Rare Disease Spina Bifida

A Retrospective Cost of Illness Analysis of Patients in Germany Between 2017 and 2020

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List of abbreviations

ASBH	Working Group Spina Bifida and Hydrocephalus (Arbeitsgemeinschaft Spina Bifida und Hydrocephalus)
BfArM	Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte)
DRG	Diagnosis Related Groups
DRKS	German Registry for Clinical Studies (Deutsches Register Klinischer Studien)
DSGVO	EU-wide General Data Protecion (Datenschutzgrundverordnung)
EBM	Uniform scale of fees (Einheitlicher Bewertungsmaßstab)
EU	European Union
FDZ	Research Data Center (Forschungsdatenzentrum)
GBA	Federal Joint Committee (Gemeinsamer Bundesausschuss)
GKV-VSTG	Statutory Health Insurance-Care Structure Act (Gesetzliche Krankenversicherungen-Versorgungsstrukturgesetz)
GOÄ	Physicians‘ Fee Schedule (Gebührenordnung für Ärzte)
KHZG	Hospital Future Act (Krankenhauszukunftsgesetz)
NLUTD	Neurogenic Lower Urinary Tract Dysfunction (Neurogene Dysfunktion des unteren Harntraktes)
SB	Spina Bifida
SGB V	Social Code five (Sozialgesetzbuch fünf)
VDEK	Association of Health Insurance Funds Germany (Verband der Ersatzkassen Deutschland)

ZSEB	Center for Rare Diseases University Hospital Bonn (Zentrum für Seltene Erkrankungen Bonn)

1. Introduction

The health of the population and the factors influencing it, as well as the general conditions, are the subject of health services research (Schlander, 2009). The German healthcare system is intended to ensure that all patients receive comprehensive, easily accessible, and needs-based medical care at a high level. For this reason, the health care system in Germany and the design and provision of health care services are subject to a continuous improvement process. This is also linked to the requirement that services be cost-effective, i.e., they must be sufficient, economical, and appropriate.

In addition to the efficiency requirement from the perspective of politics, access to care and medical care at a high level of quality plays a major role for patients and service providers. However, current developments have been increasingly challenging the healthcare system with respect to efficient care at a high quality level. The ongoing financing crisis of medical services in the outpatient and inpatient care sectors leads to tension in the healthcare system (Blum, 2020). The reasons for this are continuously rising costs for personnel, infrastructure costs, and costs for medications, along with a simultaneous decline in investment subsidies from the dual financing of hospitals. (Dual hospital financing in Germany means funding operating costs, i.e., the costs of treating patients by health insurance funds and financing investment costs by the federal states.) Moreover, the shortage of personnel in the German healthcare system is intensifying. The greatest challenge resulting from staff shortage is the lack of sufficient time for patient care (Ärzteblatt, 2022). In addition, the proportion of sick people in the population is continuously increasing, so total expenditure in the healthcare system compared to the population is rising continuously and disproportionately (Statistisches Bundesamt, 2023a).

These challenges place health policy actors and decision-makers in the spotlight with respect to their responsibility to ensure efficient medical care at a high level. To achieve these goals, not only health economics aspects but also quality of care and structural aspects of the healthcare system (efficient processes and procedures) play a relevant role.

In recent years, more and more regulatory mechanisms were put in place by health policy makers in Germany to counteract the problems of the health care sector outlined above, like for example, the Statutory Health Insurance-Care Structure Act (*Gesetz zur Verbesserung der Versorgungsstrukturen in der gesetzlichen Krankenversicherung (GKV-Versorgungsstrukturgesetz - GKV-VStG)*, 2011). Measures are also being established by the highest decision-making body of self-governance in the health care system in Germany - the Federal Joint Committee (Gemeinsamer Bundesausschuss, GBA) - to evaluate the deficits and develop measures. For example, the GBA awards substantial funding for health services research and for developing and researching new forms of health care for further development in the statutory health insurance system.

Health services research aims to adapt the needs and developments of the health care system to the challenges faced by society and to ensure it is fit for the future. In particular, the focus is on patients' processes and paths to receive excellent medical care with simultaneous optimal economic and economical use of resources. To this end, the focus of health care research is increasingly shifting towards cost-of-illness analyses and mapping the patients' paths through the healthcare system ("patient journey"). These efforts are intended to provide a basis for decision-making processes at the health policy level, ensure transparency and support efficient further development.

The transferability and transparency of the described requirements of the health care system are particularly challenging in the context of rare diseases, which represent a particular, partly unsolved task due to their special needs. According to the current status quo, it is challenging for patients with rare diseases to find suitable access and place of care in the German healthcare system, as the paths to good care and treatment options are often unclear due to lower numbers of affected patients. Clearly defined pathways describing when to visit which doctor, specialist clinic, or center, and what patients can expect along the way are often lacking. Such descriptions of the typical "patient journey" can make an essential contribution to patient satisfaction and, thus, to the quality of care in terms of patient-centered care (Bolz-Johnson et al., 2020). Furthermore, it is challenging to provide expert care because the experts are often geographically decentralized, and there are still only a few competence centers.

Incidence and prevalence of a disease do not allow direct conclusions about the medical, sociological, and economic significance, as rare diseases are significant in all of the above respects despite and precisely because of their rarity and because they are frequent when considered as a group (Graf von der Schulenburg and Frank, 2015). Numerically, a disease is classified as rare in the European Union (EU) if it affects no more than five per 10,000 people. Currently, more than 7,000 rare diseases are known (Auvin et al., 2018), so a total of four million people with a rare disease are currently estimated in Germany and 30 million in the EU (Bundesministerium für Gesundheit, 2023).

From the point of view of health services research, it is essential to record and define the patient journey and carry out a descriptive recording of the costs of illness, especially for rare diseases. Long time until access to optimal medical treatment contributes to high, often avoidable costs associated with rare diseases, which often require a larger number of costly specialized medical interventions (Bowkett and Deveral, 2012; Colombo et al., 2013).

1.1 Spina Bifida

Spina bifida (SB) is a rare disease with a prevalence in the EU of 1-5:10,000 (Bundesministerium für Gesundheit, 2023; Austin, 2008; Kurze, 2012). Each year, approximately 5,000 newborns are born with SB across the EU. SB is a congenital malformation of the spinal cord and spine caused by a neural tube defect that occurs during the embryonic developmental period (Kancherla, 2023). SB can exist as both an open “aperta” (ICD: Q05.-, ORPHA 823) and a closed “occulta” defect (ICD: Q76.0, ORPHA: 3027).

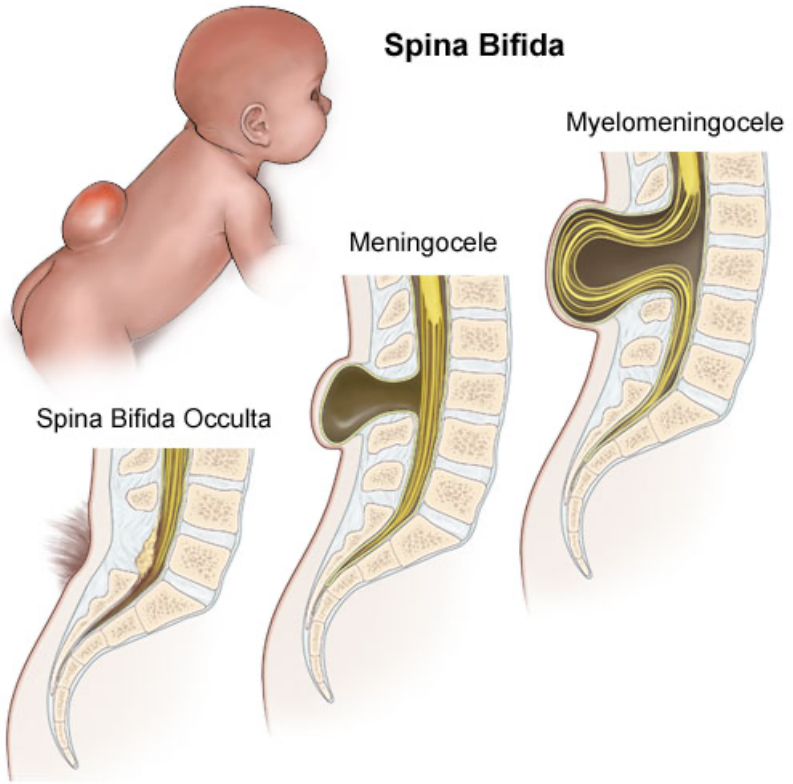

Figure 1: Disease forms SB (Singhania, 2015)

In the open defect, the neural tissue and the meninges herniate without covering by skin, while the herniation is covered by skin in SB occulta (Kancherla, 2023). The dysraphic defect may be localized in different areas of the spine. The most frequent site of expression is the lumbosacral region, with about 50 % of cases (Schulte-Wissermann and Thüroff, 2000). As a result, neurological impairment typically occurs, which is localized to the region of the spinal cord lesion. Concomitant conditions can include corpus callosum agenesis, cortical migration disorders, hydrocephalus, Chiari malformation type II, vertebral abnormalities, and genitourinary and gastrointestinal disorders (Kancherla, 2023). When a child is born with SB, neurosurgical management must follow within 2-3 days to improve survival and prevent further sequelae and complications (Blount et al., 2020). Apart from the initial closure of the SB, a variety of other neurosurgical and orthopaedic operations may be necessary for the following time (Blount et al., 2020). Furthermore, due to the chronic character of the condition and possible complications associated with the necessary surgical interventions, lifelong medical care is required (Kancherla, 2023).

In addition to many orthopaedic and neurosurgical problems, SB usually leads to neurogenic lower urinary tract dysfunction (NLUTD, Liu et al., 2018; Khoshnood et al., 2015).This is reflected by symptoms like urinary incontinence and recurrent urinary tract infections. Currently, there are several guidelines for the conservative and surgical treatment of NLUTD in individuals with SB. In addition to drug therapy (anticholinergics), the establishment of clean intermittent catheterization is an elementary step in the conservative therapy of NLUTD in SB (Stein et al., 2019). Remaining untreated, the NLUTD leads to kidney failure (Adams et al., 2023). Therefore, if conservative therapy fails, urinary bladder augmentation may be necessary to protect the upper urinary tract (Corona et al., 2019). All these conservative, surgical, and nursing measures of the different disciplines involved are already cost-intensive in themselves (Rofail et al., 2013). However, they can only develop their maximum efficiency if they are regularly monitored and carried out at the right time, which necessitates close cooperation between different areas of expertise. While there are individual national and international guidelines for the individual medical specialties, multidisciplinary guidelines and uniform pathways in care and therapy for patients with SB are still lacking (Stein et al., 2019).

1.2 Challenge rare disease: Spina Bifida

SB poses particular challenges for patients and the healthcare system, as is the case with most rare diseases. In the German healthcare system, individuals with rare diseases such as SB often struggle to locate suitable access points and care facilities due to the lack of clearly defined paths to effective care and treatment options. There is a lack of clear definitions of which medical consultations have to take place at what time and what patients can expect along the way, although predefined treatment pathways contribute to patient satisfaction and to the quality of care (Bolz-Johnson et al., 2020). Furthermore, expert care is difficult to provide because experts are often geographically decentralized, and there are still only a few centers of excellence for SB. SB imposes a high social burden on patients, their families or other informal carers, and the health care system. Therefore, research in this area is key to advancing knowledge to shape health policies and make health systems sustainable (García-Pérez et al., 2021).

As mentioned above, in addition to recording and defining the patient journey, it is also essential to conduct a descriptive recording of the medical costs of rare diseases. While costly specialized medical interventions are often necessary for rare diseases, as is the case for SB, it is important to identify avoidable costs, which can arise from long patient journeys or detours until optimal care is found (Bowkett and Deveral, 2012; Colombo et al., 2013). Detours on the path to care place an avoidable burden on the healthcare system as well as affected individuals, and there is currently insufficient data on SB associated medical costs and their effectiveness. Accurate knowledge of the costs of illness is essential and helps formulate and prioritize health policies and interventions and, by extension, allocate healthcare resources. Currently, there are no published data on the correlation between effective cost design and patient journeys for SB. There are only a few records on medical costs, dating back about ten years (Bowkett and Deveral, 2012; Colombo et al., 2013). However, these do not allow conclusions to be drawn about effective cost design and the patient journey.

Health-related data is subject to special protection, as stated by, e.g., the EU-wide General Data Protection Regulation (Datenschutzgrundverordnung, DSGVO) amendment. In addition, in Germany, where this study was conducted, medical data are not easily accessible for research due to the organizational structure of the health insurance system and the decentralized collection of health-related data, in combination with strict privacy laws. While there has been a central agency instated that receives pseudonymized health and medical data from insurance companies in order to make them available for research the Research Data Center (Forschungsdatenzentrum, FDZ) of the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM)), it has yet to go live. As of now, no applications can be submitted as the new research center's legal, technical, personnel, and organizational measures are currently being defined and implemented (Bundesinstitut für Arzneimittel und Medizinprodukte, 2023). Another option for obtaining treatment data and the associated costs in Germany is to request information on services from health insurance companies for an individual health insurance policyholder. Since 2012, health insurance policyholders in Germany have the option of requesting information on benefits from their health insurer by §305 of the German Social Code (SGB V), which was instated in an attempt towards

more transparency in the health sector. The benefit report provides a structured overview of the benefits claimed. Specifically, it shows which services were billed to the querent's health insurance by the various service providers, e.g., treating physicians and hospitals. This makes it possible to analyze the exact medical costs and trace the treatment paths of individual policy holders. Furthermore, the benefit report provides information about prescribed medicines, remedies, and aids. Specifically, §305 SGB V article 1, sentence 1 states: "*The health insurance companies inform the insured persons upon their request about the services used and their costs*." (*Sozialgesetzbuch V*, 2022). To circumvent the lack of central data access, we asked individual patients to donate the data they requested individually from their health insurance company for this study.

The aim of this study was to process and analyze the medical costs of SB patients in Germany. The objective was to create transparency regarding this rare disease by recording the treatment paths of SB patients in the German healthcare system and systematizing and analyzing the associated treatment expenditures.

1.3 Current scientific status

The burden associated with SB is significant both socially and economically (Bowles et al., 2014). The economic impact and burden on the German health care system will increase due to demographic trends. To meet this burden, understanding disease costs, especially for burdensome rare diseases, needs to be improved. The increasing interest in cost-of-illness studies in the context of the development of the health care system and worldwide developments is reflected in increasing numbers of publications over the course of the last 20 years, as shown in figure 2.

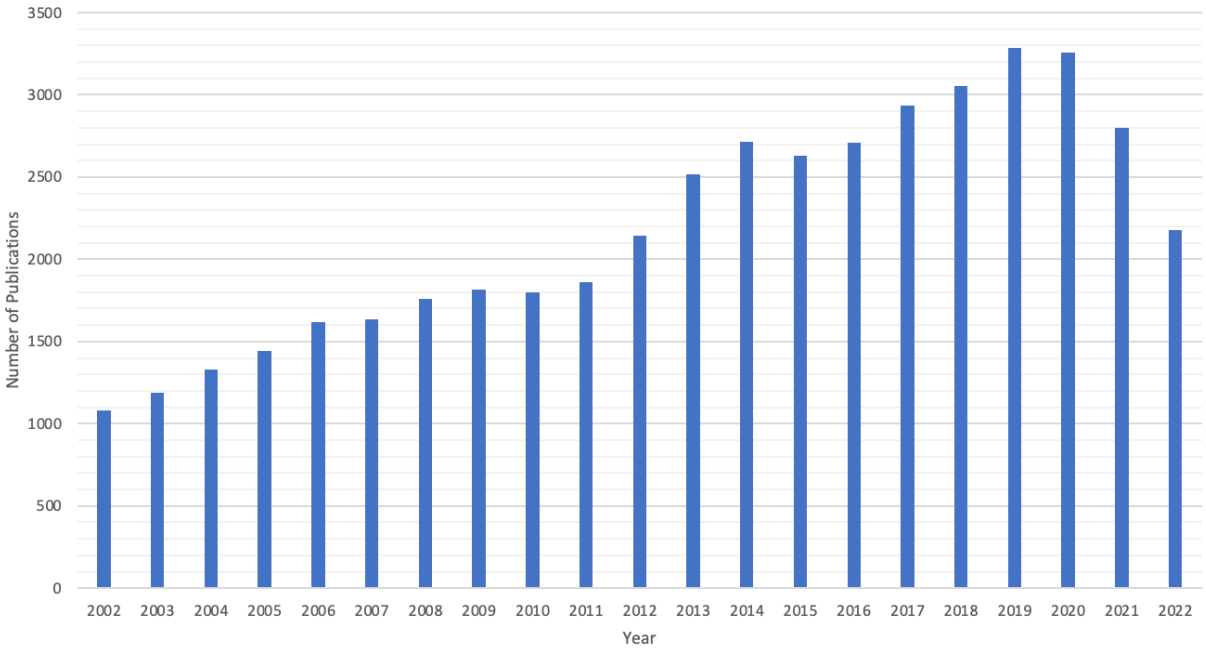

Figure 2: Development publications - cost of Illeness 2003-2023. (Reference: PubMed. Search items: cost of illness, 17.06.2023)

Interestingly, the number of publications has declined in 2021 and 2022, which coincides with the COVID-19 pandemic and the Ukraine war as two major events affecting global developments. A direct causal connection is however speculative for the time being.

Focusing on rare diseases and their impact on the German health care system, only a few studies, mostly dating back more than ten years, outline the health economic burden and its impact. So far, no study has shown the costs of disease in the context of the path of SB patients from diagnosis to access and receipt of optimal medical treatment. Neither quantitative data nor qualitative analyses from the patient's perspective have been published that address the associated hurdles and demands on the healthcare system (patient journey). As a result, it is currently not possible to formulate concrete statements on the economic impact and the influence of the medical costs of patients with SB on the healthcare system or to formulate recommendations about the optimal cost and benefit effectiveness of treatment paths. The satisfaction and experiences of patients and their relatives, as they can be mapped in a patient journey, are decisive factors in the evaluation of care (Bolz-Johnson et al., 2020).

This data gap is partly due to the fact that generating, linking, and analyzing the relevant data is particularly challenging because patients move through the healthcare system in many different ways that are not easily understood. These complex pathways necessitate cross-sector analysis.

Nevertheless, there are a few data on cost of illness for SB. From the EU member country Italy, there is an estimative cost-of-illness analysis of patients with SB from 2013. No correlation to the patient journey was made in the study, so no comparisons of different pathways were made either (Colombo et al., 2013). The data for the study were generated via three SB centers in Italy. The patient population was differentiated according to various characteristics: First, the patients were clustered into four groups according to the condition of walking ability, and second, differentiation took place according to open SB disease pattern and closed SB disease pattern. The cost-of-illness analysis concluded that most of the costs incurred by patients with SB were for medical aids, and the least was for medications. Most of the costs are incurred in the first four years of the patient's life. The total average of the illness costs amounted to 11,351 EUR / year (Colombo et al., 2013).

Another cost analysis of patients with SB from 2012 was conducted at Wellington Hospital New Zealand and evaluated inpatient costs only (Bowkett and Deveral, 2012). Six adolescents and one neonatal patient were retrospectively included in the cost analysis of inpatient medical costs in a random manner. The study demonstrates that the children underwent various surgeries accompanied by numerous diagnostic procedures, and children with SB must also undergo them. Notably, the burden on families and children was also outlined. For example, an average of 20.83 inpatient stays per child became obligatory. Furthermore, it could be determined that adolescents spend overall on average half a year in the hospital until their late adolescent age to receive optimal care for the SB disease. However, as a whole, the cost analysis did not allow for quantification of optimal treatment requirements or evaluation of relief in the patient journey. In conclusion, the retrospective analysis revealed that pediatric inpatient cases' previously estimated treatment costs were significantly higher than anticipated. On average, the cost was $944,000 per case (Bowkett and Deveral, 2012).

Another relevant aspect published in the study was that six of the seven patients received bladder augmentation surgery. In these patients, costs were especially high due to high follow-up effort - surgical measures to improve the quality of life and life expectation require regular cystoscopic control and bladder pressure measurements to prevent possible tumor diseases. At this point, however, no outlook or estimate was given as to what costs have been evaluated or can be estimated for this component of the disease (Austin, 2008; Bowkett and Deveral, 2012). In addition, it should be mentioned here that it is also described by the scientific society that children with neurogenic bladders have an increased risk of malignant tumors if they do not receive bladder augmentation. The risk for malignant diseases is considered higher without augmentation of the neurogenic bladder (Ray, 2010).

A study from Germany in collaboration with a large German health insurance company with a retrospective data analysis from 2006 to 2009 outlined the burden of SB patients. The average total expenditure/year was EUR 4,533. The data analysis from 2006 to 2009 could show that the costs for children are the highest. Furthermore, it was transparently shown that the costs for providing remedies and aids with 1,939 EUR / year (43% of the total costs) make up the largest share of the total expenditure. Based on the data from more than ten years ago, the analysis showed that the SB expenditures per year exceeded the average statutory health insurance expenditures (Bowles et al., 2014).

1.4 Aim of the work

The burdens associated with SB are substantial yet poorly quantified to date. Through this work, we aim to explore the understanding of the costs of illness, health economic trends, and burdens of multiple paradigms.

Specifically, the following research questions arise, among others, due to the health burdens, socioeconomic developments and the change in demographic development in Germany in the context of the inadequate and partly outdated knowledge:

- How do the various paths of SB patients through the healthcare system (patient journey) shape up?

- What outpatient and inpatient medical costs are incurred in Germany for the treatment of SB?
- How should the patient pathway be designed in order to achieve optimal treatment success while at the same time being efficient in terms of health economics? What cost-benefit ratios can be analyzed and described as recommendations for future treatment processes?
- Can a demographic relationship in terms of cost vs. treatment be inferred from the data?

The aim of the research work was to describe and understand disease costs and their influence on the German health care system, with SB as an example.

The study was planned based on an anonymized collection of disease data of patients with SB, their paths through the health care system, and the associated disease costs. Furthermore, it was planned to evaluate the quality of care and treatment efficiency in the context of medical and economic health aspects by multivariate analyses based on the following parameters: Age, initial diagnosis, number of outpatient treatments, number of inpatient treatments, duration of inpatient stays, number of physicians involved in the treatment, and diagnostic measures performed such as CT/MRI/X-ray, etc.. Specific groups are assigned to the interventional measures for evaluation and cost analysis. The data was then to be compared to the Uniform Scale of Fees (Einheitlicher Bewertungsmaßstab, EBM) and the Physicians' Fee Schedule (Gebührenodnung für Ärzte, GOÄ) to determine costs in the outpatient setting. The evaluation and analysis of inpatient medical costs - in the inpatient setting – was planned to be carried out using the Diagnoses Related Groups (DRGs) and the services and procedures recorded there accordingly.

The data was to be collected via the working group Spina Bifida and Hydrocephalus (Arbeitsgemeinschaft Spina Bifida und Hydrocephalus, ASBH) in addition to recruiting patients undergoing treatment at the University Hospital Bonn. Recruiting patients via the ASBH was planned to ensure a Germany-wide cross-section and a significant inference to the population. To answer the research questions, health-related data was to be

collected through patient interviews, evaluation of medical findings and reports - including the procedures recorded there - and data collection via the patients' health insurance. Through the patient surveys, aspects such as the improvement of quality of life and expectations, function-preserving aspects, preventive aspects concerning (long-term) complications, and cost efficiency and effectiveness were expected. In addition to the quantitative data analysis, a qualitative content analysis was planned, resulting from the patient interviews, and describing the Patient Journey from the patient's point of view.

As a result of the data evaluation, heterogeneous results are expected, which only allow a valid statement concerning the patients' illness costs and ways by clustering. Based on the existing studies described above, a differentiation between ambulatory and non-ambulatory patients and between the open and closed SB disease patterns could be made (Colombo et al., 2013). Other clusters may emerge from qualitative analysis of the Patient Journey.

2. Material and methods

A retrospective data collection and analysis of disease data was carried out to answer the research questions. A possible implementation for data collection via the health insurance companies in Germany and associated direct data retrieval was impossible. The health insurance companies rejected a pseudonymized data exchange for research purposes for data protection reasons. The justifications were found in the high protection requirements of health-related data and the prominence of the data protection issue. The 2018 amendment to the EU-wide General Data Protection Regulation makes this clear, among other things (“Datenschutz-Grundverordnung (DSGVO),” 2023). The 2018 amendment to the Data Protection Regulation laid the foundation for Europe-wide handling of personal data for the first time.

The legal regulations from the SGB V were consulted for the retrospective data collection in the context of the research work. By the §305 SGB V, information to insured persons is regulated on the social-legal level by the requirements of legally health-insured persons for receiving information to take up achievements. §305 SGB V para. 1 sentence 1:

„The health insurance funds shall inform the insured persons, upon their request, about the services used and their costs.“

The service information is intended to provide structured information about the services used. Specifically, it should show which services were billed from the health insurance by the various service providers - treating physicians and hospitals. This also includes the supply of remedies and aids as well as the supply of medicines. So that a data inquiry and evaluation on the basis of the §305 SGB V is possible, the data protection-juridical regulations are to be cared for. Here, Art. 15 DSGVO plays a decisive role. Article 15 of the DSGVO regulates the right to information and access to processed personal data. This is intended to provide the affected transparency and control over the processed data.

The information on benefits according to §305 SGB V is intended to provide retrospective information on the costs of illness and the pathways in the German healthcare system within the framework of the research work.

At the time of the beginning of the research work, the SGB V did not provide a framework for direct data inquiry at the health insurance company after the consent of the insured person, so it was necessary that interested study participants obtain their benefits information from their health insurance company and then make it available to the Center for Rare Diseases for the research work. This procedure should make it possible to analyze the disease's detailed costs and trace the treatment paths.

The positive ethics vote from Bonn University Hospital 176/21 to conduct the study was received on June 14, 2021. The study is registered with the German Registry for Clinical Studies (Deutsches Register Klinische Studien, DRKS) under: DRKS00025468.

2.1 Data Collection

Due to the lack of central registers on patients with SB and by thus a nationwide list of potential participants list, we collaborated with the ASBH. ASBH is the nationwide self-help organization in Germany for people with SB and hydrocephalus. The self-help organization consists of over 30 regional groups to support over 7,500 people (“Arbeitsgemeinschaft Spina Bifida und Hydrocephalus e.V.,” 2023).

Study participants for the research project were identified in conjunction with ASBH and a standard letter was sent to them based on the positive ethics vote by ASBH. We contacted potential study participants with spina bifida by mail. To record illness costs within the scope of the research work, the study participants were asked to apply for benefits information as of §305 SGB V, as well as for benefits information stating the billed diagnoses by Art 15 DSGVO in connection with §83 SGB X and then forward the data to the study center (Center for Rare Diseases, University Hospital Bonn, ZSEB).

For this purpose, the study participants received, in addition to information about the study and a declaration of informed consent, a printed out standardized cover letter for obtaining the benefits information according to §305 SGB V from their health insurance company.

Methodologically, this ensured a uniform procedure for all study participants. The standard letter for requesting information on benefits was created independently on the basis of

various sample templates from the largest German health insurance companies. The standardized documents for participation in the study were structured as follows:

Structure of the standardized Patient letter:	Attachment
• Cover letter sent by the ASBH to members o	• Attachment A
• Patienten information	• Attachment B
• Application for benefit information according to §305 SGB V	• Attachment C
• Overview sheet: Addresses of the largest German health insurance companies	• Attachement D
• Consent form - copy participant	• Not attached
• Consent form - copy PI	• Not attached
• Prepaid envelope for the application for performance information	• Not attached
• Prepaid envelope for the return of the performance information to the ZSEB	• Not attached

Table 1: Structure of the standardized Patient letter

To simplify the given effort for study participation, the above described documents were printed on different colored paper and the corresponding assignment was described in the patient information. To participate, study participants were required to send the application for benefits information according to §305 SGB V to their health insurance company. The benefit information received on paper then had to be sent to the ZSEB with the consent to participate in the health services research study using the prepaid and labeled envelope.

Participants were recruited between August 2021 and March 2022 to voluntary submission their retrospective health insurance data as described above.

Inclusion criteria were patients with a diagnosis of SB and health insurance fund in Germany. The SB support group of the ASBH established access to the study population. Exclusion criteria were the absence of spina bifida disease and inadequate health insurance records as provided by the health insurance company.

2.2 Data validation and statistics

Health insurance expenditures for illness costs were submitted voluntarily and completely in paper form by study participants. As mentioned above, standardized data were requested, included a listing the costs of medical treatment (outpatient), hospitalization (inpatient), pharmaceutical care, and the provision of therapeutic appliances and aids. All individual data were entered electronically along the aforementioned classification and stored pseudonymized.

For this purpose, an overview table was created for the pseudonymization of the study participants, including the pseudonym assignment. Assignment of the pseudonym. At the same time, the table was used to record which data were available and whether the data sets were complete and contained all requested service areas.

The services and the costs were recorded with the date of origin and sorted by quarters of each year. Furthermore, the specialist physician group was noted with each the outpatient data item, and the reason for admission was noted with inpatient costs. The therapeutic appliances and aids were clustered into corresponding groups according to treatment and therapy focus.

Service area	Grouped
Outpatient treatment	• Established hospital • Medical specialist: famliy doctor, urologist, orthopedist etc. • No information
Inpatient treatment	• SB urology • SB orthopedics • SB other • No information
Remedies	• Physical therapy • Ergotherapie • Speech therapy • Physiotherapie • No information
Aids	• Incontinence aids • Orthopedic aids • Stoma aids • No information
Pharmaceuticals	• No grouping

Table 2: Grouping service areas – data collection

Despite a uniform request to the health insurance funds for the expenditure of 48 benefit months (which was the time range defined by $305 SGB V at the beginning of this study), benefit periods of varying lengths were communicated to the insured. The benefit periods ranged from 3 years to 22 years. To compare the same time period for all participants, medical costs were narrowed down to the same 48 months from 01.01.2017 to 31.12.2020 for analysis of illness costs per year.

Due to high variances within the data, we cannot make any statements whether the actual costs vs. the health insurance companies reimbursements are covered in our study. Studies/reviews on cost-of-illness analyses show that research in this field is of great importance for a sustainable design of the health care system and health policy decisions. The published data clearly show that the strategies for data acquisition are very different and focus on investment via patient organizations, data from hospitals and centers, reference centers, or disease registries. Furthermore, it is essential to describe that no statement can be formulated on the secondary costs of illness, such as nursing care and medical trips since these were not covered by the analyzed data source.

Pseudonymized statistical analysis was performed using IBM SPSS Statistics version 29 and Microsoft Excel version 2021. All statistical procedures are stated in the figures and throughout the results section as calculated.

3. Results

Between June 2021 and December 2021, potential study participants with spina bifida were contacted twice in collaboration with ASBH and asked to participate.

A total of 51 SB diagnosed patients reported back. Of them, 12 interested study participants had to be excluded: eight of these 12 interested study participants were excluded because they did not receive a response from their health insurer despite requesting one. Further three were interested but stated that the participation requirements were too effort-intensive. One person responded that they could not understand the topic and the objective with its potential consequences fully due to a lack of knowledge in the field of social insurance (figure 3).

39 study participants received a cost of illness report from their health insurers and sent in complete documents upon request or reminder. Of these 39 study participants (n=39), further 14 study participants (n=14) had to be excluded due to poor data quality on the part of the respective patient's health insurers, i.e., these were either not available for the entire 4-year period (n=3), or overall unspecific or very incomplete in the specification of the individual service descriptions by item and year (i.e., no costs could be extracted from the data, n=11). Consequently, a structured derivation, an allocation according to characteristics of interest, and systematic processing for analyses were impossible in these cases (figure 3).

Despite a pre-formulated letter request with standardized data response specifications, a heterogeneous picture of responses emerged. For 16 participants, the requested data were complete, but for 9 participants, only outpatient service data were documented (n=25 in total, figure 3).

According to the structure of the data as presented by the insurance companies, the analysis is calculated for five different categories. Therefore, the n in the respective analyses and presentations differs (figure 3).

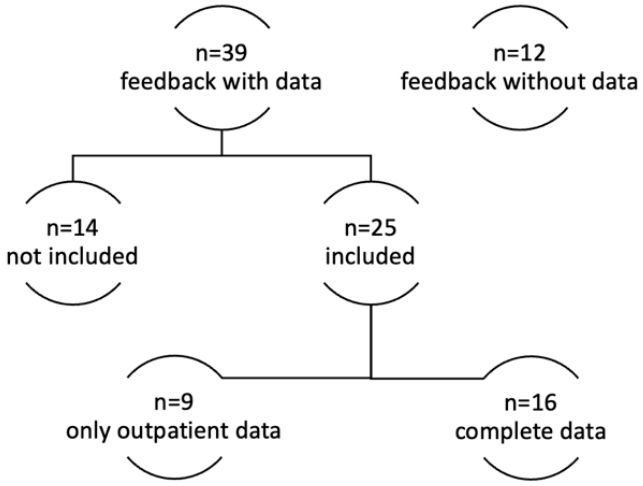

Figure 3: Flowchart of inclusion of study participants. Of the included n=25 participants, 7 were children (4 male, 3 female) and 18 were adults (8 female, 10 male).

The included study participants (n=25) are distributed by biological gender (sex) and age group (child or adult). A total of seven children (age <18 years), and 18 adults (age >18 years) were included in this study. Of the seven children, four are female, and 3 are male. Eight of the 18 adult study participants are female, and 10 are male (table 3).

Sex	Children	Adult	All
Female	4	8	12
Male	3	10	13
Total	7	18	25

Table 3: Distribution of age and biological gender of study participants

According to ICD-10 codes represented in the data from the insurers, 15 respondents had the diagnoses Q05.9 (open back, cleft spine), three had Q05.7 (lumbar spina bifida without hydrocephalus), and 2 persons each had the ICD-10 diagnoses Q76.0 (spina bifida occulta) or Q05.4 (unspecified spina bifida with hydrocephalus). Furthermore, in two cases, contradictory diagnoses were stated in the performance data; both Q76.0 (spina bifida occulata) and Q05.9 (open back, splitting of the spine) were coded (figure 4).

No diagnosis is given in the data sheets of three patients, which is surprising, as ICD-10 coded diagnoses are necessary for billing and should therefore be known to the health insurance companies.

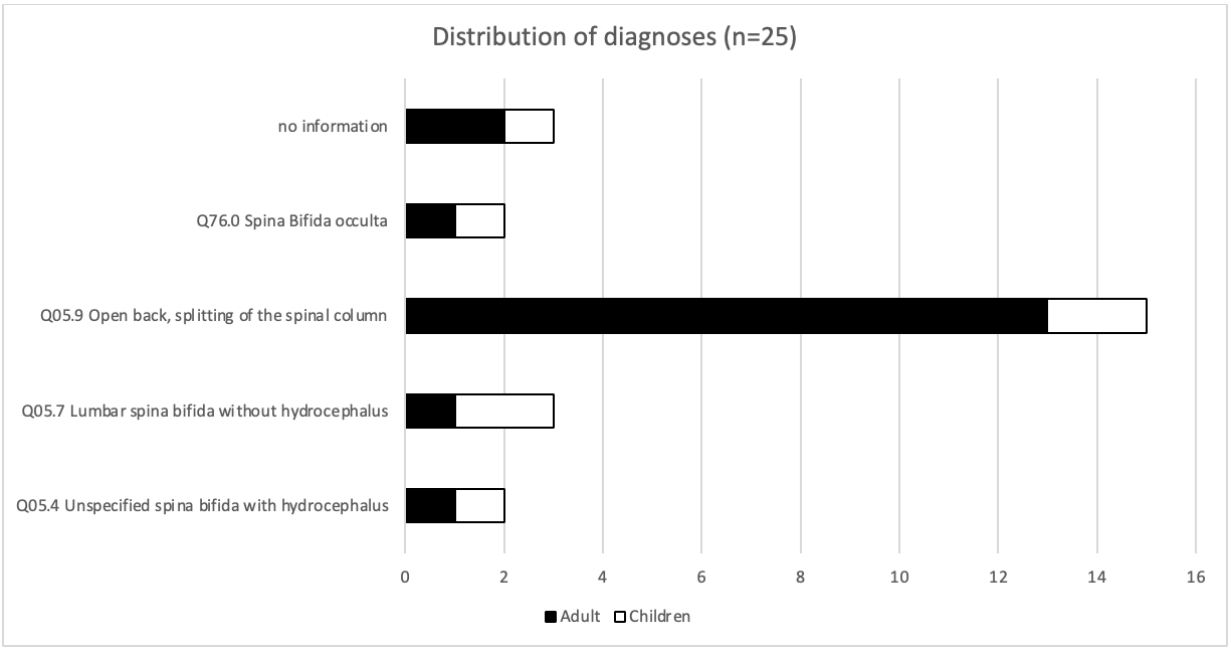

Figure 4: Distribution of diagnoses (n=25): Shown are the absolute numbers of participants with each diagnosis. Only the first documented diagnosis was considered. White bars: children, black bars: adults.

3.1 Total costs of all expenditures

The recording of medical costs is differentiated in the data obtained from the health insurance funds according to the following five areas:

1) outpatient costs (calculated for both n=25 (all participants) as well as for n=16 (participants with complete data sets),
2) inpatient costs (n=16),
3) costs for the provision of remedies, i.e., therapeutic interventions like movement and speech therapy (physiotherapy, occupational therapy, speech therapy, etc.) (n=16),

4) costs for the provision of aids, i.e. assistive devices and items to ensure the success of medical treatment or to compensate for a disability (n=16), and

5) costs for the provision of pharmaceuticals (n=16).

Considering the available data, the calculations are performed in the above five areas (see methods section). The sum of all costs for 16 SB patients with a complete data set, covering costs for outpatient and inpatient services, cost of remedies, cost of aids, and cost of pharmaceuticals over a period of four years (2017-2020), are 891,044 EUR. Of the total costs of 891,044 EUR, 110,602 EUR (12%) could not be precisely allocated due to poor data quality.

The total costs of 891,044 EUR were distributed per person per year as follows (given is the median of costs per person per year): 7,235 EUR in 2017, 7,406 EUR in 2018, 8,660 EUR in 2019, and 7,861 EUR in 2020, respectively.

The median of annual total costs per person is lower for adults than for children and shows slight variations in each disease year, with 4,955 EUR in 2017, 7,137 EUR in 2018, 6,245 EUR in 2019, and 7,393 EUR in 2020, respectively (figure 5). In 2017, the lowest costs per person for adults were 659 EUR, and the highest 15,762 EUR. However, in the subsequent years, 2018 and 2019, a significant increase in the highest expenditures can be traced, which can be attributed to outliers (shown in the boxplot as crosses, figure 5). Slight variations in total costs between disease years can be observed within the group of adult participants. Comparing between the groups (children vs. adults), total spending on illness costs is lower for adults than for children.

A group-specific analysis for children reveals a median of annual costs per person of 22,134 EUR in 2017, 20,464 EUR in 2018, 23,812 EUR in 2019, and 21,676 EUR in 2020, respectively (figure 5). In 2017, the lowest costs for children per person were 1,114 EUR, and the highest were 49,460 EUR. For children, the upper limit of the cost distribution decreased in 2018 and then increased again. Unfortunately, an explanation for this observation cannot be derived from the available data itself (figure 5).

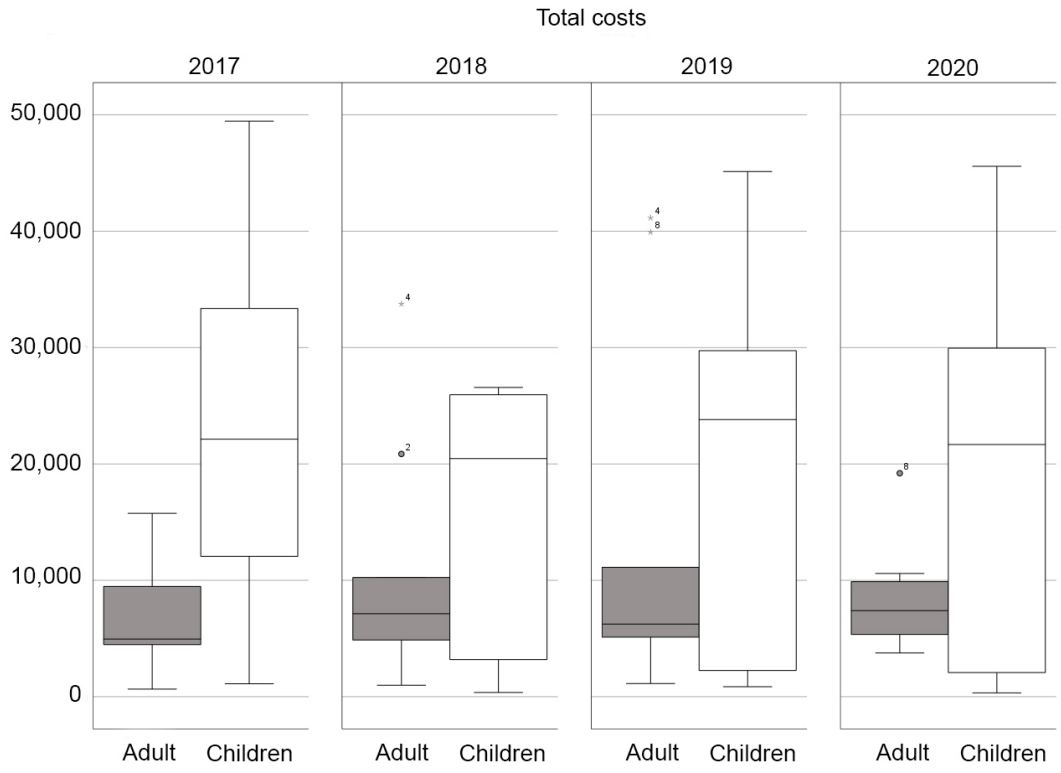

Figure 5: Total costs per patient per year 2017 – 2020 (n=16). The line in the boxplot indicates the median. The lower and upper bars of the box indicate the 1st and 3rd quartile and the interquartile range. The up and down antennas indicate the top and bottom 25% of the data distribution. Mild outliers are shown as circles, and extreme outliers as crosses. n=9 adults, n=7 children.

3.2 Costs of outpatient treatments

In the following section, only the available data on total costs of illness in the outpatient setting is considered. As there were five responses that included only data on outpatient costs, these were included in the analysis of this sector of healthcare costs, amounting to a total of 25 data sets (n=25). In the years from 2017 to 2020, the 25 respondents had a total of 1,243 consultations or treatments in an outpatient setting, with total illness costs of 119,504 EUR. In the outpatient sector, the annual median of illness costs per person were as follows: 604 EUR in 2017, 736 EUR in 2018, 805 EUR in 2019, 722 EUR in 2020.

Figure 6 clearly shows that median annual health insurance expenditures per patient are also substantially higher for children than for adults in the outpatient setting. Within the

groups, median expenditures per patient for outpatient consultations are relatively stable between years, with one exception in 2020 for children (n=7). This is likely related to the Covid-19 pandemic and associated lockdowns and contact reduction measures (2017=2,511 EUR, 2018=2,304 EUR, 2019=2,343 EUR, 2020=1,390 EUR).

In the outpatient sector, the median of annual illness costs per patient is relatively constant for adults (n=18), with a slight cost increase over the observed four-year period (2017=329 EUR, 2018=485 EUR, 2019=524 EUR, 2020=569 EUR).

The range of costs for children shows a wider distribution, and the annual median of costs per patient in the outpatient sector is substantially higher compared to adults in all four years. When considering the seven children included in the study, the median of annual costs per person was above 2,000 EUR between 2017 and 2019. However, the expenses are lower in 2020 (median of annual outpatient expenditures per person for n=7; 2017=2,511 EUR, 2018=2,304 EUR, 2019=2,343 EUR, 2020=1,390 EUR). Furthermore, there are significantly more outliers with particularly high outpatient costs per patient among adults (figure 6).

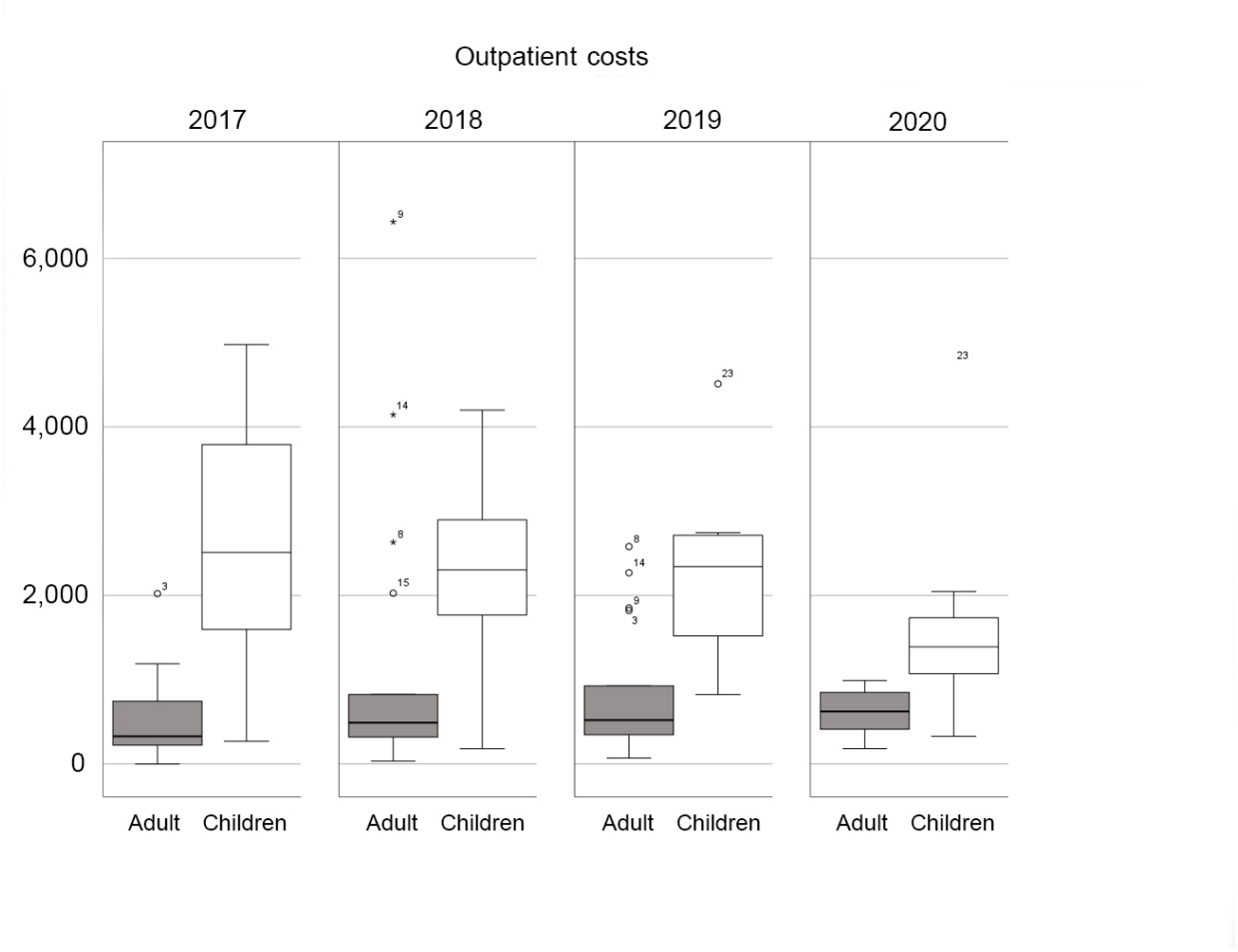

Figure 6: Outpatient costs per patient per year (2017 – 2020, n=7 children, n=18 adults). The line in the boxplot indicates the median. The lower and upper bars of the box indicate the 1st and 3rd quartile and the interquartile range. The up and down antennas indicate the top and bottom 25% of the data distribution. Mild outliers are shown as circles, and extreme outliers as crosses.

For better comparison between different areas of costs, the calculation of costs in an outpatient setting was also done with only those participants with complete cost documentation (n=16). There were no obvious differences in the cost per person distribution when either n=25 data sets (containing outpatient data) or n=16 datasets (containing data from all areas of healthcare costs) were considered (data not shown).

3.3 Costs of inpatient treatments

Inpatient costs are documented in the data sets as inpatient hospitalizations with a length of stay greater than or equal to one night. Due to the small number of cases, only the sum over a four-year period (2017-2020) is shown in figure 5 for all patients as well as for adults and children, respectively. According to the health insurance funds data, ten of 16 respondents had a hospital admission and six respondents had no inpatient admissions in 2017 to 2020. The ten respondents with a documented hospital stay collectively had a total of 36 inpatient admissions with total illness costs of 191,175EUR over the four-year period. The median of inpatient expenditures per person over four years was 650 EUR. For the latter, participants without a documented hospital stay were considered with costs of 0 EUR per person in four years.

The lowest cost per person in four years was therefore 0 EUR, and the highest was 49,570 EUR (figure 7). Per inpatient case (which does not consider participants without a documented hospital stay, as they had no documented cases), an average of costs per case of 5,310 EUR can be calculated for the period under review from 2017 to 2020, with a total number of cases of 36. The average costs per case for all insured inhabitants in Germany are documented as 3,511 EUR from 2017 to 2020. It therefore can be concluded that inpatient care of patients suffering from SB is higher than average and is therefore associated with a case severity (case-mix index, CMI) of > 1.0. The case-mix index describes the severity of a treatment case in the diagnosis related group (DRG) system. A case-mix of 1.0 is the average value [15]. In 21 of the 36 cases, we were not able to assign the medical costs per case due to insufficient documentation in the information participants received from their health insurance funds. Only nine of 36 cases could be clearly associated with SB, and two cases with urological problems.

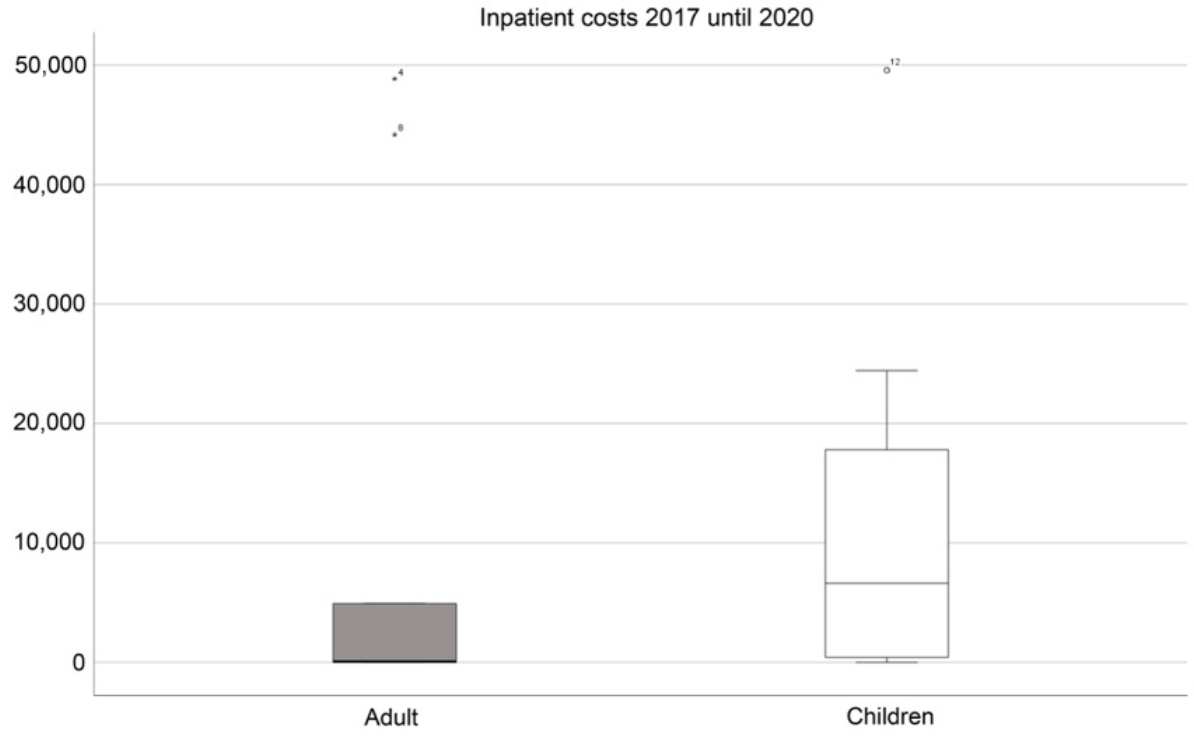

Figure 7: Inpatient costs per patient per four years (2017 – 2020, n=7 children, n=9 adults). The line in the boxplot indicates the median. The lower and upper bars of the box indicate the 1st and 3rd quartile and the interquartile range. The up and down antennas indicate the top and bottom 25% of the data distribution. Mild outliers are shown as circles, and extreme outliers as crosses.

3.4 Costs of remedies

Costs of remedies include costs for therapeutic interventions like movement and speech therapy (physiotherapy, occupational therapy, speech therapy, etc.). Not included are drugs and aids to compensate for disabilities, which are discussed below, respectively.

The available data from 2017 to 2020 show a total of 848 therapeutic prescriptions, which amount to 94,777 EUR (2017=917 EUR, 2018=1,206 EUR, 2019=1,411 EUR, 2020=1,324 EUR). Except for 2017, health insurance spending for adults (n=9) is relatively constant when comparing the median of costs per person per year (2017=939 EUR, 2018=1,500 EUR, 2019=1,567 EUR, 2020=1,429 EUR). For the seven included children, the median of annual costs per person on remedies varies from year to year (2017=895 EUR, 2018=587 EUR, 2019=992 EUR, 2020=1,217 EUR). According to health insurance data, for some children and adults there are years without prescriptions for

remedies. In contrast, the highest costs for prescribed remedies per person amount to 6120 EUR for children in 2020 and 3,832 EUR for adults in 2019, respectively. The childrens' median annual expenditure on remedies is slightly lower than for adults (figure 8).

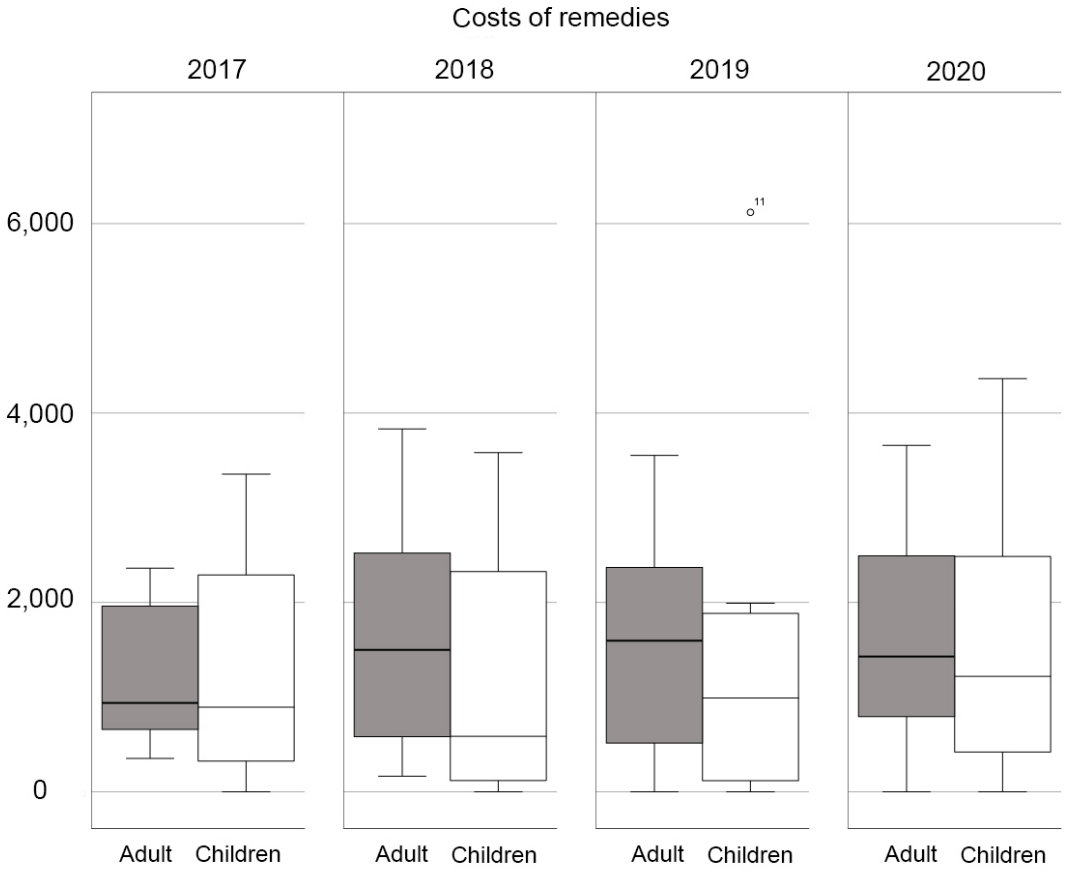

Figure 8: Costs of remedies per patient per year (2017 – 2020, n=7 children, n=9 adults).. The line in the boxplot indicates the median. The lower and upper bars of the box indicate the 1st and 3rd quartile and the interquartile range. The up and down antennas indicate the top and bottom 25% of the data distribution. Mild outliers are shown as circles, and extreme outliers as crosses.

3.5 Aid costs

The costs for aids comprise costs for assistive devices and prescriptions of items to ensure the success of medical treatment or to compensate for a disability (orthoses, orthopedic aids, incontinence aids, etc.). For the 16 participants with complete documentation, 1,165 prescriptions for remedies are issued in the observation period from 2017 to 2020. The overall costs for the prescribed aids in the observation period amount to 429,510 EUR. Looking at the four-year period data in more detail, costs for providing urine incontinence aids account for the largest share at 147,405 EUR (34% of costs), followed by orthopedic aids at 143,962 EUR (33% of costs). Urine incontinence aids are prescribed significantly more often, at an average of 295 EUR per prescription (499 prescriptions – 43% of total aid prescriptions), compared to orthopedic aids, at an average of 1,007 EUR per prescription (143 prescriptions- 12% of total aid prescriptions).

The annual expenditure per person on therapeutic appliances is as follows (median): 3,860 EUR in 2017, EUR 3,142 EUR in 2018, 4,386 EUR in 2019= 3,721 EUR in 2020 (figure 9).

The annual expenditures for aids are relatively constant when regarding costs for adults per person per year with a median of 3,303 EUR in 2017, 2,909 EUR in 2018, 4,155 EUR in 2019, 3,437 EUR in 2020. Some adult participants did not receive any assistive device prescriptions, while the maximum value was costs per person per year of 15,662 EUR in 2018 (figure 9).

Median annual aid expenditures are about twice as high for children than adults (median of annual aid expenditures per child (n=7): 2017=14,885 EUR, 2018=10,205 EUR, 2019=12,243 EUR, 2020=9,581 EUR). Looking at the data for children, some study participants did not receive any assistive device prescriptions so that the lowest expenditure per person is 0 EUR. The highest annual expenditure per person occurred in 2017 with 28,681 EUR, and in 2020 with 28,674 EUR (figure 9).

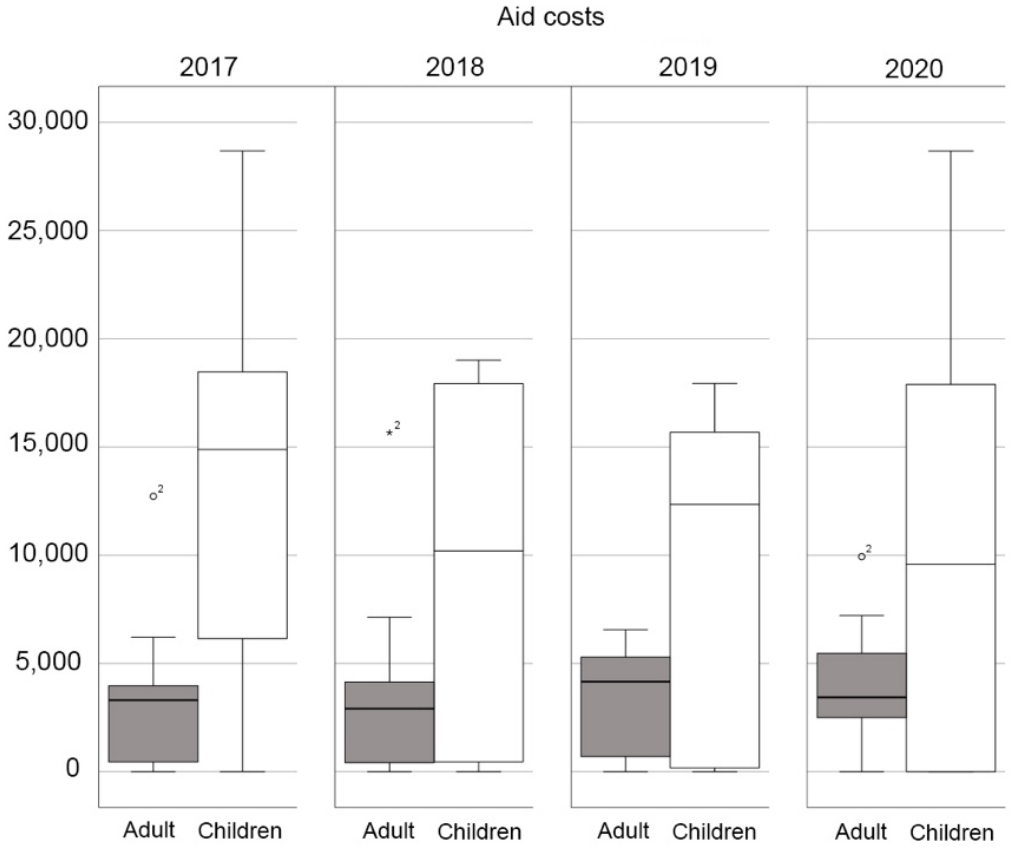

Figure 9: Aid costs per patient per year (2017 – 2020, n=7 children, n=9 adults). The line in the boxplot indicates the median. The lower and upper bars of the box indicate the 1st and 3rd quartile and the interquartile range. The up and down antennas indicate the top and bottom 25% of the data distribution. Mild outliers are shown as circles, and extreme outliers as crosses.

3.6 Costs of pharmaceuticals

Between 2017 and 2020, for sixteen participants a total of 850 drug prescriptions with a cost volume of EUR 82,494 are recorded. There were relatively constant expenditures in the observation period 2017 to 2020 (median of annual costs for pharmaceuticals per person: 2017=577 EUR, 2018=733 EUR, 2019=389 EUR, 2020=513 EUR, figure 10).

For adults, the median of annual drug expenditures per person (n=9) are constant except for a significant decline in 2019 (2017=573 EUR, 2018=595 EUR, 2019=253 EUR, 2020=472EUR). An explanation for the decrease of the cost in 2019 cannot be derived from the data (figure 10).

The median of annual drug expenditures per child in 2017 and 2018 were about twice as high as in 2019 and 2020 (2017=1,182 EUR, 2018=1,137 EUR, 2019=597 EUR, 2020=554 EUR). An explanation for this cost development cannot be derived from the data set. While in some years there were no expenditures for some children, the highest annual expenditure for one child occurred in 2017 with 6,219 EUR. In subsequent years, costs per child per year fall slightly and then remain constant (figure 10).

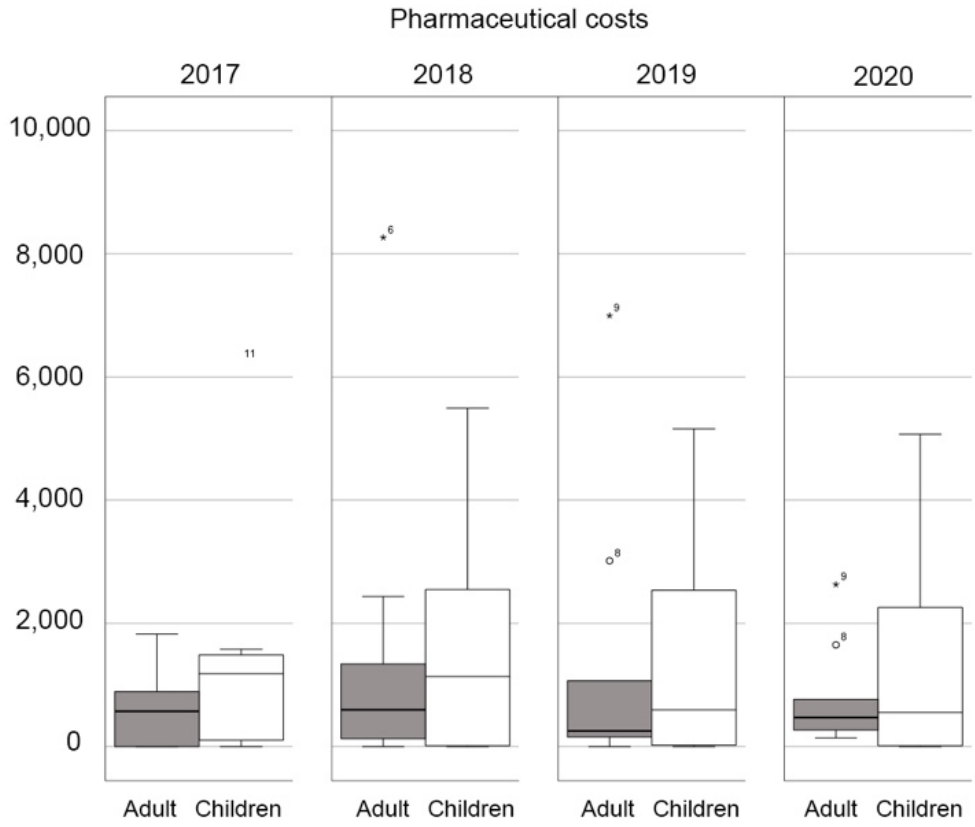

Figure 10: Pharmaceutical costs per patient per year (2017 – 2020, n=7 children, n=9 adults).. The line in the boxplot indicates the median. The lower and upper bars of the box indicate the 1st and 3rd quartile and the interquartile range. The up and down antennas indicate the top and bottom 25% of the data distribution. Mild outliers are shown as circles, and extreme outliers as crosses.

3.7 Summary of the results

In summary, the data analysis shows that the medical costs for children are significantly higher on average than for adults. A heterogeneous picture emerges if the service areas are examined in detail and differentiated according to the categorizations. It also becomes clear that the service data of the health insurance funds are provided in an insufficient and heterogeneous manner.

The total costs of 891,044 EUR were distributed per person per year as follows (given is the median of costs per person per year): 7,235 EUR in 2017, 7,406 EUR in 2018, 8,660 EUR in 2019, and 7,861 EUR in 2020, respectively.

Furthermore, the data analysis of the medical costs of patients with SB shows that the medical costs which are to be assigned to a direct doctor-patient contact account for a share of 30% of the medical costs. The largest share of medical costs, at about 50%, can be attributed to providing medical aids and appliances (table 4). With focus on data quality, the Remedies segment contains the least amount of services that cannot be assigned (table 4).

Due to the selective cohort and the heterogeneity of the data, it is impossible to formulate a reliable conclusion about the path of the patients through the healthcare. The costs incurred by the rare disease SB are summarized in the following table for the 48-month period (table 4).

Category	Total	%-share	Adults	%-share	Children	%-share
Total	891,044	100%	356,327	100%	534,720	100%
Outpatient	93,091	10%	30,314	9%	62,777	12%
Inpatient	191,175	21%	98,506	28%	92,669	17%
Remedies	94,777	11%	53,725	15%	41,052	8%
Aids	429,510	48%	134,668	38%	294,842	55%
Pharmaceuticals	82,494	9%	39,114	11%	43,380	8%
Outpatient	93,091	100%	30,314	100%	62,777	100%
Hospital	41,772	45%	8,055	27%	33,717	54%
Family Doctor	10,980	12%	8,249	27%	2,731	4%
Urologist	1,232	1%	783	3%	449	1%
Orthopedist	2,359	3%	1,258	4%	1,101	2%
Pediatrican	10,855	12%	837	3%	10,018	16%
Other	20,683	22%	10,595	35%	10,088	16%
No Information	5,210	6%	537	2%	4,673	7%
Inpatient	191,175	100%	98,506	100%	92,669	100%
SB-Orthopedic	11,592	6%		0%	11,592	13%
SB-Urological	2,370	1%		0%	2,370	3%
SB-Other	71,821	38%	49,315	50%	21,506	23%
No Information	105,392	55%	49,191	50%	56,201	61%
Remedies	94,777	100%	53,725	100%	41,052	100%
Physiotherapy	79,665	84%	47,550	89%	32,115	78%
Ergotherapy	13,338	14%	6,227	12%	7,111	17%
Speech Therapie	1,369	1%		0%	1,369	3%
No Information	405	0%	-52	0%	457	1%
Aids	429,510	100%	134,668	100%	294,842	100%
Incontinence aids	147,405	34%	64,262	48%	83,143	28%
Orthopedic aids	143,962	34%	24,125	18%	119,837	41%
Stoma aticles	26,461	6%	23,004	17%	3,457	1%
Other	26,668	6%	2,132	2%	24,536	8%
No Information	85,014	20%	21,145	16%	63,869	22%
Pharmaceuticals	82,494	100%	39,114	100%	43,380	100%

Table 4: Recorded medical expenses totaled (2017-2020, n=7 children, n=9 adults)

4. Discussion

In the following, the findings obtained from the study are evaluated and classified in the current state of research, the methodology and limitations of the approach are discussed, and a conclusion is drawn regarding further research and recommendations for action in the future.

4.1 Relevance of the results

In the present work, the medical costs of SB in Germany have been analyzed for the first time in over ten years through a previously unpublished methodological approach. As expected, the willingness to participate was moderate as the data collection was demanding and complex. This means the included study participants are a very selective collective, partly due to the recruitment process.

Despite of a standardized request procedure, the obtained data was incomplete and lacked a clear structure. While the legal regulation for the transparency of the performance data of health insurance according to §305 Abs. 2 SGB V is intended to make the health care system more transparent, the study shows that its requirements are not met quantitatively or qualitatively in practice. Based on the heterogeneity of the data and obvious data gaps, it can be assumed that disease-specific expenditures are underestimated for both groups.

The data heterogeneity and their gaps are likely connected to the fact that services are often not recorded for correct documentation but for billing purposes. Since 2000, medical practitioners have been required to encode diseases. Since 2012, ICD coding has been a prerequisite for revenue. The German National Association of Statutory Health Insurance Funds (GKV-Spitzenverband) is the central interest group of the statutory health and long-term care insurance funds in Germany. In their expert report, implausible diagnosis combinations are reported which fits to the observation made in this study of implausible diagnosis combinations, where sometimes the open and closed form of SB was coded for the same patient (GKV-Spitzenverband, 2012).

Coding according to purely economic rather than scientific incentives can be suspected as the cause of this limitation in the data, a recurring problem that also calls ICD coding for billing purposes into question from a scientific perspective (Ärzteblatt, 2017). In any case, the results of this study clearly show that better data management of valuable health data is urgently needed so that patients can gain data sovereignty over their health data and are able make it available to research according to their wishes. Current efforts from politics and research, e.g. to introduce SNOMED CT coding, are therefore to be welcomed. SNOMED CT coding allows for the world's most comprehensive health terminology for semantic interoperability in electronic health data exchange as of now (Bundesinstitut für Arzneimittel und Medizinprodukte, 2023). This study indeed confirms that limited data quality impedes robust conclusions on health expenditures on SB that could help to improve patient-centered care pathways.

Overall median annual illness costs range from EUR 7,235 to EUR 8,660 between 2017 and 2020. Compared to an analysis by the German Federal Statistical Office on the total cost of illness per inhabitant, not delimited for SB, the total cost was EUR 4,140 in 2015 and EUR 5,190 per inhabitant in 2020 (Statistisches Bundesamt, 2023b). The interdisciplinary care disease management of the disease turns out to be complex and cost intensive. The challenges in diagnosis and selection of the right therapy are characterized in particular by the imbalance of care situations in metropolitan areas and underdeveloped regions, and a related lack of interdisciplinary and cross-sector networking. Consequently, there are restrictions in daily life, and, in the case of particularly severe courses, it can shorten the patient’s life expectancy. In the overall context, this is often associated with high secondary, avoidable costs of illness (Huch and Jürgens, 2011).

The results of the utilization of outpatient care structures clearly show that most outpatient presentations arise from the use of hospital outpatient departments. An explanation of why this picture emerges in the data analysis of outpatient presentations and costs cannot be derived from the available data. It is also unclear from the data which departments or interdisciplinary care areas of the hospital outpatient departments are used. In the service data, hospital outpatient presentations are predominantly recorded with the service provider of the university outpatient clinic.

This utilization can be deduced as a trend in the German healthcare system. More and more hospitals are offering interdisciplinary health care across different departments. In addition, highly specialized outpatient services are often not offered by established physicians (GKV-Spitzenverband, 2023a).

Another finding that emerges when looking at outpatient costs and the utilization behavior of physicians in private practice (hospital outpatient departments excluded) is that the most frequently consulted specialist is the general practitioner or family doctor and, in the case of children, the pediatrician. The accompanying diseases and complaints typical of SB disease, ranging from urological to orthopedic severe limitations and complaints, are not reflected in the analyzed disease data. A possible explanation is that patients have their specialist urological treatment performed in hospitals. Furthermore, the recorded costs show that children hardly cause any costs for specialist urological treatment. In contrast, pediatric care costs are the second highest cost driver of outpatient care, accounting for 16% of costs over the 4-year period. Among adult study participants, a similar picture is reflected in costs over the 4-year period of coverage. However, among adults, the second highest costs are incurred by the general practitioner or family physician. More specific information on this cannot be derived from the service information provided by the health insurance funds (table 4).

With a view to the largest share of medical costs for patients with SB, the focus is on providing remedies and aids. Our analysis illustrates that the costs for providing remedies and aids are 5.7 times higher than those for outpatient care. The median costs for providing remedies and aid are between EUR 917 and EUR 4,386 per year of illness. The results cannot be verified and evaluated in comparison. However, they clearly show the burden that remedies and aids represent for patients so that they are cared for according to their illness, and the burden that remedies and aids represent for the healthcare system. A statistic evaluation of the association of substitute insurance funds Germany (Verband der Ersatzkassen – VDEK) shows the development of the costs of providing remedies and aids for insured persons. The average cost is 276 EUR and shows an increase of about 40% from 2016 to 2021. In the context of our results, this comparison shows the intensive care of rare diseases (Verband der Ersatzkassen, 2023).

It is clear from the costs recorded for therapeutic products and aids that these service provider areas have the lowest proportions of not assignable costs. This can be explained by the high demands placed on billing services and products by the required prescriptions. Further, the costs captured in recorded costs from 2017 to 2020 show that children incur significantly higher costs from therapeutic appliances and devices despite the smaller number of study participants (table 4). The adult study participants, on the other hand, have a significantly lower share of costs for therapeutic products and aids over the 4-year period.

An explanation or medical reason why medical aids and appliances predominate in contrast to medical outpatient care cannot be derived from the data. It is likely related to the physical disabilities caused by damage to the central nervous system that SB entails.

The comparison of the recorded expenses, as well as the overall analysis, is consistent with a published study on spina bifida disease costs in Italy from 2013, which showed that the largest share of costs is incurred by medical aids and the smallest percentage of the expenses by the provision of medicines (Colombo et al., 2013).

When compared with the data from Bowels et al. from Germany from 2006 to 2009, our data highlights the economic over the last 15 years. The medical costs per year of EUR 4,533 analyzed by the study from the 2000s are significantly lower than our average hospital costs per year. Nevertheless, SB's medical costs were higher than the average SHI expenditures at that time. This result is in line with our results, which also clearly show that the yearly sickness costs are higher than average. Inflation development likely also contributes to overall higher medical costs (Bowles et al., 2014).

Nevertheless, the distribution of medical expenses has remained largely the same when compared with these two previous studies from Italy and Germany (Bowles et al., 2014; Colombo et al., 2013). All studies observed lower median annual illness costs for adults than children. The studies have also shown that the highest proportion of medical costs is incurred for providing remedies and aids.

A study limitation with the potential for follow-up research exists regarding the patient's quality of life and their experiences in combination with different patient journeys. To allow any conclusions about optimal use of health resources to further the quality of care for patients with SB and equitable sharing of health resources, these aspects need to be addressed in future research. The current study aims to provide initial insights into the costs associated with SB and sheds light on the necessity for measures to enhance transparency in the healthcare system in Germany.

The costs of SB represent a high burden for the patients but also show; according to this data analysis, the disease is associated with a considerable economic burden for the German health care and insurance system. From the available service data of the different health insurances, conclusion about whether an outpatient presentation or whether a prescription for remedies and aids was medically necessary or effective cannot be drawn.

4.2 Methods and limitation

A significant challenge of the present research work was the design of the methodological approach. On the one hand, data protection regulations had to be fully complied with. On the other hand, a procedure had to be established to generate appropriate data to answer the formulated hypotheses. Within the scope of the ethics application, it was imperative to describe the procedure for data acquisition and processing as well as anonymization/ pseudonymization procedures in detail.

For the data collection, no direct cooperation with public health insurances for providing their data directly for the research project could be obtained. They rejected cooperation due to data protection concerns and, in their view, lack of relevance of the research question. Since there is no central research center for data retrieval and no central access for patient collectives to answer research questions like the present project as of now in Germany, cooperation with ASBH was established in order to obtain data from people with SB directly. As a result, the study population was limited to members of the ASBH.

In effect the study population was also limited to persons with benefits from statutory health insurances. While health insurance is mandatory in Germany, it is possible to forgo statutory health insurance in favor of a private insurance under certain circumstances. Currently, about 73 million people in Germany have statutory health insurance (GKV-Spitzenverband, 2023b). While we did hear back from some ASBH members with private health insurance, these could not be included in the study as they reported that they did not receive any benefit information from their health insurance. The reason given by the insurance companies was that all invoices and services were already known to the insured persons, as private health insurance entails the paying of all health bills by the insured person and subsequent refunding from the private insurance company.

At the start of the research project, the described procedure was defined based on the legal foundations at the time. After the start of the research work, the socio-legal provisions for obtaining the benefits information according to §305 SGB V were specified further. §305 SGB V para. 1 sentence 2:

„At the request of the insured persons and with their express consent, the health insurance funds shall also transmit data in accordance with sentence 1 electronically to third parties named by the insured persons.“

At the time of data collection, this sentence was not present, so that all data was collected on paper, as it was sent by the insurers to the participating patients. As of now, the amendment in sentence 2 could significantly reduce the demand and effort of study participants and therefore might lead to a higher willingness to participate, and possibly better data quality as a result of awareness of the insurers that the data would be used for research and not just for reasons of transparency for the individual. Independent of these socio-legal adjustments, the applied methodological approach of the research project has provided insights into the willingness of potential participants to participate, and resulted in some personal feedback by some participants that they indeed would like to have more transparency in the care of their rare disease and to improve the care of the rare disease. These insights would not have been possible through a direct survey of the health insurance companies.

Another methodological challenge to be discussed is the possible bias due to performance data received but not provided.

A quantifiable statement on the possible influence cannot be formulated at this point because no indications allow a conclusion to be drawn. The assumption that the payers provided data but did not forward it to the study center can be explained by the described heterogeneity in the included data sets of the study. The heterogeneous data in the scope over the service areas result despite the same request letter according to §305 SGB V over different cost units. It could be excluded that a systematic error exists, for example, due to a specific payer's request behavior or evaluation behavior. At this point, there could be a general, individual problem with the insurance companies since most payers did not yet have an automated digital process for requesting services at the time of data acquisition.

Approximately 2,800 paper pages with insurance company claim data were digitized for the 25 study participants. In order to minimize the heterogeneity of the data analyzed during data collection and data preparation, as well as very incomplete and unusable data sets due to the form of output by the health insurance company, it would have been advantageous in retrospect to supplement the cover letters to the potential study participants with a form for contact data in the event of queries. This would have the advantage that, on the one hand, it were possible to contact the study participants in the event of unclear, unusable data records. Second, qualitative research approaches and queries could have been answered using the data. Consideration was given to supplementing the form with contact information for queries as part of the reminder letter. However, the effort in preparing the form and adapting the ethics application was evaluated as very high, so that the results based on the performance queries with the described procedure were primarily used, and the contact for queries and subsequent qualitative research can be used as a follow-up work for the present health care research project.

4.3 Opportunities and recommendations

The health data collected from the health insurers' benefit reports do not allow for a holistic view. Due to the incomplete data quality and the heterogeneous data, the path through the health care system cannot be outlined. A significant potential, which results from the applied procedure, would be qualitative follow-up research. Contacting the included study participants for interviews and recording and economically evaluating the paths through the healthcare system based on the service information is possible.

Furthermore, the limitations and described results make the need for improvement for the preservation and use of research data on a solid, valid, and resilient basis transparent. For example, the federal government is pursuing a strategy to establish a research-compatible electronic patient record (Ärzteblatt, 2019). Furthermore, the research possibility to improve the socio-economic structures in the health care system is advanced by the FDZ. Through the FDZ, high-quality and secure data will be made available for scientific research purposes. It is a central facility for accessing and using microdata-based information from official statistics. The FDZ aims to provide researchers access to secure and high-quality microdata-based information from official statistics. It supports researchers in data analysis, ensures data protection and compliance with standards, and thus promotes scientific research based on official statistics (Bundesinstitut für Arzneimittel und Medizinprodukte, 2023). At the time of the research, the FDZ was not yet active and did not have the appropriate data sets available, as the data center was and is under construction.

Transparency through the usability of health data for research purposes, to relieve the burden on the health system and make it more efficient, is also being promoted by the Hospital Future Act (Krankenhauszukunftsgesetz, KHZG). Through the KHZG, efforts, and political efforts are being made to harness the data and use it not only for medical research but also to improve the healthcare system; for example, a project has been set up by a primary carrier in Germany to harness the data for patient pathways to drive processes in a patient-centric and economical manner (Klinikmanagement Aktuell, 2023).

With these developments, a sustainable design of the healthcare system in the field of tension of economization and digitalization is sustainably improved. The need to not only deal with the improvement of medical care but also to evaluate its influence on the health care system and, thus, on society as a whole is transparently demonstrated by this research work.

Overall, the research work and data analysis presented here, with the findings and results obtained, offer the potential for follow-up research. In addition to the qualitative patient interviews, tracing individual patient paths through the health care system should be possible.

In conclusion, it is essential to note that in addition to health limitations and social burdens, rare SB disease places a significant economic burden on the health care system. The disease lasts a lifetime. Based on the findings of this work and the overall developments in the healthcare system, efforts and efforts must be made to identify the patient pathways, enable needs-based care, and monitor the costs of illness in a causation-based, traceable, and allocable manner.

5. Abstract

Background: Spina bifida (SB), as a rare non-curable disease with comorbidities, requires multi-professional collaboration. Less is known about patient journeys, medical costs, health-related quality of life, and their correlation. The less existing publications date back about ten years. Thus, the current cost developments in the health care system due to constantly specialized therapies are not reflected. We aimed to elucidate the medical costs of SB patients in Germany to create transparency by recording and analyzing the treatment paths and associated costs. To gain access to relevant data, patients were asked to transmit their individual insurance data, as a Research Data Center (FDZ) for health data is not yet operational in Germany.

Results: Although the regulations require health insurance companies to provide patients with a report of medical expenses upon request, the reality is different. Access to data on treatment paths and associated costs was limited by incomplete information provided by health insurers.

We could show that the illness costs related to SB are above average per inhabitant in Germany. The highest proportion of costs was documented for remedies and medical aids. Costs for urinary incontinence aids accounted for the largest share. The data showed that cost of illness is significantly higher for children than for adults.

Conclusion: While a reasonable estimate of costs related to SB was established with this study, it became also clear that there are significant data gaps as a result of lacking transparency of the German healthcare system. Concerning cost-of-illness analysis and its impact on the healthcare system, researchers have the task to provide evidence as a basis for recommendations that ensure fairness and equitable sharing of health resources. Our results highlight the urgent need for better transparency regarding health service costs for both individual policy holders as well as researchers aiming at elucidating the cost effectiveness and impact on health-related quality of life of medical interventions and services in Germany. The recent instatement of a central Research Data Center (FDZ) is an important step in this direction, especially in the context of insufficient data quality

provided by the German statutory health insurance companies to individual policy holders observed in this study.

6. List of figures

7. List of tables

8. References

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Christopher Hauk

Attachment A – Cover letter sent by the ASBH to members

Studie zur Versorgungsforschung von Patienten mit Spina Bifida

Sehr geehrte Damen und Herren,

liebe Mitglieder,

gemeinsam mit dem Universitätsklinikum Bonn – Zentrum für Seltene Erkrankungen sowie der Klinik und Poliklinik für Urologie und Kinderurologie – möchten wir eine Studie zur Versorgungsforschung von Spina Bifida durchführen.

Das Ziel ist, ein besseres Verständnis in der Gesundheitspolitik für seltene Erkrankungen, im Besonderen für Spina Bifida zu erreichen. Hierzu soll die Studie einen Aufschluss über die Versorgungssituation von Patienten mit Spina Bifida in Deutschland liefern. Konkret stehen hierbei die Wege der Patienten bis zum Erhalt einer optimalen Versorgung im Fokus, um unter anderem Versorgungslücken aufzuzeigen. Außerdem sollen die dabei entstehenden Krankheitskosten kalkuliert werden, um die Bedeutung der Erkrankung für unser Gesundheitssystem auch in Zahlen zu erfassen.

Um dieses Ziel zu erreichen, sind wir auf Ihre Mithilfe angewiesen. Mit einer Teilnahme an der Studie können Sie aktiv etwas beitragen, um langfristig eine Verbesserung der Versorgungssituation und ein besseres Verständnis der Erkrankung zu erreichen. Aus diesem Grund nehmen wir heute Kontakt zu Ihnen auf.

Wenn Sie sich vorstellen können, uns bei der Studie zu unterstützen, würden wir uns freuen, wenn Sie sich die beiliegende Patienteninformation sorgfältig durchlesen. Bei etwaigen Fragen darüber hinaus wenden Sie sich gerne an Jürgen Wolters – Geschäftsführer ASBH – (juergen.wolters@asbh.de, 0231-861050-0) oder die in der Informationsschrift genannten Ansprechpartner.

Falls Sie sich für eine Teilnahme entscheiden, müssen Sie die Einwilligungserklärung zur Teilnahme an der Studie unterzeichnen und Kontakt zu ihrer Krankenkasse aufnehmen (Details finden Sie in der Patienteninformation). Anschließend senden Sie alle Unterlagen im bereits frankierten und adressierten Umschlag an das Zentrum für seltene Erkrankungen in Bonn.

Ihre Teilnahme an der Studie ist absolut freiwillig und kann ohne Angabe von Gründen jederzeit widerrufen werden. Sollten Sie sich gegen eine Teilnahme entscheiden, brauchen Sie nichts weiter zu tun. Ihre Daten werden in keinem Falle an Dritte weitergegeben. Es entstehen auch keine Nachteile in der weiteren Gesundheitsversorgung.

Alle weiteren Details zur Studie entnehmen Sie bitte der beiliegenden Patienteninformation.

Wir verbleiben mit herzlichen Grüßen und stehen Ihnen bei Rückfragen zur Verfügung.

Attachment B – Patient information

Patienteninformation und Einwilligungserklärung

„Krankheitskosten und Wege der Patienten (Patient Journey) mit Spina Bifida und Neuro-Urologischen Erkrankungen in Deutschland“

Liebe Patientin, Lieber Patient,
liebe Eltern,

gerne möchten wir Sie als Patienten / Eltern für diese Studie ansprechen, weil Sie / Ihr Kind die Diagnose „Spina Bifida“ erhalten haben und sämtliche Einschlusskriterien für die Teilnahme erfüllen. Diese Studie wird im Rahmen einer Doktorarbeit eines Doktoranden der medizinischen Fakultät der Rheinischen-Friedrichs-Wilhelms Universität Bonn durchgeführt.

Diese Patienteninformation soll Ihnen Zweck, Risiken und Nutzen der geplanten Studie erklären. Bitte lesen Sie sich die Information sorgfältig durch und zögern Sie nicht, auftretende Fragen zu stellen. Sollten Sie sich entschließen, an dieser Studie teilzunehmen, möchten wir Sie bitten, dies auf der letzten Seite dieses Dokumentes mit Ihrer Unterschrift zu bestätigen. Das beiliegende Duplikat ist für Ihre Unterlagen.

Ihre Teilnahme an dieser Studie ist absolut freiwillig und kann ohne Angabe von Gründen jederzeit widerrufen werden. Wenn Sie sich gegen die Teilnahme entschließen, müssen Sie keine Nachteile befürchten; ebenso wenig, wenn Sie noch nach Einreichen Ihres ausgefüllten Fragebogens Ihre Einwilligung widerrufen.

Was ist das Ziel der Studie?

Die Herausforderung, mit einer seltenen Erkrankung einen geeigneten Zugang und Versorgungsplatz in der Deutschen Krankenversorgung zu finden, soll durch diese Studie beleuchtet werden. Die Wege zu guten Versorgungs- und Behandlungsmöglichkeiten sollen so für Patienten klarer definiert werden. Aus den Erfahrungen der Betroffenen soll abgeleitet werden, wann idealerweise welcher Arzt, oder welches Fachklinikum bzw. Zentrum aufgesucht werden soll, und was die Patienten auf ihrem Weg erwartet. Eine solche Beschreibung der typischen „Patient Journey“ kann im Sinne einer patientenorientierten Versorgung einen wichtigen Beitrag zur Patientenzufriedenheit und damit zur Verbesserung der Versorgungsqualität leisten.

Ihre Teilnahme an der Studie dient der Auswertung und Analyse der Arztkonsultationen und deren Setting (ambulant/stationär) sowie der damit verbundenen Kosten. Der Fokus liegt hierbei vor allem darauf, ein genaueres Bild davon zu bekommen, wie sich die Wege im Rahmen des Behandlungsprozesses gestalten, welche Kosten damit verbunden sind, und zu welchem Zeitpunkt eine optimale und zielführende Versorgung erreicht wurde.

Wir hoffen daher, mit dieser Datenerhebung vor allem eine Sensibilisierung für den Zugang und die Versorgung von Patienten mit seltenen Erkrankungen zu schaffen sowie die Versorgung und insbesondere den Versorgungszugang zu optimieren.

Dies kann sowohl eine wertvolle Information für Patienten selbst als auch Grundlage für weitere Forschung sowie strategische Ausgestaltungen im Gesundheitssystem darstellen.

Von wem wird diese Untersuchung durchgeführt?

Die Studie wird vom Zentrum für seltene Erkrankungen Bonn der Universitätsklinik Bonn mit Beteiligung der Klinik und Poliklinik für Urologie und Kinderurologie des Universitätsklinikums Bonn sowie der Arbeitsgemeinschaft Spina Bifida und Hydrocephalus e.V. durchgeführt.

Leiter der Studie ist PD Dr. med. Martin Mücke, Arzt und Prüfarzt des Zentrums für seltene Erkrankungen der Universitätsklinik Bonn.

Sollten Sie Rückfragen haben, können Sie uns unter der Telefonnummer 0228 – 285-51472 erreichen.

Wie läuft die Studie genau ab?

1. Mit diesem Brief erhalten Sie einen Vordruck zur Einholung der Patientenquittung bei Ihrer Krankenversicherung. Die Patientenquittung gibt einen strukturierten Aufschluss über in Anspruch genommene Leistungen. Konkret wird aufgezeigt, welche Leistungen durch die verschiedenen Leistungserbringer – behandelnde Ärzte, Krankenhäuser – gegenüber Ihrer Krankenversicherung abgerechnet wurden. Hierüber besteht im Rahmen der Studie die Möglichkeit, die detaillierten Krankheitskosten zu analysieren sowie die Behandlungswege nachzuvollziehen. Für das Einholen der Patientenquittung bei Ihrer Krankenversicherung haben wir Ihnen einen Vordruck beigelegt (Gelbes Dokument). Auf dem Vordruck können Sie Ihre persönlichen Daten sowie Ihre Versicherungsnummer eintragen und anschließend das unterschriebene Schreiben in dem frankierten beiliegenden Umschlag an Ihre Krankenversicherung senden.
2. Einige Tage später erhalten Sie von Ihrer Krankenkasse Ihre Patientenquittung in Papierform per Post. Wir möchten Sie bitten, uns die Patientenquittung inkl. der beiliegenden Einwilligungserklärung zur Teilnahme an der Studie mit dem frankierten und beschrifteten Rücksendeumschlag an das Zentrum für Seltene Erkrankungen zu senden (Blaues Dokument – Unsere Exemplar).

Nachdem wir Ihre Patientenquittung sowie Ihre Einwilligung zur Teilnahme an der Studie erhalten haben, ordnen wir Ihnen ein Pseudonym (eine Buchstaben- und/oder Zahlenkombination) zu. Durch die Zuordnung des Pseudonyms stellen wir sicher, dass außer dem Studienleiter und von ihm beauftragte qualifizierte Personen keinen direkten Rückschluss auf Ihre Person ermöglicht wird.

Weiterhin werden von uns die Daten pseudonymisisert digitalisiert, sodass es uns möglich ist, statistische Analysen durchzuführen, um die Krankheitskosten zu ermitteln sowie die Patient Journey zu analysieren.

Die Daten werden ausschließlich zum Zwecke dieser Doktorarbeit sowie damit verbundener wissenschaftlicher Publikationen verwendet.

Was ist der mögliche Nutzen der Teilnahme an dieser Studie?

Die Studie dient dem wissenschaftlichen Erkenntnisgewinn. Für Sie als Patient entstehen keine direkten Vorteile im Rahmen Ihrer Behandlung, jedoch könnten die gewonnen Erkenntnisse betroffenen Patienten langfristig zu einer besseren evidenzbasierten Versorgung der Erkrankung verhelfen.

Sie können hierdurch einen direkten Beitrag zur Erforschung Ihrer Erkrankung leisten.

Was kostet Sie diese Studie?

Durch Ihre Teilnahme an dieser klinischen Studie entstehen für Sie keinerlei Kosten.

Datenschutz

- Rechtsgrundlage für die Datenverarbeitung ist Ihre freiwillige Einwilligung (Art. 6 Abs. 1 Buchst. C) DSGVO).
- Der Verantwortliche für die Datenverarbeitung ist: PD Dr. med. Martin Mücke, Leiter des Zentrums für Seltene Erkrankung Bonn (ZSEB) – Universitätsklinikum Bonn

Ihre Daten werden zu jeder Zeit vertraulich behandelt. Die Daten werden in pseudonymisierter Form an den Initiator der Studie – PD Dr. med. Martin Mücke, Zentrum für Seltene Erkrankungen (ZSEB) – bzw. von ihm beauftrage Stellen zum Zweck der wissenschaftlichen Auswertung und Versorgungsforschung weitergeleitet. Zugriff auf die personenbezogenen Daten haben nur die zuständigen Personen im ZSEB.

Pseudonmisieren bedeutet, dass die personenbezogenen Daten durch einen Nummern- und/oder Buchstabencode ersetzt werden und die Angabe des Geburtsdatums auf das Geburtsjahr beschränkt wird. Im ZSEB ist eine Liste hinterlegt, auf der die Namen den Nummern- und/oder Buchstabencodes zugeordnet sind. Diese Liste wird im ZSEB gesondert aufbewahrt und unterliegt dort technischen und organisatorischen Maßnahmen, die gewährleisten, dass die personenbezogenen Daten Ihnen durch unbefugte Personen nicht zugeordnet werden könnte. Eine Entschlüsselung der Daten erfolgt nur, um ggf. die Korrektheit der Datenübertragung zu überprüfen. Ein Zugriff auf die Liste hat der Studienleiter – PD Dr. med. Martin Mücke – bzw. von ihm beauftragte qualifizierte Personen.

Die Daten werden 10 Jahre nach Beendigung oder Abbruch der Studie aufbewahrt. Sie sind gegen unbefugten Zugriff gesichert. Sie werden gelöscht, wenn sie nicht mehr benötigt werden, um die Korrektheit der Datenauswertung nachprüfen zu können. Spätestens nach 10 Jahren werden sie gelöscht.

Zuständige und zur Verschwiegenheit verpflichtete Mitarbeiter des Initiators der Studie können, auch nachdem alle relevanten Daten bereits übermittelt wurden, Einsicht in die beim Studienzentrum vorhandenen Behandlungsunterlagen nehmen, um die Datenübertragung zu überprüfen.

Sind mit der Datenerhebung Risiken verbunden?

Bei jeder Erhebung, Speicherung, Nutzung und Übermittlung von Daten bestehen Vertraulichkeitsrisiken (z.B. die Möglichkeit, die betreffende Person zu identifizieren). Diese Risiken lassen sich nicht völlig ausschließen und steigen, je mehr Daten miteinander verknüpft werden können. Der Initiator der Studie versichert Ihnen, alles nach dem Stand der Technik Mögliche zum Schutz Ihrer Privatsphäre zu tun.

Kann ich meine Einwilligung widerrufen?

Sie können Ihre jeweilige Einwilligung jederzeit und ohne Angabe von Gründen schriftlich oder mündlich widerrufen, ohne dass Ihnen daraus ein Nachteil entsteht. Wenn Sie Ihre Einwilligung widerrufen, werden keine weiteren Daten mehr erhoben. Die bis zum Widerruf erfolgte Datenverarbeitung bleibt jedoch rechtgemäß.

Sie können im Fall des Widerrufs auch die Löschung Ihrer Daten verlangen.

Welche weiteren Rechte habe ich bezogen auf den Datenschutz?

Sie haben das Recht, vom Verantwortlichen Auskunft über die von Ihnen gespeicherten personenbezogenen Daten (einschließlich der kostenlosen Überlassung einer Kopie der Daten) zu verlangen. Ebenfalls können Sie die Berichtigung unzutreffender Daten sowie gegebenenfalls eine Übertragung der von Ihnen zur Verfügung gestellten Daten und die Einschränkung ihrer Verarbeitung verlangen.

Bei Anliegen zur Datenverarbeitung und zur Einhaltung der datenschutzrechtlichen Anforderungen können Sie sich auch an folgende Datenschutzbeauftragte wenden:

a) Datenschutzbeauftragter des Studienzentrums (Uniklinikum Bonn):
Achim Flender
Tel.: +49 (0)228-287 16075

E-Mail: achim.flender@ukb.uni-bonn.de

Sie haben ein Beschwerderecht bei jeder Aufsichtsbehörde für Datenschutz. Die landesbeauftrage für Datenschutz und Informationssicherheit Nordrhein-Westfalen – Bettina Gayk – können Sie unter folgenden Kontaktdaten erreichen:

Bettina Gayk
Kavalierstraße 2-4
40213 Düsseldorf

Telefon: 02 11 / 384 24-0
E-Mail: poststelle@ldi.nrw.de
Homepage: https://www.ldi.nrw.de

Ansprechpartner für Fragen zur Studie

PD Dr. Martin Mücke

Zentrum für seltene Erkrankungen

Uniklinikum Bonn

Venusberg Campus 1

53127 Bonn

0228-285-51472
martin.muecke@ukbonn.de

Für die Teilnahme an der oben beschriebenen Studie wären wir Ihnen sehr dankbar.

Attachment C – Application for benefit information according to §305 SGBV

Antrag auf Leistungsauskunft gem. §305 SGB V

Sehr geehrte Damen und Herren,

☐ Hiermit stelle ich einen Antrag auf Leistungsauskunft gem. §305 Abs. 1 SGB V

☐ Hiermit stelle ich einen Antrag auf Leistungsauskunft unter Angabe der abgerechneten Diagnosen gem. Art. 15 DSGVO i.V.m. §83 SGB X

Versichertendaten:

Versichertennummer: _____

Vorname und Name: _____

Geburtstag: _____

Straße und Hausnummer: _____

Postleitzahl und Ort: _____

Ich benötige eine Aufstellung aller Daten im Zeitraum:

von: *Versicherungsbeginn* bis: *heute*

- ☐ für ärztliche Behandlungen
- ☐ für zahnärztliche Behandlungen
- ☐ für Krankenhausaufenthalte
- ☐ für Arznei- und Hilfsmittelverordnungen
- ☐ für Heilmittelverordnungen
- ☐ für Hilfsmittelverordnungen

_____	_____	_____
Ort, Datum	Unterschrift	Unterschrift (Erziehungsberechtigter)

Mit freundlichen Grüßen

Attachment D – Overview sheet: Addresses of the largest German health insurance companies

AOK Rheinland/Hamburg Kasernenstraße 61 40213 Düsseldorf	AOK Baden-Württemberg Presselstraße 19 70191 Stuttgart
AOK Rheinland-Pfalz/Saarland Virchowstraße 30 67304 Eisenberg	AOK Nordwest Kopenhagener Straße 1 44269 Dortnumd
AOK Hessen Basler Str. 2 61352 Bad Homburg	Kanppschaft Pieperstraße 14-28 44798 Bochum
DAK-Gesundheit Zentrale Nagelsweg 27-31 20097 Hamburg	BARMER Axel-Springer-Straße 44 10969 Berlin
IKK – Die Innovationskasse Lachswehrallee 1 23558 Lübeck	IKK classic Tannenstraße 4b 01099 Dresden
IKK Südwest Europaallee 3-4 66113 Saarbrücken	Techniker Krankenkasse Bramfelder Straße 140 22305 Hamburg
DEBEKA BKK Im Metternicher Feld 50 56072 Koblenz	