

# The Incidence and Cost of Unexpected Hospital Use After Scheduled Outpatient Endoscopy

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**Background:** Data on complications of gastrointestinal endoscopic procedures are limited. We evaluated prospectively the incidence and cost of hospital visits resulting from outpatient endoscopy.

**Methods:** We developed an electronic medical record-based system to record automatically admissions to the emergency department (ED) within 14 days after endoscopy. Physicians evaluated all reported cases for relatedness of the ED visit to the prior endoscopy based on predetermined criteria.

**Results:** We evaluated 6383 esophagogastroduodenoscopies (EGDs) and 11 632 colonoscopies (7392 for screening and surveillance). Among these, 419 ED visits and 266 hospitalizations occurred within 14 days after the procedure. One hundred thirty-four (32%) of the ED visits and 76 (29%) of the hospitalizations were procedure related, whereas 31 complications were recorded by standard physician reporting ( $P < .001$ ). Procedure-related

hospital visits occurred in 1.07%, 0.84%, and 0.95% of all EGDs, all colonoscopies, and screening colonoscopies, respectively. The mean costs were \$1403 per ED visit and \$10 123 per hospitalization based on Medicare standardized rates. Across the overall screening/surveillance colonoscopy program, these episodes added \$48 per examination.

**Conclusions:** Using a novel automated system, we observed a 1% incidence of related hospital visits within 14 days of outpatient endoscopy, 2- to 3-fold higher than recent estimates. Most events were not captured by standard reporting, and strategies for automating adverse event reporting should be developed. The cost of unexpected hospital visits postendoscopy may be significant and should be taken into account in screening or surveillance programs.

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**A** TOTAL OF 15 TO 20 MILLION endoscopic procedures are performed annually in the United States,<sup>1-5</sup> yet comprehensive safety and complication data are relatively limited. For instance, the survey<sup>6</sup> on endoscopic complications conducted by the American Society for Gastrointestinal Endoscopy (ASGE) in 1976 remains one of the most commonly cited publications on this topic and found an overall complication rate of 0.13% for upper endoscopy and 0.35% for colonoscopy.

Subsequent reports have yielded similar results.<sup>7-14</sup> Studies, however, have not used consistent methods. Study follow-up periods have ranged from 24 hours<sup>7</sup> to 30 days,<sup>8,14-16</sup> and methods used have included physician reporting,<sup>9</sup> medical record review,<sup>7,8,14</sup> and telephone follow-up interviews.<sup>15,16</sup> Limitations of these approaches have been widely acknowledged and include reporting and selection bias and incomplete follow-up. We sought to overcome these limitations

through the use of an automated system designed to prospectively record emergency department (ED) visits within 14 days of endoscopic procedures.

The electronic medical record (EMR) at Beth Israel Deaconess Medical Center (BIDMC), Boston, Massachusetts, allows for unique monitoring of patient outcomes because it includes all clinician notes, laboratory data, and results of diagnostic tests performed at our hospital and affiliated institutions,<sup>1</sup> including ED visits. The EMR system, with over 5000 active users, is institution wide and used for all hospitalized patients and most office visits. The EMR is used by all gastroenterologists affiliated with BIDMC, whether the actual office visit or endoscopy is performed on-site or at a satellite office or free-standing ambulatory procedure unit. This allowed the development of a program to automatically track visits to our ED that occur after an outpatient gastrointestinal endoscopic procedure. The system is designed to provide clinicians and quality improvement officials with real-time data on adverse events.

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In this study, we manually reviewed and evaluated the information gathered prospectively by this system to provide data for 2 related aims: (1) to calculate the frequency of ED visits and hospitalizations resulting from gastrointestinal (GI) endoscopic procedures, and (2) to estimate the cost of hospital visits resulting from GI endoscopic procedures.

## METHODS

### SETTING AND PATIENTS

Beth Israel Deaconess Medical Center is a 621-bed teaching hospital affiliated with Harvard Medical School. In 2007 there were 40 584 inpatient discharges, 471 871 outpatient visits, and 51 763 ED encounters. Thirty-four staff gastroenterologists perform approximately 27 000 endoscopic procedures annually, and 96% of patients live in-state. We included for analysis all patients who had undergone a scheduled outpatient esophagogastroduodenoscopy (EGD) or colonoscopy at BIDMC from March 1 to November 30, 2007. Pilot data were used to estimate the necessary sample size, which indicated a study duration of 9 months.

### DATA COLLECTION

Prior to this study, we began systematically collecting data on key components of endoscopic quality, including colonoscopy withdrawal time, polyp detection rate,<sup>17</sup> cecal intubation rate, and rate of complications. Data were collected and analyzed in a central database to provide real-time data on the performance of the division in comparison with national benchmarks. In January 2007 this system was linked to an automated system that tracks patient visits by medical record number and was programmed to generate reports of all patients seen in the ED within 14 days after an outpatient endoscopic procedure. The 14-day period was based on literature suggesting that few clinically significant complications occur outside this window.<sup>14</sup> This system automatically records the endoscopy date, ED visit date, patient age and sex, type of procedure, procedure diagnosis-related group (DRG) code, and performing endoscopist.

Data were augmented for identified ED visit by manual search of the EMR to include indication for endoscopic procedure, reason for ED visit and ascertainment of whether the ED visit was caused by the endoscopic procedure. Manual review of hospital visits was performed independently on each case by 2 of 3 physicians (D.A.L., R.K., or S.G.), including at least 1 from the Department of Medicine and 1 from the Division of Gastroenterology. In cases in which the 2 reviewers reached different conclusions regarding whether the hospital visit was related, a third physician reviewed the case, and the case was discussed until consensus emerged. Cases in which the reviewing gastroenterologist was involved in the procedure were reviewed by an alternate gastroenterologist (S.R.). The  $\kappa$  value for reviewer agreement prior to discussion was 0.90.

Pre-established criteria for relatedness of a case were that the chief complaint prompting the ED visit did not predate the endoscopy and that the ED visit could reasonably have been attributed to the endoscopic procedure. Decisions were based on both the type and timing of the hospital visit and supporting clinical data. For instance, a fall in an elderly patient 1 day after a procedure would likely be deemed related, whereas the same presenting complaint 10 days later would be deemed related only if there was additional evidence, such as dehydration or electrolyte abnormalities, thought to be related to colo-

noscopy preparation. In addition, ED visits for which the chief complaint was the same as the indication for endoscopy (in most cases abdominal pain) were considered to be unrelated. In borderline cases, reviewers were instructed to err on the side of considering the hospital visit to be related to the procedure. We limited our analyses to scheduled outpatient EGDs and colonoscopies. Emergent procedures, endoscopic ultrasonography, and endoscopic retrograde cholangiopancreatography were excluded, as were all inpatient procedures.

For 2 reasons, our tracking system was not designed to capture data for patients directly admitted to the hospital without going through the ED. First, most patients admitted to the hospital directly after endoscopy are planned admissions (eg, in the case of an inflammatory bowel disease flare or post-ERCP monitoring). The automated system is unable to discriminate these cases from true adverse events. Second, physicians should be aware of complications in patients admitted to the hospital directly from the endoscopy suite. Thus, these should be reported through the voluntary reporting system, which the automated system was intended to augment but not replace. The traditional voluntary system, which had been in place prior to development of the automated system, included monthly notices sent out to all endoscopists eliciting reports of the prior month's complications and an online system in which a possible adverse event could be logged by any treating clinician (including both physicians and nurses) at the point of care.

### MAIN OUTCOME MEASURE

The main outcome measure for this study was the combined 14-day incidence of ED visit and/or hospitalization related to an endoscopic procedure. Secondary outcomes included the cost of these patient encounters estimated based on standardized Medicare payment rates, the estimated added cost of these hospital visits to the screening colonoscopy program, and the proportion of hospital visits recorded by the automated tracking system compared with the traditional voluntary system.

To estimate the cost of each related hospital visit, we used the inpatient DRG code or inpatient/outpatient *Current Procedural Terminology* codes. These were converted to costs using the Medicare base rate without adjustment for region or acuity and summed into a single dollar amount per patient encounter. In cases in which costs could not readily be attributed to a single procedure (eg, a patient presenting with abdominal pain after an EGD and colonoscopy), the cost was divided equally between the 2 examinations. For the 8 patients seen at outside hospitals for endoscopy-related complaints, we were not able to assess costs directly as described herein. To account for these cases, we estimated the cost for each individual case by using the mean cost for patients seen at BIDMC for the same chief complaint.

### STATISTICAL ANALYSIS

Our primary analyses are descriptive, evaluating the incidence of ED visits postendoscopy, as described in the previous subsection, as well as the cost associated with these visits. Relationships between categorical variables were assessed using  $\chi^2$  or Fisher exact tests, while the unpaired *t* test was used for ordinal variables.

Data were entered into a secure database (Access, Microsoft Office; Microsoft Corp, Redmond, Washington) and reviewed for errors prior to analysis. Statistical analysis was completed using SPSS for Windows (release 17.0. 2008; SPSS Inc, Chicago, Illinois). This study was approved by the Beth Israel Deaconess institutional review board (protocol 2007-P-000399/3).

**Table 1. Study Population and Demographics**

Characteristic	Overall Population, %	Complication Population, %	P Value
EGD	(n=6383)	(n=69)	
Age, mean, y	55.9	61.6	.002
Female sex	54.9	51.4	.72
Trainee involvement	36.6	45.3	.13
Colonoscopy	(n=11 632)	(n=98)	
Age, mean, y	58.0	60.6	.01
Female sex	50.7	50.0	.97
Involvement of fellows in training	17.2	22.4	.22
With polypectomy	40.6	40.4	.98
Screening or surveillance colonoscopy	(n=7392)	(n=70)	
Age, mean, y	60.4	61.1	.65
Female sex	53.2	54.9	.78
With polypectomy	48.9	47.1	.78

Abbreviation: EGD, esophagogastroduodenoscopy.

## RESULTS

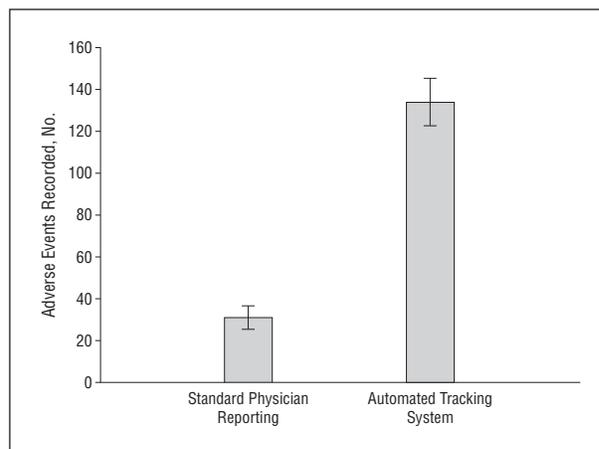
### PATIENT DEMOGRAPHICS AND PROCEDURE COUNTS FOR THE STUDY PERIOD

The study included 6383 outpatient EGDs and 11 632 outpatient colonoscopies performed by staff gastroenterologists and surgeons (**Table 1**). Of the 11 632 colonoscopies, 7392 were performed for colorectal cancer screening or surveillance. The mean age of patients undergoing colonoscopy was 58.0 years, and 46.8% were male. The mean age of patients undergoing EGD was 55.9 years, and 45.1% were male. Fellows in training participated in 36.6% of EGDs and 17.2% of colonoscopies.

### HOSPITAL VISITS CAPTURED BY THE AUTOMATED TRACKING SYSTEM

The automated tracking system recorded 419 patients seen in the ED within 14 days of their endoscopic procedure. Of these cases, 134 visits (32.0%) were considered by the physician reviewers to be related to the endoscopic procedure, and 76 of these (56.7%) resulted in hospitalization. In 20 of the 419 cases reviewed (4.8%) there was disagreement between the 2 reviewers. In these cases, discussion between the 3 physician reviewers designated 13 of these cases as related and 7 as unrelated.

Prompting the related ED visits were 68 EGDs and 98 colonoscopies, of which 70 colonoscopies were for colorectal cancer screening or surveillance and 28 were diagnostic. In 32 cases, patients underwent both EGD and colonoscopy in the same session, and the ensuing hospital visit could not be attributed definitively to one procedure or the other. To avoid underestimating the incidence of hospital visits for a procedure type, in these cases both the EGD and colonoscopy were considered to have had a related hospital visit. For this reason, although there are 134 unique hospital encounters, 166 procedures are designated as having led to a hospital visit.



**Figure 1.** Hospital visits captured by the automated system vs standard physician reporting. The error bars indicate standard deviations.

### COMPLICATIONS REPORTED BY THE STANDARD VOLUNTARY PHYSICIAN REPORTING SYSTEM

Along with the automated system, our division maintains a standard voluntary, paper-based, physician reporting system whereby each gastroenterologist must submit a monthly form reporting any complications or that no complications were known to have occurred. In addition, there is a hospital-wide online system that any treating clinician can use to report a potential adverse event at the point of care. Over the study period, 31 complications resulting in an ED visit or hospitalization were recorded using the standard physician reporting system, compared with 134 captured by the automated system ( $P < .001$ ) (**Figure 1**). Eight complications voluntarily reported by staff gastroenterologists were not captured using the automated system because the visits occurred at outside institutions. Of these, 7 were related to colonoscopy (1 for perforation, 3 for bleeding, and 3 for abdominal pain), and 1 was related to combined EGD/colonoscopy (for abdominal pain). The automated tracking system captured all hospital visits to our institution that were reported by the voluntary system.

A total of 144 total adverse events were captured by all methods during the study period (134 visits by the automated system plus 8 visits to outside institutions captured by the voluntary system). Of these, 134 of 142 (94.4%) were captured by the automated system, compared with 31 of 142 (21.8%) for the voluntary system.

### OVERALL ADVERSE EVENT RATES

We observed hospital visit rates of 0.79% (95% confidence interval [CI], 0.63%-0.88%), 1.07% (95% CI, 0.84%-1.35%), 0.84% (95% CI, 0.69%-1.03%), and 0.95% (95% CI, 0.75%-1.19%) for all endoscopies, EGDs, colonoscopies, and screening colonoscopies, respectively (there were no statistically significant differences between groups;  $P > .31$  for all groups). The hospital visit rate is slightly less for the overall group because an individual patient could be counted only once for this group, whereas an individual who underwent an EGD and a screening colonoscopy could be counted separately for each procedure type.

The mean time to ED presentation after the procedure was 6.0 days for EGDs (median, 5.5 days) and 5.2 days for colonoscopies (median, 3.5 days) ( $P = .17$ ) (Table 2). The most common reasons for these visits were abdominal pain (47%), GI tract bleeding (12%), and chest pain (11%), which together accounted for more than half of ED visits (Table 2). For both EGDs and colonoscopies, abdominal pain was the most common adverse event. For colonoscopies, the second and third most common events were chest pain and bleeding, respectively. For EGDs, the second and third most common events were fever, pneumonia, and chest pain. There were no significant differences in overall complication rates for screening or surveillance colonoscopy vs colonoscopy performed for symptoms or disease monitoring ( $P = .12$ ); however, of the 12 episodes of bleeding related to colonoscopy, 11 were in the setting of snare polypectomy and 1 was after mucosal biopsy. We also observed a variety of unusual or unexpected reasons for hospital visits that were thought by reviewers to be procedure related, including syncope, vitreous detachment, and appendicitis. A single death considered by reviewers to be procedure related occurred in a 75-year-old individual who experienced a cardiac arrest 8 days after stopping aspirin prior to an EGD for surveillance of Barrett esophagus.

#### PATIENT DEMOGRAPHICS IN THOSE WITH PROCEDURE-RELATED HOSPITAL VISITS VS THE OVERALL STUDY POPULATION

The mean age of patients with an endoscopy-related hospital visit after an EGD was 61.6 years (range, 18-99 years), which was significantly greater than the mean age of 55.9 years (range, 16-100 years) in the overall population ( $P = .002$ ). The mean age in the hospital visit cohort was also significantly greater for colonoscopies overall (60.56 years [range, 20-85 years] vs 57.95 years [range, 15-100 years]) ( $P = .01$ ) but not for screening or surveillance colonoscopies (61.09 years [range, 32-85 years] vs 60.37 years [range, 18-98 years]) ( $P = .55$ ). However, in the screening or surveillance colonoscopy group with a related hospital visit, 41.4% of patients were older than 65 years and 20.0% were older than 75 years compared with 29.3% ( $P = .03$ ) and 10.2% ( $P < .001$ ), respectively, in the overall population. There were no significant differences in sex or fellow participation between groups (see Table 1 for  $P$  values).

#### ESTIMATED COSTS OF PROCEDURE-RELATED HOSPITAL VISITS

The mean cost per hospital visit was \$6355.71 (range, \$196.40-\$174 213.23; median, \$5270.36 [95% CI, \$4066.91-\$8644.49]). For screening or surveillance colonoscopy, costs totaled \$355 489.76 (range, \$196.40-\$42 570.00 per hospital visit; median, \$3755.26 [95% CI, \$3599.28-\$6557.52]), which added \$48.09 (95% CI, \$34.08-\$62.10) per examination to the overall screening program. Given that the average Medicare reimbursement is approximately \$1140.00, including indirect costs,<sup>18</sup> this represents a 4.2% increase. For EGDs and diagnostic colonoscopies, the overall cost per case performed was \$79.92 and \$47.86, respectively. The total costs that we attributed to unplanned hospital visits re-

**Table 2. Type and Frequency of Reasons for Hospital Visits Likely Related to Endoscopic Procedures**

Type of Complication	Cases, No. (n=142)	Total Related Complications, %	Age, Mean, y	Days to Presentation, Mean, No.
All EGD related	69	51.5	61.6	6.0
All colonoscopy related	98	74.2	60.6	5.2
Abdominal pain	63	47.0	56.7	4.6
Gastrointestinal tract bleeding	16	11.9	63.9	5.7
Chest pain	14	10.5	60.4	6.6
Fever	8	6.0	53.9	3.1
Pneumonia	7	5.2	57.4	9.0
Fall	6	4.5	67.4	7.0
CHF exacerbation	5	3.7	69.0	9.0
Dehydration	4	3.0	61.8	1.5
Intestinal perforation	4	3.0	63.0	1.7
Syncope	3	2.2	65.3	2.3
Atrial fibrillation	3	2.2	66.7	3.7
Nausea and/or vomiting	3	2.2	56.3	0.7
Back pain	2	1.5	43.5	2.5
Diarrhea	2	1.5	57.0	4.0
TIA/CVA	2	1.5	73.0	10.5
Cellulitis, related to IV site	2	1.5	61.5	7.0
Appendicitis	2	1.5	55.0	7.5
Urinary retention	2	1.5	63.5	4.0
Neck pain	2	1.5	72.0	3.0
Myocardial infarction	2	1.5	65.5	9.5
Asthma exacerbation	1	0.75	44.0	0.0
Hepatic encephalopathy	1	0.75	56.0	6.0
Hypoglycemia	1	0.75	69.0	0.0
Small bowel obstruction	1	0.75	0.0	10.0
Cardiac arrest	1	0.75	8.0	8.0
Vitreous detachment	1	0.75	75.0	1.0
Leg cramps	1	0.75	67.0	2.0
Deep vein thrombosis	1	0.75	83.0	3.0
Rectal pain	1	0.75	68.0	2.0
Ruptured hepatoma	1	0.75	78.0	0.0
Sickle cell crisis	1	0.75	51.0	0.0
Acute pancreatitis	1	0.75	50.0	5.0
Colonic ileus	1	0.75	72.0	10.0

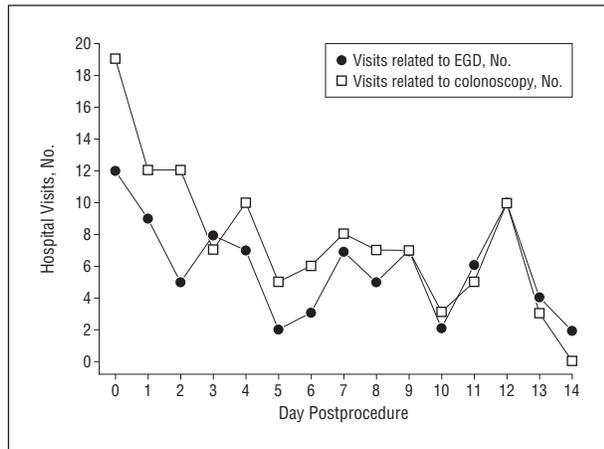
Abbreviations: CHF, congestive heart failure; EGD, esophagogastroduodenoscopy; IV, intravenous; TIA/CVA, transient ischemic attack/cerebrovascular accident.

lated to endoscopic procedures during the 9-month study period were \$1 029 624.81.

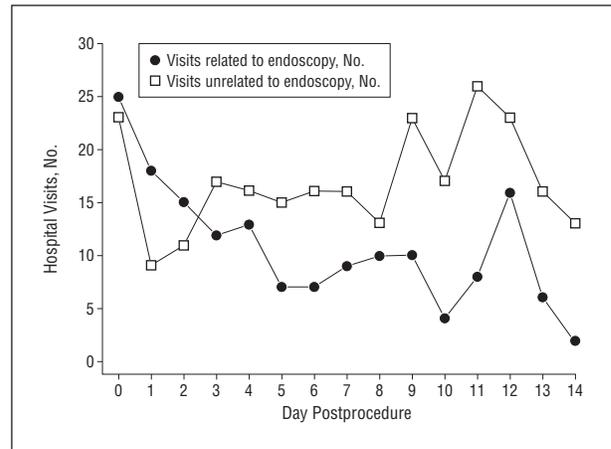
#### COMMENT

We prospectively evaluated the incidence and cost of hospital visits related to outpatient endoscopy using a combination of standard voluntary reporting and an automated system. Although the overall rate of severe complications, including perforation, myocardial infarction, and death remained low, the true range of adverse events is much greater than typically appreciated, and the overall rate of 1 in 127 patients visiting the hospital due to an outpatient endoscopic procedure is a cause for concern, especially in the setting of screening and surveillance when otherwise healthy individuals are subjected to procedural risks.

The standard physician reporting greatly underestimated the burden of medical care related to endoscopic procedures and unexpected hospital utilization, which adds considerably to the cost of our screening or sur-



**Figure 2.** Number of hospital visits related to esophagogastroduodenoscopies (EGDs) and colonoscopies by day after procedure.



**Figure 3.** Number of related and unrelated hospital visits by day after procedure.

veillance colonoscopy program. Advanced patient age was seen to be a predictor of development of procedure-related hospital visit, whereas sex and involvement of a fellow in training were not. Although the rate of bleeding and perforation was higher in patients postpolypectomy, and snare polypectomy showed a trend toward increased hospital visit rate (Table 1), the high number of mild adverse events and the inability to control for polyp size likely explain why these were not significant.

The overall cost of hospital visits related to endoscopy at our center was nearly \$1.4 million per year with an incremental cost of approximately 4% to the screening program. Although on an individual basis this cost is relatively low, projected nationwide, this is a considerable and underreported cost to the medical system, which could exceed \$650 million per year in the United States.

Prior studies suggest that voluntary reporting of complications by physicians is incomplete, with 15% to 45% of adverse outcomes unrecognized or unreported.<sup>15,19-22</sup> Reliance on physician reporting is likely the major reason for the low complication rates reported by the 1976 ASGE study.<sup>6</sup> Moreover, underreporting also may reflect a discrepancy between physician perception of the risk of endoscopic procedures and the reality experienced by patients. Other studies of endoscopic complications have addressed the deficiencies of physician reporting in a variety of ways. On the one hand, Zubarik et al<sup>15,16</sup> used telephone recall, which benefits from direct patient elicitation, and reported hospitalization rates of 1.1% and 0.6% for EGDs and colonoscopies, respectively. However, in these studies approximately 25% of participants were lost to follow-up. Furthermore, telephone follow-up is labor intensive and not pragmatic from an ongoing quality assurance standpoint. Sieg et al,<sup>9</sup> on the other hand, used a structured protocol to attempt to improve physician reporting; however, this does not address the issue that the reporting physicians will not be aware of all adverse events or may not classify all complications as such. Indeed, the complication rate reported by Sieg et al<sup>9</sup> of 1 in 5000 is unusually low. Other studies using retrospective medical chart review<sup>7,8,14</sup> have reported complication rates of approximately 0.5%. Although medical chart record review avoids issues with participant availability and physician report-

ing, this method also is subject to miscoding<sup>23-27</sup> and will capture only events specifically targeted, such as cardiovascular outcome as in the study by Gangi et al.<sup>7</sup>

There are multiple benefits of an automated reporting system. First is the ability to capture complications not known or reported by physicians. We found that only 22% of endoscopy-related hospital visits were reported in the voluntary system. Emergency department visits for minor complaints of abdominal pain or bleeding not requiring admission may not be reported by physicians because there is no reportable complication, although incurred medical costs and losses in productivity may be considerable. Conversely, patient reporting is variable, and postprocedure telephone interviews are labor intensive, may bias against individuals with language barriers, and may elicit symptoms of uncertain importance. Second, automated reporting systems represent an efficient and sustainable source of data on adverse outcomes that can be viewed in real time. This allows for monitoring of changes in complication rates, as may result from alterations in protocols or equipment.

One potential limitation of this study is the use of the 14-day cutoff by the automated system. Although the literature suggests that procedure-related hospital visits occurring more than 2 weeks after an endoscopy are uncommon,<sup>14</sup> it is possible that we have underestimated related hospital visit rates owing to delayed adverse events. However, no physician-reported complication occurred after 14 days. Furthermore, the mean (SD) time from procedure to ED visit was 5.4 (4.4) days. By this calculation, day 14 is approximately 2 SDs above the mean, suggesting that not more than 2.5% of related hospital visits would have been missed, which is also supported by the distribution of visits over time (**Figure 2**).

We also acknowledge that a proportion of patients with endoscopy-related hospital visits may be seen at outside institutions and thus be missed by our automated tracking system. We attempted to control for this by capturing complications reported by physicians of patients seen at outside hospitals, which represented 6% of the total events. In addition, 200 consecutive patients were contacted by telephone 2 to 6 weeks after an endoscopic procedure. In this sample, 1 patient reported a visit to an outside ED or being hospitalized within 14 days of their endoscopic procedure.

Another potential limitation was our methods for classifying visits as procedure related. To minimize misclassification, we used 2 reviewers (1 gastroenterologist and 1 general internist) for each case. While results may reflect a “lower bound” owing to the 14-day cutoff and patients seen at outside institutions, it could be argued that we have overestimated complications by attributing all potentially related events to the procedure. However, when evaluating the frequency of observed hospital visits against the number of days after the procedure, we found that the number of visits declined throughout the 2-week period in the “related” group, whereas the number of hospital visits for conditions unrelated to the endoscopic procedure remained constant (**Figure 3**). This expected result lends validity to our classification. Related to this, in patients undergoing sequential EGD and colonoscopy, the complication was not always attributable to one of the procedures. In these cases, we conservatively estimated event rates by considering both procedures to have led to a complication, potentially overestimating incidence.

In summary, we report the use of a novel EMR-based adverse event tracking system that allows for more accurate assessment of complications and permits real-time monitoring of adverse event rates. We found that this system significantly expanded adverse event detection rate compared with traditional voluntary reporting and suggests an unexpectedly high financial burden of these events.

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