A

DVERSE 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 manda-

tory and voluntary medical device report-

ing 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 ab-

sence of denominator data. The diverse

array of types of medical devices and com-

parable variety in potential problems as-

sociated with these devices11,14-21 create

challenges for the development and

implementation of comprehensive sur-

veillance 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

Because surveillance of adverse drug

events was facilitated by the application

of computer-rule–based methods

for screening and detection,3,29-30 we hy-

pothesized that computer-based sur-

veillance could facilitate recognition of

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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), reusable (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
been developed for surveillance of ad-
edge base and logic modules that had
rules. were available to establish triggering
selected in part because electronic data
bloody sputum as a proxy for trau-
decrease in urine output as a proxy for
pient. All flags verified in the medical
sessed data in the electronic and pa-
search nurses reviewed the reports, as-
pertinent clinical data. Each day, the re-
mation, and a brief summary of other
pient location and demographic infor-
daily, listing all patients with flags, pa-
cedures: a report was generated twice
protocol involved the following pro-
research, in consultation with
trained by individuals with extensive
computer-flag–based surveillance were
rule was confirmed.
physiologic characteristic had a value
sure measurement error). In contrast, if the
a device-related hazard (possible mea-
sumed that such measurements re-
lected artifact or disconnection from
device. Flags related to catheters
were classified as an AMDE when we
identified an associated infection or lo-
ical complication or as a device hazard
if the catheter was misplaced or inap-
ropriately detached from the patient.

Criteria for infection were based on
National Nosocomial Infection Surveil-
ance definitions. Catheter-related uri-
inary tract infection was defined as fe-
ver 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 cath-
eter. Catheter-related bloodstream in-
fec tion was defined as growth of an or-
ganism from 1 or more blood cultures
(if coagulase-negative staphylococcus
was the organism, at least 2 positive
blood culture bottles or sets were re-
presence of an intravascular
cather, and clinical signs of infec-
tion (fever or hypotension). Hazards de-
tected on chest radiograph were defined
as malposition or inappropriate break-
age of a device.

Concurrent Method: Telemetry
Checklist. Because the computer flags
did not identify many of the nurse-
reported problems with cardiac moni-
tors, we added a telemetry checklist to
the surveillance methods. For a 5-week
period, from September 8, 2000, to Oc-
tober 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 arrhyth-
was present, as judged by the telem-
try technician. Missed ectopy was de-
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 con-
sidered to have a high likelihood of in-
dicating a device problem. All were con-
sidered 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 pro-
cedure such as coronary artery bypass
surgery (eg, code 996.03, mechanical
complication caused by coronary ar-
tery 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, geni-
tourinary or orthopedic) or, if the text
description was nonspecific, as “other.”
They also were classified according to
their functional characteristics (im-
plantable or disposable).

We identified all inpatients with 1 or
more of these selected ICD-9 codes who
were admitted from January to Septem-
ber 2000. We then reviewed 141 pa-
tient 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 intrathecal drug delivery 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 surve-

**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 χ² 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 respi-

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

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Regular-Stay Patients (n = 12 593)</th>
<th>Short-Stay Patients (n = 7848)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Women</td>
<td>6615 (52.5)</td>
<td>4465 (56.9)</td>
</tr>
<tr>
<td>Men</td>
<td>5978 (47.5)</td>
<td>3383 (43.1)</td>
</tr>
<tr>
<td>Age, y &lt;30</td>
<td>1607 (12.8)</td>
<td>1622 (20.7)</td>
</tr>
<tr>
<td>30-49</td>
<td>3010 (23.9)</td>
<td>2772 (35.3)</td>
</tr>
<tr>
<td>50-69</td>
<td>3985 (31.6)</td>
<td>2268 (28.9)</td>
</tr>
<tr>
<td>≥70</td>
<td>3991 (31.7)</td>
<td>1186 (15.1)</td>
</tr>
<tr>
<td>Physician service</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgery</td>
<td>5604 (44.5)</td>
<td>5510 (70.2)</td>
</tr>
<tr>
<td>Medicine</td>
<td>4382 (34.8)</td>
<td>819 (10.4)</td>
</tr>
<tr>
<td>Gynecology</td>
<td>843 (6.7)</td>
<td>811 (10.3)</td>
</tr>
<tr>
<td>Other</td>
<td>1248 (9.9)</td>
<td>354 (4.5)</td>
</tr>
<tr>
<td>Not available</td>
<td>516 (4.1)</td>
<td>354 (4.5)</td>
</tr>
<tr>
<td>Location on admission</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical/surgery ward</td>
<td>8346 (66.3)</td>
<td>7848 (100)</td>
</tr>
<tr>
<td>Telemetry</td>
<td>1912 (15.2)</td>
<td>0</td>
</tr>
<tr>
<td>Intensive care unit</td>
<td>2335 (18.5)</td>
<td>0</td>
</tr>
<tr>
<td>Most common primary diagnosis codes, medicine or other service</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Angina or myocardial infarction</td>
<td>981 (7.8)</td>
<td>3 (0.04)</td>
</tr>
<tr>
<td>Cataract or diabetic retinopathy</td>
<td>0</td>
<td>386 (4.9)</td>
</tr>
<tr>
<td>Rehabilitation care</td>
<td>232 (2.6)</td>
<td>0</td>
</tr>
<tr>
<td>Depressive disorder</td>
<td>292 (2.3)</td>
<td>6 (0.1)</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>225 (1.8)</td>
<td>0</td>
</tr>
<tr>
<td>Most common primary procedure codes, surgery service</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Joint arthroscopy</td>
<td>7 (0.1)</td>
<td>634 (8.1)</td>
</tr>
<tr>
<td>Coronary artery bypass surgery</td>
<td>587 (4.7)</td>
<td>0</td>
</tr>
<tr>
<td>Laparoscopic cholecystectomy</td>
<td>155 (1.2)</td>
<td>397 (5.1)</td>
</tr>
<tr>
<td>Knee or hip joint replacement</td>
<td>508 (4.0)</td>
<td>0</td>
</tr>
<tr>
<td>Spinal or vertebral surgery</td>
<td>333 (2.6)</td>
<td>318 (4.1)</td>
</tr>
<tr>
<td>Length of stay, d</td>
<td>Mean (SD)</td>
<td>5.6 (8.7)</td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>3.8 (1.9-6.4)</td>
<td>0.3 (0.2-0.4)</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Computer Flags</th>
<th>Total Flags</th>
<th>Device-Related Hazards</th>
<th>AMDEs</th>
<th>Total Device Events</th>
<th>Positive Predictive Value, % (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;50% Deviation in blood pressure</td>
<td>1602</td>
<td>58</td>
<td>0</td>
<td>58</td>
<td>3.6 (2.8-4.7)</td>
</tr>
<tr>
<td>O₂ saturation &lt;80%</td>
<td>1144</td>
<td>50</td>
<td>0</td>
<td>50</td>
<td>4.4 (3.3-5.7)</td>
</tr>
<tr>
<td>Heart rate &lt;50/min</td>
<td>791</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2.4 (1.5-3.7)</td>
</tr>
<tr>
<td>Respiratory rate &lt;8/min</td>
<td>150</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0 (0-2.4)</td>
</tr>
<tr>
<td>Change in urine output</td>
<td>262</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0 (0-1.4)</td>
</tr>
<tr>
<td>Subtotal</td>
<td>3949</td>
<td>127</td>
<td>0</td>
<td>127</td>
<td>3.4 (2.9-4.1)</td>
</tr>
<tr>
<td>Line insertion/removal</td>
<td>1317</td>
<td>36</td>
<td>77</td>
<td>113</td>
<td>8.6 (7.1-10.2)</td>
</tr>
<tr>
<td>Catheter-associated urinary tract infection</td>
<td>579</td>
<td>0</td>
<td>218</td>
<td>218</td>
<td>38 (34-42)</td>
</tr>
<tr>
<td>Catheter-associated bloodstream infection*</td>
<td>249</td>
<td>0</td>
<td>88</td>
<td>88</td>
<td>35 (29-42)</td>
</tr>
<tr>
<td>Radiology report</td>
<td>899</td>
<td>6</td>
<td>0</td>
<td>6</td>
<td>0.7 (0.2-1.4)</td>
</tr>
<tr>
<td>Extended surgery</td>
<td>66</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0 (0-5.4)</td>
</tr>
<tr>
<td>Total</td>
<td>7059</td>
<td>169</td>
<td>383</td>
<td>552</td>
<td>7.8 (7.2-8.5)</td>
</tr>
</tbody>
</table>

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

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

*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 a 996 code, 10 (25%) 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 a 996 code, 10 (25%) 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 a 996 code, 10 (25%) 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 a 996 code, 10 (25%) had a confirmed AMDE. Of 40 patients

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

<table>
<thead>
<tr>
<th>Device category</th>
<th>ICD-9 Codes</th>
<th>Regular Admissions (n = 821)</th>
<th>Short Stay (n = 308)</th>
<th>Event Total (n = 1129)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orthopedic</td>
<td>996.4, 996.66, 996.67, 996.77, 996.79</td>
<td>182 (22)</td>
<td>103 (33)</td>
<td>285 (25)</td>
</tr>
<tr>
<td>Vascular access</td>
<td>996.1, 996.62, 996.74</td>
<td>188 (23)</td>
<td>26 (8)</td>
<td>214 (19)</td>
</tr>
<tr>
<td>Dialysis</td>
<td>996.56, 996.68, 996.73</td>
<td>21 (3)</td>
<td>144 (47)</td>
<td>165 (15)</td>
</tr>
<tr>
<td>Urologic catheters</td>
<td>996.64</td>
<td>102 (12)</td>
<td>0</td>
<td>102 (9)</td>
</tr>
<tr>
<td>Cardiac</td>
<td>996.01, 996.09, 996.61, 996.72</td>
<td>42 (5)</td>
<td>0</td>
<td>42 (4)</td>
</tr>
<tr>
<td>Prosthetic cardiac valve</td>
<td>996.02, 996.71</td>
<td>24 (3)</td>
<td>0</td>
<td>24 (2)</td>
</tr>
<tr>
<td>Defibrillator</td>
<td>996.04</td>
<td>6 (1)</td>
<td>0</td>
<td>6 (1)</td>
</tr>
<tr>
<td>Nervous system</td>
<td>996.2, 996.63, 996.75</td>
<td>19 (2)</td>
<td>2 (1)</td>
<td>21 (2)</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>996.32, 996.39, 996.65, 996.76</td>
<td>25 (3)</td>
<td>7 (2)</td>
<td>32 (3)</td>
</tr>
<tr>
<td>Breast implant</td>
<td>996.54</td>
<td>2 (0.2)</td>
<td>4 (1)</td>
<td>6 (1)</td>
</tr>
<tr>
<td>Ocular</td>
<td>996.53</td>
<td>0</td>
<td>6 (2)</td>
<td>6 (1)</td>
</tr>
<tr>
<td>Other</td>
<td>996.59, 996.69, 996.70, 996.79, 996.79, E878.1, E878.2, E879.4</td>
<td>210 (26)</td>
<td>16 (5)</td>
<td>226 (20)</td>
</tr>
<tr>
<td>Permanent implant</td>
<td>996.02, 996.04, 996.32, 996.4, 996.53, 996.54, 996.66, 996.67, 996.71, 996.78, 996.79, E878.1, E878.2</td>
<td>446 (54)</td>
<td>142 (46)</td>
<td>588 (52)</td>
</tr>
<tr>
<td>Disposable</td>
<td>996.31, 996.56, 996.64, 996.68</td>
<td>106 (13)</td>
<td>0</td>
<td>106 (9)</td>
</tr>
<tr>
<td>Durable equipment</td>
<td>None</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Unspecified</td>
<td>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</td>
<td>269 (33)</td>
<td>166 (54)</td>
<td>435 (38.5)</td>
</tr>
</tbody>
</table>

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

**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.
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). 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-associated 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*

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>No. of Admissions</th>
<th>AMDE Detection Method</th>
<th>No. per 1000 Admissions (95% CI)</th>
<th>No. per 1000 Admissions (95% CI)</th>
<th>No. per 1000 Admissions (95% CI)</th>
<th>No. per 1000 Admissions (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>12,593</td>
<td>349</td>
<td>27.7 (24.9-30.7)</td>
<td>814</td>
<td>64.6 (60.4-69.1)</td>
<td>201</td>
</tr>
<tr>
<td>Women</td>
<td>6615</td>
<td>194</td>
<td>29.3 (25.4-33.7)</td>
<td>411</td>
<td>62.1 (56.4-68.2)</td>
<td>11</td>
</tr>
<tr>
<td>Men</td>
<td>5978</td>
<td>155</td>
<td>25.9 (22.0-30.3)</td>
<td>403</td>
<td>67.4 (61.2-74.1)</td>
<td>7</td>
</tr>
<tr>
<td>Age, y &lt;30</td>
<td>1607</td>
<td>28</td>
<td>17.1 (12.2-25)</td>
<td>43</td>
<td>27.1 (19.3-36)</td>
<td>1</td>
</tr>
<tr>
<td>30-49</td>
<td>3010</td>
<td>64</td>
<td>21.6 (16.2-27)</td>
<td>145</td>
<td>48.2 (40.8-56.4)</td>
<td>4</td>
</tr>
<tr>
<td>50-69</td>
<td>3985</td>
<td>117</td>
<td>29.3 (24.3-35.1)</td>
<td>279</td>
<td>70.0 (62.3-78.4)</td>
<td>6</td>
</tr>
<tr>
<td>70+</td>
<td>3991</td>
<td>140</td>
<td>35.1 (29.6-41.3)</td>
<td>347</td>
<td>86.9 (78.4-96.1)</td>
<td>6</td>
</tr>
<tr>
<td>Physician service</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgery</td>
<td>5604</td>
<td>174</td>
<td>31.0 (26.5-35.6)</td>
<td>559</td>
<td>99.8 (82.0-108.0)</td>
<td>10</td>
</tr>
<tr>
<td>Medicine</td>
<td>4382</td>
<td>121</td>
<td>27.6 (22.8-32.5)</td>
<td>218</td>
<td>49.7 (43.5-56.6)</td>
<td>2</td>
</tr>
<tr>
<td>Gynecology</td>
<td>843</td>
<td>10</td>
<td>12.0 (7.5-22.0)</td>
<td>6</td>
<td>7.0 (3-20)</td>
<td>0</td>
</tr>
<tr>
<td>Other</td>
<td>1248</td>
<td>38</td>
<td>31.2 (22.3-42.5)</td>
<td>30</td>
<td>27.2 (18.9-37.9)</td>
<td>6</td>
</tr>
<tr>
<td>Not available</td>
<td>516</td>
<td>6</td>
<td>10.4 (3-30)</td>
<td>1</td>
<td>2 (0-10)</td>
<td>2</td>
</tr>
<tr>
<td>Medical or other diagnosis codes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Angina or myocardial infarction</td>
<td>981</td>
<td>13</td>
<td>13.7 (7-23)</td>
<td>24</td>
<td>24 (16-36)</td>
<td>0</td>
</tr>
<tr>
<td>Rehabilitation</td>
<td>323</td>
<td>30</td>
<td>93.1 (63-130)</td>
<td>14</td>
<td>43 (24-73)</td>
<td>2</td>
</tr>
<tr>
<td>Depressive disorder</td>
<td>292</td>
<td>0</td>
<td>0 (0-100)</td>
<td>2</td>
<td>7.0 (0-30.0)</td>
<td>1</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>225</td>
<td>9</td>
<td>40 (20-80)</td>
<td>15</td>
<td>67 (37-110)</td>
<td>0</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>5.6 (8.7)</td>
<td>21.6 (14.9)</td>
<td>10.9 (11.8)</td>
<td>21.6 (14.9)</td>
<td>12.8 (13.4)</td>
<td></td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>3.6 (1.9-6.4)</td>
<td>16.8 (10.6-27.9)</td>
<td>6.4 (8.8-14.1)</td>
<td>18.5 (9.0-29.0)</td>
<td>8.3 (4.4-16.2)</td>
<td></td>
</tr>
</tbody>
</table>

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. 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.

The intensive, real-time telemetry detection system confirmed a high incidence of false alarms. 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.

Study concept and design: Samore, Evans, Gould, Willy, Bright.
Acquisition of data: Samore, Evans, Lassen, Gould, Lloyd, Gardner, Taylor, Woodbury.
Analysis and interpretation of data: Samore, Evans, Gould, Lloyd, Gardner, Abouzelof, Willy, Bright.
Drafting of the manuscript: Samore, Abouzelof, Willy, Bright.
Critical revision of the manuscript for important intellectual content: Samore, Evans, Lassen, Gould, Lloyd, Gardner, Woodbury, Willy, Bright.
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.

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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 coauthors. 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.

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