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Costs of Adverse Drug Events in German Hospitals—A Microcosting Study

Dominik Rottenkolber, MBR[1,2,], Joerg Hasford, MD[3], Jürgen Stausberg, MD[3]*

[1]*Institute of Health Economics and Health Care Management and Munich Center of Health Sciences, LMU, Munich, Germany;* [2]*Institute of Health Economics and Health Care Management, Helmholtz Zentrum München–German Research Center for Environmental Health (GmbH), Neuherberg, Germany;* [3]*Institut für Medizinische Informationsverarbeitung, Biometrie und Epidemiologie (IBE), LMU, Munich, Germany*

A B S T R A C T

Objective: In Germany, only limited data are available to quantify the attributable resource utilization associated with adverse drug events (ADEs). The aim of this study was twofold: first, to calculate the direct treatment costs associated with ADEs leading to hospitalization and, second, to derive the excess costs and extra hospital days attributable to ADEs of inpatient treatments in selected German hospitals. **Methods:** This was a retrospective and medical record–based study performed from the hospitals' perspective based on administrative accounting data from three hospitals (49,462 patients) in Germany. Total treatment costs ("analysis 1") and excess costs (i.e., incremental resource utilization) between patients suffering from an ADE and those without ADEs were calculated by means of a propensity score–based matching algorithm ("analysis 2"). **Results:** Mean treatment costs ("analysis 1") of ADEs leading to hospitalization (n = 564) were €1,978 ± 2,036 (range €191–18,147; median €1,446; €843–2,480 [Q1–Q3]). In analysis 2, the mean costs of inpatients suffering from an ADE (n = 1,891) as a concomitant disease or complication (€5,113 ± 10,059; range €179–246,288; median €2,701; €1,636–5,111 [Q1–Q3]) were significantly higher (€970; $P < 0.0001$) than those of non-ADE inpatients (€4,143 ± 6,968; range €154–148,479; median €2,387; €1,432–4,701 [Q1–Q3]). Mean inpatient length of stay of ADE patients (12.7 ± 17.2 days) and non-ADE patients (9.8 ± 11.6 days) differed by 2.9 days ($P < 0.0001$). A nationwide extrapolation resulted in annual total treatment costs of €1.058 billion. **Conclusions:** This is one of the first administrative data–based analyses calculating the economic consequences of ADEs in Germany. Further efforts are necessary to improve pharmacotherapy and relieve health care payers of preventable treatment costs.

Keywords: adverse drug events, cost accounting, diagnosis related groups, hospitalization.

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Introduction

Drug therapies are associated with a risk of patients suffering from adverse drug events (ADEs), which may result in moderate to fatal treatment outcomes. ADEs occur frequently in both ambulatory and inpatient settings and often lead to hospitalization; these events occur more often in the elderly [1–3]. *ADEs* are defined as an injury resulting from medical interventions related to drugs either caused by medication errors or occurring despite proper drug usage [4–6]. Hence, ADEs may result from medication errors at any stage in the medication process (e.g., dispensing or administration) or from adverse drug reactions (ADRs) [7]. In Germany, recent studies indicate that no significant improvements in drug safety have been realized in recent years, resulting in many iatrogenic risks of drug therapy and insufficient patient safety [8–11]. Besides frequently preventable losses in quality of life and life expectancy, ADEs are associated with considerable costs for both payers and health care providers [12,13]. A review of selected international studies regarding the economic consequences of ADEs reported additional mean costs in the range of €934 to €5783 per case [14]. Stark et al. [15] reported costs of €816 million for ADEs resulting from outpatient treatment based on a 1-year-period probability pathway model. Despite the widespread agreement that ADEs are expensive, limited studies have been conducted from the hospital perspective. In this context, Bates et al. [16] estimated the ADE-induced annual overall costs to be $8000 per hospital bed. Costs were mostly assessed from the payers' perspective on the basis of the calculation of reimbursement tariffs. This particularly neglects the growing economic importance of treating ADE patients in hospitals under severe cost constraints. No conclusions can be drawn from prior studies, whether treatment patterns can be performed cost-covering. The objectives of our study were twofold: first, the treatment costs of ADE-induced hospitalizations were calculated ("analysis 1") and, second, the excess costs (i.e., the additional resource consumption; "analysis 2") of inpatients suffering from an ADE as a concomitant disease or complication were compared with those of a respective control group (non-ADE patients) by using a propensity score matching approach. Both objectives were performed from the hospitals' perspective. A microcosting approach based on resource consumption data from three selected German hospitals was applied. To the best of our knowledge, this is one of the first studies based on administrative data to calculate the economic consequences attributable to ADEs.

* *Address correspondence to:* Dominik Rottenkolber, Ludwig-Maximilians-Universität München, Institute of Health Economics and Health Care Management, Ludwigstr. 28 RG V, 80539 Munich, Germany.

E-mail: rottenkolber@bwl.lmu.de.

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Methods

Data description

Data for this retrospective analysis were collected from January 1, 2008, to December 31, 2008, in three public utility service hospitals including a total capacity of 1,208 beds (hospital A: 260, hospital B: 490, and hospital C: 458) in Berlin, Germany. The study base population consisted of 49,462 patients (hospital A: 10,776 [21.8%], hospital B: 17,851 [36.1%], and hospital C: 20,835 [42.1%]) who were hospitalized during this period (excluding inpatient deliveries). Computerized medical records were stored in the hospital information systems and compiled for the analyses.

Clinical, demographic, and economic data were analyzed to describe the patient sample and calculate the treatment costs. The *International Statistical Classification of Diseases and Related Health Problems, 10th Revision, German modification* (ICD-10-GM), is used for coding inpatients in German hospitals. The main reason for admission would be given as the primary diagnosis. Data collected from all patients included primary and secondary diagnoses (i.e., concomitant diseases and complications), age, sex, length of stay (LOS), and performed surgeries. Statistical data for the nationwide extrapolation were retrieved from the Federal Statistical Office in Germany [17].

Identification of ADEs

For the identification of ADEs, an algorithm (published elsewhere [6,18]) developed by two of the authors was applied. Suitable ICD codes grouped into the following categories (labeled A–C) were considered: "caused by a drug" (A.1), "caused by a drug or other substance" (A.2), "poisoning by drug" (B.1), "poisoning by or harmful use of a drug or other substance" (B.2), and "ADE very likely" (C). It is acknowledged, however, that concerning the two categories A.2 and B.2, other substances or measures may have caused the adverse event (e.g., "mental and behavioural disorders due to use of opioids" [ICD F11], "mental and behavioural disorders due to multiple drug use and use of other psychoactive substances" [F19], or "abuse of non-dependence-producing substances" [F55]). The recording of an ADE requires the identification of a drug as the cause of the symptom or the disease. This identification may be difficult, but it is imperative when using the specific codes of the ICD-10-GM (categories A.1, A.2, B.1, and B.2). A bias due to the inclusion of other causes (e.g., self-poisoning and suicide attempts) in categories "A.2" and "B.2" is acknowledged but must be accepted given the variety of different causes covered by a single ICD-10 code. In total, this selection included 360 ICD codes that were applied to our data set. Patients with relevant ICD codes in their primary diagnoses were selected in a first step ("analysis 1"). In these cases, a causal relationship between ambulatorily sustained ADEs and hospitalization can certainly be assumed, as the primary diagnosis was recorded to be the reason for hospitalization. Secondary diagnoses are concomitant diseases at the time of admission or complications that developed during hospitalization. We assumed that ICDs indicating an ADE as secondary diagnosis developed during hospitalization ("analysis 2"). This approach is in line with the German coding standards ("Deutsche Kodierrichtlinen") [19]. ADE detection was performed in both analyses in the total population described above.

Cost determination and calculation

Direct medical costs were calculated from the perspective of the treating hospitals. The data set is part of the mandatory annual report to the Institute for the Hospital Remuneration System (InEK) in order to calculate the diagnosis related groups reimbursement tariffs in Germany (§21 KHEntgG). Cost application to the cost unit "treatment case" is based on actual costing, whereby only costs and services covered by diagnosis related group reimbursement principles are considered [19]. Our analyses are based on a bottom-up approach ("microcosting") to estimate the true economic costs, whereby all services rendered are collected in-depth and monetary values are assigned [20,21]. Microcosting systems specify every resource consumed in health care service provision and assign its unit costs. This enables both high transparency and accuracy for cost assessment. For the retrieved ADE treatment cases, the relevant costs were determined and total costs were calculated for each cost unit (i.e., patient). The treatment costs per patient were assessed by summing all single cost components that contributed to the inpatient treatment. The relevant cost types for this study were retrospectively derived from the hospitals' in-house cost-unit accounting based on routine data ("InEK-Matrix") [22]. For the calculation of treatment costs, the following cost categories were covered: personnel (i.e., clinicians, nursing staff, and medical technicians) and nonpersonnel costs (i.e., pharmaceuticals, implants, grafts, and medical expenditure not otherwise specified) and personnel and material costs for medical and nonmedical infrastructure. Responsible cost centers were general ward, intensive care units, operating room, anesthesia, cardiac and endoscopic diagnostics and therapies, radiology, laboratory tests, and diagnostic and therapeutic areas not otherwise specified. For ADEs causing hospitalization, the total (annual) costs and LOS were assigned to these events. Hence, the term "cost" is defined as total hospital costs.

Statistical analyses

The excess costs of inpatients suffering from ADEs compared with non-ADE patients were calculated as the difference between cases and control subjects for each patient ("analysis 2"). Hence, we matched cases and control subjects in a stepwise manner by using a propensity score matched-pair approach called "greedy 5→1 matching algorithm" [23]. This method matches cases and control subjects on known attributes to create a control group that mimics the case group. Cases were those patients exhibiting an ADE in secondary diagnoses. Control subjects were selected by creating a comparison group by calculating a propensity score (performed via multivariate logistic regression) controlling for the patients' individual patient clinical complexity level, which reflects the severity of comorbidity, the major diagnostic category, sex, and the patients' age at the time of admission [24]. Each case was matched to one control subject. Patients suffering from multiple ADEs were considered only once in the economic analysis. Statistical analyses were performed by using SAS statistical software, version 9.2 (SAS Institute, Inc., Cary, NC). All metric and normally distributed variables were reported as mean ± SD, range, and median; nonnormally distributed data and cost data were reported as mean ± SD, range, and median (including first quartile [Q1]–third quartile [Q3]). Categorical variables were presented as frequency and percentage. *P* values of less than 0.05 were considered to be statistically significant (Mann-Whitney *U* test).

Results

Patient demographics

In our total population (n = 49,462), 51.6% of the patients were women (n = 25,543) and 48.4% of the patients were men (n = 23,919). The mean age was 56.6 ± 23.6 years (range 0–106 years, median 63 years). The mean inpatient LOS was 6.8 ± 8.7 days (range 0–273 days; median 4 days; 2–9 days [Q1–Q3]). In total, the cumulative hospitalization time was 335,961 days, with no significant difference between women and men. The 10 most common primary diagnoses (24.9%; 12,339 patients) are displayed in Table 1.

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