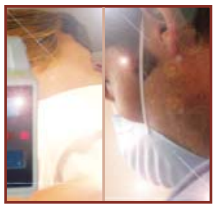

Medication Errors in Critically Ill Adults: A Review of Direct Observation Evidence

By Panagiotis Kiekkas, RN, MSc, PhD, Mary Karga, RN, MSc, PhD, Chrisoula Lemonidou, RN, MSc, PhD, Diamanto Aretha, MD, and Menelaos Karanikolas, MD, MPH

Objective To systematically review clinical evidence gathered by direct observation of medication errors in adult patients in intensive care units.

Methods Articles published between 1985 and 2008 in English-language journals indexed by the Cumulative Index for Nursing and Allied Health Literature and PUBMED were searched for studies on medication errors made by intensive care unit nurses. Studies in which errors were detected via direct observation were included.

Results Six studies met the inclusion criteria, and error incidence varied considerably among them. Wrong dose, wrong administration time and rate, and dose omission were the most common errors. Antibiotics, electrolytes, and cardiovascular drugs were commonly associated with errors, but the evidence about factors contributing to errors was inconclusive. Increased monitoring was the most common consequence of medication errors, whereas life-threatening and fatal adverse events were rare.

Conclusions Identification of patterns and characteristics of medication errors can guide preventive interventions. Factors contributing to errors, as well as drugs and error types associated with severe adverse events, deserve further investigation. (*American Journal of Critical Care.* 2011;20:36-44)

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Although patient safety has always been a primary concern for health care professionals, it is mainly within the past decade that international reports have linked errors by medical-nursing personnel to adverse events and adverse outcomes for patients.[1-3] This link is especially true in critical care, where nurses have to meet the demands of high-risk patients and administer a wide variety of pharmacological agents by multiple routes. The intensive care unit (ICU) is a complex environment, where the amount of cognitive information needed to reach a correct decision is high and often exceeds the upper limit of information that can be held in conscious memory.[4] Beyond the complexity of the ICU environment, critically ill patients are particularly susceptible to the consequences of errors, as they may be unable to compensate for additional injury because of limited physiological reserve.[5]

Medication errors have been defined as "preventable mistakes in prescribing or delivering medication to a patient, that is, an improper use of medicine or one that causes harm to a patient."[6] Of importance, a medication error is independent of the occurrence of patient injury (or of the potential for injury).[7] Although medication errors may occur at any stage of the medication process, most occur at the administration stage.[8] Drug administration constitutes a high-responsibility, primary nursing task that can consume up to 40% of clinical nurses' work time.[9] Errors associated with drugs can be particularly common in the ICU. Critically ill patients receive nearly twice as many medications as patients in general care units, and most medications involve calculations for bolus administration or continuous infusion.[10,11]

Methods used for detecting medication errors vary. In a study where true medication errors in the ICU were recorded by an independent pharmacist, Flynn et al[12] found that direct observation by trained personnel (mainly pharmacists) was significantly more valid and accurate than reviewing charts (by investigators) and incident self-reporting (by medical-nursing personnel). Comparison of the 3 error-detection methods revealed that 65.6% of true errors were detected via direct observation, whereas only 3.7% were detected via chart reviewing and 0.2% were detected via self-reporting of incidents. Error incidence could be underestimated because of unrecorded information in chart reviewing and because of subjective error assessment by untrained personnel in incident self-reporting.

The aim of this literature review was to synthesize the existing empirical evidence about medication errors occurring in adult ICU settings, focusing on the incidence, types, and clinical consequences of medication errors; drugs associated with medication errors; and factors contributing to medication errors. This review was limited to studies in which direct observation was used to detect medication errors, because that method is highly reliable for detecting errors.[12]

True medication errors were detected 65.6% by direct observation, 3.7% by chart review, 0.2% by self-report.

Materials and Methods

Articles published between January 1985 and December 2008 in English-language journals indexed by the Cumulative Index for Nursing and Allied Health Literature (CINAHL) and PUBMED (National Library of Medicine) were systematically searched for clinical studies of medication errors in critically ill adult patients. Additional articles were retrieved from the reference lists of the articles found through the initial online search. A combination of the following terms was used in the search: *errors, medication/drug errors, medication/drug safety, critical /intensive care unit, ICU/CCU, critically ill,* and *adult*.

Specific criteria used to select studies for this review were as follows:

- Types of study settings: critical/intensive care settings for adult patients, that is, medical, surgical,

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Table 1
Study characteristics and appraisal criteria

Author (year), country, setting	Stage(s) of medication process studied	Personnel informed of observation purpose	Data collection period	Observer characteristics and training	Observation design
Fahimi et al[13] (2008) Iran 12-bed mixed intensive care unit (ICU)	Preparation, administration	No	16 randomly selected shifts Data collection during peak times of intravenous drug administration	1 pharmacist trained in direct observation	During a shift, 1 pharmacist observed 1 randomly selected nurse
Kopp et al[14] (2006) United States 16-bed medical/surgical ICU	Prescription, transcription, dispensation, administration	Yes	16.5 days (33 12-hour shifts): 24-hour pilot stage and four 4-day periods 24 hours per day (2 sequential 12-hour shifts)	2 pharmacists specialized in ICU pharmacy practice	During a shift, 1 pharmacist observed 1 randomly selected nurse
Herout and Erstad[15] (2004) United States 16-bed surgical ICU	Administration (continuous infusion)	Not defined	1 month, 202 medication infusions in total	Not reported	All continuously infused drugs were evaluated at least once daily
Tissot et al[16] (1999) France 15-bed medical ICU	Preparation, administration	Yes	30 days during a 2-month period, excluding weekends and nights 6 hours per day (heaviest periods for drug preparation and administration)	2 pharmacists	Every day, 2 pharmacists observed 2 nurses
Van den Bemt et al[17] (2002) The Netherlands 2 mixed (11- and 7-bed) ICUs	Preparation, administration	No	5 consecutive days (Monday to Friday), from 7 AM to 10 PM	2 pharmacists trained in disguised observation	Every day, 1 pharmacist observed all nurses
Calabrese et al[18] (2001) United States 5 medical, surgical or mixed ICUs (100 beds in total)	Preparation, administration	No	3 months, limited to weekdays, nonconsecutively (depending on observers' discretion)	Pharmacists being ICU specialists (pharmacy students in 1 ICU)	Data collection occurred twice daily (morning / afternoon) on every ICU patient

or mixed ICUs. Studies conducted in pediatric or neonatal ICUs were excluded.

- Types of study design: prospective, single-center or multicenter, in which direct observation was used for data collection.
- Types of study subjects: nurses employed in ICUs.
- Types of exposure: medication errors occurring during drug prescription, preparation, dispensation, or administration. Studies in which medication errors were not separately reported (not distinguished from other error types) were excluded. Studies that included only medication errors that led to adverse events also were excluded (these errors may not have been representative of total medication errors).

Retrieved studies were screened for inclusion by 2 independent reviewers (P.K., M.K.) by using the titles and abstracts of the articles reporting the study results. When the reviewers disagreed about a particular study, a final determination was made jointly by both reviewers. Data extracted from selected studies were categorized according to the incidence, types and clinical consequences of medication errors, drugs associated with medication errors, and factors contributing to errors. Main study characteristics and findings are summarized in Tables 1 and 2. Because the heterogeneous nature of these studies did not allow data to be combined in a meta-analysis, a narrative literature review was preferred.

Results

Study Characteristics and Design

A total of 6 studies[13-18] (Table 1) were considered appropriate for this review. Three studies[14,15,18] were

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Table 2
Study findings on medication errors

Author (year)	Number (incidence)	Types	Associated drugs	Contributing factors	Consequences
Fahimi et al[13] (2008)	380 errors per 524 drug observations (72.5%) and per 4040 opportunities for error (9.4%)	Wrong administration rate, 43.4%; wrong continuous infusion rate, 23.0%; wrong dose (or diluent calculation), 20.1%; inappropriate diluents, 11.2%	% of errors/drug observations (corrected for opportunities for error): amikacin, 11.0%; vancomycin, 8.2%; diazepam, 7.4%; metoclopramide, 7.4%; metronidazole, 7.4%; ranitidine, 7.4%; ciprofloxacin, 6.1%	Most errors at 9 AM administration time, due to nursing distractions and workload peak	Not reported
Kopp et al[14] (2006)	172 errors per 645 drug administrations (26.7%)	Clinically important medication errors (n = 132): dose omission, 30 (22.7%); wrong dose, 26 (19.7%); wrong drug, 21 (15.9%); wrong technique, 20 (15.2%); drug-drug interaction, 13 (9.8%); wrong administration time, 12 (9.1%)	Medication errors leading to potential adverse events (n = 110) - drug category errors/total errors: cardiovascular, 17.3%; antibiotics, 15.5%; sedatives/analgesics, 13.6%; electrolytes, 8.2%; endocrine, 7.3%	Error proximal cause: lack of drug knowledge, 23%; slips and memory lapses, 14%; drug identification error, 13%; rule violations, 11%	Potential adverse events (n = 110): potentially fatal, 0.9%; potentially life-threatening, 8.2%; serious, 29.1%
Herout and Erstad[15] (2004)	26 errors per 208 continuous drug infusions (12.5%)	Drug omitted from flow sheet, 57.7%; wrong or no concentration reported, 19.2%; wrong continuous infusion rate, 15.4%; new order not reflected on flow sheet, 7.7%	Not reported	Calculation of 87.6% of doses for weight-based infusions was based on unreliable admission weights	Not severe
Tissot et al[16] (1999)	132 errors per 2009 drug administrations (6.6%)	Wrong dose, 38 (28.8%); wrong administration rate, (intravenous, perfusion by gravity, or continuous infusion), 29 (22.0%); wrong preparation technique (incorrect dilution), 24 (18.2%); physicochemical incompatibility, 19 (14.4%); wrong administration technique, 10 (7.6%); wrong administration time, 9 (6.8%)	Not reported	Not reported	Potentially life-threatening, 19.7%; need for increased monitoring, no patient harm, 41.7%
Van den Bemt et al[17] (2002)	131 errors per 233 drug administrations (56.2%)	Wrong administration time, 52 (39.7%); wrong administration technique, 36 (27.5%); wrong dose (preparation or administration), 33 (25.2%); dose omission, 7 (5.3%)	Only gastrointestinal drugs were significantly associated with more errors (odds ratio, 2.94; 95% confidence interval, 1.48-5.85)	More errors on Monday because of personnel shift change Specialized physicians and use of protocols possibly contributed to lower error rate	Need for increased monitoring, no patient harm, 38.2%
Calabrese et al[18] (2001)	187 errors per 5744 drug administrations (3.3%)	Wrong continuous infusion rate, 75 (40.1%); dose omission, 27 (14.4%); wrong administration time, 26 (13.9%); wrong dose, 22 (11.7%)	% of errors/drug observations: epinephrine, 7.9%; potassium chloride, 6.8%; digoxin, 5.8%; magnesium, 5.4%; lorazepam, 4.5%; norepinephrine, 4.3%	Not reported	Need for therapy or intervention, temporary harm, 1.1%; need for increased monitoring, no patient harm, 2.7%

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conducted in the United States; the remaining studies were conducted in Iran,[13] France,[16] and the Netherlands.[17] Errors were detected during medication preparation and administration stages in 4 studies,[13,16-18] during all stages of the medication process in 1 study,[14] and only during administration of continuously infused drugs in 1 study.[15]

Differences regarding design of included studies are summarized in Table 1. First, Herout and Erstad[15] focused on the administration of continuously infused drugs, whereas Kopp et al[14] studied all stages of the medication process of both continuously infused and intermittently delivered drugs. Second, only Calabrese et al[18] conducted a multicenter study, whereas van den Bemt et al[17] studied 2 ICUs. Third, the duration of data collection varied considerably among studies, from 6 hours[16] to 24 hours[14] per day and from 5 days[17] to 3 months[18] total. Fourth, use of the disguised-observation technique minimizes the bias that could be induced by the observer's presence.[19] Thus, the results of studies[13,17,18] in which personnel were not informed about the exact observation aim may be more reliable. Fifth, in 5 studies, direct observation was conducted by pharmacists (Herout and Erstad[15] did not report the observers' profession), who were ICU-specialized pharmacy residents in 2 studies,[14,18] and trained in direct or disguised observation in another 2 studies.[13,17] Sixth, in 3 studies,[13,14,16] each pharmacist observed only 1 nurse. Finally, in 2 studies, only the most commonly used[13] or high-risk medications[18] were observed; thus error detection was limited to predefined drug categories.

Six studies from 4 different countries were included in the review.

Incidence and Types of Medication Errors

Details about the number, incidence, types, and clinical consequences of medication errors; drugs associated with medication errors; and factors contributing to medication errors are presented in Table 2. In all 6 studies, error incidence was estimated on the basis of drug observations and ranged from 3.3% to 72.5%. Error incidence was also estimated on the basis of opportunities for error (calculated by adding all steps for potential errors during drug preparation and administration) in 1 study.[13]

Types of medication errors were reported in all 6 studies. In the studies where errors were observed during continuous drug infusion, wrong rate was reported in 4 studies and was the first,[18] second,[13] and third[15] most common error type identified. Intermittently delivered drugs were administered intravenously, intramuscularly, subcutaneously, orally, or via nasogastric tube. Regarding errors associated with intermittently delivered drugs, wrong dose was reported in 5 studies and was the first,[16] second,[14] and third[13,17] most common type of error reported. Wrong administration time was reported in 4 studies and was the first[17] and third[18] most common error type found. Dose omission was reported in 3 studies and was the first[14] and second[18] most common error type found. Wrong administration rate was reported in 2 studies and was the most common error type found.[13]

Drugs Associated With Medication Errors

The drugs associated with medication errors were reported in 4 studies. In 2 studies,[13,18] each drug was separately evaluated and the percentage of errors associated with each drug per number of observations of this drug was presented. Fahimi et al[13] found that 4 antibiotics (amikacin, vancomycin, metronidazole, and ciprofloxacin) were included among the 7 drugs most associated with errors. Calabrese et al[18] found that 3 cardiovascular drugs (epinephrine, digoxin, and norepinephrine) and 2 electrolytes (potassium chloride, magnesium) were included among the 6 drugs most associated with errors. In the other 2 studies,[14,17] drugs were studied in categories. Van den Bemt et al[17] found that only gastrointestinal drugs were significantly associated with more errors. Kopp et al[14] presented the percentage of each drug category errors per total errors that could lead to adverse events. Cardiovascular drugs, antibiotics, sedatives/analgesics, and electrolytes were the drug categories most associated with errors.

Factors Contributing to Medication Errors

The factors contributing to medication errors were reported in 4 studies. Nursing distractions and workload peak, lack of drug knowledge, and communication deficiencies were the main factors associated with errors in 1 study each.[13,14,17] Comparison of the ICUs of 2 different hospitals suggested that the presence of full-time specialized physicians and the use of drug preparation and administration protocols in 1 ICU may have contributed to fewer medication errors (compared with the other ICU, which had no full-time physicians or drug protocols).[17] Herout and Erstad[15] found that unreliable measurements of patients' weights at admission were associated with wrong dose calculation of continuously infused drugs.

Clinical Consequences of Medication Errors

The clinical consequences of medication errors were reported in 4 studies. A potentially fatal case

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was reported in only 1 study.[14] Potentially life-threatening adverse events were reported in 2 studies, corresponding to 8.2% of medication errors leading to adverse events[14] and to 19.7% of total medication errors.[16] In 3 studies, 41.7%,[16] 38.2%,[17] and 2.7%[18] of total medication errors led to the need for increased monitoring without temporary or permanent patient harm. In 1 study,[18] 1.1% of medication errors led to the need for therapy or intervention, with temporary harm of the patient.

Discussion

In this review, we focused on studies of medication errors in the ICU detected via direct observation, rather than on studies of adverse drug events. Adverse drug events have a more random occurrence than medication errors and are less statistically predictable. It seems very difficult to predict whether a medication error will lead to an adverse event, and adverse drug events are not always attributed to medication errors (eg, adverse drug events can be due to unpredictable allergic reactions). Medication errors are not only more preventable than adverse drug events,[16] but they also reveal weaknesses in the process of care. Thus medication errors are more reliable indicators of staff performance and quality of patient care than are adverse drug events.[20] From a nursing perspective, detection of medication errors can provide a valuable insight into unsafe practices and help identify opportunities for improvement.

Besides their impact on patients' morbidity and mortality, medication errors have a considerable economic and societal burden.[5,21] Thus, a number of error-prevention strategies have been proposed to increase the safety of the medication process, including pharmacists' participation in clinical rounds, having independent drug checks by many providers, and using barcode technology, medication reconciliation programs, or computerized order entry by physicians.[7,22-24] However, proper redesigning of faulty systems should be based on an in-depth understanding of the epidemiology of medication errors.[14] This knowledge can guide the application of error-prevention strategies and will allow more specifically targeted quality improvement efforts. Moreover, because the incidence of medication errors in a single ICU is generally low, error patterns and characteristics can more reliably be identified by reviewing data from several ICU studies.[25] Synthesis of data on ICU medication errors will reveal most common error types, drugs associated with and factors contributing to errors, and serious error consequences, as well as provide implications for future research.

In existing studies, the incidence of medication errors is reported either per number of drug observations or per opportunities for error. Opportunities for error are difficult to define, but may properly reflect patients' exposure to risk. Differences in health care provision (such as nurse:patient ratio, personnel experience, number and types of drugs administered, and medication delivery system) among different hospitals or countries may account for the remarkable differences in incidence of medication errors among studies.[5] Reported error incidence also depends on the exact conditions of direct observation, on the exclusion of medication errors considered to be clinically unimportant,[14] and on the selection of medication process stages to be studied (most studies[13,16-18] have focused on errors during drug preparation and administration).

> Redesigning of faulty systems should be based on understanding medication error epidemiology.

Although definitions of medication errors may vary among studies, it is important that some error types were considerably more common than others. In remarkable agreement with findings of studies included in this review, the 3 most common medication error types in ICU studies that were based on workers' voluntary self-report[26,27] or chart review[28] were wrong administration time and wrong or omitted dose, whereas administration of the wrong drug or administration to the wrong patient was generally rare. In particular, the incidence of wrong-dose errors could be underestimated in voluntary self-report studies, owing to both workers' difficulties in becoming aware of such errors and social desirability bias or self-esteem bias (because wrong-dose errors are primarily attributed to individual deficiencies, participants may tend to underreport them).[29] Even in this case, it is important that wrong dose was among the 3 most common error types in another 2 ICU personnel self-report studies,[25,30] thus indicating a similar trend between the direct observation and voluntary self-report methods.

> Because medication error rates in a single ICU are generally low, error patterns should be reviewed over several ICUs.

Tissot et al[16] found the wrong administration rate to be the second most common type of error, but errors related to continuous drug infusion and errors related to intermittently delivered drugs were recorded together. Recording data in this fashion renders analysis and extraction of conclusions difficult, as an incorrect continuous infusion rate means not only that the patient will receive a drug faster or

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slower than indicated (as in the case of wrong bolus administration rate), but that total administered dose will be inappropriate as well. Medication error types associated with continuous vs intermittent administration technique may not be comparable; therefore, these error types should be recorded separately in studies.

High number of errors associated with antibiotics, for example, may simply reflect the high number of antibiotic doses administered to ICU patients. Thus, when evaluating whether a drug (or drug category) is particularly associated with errors, more valid comparisons might be based on the incidence of errors associated with this drug (ie, the number of errors per number of observations or per opportunities for error of this drug), rather than on the absolute number of errors associated with this drug (or on the proportion of errors associated with this drug per total medication errors). In addition, more focused error prevention could be achieved through the identification of specific drugs more often associated with errors (rather than the identification of drug categories associated with errors). However, no single drug can be identified as particularly associated with errors on the basis of existing data. Consistent with findings of studies included in this review, antibiotics, sedatives/analgesics, and cardiovascular drugs (vasopressors/catecholamines) were most commonly associated with errors in a recent, self-report, multicenter ICU study.[26] Antibiotics in particular have been identified as the highest-risk drug category in non-ICU studies and are believed to be associated with a high incidence of wrong administration time errors or omitted doses, due to variations in the interval at which antibiotics are administered.[31,32]

Wrong dose, dose omission, and wrong administration time are the most common error types.

Considering the multifactorial nature of medication errors, several predisposing factors have been investigated, which can be associated either with the individual (inadequate mathematical skills or medication knowledge, personal neglect, limited experience) or the system (eg, heavy workload, unfavorable working conditions, distractions, complicated orders).[32,33] In critically ill patients, high clinical severity and high number of organ failures have also been associated with high incidences of errors.[21,26] In agreement with findings of studies included in this review, poor communication, frequent interruptions, and workload have also been reported as the main factors contributing to errors in interview or voluntary self-report studies among ICU personnel.[34,35] However, existing findings of direct observation studies are rather inconclusive, because none of the identified error-contributing factors was reported in more than 1 study. Moreover, possible associations between specific error-contributing factors and specific medication error types have not been investigated to date and may be an important area for future research. For example, wrong-dose errors may be attributed to inadequate mathematical skills or drug knowledge of nurses and preparation errors by pharmacists, whereas dose omission and wrong administration time may be mainly related to system factors, such as increased workload, drug availability, pharmacy preparation timing, and time constraints with competing priorities.

According to Reason's model,[36] most accident sequences are trapped at one or more layers of the system's defenses. In agreement with findings of studies included in this review, most ICU medication errors did not result in clinically significant consequences or patient harm in a voluntary self-report study[26] or in a review of safety incident reports of nursing staff.[37] Considering that vital functions of ICU patients are continuously monitored and supported, most physiological disorders resulting from errors can be detected and properly treated at an early stage or may even require no additional treatment. For example, opioid overdose, which could cause severe respiratory depression in spontaneously breathing patients, may not considerably affect a patient receiving mechanical ventilation.[25]

Although only a limited proportion of medication errors have life-threatening or fatal consequences, the incidence of preventable adverse drug events is not insignificant, ranging from 19 to 36.2 per 1000 ICU patient-days in US studies.[6,38] Moreover, late consequences of medication errors could be overlooked in studies, because adverse events are generally recorded proximal to the timing of medication administration. For example, the Joint Commission has emphasized the importance of effective timing of antibiotic administration in pneumonia core measures.[39] However, although timely antibiotic administration is important in patients with severe infections, adverse patient outcomes associated with antibiotic dose omission or wrong administration time are not recorded in most studies.[40] Meaningful questions for future research could include whether specific medication error types or drugs are associated with a high incidence of adverse events, both early and late, and particularly with life-threatening or fatal consequences.

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The small number of studies that met the inclusion criteria and the limited information about the characteristics of medication errors in some of the studies are the major limitations of this review. Another limitation is the heterogeneity of the studies, which used inconsistent definitions of errors and error incidence, were focused on different medication process stages or on different drug administration techniques, and involved different critical care settings. Additionally, although superior to other error detection methods, direct observation cannot capture errors completely. Flynn et al[12] reported that with direct observation, 34% of true medication errors were missed and the rate of false positives (3.5%) was considerable.

Conclusion

Data derived from studies of ICU medication errors via the direct observation method suggest that the incidence of medication errors varies significantly among ICUs. Identification of the most common error types, the drugs associated with errors, the factors contributing to errors, and serious consequences of errors, is necessary to guide focused efforts to prevent medication errors. Wrong dose, dose omission, wrong administration time, and wrong administration rate (especially of continuously infused drugs) are the most common error types. The most common drug categories associated with medication errors in the ICU included antibiotics, electrolytes, cardiovascular drugs, sedatives/analgesics, and gastrointestinal drugs. Distractions, high workload, lack of drug knowledge, and poor communication may contribute to errors. Although most medication errors do not result in harm of patients, life-threatening or fatal adverse events have been reported.

Nursing personnel should design and lead future studies on their own medication errors. Research based on direct observation has yet to address many issues, mainly establishing the specific drugs most associated with medication errors and the factors contributing to medication errors in general or to specific types of medication errors. Investigation of medication error types most associated with severe adverse events is also of particular importance.

FINANCIAL DISCLOSURES
None reported.

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