

SPECIAL ARTICLE

A Spike in Fatal Medication Errors at the Beginning of Each Month

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At the beginning of each month, there is a spike in government payments to individuals, resulting in a beginning-of-the-month spike in purchases of prescription drugs and in increased pharmacy workloads. Studies suggest that pharmacy error rates increase with increased workloads. These facts raise an important and previously unanswered question: is there a spike in fatal medication errors at the beginning of each month? We examined all United States death certificates from 1979–2000 (> 47,000,000 deaths) and showed that medication error deaths for which the decedent was dead on arrival or died in the emergency room or as an outpatient spiked by 25% above normal at the beginning of each month. This beginning-of-the-month spike ($25\% \pm 4\%$) was larger than for any other major cause of death. The beginning-of-the-month spike did not vary by socioeconomic status and was not larger for substance abusers than for others. Five explanations for the findings were tested. Evidence suggested that the spike in medication error deaths cannot be solely attributed to a spike in the consumption of alcohol or drugs. An increase in pharmacy error rates might play a role.

Key Words: medication errors, pharmacy error rates, timing of medication error deaths.

(*Pharmacotherapy* 2005;25(1):1–9)

Much recent research has examined medication errors and error prevention.^{1–3} As noted by one group of authors,^{4–6} many studies on this topic were conducted within hospitals or pharmacies and were limited to small geographic areas. Complementing the earlier studies, these authors used a population-based approach to identify factors associated with the causes of medication errors.^{4–6} Their studies identified hospital characteristics,⁴ clinical pharmacy services,⁵ and pharmacy staffing practices^{5, 6} that are associated with medication errors. However, their study

design did not allow them to focus on fatal medication errors.

Fatal medication errors are increasing rapidly.^{7, 8} According to official data from the United States, the number of accidental drug-related deaths nearly quadrupled from 2707 in 1979 to 10,133 in 1998.⁸ This increase far exceeded the percentage increase in the number of prescriptions filled, suggesting that these additional fatal medication errors are not entirely due to increased consumption of drugs. Because of these findings, understanding the etiology of medication errors has become increasingly important in order to reduce the number of deaths resulting from them.

One way to analyze mortality from medication errors is to focus on periods when these errors are abnormally frequent. Identifying these high-fatality periods may help illuminate additional processes producing medication errors and perhaps facilitate their reduction.

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In this study, we used computerized death certificates from throughout the United States to examine temporal fluctuations in deaths from medication errors (131,952 deaths) and in deaths from other causes (47,603,091 deaths). We built on the results of our previous study,⁹ which showed a systematic increase in all-cause mortality at the beginning of each month. This increase was particularly large for poor persons whose deaths involved substance abuse. Government payments in the form of Social Security pensions, Social Security disability, and welfare benefits all typically occur at the beginning of the month^{10, 11} (although this is no longer true for a small fraction of Social Security pensions).¹⁰ In our previous study,⁹ we provided some evidence suggesting that the spike in substance-abuse deaths at the beginning of each month resulted partly from beginning-of-the-month government payments, which abruptly increased the ability of poor persons to pay for alcohol and street drugs.

At the start of each month, there is a spike not only in the purchase of street drugs,¹²⁻¹⁴ but also in the purchase of medicinal drugs.¹⁵⁻¹⁸ For example, Pathmark, a multistate chain of supermarkets and drugstores, reports a surge in purchases at the beginning of the month because of social service payments.¹⁵ A Florida law decreed that Medicaid audits of pharmacies “may not be scheduled during the first 5 days of any month due to the high volume of prescriptions filled during that time.”¹⁶ In a press release from the Indiana Office of the Governor, the Governor noted, “Seniors all across the state have told us they have to make terrible choices—whether to pay for utilities or groceries, or the medicines they need.”¹⁷ In the same news release, a pharmacist noted, “These first few days of the month, so many seniors cash their Social Security checks and come in for the medicine they need.” Similarly, Affiliated Computer Services, which processes Medicaid prescriptions for 20 states, notes a surge in prescriptions at the beginning of the month.¹⁸

Pharmacists have identified high prescription volume as an important factor associated with medication errors.^{6, 19-21} The North Carolina Board of Pharmacy limits pharmacy workload to 150 prescriptions/pharmacist/day.²⁰ Most state boards of pharmacy recommend that “pharmacists, as licensed professionals should ‘pace themselves’ to ensure safety.”²¹ Thus, because there is increased pharmacy workload at the beginning of each month, some pharmacists may be unusually

prone to error in the filling and labeling of prescriptions and may have less time than usual to explain necessary precautions to their patients.

These considerations raise an important and previously unanswered question: do fatal medication errors spike at the beginning of each month? In this study, we discovered that some types of fatal medication errors spike by 25% above normal at the beginning of the month. This spike is an extreme outlier—higher than the spike for any other major cause of death. Identification of this spike and the search for its causes have the potential to reduce the number of deaths from medication errors and to improve the quality of medical care. Our evidence suggests that the spike in drug-related deaths cannot be solely attributed to increased consumption of drugs; an increase in prescription error rates might also play a role.

Methods

We examined all United States computerized death certificates (47,735,043 certificates) from 1979 (the start of the *International Classification of Diseases, Ninth Revision* [ICD-9]) to 2000 (the latest data-year available at the start of this study). This is an administrative database maintained by the National Center for Health Statistics (NCHS)²² and provides information on all American deaths, but little clinical detail on prescription drugs (e.g., no information on dosage, day supply, number of prescriptions, or detailed type of prescription). The NCHS makes great efforts to ensure privacy by omitting detailed identification variables from each electronic death certificate (e.g., the name and Social Security number of the decedent.) Because our data set did not contain highly specific clinical information, it could not provide a detailed cause of medication errors. However, our data set did allow us to conduct a population-level examination of mortality from medical errors and did allow us to demonstrate large, recurrent, previously unknown spikes in this mortality.

We examined the following data from the death certificates: date, cause, and location of death (dead on arrival [DOA], emergency room [ER], outpatient, or inpatient), and age, sex, years of education, and substance abuse status (listed as a secondary cause of death) of the decedent. We used years of education to measure socioeconomic status because income is not coded in the computerized death certificate. In 1989, the NCHS added years of education to the

death certificate in order to provide an explicit measure of socioeconomic status.²³ A positive correlation between education and income has been well established,^{24–28} and education has been widely used to measure socioeconomic status in epidemiologic studies.^{29,30}

Classification of Causes of Deaths

We focused on deaths the primary cause of which was poisoning accidents from drugs (131,952 medication error deaths). These are classified by the ICD into two categories, whose definitions and ICD codes are listed below. The ICD-9 codes below pertain to the ninth revision of the ICD (which applied from 1979–1998), whereas the equivalent ICD-10 codes pertain to the tenth revision (which applied from 1999 onward). To avoid problems that might arise from the change from ICD-9 to ICD-10, we omitted from all analyses the 28-day period centered on January 1, 1999.

Category 1

This category (E850–E858 [ICD-9], X40–X44 [ICD-10]) includes “accidental overdose of drug, wrong drug given or taken in error, and drug taken inadvertently” and excludes “correct drug properly administered in therapeutic or prophylactic dosage, as the cause of any adverse effect.”^{31,32} Category 1 accounts for nearly all the cases in our data set (96.8% of all fatal poisoning accidents from drugs). Although category 1 refers to medication errors, it does not indicate the type of error (e.g., whether the error resulted from an overdose of the correct drug, or from the wrong drug given or taken).

Category 2

In our data set, this category (E930–E949 [ICD-9], Y40–Y59 [ICD-10]) accounts for 3.2% of all poisoning accidents from drugs. In contrast to nearly all the deaths in our data set, this category includes “correct drug properly administered in therapeutic or prophylactic dosage, as the cause of any adverse effect” and excludes “accidental overdose of drug and wrong drug given or taken in error.”^{31,33} Thus, category 2 refers to adverse effects of drugs.

Mortality Comparison

It is instructive to compare mortality in the two categories, and in such comparisons, we distinguish the terms medication error and

adverse effects. However, when examining the two categories combined, we refer to this combined category as medication errors because nearly all the fatal poisoning accidents under examination (96.8%) consisted of medication errors (rather than adverse effects).

When comparing the mortality risks of two groups, epidemiologists typically use a death rate (i.e., number of deaths/person-time at risk) rather than the number of deaths alone. In this study, however, standardizing on person-time at risk is unnecessary because the groups being compared (the United States in the first week of the month vs the United States in the last week of the preceding month) have essentially the same person-time at risk. Thus, as in our previous study,⁹ we measured the beginning-of-the-month effect (BOME) by the ratio of number of deaths in the first week of the month:the number of deaths in the last week of the preceding month. A BOME ratio of 1.00 indicates the same number of deaths in the first week as in the last week, whereas a ratio of 1.25 indicates there were 25% more deaths in the first week of the month than in the last week of the preceding month.

Following official recommendations³⁴ and our earlier practice,^{7–9, 35–39} we calculated standard errors for our data, even though we examined populations, not samples. The formula for the standard error of a count³⁴ and the formula for the standard error of the BOME ratio of two counts⁴⁰ come from previously published works. The latter formula generates an asymmetric standard error, with the asymmetry declining with the size of the data set; for our large data sets, the asymmetry is frequently imperceptible. In general, when stating a BOME ratio, we also provide, in parentheses, the margin of error (i.e., ± 1.96 standard errors). The 95% confidence interval (CI) for a given BOME ratio can be determined as follows: (BOME ratio – 1.96 standard error) to (BOME ratio + 1.96 standard error). Given the null hypothesis, observed BOME ratios typically will be in the range of 1.00 ± 1.96 standard errors. Given the alternative hypothesis of a peak in deaths at the beginning of the month, observed BOME ratios will be above this range.

We wished to identify dates when errors were particularly likely, but only the date of the death—not the date of the error—is provided in the U.S. computerized death certificate. Because there can be a long and variable lag between a medication error and the death resulting from that error, a plot of deaths by day gives a “fuzzy”

picture of a plot of errors by day. However, there is very little fuzziness if one can focus on a category of errors that lead rapidly to death. One such category (DOA errors) can be identified with the aid of a California mortality database (1980–1997).⁴¹ In contrast to the U.S. database under study, the California database identifies both the date of a drug accident and the date of death resulting from that accident. The California database also distinguishes DOA from non-DOA deaths. This database indicates that the average lag from medication error to death is very short for those who are DOA (average 0.16 day, SD 0.39 day). In strong contrast, for the remaining non-DOA fatal medication errors, the average lag from accident to death is longer and highly variable (average 2.86 days, SD 28.99 days). For the California database, a daily plot of DOA medication error accidents closely resembles a daily plot of DOA medication error deaths that result from those accidents. We assumed that

this resemblance would hold outside of California as well.

Some fatally ill patients will barely escape the DOA status and will die in the ER. Thus, we thought it likely that ER medication error deaths (like DOA deaths) would also exhibit a brief lag between accident and death. This proposition, though plausible, cannot be empirically tested with the California mortality database because it does not identify ER deaths.

Results

From 1979–2000, the U.S. computerized death certificate identified two locations of death, which, in our view, suggested rapidly fatal errors: the first is DOA, and the second is ER-outpatient (ER and outpatient statuses are not distinguished in the computerized certificate). Figure 1 plots mortality for DOA and ER-outpatients, and for inpatients. For DOA and ER-outpatients, deaths

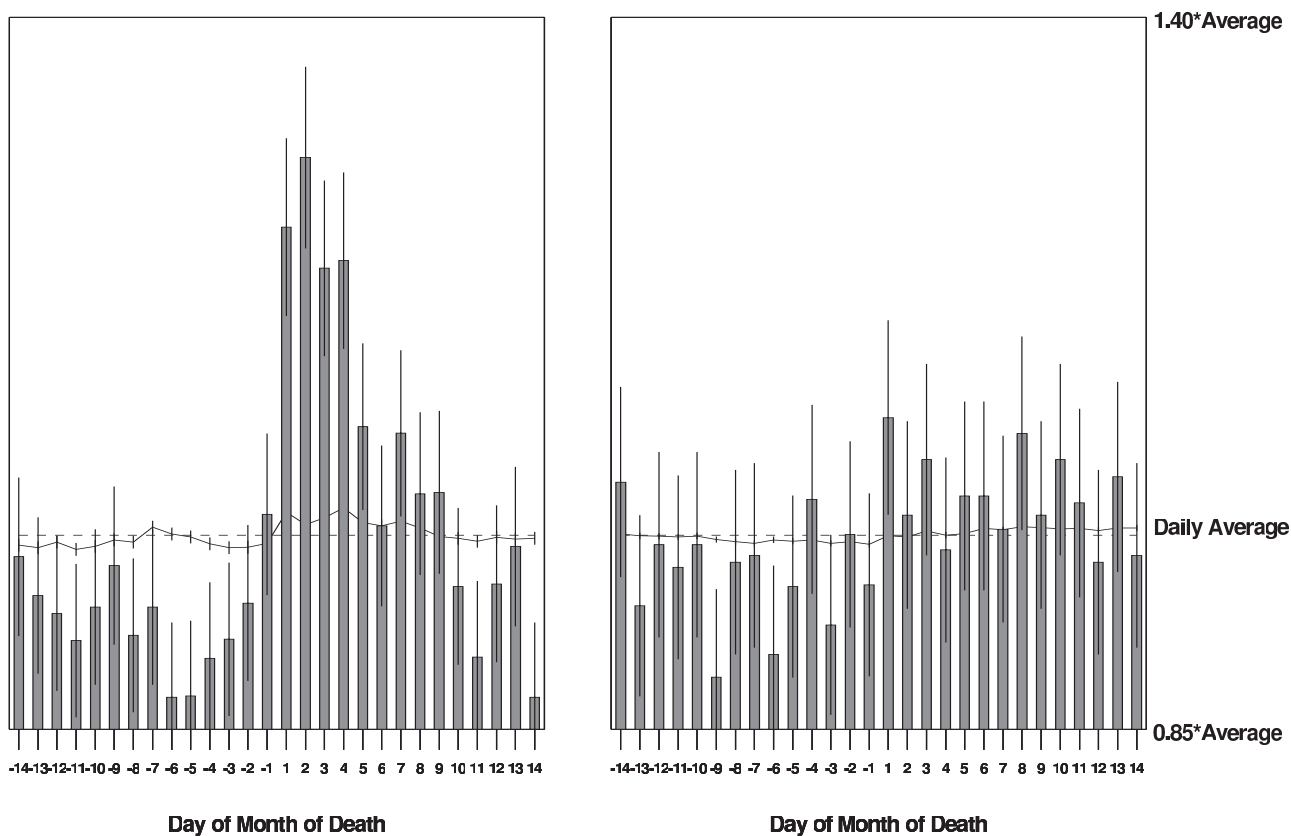


Figure 1. Total numbers of U.S. deaths related to medication errors (± 1.96 standard errors) on each of the first 14 days of the month (days 1–14) and the last 14 days of the preceding month (days -14 to -1), 1979–2000. The horizontal solid lines show total numbers of deaths from all causes. The bar graph indicates the total number of deaths from fatal medication errors. The dotted line indicates the average number of deaths that would be expected if the numbers did not fluctuate around the first day of the month. The left panel shows data for patients who were dead on arrival and for those who died in the emergency room and as outpatients; the right panel shows data for inpatients who died. The upper limit in both panels is set at 1.40 x daily average, whereas the lower limit is set at 0.85 x daily average.

from medication errors dip sharply at the end of the month and peak sharply at the beginning of the month. In the beginning of the month, the number of fatal medication errors is more than 7 standard errors higher than the number to be expected under the null hypothesis. By contrast, a much weaker pattern is evident for inpatients.

To more closely estimate the timing of medication errors, subsequent analyses focused on DOA and ER-outpatients rather than on inpatients. Although we focused on DOA and ER-outpatients, our data set remains large—there are more medication error deaths in the first category than in the second, with a ratio of 1.35:1.

Figure 1 indicates that the BOME ratio is strikingly larger for medication error deaths than for deaths in general: 1.25 (\pm 0.04) vs 1.016 (\pm 0.003). The BOME ratio for medication error deaths does not vary significantly by sex: 1.26 (\pm 0.05) for men versus 1.21 (\pm 0.08) for women.

As noted earlier, nearly all (96.8%) accidental drug deaths consisted of medication errors, rather than adverse effects. For medication errors (codes E850–E858, X40–X44), the BOME ratio was 1.25 (\pm 0.04); for adverse effects (codes E930–E949, Y40–Y59), the BOME ratio was 1.16 (95% CI 0.92–1.43). The large, asymmetric error

bars for the latter BOME ratio result because deaths from adverse effects constitute such a small part of the data set.

No other major cause of death produced a BOME ratio as large as the BOME ratio for medication error deaths. Figure 2 displays the outlier status of medication error deaths and identifies some other major causes of death that produce an unusual BOME ratio. The NCHS classifies causes of death into 113 standard categories, some of which have very few cases.⁴² We calculated the BOME ratio for each of the populated cause categories (those with at least 100 cases/yr). Two of the largest five BOME ratios were associated with problematic medical care: medication errors (category F) and surgical complications (category C). Two of the largest five BOME ratios were associated with poisonings (categories B and F) and with a third category (category D) that also involves some poisonings.

Four of the smallest five BOME ratios were associated with neoplasms: the categories producing the smallest BOME ratios were (starting with the smallest) malignant neoplasms of kidney and renal pelvis; bronchitis, chronic and unspecified; malignant neoplasms of lip, oral cavity, and pharynx; in situ neoplasms; benign neoplasms and neoplasms of uncertain or unknown behavior; malignant neoplasm of stomach.

For all categories in Figure 2, the average (\pm SD), unweighted value of the BOME ratio was 1.026 (\pm 0.053). In contrast, the BOME ratio for medication error deaths was much larger (1.25 vs 1.026), that is, fatal medication errors spiked 25% at the beginning of the month versus a 2.6% spike for the average cause of death. When compared with other causes of death, medication error deaths were an extreme outlier ($p < 0.001$, Grubbs test).⁴³

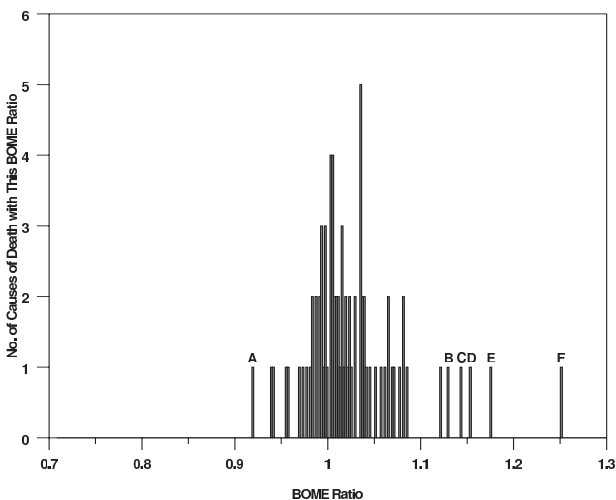


Figure 2. Size of the beginning-of-the-month effect (BOME) ratio for major disease groups, 1979–2000. A = malignant neoplasms of kidney and renal pelvis; B = accidental nondrug poisonings; C = complications of surgical care; D = accidents from smoke, fumes, fire, and flames; E = deaths undetermined whether accidental or purposeful (residual category); F = accidental drug poisonings. The data are restricted to accidents that are likely to be rapidly fatal: those for which the decedent was dead on arrival or died in the emergency room or as an outpatient.

Size of the BOME Ratio with and without Comorbidity

Starting in 1983, information was also available on secondary, contributory causes of death. It is conceivable that the large medication error BOME ratio resulted only because of an interaction between medication errors and natural causes of death. If so, the medication error BOME ratio with disease listed as a contributory cause should be larger than the medication error BOME ratio without disease listed as a contributory cause. This expectation was not supported by the data: BOME ratio 1.23 (\pm 0.06) with disease listed as a contributory cause

(12,680 deaths) versus BOME ratio 1.28 (\pm 0.06) without disease listed as a contributory cause (16,308 deaths).

Four Additional Potential Explanations for the Findings

Explanation 1: Spike in Drug Consumption and in Pharmacy Error Rate

The first explanation posits that there is both a beginning-of-the-month spike in the consumption of prescription drugs and an accompanying spike in the rate of errors committed when these prescriptions are filled and taken. Under this hypothesis, pharmacy error rates spike at the beginning of the month because pharmacy workloads increase at that time¹⁵⁻¹⁸ and because pharmacy error rates are thought to increase with workload.^{6, 19-21} Any errors resulting from this increased workload should affect all patients filling prescriptions at the beginning of the month. Thus, given this consumption- and error-spike hypothesis, all groups should display large beginning-of-the-month spikes in death, not merely those whose drug consumption spikes at the beginning of the month.

Explanation 2: Spike in Drug Consumption and No Spike in Pharmacy Error Rate

The second explanation posits that there is a beginning-of-the-month spike in the consumption of prescription drugs, with no accompanying spike in the rate of errors committed when these prescriptions are filled or taken. Under this hypothesis, pharmacy error rates do not increase at the beginning of the month, even though pharmacy workloads increase at that time.¹⁵⁻¹⁸ Given this hypothesis, deaths from drugs should spike at the beginning of the month mainly for those groups whose drug consumption increases at the beginning of the month.

In short, these two potential explanations for the BOME ratio generate contradictory predictions that can be tested with data. These predictions were tested in the following two scenarios.

The BOME Ratio for Patients with Low versus Those with High Socioeconomic Status. As documented earlier,¹⁵⁻¹⁸ despite pharmacy assistance programs, many of the poor live from month to month²⁴ and experience an abrupt increase in the ability to pay for drugs at the start of the month. In contrast, middle-income and

upper-income consumers can generally purchase drugs throughout the month. Given the consumption-spike but no error-spike hypothesis, the BOME ratio should vary by socioeconomic status, with affluent groups displaying small BOME ratios. Figure 3 contradicts this prediction. There is no relationship between BOME ratio and socioeconomic status. Thus, these findings undermine the consumption-spike but no error-spike hypothesis and are consistent with the consumption- and error-spike hypothesis.

The BOME Ratio for Those Above versus Those Below Retirement Age. For elderly Americans, Social Security is by far the largest source of income.⁴⁴ For elderly Americans in the lowest income quintile, 91% of their income stems from Social Security and public assistance payments.⁴⁴ Thus, as noted earlier,¹⁵⁻¹⁸ some older Americans can pay for prescription drugs only at the beginning of the month, when their Social Security benefits arrive. Consequently, given the consumption-spike but no error-spike hypothesis, the BOME ratio should be larger for persons old enough to receive Social Security retirement pensions. For those who have reached Social Security retirement age, the BOME ratio was 1.09 (95% CI 0.90-1.30); for those younger than this age, the BOME ratio was 1.26 (95% CI 1.22-1.30). Because these 95% CIs overlap completely, there is no statistically significant difference between

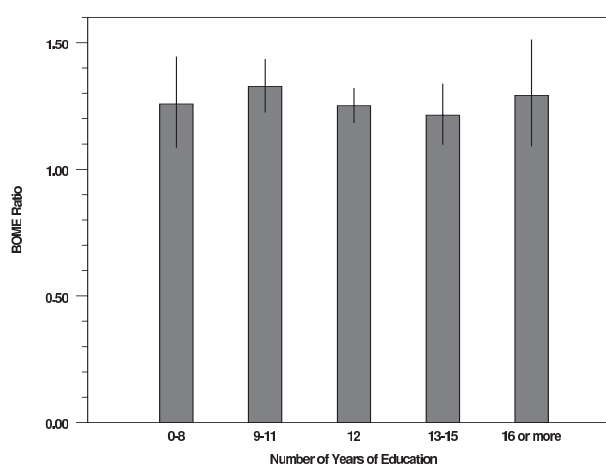


Figure 3. Beginning-of-the-month effect (BOME) for medication error fatalities (\pm 1.96 standard errors) classified by the decedent's years of education. Data are for 1989-2000, when the decedent's education was available in the computerized death certificate.²³ The data are restricted to accidents that are likely to be rapidly fatal: those for which the decedent was dead on arrival or died in the emergency room or as an outpatient.

the BOME ratios for postretirement and pre-retirement age groups. Thus, these findings undermine the consumption-spike but no error-spike hypothesis and are consistent with the consumption- and error-spike hypothesis.

In short, the evidence from two different analyses favors the consumption- and error-spike hypothesis and undermines the consumption-spike but no error-spike hypothesis: the BOME ratio is not larger for the poor than for the affluent and not larger for the elderly than for others.

Explanation 3: Misclassification of the Cause and Date of Death

Perhaps the BOME ratio is caused by misclassification on the death certificate. Death certificate data are likely to be more accurate when an autopsy has been performed. Autopsy status was recorded in the computerized death certificate from 1979–1994. For these years, an autopsy had been performed for most medication error deaths (87.7%). The BOME ratio for autopsy cases (1.25 ± 0.06) was not significantly different from the BOME ratio for all cases (1.24 ± 0.06). Hence, the misclassification hypothesis does not seem plausible.

Explanation 4: Increased Substance Abuse at Beginning of Month

Because of our earlier study,⁹ we considered the hypothesis that the spike in fatal medication errors resulted from a spike in consumption of street drugs or alcohol, which interact dangerously with some prescription drugs. Given this hypothesis, the BOME ratio for fatal medication errors should be larger when substance abuse is also listed on the death certificate. However, the BOME ratio when street drugs or alcohol were also listed did not differ significantly from the BOME ratio when street drugs or alcohol were not listed (BOME ratio 1.25 ± 0.08 and 1.26 ± 0.05 , respectively).

Discussion

At the beginning of each month, there is a spike in government payments to the elderly, the sick, and the poor.^{10, 11} Because of this, there is also a beginning-of-the-month spike in purchases of prescription drugs,^{15–18} and consequently pharmacy workloads increase at the beginning of each month.^{15–18} Evidence suggests that the error rate of pharmacists increases with workload.^{6, 19–21}

These facts prompted us to investigate an important and previously unanswered question: is there a spike in deaths from drugs at the beginning of each month? If so, is there evidence suggesting that increased pharmacy workloads play a role in causing this spike?

To our knowledge, this study is the first to document such a spike: for DOA and ER-outpatient medication error deaths, mortality is 25% higher than normal at the beginning of each month. This beginning-of-the-month spike for medication error deaths, or BOME ratio, is an extreme outlier—larger than the spike for any other major cause of death.

We tested five potential explanations for the BOME ratio. One explanation posits that there is a beginning-of-the-month spike in the purchase of prescription drugs, accompanied by a spike in the workload at pharmacies and a resultant spike in the rate of prescription errors committed. Another explanation posits that there is a beginning-of-the-month spike in the purchase of prescription drugs, with no accompanying spike in the rate of prescription errors committed. Our findings are consistent with the first explanation and inconsistent with the second.

The data used in this study are suitable for some purposes, but not for others. The data were generated from a large, nationwide, multiyear data set (> 47,000,000 deaths) and are suitable for demonstrating the existence of a previously unknown, systematically recurring, 25% spike in mortality. However, our data are not suitable for definitively demonstrating the detailed causes of this spike. Our evidence is consistent with a beginning-of-the-month spike in prescription error rates and cannot be attributed solely to a beginning-of-the-month spike in the consumption of drugs, with no increase in prescription error rates. However, our national mortality data set does not provide specifics on patients, their delivery systems, or pharmacies, information that could provide a highly detailed understanding of the processes producing the BOME. To achieve this understanding in future studies, researchers will need to consult data sets that are richer in detail but that will almost certainly be more limited in size, geographic area, and time period. Such detailed data sets may help to provide more precise answers to various questions raised by our findings, for example, why the BOME ratio is so much larger for DOA and ER-outpatients than it is for inpatients.

If subsequent investigations should determine that a beginning-of-the-month spike in pharmacy

error rates plays a substantial role in the BOME ratio, then government officials might consider reducing the “spiking” of public payments by spreading them over the entire month. In addition, pharmacies that do not already do so might consider increasing staff levels at the beginning of the month.

Even in the absence of further research, it seems appropriate for patients to be especially careful to check the accuracy of their prescriptions at the beginning of each month, and intensified checking should be practiced, not only by patients but also by clinical staff. If these preliminary changes are adopted, it seems plausible that some lives will be saved.

Acknowledgments

We thank Rosemarie Curran, Robert D. Kleinberg, Christy G. Kwan, Susan McGuinness, Miranda E. Phillips, and three anonymous referees for their insightful comments.

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