Adverse drug events caused by medication errors in medical inpatients

Beat Hardmeiera, b, Suzanne Braunschweigb, c, Marzia Cavallaro b, Malgorzata Roo d, Christiane Pauli-Magnus a, Max Giger b, Peter J. Meier a, Karin Fattinger a

a Division of Clinical Pharmacology and Toxicology, Dept. of Medicine, University Hospital, Zürich, Switzerland
b Foundation for Drug Safety and Comprehensive Hospital Drug Monitoring (SAS/CHDM), University Hospital, Zürich, Switzerland
c Dept. of Medicine, Kantonsspital, St. Gallen, Switzerland
d Biostatistics, ISPM, University of Zürich, Switzerland

Principles: In view of growing concern in recent years regarding medication errors as causes of adverse drug events (ADEs), we explore the frequency and characteristics of error-associated ADEs in medical inpatients.

Methods: All patients with ADEs or ADE-related hospital admission in a cohort of medical inpatients identified by “event monitoring” (SAS/CHDM database, Br J Clin Pharmacol 2000;49:158–67) were evaluated independently by two experienced physicians. ADEs were first divided into ADEs occurring during cohort stay (incident ADE) and ADE present prior to/at admission. ADEs were then grouped as error-associated ADEs (eADEs: indication error, missed contraindication, wrong dosage regimen or inadequate surveillance) and adverse drug reactions (ADRs: indication established, no contraindications, appropriate dosage regimen and adequate surveillance).

Results: Among the 6383 patients analysed (100%), 481 (7.5%) experienced at least one incident ADE. Incident ADRs occurred in 457 (7.2%). Incident eADEs were recorded in 28 patients, corresponding to an eADE incidence of 0.4% (95% CI: 0.2, 0.7). Error types were missing/inappropriate indication (4 cases), missed contraindications (9), relative overdoses (8), absolute overdoses (3) and inadequate clinical surveillance (4). The responsible drugs included antithrombotics (6), cardiovascular drugs (5), antibiotics (5), hypnotics (4) and non-steroidal anti-inflammatory drugs (3). ADE-related hospital admissions were observed in 262 patients (4.1%); 183 (2.9%) were classified as ADRs and 79 (1.2%) as eADEs.

Conclusions: Incident eADEs were observed in 1 out of 250 patients and accounted for approximately 6% of ADEs. In contrast, eADEs accounted for 30% of ADE-related hospital admissions. Hence, in medical inpatients, eADEs represented a small fraction of total incident ADEs, whereas they contributed significantly to hospital admissions.

Key words: adverse drug events; preventable adverse drug events; adverse drug reactions; medication error; medical inpatients

Summary

Adverse drug events (ADEs), usually defined as harm caused by the (appropriate or inappropriate) use of a drug [1], constitute a major health concern for the individual patient and the community. It has been estimated that ADEs account for approximately 5% of all hospital admissions, occur during 10–20% of hospitalisations [2] and are responsible for 7–9% of hospitalisation days [3, 4]. ADEs can be classified according to their potential preventability. They cannot be prevented if the causative drug is used for an established indication, in the absence of contraindications, at the appropriate dosage and under adequate surveillance. These non-preventable ADEs are classified as adverse drug reactions (ADRs). All other ADEs are potentially preventable. These include ADEs where the causative drug is used without an established indication, despite the presence of contraindications, at an inappropriately high dosage, as an inappropriate formulation, by an incorrect route or under inadequate surveillance. These potentially preventable ADEs can be classified as error-associated adverse drug events (eADEs).

The currently available estimates of the inci-
dence of eADEs in hospitalised patients vary considerably. In 1991, Leape et al. evaluated the incidence of several types of adverse event by reviewing the records of more than 30 000 inpatients [5]. Among 178 ADEs, 17.7%, corresponding to approximately 32 ADEs, were caused by errors, resulting in an eADE incidence of 0.11%. On the basis of a review of 15 000 medical records from Utah and Colorado, the incidence of eADEs was estimated at 0.17% for patients aged between 16 and 64 years and at 0.64% for patients over 64 [6]. A prospective study in 1120 paediatric inpatients resulted in a comparable eADE incidence of 0.45% [7]. In contrast, in three prospective studies Bates et al. estimated considerably higher eADE incidences of 1.3%, 1.8% and 3.6% [8–10]. Furthermore, extrapolations of medication error-associated death rates yielded an eADE-related mortality estimate of up to 98 000 deaths per year for the US [11], though these latter studies were controversial [12–14]. Since detailed knowledge of the incidence and characteristics of eADEs are a prerequisite for appropriate planning of error prevention strategies and for adequate allocation of financial resources, we evaluated the contribution of medication errors to total ADEs recorded prospectively in the pharmaco-epidemiological database SAS/CHDM (Stiftung für Arzneimittelsicherheit/Comprehensive Hospital Drug Monitoring) [4]. We determined the overall eADE incidence and characterised eADEs with respect to types of error, drugs involved and types of event. We further estimated the contribution of eADEs to hospital admissions.

**Methods**

The SAS/CHDM (Stiftung für Arzneimittelsicherheit/Comprehensive Hospital Drug Monitoring) project maintains a pharmaco-epidemiological database for study of ADEs in a cohort of medical inpatients [4]. The cohorts are located at the Departments of Medicine of Zürich University Hospital and the Kantonsspital St. Gallen. While the former is mainly a tertiary referral centre and serves only as a primary hospital for some parts of the city, the latter serves as a primary city hospital and as a secondary referral centre for northeast Switzerland. At Zürich University Hospital the monitored units belong to the Department of Internal Medicine, where admissions are based on available beds irrespective of the suspected diagnoses, whereas in the Kantonsspital St. Gallen the monitored units belong to one of three divisions of the Department of Internal Medicine, preferentially focusing on infectious, endocrine and pulmonary diseases. For each patient admitted to one of the monitored units we collect on admission structured data regarding patient characteristics, drug exposure before hospitalisation and the cause(s) of hospital admission. During cohort stay, structured data on “events” (symptoms, laboratory results) and drug exposure are prospectively collected on a daily basis and entered into the database. At discharge, data on diagnoses (ICD10) are added. The monitoring physician also evaluates the cause(s) of hospital admission and all clinical events and pathological laboratory results with respect to discharge letters and medical records, and determined all ADEs on the basis of database entries, physician’s notes, and from the hospital records. ADEs were classified as adverse drug reaction (ADR) if the causative drug was administered for an established indication in the absence of contraindications, at the appropriate dosage and under adequate surveillance. Indications were considered appropriate if they were either included in the labelling or had been described elsewhere. In contrast, ADEs were classified as error-associated ADE (eADE), if the causative drug was used inappropriately with respect to selection, dosage or surveillance. Selection errors included missing or inappropriate indications (indication errors), missed contraindications and missed drug interactions. Dosage errors included a) absolute overdoses, i.e. dosages exceeding the usual therapeutic, prophylactic or diagnostic dosages, b) relative overdoses, i.e. dosages too high for the individual patient, such as e.g. the standard therapeutic digoxin dosage in the case of impaired renal function, and c) administration errors such as inappropriate formulation, wrong route of administration or wrong dosage interval. Surveillance errors included eADEs caused by inadequate clinical surveillance or insufficient laboratory checks. For ADEs at admission, additional category called patient errors included eADEs caused by the patients themselves, ADE severity was graded into a) significant, i.e. ADEs demanding a dosage reduction or therapy cessation, b) moderate, i.e. ADEs requiring additional therapeutic measures, c) serious, i.e. ADEs prolonging hospitalisation, leading to permanent defects or life-threatening complications, and d) lethal, i.e. ADEs leading to death.

**Figure 1**

Venn diagram on adverse drug events (ADE) and its subdivision into incident ADE vs. ADE at admission and error-associated ADE (eADE) vs. adverse drug reaction (ADR).
Interphysician rating differences were evaluated using Cohen’s Kappa together with proportion of observed agreement ($p_o$) and the observed proportions of positive ($p_{pos}$) and negative ($p_{neg}$) agreement, where the $p_{pos}$ and $p_{neg}$ indicate the consistency of the two observers on positive and negative decisions [15, 16].

Incidence and prevalence rates were determined by dividing the number of patients with a corresponding incident event or admission by the number of monitored or exposed patients. The reported 95% confidence interval corresponds to the exact 95% confidence interval for proportions calculated by solving equations (777) and (778) given in [17] for the (the lower limit of the 95% confidence interval) and $pr$ (the upper limit of the 95% confidence interval). The corresponding procedure was programmed in Splus5.1, as the available tables with exact 95% confidence intervals [17] are only applicable to samples with a number of observations not exceeding 100.

Results

Among 6383 patients (100%) monitored between 1996 and 2000, 62% were recorded in Zürich and 38% in St. Gallen. 3710 (58%) were males and 2673 (43%) females. The median ($Q_1$, $Q_3$) age was 61 (45, 74) years. In 65%, 30%, 21% and 23% of the hospitalisations at least one diagnosis concerned the cardiovascular system (ICD10 I00-I99), the respiratory system (ICD10 J00-J99), infectious diseases (ICD10 A00-B99) and neoplasms (ICD10 D50-D89) respectively. The median ($Q_1$, $Q_3$) number of different drugs per patient and day amounted to 6 (4, 8). The median ($Q_1$, $Q_3$)

No. % (95% CI)

| Patients with at least 1 incident ADE | 457 | 7.2 (6.5, 7.8) |
| Patients with eADE | 28 | 0.4 (0.2, 0.7) |

significant | 12 | 0.19 (0.08, 0.30) |
moderate | 6 | 0.09 (0.01, 0.17) |
significant | 10 | 0.16 (0.03, 0.26) |
lethal | 0 | 0 (0.05) |

* In 4 patients, an ADR as well as an eADE was observed.
The systems and organs most frequently affected by eADEs were the gastrointestinal tract, the haemostasis system, the skin and the respiratory and cardiovascular systems (figure 2B). The drug classes most frequently causing eADEs were antithrombotics (ATC B01), cardiovascular drugs (C*), antibacterials (J01), sedatives (N05B/C) and non-steroidal anti-inflammatory drugs (NSAIDs, M01A) (figure 2C). If we compare the number of eADEs with the number of patients exposed to the corresponding drug classes, eADE incidences were 0.42% for NSAIDs, 0.20% for antibacterials, 0.15% for antithrombotics, 0.12% for cardiovascular drugs and 0.11% for sedatives. Thus, eADEs were observed with an overall incidence of 0.4%, related chiefly to selection and dosage errors and involving several organ systems and drug classes.

Table 2 reports additional details on the eADEs in the 28 incident cases. Among the selection errors, 4 cases represented indication errors and 9 missed contraindications. In 2 of the 4 cases with indication errors, the patients had no clear indication for anticoagulation but experienced bleeding complications. Among the cases caused by missed contraindications, 4 patients experienced allergic skin reactions against antibacterials despite known allergy against the same drugs. Three further patients suffered from bleeding complications in the presence of known contraindications against NSAIDs and/or anticoagulants. Among the dosage errors, the causes were mainly overdoses of benzodiazepines (4 cases) and digoxin (4 cases). The 3 absolute overdose cases included 2 cases of benzodiazepine overdose occurring during intravenous sedation with midazolam for a medical intervention and after repeated generous lorazepam administrations in an opioid-addicted patient. The third patient with an absolute overdose developed somnolence while receiving high doses of combined clozapine and morphine. Two further patients exhibiting benzodiazepine oversedation suffered from polymorbidity with

<table>
<thead>
<tr>
<th>Patient</th>
<th>Drug</th>
<th>Events, contraindications and risk factors</th>
<th>Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Selection errors:</td>
<td>Indication errors</td>
<td></td>
</tr>
<tr>
<td>F 89</td>
<td>phenprocoumon</td>
<td>skin and muscle haematomas</td>
<td>moderate</td>
</tr>
<tr>
<td>M 72</td>
<td>phenprocoumon</td>
<td>muscle haematoma</td>
<td>significant</td>
</tr>
<tr>
<td>F 60</td>
<td>iloprost</td>
<td>hypotension, abdominal cramping</td>
<td>significant</td>
</tr>
<tr>
<td>F 70</td>
<td>nasal decongestant</td>
<td>rhinitis medicamentosa</td>
<td>significant</td>
</tr>
<tr>
<td></td>
<td>Indication errors: Missed contraindications</td>
<td></td>
<td></td>
</tr>
<tr>
<td>M 68</td>
<td>amoxicillin, clavulanic acid</td>
<td>rash and skin oedema, known amoxicillin allergy</td>
<td>serious</td>
</tr>
<tr>
<td>M 46</td>
<td>amoxicillin, clavulanic acid</td>
<td>rash, known amoxicillin allergy</td>
<td>significant</td>
</tr>
<tr>
<td>M 62</td>
<td>amoxicillin, clavulanic acid</td>
<td>rash, known amoxicillin allergy</td>
<td>significant</td>
</tr>
<tr>
<td>M 58</td>
<td>co-trimoxazole</td>
<td>rash, known co-trimoxazole allergy</td>
<td>significant</td>
</tr>
<tr>
<td>M 40</td>
<td>diclofenac, acetylsalicylic acid</td>
<td>GI bleeding, history of peptic ulcer disease</td>
<td>moderate</td>
</tr>
<tr>
<td>F 80</td>
<td>acetylsalicylic acid</td>
<td>GI bleeding, history of peptic ulcer disease</td>
<td>serious</td>
</tr>
<tr>
<td>M 75</td>
<td>phenprocoumon</td>
<td>subdural haematoma, multiple risk factors for falls</td>
<td>serious</td>
</tr>
<tr>
<td>F 63</td>
<td>ceftriaxone</td>
<td>thrombopenia, previous ceftriaxone-associated thrombopenia</td>
<td>serious</td>
</tr>
<tr>
<td>M 69</td>
<td>flurbiprofen</td>
<td>aggravation of known renal insufficiency</td>
<td>significant</td>
</tr>
<tr>
<td></td>
<td>Dosage errors: Absolute overdoses</td>
<td></td>
<td></td>
</tr>
<tr>
<td>M 36</td>
<td>midazolam</td>
<td>respiratory insufficiency</td>
<td>serious</td>
</tr>
<tr>
<td>M 19</td>
<td>lorazepam</td>
<td>somnolence</td>
<td>moderate</td>
</tr>
<tr>
<td>M 93</td>
<td>morphine, clozapine</td>
<td>somnolence</td>
<td>significant</td>
</tr>
<tr>
<td></td>
<td>Relative overdoses</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F 78</td>
<td>digoxin</td>
<td>nausea and vomiting, renal insufficiency</td>
<td>moderate</td>
</tr>
<tr>
<td>F 96</td>
<td>digoxin</td>
<td>vomiting, renal insufficiency</td>
<td>moderate</td>
</tr>
<tr>
<td>M 79</td>
<td>digoxin</td>
<td>nausea, renal insufficiency</td>
<td>significant</td>
</tr>
<tr>
<td>F 84</td>
<td>digoxin</td>
<td>blurred vision, renal insufficiency</td>
<td>significant</td>
</tr>
<tr>
<td>M 43</td>
<td>midazolam</td>
<td>respiratory insufficiency, hepatic insufficiency</td>
<td>moderate</td>
</tr>
<tr>
<td>M 69</td>
<td>lorazepam</td>
<td>nocturnal apnea episodes, multimorbidity</td>
<td>moderate</td>
</tr>
<tr>
<td>F 75</td>
<td>metoprolol</td>
<td>bradycardia and hypotension, rapid dose escalation</td>
<td>serious</td>
</tr>
<tr>
<td>M 92</td>
<td>paracetamol</td>
<td>toxic liver injury, old age and poor nutrition</td>
<td>significant</td>
</tr>
<tr>
<td></td>
<td>Surveillance errors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F 45</td>
<td>phenprocoumon, heparin</td>
<td>large psoas haematomata leading to N. femoralis impairment</td>
<td>serious</td>
</tr>
<tr>
<td>M 60</td>
<td>heparin</td>
<td>haematuria requiring surgical treatment and transfusions</td>
<td>serious</td>
</tr>
<tr>
<td>F 84</td>
<td>intravenous insulin</td>
<td>hypoglycaemia, inadequate control of blood glucose levels</td>
<td>serious</td>
</tr>
<tr>
<td>M 77</td>
<td>iron</td>
<td>phlebitis after paravenous infusion</td>
<td>significant</td>
</tr>
</tbody>
</table>

For each of the 28 incident cases, patient data (sex, age), the causative drug(s), the eADE predisposing risk factors (for relative overdosages) and the severity are included. The cases are classified according to the types of error.
impaired renal function and hepatic insufficiency respectively, and were therefore classified as relative overdoses. All four patients with digoxin toxicity exhibited impaired renal function and thus also represented relative overdose cases. Since, overall, 594 patients were treated with digoxin, the eADE incidence for digoxin was 0.64%. Among ADEs caused by surveillance errors, two further patients exhibited bleeding complications. On the basis of the 4 phenprocoumon-associated eADEs and the 946 phenprocoumon-treated patients, the eADE incidence for phenprocoumon was 0.42%. In summary, the eADEs consisted mainly of allergic reactions to antibacterials in patients with known allergy, bleeding complications associated with inappropriate indications, missed contraindications and/or inadequate surveillance and overdoses of benzodiazepines and digoxin.

**ADE at admission**

Overall, 279 (4.4%) patients presented with an *ADE at admission* (table 3). 194 (3.0%) of these exhibited ADRs and 85 (1.3%) eADEs. Among the 194 patients with ADR at admission, 183 (2.9%) were admitted for the ADR and therefore classified as ADR-related admissions. The remaining 11 (0.2%) presented with an ADR at admission but were admitted for other conditions and thus represent admissions with ADR. In 79 (1.2%) of the 85 patients with eADE at admission, the eADE was the cause of the admission and these cases therefore represent eADE-related admissions. In 6 patients (0.1%) the eADE was detected at admission but the patients were admitted for other conditions, i.e. they represented admissions with eADE. Errors were thus causative in about in 1 in 3 cases for both subgroups of *ADE at admission*, i.e. for *ADE-related admissions* and *admissions with ADE*. The causes of eADEs at admission were *selection errors* in 36 cases (0.56%), *dosage errors* in 10 (0.16%) and *surveillance errors* in 15 (0.23%) (figure 3A). Among the *selection errors*, 14 were indication errors, 9 missed contraindications and 13 missed drug interactions. The *dosage errors* occurred due to relative overdoses in 4 cases and to absolute overdoses in 3. In the remaining 3 cases, the errors concerned the route of administration and the dosage interval. Interestingly, in 24 (0.4%) of the 85 cases with eADE at admission the error was induced by the patient and not by a health professional, and these cases thus represent *patient errors*. The eADEs at admission most frequently concerned the gastrointestinal tract, the kidney and the cardiovascular or central nervous systems (figure 3B), and were commonly caused by NSAIDs, cardiovascular drugs and antithrombotics (figure 3C). Frequently observed eADEs at admission were NSAID-associated gastrointestinal complications (25 cases): of these, 8 cases took the NSAID without contacting a health professional (*patient errors*), 5 were caused by a combination of NSAIDs with anticoagulants (missed drug interactions), 2 received an NSAID despite a known history of peptic ulcer (missed contraindications) and 2 were treated with a combination of two or more NSAIDs (indication errors). Five patients were admitted for NSAID-associated renal insufficiency (*patient errors*, 2 indication errors and 1 missed contraindication). 13 patients were admitted for cardiovascular agent-induced hypotension or bradycardia (3 missed drug interactions, 6 *surveillance errors*, 2 *patient errors*, 1 indication error and 1 relative overdose). The severity of the eADEs at admission was signifi-

**Table 3**

<table>
<thead>
<tr>
<th>patients</th>
<th>No.</th>
<th>% (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of patients</td>
<td>6383</td>
<td>100</td>
</tr>
<tr>
<td>ADE at admission</td>
<td>279</td>
<td>4.4 (3.8, 4.9)</td>
</tr>
<tr>
<td>ADR at admission</td>
<td>194</td>
<td>3.0 (2.6, 3.5)</td>
</tr>
<tr>
<td>ADR-related admission</td>
<td>183</td>
<td>2.9 (2.4, 3.3)</td>
</tr>
<tr>
<td>Admission with ADR</td>
<td>11</td>
<td>0.2 (0.07, 0.3)</td>
</tr>
<tr>
<td>eADE at admission</td>
<td>85</td>
<td>1.3 (1.0, 1.7)</td>
</tr>
<tr>
<td>eADE-related admission</td>
<td>79</td>
<td>1.2 (0.9, 1.5)</td>
</tr>
<tr>
<td>Admission with eADE</td>
<td>6</td>
<td>0.1 (0.01, 0.2)</td>
</tr>
</tbody>
</table>
in 2 cases (0.03%), moderate in 4 (0.06%), serious in 77 (1.2%) and lethal in 2 (0.03%) (figure 3). Bleeding complications from oral anticoagulation without comprehensible indication caused one of the 2 eADE-related fatalities. The other fatality concerned a patient who had consulted at least two physicians for angioedema and finally died of hypoxic brain damage due to enalapril-induced angioedema. In summary, 1.2% of all admissions were caused by eADEs, with two-thirds caused by health professionals and one-third by the patients themselves.

Discussion

In this study we determined the incidence of eADE in a cohort of 6383 medical inpatients hospitalised in two Swiss teaching hospitals as 0.4%. Six per cent of all incident ADE, or about 1 in 17 incident ADE, were caused by error (table 1). The most frequently observed types of error in patients with incident eADE were missed contraindications and relative dosage errors (figure 2, Table 2). Further, eADEs at admission were observed in 1.3% of all patients and contributed about 1 in 3 of ADEs at admission (table 3). In the majority of patients with eADEs at admission, the eADE was the cause of hospital admission (table 3). eADEs at admission were eventually lethal in 0.03% of patients. Among the eADEs at admission, the most frequent error types were missed drug interactions, surveillance and patient errors (figure 3).

The eADE incidence rate of 0.4% obtained in the present study agrees well with the values obtained in several other studies [5–7, 18]. Furthermore, the overall incident ADE rate of 7.5% in this study is close to the value of 6.5% reported by Bates et al. [9, 19, 20], although Bates et al. reported considerably higher eADE rates of 1.3%–3.6% [8–10, 19, 20]. Differences between centres are a well-known phenomenon in epidemiological studies and may be due to local differences in drug utilisation, patient populations and/or methodological differences [21]. In our study, for example, the incident eADE list is headed by digoxin, NSAIDs, antithrombotics, cardiovascular, antibacterials and sedatives, whereas Bates's list is headed by analgesics, antibacterials, sedatives and antipsychotics [9]. This suggests that analgesics and antipsychotics may have been administered less frequently in our patient cohort, resulting in lower eADE rates for these drugs and thus lower overall eADE rates. Another possible cause of eADE incidence differences are differences in patient collectives; our study cohort was limited to general medical care units and did not include intensive care units, which show an approx. twofold higher eADE rate [9]. eADE incidence differences may also have resulted from methodological differences in ADE screening. ADEs in our study were recorded prospectively; the study physicians visited the monitored units daily on workdays, a procedure which has so far resulted in rather high eADE incidence rates [9, 19, 20]. Further, individual differences in the perception of preventability, as discussed recently for error-associated deaths [22], may influence eADE incidence estimates.
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prescription and the overview of all medications by a primary care physician or pharmacist would be sufficient to detect and possibly prevent missed drug interactions. However, tackling patients’ errors and surveillance errors will be considerably more difficult.

In this analysis we observed five deaths due to incident ADRs and three deaths due to ADRs at admission [4] (data not shown). Thus, ten ADE-related deaths were observed overall, corresponding to 3% of all deaths and 0.16% of all patients. The former number is close to the value of 5% ADE-related deaths in a recent study evaluating 1511 in-hospital deaths [24] and somewhat lower than the 9% directly drug-related deaths in another study evaluating 732 in-hospital deaths [25]. Most of ADR-related deaths (6 of 8 deaths) were cancer chemotherapy-related [4]. It is reassuring that overall we observed only two eADE-related deaths, both of which occurred in patients admitted for the corresponding eADEs, resulting in an overall rate of eADE-related deaths of 0.03%. Again, the number of 0.03% seems more worrisome, if we consider that 0.03% of the 10% of the population admitted to hospital per year could die of eADEs, corresponding to some 3 eADE-related deaths per 100,000 population per year. Such extrapolations to the entire country must of course remain speculative, since there may be considerable local differences in drug utilisation, prescription and surveillance. However, the patient who died because of enalapril-associated angiooedema despite multiple physician contacts for this complaint demonstrates the importance of adequate therapy surveillance and prompt recognition of possible ADEs.

In conclusion, we determined an overall eADE incidence of 0.4% in a cohort of 6383 medical inpatients and identified missed contraindications and relative dosage errors as the main causes of eADEs in inpatients. eADEs were associated with a variety of drugs and symptoms. Furthermore, with an incidence of 1.2% eADE contribute considerably to hospital admissions. In contrast to in-hospital eADEs, eADE at admission were chiefly caused by patients’ errors, missed drug interactions and surveillance errors. Further investigation will be needed to determine whether sophisticated electronic prescribing and elaborate decision support systems will substantially reduce eADE rates.

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