Original paper

Chronic Respiratory Disease

Chronic Respiratory Disease
Volume 17: 1–9

DOI: 10.1177/1479973120964814
journals.sagepub.com/home/crd

SAGE

The quality of COPD care in German general practice—A cross-sectional study

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Abstract

Objectives: Chronic Obstructive Pulmonary Disease (COPD) is a common health problem to be dealt with in primary care. Little is known about the quality of care provided for patients with COPD in Germany. Therefore, we wanted to assess the current quality of care delivered by a primary care network (PCN) for patients with COPD. **Methods:** A cross-sectional study was conducted in collaboration with a primary care network (PCN). All patients of the PCN aged 40 years and older with a diagnosis of COPD were identified through electronic health records (EHR). A set of quality indicators (QIs) developed in accordance with current COPD-guidelines were appraised through numerical data retrieved from the EHR. **Results:** In total, 2,568 patients with COPD were identified. Their mean age was 67 (SD ± 12) years, 49% were male. Thirty-five percent had a parallel diagnosis of asthma. There was no documentation of any spirometry for 54% of patients; 29% had a spirometry within the previous year. An influenza vaccination was documented for 37% within the preceding 12 months; 12% received a pneumococcal vaccination in the last 6 years. Smoking status was documented for 44% within the last year. **Conclusion:** The quality of care for patients with COPD in the PCN seemed suboptimal, despite the presence of a Disease Management Program (DMP). This finding is likely to apply widely to German general practice. Quality assessment through currently available EHR data was challenging due to non-standardized and insufficient documentation.

Keywords

Pulmonary disease, chronic obstructive, general practice, quality of health care, practice guideline, documentation

Date received: 15 July 2020; accepted: 18 September 2020

Introduction

Chronic Obstructive Pulmonary Disease (COPD) is a major health problem in most industrialized countries. In 2010, it affected around 8% of the German population and it is expected that prevalence will increase to around 10% by 2030.[1] On an international scale, COPD care frequently does not comply with clinical practice guidelines' (CPG) recommendations[2,3] and there is a lack of knowledge regarding the quality of care delivered to patients with COPD in Germany.

The idea of controlling or managing doctors and the quality of care they deliver is not new.[4] In the

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Table 1. Definition for a long-term patient with regular practice visits, definition for a patient with COPD.

Definition for a long-term patient with regular practice visits	Definition for a patient with COPD
≥40 years of age insured with a German statutory health insurance first patient–doctor contact in a general practice of the GPN ≥24 months prior to the date of data extraction ≥5 patient–doctor contacts to GPs from the GPN ≥1 patient–doctor contact in a general practice of the GPN within 12 months before the date of data extraction	≥40 years of age ≥3 documentations of a COPD diagnosis (i.e. an ICD-10-GM-code starting with "J44.") within 24 months before the date of data extraction

United Kingdom (UK), Clinical Governance (CG) has been widely implemented as a "top-down" procedure in both general practice and in-patient care.[5] The attainment of predefined quality marks based on recommended clinical pathways in general practice was linked to financial incentives in the "Quality and Outcomes Framework" (QOF). Although CG is widely unknown in Germany, German general practice also experienced a "top-down" tightening of regulations with regard to quality assurance since the turn of the millennium. In 2006, a Disease Management Program (DMP) for COPD was introduced, aiming at standardizing and improving care, and cutting down health care expenses. This is sought to be achieved by encouraging regular follow-up visits, GP training, patient education, standardized electronic documentation offering performance feedback and benchmarking, and other measures. Both DMPs and QOF represent a form of governing intrusion by politics into the GPs' professional independence making them accountable for high(er) quality services.

In a research project we approached the implementation of CG in German general practice. However, instead of a "top-down" strategy we rather aimed for a "bottom-up" approach, by engaging GPs in the implementation of CG as part of their professional duties such as self-reflection and taking control over their field of work.[6] After having conducted a pilot trial in a practice attached to the Institute for General Practice of the University of Erlangen (results submitted June 24, 2020 to *Zeitschrift für Allgemeinmedizin* (German), transl. Journal for General Practice) we wanted to test its feasibility in a larger network of practices. The principal aim of this study was to assess the current quality of COPD care in a higher number of German general practices. Firstly, quality indicators (QIs) were derived from different Clinical Practice Guidelines (CPGs). These were then appraised through numerical data retrieved from the EHR, to find out how many of the cases of COPD fulfilled the individual quality criteria.

Methods

A cross-sectional study design was chosen to assess COPD care quality with the means of QIs.

Practice recruitment

We approached a primary care network (PCN) in the region of Franconia that is managed centrally and is using a common EHR software with central data storing. The PCN comprises around 25 practices in rural, suburban and urban areas, with more than 75 physicians who are either specialized in general practice/general internal medicine or in other specializations. Patients treated exclusively by specialist doctors were not considered.

Study population

Our analysis was based on billing codes within the German statutory health insurance system for publicly insured patients which involves approximately 87% of the German population.[7] Only long-term patients with regular practice visits were included, if they met the following three criteria (Table 1): 1) The first doctor-patient contact in a general practice of the PCN had taken place 24 months prior to the date of data extraction or earlier. 2) There were at least five doctor–patient contacts to GPs of the PCN. 3) At least one doctor–patient contact in a practice of the PCN had occurred within twelve months before the date of data extraction. In Germany, coding of all diagnoses with the German Modification of the 10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10-GM) is mandatory for quarterly billing purposes.[8] A patient was

Table 2. Descriptions of ICD-10-GM diagnoses for COPD with FEV1 values.

ICD-10-GM-code	Definition	additional digit for ICD-10-GM-code specifying degree of COPD	FEV1 (% predicted)
J44.0	Chronic obstructive pulmonary disease with acute lower respiratory infection	0	<35%
J44.1	Chronic obstructive pulmonary disease with acute exacerbation, unspecified	1	≥35% but <50%
J44.8	Other specified chronic obstructive pulmonary disease	2	≥50% but <70%
J44.9	Chronic obstructive pulmonary disease, unspecified	3	≥70%

Notes: The ICD-10-GM-code specifies the type of COPD. The additional digit is added to the ICD-10-GM-code classifying COPD-severity on the basis of FEV1 values.
Example: "J44.83" represents an "other specified chronic obstructive pulmonary disease" with the patient's FEV1-value being greater than or equal to 70% of the FEV1 predicted. Consequently, this code can only be assigned if the patients' current FEV1 value is known.

defined as "patient with COPD" if he/she had at least three documented diagnoses of COPD in his/her EHR within 24 months before the date of data extraction (Table 1). As COPD is uncommon in young patients only patients aged ≥40 years were included.

Selection of QIs

The QIs applied were derived from both current German and international CPG recommendations as well as from relevant publications (A list of the CPG and publications can be obtained from the corresponding author). These were identified through a literature search within CPG databases, namely the Scottish Guidelines International Network (G-I-N), the American former National Guideline Clearinghouse (NGC), the British National Institute for Health and Care Excellence (NICE) and the Scottish Intercollegiate Guidelines Network (SIGN), on PubMed and Google Scholar, and by reference tracking. The authors discussed and agreed on a set of 17 QIs for this study (Table 3, column "QI"), focusing on various aspects of COPD care. For each QI, both absolute and relative frequencies were calculated. Except for the QIs regarding therapy (QI #13-QI#15, Table 3), a lower percentage clearly corresponded to a lower quality of care and vice versa (Table 3, column "Percentage").

Data collection

Data extraction was performed by the PCN's IT-personnel with the remote support of our research staff. Since the EHR software of the PCN did not offer sufficient options for data retrieval itself, the PCN's IT-personnel directly accessed the EHR database using SQL (Standardized Query Language). QIs were "translated" into electronic SQL queries for the identification of patients with COPD, the grading of the severity of the disease and the detection of comorbid diseases like asthma. For the assessment of the number of patient–doctor contacts and the identification of performed diagnostic and therapeutic procedures billing codes were used. Prescribed medication is automatically coded with the Anatomical Therapeutic Chemical (ATC) classification in the electronic prescribing process. By applying these search queries, we were able to gain the information needed for the determination of 11 QIs (Table 3). For the remaining six QIs, a free-text search was conducted. Grading of disease severity according to the German National Guideline for COPD follows the old Global Initiative for Chronic Obstructive Lung Disease (GOLD) definitions based on FEV1 values, without the A-D assessment of the current GOLD-guideline.[9] Furthermore, the FEV1 cut-off values for the grades of COPD-severity, as defined by ICD-10-GM are different from those given in the national CPG,[9] the difference being small though and maybe unimportant (Table 2). The A-D assessment is taking clinical measures like exacerbations and symptoms into account, using mMRC (modified British Medical Research Council dyspnea scale) or CAT (COPD Assessment Test) scores.[10] To find out whether these scores had been used to assess patients with COPD, the EHR were searched for these terms as a letter string. Definitions for the free-text based searches can be found in the column "Alternative definition of numerator" in Table 4.

Table 3. QIs for COPD.

#	QI	Definition of numerator*	Value of numerator*	Percentage+
1	COPD confirmed by PBD spirometry	all patients with COPD ≥40 years with at least one documentation of post-bronchodilator spirometry (ever)	*not extractable*	
2	Ever spirometry	all patients with COPD ≥40 years with at least one documented billing code for spirometry (ever)	1182	46%
3	Recent spirometry	all patients with COPD ≥40 years with a billing code for spirometry documented at least once within the last 12 (24) months	756 (927)	29% (36%)
4	Detailed ICD-10-GM diagnosis	all patients with COPD ≥40 years with at least one documented ICD-10-GM code, that takes FEV1-values into account§	735	29%
5	DMP-participation	all patients with COPD ≥40 years who are enrolled in the DMP for COPD and appear for their scheduled follow-up appointments regularly	776	30%
6	Influenza vaccination	all patients with COPD ≥40 years with a billing code for influenza vaccination documented at least once within the last 12 (24) months	951 (1116)	37% (43%)
7	Pneumococcal vaccination	all patients with COPD ≥40 years with a billing code for pneumococcal vaccination documented at least once within the last 72 months	318	12%
8	Smoking status	all patients with COPD ≥40 years with at least one documented smoking status within the last 12 (24) months	*not extractable*	
9	Smoking cessation advice	all smoking patients with COPD ≥40 years with at least one documentation about given smoking cessation advice within the last 12 (24) months$	*not extractable*	
10	Assessment of inhaler technique	all patients with COPD ≥40 years with at least one documentation about an assessment of their inhaler technique within the last 12 (24) months€	*not extractable*	
11	Height/weight/ BMI	all patients with COPD ≥40 years with at least one documentation of either their body height and weight or their BMI within the last 12 (24) months	*not extractable*	
12	mMRC or CAT	all patients with COPD ≥40 years with at least one documentation of a conducted COPD assessment (mMRC or CAT) in the last 12 (24) months	*not extractable*	
13	Inhaled medications	all patients with COPD ≥40 years with at least one prescription of inhaled medications within the last 12 (24) months	1053 (1288)	41% (50%)
14	(Any) bronchodilator	all patients with COPD ≥40 years with at least one prescription of an inhaled bronchodilator within the last 12 (24) months	990 (1238)	39% (48%)
15	ICS therapy	all patients with COPD ≥40 years with at least one prescription of an ICS (or another ICS-containing drug) in the last 12 (24) months	599 (736)	23% (28%)
16	Patient medication scheme provided	all patients with COPD ≥40 years for whom a patient medication scheme was newly documented or updated within the last 12 (24) months	1238 (1238)	48% (48%)
17	Patient education program	all patients with COPD ≥40 years with a billing code for the patient education program documented	9	<1%

Notes: Percentages in this table are rounded to whole numbers. Values and percentages shown in parentheses refer to the different time periods within the column "Definition of numerator" which are also presented in parentheses.

* **Definition of denominator: all patients with COPD ≥40 years; Value of denominator (*n*) = 2568**; + Result of the fraction "(numerator/denominator) x 100"; § for details see section "Selection of quality indicators" and Table 2; $ denominator for QI #10 = all *smoking* patients with COPD ≥40 years; € denominator for QI #11 = all patients with COPD ≥40 years with inhaled medications; it must be noted that for QI #13-15 a higher percentage does not clearly correspond to a higher quality of care

Abbreviations: # = number, ATC-Code = code according to the Anatomical Therapeutic Chemical Classification System, BMI = body mass index, CAT = COPD assessment test, COPD = chronic obstructive pulmonary disease, DMP = disease management program, FEV1 = forced expiratory volume in 1 s in spirometry, ICD-10-GM = International Statistical Classification of Diseases and Related Health Problems (German Modification), ICS = inhaled corticosteroid(s), mMRC = modified British Medical Research Council, PBD = post-bronchodilator, QIs = quality indicators

Table 4. QIs for COPD—alternative searches.

#	QI	Alternative definition for numerator (based on free-text/hybrid searches)$	Value of numerator$	Percentage+
1	COPD confirmed by PBD spirometry	n/a	*still not extractable*	
8	Smoking status	all patients with COPD ≥40 years with at least one documentation of the German terms for "smok*," "tobacco," "cigar*," "pack years or "PY" and/or the ICD-10-GM code "F17." within the last 12 (24) months §	1118 (1144)	44% (45%)
9	Smoking cessation advice	n/a	*still not extractable*	
10	Assessment of inhaler technique	n/a	*still not extractable*	
11	BMI/height and weight	all patients with COPD ≥40 years with at least one documented value of a BMI (or a combination of height and weight) within the last 12 (24) months	156 (256)	6% (10%)
12	mMRC or CAT	all patients with COPD ≥40 years with at least one free-text documentation of the term "mMRC" and/or the term "CAT"§	1 (1)	<1% (<1%)

Notes: Percentages in this table are rounded to whole numbers. Values and percentages shown in parentheses refer to the different time periods within the column "Alternative definition for numerator" which are also presented in parentheses.
$ **Definition of denominator = all patients with COPD ≥40 years; Value of denominator (*n*) = 2568**; + Result of the fraction "(numerator/denominator) × 100"; § for details see section "Data collection and analysis"
Abbreviations: # = number, BMI = body mass index, CAT = COPD assessment test, COPD = chronic obstructive pulmonary disease, ICD-10-GM = International Statistical Classification of Diseases and Related Health Problems (German Modification), mMRC = modified British Medical Research Council, PBD = post-bronchodilator, QIs = quality indicators

Extracting information about patients with COPD enrolled in the German DMP for COPD was not possible as the electronic DMP-form being completed after a DMP consultation, is not accessible within the regular EHR software. As DMP-forms are filled in by non-physician staff based on the information in the EHR, it can be presumed, that DMP documentation does not contain more information than routine EHR documentation.

Results

Data extraction was conducted on January 17, 2019 identifying a total of 20,993 long-term patients (≥40 years of age) with regular practice visits for the entire PCN. Of these patients, 2,568 (12%) fulfilled our inclusion criteria (see "Study population" and Table 1).

Patient characteristics and documentation of coded diagnoses

Investigated patients with COPD (≥40 years) had a mean age of 67.2 (SD ± 12) years; 49% of them were male. COPD was not documented as long-term diagnosis (in the problem list) in 73% of patients with COPD. An additional diagnosis of asthma could be found in 35% of patients with COPD. For 25% of the patients an ICD-10-GM code for an acute exacerbation of COPD was documented at least once within the previous 24 months.

Quality indicators

Numerical data allowing for the descriptive analysis of the QIs were available for 9 of the 17 QIs (Table 3). In 1,182 (46%) of the 2,568 cases with COPD a spirometry was at least once documented in their EHR. A specific ICD-10-GM diagnosis for the grade of COPD that takes the FEV1-value of a previous spirometry into account (see example in table caption of Table 2) was found in 735 (29%) patients (QI #4). Enrolment in the DMP for COPD and regular appearance for the DMP follow-up visits (at least half-yearly) was documented for 776 (30%) patients (QI #5). Inhalable medication (irrespective of the sort of drug and the number of prescriptions) was prescribed to 1,053 (41%) patients with COPD in the preceding twelve months (QI #13), 990 (39%) of which received any bronchodilator (QI #14) (including monotherapy and

fixed combinations) and 63 (2%) of which received inhalable corticosteroid (ICS) only (monotherapy).

The results of the remaining six QIs, are based on free-text or hybrid searches. Nevertheless, we were only able to obtain numerical values for three of the six remaining QIs. The QIs "COPD confirmed by post-bronchodilator spirometry" (QI #1), "Smoking cessation advice given" (QI #9) and "Assessment of inhaler technique" (QI #10) could not be conclusively extracted from the EHR (Table 3 and Table 4).

Documentation of smoking status could be found in 1,118 (44%) of the 2,568 patients with COPD within the previous twelve months (QI #8). The body mass index (BMI) or a combination of height and weight (allowing for the post hoc calculation of the BMI) was documented for 156 (6%) of patients with COPD in the last year (QI #11). Text sections within the EHR indicating that an assessment of COPD symptom severity was conducted using mMRC or CAT were found for 1 (<1%) COPD patient in the previous twelve months (QI #12).

Discussion

Our analysis revealed insufficient quality of COPD care in the PCN which is probably representative for other German GP practices, despite the existing DMP COPD. Because of shortcomings of documentation quality, assessment of some QIs was challenging. Overall, the EHR software does not adequately support standardized documentation and hence data analysis.

Quality of care

Concerning COPD care quality, two published cohort evaluations of the DMP COPD revealed an improvement in adherence to guidelines[11,12] but also mentioned the problem of any DMP-evaluation, namely participation bias, with motivated patients being more likely to participate and less likely to drop out of DMPs. Knowing that only about 10% of all the patients with COPD are enrolled,[12] highlights the importance of improving the care process, irrespective of enrollment in this program.

To estimate the room for improvement, we compared certain QI results internationally. For the diagnosis of COPD, spirometry is mandatory. Moreover, for patients with confirmed COPD, spirometry is recommended to be repeated yearly.[10] The proportion of patients in our study who ever had a spirometry documented was only 46%. This low number seems not to be limited to Germany. The corresponding numbers are 11.7% for Austria[13] and 60.9% for Italy.[14] In our study, spirometry had been performed in 29% of patients with COPD within the preceding year. A US study revealed this number to be 35.5%[15] and in Switzerland it was 51%, even outside an integrated care program.[3] Because treatment should follow the grade of disease severity, its determination and documentation is necessary. We found only 29% of patients with COPD to be classified according to disease severity with ICD-10-GM. Other studies found documentation of FEV1-based GOLD grades in 48% (USA) (15) and 72% (Switzerland).[3] The use of mMRC or CAT scores, part of the more recent GOLD grading, was found for <1% of patients with COPD. The German DMP for COPD includes electronic documentation asking for the latest FEV1 value but strangely not for the grade of disease severity. To what extent knowledge of the FEV1 value alone, without translating it into a disease severity code, is influencing grade-adjusted prescribing is unclear. Within the COPD DMP also many items regarding general health such as blood pressure, openness to healthy diet counseling and the evaluation of the risk for osteoporosis, are evaluated. It seems like the German DMP could put a stronger emphasis on the core areas of COPD care.

The QIs of treatment revealed a comparably low performance level as the diagnostic ones.

Influenza vaccination. Most CPG recommend a yearly influenza vaccination for patients with COPD.[9,16] In our study only 37% had received it in the previous twelve months, which is low compared to the vaccination rate in an Italian (44.2%),[14] a Swiss(49%)[3] and a Welsh 66.0%[17] study.

Smoking. Knowing that only smoking cessation can slow down the course of COPD (10), smoking cessation counseling probably is the most important treatment. A proxy for counseling might be the repeated documentation of smoking status. We perceive the fact that many German EHR software systems lack an entry field for the documentation of smoking status as remarkable in itself. Still, in our study approximately 44% of patients with COPD had their smoking status documented in some form within the last year. Other countries seem to achieve higher rates: 77.4% of Welsh patients with COPD had their smoking status documented in the preceding 15 months.[17] In a Danish study, it was found for 92.1% of patients with COPD in general practice[2] and a Swiss study even reported a rate of 95%.[3]

Inhalable medication

The description of the QIs concerning inhalable medication needs some interpretation. Twenty-three percent of patients with COPD received an ICS (as mono- or in combination therapy) within the last year. As we were not able to assess the disease severity grade and 35% of the patients had both diagnoses COPD and asthma documented, it was not possible to determine whether ICS treatment in these patients was adequate. A small number (2%) received an ICS in monotherapy in the last twelve months, although there is no indication for ICS monotherapy in COPD. Either these patients are treated incorrectly or the diagnosis COPD is wrong and should have been asthma instead. We assume that many of the 23% of patients in our study treated with ICS are overtreated. This assumption is strengthened by a recently published German study, in which a cohort of patients with COPD was classified according to the most recent GOLD grades (with A-D assessment). A comparison between their actual medication and the GOLD recommendations revealed that "two thirds of German patients with COPD received an ICS which . . . was not indicated in about half of these cases . . . ."[18]

Quality of documentation

Despite the additional application of alternative search queries, three of 17 QIs could not be determined. Thus, regarding the QI "COPD confirmed by post-bronchodilator spirometry" it remains unclear whether there is only poor documentation (partly caused by the missing option to diagnose asthma-COPD-overlap-syndrome in ICD-10) or also lacking diagnostic differentiation with the double diagnosis asthma and COPD. Seventy-three percent of patients with the diagnosis of COPD reported three times in the last 2 years (inclusion criteria), didńt have the diagnosis documented in his/her problem list. Notwithstanding this uncertainty about the extent to which lacking standardization of the EHR is hampering the process of care in daily practice, this lack itself calls for improvement in structure quality. An electronic checklist might serve as a reminder for important elements of care and as a quick means of structured documentation leading to good quality data at the same time. A good EHR should provide an opportunity to enter structured information and offer physicians hands-on feedback, comparable to the pop-up system for missing Quality and Outcomes (QOF) indicators in the UK. However, this top-down clinical governance was shown not to result in better mortality outcomes.[19] As patients with the most complex needs are more likely to be excluded from the scheme, a probably considerable participation bias complicates evaluations, as mentioned earlier for the German DMPs. Furthermore, some doctors in the UK may feel deprived of their professional freedom and argue that the QOF created perverse incentives.[20] Therefore we hypothesize that a "bottom-up" approach tailored to what motivates GPs to optimize their care for chronic patients and with the necessary amount of process-ownership, with a sustaining EHR, might be the way to go.

Strengths and limitations of this study

To our knowledge, this is the first study in Germany using a large number of routine data directly derived from EHR for the evaluation of COPD care quality in general practice. Another strength can be seen in the fact that a large number of long-term patients with COPD were included, irrespective of their DMP enrollment. However, there are also a number of limitations. As stated in the quality of documentation section above, documentation may have been incomplete or incorrect. Although missing documentation is not necessarily equal to low performance, this limitation needs to be acknowledged. In Germany patients do not need a referral from their GP to seek specialist care and without referral the GPs do frequently not receive a medical report from the specialist. Reports mostly arrive via fax and are incorporated into the EHR in a pdf-format making electronic search for the relevant data impossible. Thus, some procedures (e.g. spirometry) may have been performed more often than reported in this study. Although the majority of DMPs is carried out by GP practices, few of them are even exclusively managed by pulmonologists (1–2%) and other specialists (1–2%).[11] A final weakness may be the limited generalizability of our results. Not only did we analyze general practices from just one region but also these general practices were employed in the same PCN whereas usually GPs in Germany are self-employed, many of them still in single handed practices.

Conclusion

Even with the limitations of data quality taken into account our study clearly seems to reveal suboptimal COPD care in the German general practice. The fact of non-standardized and incomplete documentation in

EHR can be seen as a major indicator of insufficient quality of care in itself. Our findings highlight the need for better EHR software that contributes to both, better electronic documentation and thereby improved COPD care.

Acknowledgements

The authors want to thank the PCN which wishes to remain anonymous as well as its IT

Author contributions

SH, AS and TK conceived and designed the study. SH conducted the literature search. SH, ES, AH, KS and ML extracted, analyzed and interpreted the data. SH, ES and TK wrote the manuscript. AS and LF revised the manuscript. All authors read and approved the final version of the manuscript.

personnel for the good cooperation.

Declaration of conflicting interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: SH, ES, LF, AH, KS, AS and TK declare no competing interests. ML is both a doctoral candidate at our Institute for General Practice and an IT-specialist employed by the PCN. Although he wasn't involved in the study design, influence in the data extraction process could not be completely excluded. Considering the results of our study this seems rather unlikely though. ML declares no competing interests, as do all other authors.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: The study was funded through the regular budget of the Institute of General Practice (Universitätsklinikum Erlangen, Erlangen, Germany).

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