming of an infusion pump, resulting in excessive dosing of intravenous narcotic and leading to oversedation; and loosening of a prosthetic joint, requiring replacement. AMDEs were not classified with respect to preventability or severity because of the limitations of making this assessment on the basis of available data.

Spectrum of Devices and Device-Related Problems

During the study-planning process, commonly used devices were categorized by the part of the body or organ system for which they were used and by functional characteristics such as implantable (eg, artificial hip), reuseable (eg, ventilator), or disposable (eg, catheter). Meetings were held with clinical personnel in various hospital departments to learn which device problems were encountered most often. Nurses were surveyed about personal experiences and attitudes toward medical devices. Device-related incident reports sent to the hospital risk manager during a previous 6-month period were reviewed. Events were reviewed to determine whether they were documented in the patient's electronic or paper record and whether they were amenable to detection by a computer flag. We used this information to create a database of devices, including the spectrum of problems associated with each device, and their causes.

Surveillance Methods

Online Incident Event Reporting. The existing online incident event-reporting system relies on voluntary, nonanonymous submission of error and adverse event cases by health care workers. Incident reports were reviewed to determine whether medical devices were involved and to determine the outcome. Device-related incidents were classified by patient characteristics and medical department.

Computer-Flag–Based Surveillance. Concurrent with the incident event reports, surveillance was conducted with computer flags. Seven categories of computer flags were established: (1) local complications and hazards associated with a variety of catheter types (excluding peripheral intravenous catheters), including line replacement or removal for reasons other than "no longer needed," documented by nurse or intravenous teams; (2) infectious complications of urinary and intravascular catheters (excluding peripheral intravenous catheters) assessed by positive microbiological cultures and corresponding dates of collection; (3) device hazards manifested on chest radiograph (key words searched for included *malposition*, *broken*, *sheared*, *tip*, *bent*, "*out of place*," *reposition*, *folded*, and

coiled, combined with terms indicating presence of a device, such as *wire*, *device*, *tube*, *catheter*, *pacemaker*, *line*, and *lead*; *pneumothorax* was another search term); (4) surgery lasting longer than the 90th percentile for the specific surgery type; (5) abnormal measurements from physiologic monitoring devices such as pulse oximeters, cardiac monitors, and automated sphygmomanometers[31,32]; (6) decrease in urine output as a proxy for obstruction of a Foley catheter; and (7) bloody sputum as a proxy for traumatic intubation. These categories were selected in part because electronic data were available to establish triggering rules.

These flags were added to the knowledge base and logic modules that had been developed for surveillance of adverse drug events.[5,30,33] The flags were pilot tested to establish that electronic data were being appropriately processed. For example, among patients who were flagged as having had a more than 50% decrease in blood pressure, the electronic medical record was reviewed to establish that such a drop in blood pressure had been recorded. In addition, for independently identified instances of a more than 50% decline in blood pressure, appropriate firing of the rule was confirmed.

Research nurses who conducted the computer-flag–based surveillance were trained by individuals with extensive experience in electronic adverse drug event surveillance, in consultation with a US Food and Drug Administration expert on adverse device events (R.A.B.). From January through September 2000, the protocol involved the following procedures: a report was generated twice daily, listing all patients with flags, patient location and demographic information, and a brief summary of other pertinent clinical data. Each day, the research nurses reviewed the reports, assessed data in the electronic and paper medical record to determine whether criteria for an AMDE or device-related hazard were met, and, where possible, solicited additional information from the nurse caring for the patient. All flags verified in the medical record (true positives) were retrospectively reviewed by another nurse reviewer and discussed by the investigative team.

For flags based on physiologic monitoring devices, the goals were (1) to detect episodes of clinical deterioration that were complications of devices; and (2) to detect measurement errors on the part of the monitoring devices. We attempted to identify blood pressure, heart rate, and oxygen saturation values that were possibly due to measurement error and that might have led to erroneous interpretation. We searched for explanations of abnormal hemodynamic values, but we were limited by the lack of direct observation of possible device-related problems. For example, when we identified an instance of a single oxygen saturation value of 70%, we examined the record for evidence of a procedure or an acute condition that might have triggered desaturation or respiratory compromise. If no explanation was forthcoming and other recorded oxygen saturations from the patient before and after the isolated aberrant value were in the normal range, the episode was classified as a device-related hazard (possible measurement error). In contrast, if the physiologic characteristic had a value of zero, it was not categorized as a device-related hazard because it was assumed that such measurements reflected artifact or disconnection from the device. Flags related to catheters were classified as an AMDE when we identified an associated infection or local complication or as a device hazard if the catheter was misplaced or inappropriately detached from the patient.

Criteria for infection were based on National Nosocomial Infection Surveillance definitions.[34] Catheter-related urinary tract infection was defined as fever or other sign of infection plus urine culture with a growth of more than 10^4 colony-forming units per cm^3, coupled with the presence of a urinary catheter. Catheter-related bloodstream infection was defined as growth of an organism from 1 or more blood cultures (if coagulase-negative staphylococcus was the organism, at least 2 positive blood culture bottles or sets were required), presence of an intravascular catheter, and clinical signs of infection (fever or hypotension). Hazards detected on chest radiograph were defined as malposition or inappropriate breakage of a device.

Concurrent Method: Telemetry Checklist. Because the computer flags did not identify many of the nurse-reported problems with cardiac monitors, we added a telemetry checklist to the surveillance methods. For a 5-week period, from September 8, 2000, to October 11, 2000, telemetry technicians with the cardiac telemetry unit marked false alarms or missed ectopy during each shift on paper checklists. A false alarm was defined as each instance that the alarm was triggered when no arrhythmia was present, as judged by the telemetry technician. Missed ectopy was defined as each instance that an arrhythmia occurred when the alarm did not fire.

Retrospective Method: *ICD-9*-Code–Based Surveillance. We identified *ICD-9* codes that specified devices in their definitions and therefore were considered to have a high likelihood of indicating a device problem. All were considered AMDEs because it was presumed that only events with overt clinical consequences were likely to be coded. Briefly, we included codes 996.0-996.79, except for codes that referred to tissue grafting or to a specific procedure such as coronary artery bypass surgery (eg, code 996.03, mechanical complication caused by coronary artery bypass graft) rather than a device or prosthetic implant, and injury codes E878.1, E878.2, and E879.4 (BOX). The *ICD-9* codes were classified according to organ system or device type (eg, genitourinary or orthopedic) or, if the text description was nonspecific, as "other." They also were classified according to their functional characteristics (implantable or disposable).

We identified all inpatients with 1 or more of these selected *ICD-9* codes who were admitted from January to September 2000. We then reviewed 141 patient records randomly selected from

Box. *International Classification of Diseases, Ninth Revision (ICD-9)* Codes

996.01 Mechanical complication due to cardiac pacemaker (electrode)
996.02 Mechanical complication due to heart valve prosthesis
996.04 Mechanical complication of automatic implantable cardiac defibrillator
996.09 Other mechanical complication of cardiac device, implant, and graft
996.1 Mechanical complication of other vascular device, implant, and graft
996.2 Mechanical complication of nervous system device, implant, and graft
996.32 Mechanical complication due to intrauterine contraceptive device
996.39 Other mechanical complication of genitourinary device, implant, and graft
996.4 Mechanical complication of internal orthopedic device, implant, and graft
996.53 Mechanical complication of prosthetic ocular lens prosthesis
996.54 Mechanical complication of breast prosthesis
996.56 Mechanical complication due to peritoneal dialysis catheter
996.59 Mechanical complication of other implant and internal device, not elsewhere classified
996.61 Infection and inflammatory reaction due to cardiac device, implant, and graft
996.62 Infection and inflammatory reaction due to other vascular device, implant, and graft
996.63 Infection and inflammatory reaction due to nervous system device, implant, and graft
996.64 Infection and inflammatory reaction due to indwelling urinary catheter
996.65 Infection and inflammatory reaction due to other genitourinary device, implant, and graft
996.66 Infection and inflammatory reaction due to internal joint prosthesis
996.67 Infection and inflammatory reaction due to other internal orthopedic device, implant, and graft
996.68 Infection and inflammatory reaction due to peritoneal dialysis catheter
996.69 Infection and inflammatory reaction due to other internal prosthetic device, implant, and graft
996.70 Other complications due to unspecified device, implant, and graft
996.71 Other complications due to heart valve prosthesis
996.72 Other complications due to other cardiac device, implant, and graft
996.73 Other complications due to renal dialysis device, implant, and graft
996.74 Other complications due to other vascular device, implant, and graft
996.75 Other complications due to nervous system device, implant, and graft
996.76 Other complications due to genitourinary device, implant, and graft
996.77 Other complications due to internal joint prosthesis
996.78 Other complications due to other internal orthopedic device, implant, and graft
996.79 Other complications due to other internal prosthetic device, implant, and graft
E878.1 Surgical operation with implant of artificial internal device causing abnormal patient reaction, or later complication, without mention of misadventure at time of operation
E878.2 Surgical operation with anastomosis, bypass, or graft, with natural or artificial tissues used as implant causing abnormal patient reaction, or later complication, without mention of misadventure at time of operation
E879.4 Aspiration of fluid as the cause of abnormal reaction of patient, or of later complication, without mention of misadventure at time of procedure

the 1126 patients to assess the PPV of the *ICD-9* codes. Events confirmed in the medical record were classified according to the level of harm, the cause of hospitalization, and the duration the device had been in place.

Postdischarge Patient Survey. In addition to the patient-record–based surveillance methods, we wanted to obtain a patient-centered perspective on device-related problems. From November 2000 through January 2001, pretested questions about device-related problems were added to our hospital's standard hospital postdischarge telephone satisfaction survey (available from the authors on request). Patients were randomly selected from the discharge lists from the previous calendar month until a predetermined, floor-specific number was reached.

Clinical Engineering Database. Service reports for electronic and mechanical devices entered in the hospital clinical engineering department's database of service and maintenance activities were reviewed for January through September 2000 and classified according to the type of device and corrective action. This information could not be linked to specific patients or events. This supplemental analysis was intended to provide an independent estimate of the frequency of problems associated with equipment from an engineering perspective.

Statistical and Data Analysis. For computer-flag–based surveillance, the PPV of computer flags was calculated by dividing the number of true-positive flags by the total number of flag alerts. Computer flags were categorized by type of device and whether harm occurred. Binomial confidence intervals (CIs) and *P* values for statistical comparisons were calculated with Stata 7.0 (College Station, Tex) or StatXact 3 (Cambridge, Mass). The χ^2 test was used for count data and Wilcoxon rank sum test for nonnormally distributed continuous data. $P<.05$ was considered significant.

For AMDEs detected by computer flags, *ICD-9* codes, and incident reports, AMDEs were classified by sex, age group, physician service, and primary diagnosis. Rates and confidence intervals of AMDEs per 1000 patient admissions were calculated. Device events detected by computer flags were expressed as rates per 1000 device-days for selected devices.

Pairwise comparisons of the incident report, computer flag, and *ICD-9* diagnosis methods for finding device-

related hazards and AMDEs were performed sequentially. Because no individual methods constituted a gold standard, sensitivity and specificity were not calculated.

RESULTS

Description of the Study Population

From January through September 2000, there were 19704 regular admissions, representing 94187 patient-days, and 7861 short-stay patient admissions. A total of 7124 patients were admitted to the obstetric service or were newborn; these patients were not included in the study because rates of detected medical device events in these populations were extremely low. Therefore, the study population comprised a total of 20441 regular and short-stay patients (TABLE 1). The total number of device-days was 20948 for urinary catheters, 3530 for peripherally inserted central catheters (PICCs), 3937 for central venous catheters, 8197 for arterial catheters, and 5687 for ventilators.

Online Incident Event Reporting

The online incident reporting system yielded 80 device-related events, of which 21 were device-related hazards, 20 were AMDEs, and 39 could not be classified. Twenty-three involved disposable devices (2 hazard, 11 AMDEs, 10 unclassified) and 46 involved durable equipment (14 hazards, 7 AMDEs, 25 unclassified). Examples of device problems listed in the incident event reporting system included a sheared Jackson-Pratt drain, clotted central venous catheter, and malfunction of a patient-controlled analgesia pump.

Computer-Flag–Based Surveillance

Of the 7059 flags triggered during the study period, 552 (7.8%) indicated a device-related hazard or AMDE (TABLE 2). Patient medical record review of positive flags verified 95% of the flags that were initially classified as true positive according to the computer record alone.

A total of 3687 (52%) flags were generated for changes in blood pressure, oxygen saturation, heart rate, or respiratory rate. The PPV for these hemodynamic flags was 3.4% (95% CI, 2.9%-4.1%). In most instances, the aberrant measurements were either clearly attributable to artifact or accurately reflected a deterioration in physiologic status that was not caused by a device-related complication. True-positive signals represented abnormal values attributed by the nurse reviewers to device failure; none were associated with patient harm. Change in urine output had a PPV of 0%.

Line insertion and removal flags had a PPV of 8.6% (95% CI, 7.1%-10.2%); 68% of the true-positive events were classified as AMDEs. The most common AMDEs were phlebitis or evidence of ischemia associated with arterial lines; typical device-related hazards were clotting and leaking.

Flags for detection of urinary tract–related and intravascular bloodstream infection had a PPV of 38% (95% CI, 34%-42%) and 35% (95% CI, 29%-42%), respectively; all true positives were classified as AMDEs. Radiology reports detected a small number of device-related hazards, usually tube malposition, with a PPV of 0.7% (95%

Table 1. Characteristics of the Hospital Population, Excluding Obstetric and Newborn Patients

Characteristic	No. (%) Regular-Stay Patients (n = 12593)	No. (%) Short-Stay Patients (n = 7848)*
Women	6615 (52.5)	4465 (56.9)
Men	5978 (47.5)	3383 (43.1)
Age, y		
<30	1607 (12.8)	1622 (20.7)
30-49	3010 (23.9)	2772 (35.3)
50-69	3985 (31.6)	2268 (28.9)
≥70	3991 (31.7)	1186 (15.1)
Physician service		
Surgery	5604 (44.5)	5510 (70.2)
Medicine	4382 (34.8)	819 (10.4)
Gynecology	843 (6.7)	811 (10.3)
Other	1248 (9.9)	354 (4.5)
Not available	516 (4.1)	354 (4.5)
Location on admission		
Medical/surgery ward	8346 (66.3)	7848 (100)
Telemetry	1912 (15.2)	0
Intensive care unit	2335 (18.5)	0
Most common primary diagnosis codes, medicine or other service		
Angina or myocardial infarction	981 (7.8)	3 (0.04)
Cataract or diabetic retinopathy	0	386 (4.9)
Rehabilitation care	323 (2.6)	0
Depressive disorder	292 (2.3)	6 (0.1)
Congestive heart failure	225 (1.8)	0
Most common primary procedure codes, surgery service		
Joint arthroscopy	7 (0.1)	634 (8.1)
Coronary artery bypass surgery	587 (4.7)	0
Laparoscopic cholecystectomy	155 (1.2)	397 (5.1)
Knee or hip joint replacement	508 (4.0)	0
Spinal or vertebral surgery	333 (2.6)	318 (4.1)
Length of stay, d		
Mean (SD)	5.6 (8.7)	0.4 (0.5)
Median (IQR)	3.6 (1.9-6.4)	0.3 (0.2-0.4)

Abbreviation: IQR, interquartile range.
*Short-stay patients were those expected to be discharged within a day of admission, including same-day surgery.

Table 2. Positive Predictive Value of Individual Computer Flags

Computer Flags	Total Flags	Device-Related Hazards	AMDEs	Total Device Events	Positive Predictive Value, % (95% CI)
>50% Deviation in blood pressure	1602	58	0	58	3.6 (2.8-4.7)
O_2 saturation <80%	1144	50	0	50	4.4 (3.3-5.7)
Heart rate <50/min	791	19	0	19	2.4 (1.5-3.7)
Respiratory rate <8/min	150	0	0	0	0 (0-2.4)
Change in urine output	262	0	0	0	0 (0-1.4)
Subtotal	**3949**	**127**	**0**	**127**	3.4 (2.9-4.1)
Line insertion/removal	1317	36	77	113	8.6 (7.1-10.2)
Catheter-associated urinary tract infection	579	0	218	218	38 (34-42)
Catheter-associated bloodstream infection*	249	0	88	88	35 (29-42)
Radiology report	899	6	0	6	0.7 (0.2-1.4)
Extended surgery	66	0	0	0	0 (0-5.4)
Total	**7059**	**169**	**383**	**552**	7.8 (7.2-8.5)

Abbreviations: AMDE, adverse medical device event; CI, confidence interval.
*Includes peripherally inserted central catheters, central venous catheters, arterial catheters, pulmonary artery catheters, and hemodialysis catheters.

Table 3. Computer-Flag–Based Surveillance: Number of Device Events by Device Type

Device Type	No. (%)		
	Device-Related Hazard	Adverse Medical Device Event	Total No. of Device-Related Problems (n = 552)
Combination of durable equipment and disposable device			
Cardiac/blood pressure monitor	59 (35)	0	59 (11)
Pulse oximeter	50 (30)	0	50 (9)
Subtotal*	**109 (64.5)**	**0**	**109 (20)**
Disposable device			
Foley catheters	0	218 (57)	218 (39)
Arterial catheter	32 (19)	66 (17)	98 (18)
Central venous catheter	10 (6)	64 (17)	74 (13)
Peripherally inserted central catheter	6 (4)	28 (7)	34 (6)
Hemodialysis device	0	3 (1)	3 (1)
Pulmonary artery catheter	8 (5)	2 (1)	10 (2)
Epidural catheter	0	2 (1)	2 (0.4)
Nasogastric tube	2 (1)	0	2 (0.4)
Other	2 (1)	0	2 (0.4)
Subtotal*	**60 (35.5)**	**383 (100)**	**443 (80)**
Total	**169**	**383**	**552**

*Percentages may not sum to subtotal percentage because of rounding.

CI, 0.2%-1.4%). Extended surgery duration had a PPV of 0% (95% CI, 0%-5.4%). The overall PPV of computer flags was 7.8% (95% CI, 7.2%-8.5%).

TABLE 3 shows the most common types of devices associated with AMDEs and device-related hazards. Foley catheters (57% of total AMDEs) and arterial catheters (17%) were the devices most commonly associated with AMDEs, whereas cardiac/blood pressure monitors and pulse oximeters were the devices most commonly associated with hazard (35% and 30%, respectively). Rates of AMDEs per 1000 device-days, as detected by computer flags, were 10.4 (95% CI, 9.1-11.8) for urinary catheters, 7.9 (95% CI, 5.3-11.4) for PICCs, 16.0 (95% CI, 12.5-20.7) for central venous catheters, and 9.9 (95% CI, 7.8-12.2) for arterial catheters.

Telemetry Checklist

During 516 hours of monitoring, the voluntary checklist system revealed a total of 593 false alarms and 4 missed ectopic events. The distribution of false alarms was 223 episodes of ventricular tachycardia, 131 of asystole, 104 of bradycardia, 83 of sinus pause, 20 of premature ventricular contraction, and 32 other. None of these events were considered AMDEs (ie, none of the false alarms or missed arrhythmias resulted in overt patient harm). Device events detected by this surveillance method did not overlap with events uncovered by other surveillance methods.

ICD-9-Code–Based Surveillance

During the study period from January through September 2000, 1122 (5.5%) admissions had 1 or more of the target *ICD-9* codes (TABLE 4). The device categories most often associated with *ICD-9* events were orthopedic (25% of the total), vascular (19%), dialysis (15%), and urologic catheters (9%). Overall, 27% of patients identified by this surveillance method were short stay, for whom it can be reliably assumed that the device problem was the reason for admission. Most of the short-stay problems were related to dialysis (47%) and orthopedic devices (33%). Events uncovered by querying *ICD-9* codes represented the primary discharge diagnosis in the majority (51%; 568/1122) of instances, more so in short-stay than regular-stay patients (93.5% [288/308] vs 34% [280/814]; $P<.001$). Analyzing the events by type

showed that 52% involved permanent implants, 9% involved disposable devices, none involved durable equipment, and the remainder (38.5%) had codes that did not allow inference of device type. None of the diagnostic codes for short-stay admissions involved disposable devices.

The record review of the random sample of 141 hospitalizations with 1 or more of the study *ICD-9* codes revealed that 101 (72%) had a confirmed AMDE. Most instances of failure to confirm an AMDE were explained by the occurrence of a procedure-associated adverse event that was not device related. All of the patients experienced some harm, confirming the supposition that only events resulting in patient harm were documented among the *ICD-9* discharge diagnoses. Ninety-one of 101 (90%) records of patients with a 996 code had a confirmed AMDE. Of 40 patients with an E878.1 or E878.2 or E879.4 code but not a 996 code, 10 (25%) had a confirmed AMDE. Excluding patients with code 996.64 (urologic catheters), the most common type of device injury was device failure requiring device replacement or repositioning (48%). For 84% of these patients, the device failure (generally an implant) was the cause of hospitalization. Fourteen of the records reviewed were of short-stay patients, and in all instances the AMDE was the cause of hospitalization.

Postdischarge Patient Survey

Of 888 patients who participated in the postdischarge survey, 72 (8%) responded affirmatively to the question, "Did you have any problems with any of the medical equipment used in your care or treatment?" For 58 of the 888 (7%) patients, we could infer from their narrative that a medical device was actually involved (some patients provided unclear or no narrative or cited nonmedical items such as televisions or windows); for 38 of the 58 (66%) individuals, the problem with the medical equipment bothered the respondent "somewhat" or "very much." For 29 of the 58 (50%) individuals, the device was an intravenous catheter, needle, or pump. Other types of devices reported included epidural catheter or pump (5 patients), blood pressure machines or cardiac monitors (6 patients), and beds or call buttons (4 patients). Overall, 16 patients reported device-related harm, resulting in an estimated rate of 18 (95% CI, 9-27) per 1000 patients; 2 instances of harm were related to durable equipment and 12 to disposable devices (the other 2 could not be classified). Twelve patients reported device-related hazards, 8 related to durable equipment, 3 to disposables, and 1 that could not be classified.

Clinical Engineering Database

During the study, a total of 1359 service reports were logged into the database. Devices most frequently sent to engineering for assessment were traction or hydraulic elevators (n=262; 19%), cardiac monitors (n=95; 7%), ventilators (n=85; 6%), and anesthesia units (n=78; 6%). Disposable devices and permanent implants were not included in the database. In 68 (5%) of instances, no repairs were necessary and in 1060 (78%), minor work was sufficient to restore equipment function.

Table 4. Adverse Medical Device Events (AMDEs) Detected by *ICD-9* Codes During January-September 2000*

	ICD-9 Codes	Events by Type of Admission, No. (%)		
		Regular Admissions (n = 821)	Short Stay (n = 308)	Event Total (n = 1129)
Device category				
Orthopedic	996.4, 996.66, 996.67, 996.77, 996.78	182 (22)	103 (33)	285 (25)
Vascular access	996.1, 996.62, 996.74	188 (23)	26 (8)	214 (19)
Dialysis	996.56, 996.68, 996.73	21 (3)	144 (47)	165 (15)
Urologic catheters	996.64	102 (12)	0	102 (9)
Cardiac	996.01, 996.09, 996.61, 996.72	42 (5)	0	42 (4)
Prosthetic cardiac valve	996.02, 996.71	24 (3)	0	24 (2)
Defibrillator	996.04	6 (1)	0	6 (1)
Nervous system	996.2, 996.63, 996.75	19 (2)	2 (1)	21 (2)
Genitourinary	996.32, 996.39, 996.65, 996.76	25 (3)	7 (2)	32 (3)
Breast implant	996.54	2 (0.2)	4 (1)	6 (1)
Ocular	996.53	0	6 (2)	6 (1)
Other	996.59, 996.69, 996.70, 996.79, E878.1, E878.2, E879.4	210 (26)	16 (5)	226 (20)
Device type				
Permanent implant	996.02, 996.04, 996.32, 996.4, 996.53, 996.54, 996.66, 996.67, 996.71, 996.77, 996.78, 996.79, E878.1, E878.2	446 (54)	142 (46)	588 (52)
Disposable	996.31, 996.56, 996.64, 996.68	106 (13)	0	106 (9)
Durable equipment	None	0	0	0
Unspecified	996.01, 996.09, 996.1, 996.2, 996.39, 996.59, 996.61, 996.62, 996.63, 996.65, 996.69, 996.70, 996.72, 996.73, 996.74, 996.75, 996.76, E879.4	269 (33)	166 (54)	435 (38.5)

*The total exceeds 1122 because 7 patients met criteria for more than 1 device category.

Comparison of the Surveillance Results

Compared with the total number of AMDEs identified by any method, each method individually detected a minority of AMDEs. The line/insertion removal flag identified the same AMDEs as a vascular device *ICD-9* code in 12 patients (16% of the line/insertion removal flags and 22% of vascular device–related *ICD-9* codes). The catheter-related urinary tract infection flag identified the same AMDEs as the *ICD-9* code for urologic catheters in 34 patients (16% of catheter-related urinary tract infection flags and 33% of urologic catheter-related *ICD-9* codes). The catheter-associated bloodstream infection flag identified the same AMDEs as the *ICD-9* code for vascular devices in 36 patients (41% of catheter-associated bloodstream infection flags and 22% of vascular device–related *ICD-9* codes). None of the AMDEs detected by the Patient Satisfaction Survey were detected by the incident reporting, *ICD-9*, or computer-flag–based methods.

AMDE Rates by Patient Characteristics

Table 5 depicts the characteristics of regular-stay patients who experienced AMDEs, as detected by computer flags, *ICD-9* codes, or incident reports. The AMDE detection methods yielded rates, expressed per 1000 regular-stay patients for the period, that were statistically significantly different from each other. The detected rate was 1.6 per 1000 patients (95% CI, 0.9-2.5) for incident reports, 27.7 per 1000 patients for computer flags (95% CI, 24.9-30.7), and 64.6 per 1000 for *ICD-9* codes (95% CI, 60.4-69.1). The overall incidence of AMDE detected by any of these methods was 83.7 per 1000 (95% CI, 78.8-88.6). One AMDE, a catheter-related bloodstream infection, was directly associated with death during hospitalization. Longer-term follow-up was not performed.

Table 5. Characteristics of Regular-Stay Patients Who Experienced an Adverse Medical Device Event (AMDE), January-September 2000, by Surveillance Method*

		AMDE Detection Method							
		Computer Flags		*ICD-9* Codes		Incident Reports		Any of These 3 Methods	
Characteristic	No. of Admissions	No.	No. per 1000 Admissions (95% CI)	No.	No. per 1000 Admissions (95% CI)	No.	No. per 1000 Admissions (95% CI)	No.	No. per 1000 Admissions (95% CI)
Total	12 593	349	27.7 (24.9-30.7)	814	64.6 (60.4-69.1)	20†	1.6 (0.9-2.5)	1053	83.7 (78.8-88.6)
Women	6615	194	29.3 (25.4-33.7)	411	62.1 (56.4-68.2)	11	1.6 (0.8-3.0)	540	81.6 (75.1-88.4)
Men	5978	155	25.9 (22.0-30.3)	403	67.4 (61.2-74.1)	7	1.2 (0.5-2.4)	513	85.8 (78.8-93.2)
Age, y									
<30	1607	28	17 (12-25)	43	27 (19-36)	1	0.6 (0.01-4)	64	40 (31-51)
30-49	3010	64	21 (16-27)	145	48.2 (40.8-56.4)	4	1.0 (0.4-3.0)	186	61.8 (53.5-71.0)
50-69	3985	117	29.3 (24.3-35.1)	279	70.0 (62.3-78.4)	6	2.0 (0.6-3.0)	363	91.1 (82.3-101)
≥70	3991	140	35.1 (29.6-41.3)	347	86.9 (78.4-96.1)	6	2.0 (0.5-3.0)	440	110 (101-120)
Physician service									
Surgery	5604	174	31.0 (26.5-35.6)	559	99.8 (92.0-108.0)	10	1.8 (0.9-3.3)	669	119 (111-128)
Medicine	4382	121	27.6 (22.8-32.5)	218	49.7 (43.5-56.6)	2	0.40 (0.05-2.00)	298	68.0 (60.7-75.9)
Gynecology	843	10	12.0 (5.7-22.0)	6	7 (3-20)	0	0 (0-4)	15	18 (10-29)
Other	1248	38	31.2 (22.3-42.5)	30	27.2 (18.9-37.9)	6	4.8 (1.8-10)	66	52.8 (41.1-66.8)
Not available	516	6	10 (4-30)	1	2 (0-10)	2	4 (0.5-10)	5	10 (3-20)
Medical or other diagnosis codes									
Angina or myocardial infarction	981	13	13 (7-23)	24	24 (16-36)	0	0 (0-40)	33	34 (23-47)
Rehabilitation care	323	30	93 (63-130)	14	43 (24-73)	2	6.0 (0.8-20.0)	42	130 (95-170)
Depressive disorder	292	0	0 (0-100)	2	7.0 (0.8-30.0)	1	3 (1-20)	3	10 (2-30)
Congestive heart failure	225	9	40 (20-80)	15	67 (37-110)	0	0 (0-20)	23	100 (66-150)
Surgical procedure codes									
Coronary artery bypass surgery	587	32	55 (37-77)	98	170 (140-200)	2	3.0 (0.4-10.0)	118	201 (169-236)
Laparoscopic cholecystectomy	155	0	0 (0-20)	1	7.0 (0.2-40.0)	0	0 (0-20)	1	7.0 (0.2-40.0)
Prosthetic knee or hip joint	508	3	6 (1-20)	90	180 (140-210)	0	0 (0-7.2)	93	180 (150-220)
Spinal or vertebral surgery	333	5	20 (5-40)	19	57 (35-88)	0	0 (0-10)	21	63 (40-95)
Length of stay, d									
Mean (SD)	5.6 (8.7)		21.6 (14.9)		10.9 (11.8)		21.6 (14.9)		12.8 (13.4)
Median (IQR)	3.6 (1.9-6.4)		16.8 (10.6-27.9)		6.4 (3.8-14.1)		18.5 (9.0-29.0)		8.3 (4.4-16.2)

Abbreviations: CI, confidence interval; IQR, interquartile range.
*Results are tabulated as number of unique patient admissions rather than unique events, as in Tables 2-4. Rates are expressed per 1000 regular-stay admissions.
†Data unavailable for 2 patients.

As described above, in contrast to the other surveillance methods, *ICD-9*-code–based surveillance included AMDEs that were present at admission and those that were hospital acquired. The detected AMDE rates among regular admissions were not statistically different between men and women. Rates of AMDEs rose with increasing age; detected rates of AMDEs were quite low for gynecology. Patients with AMDEs identified by the computer-flag–based system had much longer lengths of stay than average (21.6 days vs 5.6 days; $P<.001$). Differences in AMDE rates across different types of primary diagnoses presumably reflected, at least in part, variation in device use. For instance, most AMDEs detected in patients admitted for rehabilitation care were Foley-catheter–associated urinary tract infections, and most AMDEs in patients admitted for prosthetic joint surgery involved orthopedic devices.

COMMENT

This study of methods for medical device event surveillance in hospitalized patients established a broad-based taxonomic scheme for identification and classification of medical device events. Explicit case criteria were developed that included many device-related problems and differentiated *hazard*, a state of increased risk related to device use, from *harm*, patient injury related to device use. However, neither of these states depended on the specification of error, a term that was difficult to apply in the circumstances encountered.

Active surveillance methods yielded substantially more information than voluntary reporting, as did the experience with adverse drug events.[5,35] We had hoped that computer flags would facilitate timely detection of device events to allow secondary prevention and mitigate severity of harm, as they have for adverse drug events. However, aside from rules to detect device-related infections, the PPV of the flags was low. Anecdotal observations during the course of the study also suggested that device events were missed by the computer flag system. For instance, health care workers informed us that cardiac monitors were a source of frustration because of misreading of ectopy and that a problem with patient-controlled analgesia pumps was the lack of an obstruction alarm when the catheter segment above the pump was occluded. Electronic data were not available to generate flags according to absence or presence of alarms and, even when alarm problems occurred, documentation of such events in the medical record was minimal to nonexistent, making it more difficult to evaluate triggers to determine whether an adverse event had occurred. It appeared that the typical health care worker response to a device problem was to fix it or to retrieve a new device that worked and then move on, an appropriate solution at the individual patient level but not an effective systems approach.

ICD-9 codes represent an attractive method for adverse event surveillance because of the potential for consistent application across different health care systems and institutions. By reviewing a sample of records, we confirmed the predictive utility of 996 codes, whereas E codes were of less value by themselves. The disadvantages of *ICD-9*-code–based surveillance were that only episodes of overt harm were uncovered, classification of events by device type was only possible into broad device categories, and ameliorative intervention for the specific patient was impossible. *ICD-9* codes appeared to be particularly useful for device-related events that caused hospitalization and less so for AMDEs that occurred during the hospitalization. Also, duplicate coding of the same event needs to be identified when events from administrative databases are tracked.

The postdischarge survey provided a novel, alternative source of data. The patients' attention focused on simple devices in common daily use that were a cause of discomfort. This information may be a useful element to include when patient satisfaction is assessed; whether it has a substantial influence on health care–related quality of life requires additional study. Patient interview has been a useful source of information for detection of adverse drug events in outpatients.[36]

The intensive, real-time telemetry detection system confirmed a high incidence of false alarms.[37] The clinical engineering database indicated that telemetry monitors were the second most common device serviced.

Each surveillance method was useful for detecting different types of problems, but they exhibited relatively little overlap. Taken together, the complementary detection methods examined in this study indicated that device problems were frequent. However, none of the techniques described here were adequate to serve as a gold standard. Although our approach to the complex subject of device-related patient safety was more comprehensive than others previously reported in the literature, we were not able to derive a definitive measure of the incidence of device-related problems, nor would such an estimate necessarily be generalizable to other institutions. Just as medication errors and adverse drug events required extensive investigation to estimate incidence and develop interventions to prevent events, so also is intensive investigation in multiple centers required to define the epidemiology and establish surveillance and control of medical device problems.

Author Contributions: Dr Samore, as principal investigator, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
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Acquisition of data: Samore, Evans, Lassen, Gould, Lloyd, Gardner, Taylor, Woodbury.
Analysis and interpretation of data: Samore, Evans, Gould, Lloyd, Gardner, Abouzelof, Willy, Bright.
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Statistical expertise: Samore, Bright.
Obtained funding: Samore, Evans, Lloyd, Bright.
Administrative, technical, or material support: Evans, Lassen, Gould, Lloyd, Gardner, Abouzelof, Taylor, Woodbury, Willy, Bright.
Study supervision: Samore, Evans, Lloyd.
Funding/Support: Funding was provided primarily by the Food and Drug Administration's (FDA's) Office of Women's Health and secondarily by the Office of Surveillance and Biometrics in the FDA's Center for Devices and Radiological Health, contract number 223-99-6101.

Role of the Sponsor: Dr Bright was the project officer from the sponsor (FDA). Dr Bright generated the initial idea for the study. Drs Samore and Bright shaped the design and conduct of the study, with substantial input from other coinvestigators. Drs Samore and Bright interpreted the analysis results and Dr Bright contributed to the drafting of the manuscript. All coauthors including Dr Bright reviewed and approved the manuscript. In addition, the manuscript passed through an FDA approval process.

Acknowledgment: We thank Mark Bruley, BS, of ECRI for useful comments.

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