CORRESPONDENCE

Research Letter

Prescriptions of Cannabinoid Drugs, 2019–2022

A Comparison of Data from the German Federal Institute for Drugs and Medical Devices and the BARMER Health Insurance Fund

Since March 2017, it has been possible to prescribe cannabis-based medicines (CbMs) in Germany with subsequent funding by the statutory health insurance system. The Federal Institute for Drugs and Medical Devices (BfArM) conducted a survey that ran until 31.03.2022 with the purpose of classifying the risks and benefits of these medicines. It was not possible to verify whether the legally binding participation in the survey was fully adhered to by the doctors involved since their confirmation was anonymized. In their final report on the survey, the BfArM pointed out that less than one half of cases were likely to have been registered (1). In order to verify this assumption, data from the Barmer Ersatzkasse (BEK) health insurance fund was compared with that of the BfArM survey with respect to indications, age and sex of the insured patients, prescribed CbMs, and the specialties applying for funding or prescribing the medications.

Methods

A differentiated analysis of the BEK data was not possible until 01.04.2019 because until then cannabinoid formulations and processed cannabis flowers and extracts were invoiced under the same special PIP code (06460665). The BEK data therefore cover the period from 01.04.2019 until 31.01.2021. Treatment data from the survey was reported one year (12–14 months) after starting treatment. Data from 01.04.2020 until 31.03.2022 were therefore taken into account for the comparative analysis. Also included in the analysis were data on those cases where treatment was started between 01.04.2019 and 31.01.2021 but was discontinued within one year. A total of 8081 complete data sets from the survey were included in the analysis. They were transferred to the BfArM via the online survey application LimeSurvey. The survey retrieved information on demographic data, the CbM used, the specialist title of the prescribing doctors, as well as duration of treatment, side effects, and reasons for discontinuation of the medication, amongst other things. It was required that data be reported one year after the start of treatment. Where therapy was discontinued prematurely, a report was to be made to the BfArM immediately after the end of the treatment (2). The BEK analyzed the data of ensured members who had received approval for funding during the period from 01.04.2019 until 31.01.2021 (N = 6313) and who had been prescribed CbMs from 01.04.2019 until 31.01.2022 (N = 5816). The number of funding approvals by the BEK for CbMs were extrapolated by age and sex for all members of statutory health insurance funds in Germany for the year 2020 (3).

Results

Extrapolated for all the members of statutory health insurance system in Germany, around 43 974 treatments with CbMs funded by the statutory health insurance funds were started between 01.04.2019 and 31.01.2021. However, in the survey only 8081 complete reports were processed for these approved treatments.

TABLE 1

Demographic and medical data of the Barmer health insurance fund patients with prescriptions for cannabis-based medicines and the survey of the Federal Institute for Drugs and Medical Devices (BfArM)

	Barmer	BfArM
Total, N	5816	8081
Female sex	61.8 %	56.8%
Age group		
<18 years	1%	2%
18–40 years	9%	13%
41–60 years	33%	40%
61–80 years	44%	35%
>80 years	13%	9%
Cannabis-based medicines		
Dronabinol	50%	61%
Nabiximols	13%	14%
Cannabis extracts	8%	13%
Cannabis flowers	28%	12%
Nabilone	0%	0%
Applicant/prescribing specialty		
General medicine	20%	12%
Anesthesiology	24%	59%
Internal medicine	12%	7%
Neurology	6%	12%
others	39%	10%

This corresponds to a reporting rate of less than 20%. Three quarters of the prescriptions in both sample groups were written out for the age groups between 41 and 80 years. The most frequently prescribed CbM was dronabinol (BEK 50%, BfArM 61%). Cannabis flowers accounted for 20% of the applications to the BEK, while only 12% of the reports for the survey were related to cannabis flowers. The majority of the applicant/prescribing specialties for the BEK were "others" (39%) and anesthesiologists for the BfArM (59%). (*Table 1*).

The most common indication in both data sets was non-cancer pain (BEK 54%, survey 68%). The second most common indications amongst the BEK diagnoses were from oncology and palliative situations (30%) and neurological disorders amongst BfArM diagnoses (14%). The remaining indications in both data sets were predominantly diagnoses from psychiatry (tic disorders, depressive disorders) and internal medicine (chronic obstructive pulmonary disease [COPD], Crohn's disease). For all indication groups, it was noted that the larger proportion of cannabis flowers was amongst BEK-insured cases as compared with BfArM cases. The applicant/prescribing specialties also showed relevant differences: For the indication groups oncology/palliative care, non-cancer pain, and other diagnoses, the proportion for the specialty anesthesiology was lower for BEK than for BfArM and the proportion of "other" specialties was higher (*Table 2*).

TABLE 2

Demographic and medical data of the patients with an oncological or palliative primary diagnosis, with a primary diagnosis of pain, or with a primary diagnosis of a neurological disorder*

	Oncology/palliative		Non-cancer pain		Neurology	
	BEK	BfArM	BEK	BfArM	BEK	BfArM
Total, N	1771	971	3159	5515	625	1 089
Female, N (%)	1005 (56.7)	498 (51.3)	2107 (66.7)	3300 (59.8)	359 (57.4)	576 (52.9)
Age, (mean, SD)	64 (14.9)	63 (15.57)	63 (15.7)	60 (16.18)	54 (17.3)	51 (18.00)
<18 years, N (%)	19 (1.1)	11 (1.1)	11 (0.3)	36 (0.7)	21 (3.4)	63 (5.8)
18–40 years, N (%)	100 (5.6)	73 (7.5)	258 (8.2)	633 (11.5)	97 (15.5)	214 (19.7)
41–60 years, N (%)	488 (27.6)	305 (31.4)	1095 (34.7)	2281 (41.4)	267 (42.7)	499 (45.8)
61–80 years, N (%)	934 (52.7)	465 (47.9)	1322 (41.8)	2001 (36.3)	207 (33.1)	273 (25.1)
>80 years, N (%)	230 (13.0)	117 (12.0)	473 (15.0)	564 (10.2)	33 (5.3)	40 (3.7)
Cannabis drugs						
Dronabinol, N (%)	1166 (65.8)	746 (76.8)	1554 (49.2)	3380 (61.3)	270 (43.2)	554 (50.9)
Nabiximols, N (%)	108 (6.1)	44 (4.5)	501 (15.9)	756 (13.7)	149 (23.8)	259 (23.8)
Cannabis extracts, N (%)	99 (5.6)	77 (7.9)	320 (10.1)	844 (15.3)	50 (8.0)	97 (8.9)
Cannabis flowers, N (%)	428 (24.2)	102 (10.5)	1004 (31.8)	532 (9.6)	206 (33.0)	179 (16.4)
others, N (%)	10 (0.6)	2 (0.2)	10 (0.3)	3 (0.1)	2 (0.3)	0 (0)
Applicant/prescribing specialties						
General medicine, N (%)	353 (19.9)	182 (18.7)	650 (20.6)	561 (10.2)	96 (15.4)	109 (10.0)
Anesthesiology, N (%)	233 (13.2)	437 (45.0)	1085 (34.3)	3819 (69.2)	55 (8.8)	321 (29.5)
Internal medicine, N (%)	356 (20.1)	248 (25.5)	242 (7.7)	214 (3.9)	42 (6.7)	47 (4.3)
Neurology, N (%)	19 (1.1)	15 (1.5)	153 (4.8)	394 (7.1)	142 (22.7)	509 (46.7)
others, N (%)	810 (45.7)	89 (9.2)	1029 (32.6)	527 (9.6)	290 (46.4)	103 (9.5)

*The category "others primary diagnosis" is not included in the *Tables*. BEK, Barmer Ersatzkasse health insurance fund; BfArM, Federal Institute for Drugs and Medical Devices

Discussion

The results of the present study allow an estimation of the degree of underreporting in the survey data as originally suspected by the BfArM. It is about 80% and relates primarily to the missing reports of treatments with cannabis flowers by specialists in general medicine and other family doctors, as well as reports from the indication group oncology/palliative care. The opportunity was therefore missed to generate important data on the use of CbMs. Clinical data are particularly missing on inhaled cannabis flowers which have a higher potential for abuse in comparison with cannabis-based formulated medicinal products or cannabis-based extemporaneous products (4).

The study has the following limitations: Differences in recording the diagnoses and the lack of verifiability of data entries limit the comparability of both data sets. Furthermore, the category "others" (prescribing specialties) for BEK is based on the very high proportion of funding applications by hospital outpatient clinics, which limits allocation of the observed underreporting during the survey to individual specialties.

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Conflict of interest statement

Frank Petzke is spokesperson of Ad-hoc Commission "Cannabis in Medicine" and advisory board member of the German Pain Society. He receives reimbursement of travel expenses and conference fees from the German Pain Society.

Winfried Häuser is a member of the Ad-hoc Commission "Cannabis in Medicine" of the German Pain Society and spokesperson of the working group of the European Pain Federation for drawing up a position paper on appropriate use of cannabis-based medicines and medicinal cannabis for chronic pain. He receives reimbursement of travel expenses and conference fees from the German Pain Society and the European Pain Federation.

The other authors declare that no conflict of interest exists.

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