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Medical Care in Germany

Epidemiology, Health Economics and Outcome Research with IMS Patient Databases

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Introduction

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Pharmacoepidemiological databases are a very useful tool, without which well-directed quality improvements and targeted risk management of adverse drug effects would not be possible. Data from such retrospective databases allow investigations into specific subpopulations – e.g., groups with specific diagnoses – thanks to their size and duration of observation. Regarding the quality of such data, it has been proven that carefully planned observational studies can produce results comparable to those of randomized controlled trials.

Patient and health care databases are available in many countries and are often based on routinely collected diagnosis and prescription data. Over time, patient data from such databases have been linked with each other via pseudonyms and analyzed. Examples of these databases include the General Practice Research Database (GPRD), IMS Disease Analyzer, and IMS LRx. These databases can be used to evaluate important questions concerning health services, such as whether therapy regimens being applied reflect the current state of scientific knowledge or whether supply shortages, surpluses, or mismatches occur. Using these databases, a great number of studies have been conducted to analyze the duration, adverse effects, success, costs, and courses of and compliance with therapies and therapy changes. The studies also play an important part in drug safety and risk prevention. To guarantee the scientific relevance of pharmacoepidemiological and pharmacoeconomic studies, a sufficiently valid database is required.

The Disease Analyzer patient database is one of the most comprehensive pharmacoepidemiological databases in Europe. It has been the basis of a number of studies and peer-reviewed scientific publications in the fields of pharmacoepidemiology, health economics, pharmacovigilance, compliance/persistence, pharmaceutical guidelines, prescribing behavior, and drug application.

Disease Analyzer is one of the major European patient databases. It contains data from Germany, the UK, and France and allows anonymous access to a selected panel of physicians' practices and patients.

The data are generated directly from the computers in the physicians' practices via standardized interfaces and provide daily routine information on patients' diseases and therapies. A practice transmits patient data stored in the physician's computer to IMS on a monthly basis. Before transmission, the data are encrypted for data protection and contain in similar scope and detail the information in the files of patients in the doctor's practice. Each month, the physician receives a doctor feedback report reflecting his own prescription pattern and providing a means to compare it to those of collaborating colleagues in the IMS panel within his specialist group.

Patients and practices can be analyzed in a cross-sectional and a longitudinal way. Longitudinal data in Germany date back to July 1, 1989. Monthly updates are available six weeks after the end of a month. Within the past three years, approximately ten million patients with 238 million prescriptions have become available at a pan-European level for longitudinal analyses (Table 1). This table shows that the number of prescriptions per patient per year varies largely between countries. This is due to the different health systems that offer patients varying levels of autonomy to change physicians and due to the differences in prescription package sizes between countries.

Altogether, the database contains data from 2,351 practices and approximately seventeen million patients in Germany from August 2005 to July 2008. In addition to data from general practitioners and specialists in internal medicine, data for various specialist groups are also recorded in Germany. The Disease Analyzer database provides a complete listing of all relevant patient details for each practice. Data about risk factors are only available if they are directly relevant to a diagnosis. For instance, smoking status is recorded for COPD patients and BMI is recorded for fat metabolism disorder patients. However, the portion of missing risk factor entries is relatively high, so studies using data about lifestyle factors are only possible to a limited extent. The data obtained directly from the practice computers are checked for plausibility, linked to relevant additional information such as the price of a medicinal product, ATC and ICD coded, saved, and updated on a monthly basis. The data bank includes only anonymized data in compliance with the regulations of the applicable data protection laws.

The sampling method for the Disease Analyzer database is based on summary statistics from all doctors in Germany published yearly by the German Medical Association (*Bundesärztekammer)* [http://www.baek.de]. The statistical unit of IMS uses these statistics to determine the panel design according to the following strata: specialist group, German federal state, community size category, and age of physician.

This panel design forms the basis for the acquisition of the practices processed in the Disease Analyzer. The acquisition of and support for the practices is performed by cooperating software companies with a standardized interface for IMS that enables the practices to collect the required data and send them to IMS in an anonymized form.

To account for natural fluctuation in the practices and an annual check of the summary statistics by the German Medical Association, the panel design is adjusted each year. Whenever a practice ends its collaboration with IMS, it is replaced by a new one. In 2007, 3.6 % of the practices ended their collaboration. The reasons for terminating collaboration are not recorded by IMS, but a large proportion ceases due to the age of the practice's managing physician and retirement.

Altogether, eleven specialist fields are taken into account in the random sampling plan. For this purpose, the field of internal medicine has been subdivided into five subgroups. Furthermore, the field of neurology also includes pediatric and juvenile psychiatrists.

The sampling plan is subdivided into 8 regions, which are summaries of the sixteen German federal states. This stratification results in 176 cells derived from the summary statistics with regard to specialist fields and proportional to the summary statistics with regard to the German federal states. Within each specialist field, at least thirty doctors must be sampled. Within each region, a minimum of seven physicians must be sampled within each specialist field to allow for estimates at the specialist field level for each region.

Sometimes the IMS® LRx database can also be used as a data source for epidemiological research. It accesses nationwide pharmacy data centers processing prescription data of all German patients with statutory health insurance for reimbursement purposes. Data entries covered patient-specific data over time, such as anonymized identification number, age, gender, insurance company, and

area of living as well as prescription information including prescriber's anonymized identification number, date, and package size. Information about diagnoses was not part of the data sets. The IMS® LRx database contained roughly 95 % of all prescriptions issued nationwide since 2008.

This book presents eight epidemiological and health-economic studies based on the Disease Analyzer database and two studies based on the LRx database. In the first chapter, the consumption of the two corticosteroid nasal sprays, mometasone nasal sprays (MNS) and budesonide nasal sprays (BNS), is determined and the treatment costs of these sprays are compared. The second chapter is dedicated to the persistence of basal insulin regimens under real life conditions. The third chapter is a cost comparison of insulin glargine and exenatide in type 2 diabetes. The study presented in chapter 4 examines whether and in what amount savings for the statutory health insurance company can be achieved by choosing a particular basal insulin when starting insulin therapy. The costs of insulin glargine-based treatment are compared with an NPH-based BOT regime over a period of ten years from the start of insulin therapy in chapter 4. Chapter 5 describes a study comparing basal insulins in terms of resource consumption and associated direct costs of treatment in type 1 diabetics receiving intensified conventional therapy. Chapter 6 is a cost comparison of outpatient treatment with granulocyte colony-stimulating factors (G-CSF) in Germany. In this study, the direct cost per cycle and per patient was determined in the context of outpatient tumor therapies. In chapter 7, consumption of erythropoiesis-stimulating agents in the treatment of renal anemia is described. The study tried to determine the actual consumption of different erythropoiesis-stimulating agents in the treatment of anemia to estimate the actual daily cost of therapy. In chapter 8, the actual costs incurred by health insurances due to usage of the two drugs omeprazole and pantoprazole are determined. Chapter 9 details a retrospective cohort study analyzing the relation of medication, compliance and persistence with the risk of the first hypertension-associated event in naïve hypertensive patients after initiating therapy with any of the five recommended first-line antihypertensive drug classes in Germany. Finally, the study presented in chapter 10 addressed the negative impact of discount agreements in Germany on compliance/persistence and on the effectiveness of treatment with lipid-lowering agents, antidepressants, and human insulins. This study is an example of health economic research in combination with health political questions.