Med error reports to FDA show a mixed bag

The medication errors staff in the Office of Post-Marketing Drug Risk Assessment (OPDRA) search the Food & Drug Administration Adverse Event Reporting System (AERS) database for all cases of medication errors. Since the FDA often receives multiple reports regarding one case, the best representative report (with the most complete information) is reviewed and classified according to the Taxonomy of Medication Errors developed by the National Coordinating Council for Medication Errors Reporting and Prevention (NCC-MERP) and adopted by the FDA in 1999.

In May 2001, the FDA received 273 reports of medication errors. Excluding duplicated reports and those associated with intentional suicide, 265 cases were identified for review and classification. Among these, 129 cases were serious and 136 were nonserious. The FDA defines *serious* as any adverse event that is fatal; life-threatening; associated with disability, hospitalization, or congenital anomaly; or which required intervention to prevent permanent impairment. Out of the 129 cases that were classified as serious, 18 were fatal, 12 were life-threatening, 56 required hospitalization, eight were disability reports, and 35 required intervention to prevent permanent impairment/damage. Each report was reviewed and classified into one of the following:

1. Communication (written miscommunication, misinterpretation of the order)
2. Name confusion (proprietary name confusion and established name confusion)
3. Labeling (immediate container labels of product manufacturer, distributor, or repackager, labels of dispensed product—practitioner, package insert, printed reference material)
4. Human factors (knowledge deficit, performance deficit, miscalculation of dosage or infusion rate, drug preparation error, transcription error, stress)
5. Packaging/design (inap-

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Table 1.
Medication errors by cause, May 2001

Causes	Number	% of total (n = 341)
Communication (n = 64, 19%)		
Verbal miscommunication	1	0.3%
Written miscommunication	28	8.1
Misinterpretation of the order	35	10.3
Name confusion (n = 44, 13%)		
Proprietary name confusion	35	10.3
Established name confusion	9	2.6
Labeling (n = 68, 20%)		
Immediate container labels of product manufacturer, distributor, or repackager	32	9.4
Labels of dispensed product – practitioner	15	4.4
Carton labeling of product	15	4.4
Package insert	1	0.3
Electronic reference material	2	0.6
Printed reference material	3	1
Human factors (n = 145, 42%)		
Knowledge deficit	42	12.3
Performance deficit	45	13.2
Miscalculation of dosage or infusion rate	24	7
Drug preparation error	8	2.3
Transcription error	24	7
Fatigue	1	0.3
Computer error	1	0.3
Packaging/design (n = 20, 6%)		
Inappropriate packaging or design	10	3
Dosage form (tablet/ capsule) confusion	9	2.6
Devices (infusion)	1	0.3

Table 2.
Medication errors by type, May 2001

Type	Number	% of total (n = 36)
Dose omission	3	1%
Noncompliance	16	7
Overdosage	40	17
Underdosage	6	2.5
Extra dose	8	3
Wrong strength/concentration	16	7
Wrong drug	52	22
Wrong dosage form	1	0.5
Wrong technique	16	7
Wrong route of administration	19	8
Wrong duration	2	1
Wrong time	5	2
Wrong rate	2	1
Wrong patient	2	1
Monitoring error	16	7
Deteriorated drug	3	1
Other	29	12

propriate packaging or design, dosage form—tablet/capsule—confusion)

The analysis of the 265 cases revealed a total of 341 causes (see Table 1). The most common causes identified were human factors represented by 42%, followed by labeling problems represented by 20%, and communication problems represented by 19%.

Additionally, the analysis of each of the 265 cases showed 236 types of medication errors (see Table 2). Twenty-two percent of them were wrong drug errors, followed by improper dose administered to a patient resulting in overdosage (17%) and by the "other" category (12%).

Table 3 shows the top 10 suspect drugs with the greatest number of medication error cases reported in May 2001. Among the 265 cases reviewed, 8% pertained to morphine sulfate, followed by 5% for Xylocaine and 4.5% for Novolin 70/30.

Table 3.

Number of medication error case reports for the top 10 suspect drugs, May 2001

Drugs	Number of cases	% of total (n = 265)
Morphine sulfate	22	8%
Xylocaine	14	5
Novolin 70/30	12	4.5
Aricept	5	2
Aciphex	5	2
Timolol maleate	5	2
Estratest	4	1.5
Zyrtec	4	1.5
Depakote	4	1.5
Lovenox	4	1.5

In summary, these results demonstrate that the most common causes of medication errors were human factors (42%), followed by labeling problems (20%), and communication problems (19%). In addition, the most common type of error was wrong drug administered (22%), followed by improper dose administered resulting in overdosage (17%) and the "other" category (12%). Of the 265 cases reviewed, 18 (5%) were fatal errors and 43 (13%) were potential errors. Moreover, 8% of the medication error cases were related to morphine sulfate.

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