

Pharmaceutical Care in Community Pharmacies: Practice and Research in Germany

Christiane Eickhoff and Martin Schulz

OBJECTIVE: To discuss the provision of pharmaceutical care in community pharmacies in Germany including community pharmacy, organization and delivery of health services, pharmacy education, community pharmacy services, research in community pharmacy, and future plans for community pharmacy services.

FINDINGS: In Germany, cognitive pharmaceutical services have been developed for more than 12 years. Several studies and programs have shown that pharmaceutical care and other pharmaceutical services are feasible in community pharmacy practice and that patients benefit from these services. In 2003, a nationwide contract was established between representatives of the community pharmacy owners and the largest German health insurance fund. In this so-called family pharmacy contract, remuneration of pharmacists for provision of pharmaceutical care services was successfully negotiated for the first time. In 2004, a trilateral integrated care contract was signed that additionally included general practitioners, combining the family pharmacy with the family physician. Within a few months, the vast majority (>17 000) of community pharmacies have registered to participate in this program.

CONCLUSIONS: German community pharmacies are moving from the image of mainly supplying drugs toward the provision of cognitive pharmaceutical services.

KEY WORDS: community pharmacy services, Germany, health services, pharmaceutical care, pharmacy practice.

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This article discusses community pharmacy-based pharmaceutical care services and research in Germany. It aims at providing information for comparison with pharmacy practice in other countries, as well.

In Germany, community pharmacy is a major component in the healthcare system for a population of more than 82 million.¹ There are approximately 21 400 community pharmacies, each serving, on average, 3900 inhabitants.² Ownership of a pharmacy is restricted to pharmacists and, until 2004, each pharmacist was permitted to manage only one pharmacy; however, that number is now 4. In Germany, there is no restriction on the number and distribution of community pharmacies. To operate a pharmacy, a license (Apothekenbetriebslaubnis) is required. Requirements that must be met by a pharmacist to get that license are stipulated by § 2 Apothekengesetz (German Pharmacy law³).

A typical German community pharmacy is about 170 m² and employs 6.4 persons including the owner.⁴ In total, nearly 137 000 people are working in community pharmacies including approximately 46 000 pharmacists.² The average turnover is about €1.5 million (\$1.8 million USD) not including the value-added tax (VAT) of 16%.² Median turnover amounts to €1.1 million (\$1.4 million), not including VAT. Therefore, the turnover of two-thirds of all pharmacies is below the average value of €1.5 million (\$1.8 million).

A community pharmacy in Germany is a service enterprise in which customers' needs have the highest priority. In addition to dispensing drugs (by prescription or self-medication), community pharmacies provide information about the effects, dosing, application, possible adverse effects, and interactions of drugs. This is complemented by advice given on lifestyle and healthy living for populations such as children, pregnant women, nursing mothers, and disabled persons.

Author information provided at the end of the text.

In Germany, a strict distinction is drawn between drugs that are available only in pharmacies (including prescription-only and pharmacy-only drugs) and freely available medicines, that is, general sales list (GSL) or free-trade over-the-counter (OTC) drugs, also sold by chemists and supermarkets, among others. Hence, there is a wide-ranging monopoly on medicines for pharmacies, (§ 1 Apothekenengesetz³).

The volume of prescribed medicines in 2004 paid for by statutory health insurance funds, that is, Gesetzliche Krankenversicherung (GKV), private insurers (PKV), and others was €25.1 billion (\$30.7 billion), and the total turnover in German pharmacies amounted to €32.5 billion (\$39.8 billion) excluding VAT.² The ratio of prescription sales to nonprescription sales in German pharmacies is about 80:20 on average.^{2,5} The nonprescription category (22.8% of turnover in 2004) consists primarily of OTC products (15.4% in 2004), but also includes non-pharmaceuticals as well as supplementary products.²

Supplementary goods sold in pharmacies in addition to drugs/medicines are governed by § 25 of the Ordinance on Pharmacies (Apothekenbetriebsordnung,⁶ comparable to a code of ethics). These are, among other items, bandages, infant care goods, medical, dental, and veterinary instruments, means and items of hygiene and body care, and health- and illness-related books and brochures. This supplementary range of goods customarily sold in pharmacies contributed to 3.4% (€1.1 billion, \$1.4 billion) of the pharmacies' turnover in 2004,² whereas another 4% (€1.3 billion, \$1.6 billion) was attributable to nursing care items and other goods.

In 2004, more than 14.5 million individually prepared formulations (extemporaneous preparations) were dispensed in German pharmacies (turnover €1.1 billion, \$1.4 billion). Of this total, 8.6% of the formulations contained cytostatic agents and amounted to 61% of turnover.

Free-trade OTC drugs (GSL) sold in pharmacies amounted to 2.5% (€0.8 billion, \$1.0 billion) of the turnover in 2004. The turnover of free-trade OTC drugs sold outside pharmacies was €0.4 billion (\$0.5 billion).

In Germany, the government sets the framework of pharmaceutical legislation, including laws and ordinances. As far as the overall reimbursement of community pharmacies is concerned, the government decided on dispensing fees instead of margins based on the drug price. This came into effect in January 2004. So far, nothing is regulated by the government regarding the remuneration of additional cognitive services.

Drugs and pharmaceutical services for nursing/elderly homes are also supplied by community pharmacies. These pharmacies must establish contracts with the nursing homes. Regular monitoring of drug storage, as well as documentation of all drugs provided, must be part of the contract.

Organization and Delivery of Health Services

Germany's health system and health policy aim to reduce deaths, extend people's active and healthy lives, and ensure the best possible quality of life for all. The GKV is made up of approximately 260 individual health insurance funds. Up to a certain level of income, membership in the GKV is obligatory. Once this income level is exceeded, employees may insure themselves privately (PKV).

The GKV charges contributions from their members. These contributions amount to a certain percentage of the member's income, currently approximately 13% of one's gross income, and is currently paid by employee and employer, each paying half. Family members without an income of their own are also insured and are exempt from paying a contribution.

All out- and inpatient medical and dental care, as well as drugs (with some exceptions, eg, "negative-list" drugs, patient minimum prescription fees, so-called lifestyle drugs, eg, nicotine replacement therapy, drugs for erectile dysfunction, or anti-obesity drugs) and other medicines and medical devices required and prescribed by a physician are paid for by the GKV and PKV.

In 2004, total expenditures of the GKV were about €140 billion (\$171 billion). About half was spent on hospitals (34.0%) and physicians (16.4%). Expenditures on drugs were 14.5%. PKV had total expenditures of €27 billion (\$33 billion) in 2003.⁷ Total health expenditure in Germany amounts to 10.9% of the GDP⁸ (data from 2001).

The primary organization of all pharmacists in Germany is the ABDA—Federal Union of German Associations of Pharmacists, located in Berlin. The ABDA is comprised of 34 member organizations. These are 17 state chambers of pharmacists being responsible for professional interests. Membership is mandatory for all pharmacists. In the remaining 17 pharmacists' associations, only community pharmacy owners may apply for membership on a voluntary basis. More than 90% of German community pharmacy owners are members of these associations representing their economic interests. These associations are negotiating with other representatives in self-administration (eg, insurance companies) to achieve remuneration for pharmacists for provision of pharmaceutical care on a state or national level (Deutscher Apothekerverband, DAV).

Pharmacy Education

UNIVERSITY

Pharmacy can be studied at 22 universities throughout the country in a uniform schedule.⁹ Its legal basis is the Approbationsordnung für Apotheker, which provides details on the curriculum as well as subjects. In 2001, some changes were made in this ordinance, introducing clinical pharmacy as a fifth subject in the second state examination.

University studies can be completed in at least 4 years, followed by a year-long internship. At least half of the internship must be spent in a community pharmacy. There is an opportunity to perform the remaining 6 months in the pharmaceutical industry, hospital pharmacy (including 3 months on the ward), or in academia. Students must pass 3 state examinations before they can become registered pharmacists. Currently, there are about 13 000 students studying pharmacy in Germany.

Continuing Education

In Germany, pharmacists are obliged by law to engage in continuing education although, until now, there has been no control over or requirement to prove completion of this education. There are many possibilities for pharmacists to refresh and extend their knowledge, such as regional and national symposia organized by the chambers of pharmacists, universities, and scientific organizations; seminars of commercial providers; individual continuing education via professional journals, databases, and interactive Internet-based approaches; and congresses organized by the Federal Chamber of Pharmacists (BAK) several times a year. Certified continuing education programs have been developed, such as pharmaceutical care for adults with asthma, children with asthma, diabetes, coronary heart disease, hypertension, or case management. These programs are offered by all 17 state chambers of pharmacists.

Postgraduate Specialization

Pharmacists have the opportunity to specialize in different areas associated with their professional activity within a postgraduate program. Specialization is possible in, for example, community pharmacy, drug information, clinical/hospital pharmacy, toxicology, pharmaceutical analytics, and pharmaceuticals. The legal bases of postgraduate specialization are within the responsibility of the states. These laws authorize the chambers of pharmacists for each state to establish postgraduate education regulations, which give details on structure and content of the respective programs. Currently, all 17 chambers of pharmacists have postgraduate education regulations. The postgraduate programs take at least 3 years in a full-time position under the guidance of an authorized, certified pharmacist. The specialization program is evaluated using an oral examination.

Quality Management System

Members of the healthcare system, including pharmacists, are obliged by law (German Code of Social Law¹⁰) to ensure high quality of their products and services. However, the procedures as such are not regulated. Therefore, the establishment of a quality management system specific to the needs of pharmacists in Germany seemed appropriate.

In 1999, the BAK issued an example ordinance for its members. Based on this guideline, every state chamber issued a quality management guideline describing requisitions for quantity and form of specified processes in detail. The quality management systems aim at eliminating sources of error and structuring operational procedures, and their overall aim is to achieve high patient satisfaction. The BAK has been continuously working on guidelines for quality management since 2000.¹¹⁻¹³ These guidelines aim to assist pharmacy staff by recommending processes for specific pharmaceutical activities and services.

Community Pharmacy Services

Community pharmacy services in Germany can be divided broadly into the following points:

1. supply of drugs, especially prescription-only and pharmacy-only drugs, and other healthcare products;
2. provision of appropriate drug information and advice for patients as well as other health professionals;
3. optimization of drug therapy and the detection as well as prevention or solution of drug-related problems; these tasks require close cooperation and a good working relationship with other healthcare professionals, mainly physicians;
4. provision of pharmaceutical care, the responsible and continuous provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's health-related quality of life, including medicine management;
5. preventive care services, mainly for patients with chronic diseases, but also for those not yet being diagnosed and treated, including services like screening for diseases (eg, diabetes, osteoporosis, hypertension, coronary heart disease, dyslipidemia, chronic obstructive pulmonary disease), health promotion, and organization of campaigns and programs (eg, smoking cessation); and
6. contribution to health promotion and, in case of illness, to the promotion of rational prescribing and the appropriate use of medicines.

In Germany, cognitive pharmaceutical services have been developed over the past 10 years. In 1993, the ABDA issued a concept paper.¹⁴ This was the official starting point of the change that led to community pharmacists moving from the image of a person primarily dispensing medicines toward a highly qualified advisor taking responsibility for patients' drug-related needs.

Since then, many different projects in pharmaceutical care have been conducted in community pharmacies, mainly commissioned by our department at ABDA. One of these projects is the asthma program, which was based on a 3 stage concept (Figure 1) that started with a controlled trial with the aim to prove efficacy (stage 1).

In this 12 month, controlled intervention trial, pharmaceutical care services were offered for 161 intervention patients (81 controls) with asthma in Hamburg, involving 26 intervention and 22 control pharmacies, as well as approximately 120 physicians.¹⁵ In this study, it was shown for the first time in Germany that community pharmacy-based interventions significantly improved clinical parameters, asthma-specific quality of life, self-efficacy, self-management, and knowledge of the patients enrolled in the intervention group when compared with controls receiving “usual care.”¹⁵

Stage 2 was an intervention study with the aim to prove effectiveness of the program as well as health economic savings (Figure 1). In this longitudinal study, pharmaceutical care services for asthma patients ($n = 183$) were provided in the region of Trier, also involving 2 of the largest statutory insurance companies (AOK Rhineland-Palatino and BARMER Ersatzkasse) and local physicians' associations.¹⁶ The main results were a significant improvement in clinical parameters (eg, peak flow, clinical symptoms, asthma severity), as well as humanistic outcomes (asthma-specific quality of life, self-efficacy, knowledge, adherence, inhalation technique) due to pharmaceutical care. Additionally, guidelines on drug therapy were followed more closely. For the first time in Germany, both physicians' and pharmacists' associations jointly and officially supported a pharmaceutical care program. Moreover, for the first time, health insurance funds provided claims data to evaluate such a program.

The third stage was the nationwide implementation of this program into daily practice, including remuneration as agreed to in a contract.¹⁷ This so-called family pharmacy contract was established in late 2003 between the DAV, representing the interests of community pharmacy owners, and the largest nationwide operating health insurance fund (BARMER Ersatzkasse, with ~7.26 million insured people). Two statewide contracts with regional health insurers had preceded this contract.

In December 2004, a trilateral contract was signed between the DAV, the general practitioner's (GP's) association, and the BARMER Ersatzkasse.¹⁸ This trilateral contract combines the family physician and the family phar-

macy concept, with patients choosing both their GP and their family pharmacy. This concept includes direct communication between the community pharmacist and the GP on issues concerning drug therapy that is remunerated by the health insurance company. By October 2005, 17 790 (83%) of the community pharmacies, nearly 34 000 (~60%) of the GPs, and 1 400 000 (~20%) members of the BARMER Ersatzkasse had joined the contract.

A change in legislation of great importance in the development of these contracts was the introduction of disease management programs in 2001/2002, with financial benefits for health insurance funds for each patient participating in these programs.^{19,20} Different diseases were defined for which these programs can be offered, such as asthma/chronic obstructive pulmonary disease, coronary heart disease/angina, diabetes, and breast cancer. Although pharmacists are not explicitly mentioned as partners in disease-management programs, these programs still offer new options for community pharmacies.

The family pharmacy concept includes remuneration for advanced services, that is, pharmaceutical care (drug profiles, medication reviews, counseling, medication reports), starting with asthma/chronic obstructive pulmonary disease services as the first indication. The family pharmacy concept is aimed at optimizing care, that is, therapeutic outcomes related to drug safety and efficacy as well as efficiency.²¹ Under this program or contract, patients choose their family pharmacy from a list of participating community pharmacies and use it for a set term, usually at least one year. This means that all medicines, both prescription-only and OTC, supplements, and devices are delivered by this pharmacy. To qualify for this program, pharmacists must complete a one day, certified education program, among other requirements, such as the availability of the appropriate computer software.

Each patient selecting the family pharmacy program is offered the following services:

1. Relevant personal and all medication data (prescription as well as OTC/pharmacy-only drugs) are recorded and processed in the pharmacy's computer. Every time the patient visits the pharmacy, the new medication is checked on the basis of the recorded data to identify possible DRPs. Routinely, medication is checked for possible drug-drug and drug-food interactions using a software program (database).
2. Patients are offered home delivery, mainly for prescribed medications, as an attractive alternative to mail-order delivery.
3. Patients are offered financial benefits on products other than medicines purchased in the pharmacy.

In addition, family pharmacies can offer so-called “pharmaceutical management” to patients with asthma/chronic obstructive pulmonary disease, and the main addi-

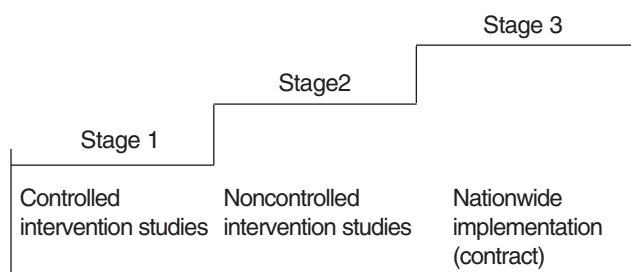


Figure 1. The 3 stage concept of the ABDA to implement pharmaceutical care.

tional content is a medication profile that is routinely generated for each patient. For this service, specific pharmaceutical care software is required. On demand, the pharmacy offers medication regimen reviews that are provided to the patient and, if he/she agrees, also to the GP. Cost analysis is an additional feature to be added.

To support the implementation of these programs, the ABDA has developed quality management programs, protocols, curricula,²² and manuals,²³⁻²⁶ for many diseases. Certified continuing education programs, in accordance with physicians' associations, are offered by all 17 state chambers of pharmacists. Additionally, quality circles on pharmaceutical care have been established by a number of state chambers of pharmacists.²⁷ The major software companies have developed specific pharmaceutical care software. These services are an important tool for negotiations with health insurers.

To successfully negotiate and sign family pharmacy contracts, it is important to effectively meet the third-party payer's perspective and to learn their main driving forces. Health insurers look for additional benefits for their customers, such as price reductions, home deliveries, and check-up services, to prevent them from changing to another (cheaper) insurance company. Cost containment is, of course, another driving force.

Research in Community Pharmacy

Introduction, in 2001, of clinical pharmacy into the curriculum has promoted the formation of research groups in academia focusing on this subject. At the university level, some research has been done in the field of pharmacy practice, especially pharmaceutical care. However, the majority of these groups are working primarily on studies and issues related to secondary care or clinical pharmacy services rather than primary care practice. Pharmacy practice research units per se do not exist in pharmacy schools.

Because research in community pharmacy in Germany is not primarily based in the nation's 22 faculties of pharmacy, many projects and studies in the area of pharmacy practice have been developed, sponsored, and performed mainly by the ABDA and/or the state chambers of pharmacists. This research was carried out in several areas, including pharmaceutical care for elderly patients,²⁸ self-medication for dyspepsia,²⁹ hypertension,^{30,31} diabetes,³²⁻³⁴ cancer,³⁵ and dyslipidemia,³⁶ as well as evaluation of drug-related problems in general.

Another important issue is the counseling quality in community pharmacies. Pivotal studies were conducted in which the pseudo-customer approach was successfully applied as a new method in Germany for evaluating counseling performance and to reinforce skill acquisition.^{37,38} The concept has now been implemented nationwide as part of a continuous quality improvement program.³⁹

Research on the readability of package inserts, based on a European Medicines Agency guideline, has also been performed,⁴⁰ as this issue is a key concern of patients and consumer organizations. In this project, the extent to which the text and format of the package insert influence a patient's ability to understand the content of the principal sections and to locate information after a single reading was examined.

In 1997, the ABDA initiated the "Förderinitiative Pharmazeutische Betreuung e.V.," a foundation supporting the implementation of pharmaceutical care in Germany by bridging the gap between research and pharmacy practice.⁴¹ Its aims are:

1. supporting basic research, as well as research on the practical implementation of pharmaceutical care;
2. promoting role models;
3. promoting projects on the efficacy, effectiveness, and efficiency of pharmaceutical care; and
4. creating public awareness of pharmaceutical care.

Since its inception, a number of projects have been supported and successfully completed, including pharmaceutical care for patients with hypertension, those with cancer who are receiving ambulatory chemotherapy, and stroke patients (seamless care).⁴² The society is financed by regular contributions from its members, as well as by donations.

The Future

We are working to further strengthen the role of pharmacists by intensifying the focus on pharmaceutical services. Integrated approaches, such as the trilateral contract between pharmacists, physicians, and a health insurance fund, seem to be effective in combining the efforts of different players. An important goal is to evaluate the current contracts to show the benefit for patients and to make use of these results in further negotiations with third-party payers. Furthermore, studies and projects are being conducted to develop and implement new pharmaceutical services aimed at establishing them as part of the family pharmacy contracts. Further family pharmacy contracts with several insurance funds have been closed, and more are being negotiated.

It is also planned to intensify efforts to improve counseling quality. The pseudo-customer concept has been successfully implemented on a nationwide level. However, the number of pharmacies registered to participate in the program are still low. Therefore, further promotion of the concept is planned. Some chambers of pharmacists are now discussing whether to make participation in the pseudo-customer concept a compulsory part for community pharmacies to certify their quality management system. Several chambers of pharmacists also started evaluating counseling quality of their members without the voluntary approach of the pseudo-customer concept (mystery shopping). This ap-

proach aims to explore where improvement is necessary. The training that the chambers offer their members can then be tailored to the evaluated needs. Another aim is to improve awareness among the pharmacy staff of the overall importance of their role as healthcare providers.

Summary

Cognitive pharmaceutical services that have been developed in Germany for more than 10 years have shown to be feasible as well as effective. Based on the results of numerous studies and programs, a nationwide family pharmacy contract was established in 2003, when remuneration of pharmacists for pharmaceutical services was successfully negotiated for the first time. Further family pharmacy contracts have been closed, and more are being negotiated.

In the near future, the focus will be on evaluating these contracts, as well as on further intensifying the efforts to improve counseling quality and implement additional cognitive pharmaceutical services.

Christiane Eickhoff PhD, Research Associate, Center for Drug Information and Pharmacy Practice, ABDA—Federal Union of German Associations of Pharmacists, Berlin, Germany

Martin Schulz PhD, Head, Center for Drug Information and Pharmacy Practice, ABDA; Adjunct Professor, Department of Pharmacology, Johann Wolfgang Goethe-University, Frankfurt at Main, Germany

Reprints: Dr. Schulz, Center for Drug Information and Pharmacy Practice, ABDA, Jaegerstrasse 49/50, 10117 Berlin, Germany, fax 49 30 40004 243, m.schulz@abda.aponet.de

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EXTRACTO

OBJETIVO: Describir la práctica de cuidado farmacéutico en farmacias de comunidad en Alemania incluyendo los siguientes tópicos: farmacia de comunidad, organización de servicios de salud, educación farmacéutica, servicios en farmacia de comunidad, investigación en farmacias de comunidad, y planes futuros para los servicios en farmacias de comunidad.

HALLAZGOS: En Alemania, los servicios farmacéuticos cognoscitivos se han ofrecido durante más de 12 años. Algunos estudios y programas han demostrado que el cuidado farmacéutico y otros servicios farmacéuticos se pueden llevar a cabo en farmacias de comunidad y que los pacientes se benefician de estos servicios. En 2003, se estableció un contrato nacional entre representantes de los dueños de farmacias de comunidad y el fondo de seguros de salud más grande en el país. En este llamado contrato de farmacia de familia, se negoció exitosamente por primera vez la remuneración a los farmacéuticos por proveer cuidado farmacéutico. En 2004, se firmó un contrato integrado trilateral incluyendo también a los médicos generalistas, combinando así la farmacia de familia con el médico de familia. En pocos meses, la gran

mayoría de las farmacias de comunidad (>17 000) han firmado para participar en este programa.

CONCLUSIONES: Las farmacias de comunidad alemanas están cambiando su imagen de principalmente suplir fármacos hacia el proveer servicios farmacéuticos cognoscitivos.

Giselle C Rivera-Miranda

RÉSUMÉ

OBJECTIF: Discuter de la façon de dispenser des soins pharmaceutiques dans les pharmacies communautaires en Allemagne en décrivant la pharmacie communautaire, l'organisation et la dispensation de soins de santé, l'éducation en pharmacie, les services de pharmacie communautaire, la recherche au sein de ces pharmacies, et les projets de développement de tels services.

RÉSUMÉ: En Allemagne, les services cognitifs pharmaceutiques sont développés depuis plus de 12 ans. Plusieurs études et programmes ont démontré que les soins pharmaceutiques et autres services pharmaceutiques étaient possibles au sein d'une pratique communautaire et que les patients bénéficiaient de ces services. En 2003, un contrat national fut établi entre les représentants des propriétaires des pharmacies communautaires et la plus importante compagnie d'assurance allemande. À l'intérieur de ce contrat, la rémunération des pharmaciens pour la dispensation de soins pharmaceutiques a été négociée avec succès. En 2004, un contrat tripartite de soins de santé intégrés a été signé combinant dans ce même contrat des médecins de famille et des pharmaciens communautaires. En l'espace de quelques mois, la majorité des pharmacies communautaires (>17 000) a signé cette entente.

CONCLUSIONS: Les pharmacies communautaires allemandes sont en transition vers la dispensation de services pharmaceutiques cognitifs.

Marc M Perreault