Retrospective analysis of mortalities associated with medication errors

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Abstract: The types, causes, contributing factors, and patient demographics of fatal medication errors were reviewed.

Case reports of medication errors from hospitals, ambulatory care settings, and patients' homes that were entered in FDA's Adverse Event Reporting System during 1993–98 were the source of information on fatal medication errors. Each report was classified using predefined criteria and a taxonomy developed by the National Coordinating Council for Medication Error Reporting and Prevention. The types, causes, contributing factors, and patient demographics were identified, and the causality of each case was assessed to prevent future fatalities.

The data indicated 5366 medication error reports. Fifty-nine reports were excluded and classified as duplicate reports or intentional overdoses. Of the remaining medication error reports, 68.2% resulted in serious patient outcomes and 9.8% were fatal. Of the 469 fatal medication error reports, 48.6% occurred in patients over 60 years. The most common types of errors resulting in patient death involved administering an improper dose (40.9%), administering the wrong drug (16%), and using the wrong route of administration (9.5%). The most common causes of errors were performance and knowledge deficits (44%) and communication errors (15.8%). Fatal medication errors accounted for approximately 10% of medication errors reported to FDA and were most frequently the result of improper dosing of the intended drug and administration of an incorrect drug.

A review of case reports of medication errors from 1993 to 1998 yielded information on the most frequent causes of and contributing factors involved in fatal medication errors.

Index terms: Communication; Data collection; Death; Dosage; Drug administration routes; Errors, medication; Food and Drug Administration (U.S.); Reports; Toxicity

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A medication error, as defined by the National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP), is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labeling, packaging, nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use. Medication misadventures, a broad categorical group, include adverse drug events (ADEs), adverse drug reactions (ADRs), and medication errors.[1]

ADRs result in injuries that are unavoidable and may be classified as

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type A or type B.[2] Type A ADRs are *known* and need to be better quantified. They are usually predictable and dose dependent (e.g., respiratory depression with opiates). Type B ADRs are *unknown* and need to be quickly identified, quantified, and communicated. They are usually idiosyncratic (e.g., liver toxicity associated with troglitazone).

ADEs cause injuries that are known and expected (e.g., drowsiness from diphenhydramine).[3] They may be classified as preventable or unavoidable.

Medication errors are preventable events that may cause or lead to inappropriate medication use or patient harm and may be classified as potential or actual. Potential errors are defined as reports of confusion or an intuition that an error will occur in the future. They are not considered ADRs or ADEs. Actual errors may or may not reach the patient. For example, when the wrong drug is prepared but system checks prevent the drug from being administered to the patient, an actual error that did not reach the patient occurred. Again, this type of error is neither an ADR nor an ADE. Medication errors that reach the patient either cause harm or no harm. For example, when an extra dose is administered with no adverse outcome, no harm is done to the patient. This is neither an ADE nor ADR. However, if a patient's death was caused by an unintentional overdose of warfarin, this would be classified as a preventable ADE.

The November 1999 Institute of Medicine report *To Err Is Human* estimates that medication errors account for 7000 deaths per year. ADRs may be responsible for more than 100,000 deaths nationwide each year and may be between the fourth and sixth leading causes of death in the United States.[4] It has been estimated that more than 50% of 1.8 billion prescriptions are used incorrectly and that drug-related problems, including ADRs, account for nearly 10% of all hospital admissions and up to 140,000 deaths annually in the United States.[5] Drug-related morbidity and mortality in the United States have been estimated to cost the American health care system $76.6–$136 billion annually.[6]

In a case-control study covering a four-year period at a single hospital, there was an almost twofold increase in the risk of death associated with ADEs, of which 1% was attributable to medication errors.[7] In the Harvard Medical Practice Study, ADEs accounted for 19.4% of all disabling adverse events, of which 45% were caused by medication errors, and 30% of patients with drug-related injuries died.[8] In a prospective cohort study, 247 ADEs were evaluated, of which 28% were judged preventable, 1% were fatal (not preventable), 12% were life-threatening, 30% were serious, and 57% were significant.

Medication errors may result from single or multiple breakdowns in a system's continuum of diagnosing an ailment, planning a therapeutic regimen, prescribing and dispensing drugs, and administering the drug. In a systems analysis of a prospective cohort study evaluating 264 preventable ADEs, 78% of the errors were caused by seven system failures, and the leading problem (29%) was attributed to the failure to disseminate drug knowledge.[8] In another study that evaluated 696 errors, the most common causes were related to drug knowledge (30%), knowledge about the patients (29.2%), the use of calculations and decimal points (17.5%), and nomenclature issues (incorrect drug name, dosage form, or abbreviation) (13.4%).[9]

We reviewed all reports of death associated with medication errors received by FDA that were entered into the Adverse Event Reporting System (AERS) database over a six-year period to better understand the drug products involved and the various risk factors and root causes associated with these preventable adverse events.

Methods

AERS is a relational safety database that operates as an internationally compatible system in full accordance with the International Conference on Harmonization initiatives. The fundamental piece of information stored in AERS is the Individual Safety Report (ISR), which contains all of the information contained on the MedWatch form (FDA form 3500 or 3500A). This database allows for increased efficiency in receiving and recording adverse event reports. In addition, it provides faster access for FDA reviewers who analyze the data from these reports.

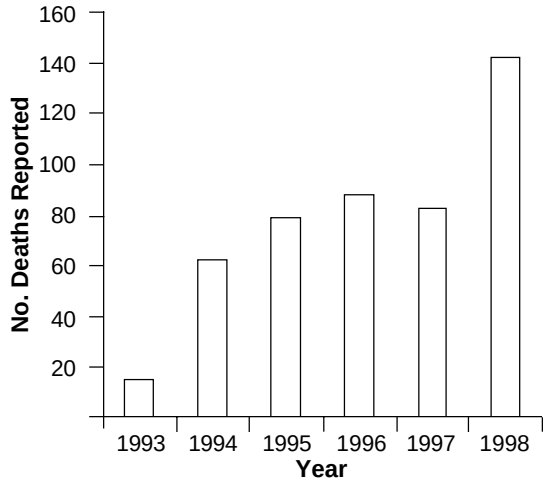
A search of the AERS database was conducted for all adverse events with a patient outcome of death coded as "Drug Maladministration." "Drug Maladministration" is a Medical Dictionary for Regulatory Activities term used to index medication error events in the AERS database.

FDA receives both U.S. and foreign reports of adverse events from manufacturers that have a drug application filed with FDA. Thus, we included both domestic and foreign reports in this analysis. The deaths that occurred between January 1, 1993 and December 31, 1998 were reviewed. This defined six-year time period was chosen because FDA first began coding for medication errors during the latter part of 1993.

We reviewed and classified each report independently to determine whether a death was thought to be related to a medication error (expected event with no significant confounding factors and a positive temporal association), possibly related (expected event with some confounding factors, weaker temporal association, or incomplete data), or unrelated (no association with an error could be established). The medication error team discussed those cases that were difficult to classify in-

dependently and reached a consensus for each one. Each report was categorized according to the *Taxonomy of Medication Errors*, developed by NCCMERP and adopted by FDA,[10] and analyzed by (1) event or setting of the error, (2) patient outcome, (3) product information, (4) personnel (by professional category) involved, (5) type of error, (6) causes of error, and (7) contributing factors. In addition, patient demographics (e.g., age, gender, and geographic location of the reporter) and the year the information was reported were captured.

Figure 1. Reports of deaths per year received by FDA.



Results

Reports. 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.

Causality. 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).

Setting. 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 cen-

Table 1.
Distribution of Deaths by Age

Age (yr)	No. (%) Deaths[a]
0–9	49 (10.4)
10–19	20 (4.3)
20–29	23 (4.9)
30–39	28 (6.0)
40–49	32 (6.8)
50–59	30 (6.4)
60–69	47 (10.0)
70–79	71 (15.1)
80–89	43 (9.2)
> 90	11 (2.3)
Unknown	115 (24.5)

[a] $n = 469$.

tral 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 case-series 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 overdose 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

Table 2.
Distribution of Deaths Associated with Concurrent Drug Usage

No. Drugs Taken	No. (%) Deaths[a]
1	246 (52.5)
2	82 (17.5)
3	43 (9.2)
4	28 (6.0)
5	48 (10.2)
≥6	22 (4.7)

[a] $n = 469$.

Table 3.
Distribution of Deaths by Pharmacologic Category

Pharmacologic Class	No. (%) Deaths	Representative Example(s) (No. Cases)
Antihistamine drugs	4 (0.8)	Seldane (3)
Anti-infective agents	35 (7.5)	Amphotericin (5); Diflucan (4)
Antineoplastic agents	72 (15.4)	Cisplatin (12); Vincristine (14)
Autonomic drugs	26 (5.5)	Epinephrine (4); Albuterol (3)
Blood derivatives	7 (1.5)	Albumin (3)
Blood formation and coagulation agents	25 (5.3)	Coumadin (10); Heparin (7)
Cardiovascular drugs	59 (12.6)	Brevibloc (10); Lidocaine (7)
Central nervous system agents	126 (26.9)	Opiates (31); acetaminophen (8)
Diagnostic agents	8 (1.7)	Renografin-60 (1)
Electrolytic, caloric, and water balance	31 (6.6)	Potassium chloride (14)
Antitussives, expectorants	3 (0.6)	Rondec-DM (1); Tessalon (1)
Eyes, ears, nose, and throat	1 (0.2)	Epinephrine mist (1)
Gastrointestinal agents	11 (2.3)	Propulsid (5); Fleet enema (1)
Hormones and synthetic substitutes	31 (6.6)	Insulin (10), Depo-Medrol (3)
Local anesthetics	1 (0.2)	Marcaine (1)
Oxytocics	2 (0.4)	Pitocin (1)
Unclassified or other therapeutic agents	27 (5.8)	Exosurf (3)
Total	469 (100)	

Table 4.
Types of Errors

Error	No. (%)
Improper dose	
Overdose	216 (36.4)
Underdosage	8 (1.3)
Extra dose	6 (1.0)
Not classified	13 (2.2)
Wrong drug	96 (16.2)
Wrong route of administration	
Intrathecal instead of i.v.	14 (2.4)
I.V. instead of oral	8 (1.3)
I.V. instead of i.m.	4 (0.7)
I.M. instead of i.v.	1 (0.2)
Other	30 (5.1)
Wrong patient	16 (2.7)
Wrong rate	33 (5.6)
Wrong strength/ concentration	34 (5.7)
Wrong dosage form	3 (0.5)
Wrong technique	11 (1.9)
Wrong time	3 (0.5)
Monitoring error	27 (4.5)
Deteriorated drug error	10 (1.7)
Wrong duration	15 (2.5)
Dose omission	3 (0.5)
Noncompliance	9 (1.5)
Other	34 (5.7)
Total	594 (100)

Table 5.
Causes of Errors[a]

Cause	No. (%)	Representative Example(s) (No. Occurrences)
Human factors (*n* = 380)		
Performance deficit	174 (29.8)	Administering an i.v. Injection when intended to be given i.m.
Knowledge deficit	83 (14.2)	Reasonable practice standards would have prevented an error
Miscalculation of dosage	76 (13.0)	
Drug preparation	34 (5.8)	Using the wrong amount of diluent (5), adding the wrong drug (9), adding the wrong amount of active ingredient (4)
Other	13 (2.2)	Incorrect selection of drug from a computer (2), transcription errors (7)
Communication (*n* = 92)		
Misinterpretation of order	43 (7.4)	
Oral miscommunication	10 (1.7)	
Written miscommunication	39 (6.7)	Misreading order (17), making 10-fold errors because of decimal points (12)
Name confusion (*n* = 52)		
Proprietary name confusion	28 (4.8)	Sound alike (11), look alike(9)
Established name confusion	24 (4.1)	Sound alike (8), look alike (9)
Labeling (*n* = 32)		
Immediate container label of the manufacturer	21 (3.6)	Appears misleading (7), too similar within the same company's line (6)
Label of dispensed product (practitioner)	5 (0.9)	Wrong directions (2), wrong drug name (1)
Manufacturer's carton	5 (0.9)	Looks similar to another manufacturer's (2)
Printed reference material	1 (0.2)	Inaccurate printed information (1)
Packaging and design (*n* = 27)		
Device problems	16 (2.7)	Malfunction (4), infusion problems (6), wrong device selected (2)
Inappropriate packaging or design	8 (1.4)	Topical product packaged in sterile i.v. multiple-dose vial
Tablet or capsule confusion	3 (0.5)	

[a] *n* = 583.

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).

Our analysis reviewed a number of reports in which confusion between drug products whose names sound or look alike or packaging similarities played a role in the occurrence of a medication error. A patient experienced fatal bleeding when Coumadin 5 mg was erroneously dispensed for Cogentin 0.5 mg. Both illegible handwriting and similarly

named drugs contributed to a fatal medication error when Plendil was dispensed instead of Isordil. A health care professional stated that the packaging similarities of Doxil (liposomal doxorubicin) and doxorubicin hydrochloride may have contributed to a fatal medication error. Similar packaging for premixed intravenous solutions was also associated with fatal medication errors; lidocaine was placed in a stock bin for hetastarch and erroneously infused. Heparin was also mistaken for hetastarch and administered to a patient. A nondiabetic patient received an overdose of glyburide, possibly because of similarities in sample packages provided for a nonsteroidal anti-inflammatory drug.

Discussion

The elderly have more ADEs than any other age group does because their exposure to a greater number of medications provides more opportunities for medication errors and drug–drug interactions. In addition, their altered pharmacokinetic values result in an enhanced sensitivity to many drugs.[11] The data presented in this study indicate that elderly patients have the highest rate of death from medication errors. These findings are consistent with previously reported data describing medication use by the elderly, including that polypharmacy can be a contributing risk factor to increased morbidity and mortality in this population.[12] It has been estimated that over one third of elderly patients taking three or more prescription drugs for chronic conditions are rehospitalized within six months of hospital discharge, and 20% of readmissions were caused by drug-related problems.[13] In this review, 55% of patients over 60 years died while taking more than one drug. Twenty-eight percent of hospitalizations of older Americans are a result of noncompliance with drug therapy and adverse reactions.[14] ADEs rank fifth, after congestive heart failure, breast cancer, hypertension, and pneumonia, among the leading causes of preventable threats to the health of older Americans.[15]

Growth in these numbers is expected to occur for two reasons. First, the number and potency of drug products being developed and used are increasing. Second, the elderly population, who consumes the greatest quantity of medications, continues to increase in number.[16]

This review does have several limitations. Because this was a retrospective analysis, we could not interview each reporter to more accurately assess causality of the medication error. Data collected were limited to the AERS database for ease of data extraction and because of time constraints. The FDA's Drug Quality Reporting System database contains another 8784 reports of medication errors resulting in approximately 400 additional deaths. However, some of these reports are duplicated within the AERS database. Another limitation includes underreporting. Thus, the number of deaths within the six-year study period is probably not reflective of a true incidence rate. One study found that only 1% of serious events are reported to FDA.[17] Differential reporting is another possible limitation in that reports of deaths might be disproportionately reported compared with reports of medication errors.

By dissecting the different types of medication errors reported and their root causes, we can direct our efforts toward preventing similar errors by improving health care professionals' communication skills, access to drug information, and the system of drug administration. This could be accomplished by (1) implementing a linked automated system (e.g., computerized direct order entry system, computerized medication administration records, and bar coding), (2) providing easily accessible product information as close to the point of use as possible, and (3) directing immediate attention to the list of drug products in this study and implementing system improvements to minimize future errors. In addition, clinical pharmacists who participate in physician rounds and provide ward-based interventions can dramatically reduce medication errors and costs.[18,19] Numerous researchers and organizations, including NCCMERP, the American Society of Health-System Pharmacists, the Institute for Safe Medication Practices, and the National Patient Safety Foundation, among others, have elucidated additional recommendations for preventing medication errors. FDA is committed to educating the public about the safety of its products. This is an initial effort to provide that accountability as outlined in the February 2000 Quality Interagency Coordination Task Force's report to the President, *Doing What Counts for Patient Safety: Federal Actions to Reduce Medical Errors and Their Impact*. In addition, FDA's Office of Post-Marketing Drug Risk Assessment (OPDRA) is actively assessing the risks involved when naming, labeling, and packaging its products. OPDRA is reviewing all proprietary names before approving drug products to minimize the possibility of drug products that are named or packaged similarly. In addition, OPDRA is monitoring all reports of medication errors and recommending appropriate interventions, including changing the naming, labeling, or packaging of a drug product.

Conclusion

A review of case reports of medication errors from 1993 to 1998 yielded information on the most frequent causes of and contributing factors involved in fatal medication errors.

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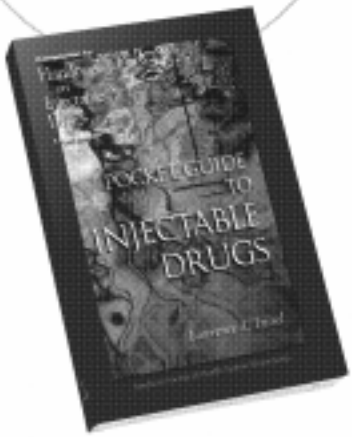

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