New prescription of antihyperglycemic agents among patients with diabetes in Germany: Moderate concordance between health insurance data and self-reports

Manuela Brüne1,2,3 | Silke Andrich1,2,3 | Burkhard Haastert1,4 | Andrea Icks1,2,3
Matthias Kaltheuner5

1Institute for Health Services Research and Health Economics, Center for Health and Society, Faculty of Medicine, Heinrich-Heine-University Düsseldorf, Düsseldorf, Germany
2Institute for Health Services Research and Health Economics, German Diabetes Center, Leibniz Center for Diabetes Research at the Heinrich-Heine-University Düsseldorf, Düsseldorf, Germany
3German Center for Diabetes Research (DZD), München-Neuherberg, Germany
4mediStatistica, Neuenrade, Germany
5Specialized Diabetes Practice Leverkusen, Leverkusen, Germany

Correspondence
Manuela Brüne, Institute for Health Services Research and Health Economics, Center for Health and Society, Faculty of Medicine, Heinrich-Heine-University Düsseldorf, Moorenstraße 5, 40225 Düsseldorf, Germany. Email: manuela.bruene@hhu.de

Funding information
German Center for Diabetes Research (DZD), Grant/Award Number: no number available; institutional grant; German Diabetes Foundation (DDG), Grant/Award Number: no number available; German Federal Ministry of Education and Research (BMBF), Grant/Award Number: 01GY1133

Abstract
Purpose: To analyze the concordance of new prescription of antihyperglycemic agents between two data sources: patients' self-reports and statutory health insurance (SHI) data among patients with diabetes.

Methods: Within a cross-sectional study, 494 patients with diabetes were interviewed if and which new prescriptions of diabetes medication they received within the last 3 or 6 months. SHI data for 12 months were linked to cover these periods. For the agreement measurement, SHI data was set as reference, and kappa, positive predictive value (PPV), and sensitivity were calculated for single Anatomical Therapeutical Chemical (ATC) codes and cumulated code groups.

Results: The number of new prescriptions within 3 or 6 months was low, with 5.5% (n = 27) for Metformin/self-report being the highest. Contingency tables were unbalanced and showed large numbers in the no/no-cells. Regarding non-agreement, we found new prescriptions slightly more often in SHI data only than in self-reports only, with insulin and metformin representing an exception. Agreement results were moderate with large confidence intervals (CI). The values for cumulated “all drugs in diabetes” were: kappa = 0.58 (95% CI: 0.51-0.65), PPV = 62.0 (53.4-70.2), sensitivity = 55.6 (47.3-63.6).

Conclusions: Patients reported a low number of new prescriptions within the last 3 or 6 months. In general we found moderate agreement and in case of non-agreement that self-report no/SHI yes was slightly more frequent than vice versa. These results were based on small case numbers, but could nevertheless be considered when collecting self-reported information on the prescription of antihyperglycemic agents.

Keywords
diabetes mellitus, health, hypoglycemic agents, insurance, pharmacoepidemiology, self report, validation studies
1 | INTRODUCTION

Studies on health care provision or economic evaluations require data on the intake and the course of medication within a defined time period. Various aspects are relevant: current use, duration of intake, and starting or stopping pharmacotherapy. This information can be derived from different data sources, for instance patients’ self-reports or administrative data such as community pharmacy records or national prescription register data, health insurance data or medical records. These sources are inherently not entirely congruent because they reflect different aspects: medical records cover prescriptions issued by healthcare providers, pharmacy records cover submitted prescriptions and over-the-counter drugs, health insurance data only cover reimbursed prescriptions, and patients’ self-reports cover the intake of the medication regardless of the origin. There is no defined gold standard within the scientific community. Nevertheless, studies often collect medication information as self-reports, most likely because it best reflects actual intake in the light of the aforementioned systematic discrepancies.

Agreement studies which compare self-reports with other data sources help researchers who only have access to self-reports to interpret their accuracy and understand the reasons for deviations. These studies are particularly helpful if they consider specific medication classes with their particularities, for example antihyperglycemic agents. Numerous studies have analyzed the concordance of self-reported intake of antihyperglycemic agents with administrative data regarding current use and regular intake during the last month or during the last 2 years. In general, the reported agreement is good. However, we were unable to find any publications which focused on the concordance of either the duration or starting/stop- ping antihyperglycemic pharmacotherapy. Knowledge of concordance, especially with a focus on starting therapy, is important because misclassification of newly taken drugs might affect cost calculation within economic evaluations or the utilization of diabetes medication in epidemiologic studies. Indeed, this topic is also relevant for physicians in ascertaining a patient’s medical history from self-reports. Incorrect reports of medication history could lead to the wrong medication being prescribed in future. In this study, we have focused on new prescriptions, as this topic is particularly relevant to complement the analysis of the current intake.

The aim of our study is therefore to analyze the concordance of new prescription of antihyperglycemic agents from patients’ self-reports and SHI data among patients with diabetes.

2 | METHODS

2.1 | Study design and sample

The original cross-sectional study was initially designed to analyze the impact of different observation periods on the congruence of self-reported physician visits and those documented within statutory health insurance (SHI) data. An experimental design with two versions of the survey was used there: one with an observation period of 3 months and one with 6 months. Participants were randomly assigned to one of the two groups. Available self-reports were linked with SHI data to analyze the concordance of newly prescribed antihyperglycemic agents. The study was approved by the ethics committee of Heinrich-Heine-University Düsseldorf (study references 3455, 3595).

The survey was conducted among patients attending a specialized outpatient diabetes practice in Leverkusen, North Rhine-Westphalia from March 2011 to November 2012. We identified all eligible individuals using the following inclusion criteria based on the practice’s medical records: (a) minimum age 18, (b) clinically diagnosed diabetes, and (c) insured with “pronoVa Betriebskrankenkasse”. Exclusion criteria were: diagnosed dementia and insufficient German language skills.

Patients who met the inclusion criteria were continuously randomly selected until we had the 500 participants necessary to answer the primary research question on physician visits with sufficient statistical power. We invited patients by phone to participate in the study during their next scheduled doctor’s appointment at the practice, whereupon patients were provided with information by practice staff and had the opportunity to discuss remaining questions with the study team. After signing the consent form, they were randomly assigned to one of the two groups. Figure 1 shows our recruitment process flowchart.

2.2 | Data sources and variables

2.2.1 | Self-reported survey data

Trained research assistants with no knowledge of the patients’ medical records conducted face-to-face interviews with patients to document current medication use with a self-designed electronic case report form (eCRF). Patients were requested to bring all their currently used medication packages (brown bag method), allowing the central pharmaceutical number (Pharmazentralnummer—PZN) to be scanned and the Anatomical Therapeutic Chemical (ATC) code to be automatically assigned from a drug compendium (“Rote Liste” 2012). Where automatic assignment was not successful, the code was matched manually from various drug compendia (“Rote Liste”
"Gelbe Liste", German ATC Index 2012) using the medication name or active agent. To minimize recall bias, participants were permitted to use further memory aids, for example medication lists or prescriptions. Besides current use, each participant was also asked about their individual observation period: "Were there any changes in your diabetes medication? For example, new prescriptions or discontinued medications?" Additionally, patients filled out a questionnaire on health-related resource use and expenditure, which was developed by our working group. It included sociodemographic and socioeconomic information like gender, age, relationship status (living with/without partner) and the type of education, which was translated to the number of years of formal education according to ISCED. Furthermore, type and duration of diabetes were requested.

2.2.2 Statutory health insurance data

SHI data are routinely used for accounting purposes. After dispensation, prescription forms are forwarded by pharmacies to local pharmacy data processing centers where the information is digitally recorded for reimbursement. SHI data contain prescription and product details, in particular drug name, ATC code, and date of prescription. We analyzed data collected over the 12 months prior to the survey date for each patient. Patients were excluded from analyzes if SHI data did not cover this period.

2.3 Data linkage and definition of new prescription

Data linkage was performed on two levels. Firstly, person-specific self-reports and SHI data were matched using a unique pseudonymized identification number. Secondly, medication data were linked by 7-digit ATC code. We excluded incomplete codes containing less than 7 digits from both sources.

All complete ATC codes of antihyperglycemic medication beginning with "A10" were included in the analysis. To assess agreement for each ATC code, two dichotomous variables were generated which indicate the existence of a new prescription (yes/no) for each of the two data sources. The dichotomous variables for the self-report were taken directly from the interview data where patients reported whether they had taken newly prescribed medication within their observation period of 3 or 6 months and named them. Figure 2 shows the definition of the dichotomous variables for SHI data where new prescription is understood as at least one prescription being present during the observation period after a prescription-free period of at least 6 months. Furthermore, a new prescription also includes cases in which active agents replaced others within the same class of drugs.

2.4 Statistical analysis

Descriptive statistics are provided for sociodemographic and diabetes-related variables for the population included in the analyzes. We also described the gender and age in 2012 of participants and of individuals not included in the analyzes (non-participants and excluded persons, see Figure 1). Prescription prevalence of reimbursed antihyperglycemic agents from SHI data for the 12 months up to the survey was estimated for different ATC codes and code groups. We used all 7-digit antihyperglycemic ATC codes (single codes) present in our data for the concordance analysis. However, if for a specific ATC code less than 10 individuals with new prescriptions were observed in both data sources, the corresponding results are shown only in Table S2. We subsequently defined three code groups: all antihyperglycemic drugs (A10), insulin and analogs (A10A), and non-insulins (A10B). These code groups cover all relevant single codes as 7-digit ATC codes. Finally, we stratified the code groups by observation period.

All analyzes were performed on prescription level. The number of observation units for the code groups consists of individuals × number of cumulated single codes. For the single codes, the observation units correspond to the number of individuals.

We show numbers of new prescriptions according to both data sources. SHI data was used as reference for agreement measurement,
**FIGURE 2** Definition of new prescription as per health insurance data

1. at least one prescription within the observation period and
2. no prescription within 6 months prior to the observation period

For subsample with observation period = 3 months

For subsample with observation period = 6 months

**FIGURE 3** Definition of agreement measurements for new prescription

| New prescription as per health insurance data | Yes | No |
|---------------------------------------------|-----|----|
| New prescription as per self-report         | a   | b  |
| No                                          | c   | d  |

\[ N = a + b + c + d \]

Sensitivity = \[ \frac{a}{a + c} \]

Sensitivity measures the proportion of new prescription as per SHI data that are correctly reported by patients.

Positive predictive value (PPV) = \[ \frac{a}{a + b} \]

PPV measures the proportion of new prescription as per self-report that are correctly documented within SHI data.

Kappa-Value = \[ \frac{p_0 - p_e}{1 - p_e} \]

with \[ p_0 \] (overall concordance) = \( \frac{(a+d)}{N} \)

and \[ p_e \] (chance concordance) = \( \frac{((a+b)/(N)) \times ((c+d)/(N)) + ((c+d)/(N)) \times ((b+d)/(N))}{N} \)

Kappa measures the agreement and takes into account the possibility that the agreement is occurring by chance.

The results of all three measures range from 0 (no agreement) to 1 (complete agreement).
because some of the agreement measurements require the definition of a reference. We describe the numbers from the contingency tables and several probability measurements (sensitivity, positive predictive value (PPV), and Cohen’s kappa) with 95% confidence intervals (CI) (Pearson Clopper method). The calculation and interpretation of measurements are shown in Figure 3. Analyzes were performed using SAS 9.4. We prepared this publication according to STROBE21 and STROSA22 guidelines.

3 | RESULTS

3.1 | Sample

Out of 921 eligible persons, 494 constitute our analysis set (53.6%). Age ranged from 18 to 89 years in 2012 (mean = 59.9, SD = 14.6) with a majority of male participants (59.3%). Most of the participants (71.9%) had received up to 13 years formal education according to ISCED.19 Compared to all patients with diabetes in Germany, the proportion of type 2 diabetes was low (77%) and of type 1 high (22%). Most patients were treated with medication: 89% received antihyperglycemic drugs and 62% insulin. Non-analyzed individuals (n = 427) were slightly older (21-90 years, mean = 63.2, SD = 15.2, P = .01) and the proportion of males was lower (54.1%, P = .11).

3.2 | Prescription prevalence of reimbursed antihyperglycemic agents

Table 1 presents the prescription prevalence for antihyperglycemic agents (88.5%), insulins and analogs (62.3%) and non-insulins (52.4%) based on SHI data covering 12 months. The 3-month subgroup showed slightly higher prescription prevalence than the 6-month subgroup for all three code groups, in particular for insulins. Prescription prevalence data for all reimbursed single ATC codes are provided as Table S1. We found prescription prevalence of above 5% for 11 of 24 ATC codes. The most frequently reimbursed codes were thus metformin (44.7%, 95% CI: 40.3-49.2) and fast-acting human insulin (27.1% [23.3-31.3]).

| TABLE 1 | Description of the analyzed study population |
| --- | --- | --- | --- |
| | Full sample (n = 494) | 3-month subsample (n = 249) | 6-month subsample (n = 245) |
| Sex — n (%) | Male | 293 (59.3) | 153 (61.5) | 140 (57.1) |
| | Female | 201 (40.7) | 96 (38.6) | 105 (42.9) |
| Age — Mean (SD) | Years | 59.9 (14.6) | 59.8 (14.7) | 60.0 (14.5) |
| Duration of education — n (%) | ≤10 y | 93 (18.8) | 44 (17.7) | 49 (20.0) |
| | 11-13 y | 262 (53.0) | 139 (55.8) | 123 (50.2) |
| | 14-17 y | 118 (23.9) | 55 (22.1) | 63 (25.7) |
| | ≥18 y | 21 (4.3) | 11 (4.4) | 10 (4.1) |
| Living with a partner — n (%) | Yes | 363 (73.6) | 177 (71.4) | 186 (75.9) |
| | No | 130 (26.4) | 71 (28.6) | 59 (24.1) |
| Diabetes type — n (%) | Type 1 | 109 (22.2) | 63 (25.4) | 46 (18.9) |
| | Type 2 | 378 (76.9) | 181 (73.0) | 197 (80.7) |
| | Other type | 4 (0.8) | 3 (1.2) | 1 (0.4) |
| | Unknown | 1 (0.2) | 1 (0.4) | 0 (0.0) |
| Diabetes duration — mean (SD) | Years | 12.7 (10.7) | 13.7 (11.5) | 11.7 (9.8) |
| SHI prescription prevalence for antihyperglycemic agents — n (%) | All drugs used in diabetes (A10) | 437 (88.5) | 225 (90.4) | 212 (86.5) |
| | Insulins and analogs (A10A) | 308 (62.3) | 162 (65.1) | 146 (59.6) |
| | Blood glucose lowering drugs, excluding insulins (A10B) | 259 (52.4) | 132 (53.0) | 127 (51.8) |

*As per self-report/questionnaire.
Statutory health insurance.
Prevalence on person-level stems from SHI data covering 12 months prior to the survey.
| Drugs/groups | ATC b code | Number of ATC b codes | Observations (n) | Numbers of new prescription as per data sources | Numbers for contingency tables | Estimates of agreement (95% CI a) |
|-------------|-------------|-----------------------|------------------|----------------------------------------|-------------------------------|----------------------------------|
|             |             |                       |                  | SR c (n (%)) | SHId (n (%)) | Only SR c (n) | Only SHId (n) | None (n) | Both (n) | PPV (positive predictive value) | Sensitivity | Kappa |
| Full sample (n = 494 individuals) | | | | | | | | | | | | |
| Drugs used in diabetes | A10 e 24 | 11856 (24*494) | 137 (1.2) | 153 (1.3) | 52 | 68 | 11651 | 85 | 62.0 (53.4-70.2) | 55.6 (47.3-63.6) | 0.58 (0.51-0.65) |
| Insulins and analogs | A10A e 10 | 4940 (10*494) | 67 (1.4) | 89 (1.8) | 24 | 46 | 4827 | 43 | 64.2 (51.5-75.5) | 48.3 (37.6-59.2) | 0.54 (0.45-0.64) |
| Blood glucose lowering drugs, excl. Insulins | A10B e 14 | 6916 (14*494) | 70 (1.0) | 64 (0.9) | 28 | 22 | 6824 | 42 | 60.0 (47.6-71.5) | 65.6 (52.7-77.1) | 0.62 (0.53-0.72) |
| Insulin (human), fast-acting | A10AB01 1 | 494 | 13 (2.6) | 18 (3.6) | 4 | 9 | 472 | 9 | 69.2 (38.6-90.9) | 50.0 (26.0-74.0) | 0.57 (0.36-0.78) |
| Insulin (human), intermediate-acting | A10AC01 1 | 494 | 9 (1.8) | 10 (2.0) | 4 | 5 | 480 | 5 | 55.6 (21.2-86.3) | 50.0 (18.7-81.3) | 0.52 (0.24-0.79) |
| Insulin glargine | A10AE04 1 | 494 | 11 (2.2) | 19 (3.8) | 3 | 11 | 472 | 8 | 72.7 (39.0-94.0) | 42.1 (20.3-66.5) | 0.52 (0.30-0.74) |
| Insulin detemir | A10AE05 1 | 494 | 18 (3.6) | 22 (4.5) | 6 | 10 | 466 | 12 | 66.7 (41.0-86.7) | 54.5 (32.2-75.6) | 0.58 (0.40-0.77) |
| Metformin | A10BA02 1 | 494 | 27 (5.5) | 19 (3.8) | 13 | 5 | 462 | 14 | 51.9 (31.9-71.3) | 73.7 (48.8-90.9) | 0.59 (0.42-0.76) |
| Glimepiride | A10BB12 1 | 494 | 10 (2.0) | 11 (2.2) | 5 | 6 | 478 | 5 | 50.0 (18.7-81.3) | 45.5 (16.7-76.6) | 0.46 (0.20-0.73) |
| Sitagliptin | A10BH01 1 | 494 | 11 (2.2) | 9 (1.8) | 3 | 1 | 482 | 8 | 72.7 (39.0-94.0) | 88.9 (51.8-99.7) | 0.80 (0.60-0.99) |
| Liraglutide | A10BX07 1 | 494 | 8 (1.6) | 11 (2.2) | 1 | 4 | 482 | 7 | 87.5 (47.3-99.7) | 63.6 (30.8-89.1) | 0.73 (0.51-0.96) |
| Subsample with 3-month observation period (n = 249 individuals) | | | | | | | | | | | | |
| Drugs used in diabetes | A10 e 24 | 5976 (24*249) | 49 (0.8) | 58 (1.0) | 21 | 30 | 5897 | 28 | 57.1 (42.2-71.2) | 48.3 (35.0-61.8) | 0.52 (0.40-0.63) |
| Insulins and analogs | A10A e 10 | 2490 (10*249) | 24 (1.0) | 40 (1.6) | 9 | 25 | 2441 | 15 | 62.5 (40.6-81.2) | 37.5 (22.7-54.2) | 0.46 (0.31-0.61) |
| Blood glucose lowering drugs, excl. Insulins | A10B e 14 | 3486 (14*249) | 25 (0.7) | 18 (0.5) | 12 | 5 | 3456 | 13 | 52.0 (31.3-72.1) | 72.2 (46.5-90.3) | 0.60 (0.43-0.78) |
| Subsample with 6-month observation period (n = 245 individuals) | | | | | | | | | | | | |
| Drugs used in diabetes | A10 e 24 | 5880 (24*245) | 88 (1.5) | 95 (1.6) | 31 | 38 | 5754 | 57 | 64.8 (53.9-74.7) | 60.0 (49.4-69.9) | 0.62 (0.53-0.70) |
| Insulins and analogs | A10A e 10 | 2450 (10*245) | 43 (1.8) | 49 (2.0) | 15 | 21 | 2386 | 28 | 65.1 (49.1-79.0) | 57.1 (42.2-71.2) | 0.60 (0.48-0.72) |
| Blood glucose lowering drugs, excl. Insulins | A10B e 14 | 3340 (14*245) | 45 (1.3) | 46 (1.3) | 16 | 17 | 3368 | 29 | 64.4 (48.8-78.1) | 63.0 (47.5-76.8) | 0.63 (0.52-0.75) |

aConfidence interval.
bAnatomical therapeutic chemical.
cSelf-report.
dStatutory health insurance.
eIncludes all ATC codes beginning with the given digits.
### 3.3 Numbers and agreement of new prescription

Table 2 presents numbers of new prescription for three code groups and eight selected single codes with at least 10 new prescriptions. Data for all 24 single codes are presented in Table S2. As expected, the probabilities of new prescription for stratified code groups are higher within the longer observation period.

Table 2 also presents the numbers from the contingency tables. We found unbalanced contingency tables with large numbers of nonexistent new prescriptions (no/no-agreement). Where a new prescription appears in at least one data source, agreement (yes/yes) is usually located below non-agreement (sum of yes/no and no/yes). When focusing on non-agreement, we found a slightly higher number of new prescriptions in SHI data than in self-reports for "all drugs in diabetes" (68 vs 52). If the subcategories are taken into account, it is noticeable that this tendency tends to come from insulin (46 vs 26).

For non-insulins, however, the opposite can be seen: numbers from SHI data are lower than from self-reports (22 vs 28). Yes/yes agreement for a 6-month observation was approximately double that of a 3-month period in the subsamples for the code groups A10, A10A and A1OB. No/no-agreement remains quite similar, and non-agreement was slightly higher in a 6-month period in most cases.

Furthermore, agreement estimates are presented in Table 2. The results were found to be comparable for single codes and code groups. PPV measures the proportion of self-reported new prescription that is true positive (as occurring in SHI data). Estimates ranged from 50.0% to 87.5%. Sensitivity measures the percentage of new prescriptions according to SHI data, which are correctly reported by patients with 42.1% to 88.9%, and Kappa considers random matches and ranged from 0.46 to 0.80. Agreement seems to be moderate in general: for "all drugs in diabetes" PPV was 62.0 (53.4-70.2), sensitivity was 55.6 (47.3-63.6), and kappa was 0.58 (0.51-0.65). Some active agents had better results for PPV, sensitivity and kappa, such as metformin: 51.9 (31.9-71.3), 73.7 (48.8-90.9), 0.59 (0.42-0.76); Sitagliptin (DPP-4 inhibitor): 72.7 (39.0-94.0), 88.9 (51.8-99.7), 0.80 (0.60-0.99); and Liraglutide (Victoza): 87.5 (47.3-99.7), 63.6 (30.8-89.1), 0.73 (0.51-0.96). However, small numbers of new prescription nevertheless led to large CIs and thus imprecise estimates.

The results regarding the code groups stratified by observation period are in line with the ranges described above. Values were higher for the longer 6-month observation period, except sensitivity for A10B.

### 4 DISCUSSION

#### 4.1 Main findings and possible explanations

We compared self-reported newly prescribed antihyperglycemic medications for two different observation periods with health insurance data. Contingency tables were found to be very unbalanced, resulting in agreement estimates with limited explanatory power, likely due to the few existing cases of new prescription.

As shown by the results of the group "all drugs in diabetes", concordance was moderate in general. Sitagliptin, a DPP-4 inhibitor, and liraglutide (Victoza) seem to have better agreement values with PPV above 70%, kappa above 0.70. Additionally, sitagliptin has a sensitivity above 88%. However, it has to be considered that confidence intervals are broad, thus the estimates have to be interpreted with caution. Metformin, which has the highest prescription prevalence (SHI data), shows a high sensitivity, meaning that a high percentage of the SHI data were correctly reported by the patients. At the same time, we identified many self-reported new prescriptions for metformin that were not documented in the SHI data, resulting in a moderate PPV value. We would have expected better results for metformin, as the German guidelines for type 2 diabetes, which addresses both physicians and patients, recommend it as first-line pharmacotherapy. We therefore expected increased awareness among patients on the one hand, and on the other hand that the first medication would be remembered correctly. The moderate PPV value of metformin might also be caused by the attention that is given to metformin in the guidelines. Subjects might remember metformin, whilst they do not use it themselves. Furthermore it is conceivable that free samples of metformin are given more often than free samples of the other study drugs. For sitagliptin the agreement might be better as a guideline-recommended second-stage medication, and for liraglutide/Victoza with the special form of application as an injection.

Regarding non-concordance, we have generally found that it is somewhat more common for new prescriptions to be present in the SHI data and not in the self-report than vice versa, thus suggesting that the first mentioned type of disagreement is the greater problem in our study. For insulin self-report no/SHI yes was much more prevalent as well. For non-insulin, however, new prescriptions were more often found in the self-report but not in the SHI data, which is especially pronounced with metformin. However, our results do not allow a conclusion to be drawn as to which data source is more reliable, especially as the occurrence of opposite types of disagreement was observed at the same time and because case numbers were low. It is, however, particularly noteworthy that for the insulin group self-report no/SHI yes was more frequent, while for Metformin self-report yes/SHI no was more frequent. These results are valuable for the assessment of self-reports and SHI data. Further research can build on this. Generally, redeemed reimbursable medications such as antihyperglycemic drugs are fully reflected in the SHI data. The reliability of SHI data decreases when patients obtain their medicines from other sources, for instance free samples of new medication, hospital medication or family medicines. However, these options are usually not permanent, and SHI data can thus be considered quite reliable.

Although there is a lack of validation studies for newly prescribed antihyperglycemics, we were able to identify studies which validated current/past use of diabetes medications. Yasein et al showed for the regular intake of insulin within the previous 2 years that self-report no/medical record yes outweighs self-report yes/medical record no. However, two other publications reported this the other way round: Monster et al and Fujita et al validated insulin and/or...
Our work does, however, also have some limitations. Firstly, being a piggy-back analysis, we only had access to a relatively small amount of pregiven new prescription data. This resulted in rather imprecise estimates, as shown by large confidence intervals. Therefore, no statistical tests or model-based adjustment were performed. Nevertheless, this study does provide first estimates on a new topic and could be used to plan specific studies on self-reports of new prescriptions.

Secondly, our results are not entirely generalizable due to our sample being quite highly educated and more than half of participants (approximately 60%) male. Furthermore, our participants were recruited from a diabetic practice, where severe cases are overrepresented with high proportions of type 1 diabetes (22.2%), antihyperglycemic medication (88.5%), and insulin treatment (62.3%) even among patients with type 2 diabetes. Another reason why our results cannot be entirely generally applied to the population with diabetes as a whole is that higher prevalence for new prescription is to be expected, because: (a) the practice provides healthcare especially for newly diagnosed patients and for severe cases referred by their general practitioners for medication adjustment; (b) even type 2 patients with end-stage insulin treatment might require some medication adjustment and are part of our specific sample; (c) as per the description in the methods section, “new prescription” was defined as the prescription of a new active agent, even if prescribed as a substitution within the same medication class. For instance, changing from glimepiride to glibenclamide within the sulfonylureas is also counted as a “new prescription”.

4.3 | Implications and conclusion

Concordance between self-reported new prescription of antihyperglycemic agents and SHI data appears to be moderate. Potential disagreement should be considered where epidemiological or health-economic studies use only one of these sources. To improve knowledge of this topic, further analyzes could include more participants to achieve larger sample sizes. Additionally, medical records could be included as a third data source to incorporate all possible providers who prescribe medications in the sample.

ACKNOWLEDGEMENTS

We would like to thank Prof. Dr. Falk Hoffmann for the critical revision of the manuscript, Dr. med. Imke Schmitz-Losem for the cooperation regarding the provision of SHI data, and Jeremy Groves and Ute Linnenkamp for providing language assistance in writing the manuscript. The manuscript is not under consideration for publication elsewhere. The results have not been published or presented elsewhere. The study received funding from the German Federal Ministry of Education and Research (BMBF, No. 01GY1133), and the German Diabetes Foundation (DDS) and German Center for Diabetes Research (DZD), both funded by the German Federal Ministry of Education and Research (BMBF). The German Diabetes Center is institutionally funded by the German Federal Ministry of Health (BMG) and the

4.2 | Strengths and limitations

The major strength of our study is its innovative design. Research on agreement of self-reported intake of antihyperglycemic agents with administrative data usually focuses on current use. However, we analyzed new prescription concordance, thus taking significant changes in pharmacotherapy into account.

oral diabetes medications for current use. Patients responded to the question about taking diabetes medication with either yes or no. Our hypothesis is that the type of disagreement self-report no/other data source yes is more frequent when specific medications have to be named rather than the superordinate categories insulin/oral antihyperglycemics. This might be transferable to the results concerning new prescriptions.

In a broader perspective, in 2018 Hafferty et al. evaluated the agreement of self-reported current use (yes/no) and information from the national prescribing information system for a Scottish population-based cohort (n = 10 244). While results for insulin were better than in the present study (kappa: 0.87 (0.82-0.93), sensitivity: 1.00 (0.92-1.00), PPV: 0.78 (0.67-0.86)), the questionnaires did not inquire about specific active agents. Nevertheless, this study provides insight into pharmacy-dispensing data as a comparable data source as well as into three other medication groups which showed very good agreement for antidepressants and antihypertensives and moderate agreement for mood stabilizers.

Interestingly, within the code groups A10, A10A, and A10B the SHI-prevalence of reimbursed antihyperglycemic medications is higher for the 3-month subsample than for the 6-month sample. It would seem that a 3-month observation period is sufficient to collect nearly all relevant prescribed medications from the SHI data, and a time extension would not necessarily provide significantly more information. Indeed, a more intensive diabetes treatment within the 3-month subsample might indicate a more severe diabetes status. These differences within sample characteristics might affect the comparison of both subsamples: type 1 diabetes subjects are more frequent in the 3-month group (25% vs 19%) and diabetes duration is longer in the 3-month group (mean of 13.7 vs 11.7 years), too. More generally, the different length of the observation period could also have an influence on agreement.

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Ministry of Culture and Science of the State of North Rhine-Westphalia (MKW NRW).

CONFLICT OF INTEREST
The authors declare no conflicts of interest.

ORCID
Manuela Brüne https://orcid.org/0000-0003-0023-8513

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SUPPORTING INFORMATION
Additional supporting information may be found online in the Supporting Information section at the end of this article.

How to cite this article: Brüne M, Andrich S, Haastert B, Kaltheuner M, Icks A. New prescription of antihyperglycemic agents among patients with diabetes in Germany: Moderate concordance between health insurance data and self-reports. Pharmacoepidemiol Drug Saf. 2021;30:304–312. https://doi.org/10.1002/pds.5160