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Medication Errors Outside Healthcare Facilities: A National Poison Centre Perspective

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Abstract: Medication errors (ME) are a major concern to healthcare systems. Most studies evaluated ME occurring in healthcare facilities; only few focused on ME outside them. The objective was to characterise ME occurring outside healthcare facilities. A prospective observational follow-up study evaluating all ME occurring outside healthcare facilities reported to a national poison information centre during a 5-month period. For each ME case, a detailed questionnaire was filled and a follow-up call was made within 7 days. The collected data included demographics, circumstances, type of error and outcome. Of 1381 consecutive ME cases were included; 97.8% involved a single incident and 88.3% one drug. The main characteristics of the ME were as follows: children younger than 6 years old (58.9%), parents responsible for 55.6% of cases, wrong dose 34.5% and different medication 30.1%. Analgesics (27.4%) and antimicrobials (12.2%) were the most common pharmaceuticals. The main reasons for the ME were look-alike packaging (31.4%) and misunderstood instructions (28%). Most followed up patients (97.1%) were asymptomatic or mildly affected; there was one severe case and no mortality. Most ME occurring outside healthcare facilities are single incidents, involving young children who were administered a wrong dose or medication due to look-alike packaging or misunderstood instructions with asymptomatic or mild outcome. Improved packaging, labelling and patient education are suggested to reduce ME.

Medication errors (ME) are a major cause of morbidity and mortality [1]. In the USA, the estimated annual death toll of ME is 98,000 cases [2]. While most research on ME is conducted in healthcare facilities, there is limited information on ME occurring in the patients' home. Data collection on patient behaviour and use of medications in the home is difficult and inconsistent. Poison centres serve the general public and record relevant data on ME reported by the public. Several studies from poison centres on ME were published over the years [3–15], and most were retrospective [4–11,13,15]. Some evaluated only specific age groups, young children [3,7,12,13] and elderly patients [8,9]. Some studies concentrated on iatrogenic errors and did not report any ME outside healthcare facilities [4,5,10]. Shah and Barker published a retrospective study with no follow-up on ME occurring outside hospitals [11]. A more comprehensive assessment of ME in the public may improve our understanding of the characteristics and origin of such errors and lay the ground for preventive measures. The objective of our study was to characterise ME occurring outside healthcare facilities.

Methods

We conducted a prospective observational follow-up study of all ME outside healthcare facilities reported to the Israel National Poison Information Center (IPIC) between 1 August and 31 December 2008. The IPIC serves a population of 7,956,000 people [16]. This is the only national poison information centre in the country and the only one to serve both the general public and healthcare facilities around the clock. In 2007, the IPIC received 26,738 calls; 73% were made by the public and 99.3% of cases occurred outside healthcare facilities. Pharmaceuticals were the reason for 44.2% of these calls [17]. Reporting to the IPIC is not mandatory. Case records in its database comprise self-reported calls, and they contain information provided by the public or healthcare professionals reporting an actual or potential exposure [17,18]. The consultation process includes history taking, assessment of the patient's condition and exposure, advice on first aid, survey of data, triage and management recommendations. All toxicological consultation data are recorded in a comprehensive structured form that includes caller and patient demographic details, substances involved, route, site and circumstances of exposure, time elapsed until consultation, clinical manifestations in a system-oriented approach, evaluation (including laboratory confirmation of exposure whenever possible) and management and follow-up recommendations. The clinical severity of each case is graded according to previously published criteria [17,18] as minor, moderate, major, death, unknown or not applicable. All data are entered and stored in a designated tailored database using Access® 2007 (Microsoft Corporation, Redmond, WA, USA) on an SQL server. All records are subjected to routine quality control. Each case is classified according to a previously prepared list of categories, classifications and subclassifications available at the IPIC. This method of data collection and classification of the IPIC toxicological consultations was reported in detail previously [17,19,20].

Medication errors are recorded as unintentional therapeutic errors. At IPIC, the definition of unintentional ME is a case of erroneous intake of a drug due to any error at any stage of the medication process. During the study period, all cases of ME were recorded in a designated questionnaire. In addition, all medical records of the IPIC were daily surveyed for ME, and the questionnaire filled accordingly. All ME records were sorted according to the site of exposure. Exclusion criteria were exposures occurring in healthcare facilities (e.g., hospitals, community clinics), misclassification as unintentional ME and insufficient information. A follow-up call was performed

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within 3–7 days after the call to the IPIC. During this call, missing data were collected and clinical outcome including clinical manifestations and medical interventions was recorded. Follow-up calls were made twice on different days for each case, and if unsuccessful, the case was classified as lost to follow-up. All data from the original consultation record and the follow-up call were collected in a designated form prepared for the study. The collected data included personal demographics, medication details (type, dose, formulation and route), information on prescription, dispensing and administration, error details (type, timing, person involved and causes), clinical manifestations and severity, IPIC recommendations and medical interventions (referral to healthcare facility, treatment and evaluation). Data were subjected to descriptive analysis and chi-square analysis when relevant (Excel® 2007; Microsoft Corporation).

The study was approved by the Institutional Review Board of Rambam Health Care Campus, Haifa, Israel.

Results

During the study period, 1409 consecutive cases of unintentional ME occurring outside healthcare facilities were recorded at the IPIC. Twenty-eight cases were excluded due to misclassification of ME, leaving 1381 cases for analysis. These cases comprise 12.4% of the total cases reported to the IPIC during the study period, and an annual incidence of 44 ME events per 100,000 population in the general public.

Children under the age of 6 years were the largest sector of the population subjected to ME (814, 59%), 36.6% in children up to the age of 2 years. Adults counted 397 (28.7%) ME cases. In 14 cases, the age was not recorded. Female patients were involved in 708 cases (51.3%).

One medication was the culprit in 1350 (97.8%) ME cases. Most cases were a single error event (1220, 88.3%).

Medication errors were significantly more frequent at night (836, 60.5%) compared with daytime (512, 37.1%), $p < 0.0001$. Most cases were reported within 1 hr after the exposure (909, 65.8%), 263 (19%) between two to 24 hr and 34 (2.5%) later than 24 hr.

The distribution of the error types is presented in table 1. The main person responsible for the error was a parent (773, 56%), followed by the patient (435, 31.5%), another caregiver (93, 6.7%) and medical personnel (40, 2.9%).

The distribution of the pharmacological groups involved in ME is presented in table 2, formulations and route of administration in table 3 and causes for ME in table 4. Over the counter medications (OTC) were involved in almost half of cases (661, 47.9%).

Table 1.
Distribution of type of medication error.

Type of medication error	Number of cases (%)
Different dose	476 (34.5)
Different medication	415 (30.1)
Additional extra dose	309 (22.4)
Timing error	70 (5.1)
Expired or unrefrigerated drug	54 (3.9)
Wrong route of administration	29 (2.1)
Different patient	12 (0.9)
Drug interaction	2 (0.1)
Combination of errors	14 (1.0)

Table 2.
Pharmacological groups and medications involved in medication errors.

Pharmacological group[1]	Number of cases (%)
Analgesics	378 (27.4)
Antibiotics	169 (12.2)
Ear, eye, nose and throat preparations	96 (7.0)
Vitamins	99 (7.2)
Cold and cough preparations	88 (6.4)
Topical preparations	65 (4.7)
Cardiovascular medications	56 (4.1)
Sympathomimetics	68 (4.9)
Antihistamines	40 (2.9)
Hormones	30 (2.2)
Other	292 (21.1)

[1]The most frequent medications involved included acetaminophen (165, 11.9%), ibuprofen (144, 10.4%), vitamin D (88, 6.4%) and penicillins (81, 5.9%).

Most cases were classified as asymptomatic (1202, 87%), 144 (10.4%) cases were mild, 34 (2.5%) moderate and only one severe.

In 1120 (81.1%) cases, the recommendation of the IPIC clinical toxicologist was home observation; 252 (18.2%) were referred to a healthcare facility.

Follow-up calls were completed in 846 (61.3%) cases. The reasons for unsuccessful follow-up calls were missing or wrong telephone number, a contact person who did not know the outcome and unanswered call. The demographic data distribution of the follow-up cases was similar to the whole ME group.

Table 5 presents the body systems affected and the main clinical manifestations in the 113 symptomatic patients followed up. The distribution of severity in the followed up patients was similar to that recorded at the time of consultation with the IPIC. The severely affected patient was a 10-year-old child who developed respiratory distress and impaired consciousness after being administered a rectal suppository of tramadol instead of acetaminophen. No mortality was recorded.

Two hundred and twenty-nine (27.1%) patients followed up reached a healthcare facility; 11 (1.3%) patients were hospitalised, 121 of them referred themselves to a healthcare facility due to anxiety or for second opinion. Seven hundred and five (83.3%) followed up patients complied with IPIC recommendation. The main pharmacological groups related to the symptomatic cases were cold and cough preparations, β_2-agonist bronchodilators, sedatives, narcotics, antihistamines and psychiatric medications.

Discussion

We evaluated 1381 ME reported from outside healthcare facilities. Most of the recorded ME involved a single incident, night-time, oral route, one medication, young children, analgesics or antibiotics, and an asymptomatic or mild clinical

Table 3.
Formulations and routes of administration involved in medication errors.

Formulation	Number of cases (%)	Route of administration	Number of cases (%)
Oral solution	598 (43.3)	Oral	1110 (80.4)
Tablet/capsule	404 (29.3)	Rectal	87 (6.3)
Eye, ear, nose or throat drops	107 (7.7)	Ocular	61 (4.4)
Rectal suppository	88 (6.4)	Inhalation	44 (3.2)
Solution for external use	73 (5.3)	Nasal	31 (2.2)
Solution for inhalation	51 (3.7)	Ear	19 (1.4)
Topical preparation	27 (2.0)	Subcutaneous/intramuscular injection	18 (1.3)
Solution for injection	17 (1.2)	Dermal (topical)	6 (0.4)
Dermal patch	1 (0.1)	Vaginal	4 (0.3)
Unclear formulation	15 (1.1)	Unclear route	1 (0.1)

Table 4.
Causes of medication errors.

Cause	Number of cases (%)
Similar packaging	433 (31.4)
Unclear or misunderstood instructions	386 (28.0)
Memory and co-ordination faults	311 (22.5)
Measurement and preparation	104 (7.5)
Dispensing	18 (1.3)
Wrong instruction	17 (1.2)
Unknown cause	112 (8.1)

outcome. OTC medications were involved in about half of cases. Look-alike packaging was the main cause for ME.

Approximately one of every eight calls to the IPIC was about ME (12.4%). Published studies show a similar frequency of ME reported to poison centres: 9.6% in Ireland from 2007 to 2009 [14] and 8.3% in the USA from 2000 to 2005 [11]. The distribution of the sites of exposures reported to the Irish Poison Center and to the US National Poison Data System (98.3% and 99.7% outside healthcare facilities, respectively) is similar to ours (99.3%). These similarities suggest that our results are comparable to previously published data [18,21].

The incidence of ME events in the general public in this study was 44 per 100,000 population. The actual incidence of ME outside healthcare facilities is possibly much higher as only a small number of cases are reported to poison centres. It is estimated that the actual incidence of ME may be at least 100-fold higher than the reported figures [22]. Possible reasons for not reporting ME to a poison centre include asymptomatic patient, competent physician and undetected errors.

The main types of ME reported to IPIC were wrong dose (34.5%), wrong medication (30.1%) and an unnecessary double dose (22.4%). Cassidy *et al.* [14] from Ireland reported a slightly different distribution of causes for ME: double dose (44.3%), wrong drug (25.4%) and wrong dose (16.8%). Taking a medication twice was the commonest ME (30.3%) reported by the American National Poison Data System [11,18]. Each of the prime error types had mainly one cause. Administering the wrong medication was most often due to look-alike packaging. Giving a wrong dose was most often a result of misunderstood or unclear instructions. An extra dose most often resulted from memory and co-ordination problems.

Look-alike drug packaging and misleading graphics on medication containers and labels can increase the incidence of ME in healthcare facilities [23–27], similar to our findings on ME occurring outside these facilities. Despite numerous reports on errors associated with packaging and efforts to improve them, many medications are still poorly packed and labelled [28,29]. It is suggested that pharmaceutical companies develop safer packaging, less prone to confusion, and that health agencies impose stricter safety regulations.

Healthcare professionals should provide patients with clear instructions and ascertain that the instructions are properly understood [30–37]. The issue of insufficient guidance by healthcare professionals is illustrated by our finding of OTC involvement in almost 50% of ME. Directed approach by regulatory authorities and implementation of proper methods for the correct use of medications in a physician-free and pharmacist-free scenario are warranted [12,38].

Table 5.
Clinical manifestations.

Body system affected by medication errors	Number of cases	Main clinical manifestations (number of cases)
Cardiovascular	14	Tachycardia (6), low blood pressure (4)
Neurological	39	Sleepiness (18)
Gastrointestinal	30	Vomiting (11), abdominal pain (10), nausea (6)
Airways	6	Throat irritation (3)
Ophthalmological	17	Eye irritation (14)
General/other	23	Restlessness (9), weakness (8)

Inaccurate age-related dose calculation may explain the high percentage of ME we found in young children [22,39–42].

Recording, co-ordinating and memorising drug administration procedures by the public are usually limited, emphasising the need for adequate education and guidance by the healthcare system [30,35]. Extra caution of care givers and healthcare providers is warranted when administering medications to high-risk patients (e.g., young children, elderly, polypharmacy) [32,35,43].

Analgesics and antibiotics were the commonest ME in our study, as reported by others [3,6,8,9,11–14]. Vitamin D was also common, unlike other studies from the USA, Ireland, Australia and France [3,11,12,14]. A possible cause for this discrepancy is the guidelines issued by the Israeli Ministry of Health encouraging vitamin D supplementation in infants. Cold and cough preparations were relatively less commonly reported in our study compared with other poison centre studies [11,12,14], possibly reflecting different OTC status and prescribing practice.

Our findings show that patients were generally compliant with IPIC recommendations. It is suggested that poison centre consultations can prevent unnecessary referrals to healthcare facilities, as previously reported [44,45].

The main limitations of our study include reliance on self-reporting and recall bias in the follow-up interviews. These limitations are common to reports from other national poison centres [9,11,14]. Follow-up was limited; no significant difference was found between the demographics and ME characteristics of the followed up and not followed up cases, giving credence to our results. The strengths of our study include its prospective and follow-up design, large number of cases collected and the national role of the IPIC. The main advantages of the prospective design over the previously published retrospective studies are the validation of the clinical outcome of the ME and the evaluation of the adherence to poison centre recommendation.

In conclusion, the main characteristics of ME occurring outside healthcare facilities as reported to a national poison centre include young children, parents' responsibility, misunderstood instructions, night-time, single incident, one medication, oral route, liquid formulation, analgesics or antibiotics, wrong dose or medication, and an asymptomatic or mild clinical outcome. OTC medications were involved in about half of cases. Look-alike packaging was the main cause for ME. A mutual effort of proper measures promoted by the pharmaceutical industry, regulatory health agencies and healthcare professionals aimed at improving drug packaging, patient and caregiver education, and OTC regulatory policy is advised.

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