

International Series: Integration of community pharmacy in primary health care

Primary healthcare policy and vision for community pharmacy and pharmacists in Germany

Christiane EICKHOFF , Nina GRIESE-MAMMEN , Uta MUELLER , André SAID , Martin SCHULZ .

Published online: 20-Jan-2021

Abstract

Germany is the highest populated country in Europe with a population of 82.3 million in 2019. As in many other developed countries, it has an aging population. Approximately 10% of the gross domestic product is spent on healthcare. The healthcare system is characterized by its accessibility. Patients are generally free to choose their primary care physicians, both family doctors and specialists, pharmacy, dentist, or emergency service. Up to a certain income, health insurance is mandatory with the statutory health insurance (SHI) system, covering 88% of the population. Major challenges are the lack of cooperation and integration between the different sectors and healthcare providers. This is expected to change with the introduction of a telematic infrastructure that is currently being implemented. It will not only connect all providers in primary and secondary care in a secure network but will also enable access to patients' electronic record/medical data and at the same time switch from paper to electronic prescriptions. Approximately 52,000 of the 67,000 pharmacists are working in approximately 19,000 community pharmacies. These pharmacies are owner-operated by a pharmacist. Pharmacists may own up to three subsidiaries nearby to their main pharmacy. Community pharmacy practice mainly consists of dispensing drugs, counselling patients on drug therapy and safety, and giving advice on lifestyle and healthy living. Many cognitive pharmaceutical services have been developed and evaluated in the past 20 years. Discussions within the profession and with stakeholders on the national level on the roles and responsibilities of pharmacists have resulted in nationally agreed guidelines, curricula, and services. However, cognitive services remunerated by the SHI funds on the national level remain to be negotiated and sustainably implemented. A law passed in November 2020 by parliament will regulate the remuneration of pharmaceutical services by the SHI funds with an annual budget of EUR 150 million. The type of services and their remuneration remain to be negotiated in 2021. The profession has to continue on all levels to advocate for a change in pharmacy practice by introducing pharmacy services into routine care.

Keywords

Pharmacies; Primary Health Care; Delivery of Health Care, Integrated; Ambulatory Care; Community Health Services; Pharmacists; Community Pharmacy Services; Professional Practice; Germany

THE GERMAN HEALTHCARE SYSTEM

Germany consists of 16 partly sovereign federal states. In 2018, Germany's annual gross domestic product amounted to approx. EUR 3,356 billion, 11.7% (EUR 391 billion) of which was spent on healthcare, with an expenditure rate of EUR 4,712 per inhabitant.¹

With 83.2 million inhabitants in 2019, Germany is the highest populated country in the European Union. Life expectancy has reached 78.5 years for newborn males and 83.3 years for females. Germany's population is aging rapidly, with the largest group, 23.9 million (2018), being 40-59-year-olds. The next-largest age group is 65 years and older, at 17.9 million.² The demographic change in Germany is expected to increase the future demand for

healthcare services and related expenditures.³

Health insurance is mandatory, either through statutory health insurance (SHI) or private insurance.⁴ The contribution rate in the SHI is 14.6% of the salary up to an income threshold in 2021 of EUR 4,837.50 per month, of which employers pay half. Private health insurance is only available for employees whose monthly income exceeds a certain threshold (EUR 5,362.50 in 2021) or by persons that are self-employed.

The SHI system covers 88% of the population i.e., approximately 73.3 million people. In 2019, total expenditures of the SHI were about EUR 252 billion (+5.3% from 2018), of which most was spent for hospitals (EUR 81 billion), followed by drugs (EUR 43 billion).⁵ More than 100 SHI funds remunerate providers for inpatient and outpatient care, and prescription drug coverage for pharmacies, in a single national formulary that covers all drugs authorized nationally or by the European Medicines Agency (EMA), limiting patients' copayment to a maximum of EUR 10 per prescribed drug.⁴

PRIMARY CARE IN GERMANY

The German healthcare system consists of a network of around 1,900 hospitals, approximately 150,000 ambulatory care/office-based physicians, and 19,000 community pharmacies. Primary care physicians treating SHI insured patients are organized in regional associations and provide all ambulatory medical care. The regional associations

Christiane EICKHOFF, RPh, PhD. Division Scientific Development, Department of Medicine, Federal Union of German Associations of Pharmacists (ABDA). Berlin (Germany). c.eickhoff@abda.de

Nina GRIESE-MAMMEN, RPh, PhD. Head, Division Scientific Evaluation, Department of Medicine, Federal Union of German Associations of Pharmacists (ABDA). Berlin (Germany). n.griese-mammen@abda.de

Uta MUELLER, RPh, PhD. Head, Division Scientific Development, Department of Medicine, Federal Union of German Associations of Pharmacists (ABDA). Berlin (Germany). u.mueller@abda.de

André SAID, RPh, PhD. Head, Office of the Drug Commission of German Pharmacists, Department of Medicine, Federal Union of German Associations of Pharmacists (ABDA). Berlin (Germany). a.said@arzneimittelkommission.de

Martin SCHULZ, RPh, PhD, FFIP, FESCP. Adjunct Professor. Director, Department of Medicine, Federal Union of German Associations of Pharmacists (ABDA). Berlin (Germany). m.schulz@abda.de

negotiate the overall budgets prospectively for their members with the SHI funds and refund the physicians for the provided services on a quarterly basis.⁶ General practitioners make up 49% of office-based physicians.⁷

General practitioners and community pharmacies often serve as the first contact for patients in cases of health complaints. Patients are generally free to choose their physician (general practitioners and specialists), pharmacy, dentist, or emergency service. The German ambulatory sector is characterized by a high number of healthcare providers per inhabitant and, hence, good accessibility to care.⁸ However, due to the lack of a formal gatekeeper system, especially in primary care, physician hopping is observed.⁹

GERMAN COMMUNITY PHARMACIES

Community pharmacies are a major component of the German healthcare system. In addition to dispensing drugs, pharmacists and pharmacy technicians provide counselling about dosing, application, potential adverse effects, and drug/drug- or drug/food-interactions, complemented by advice given on lifestyle and healthy living e.g., nutrition counselling and preventive care.^{10,11} In 2019, over 52,000 of the approximately 67,000 pharmacists worked in community pharmacies.

A third-party pharmacy ownership ban means that all community pharmacies are owner-operated by a pharmacist. Pharmacists may operate up to three subsidiaries nearby their main pharmacy, with one pharmacist each as a mandatory subsidiary manager. Therefore, no pharmacy chains exist in Germany. A license is required to operate a pharmacy, as stipulated by the German Pharmacy Act. Although the establishment of a new pharmacy is not state-regulated e.g., regarding pharmacy numbers, density or population, the number of community pharmacies has continuously declined since 2009. In 2019, there were 19,075 community pharmacies, of which 4,602 were subsidiaries. On average, there are 23 pharmacies for every 100,000 residents, which is below the mean for the EU (32/100,000 residents).¹²

In Germany, there is a strict distinction between drugs only available in pharmacies (pharmacy-only drugs, including prescription-only and controlled drugs) and freely available drugs (e.g., many herbals and diet supplements), also sold by drug stores and supermarkets (general sales list). Typical non-prescription medicines such as analgesics, NSAIDs, paracetamol, cough and cold medicines, among others, are pharmacy-only products. Hence, there is a wide range monopoly on drugs for pharmacies. In total, pharmacies dispensed 1,376 million drug packages in 2019, including 760 million packages of prescription-only drugs (55.3%). Since 2013, the pharmacy sales price for prescription drugs is determined by adding a margin of 3% to the wholesale price, plus a fixed pharmacy service compensation of EUR 8.35, and the value added tax (VAT, according to the Drug Price Ordinance). The price for non-prescription drugs (pharmacy-only as well as freely available drugs) is not regulated and is set by the individual pharmacy or by the drug stores and supermarkets. The turnover of all community pharmacies in 2019 was EUR 54.15 billion

(without VAT), with drug dispensing accounting for 90.7% (83.8% for prescribed and 6.9% [EUR 3.75 billion] for self-medication).¹²

Membership in a regional chamber of pharmacists – one in each of Germany's 16 federal states (with two chambers in North Rhine-Westphalia) – is mandatory for every pharmacist. The chambers are responsible for education and training, professional law, and pharmaceutical quality, among others. Membership in one of the complementing 17 regional associations of pharmacists, representing economic and commercial interests, is voluntary and restricted to community pharmacy owners. The Federal Chamber of Pharmacists [Bundesapothekerkammer; BAK] and the German Pharmacists' Association [Deutscher Apothekerverband; DAV] represent the regional institutions on the federal level. The ABDA – Federal Union of German Associations of Pharmacists is the umbrella organization of the 17 chambers and 17 associations.

PRIMARY HEALTHCARE POLICY

The main goal in German healthcare policy is that comprehensive healthcare is available for everybody regardless of where people live, an individual financial situation, age, or gender.¹³ The separation of outpatient and inpatient sectors and the lack of cooperation between the different healthcare providers is considered a fundamental problem in German healthcare.¹⁴ In recent years, various provisions for integrated care were introduced, aiming to improve cooperation and information flow within and between ambulatory care providers, community pharmacies among others, and hospitals.

The action plan to improve medication safety in Germany, funded by the Federal Ministry of Health since 2008, and an innovation fund, set up in 2015 with an annual budget of about EUR 300 million, both promote innovations in the German healthcare system. The sponsoring of research projects, information campaigns, drug databases, and intervention strategies, intends to support patients, physicians, and pharmacists to ensure an optimal medication process and to improve quality of care, eventually.^{15,16}

Digital health strategy

Although electronic documentation is common across all sectors, patient records are not yet exchanged electronically but sent by letter or fax. Currently, prescriptions are still paper-based and there is no central electronic database with patients' data on prescribed drugs or medical records.

Thus, at the beginning of the millennium, the Federal Ministry of Health and major stakeholders in healthcare launched the eHealth Initiative. In 2005, the gematik was established by leading organizations with the aim to build a secure, cross-sector telematics infrastructure (TI).¹⁷ In 2019, the Federal Ministry of Health joined the gematik as a major shareholder to accelerate the development. In fact, progress was hampered significantly, since firstly the gematik only developed the standards from a technical point of view without being given any legal responsibility in

coordinating the technical or political development, and secondly consensus-based decisions often failed due to the different positions of the stakeholders.

Additionally, the current Federal Ministry of Health established a department for digitalization and in 2016, the eHealth Act came into force.^{18,19} The TI, as the key component for digital healthcare, is rolled out to connect all healthcare providers in primary and secondary care in a secure network.¹⁷ Primary care physicians are currently connected and community pharmacies will follow by July 2021.

An important application within this infrastructure will be a safe communication between healthcare professionals ensuring maximum data protection. The eHealth Act furthermore regulates that all patients will get an electronic health record (EHR), starting from January 2021. Progressively, the EHR will include further medical information, an electronic medication plan, important information for emergencies, and vaccinations. Healthcare professionals will be able to access these EHR in a two-key authorization process by using an electronic healthcare professional ID card and a corresponding electronic patient card. Electronic prescriptions are currently being piloted with the aim to complete the switch from paper-based to electronic prescribing by January 2022.

In December 2019, the Act for Digital Supply became effective regulating the prescription of SHI-remunerated medical apps and the implementation of video consultations.²⁰

The pharmacists' white paper

In 2014, the ABDA released the position paper "Pharmacy 2030 – Perspectives on provision of pharmacy services in Germany".²¹ Pharmacists are positioned to maintain a key role in primary care and to improve and increase collaboration with other healthcare professionals and to actively shape the healthcare network with clearly defined competencies, assuming responsibility for the safety and optimization of medication therapy and practices. Although no specific services were prioritized, the relevance of community pharmacy services were outlined in general, alongside future prospects regarding the pharmacists' role in primary care.

COMMUNITY PHARMACY SERVICES

Overview

Although many patient-oriented pharmaceutical services have been developed in Germany, their implementation appears to be slow compared to other countries.²² One major barrier is the lack of remuneration, with no reimbursed cognitive pharmaceutical services implemented nationwide. Many of the services developed are summarized in a catalogue named LeiKa, including:

- Services linked to the medication e.g., checking inhalation technique, medication management, medication review, monitoring opioid substitution.
- Measurement of clinical parameters e.g., blood pressure, blood glucose, peak flow.

- Health promotion e.g., vaccination advice, nutrition counselling, smoking cessation, self-measurement of blood glucose, risk assessment for diabetes with FINDRISC.
- Other services e.g., leasing medical devices, home care.²³

The BAK developed the catalogue and defined quality standards, which includes guidelines and requirements in terms of e.g., staff qualification and equipment. Furthermore, there are working materials available to facilitate implementation such as standard operating procedures, checklists, and documentation forms as well as templates for patient information and marketing instruments. The catalogue further suggests which parameters are to take into account for cost calculation. An example of a price covering the actual costs was agreed upon in the medication management project ARMIN described below. There, the interdisciplinary medication review is currently remunerated with EUR 112.10 (excluding VAT) and the follow up interventions with EUR 24.90 for both the pharmacist and the physician.

Cognitive pharmaceutical services in community pharmacies are still not common despite the strong wish, especially from young pharmacists and those wishing to enhance job satisfaction and reputation of the profession. However, there is no data on the number of pharmaceutical services currently provided.

Defining roles and responsibility of pharmacists and physicians in primary healthcare

Cooperation between community pharmacists and physicians, with clarity of respective roles and responsibilities, is essential for effective patient care.²⁴ Therefore, the ABDA aims to develop a common understanding at the national level with different professional bodies and societies. A result of the ongoing process is the acknowledgement of pharmacist care and interdisciplinary care for patients with different chronic diseases by incorporating pharmacists' tasks into the national guidelines. There is also an objective to define threshold values for monitoring parameters when pharmacists should refer the patient to a physician. For blood glucose and blood pressure control guideline worksheets have been agreed between the ABDA and the German Diabetes and Cardiac Societies, respectively.^{25,26}

Involving pharmacists in clinical practice guidelines

Traditionally, National Disease Management/Clinical Practice Guidelines (NVL) were developed by committees composed of physicians representing the clinical disciplines/societies/associations. These committees are managed and controlled by National Physicians' organisations. However, pharmacist care contributing to significantly improving patient outcomes as demonstrated in many national and international studies, led to include pharmacists in a number of committees developing NVLs and S3-guidelines.²⁷⁻³³

- National Disease Management-/Clinical Practice Guidelines [NVL]
 - Asthma (4th ed. 2020)

- Chronic Heart Failure (3rd ed. 2019)
- COPD (2nd ed. 2020)
- Diabetes (1st comprehensive ed. 2020)
- Hypertension (under development)
- Unipolar Depression (under development)
- S3 guidelines:
 - Drug-related disorders (2020)
 - Multi-medication/polypharmacy (under development)

The first NVL to include pharmacists was on asthma in 2008, based on the results of two pharmaceutical care studies and a study on improving patients' inhalation technique.^{28,29,34,35} In 2013, community pharmacists were additionally included in the NVL diabetes.³⁷ An interdisciplinary working group was established with the German Diabetes Society (DDG) in 2000 to discuss the role of community pharmacists in diabetes care.²⁵ A curriculum to qualify as a "pharmacist in diabetology (BAK/DDG)" was developed and responsibilities and limitations of pharmacist interventions were defined.³⁸ Furthermore, a study was conducted that showed the effect of individual patient counselling on self-measurement of blood glucose.³⁰ By 2020, approximately 1,700 pharmacists have participated in a certified curriculum and qualified to offer services for asthma and 3,700 pharmacists qualified for diabetes.³⁹

The NVL chronic heart failure describes the tasks of pharmacists as illustrated in Figure 1, demonstrating the complexity of the different tasks and interventions.

Pharmacists' role in blood pressure screening

Community pharmacies can identify a significant number of patients with undetected/undiagnosed hypertension or

poorly controlled blood pressure. However, national and European guidelines do not provide specific guidance when and how to refer patients with elevated blood pressure to a physician. In order to enable community pharmacists to provide recommendations based on the measured blood pressure values, the German Society of Cardiology (DGK) and the ABDA developed and tested referral recommendations for community pharmacists. These recommendations are embedded in two different worksheets, published nationally and internationally that are available online (<https://doi.org/10.1111/jch.14020>). They guide community pharmacists screening patients with suspected or known hypertension.²⁶

Three risk categories were defined including recommendations for action and urgency depending on the measured values. It was shown, that these guideline-directed blood pressure measurements, documentation, and application of referral criteria are feasible in German community pharmacies. In addition, evaluation of the worksheets in a study with 187 individuals (86 with known hypertension, 101 without known hypertension from 17 community pharmacies) uncovered 16% of patients with undetected/undiagnosed hypertension and 55% of hypertensive patients with poorly controlled blood pressure, illustrating the potential public health importance.²⁶ Data on the extent of implementation in daily community pharmacy practice are currently not available.

Pharmacists' role in diabetes prevention

The role of pharmacists in the prevention of diabetes was defined by the above mentioned interprofessional working group.²⁵ It was agreed, that pharmacists are highly qualified and have frequent contacts (approx. 1.6 million per day) to the general population.¹² Thus the development of programs to establish pharmacists as "prevention managers" was recommended.⁴¹ An example for such a

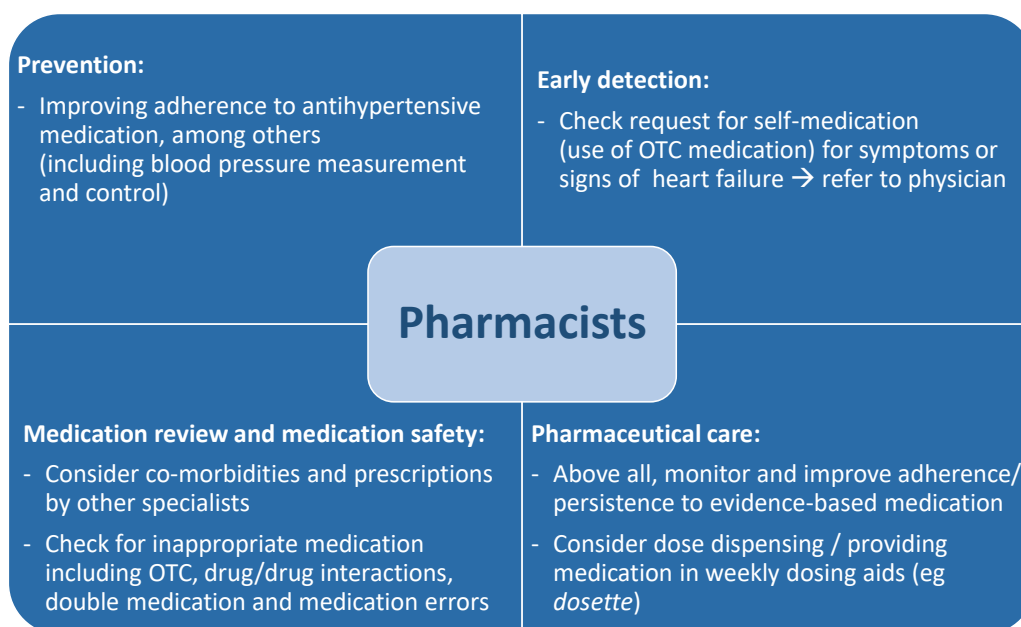


Figure 1. Tasks for pharmacists according to the National Disease Management/Clinical Practice Guideline Chronic Heart Failure, 3rd ed. 2019.^{26,40,32}

program is GLICEMIA for the primary prevention of type 2 diabetes, where pharmacists assessed the risk score with the FINDRISC.^{27,42} The intervention consisted of eight counselling sessions (individual or group-based) in the pharmacy and resulted in a significant reduction of the risk score. Data on the extent of implementation in daily community pharmacy practice are currently not available.

The medication plan

The German Federal Ministry of Health initiated the development of a standardized medication plan format as part of the above mentioned action plan to improve medication safety.⁴³ A complete medication list was identified as a relevant patient safety indicator.⁴⁴⁻⁴⁶ This medication plan (medication schedule) is a printable document for the patient, listing all relevant information on the medication including the active ingredient (INN name), brand name, dosage, and indication as well as general information for use, if needed (Figure 2).^{43,47}

The practicability and acceptance of the medication plan, with an interprofessional cooperation of physicians and pharmacists in an ambulatory setting, was tested in three studies. One of these, the project ARMIN, is described in more detail below.⁴⁸ Overall, the medication plan was well received and it seemed to contribute to patients' satisfaction and facilitate interprofessional collaboration. The main challenges from the healthcare providers' perspective were: the time needed to generate and update the medication plan; the missing TI; and that processes and responsibilities between the healthcare professionals needed to be defined and implemented into routine care.

Missing processes in two of the projects resulted in incomplete and outdated medication plans in the majority of patients. Although these issues have not been solved yet, the medication plan was introduced nationwide in October 2016.¹⁹ Since then, all patients with at least three prescribed drugs are eligible to receive a paper-based

medication plan. This plan is issued through a patient's request by the prescribing physician, who receives a small honorarium. Changes to the plan can be made by any other physician as well as the pharmacist without being remunerated. The lack of remuneration has been criticized by the pharmacists organizations.⁴⁹ In addition, processes and responsibilities are not yet defined that would ensure that this medication plan is complete (with regard to both, prescribed and OTC drugs), checked for patient safety including drug-related problems, and regularly updated. As a result, the medication plan is not yet widespread in Germany.

However, it is expected that the implementation of the TI will promote the electronic medication plan (eMP). This will be an electronic version of the paper-based plan with additional information for healthcare providers on e.g., pregnancy, breastfeeding, kidney function, and allergies of the patients.

CURRENT PROJECTS ON PHARMACEUTICAL SERVICES


Influenza vaccination

Influenza vaccination in community pharmacies has already been successfully introduced in many countries. In Germany, there has been some reluctance to follow that example mainly due to protests from the medical profession, although the vaccination coverage in the population at risk is low.⁵⁰

To increase the number of influenza vaccinations, pharmacists are legally allowed to administer this vaccination from March 2020 within "model projects".⁵¹ Pharmacists delivering this service have to qualify by participating in an advanced training. The curriculum was developed by the BAK in cooperation with the Robert Koch-Institute (RKI), which is the government's central scientific institution in the field of biomedicine and one of the most

medication plan


Seite 1 von 1



for: **Michaela Mustermann** born: **13.12.1936**

issued by:
Dr. Helga Herz
Hauptstraße 55, 01234 Am Ort
Tel.: 04562-12345
E-Mail: h.herz@mein-netz.de

issue date: 16.10.2020



Active ingredient	Brand name	Strength	Form	Dosage	Unit	Instructions	Indication
Magnesiumoxid	Magnesium-Diasporal® 150	250mg	Caps	0 0 1	Pcs		Cramps
Metoprololsuccinat	Metoprololsuccinat - 1A Pharma®	95mg	Tabl	½ 0 0	Pcs		Heart failure
Omeprazol	Antra MUPS® 20mg	20mg	Tabl	1 0 1	Pcs		Heart burn
Methotrexat	MTX HEXAL® 15mg	15mg	Tabl	once a week. Monday	Pcs	at night with a glass of water	Joint inflammation
Metamizol natrium-1-Wasser	Novaminsulfon 500 mg Lichtenstein	500mg/ml	Drops	30 30 0 30	Drops		Pain
Combination	Baldriparan® zur Beruhigung		Tabl	1 1 1 1	Pcs		Restlessness

important information

please measure your blood pressure daily!

Figure 2. Medication plan format (unauthorized English translation)

important bodies for the safeguarding of public health in Germany, and the Paul Ehrlich Institute (PEI), which is the Federal Institute (regulatory body) for Vaccines and Biomedicines. A guideline and working materials were developed to facilitate implementation.⁵² First contracts with health insurance funds were closed in October 2020 with more to follow in 2021. These regional projects are limited to five years with a subsequent evaluation to decide whether this service will be introduced into routine care.

Establishing medication reviews

In Germany, there has been significant efforts to introduce cognitive pharmaceutical services into standard care and practice. Training programs, guidelines, and working materials have been developed, and changes in the legislation were achieved. Relevant milestones were:

- Introduction of clinical pharmacy in the academic curriculum for pharmacists in 2001
- Legal anchoring of medication management as a pharmaceutical service in 2012 in the pharmacy operating regulations
- Development of advanced training concepts for medication review e.g.,
 - Apo-AMTS and ATHINA (since 2012)
 - Curriculum of the BAK (2015)
- Development of a guideline for medication reviews (2014, revision in 2017)

Furthermore, a comprehensive concept of an interdisciplinary medication management approach was developed at the national level by the ABDA and the Federal Association of Statutory Health Insurance Physicians (KBV) in 2011.⁵³ This ABDA/KBV-concept was well received politically and as a consequence, legislation has been changed, enabling the ARMIN project.⁴⁸

Concurrently, numerous projects have been conducted to develop and evaluate suitable cognitive pharmaceutical services. The PHARM-CHF randomized controlled trial being one example (described below).

Projects to qualify pharmacists: ATHINA and Apo-AMTS

Medication reviews are still not implemented in daily routine and are not a mandatory part of the university training of pharmacy students. Thus, two educational concepts Apo-AMTS and ATHINA were developed in parallel with the cooperation of different chambers of pharmacists and pharmacy schools.^{31,54} Pharmacists (also pharmacist students in Apo-AMTS) are trained on medication review and pharmacologically relevant topics linked to aspects of pharmacotherapy and medication safety. Additionally, the pharmacists have to conduct a certain number of medication reviews. Supervision by a medication coordinator (in Apo-AMTS) or a tutor (in ATHINA) allows qualified feedback on the reviews. ATHINA is now offered by 11 out of 17 regional chambers of pharmacists. However, remuneration of medication reviews by insurers remains an issue. Some regional contracts with SHI funds exist, but are always limited in time and patients often have to pay by themselves. Both programs have been evaluated showing feasibility as well as an effect in terms of drug-related problems being identified and solved by the pharmacist.³¹ As a limitation, physicians are not yet involved as cooperating partners.

Implementing medication management: the model project ARMIN

ARMIN [Arzneimittelinitiative Sachsen-Thüringen] was the first model project developed on the basis of the interdisciplinary medication management approach agreed upon by the ABDA and KBV at the national level.^{48,55} ARMIN is conducted in two federal states, Saxony and Thuringia, involving two state associations of pharmacists and physicians, and a large SHI fund (AOK PLUS).

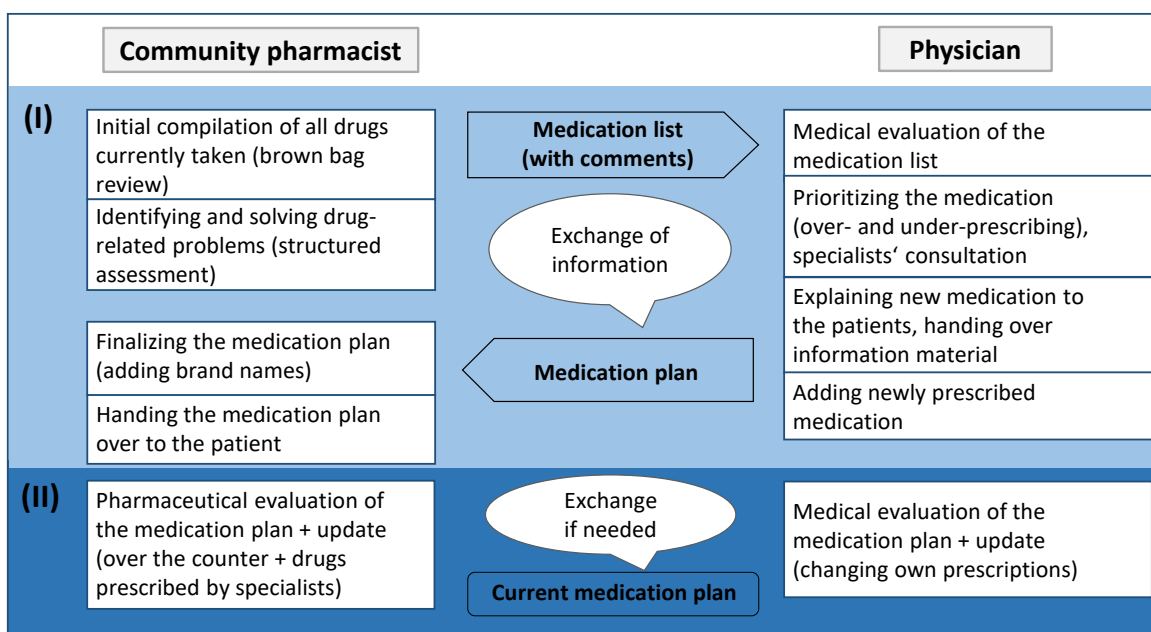


Figure 3: The medication management process in ARMIN. (I) initial intervention; (II) continuous management

One main achievement in ARMIN is that the processes and responsibilities are clearly defined, as described in Figure 3; i.e.

- Clearly defined roles and responsibilities should facilitate the communication between the professions.
- Defining the processes should ensure that the medication of the patients has been checked for risks and the generated medications plans are comprehensive and updated regularly.

The initial intervention in ARMIN is a type 3 medication review according to the Pharmaceutical Care Network Europe's (PCNE) definition starting with a patient interview in the pharmacy including a brown bag review.⁵⁶ Additionally, claims data from the SHI fund as well as data from the general practitioner are taken into consideration to complete the medication plan. After a structured pharmaceutical and medical risk assessment according to defined standards the medication plan is printed out for the patient.^{57,58} The follow-up intervention takes place during every patient visit in the pharmacy or general practice to ensure that newly dispensed medication, prescribed as well as self-medication, is checked and the medication plan is updated. Since the TI is still not implemented in Germany, a central server was established for this contract in order to be able to exchange the medication plans between pharmacies and physicians involved.

The contract is now widely accepted and regarded as pilot for a successful interdisciplinary cooperation. Approximately 350 pharmacists and 350 general practitioners and 7,000 patients are currently participating.

Generating evidence in research projects - PHARM-CHF

PHARM-CHF was the first per patient randomized, controlled interdisciplinary trial in Germany to examine the effects of a medication review followed by structured care aiming to improve medication adherence.³² The intervention aimed to improve adherence to three heart failure medication classes and health-related quality of life in elderly patients with chronic heart failure. At baseline, a medication review (Type 2a) was conducted in the community pharmacy.⁵⁶ Based on the subsequently consolidated medication plan, the patient received a weekly dosing aid together with a printout of the medication plan. Pharmaceutical care continued by weekly

or bi-weekly visits to the pharmacy including counselling regarding medication, adherence, potential side effects, signs and symptoms of decompensation and measurement of blood pressure and pulse rate.

The PHARM-CHF intervention improved mean adherence to heart failure medication and the proportion of adherent patients. The intervention led to a clinically meaningful improvement in patients' quality of life.³²

NATIONWIDE IMPLEMENTATION OF COGNITIVE SERVICES – THE FUTURE

On 29 October 2020, the On-site Pharmacy Strengthening Act was adopted by the German Parliament. A main aspect is the introduction and remuneration of additional pharmaceutical services. The type of services and their specific remuneration remain to be negotiated between the DAV and the National Association of SHI funds. The services should aim to improve medication effectiveness and safety and may lead to competition between pharmacies with regard to service quality. Several examples are given e.g. of suitable target groups (patients with polypharmacy as well as patients with a high need for counselling) and topics that should be addressed (medication adherence; prevention). Reference is also made to medication management services. A total of EUR 150 million in annual net additional funding will be made available for this purpose.

This nationwide remuneration of cognitive services, by law, is an important and critical step in Germany. The main challenge will be to implement and sustain these services in the majority of pharmacies, truly integrating them into primary care. Especially relevant will be to further develop already known facilitators like clinical training as well as strengthening the cooperation with physicians. Further challenges will also be the implementation of e-prescription and telepharmacy as well as using the new electronic data meaningfully.

CONFLICT OF INTEREST

None.

FUNDING

None.

References

1. Federal Statistical Office. https://www.destatis.de/EN/Home/_node.html;jsessionid=E8C2F6CF5A2476C04A452E1CD0D1BFC1.internet8731 (accessed Oct 30, 2020).
2. Statista. Germany: population by age. Available from: <https://www.statista.com/statistics/454349/population-by-age-group-germany/> (accessed Oct 30, 2020).
3. Busse R, Ognyanova D, Blümel M. [The German health care system: Stakeholders, data, analyses]. Stuttgart: Medizinisch Wissenschaftliche Verlagsgesellschaft; 2013.
4. Busse R. Disease management programs in Germany's statutory health insurance system. *Health Aff (Millwood)*. 2004;23(3):56-67. <https://doi.org/10.1377/hlthaff.23.3.56>
5. Schwabe U, Ludwig, WD. [Drug Report 2020]. Berlin: Springer; 2020.
6. Kringos DS, Boerma WGW, Hutchinson A, Saltman RB, eds. Building primary care in a changing Europe: Case studies. Copenhagen: European Observatory on Health Systems and Policies; 2015.

7. Schlette S, Lisac M, Blum K. Integrated primary care in Germany: the road ahead. *Int J Integr Care*. 2009;9:e14. <https://doi.org/10.5334/ijic.311>
8. Knieps F, Amelung V, Wolf S. [Healthcare in regions difficult to cover: Basic principles, definitions, problem analyses]. *GuS*. 2012;66(6):8-19. <https://doi.org/10.5771/1611-5821-2012-6-8>
9. Schulte H, Schulz C. [Medical care centers: improving ambulatory care versus selection and exclusion of patient groups]. Baden-Baden: Nomos; 2007.
10. Eickhoff C, Schulz M. Pharmaceutical care in community pharmacies: practice and research in Germany. *Ann Pharmacother*. 2006;40(4):729-735. <https://doi.org/10.1345/aph.1q458>
11. Schmiedel K, Schlager H, Dörje F. Preventive counselling for public health in pharmacies in South Germany. *Int J Clin Pharm*. 2013;35(1):138-144. <https://doi.org/10.1007/s11096-012-9722-3>
12. ABDA. [German Pharmacies: Figures Data Facts 2020]. <https://www.abda.de/aktuelles-und-presse/publikationen/detail/german-pharmacies-figures-data-facts-2019/> (accessed Oct 30, 2020).
13. Federal Ministry of Health. The German healthcare system - Strong. Reliable. Proven. <https://www.bundesregierung.de/breg-de/service/publikationen/the-german-healthcare-system-strong-reliable-proven--1765016> (accessed Oct 30, 2020).
14. Amelung V, Hildebrandt H, Wolf S. Integrated care in Germany-a stony but necessary road!. *Int J Integr Care*. 2012;12:e16. <https://doi.org/10.5334/ijic.853>
15. Sommer H, Dwenger A. [Action plan of the Federal Ministry of Health for improvement of medication safety in Germany : An inventory]. *Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz*. 2018;61(9):1062-1065. <https://doi.org/10.1007/s00103-018-2778-z>
16. Milstein R, Blankart CR. The Health Care Strengthening Act: The next level of integrated care in Germany. *Health Policy*. 2016;120(5):445-451. <https://doi.org/10.1016/j.healthpol.2016.04.006>
17. gematik. [Legal foundations: Company for telematic applications of the electronic health card]. <https://www.gematik.de/ueber-uns/gesetzliche-grundlagen> (accessed Oct 30, 2020).
18. Klein M. Minister-Premiere bei der conhIT: [Jens Spahn established a department for digitalization at the German Federal Ministry of Health]. <https://www.egovernment-computing.de/jens-spahn-gruendet-abteilung-fuer-digitalisierung-im-bmg-a-710233/> (accessed Oct 30, 2020).
19. [Law for secure digital communication and applications in the health care system. E-Health act]. [https://www.bgbl.de/xaver/bgbl/start.xav?startbk=Bundesanzeiger_BGBl&start=/*\[@attr_id=%27bgbl115s2408.pdf%27#_bgbl_%2F%2F%5B%40attr_id%3D%27bgbl115s2408.pdf%27%5D_1601463267910](https://www.bgbl.de/xaver/bgbl/start.xav?startbk=Bundesanzeiger_BGBl&start=/*[@attr_id=%27bgbl115s2408.pdf%27#_bgbl_%2F%2F%5B%40attr_id%3D%27bgbl115s2408.pdf%27%5D_1601463267910) (accessed Oct 30, 2020).
20. [Law for better care through digitalization and innovation. Digital care act]. https://www.bgbl.de/xaver/bgbl/start.xav?startbk=Bundesanzeiger_BGBl&jumpTo=bgbl119s2562.pdf#_bgbl_%2F%2F%5B%40attr_id%3D%27bgbl119s2562.pdf%27%5D_1602761776063 (accessed Oct 30, 2020).
21. ABDA. [Pharmacy 2030 - Perspectives on provision of pharmacy services in Germany]. <https://www.abda.de/themen/perspektivpapier-apotheke-2030/> (accessed Oct 30, 2020).
22. Rose O, Schaffert C, Czarniecki K, et al. Effect evaluation of an interprofessional medication therapy management approach for multimorbid patients in primary care: a cluster-randomized controlled trial in community care (WestGem study protocol). *BMC Fam Pract*. 2015;16:84. <https://doi.org/10.1186/s12875-015-0305-y>
23. Bundesapothekerkammer. [LeiKa: Catalogue of counselling and other services in pharmacies]. Available from: <https://www.abda.de/fuer-apotheker/leika/> (accessed Oct 30, 2020).
24. Weissenborn M, Haefeli WE, Peters-Klimm F, Seidling HM. Interprofessional communication between community pharmacists and general practitioners: a qualitative study. *Int J Clin Pharm*. 2017;39(3):495-506. <https://doi.org/10.1007/s11096-017-0450-6>
25. [Committee pharmacists in diabetology. Cooperation - diabetes]. <https://www.abda.de/themen/anzneimitteltherapiesicherheit/weitere-kooperationen-apotheker/kommission-bak-ddg/> (accessed Oct 30, 2020).
26. Schulz M, Griese-Mammen N, Schumacher PM, et al. Development and implementation of blood pressure screening and referral guidelines for German community pharmacists. *J Clin Hypertens (Greenwich)*. 2020;22(10):1807-1816. <https://doi.org/10.1111/jch.14020>
27. Schmiedel K, Mayr A, Fießler C, Schlager H, Friedland K. Effects of the lifestyle intervention program GLICEMIA in people at risk for type 2 diabetes: a cluster-randomized controlled trial. *Diabetes Care*. 2015;38(5):937-939. <https://doi.org/10.2337/dc14-2206>
28. Schulz M, Verheyen F, Mühlig S, et al. Pharmaceutical care services for asthma patients: a controlled intervention study. *J Clin Pharmacol*. 2001;41(6):668-676. <https://doi.org/10.1177/00912700122010438>
29. Hämmerlein A, Müller U, Schulz M. Pharmacist-led intervention study to improve inhalation technique in asthma and COPD patients. *J Eval Clin Pract*. 2011;17(1):61-70. <https://doi.org/10.1111/j.1365-2753.2010.01369.x>
30. Müller U, Hämmerlein A, Casper A, Schulz M. Community pharmacy-based intervention to improve self-monitoring of blood glucose in type 2 diabetic patients. *Pharm Pract (Granada)*. 2006;4(4):195-203. <https://doi.org/10.4321/s1885-642x2006000400008>
31. Seidling HM, Send AFJ, Bittmann J, et al. Medication review in German community pharmacies - Post-hoc analysis of documented drug-related problems and subsequent interventions in the ATHINA-project. *Res Social Adm Pharm*. 2017;13(6):1127-1134. <https://doi.org/10.1016/j.sapharm.2016.10.016>
32. Schulz M, Griese-Mammen N, Anker SD, et al. Pharmacy-based interdisciplinary intervention for patients with chronic heart failure: results of the PHARM-CHF randomized controlled trial. *Eur J Heart Fail*. 2019;21(8):1012-1021. <https://doi.org/10.1002/ejhf.1503>
33. [National disease management guidelines]. <https://www.leitlinien.de/nvl/> (accessed Oct 30, 2020).
34. Schulz M, Dalhoff K, Alsdorf E, et al. [National Asthma Care Guideline]. Berlin: AWMF; 2020.

35. Mangiapane S, Schulz M, Mühlig S, Ihle P, Schubert I, Waldmann HC. Community pharmacy-based pharmaceutical care for asthma patients. *Ann Pharmacother*. 2005;39(11):1817-1822. <https://doi.org/10.1345/aph.1q180>
36. [National disease management guideline for the treatment of type 2 diabetes]. 2013. Available from: <https://www.leitlinien.de/mdb/downloads/nvl/diabetes-mellitus/archiv/therapie/dm-therapie-1aufl-vers4-lang.pdf> (accessed Oct 30, 2020).
37. Bundesärztekammer. [National Diabetes Care Guideline: Structured training programs]. <http://www.leitlinien.de/mdb/downloads/nvl/diabetes-mellitus/dm-schulungsprogramme-1aufl-vers4-lang.pdf> (accessed Oct 30, 2020).
38. Kommission Apotheker in der Diabetologie. [Consensus paper of the German Diabetes Society and the Federal Chamber of Pharmacists. Pharmaceutical care for people with diabetes and health counselling of people with a risk for diabetes: options and limitations]. https://www.abda.de/fileadmin/user_upload/assets/Qualitaetssicherung/Kooperationen/Kooperationen-Diabetes/Koop-Diabetes_Konsensusvereinbarungen/Konsensusvereinbarung.pdf (accessed Oct 30, 2020).
39. Bundesapothekerkammer. [Inquiry at the Regional Chambers of Pharmacists on the number of certified advanced trainings conducted]; 2017.
40. [National disease management guideline chronic heart failure]. 3rd ed. Berlin. https://www.awmf.org/uploads/tx_szleitlinien/nvl-006l_S3_Chronische_Herzinsuffizienz_2020-06.pdf (accessed Oct 30, 2020).
41. Schwarz PE, Müller U, Schulz M, Hauner H, Landgraf R. [Prevention of type 2 diabetes in Germany--a challenge for health professionals]. *Med Monatsschr Pharm*. 2007;30(8):289-296.
42. Schwarz PE, Li J, Lindstrom J, Tuomilehto J. Tools for predicting the risk of type 2 diabetes in daily practice. *Horm Metab Res*. 2009;41(2):86-97. <https://doi.org/10.1055/s-0028-1087203>
43. [Coordination group on implementing and updating the action plan for improvement of medication safety (Version 2.0, updated version)]. <https://www.akdae.de/AMTS/Medikationsplan/docs/Medikationsplan.pdf> (accessed Oct 30, 2020).
44. Wenger NS, Young RT. Quality indicators for continuity and coordination of care in vulnerable elders. *J Am Geriatr Soc*. 2007;55 Suppl 2:S285-S292. <https://doi.org/10.1111/j.1532-5415.2007.01334.x>
45. Kuske S, Lessing C, Lux R, Schmitz A, Schrappe M. [Patient safety indicators for medication safety (AMTS-PSI): international status, transferability and validation]. *Gesundheitswesen*. 2012;74(2):79-86. <https://doi.org/10.1055/s-0030-1269838>
46. Committee on Identifying and Preventing Medication Errors. What can you do to avoid medication errors: fact sheet; Washington, DC: IOM; 2006.
47. Schulz M, Botermann L. [Basic preconditions for the electronic configuration of medication data with regard to the medication plan: Action plan of the Federal Ministry of Health to improve medication safety in Germany]. Available from: <https://www.bundesgesundheitsministerium.de/service/publikationen/gesundheits/details.html?bmg%5Bpubid%5D=2590> (accessed Oct 30, 2020).
48. Müller U, Schulz M, Mätzler M. [Electronically supported co-operation of physicians and pharmacists to improve medication safety in the ambulatory setting : The "Arzneimittelinitiative Sachsen-Thüringen" (ARMIN)]. *Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz*. 2018;61(9):1119-1128. <https://doi.org/10.1007/s00103-018-2780-5>
49. Dormann H, Maas R, Eickhoff C, et al. [Standardized national medication plan : The pilot projects MetropolMediplan 2016, model region Erfurt, and PRIMA]. *Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz*. 2018;61(9):1093-1102. <https://doi.org/10.1007/s00103-018-2789-9>
50. [General practitioners disapprove of pharmacists administering influenza vaccinations]. <https://www.aerzteblatt.de/nachrichten/115139/Hausaerzte-lehnen-Grippeimpfungen-durch-Apotheker-ab> (accessed Oct 30, 2020).
51. [Social Code Book V - Statutory Health Insurance. § 132j Regional model projects on influenza vaccinations in community pharmacies]. https://www.gesetze-im-internet.de/sqb_5/_132j.html (accessed Oct 30, 2020).
52. Bundesapothekerkammer. [Guidelines and working materials: Influenza vaccination (model projects)]. <https://www.abda.de/fuer-apotheker/qualitaetssicherung/leitlinien/leitlinien-und-arbeitshilfen/> (accessed Oct 30, 2020).
53. KBV - ABDA. [Future concept for drug provision: the ABDA-KBV-concept]. <https://www.kbv.de/html/2947.php> (accessed Oct 30, 2020).
54. Waltering I, Schwalbe O, Hempel G. [Information content of medication schedules prior to the implementation of the federal standard medication plan]. *Z Evid Fortbild Qual Gesundhwes*. 2016;115-116:24-32. <https://doi.org/10.1016/j.zefq.2016.06.004>
55. [ARMIN Medicines Initiative Saxony-Thuringia]. <http://www.arzneimittelinitiative.de> (accessed Oct 30, 2020).
56. Griese-Mammen N, Hersberger KE, Messerli M, et al. PCNE definition of medication review: reaching agreement. *Int J Clin Pharm*. 2018;40(5):1199-1208. <https://doi.org/10.1007/s11096-018-0696-7>
57. Bundesapothekerkammer. [Medication review: Guideline of the Federal Chamber of Pharmacists]. <https://www.abda.de/fuer-apotheker/qualitaetssicherung/leitlinien/leitlinien-und-arbeitshilfen/> (accessed Oct 30, 2020).
58. Bergert FW, Braun M, Ehrenthal K, et al. [General practitioners guideline: Recommendations on the use of polymedication for adults and geriatric patients]. https://www.degam.de/files/Inhalte/Leitlinien-Inhalte/Dokumente/DEGAM-S1-Handlungsempfehlung/053-043%20Hausaerztliche%20Leitlinie%20Multimedikation/053-043l_S2e_Multimedikation_2014-05.pdf (accessed Oct 30, 2020).