German Pharmacoepidemiological Research Database (GePaRD)

During the last decade, research using secondary data resources has become increasingly important in the field of pharmacoepidemiology. Pharmacoepidemiological research databases allow the investigation of the utilization and safety of drugs and vaccines in the daily routine of care as well as the identification of rare risks of these substances over long periods of time. At the same time, they allow an analysis of drug and vaccine utilization after approval and thus provide valuable data for health services research.

Since 2004, the Leibniz Institute for Prevention Research and Epidemiology – BIPS has been working on the establishment and maintenance of the project-based German Pharmacoepidemiological Research Database (short GePaRD). GePaRD is based on claims data from statutory health insurance (SHI) providers and currently includes information on about 20 million persons who have been insured with one of the participating providers since 2004. Per data year, there is information on approximately 17% of the general population from all geographical regions of Germany.

In addition to demographic data, GePaRD contains information on drug dispensations, outpatient and inpatient services and diagnoses starting with the year 2004. New data are added on an annual basis. Before data are entered into the GePaRD database they are pseudonymized and validated through numerous plausibility checks. The entire process from data delivery to availability for studies can take up to two years, i.e., data from the year 2015 can be used in 2017.

Data Subsets and Variables

GePaRD is linked via the central pharmaceutical number (PZN) to information from a central pharmaceutical reference database (CPR) established at BIPS. The structure of GePaRD and of the CPR is displayed in table 1.

Table 1: Structure and content of GePaRD and of the CPR

GePaRD				CPR
Core data	**Hospital data[$]**	**Outpatient data[$$]**	**Outpatient prescription data[$$$]**	**Pharmaceutical information**
– Subject ID No. – Birth year – Sex – SHI code – Region of residence – Nationality (German/other) – Dates of insurance coverage (entry and exit) – Occupational code – Reasons for exit (e.g. death) – Insurance status (self/relative-spouse/child) – Family ID No. – Participation in Disease Management Program (DMP)	– Subject ID No. – Hospital ID No. – Day of admission/ discharge – Admission diagnoses* – Reason for admission – Discharge diagnoses* – Secondary and ancillary diagnoses* – Diagnostic and surgical/medical procedures[#] – Reasons for discharge (incl. death) – Day of delivery – Weight of infants less than 1 year old	– Subject ID No. – Physician ID No. – Physician specialty – Diagnoses* (quarterly**) – Types and dates of treatment/ diagnostic procedures[##]	– Subject ID No. – Central pharmaceutical No. (PZN) – Pharmacy ID No. – Date of prescription – Date of dispensation – Physician ID No. – Physician specialty – Quantity prescribed	– Central pharmaceutical No. (PZN) – Generic name – Brand – Manufacturer – Packaging size – Strength – Defined daily dose (DDD) – Pharmaceutical formulation – ATC GM code[###]

** Hospital and outpatient diagnoses are coded using the International Classification of Diseases, version 10 - German Modification (ICD-10-GM) with at least 4 digits*
*** Outpatient diagnoses refer to a period of three months, as physicians' services are settled quarterly*
[#] Diagnostic and surgical/medical procedures are coded using the Operations and Procedures Coding System (OPS)
[##] Outpatient treatment / diagnostic procedures are coded using claim codes for outpatient services and procedures [Einheitlicher Bewertungsmaßstab, EBM]
[###] Anatomical Therapeutic Chemical Classification System, German Modification
[$] Provided to SHIs by hospitals
[$$] Provided to SHIs by regional associations of statutory health insurance physicians [Kassenärztliche Vereinigungen]
[$$$] Provided to SHIs by pharmacies' electronic data processing centers [Apothekenrechenzentren]

Legal Restrictions

Access to the database is granted only to BIPS employees within the framework of officially approved research projects. It is not permitted to give third parties access to the data. However, BIPS can be commissioned to carry out drug utilization or drug safety studies that are requested by health authorities (e.g., European Medical Agency). Further projects can be carried out in collaboration with BIPS as long as the research question is of scientific and public health relevance and in line with the research strategy of the institute. BIPS does not own the data and thus is not allowed to decide for which specific projects the data can be used. Data use approval is based on the authorization by the SHI providers and the respective governing authorities (e.g., the Federal Insurance Office for national SHI providers). According to § 75 SGB X a crucial aspect for approval is whether the interest of the specific project to public health is superior to the right to personal data protection. The process of approval by the SHI providers and the governing authorities may take several months.

Information obligations

When asking for approval of a study, BIPS is required to send a short study outline (the so-called ‘study proposal’) to the SHIs and the governing authorities. The study proposal includes a short background, the research questions, the study methods, the variables, the data years, the scheduled operational time of the study, and the sponsor of the study. On request, the authorities may also receive a copy of the service agreement between BIPS and the sponsor of the study.

As a prerequisite to use the data from SHI providers for research purposes, BIPS is obliged to regularly inform the SHIs and the regulatory authorities about the progress of the study and to provide them with the final study report. Upon demand and after informing the sponsor of the study, SHI providers whose data are analyzed as well as the authorities may also receive the study protocol. Furthermore, BIPS has the obligation to regularly inform its Scientific Advisory Board about the progress of the study.

BIPS performs its studies according to applicable regulations and guidelines, such as the guidelines for Good Pharmacoepidemiology Practices (GPP) and for Good Epidemiological Practice (GEP). According to these guidelines and the standards of the Leibniz Association, BIPS is obliged to disseminate all results of its research in literature and at relevant scientific congresses.

A short description, including the name of the study sponsor, of each study performed by BIPS is released on the BIPS website. In addition, BIPS aims to record all of its studies in relevant (inter-)national registers.

Selected publications

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