MEDSCAPE

American Journal of Health-System Pharmacy

Retrospective Analysis of Mortalities Associated With Medication Errors

Jerry Phillips, Sammie Beam, Allen Brinker, Carol Holquist, Peter Honig, Laureen Y. Lee, and Carol Pamer

Am J Health Syst Pharm. 2001;58(19)

Results

A total of 5366 medication error reports were identified during the time period. Of these, 3660 (68.2%) were classified, from a regulatory perspective (21 CFR 314.80), as serious (causing death, a threat to life, hospitalization, disability, congenital anomaly or requiring intervention to prevent permanent impairment or damage). Death resulted in 528 (9.8%) of these cases. We excluded 59 reports as duplicates or intentional overdoses. A total of 469 deaths were caused by medication errors. These are sorted by the year they were reported to FDA in Figure 1. Of these, 84 reports (18%) were directly reported to FDA by consumers and health care providers via the MedWatch program. Manufacturers reported 385 reports (82%) to FDA. The increase in reports during calendar year 1998 is probably reflective of FDA's decision to capture all medication error reports within one database (AERS) and no longer support a related database, the Drug Quality Reporting System.

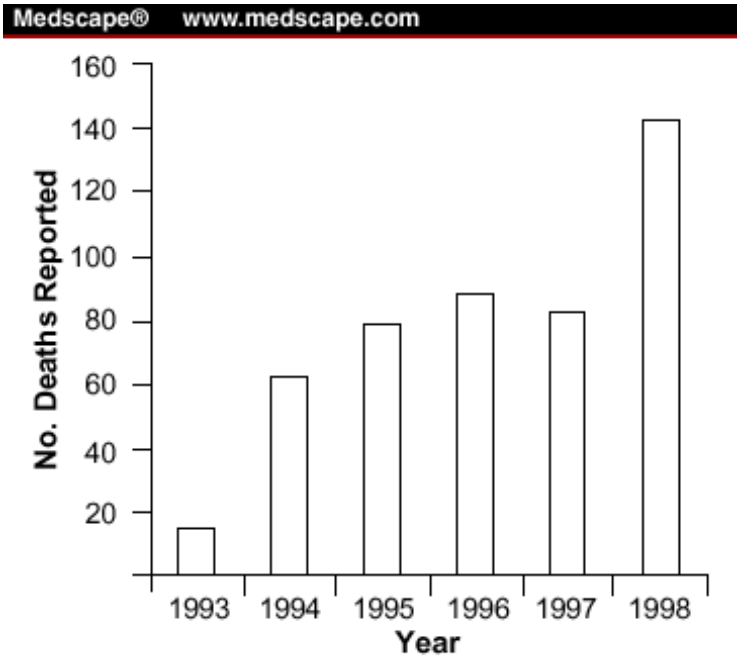

Figure.

Reports of deaths per year received by FDA.

Two hundred and seven deaths were assessed as related to an error, 219 as possibly related, and 43 as unrelated.

Age, Gender, and Demographics

We examined the age distribution of deaths reported in 354 patients (Table 1). In the remaining 115 reports, no age was identified. Patients over 60 years of age represented the largest number of reports, with 172 deaths (48.6%). Twenty percent (71) occurred in patients 70-80 years old, and 10% (49) occurred in patients under 10 years, with 28 deaths in patients between birth and 2 years of age.

We reviewed the reported deaths of 219 men (46.7%), 179 women (38.2%), and 71 patients (15%) whose genders were not stated.

Of the 469 reports received, 364 deaths occurred in the United States and were distributed throughout 46 states. The largest numbers of deaths were reported in California (29), Maryland (28), Florida (26), Pennsylvania (23), and Texas (17). Outside the United States, 105 deaths were distributed throughout 29 nations. The largest numbers of deaths were reported in the United Kingdom (26), France (15), Canada (9), Japan (7), and Germany (7).

Of the medication errors reported, 219 (46.7%) occurred in hospitals, 70 (14.9%) occurred in patients' homes, 22 (4.7%) originated in ambulatory pharmacies, 22 (4.7%) happened in physicians' offices, 21 (4.5%) originated in other sites, and the location of 115 (24.5%) was not stated.

Drugs

A prescription drug product was administered to 458 patients (97.6%) who died from medication errors. Nonprescription drugs were given to 10 patients (2.1%), and a compounded prescription was given to 1 patient (0.2%). The dosage forms associated with the medication error deaths included 234 injectable drug products (49.9%), 115 tablets (24.5%), 27 capsules (5.8%), 31 oral solutions (6.6%), 7 transdermal patches (1.5%), 3 creams or ointments (0.6%), and 8 aerosol formulations (1.7%).

A majority of patients (52%) took only one drug (Table 2). Approximately 55% of patients over 60 years took more than one drug.

We also identified 17 general pharmacologic categories of drug products involved in these 469 deaths (Table 3). The largest number of deaths (54.9%) occurred with central nervous system, antineoplastic, and cardiovascular drug products.

Types of Errors

Analysis of each of the 469 reports revealed a total of 594 errors, each of which was classified into one of 14 general types of errors (Table 4). The most common type of error was administering an improper dose, which accounted for 243 (40.9%) of all medication error types, with 216 patients (36.4%) receiving an overdose. The second most prevalent type of error was administering the incorrect drug to a patient. This error occurred 96 times (16%). We identified 73 deaths associated with the inadvertent administration of one product for another product. For example, potassium chloride injection was administered instead of furosemide, heparin, or sodium chloride to eight patients. Cisplatin was administered instead of carboplatin to three patients. Isophane insulin (Humulin N) was administered instead of regular insulin to two patients. Amiodarone was administered instead of amrinone, resulting in three deaths. MS Contin was administered to three patients instead of an immediate-release morphine formulation.

The third most prevalent type of error was administering a drug by the incorrect route. This error occurred in 57 patients (9.5%). A drug was administered intrathecally rather than by the intended intravenous route, resulting in 14 deaths. Eight deaths were associated with patients receiving an oral product intravenously. Four patients died as a result of an i.v. injection of an i.m. product. One patient died as a result of an i.m. injection of an i.v. product.

Causes of Errors

An analysis of each of the 469 reports revealed a total of 583 causes, each of which was classified, in accordance with the NCCMERP's Taxonomy of Medication Errors, into one of five major categories: (1) communication (e.g., oral and written miscommunication), (2) name confusion (e.g., proprietary names that sound or look alike), (3) labeling (e.g., similar or misleading container labels), (4) human factors (e.g., performance or knowledge deficits), and (5) packaging or design (e.g., inappropriate package or device design) (Table 5). The most common causes identified were human factors, which accounted for 380 causes (65.2%), followed by communication problems, which accounted for 92 causes (15.8%).

Communication, transcription, and handwriting errors were likely responsible for fatal overdoses associated with medication errors. In this caseseries analysis, a long-acting form of morphine sulfate 60 mg was erroneously administered every 15 minutes as needed because of a transcription error; the physician's oral order was for immediate-release morphine sulfate 10 mg every 15 minutes as needed. In one report, a patient developed a fatal hemorrhage when administered another patient's prescription for warfarin, which was transcribed into the chart erroneously.

Misinterpreting handwriting may have been a factor when a prescription for warfarin 2 mg was interpreted as 5 mg. An elderly patient died after she received a methotrexate overdose of 10-mg daily, rather than the intended 10-mg weekly dose for rheumatoid arthritis. A transcribing error also resulted in a fourfold over-dose of cisapride in a child. The child had been receiving one fourth of a cisapride 10-mg tablet four times daily at home. Upon admission to a hospital, this dose was erroneously transcribed as 10-mg four times daily.

In one instance, a patient received a 20-fold overdose of morphine sulfate oral solution when given 10 mL (200 mg), rather than 10 mg, of the solution. Confusion between two strengths of thioridazine oral concentrate resulted in a 450-mg dose instead of the prescribed 25-mg dose. A similar error occurred when morphine sulfate 100 mg/4 mL was injected instead of the 10 mg/mL formulation.

A zero should always be placed before a decimal point for doses of less than one unit. In one case-report evaluation, a 10-fold dosing error resulted in death when digoxin .09 mg was misread as 0.9 mg.

The complexity of drug protocols and subsequent miscalculations, necessity for speed of action in emergency situations, marketing of multiple concentrations of drug products, and availability of highly concentrated drug products on nursing units appear to have contributed to fatal medication errors. Reports were received describing patients who received an overdose of esmolol. In one instance, a patient received a loading dose, which constituted a 100-fold overdose, of 3.5 g instead of a likely dose of 35 mg based on the patient's weight. A miscalculation did occur, but the concentrated form of the drug (intended only for compounding infusions) was readily available on the nursing unit. A similar error resulted in a fatality when 6 mL of the infusion concentrate, 1500 mg, was given undiluted as a loading dose, rather than a likely dose of 38 mg based on the patient's weight. Cancer chemotherapy protocols are often expressed as a cumulative dose, which is divided and administered over the course of several days. Examples of miscalculations for cancer chemotherapy resulting in fatal medication errors were also seen among the cases we evaluated. One patient was prescribed a cumulative dose of cisplatin 100 mg per square meter (m^2) of body surface area over a period of four days (e.g., 25 mg/m^2 per day for four days). Instead, the patient received 100 mg/m^2 per day for four days, a fourfold overdose of cisplatin. Another patient received adriamycin 131 mg daily for four days, rather than a cumulative dose of 131 mg to be given in divided doses over four days (e.g., 33 mg/day)

-END-