Understanding the Pharmaceutical Care Concept and Applying it in Practice

Commissioned by the Austrian Federal Ministry of Health

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Understanding the pharmaceutical care concept and applying it in practice

Results of a scoping exercise

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Abstract

In the year 2008 the project "Development of indicators for assessing pharmaceutical care in Europe" was launched by the European Directorate for the Quality of Medicines & Health Care (EDQM) (Council of Europe) with the objectives to develop pharmaceutical care indicators and the promotion of their use. In the course of the project, topic groups led by scientific collaborators were formed in order to explore already existing indicators and pharmaceutical care practices in a scoping exercise. The results of the scoping exercise undertaken by the Gesundheit Österreich GmbH / Geschäftsbereich Österreichisches Bundesinstitut für Gesundheitswesen (GÖG/ÖBIG) which has the lead in the topic group "Health systems: policy aspects: Understanding the pharmaceutical care concept and applying it in practice" were presented in an expert workshop in Strasbourg on 19 November 2009 where possible indicators to be developed were discussed.

The aim of the present report is to understand the integration of the pharmaceutical care concept within a health system, by identifying concrete pharmaceutical care practices which could serve as good practice models for other countries. A two-step methodological approach was undertaken, which included a literature review and a case study survey.

The literature survey shows a long tradition in pharmaceutical services and care in some European countries, in particular the Nordic countries, UK, the Netherlands, Germany, but also in a few Mediterranean countries (e. g. Portugal). However, in Central and Eastern European countries the implementation of pharmaceutical care has not proven to be as advanced as in Western European countries. Another result which emerged from the literature review and personal talks with relevant stakeholders was that disease-specific pharmaceutical care (e. g. programmes for coronary heart disease, hypertension, and asthma) play an important role.

Several international initiatives related to pharmaceutical care have been undertaken such as the Pharmaceutical Care Network Europe that brought up some joint pharmaceutical care projects. Other international initiatives have been undertaken by the World Health Organisation, the Pharmaceutical Group of the European Union and the Council of Europe.

The case studies that were carried out by means of personal interviews with representatives from the Austrian Chamber of Pharmacists and the Portuguese Association of Pharmacies give an insight into specific pharmaceutical care-related projects such as the Pharmaceutical Safety Belt in Austria or the comprehensive pharmaceutical care programmes in Portugal.

A few indicators were identified in the course of the present scoping exercise which will form a basis for further development of indicators. Pharmaceutical care related outcome indicators are good to measure in particular specific disease-related programmes where smaller groups are targeted, and thus in-depth documentation with a range of data is possible. However, when following the concept of pharmaceutical care as defined by Hepler & Strand, which comprises a fairly large group of people instead of focussing on specific indication groups, an outcome-indicators focused approach seems rather difficult to be implemented. Compared to outcome indicators in pharmaceutical care, process indicators seem to be more appropriate. A suggested way to move forward with indicators for pharmaceutical care is based on a check-list including several, mainly process, indicators.

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Table of contents

Abstract III

Acknowledgement V

List of Tables VIII

1 Introduction 1
- 1.1 Objective of the scoping exercise 2
- 1.2 Methodology 2

2 Overview on pharmaceutical care initiatives in Europe 5

3 International Projects 8
- 3.1 Pharmaceutical Care Network Europe 8
  - 3.1.1 Therapeutic Outcome Monitoring (TOM) 8
  - 3.1.2 Elderly Medication Analysis (OMA) 9
- 3.2 Other international initiatives 9

4 Case studies – Pharmaceutical care in selected countries 11
- 4.1 Pharmaceutical care in Austria 11
  - 4.1.1 Case study I: Pharmaceutical Safety Belt (Arzneimittel-Sicherheitsgurt) 11
  - 4.1.2 Case study II: Pharmacy days 12
  - 4.1.3 Case study III: Clinical pharmacy in Austria 13
- 4.2 Pharmaceutical care in Portugal 13
  - 4.2.1 Case study I: Pharmaceutical care programmes 14
  - 4.2.2 Case Study II: Campaigns 16

5 Specific diseases and pharmaceutical care 18
- 5.1 Coronary heart disease 18
- 5.2 Hypertension 18
- 5.3 Asthma 19
- 5.4 Others 19

6 Indicators 20
- 6.1 Indicators proposed in literature 20
- 6.2 Expert opinions on indicators 22

7 Conclusion 23

8 References 25

List of abbreviations

ANF	Associação Nacional das Farmácias / National Association of Pharmacies (Portugal)
BPCS	Behavioural Pharmaceutical Care Scale
CD-P-PH/PC	Committee of Experts on Quality and Safety Standards for Pharmaceutical Practices and Pharmaceutical Care
CEFAR	Centro de Estudos e Avaliação em Saúde / Centre for Health Studies and Evaluation (Portugal)
CoE	Council of Europe
COPD	Chronic obstructive pulmonary disease
CPS	Cognitive pharmaceutical services
DMP	Disease management programme
DRP	Drug-related problem
EDQM	European Directorate for the Quality of Medicines & HealthCare
ELGA	Elektronische Gesundheitsakte / Electronic Health Record
E-MD	E-medication database
EUnetPas	European Network for Patient Safety
GÖG/ÖBIG	Gesundheit Österreich GmbH / Geschäftsbereich Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute
NHS	National Health Service
OMA	Elderly Medication Analysis
PGEU	Pharmaceutical Group of the European Union
PSB	Pharmaceutical safety belt
SNS	Serviço Nacional de Saúde / National Health Service (Portugal)
TOM	Therapeutic Outcome Monitoring
WHO	World Health Organisation

List of Tables

Table 1.1: Guide for a semi-structured interview 4

Table 6.1: Pharmaceutical care indicators proposed in literature and interviews..... 21

1 Introduction

Pharmaceutical care is a necessary element of healthcare. According to the definition of Hepler & Strand (1989)[1], pharmaceutical care is the responsible provision of medicine therapy for the purpose of a definite outcome that improves a patient's quality of life. Pharmaceutical care is based on a relationship between the patient and the healthcare providers who accept responsibility for the patient. This concept implies the active participation of the patient in medicine therapy decisions, the cooperation of healthcare providers across disciplines, and gives priority to the direct benefit of the patient.

The Committee of Experts on quality and safety standards in pharmaceutical practices and care (CD-P-PH/PC), coordinated by the European Directorate for the Quality of Medicines & HealthCare (EDQM) (Council of Europe),[I] was tasked "...to improve pharmaceutical care and pharmaceutical practices in Europe through public health oriented policies and practical programmes, putting first the needs of patients and society in general, having in mind the social and ethical context of healthcare...". The Committee of Experts CD-P-PH/PC set up a working programme dealing with the assessment of the quality of pharmaceutical care and medication use in Europe and its impact on patients' quality of life in order to provide support for health policy-makers and to improve professional standards for all professionals involved in the medication chain.

The Committee of Experts CD-P-PH/PC contributes to the mission of the EDQM which is to ensure access to good quality healthcare. It carries out progammes and develops policies, giving priority to the needs of patients and the social and ethical values of healthcare. Within its programme of activities, the Committee of Experts studied, in 2008/2009, the current awareness and understanding of the concept of pharmaceutical care in Europe, approaches to the quality assessment of pharmaceutical care, the extent to which pharmaceutical care is implemented in practice, and the competences and skills required (cf. section 2).

The present publication was prepared in the frame of the above mentioned project of the Committee of Experts CD-P-PH/PC coordinated by the EDQM.

[I] The European Directorate for the Quality of Medicines & HealthCare (EDQM) is a Directorate of the Council of Europe, an international organisation founded in 1949 which, to date, has a membership of 47 states in Europe. The primary aim of the Council of Europe is to create a common democratic and legal area throughout the whole of the continent, ensuring respect for its fundamental values: human rights, democracy and the rule of law.

The project is carried out with the support of scientific collaborators. Gesundheit Österreich GmbH / Geschäftsbereich Österreichisches Bundesinstitut für Gesundheitswesen (GÖG/ÖBIG) / Austrian Health Institute is one scientific collaborator in this project, nominated by the Austrian Federal Ministry of Health, which supports the work of GÖG/ÖBIG for this project.

The scientific collaborators were organised in topic groups with the aim to scientifically work on the development of indicators. GÖG/ÖBIG has the lead in the topic group "Health systems: policy aspects". In a first step, the topic group leaders carried out a scoping exercise on their topic in autumn 2009. On 19 November 2009 the European Directorate for the Quality of Medicines & HealthCare (EDQM) held an expert workshop in Strasbourg, where preliminary results based on the first scoping exercise were presented and possible indicators for the continuation of the work were discussed with the participants of the workshop. The work of the topic groups continues during 2010.

1.1 Objective of the scoping exercise

The topic group "Health systems: policy aspects" aims to better understand the integration of the pharmaceutical care concept within the health system by identifying concrete practices of pharmaceutical care which could serve as good practice models for other countries.

The present report shows the outcomes of a scoping exercise which provides a broad overview on pharmaceutical care practices throughout Europe, including two detailed country examples (case studies). The scoping exercise should not be understood as a comprehensive analysis, but rather as a quick mapping in order to provide an idea and a basis for deciding on the further procedure. The GÖG/ÖBIG team who undertook the scoping exercise started in September 2009; the report was submitted to the Austrian Ministry of Health at the beginning of November 2009 and after discussion with the Ministry of Health, shared with the Committee of Experts CD-P-PH/PC and the scientific collaborators.

1.2 Methodology

The scoping exercise included, in principle, a two-phase methodological approach based on the definition of pharmaceutical care of Hepler & Strand[II]:

[II]Pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life. These outcomes are: *cure of a disease; *elimination or reduction

» Literature review
» Case studies survey

The application of a modified Delphi method was discussed among the experts working on this project. However, in this topic group, it was not applied during the scoping exercise; it might be considered at a later stage.

Literature review

The literature review and analysis was undertaken at the beginning and during the scoping exercise.

It focused on

» Identifying (good) practice models of pharmaceutical care

» Possible evaluation reports and reviews, including assessment criteria and indicators

Case studies

A key focus of the scoping exercise is the case studies in which the implementation of the pharmaceutical care concept and its application in practice were analysed.

Pharmaceutical care initiatives of two countries, Austria and Portugal, were analysed in detail. Face to face interviews with representatives of the Austrian Chamber of Pharmacists and the Portuguese Association of Pharmacies were undertaken in order to receive a specialist opinion in relation to pharmaceutical care. The interviews were held in October 2009.

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of a patients' symptomatology; *arresting or slowing of a disease process; or *preventing a disease or symptomatology.

Pharmaceutical care involves the process that a pharmacist co-operates with the patient and healthcare professionals in designing, implementing, and monitoring a therapeutic plan that will produce specific therapeutic outcomes for the patient. This in turn involves three major functions: *identifying potential and actual drug-related problems; *resolving actual drug-related problems; and *preventing drug-related problems.

Pharmaceutical care is a necessary element of health care, and should be integrated with other elements. Pharmaceutical care is, however, provided for the direct benefit to the patient, and the pharmacist is responsible directly to the patient for the quality of that care. The fundamental relationship in pharmaceutical care is a mutually beneficial exchange in which the patient grants authority to the provider and the provider gives competence and commitment (accept responsibility) to the patient. These fundamental goals, processes, and relationships of pharmaceutical care exist regardless of practice setting and of professional background.

Table 1.1:
Guide for a semi-structured interview

Tool/questions for semi-structured interviews	
1.	Presentation and discussion on pharmaceutical care definition of Hepler & Strand
2.	In general is this definition applicable in your country?
3.	What are the most important pharmaceutical care initiatives in your country? (e. g. safety programmes, disease management programmes etc.)
In the following – to be discussed for the major pharmaceutical care initiative each:	
4.	Who (which stakeholders) are involved in the pharmaceutical care initiatives?
5.	When was it started?
6.	Why did you start this initiative?
7.	Was it changed in the course of time – why?
8.	Was it made public? Have there been a publication / presentation of it (for the public, for interested parties)?
9.	Are these publications available? Where?
10.	Which were the experiences?
11.	Which were the lessons learned?
12.	Was the pharmaceutical care initiative subject to an evaluation (formal/informal) – any publication of the review (e. g. in a peer-reviewed journal)?
13.	Is information on evaluation available? Where?
14.	Which indicators were used to measure the pharmaceutical care initiatives?
15.	Which are the plans for the future regarding this pharmaceutical care initiative and further ones?
16.	In general: Which indicators should be implemented to evaluate pharmaceutical care?

Source: GÖG / ÖBIG 2009

2 Overview on pharmaceutical care initiatives in Europe

A first deliverable of the project of the Committee of Experts CD-P-PH/PC coordinated by the EDQM was a pharmaceutical care survey report undertaken in 2008/2009[2] by the European Directorate for the Quality of Medicines & Health Care (EDQM) (Council of Europe). This report analyses and presents conclusions of 58 replies from national public health authorities, doctors', pharmacists', nurses', and patients' associations from 17 countries. It was found that pharmaceutical care is increasingly being considered an important goal but not yet implemented in practice due to varying awareness and education levels among healthcare providers, and inadequate cooperation among healthcare providers. The quality of management of medicine therapy, outcomes for the patient, and the safe use of medicines are not measured on a routine basis in most countries in Europe. Only a few countries have a legal basis for the implementation of pharmaceutical care or have regular contacts between healthcare professionals and insurers for the purpose of implementing pharmaceutical care. Most frequently mentioned barriers that make the implementation of the Pharmaceutical care concept difficult include lack of 1) cooperation between health care professionals, 2) pharmaceutical care-related education and 3) awareness of the concept. In general the comprehensive pharmaceutical care approach, according to the definition of Hepler & Strand, is not yet widely used in all of the countries which participated in this survey.

Based on the findings of the report, the authors undertook a mapping of initiatives and programmes of pharmaceutical care throughout Europe which were recorded in the literature. The results showed that different aspects of pharmaceutical care and services are applied in several European countries, however to different extents and with different focuses. In the following overview, Austria and Portugal are not mentioned as their pharmaceutical care initiatives will be described in further detail in Section 4.

In Sweden there have been several pharmaceutical care initiatives. On the one hand yearly theme campaigns that aim at specific patient groups have been introduced and on the other hand the documentation of drug-related problems has been gaining importance in the course of the last years. A classification system for documenting drug-related problems and pharmacy interventions as well as a specific counselling technique have been developed and implemented. In several pharmacies patient medication profiles were introduced. Researchers in pharmaceutical care put their focus mainly on drug-related problems.[3]

Patient medication counselling by pharmacists is laid down by law in Finland and since the year 2000 improvements in medication counselling rates have been noticed. Pharmaceutical care initiatives in Finland range from long lasting projects such as

» EuroPharm Forum´s Questions to Ask About Your Medicines campaign (cf. section 3.2)

» Customized Information for the Benefit of Community Pharmacy Patients project,

to disease-oriented pharmaceutical care initiatives such as diabetes, asthma and heart diseases. At present the introduction of automated dose dispensing and electronic prescribing is underway. Another focus related to pharmaceutical care will be on elderly people.[4]

Pharmaceutical care and research in pharmacy practice is well developed in Denmark. Besides medication counselling and offers such as cholesterol, blood glucose or blood pressure measurement, pharmaceutical care best practice models have been developed. These models include the "self-medication and self-care model" and "pharmaceutical care at-the-counter model" which focuses on the identification, solving and prevention of drug-related problems related to specific diagnosis. Furthermore each year is dedicated to a health topic where most pharmacies actively participate. Topics included, amongst others, have been specific diseases such as diabetes and patient safety.[5] However, besides the positive development of pharmaceutical care the top-down approach of implementing such activities has been criticized.[6]

Pharmaceutical care in the Netherlands is influenced by the fact that customer retention is very high, meaning that most customers are coming back to the same pharmacy. Also a well working surveillance service has been implemented and patient counselling with regard to medication is of high quality. A result of this is that drug-related problems are kept to a minimum.[7]

In the year 2005 the National Health Service (NHS) in England put into practice a NHS pharmacy contract with the aim that all NHS pharmacies offer seven essential services related to pharmaceutical care and also correspond to the quality assurance framework. Services that are offered in pharmacies include the controlled administration of methadone or smoking cessation programmes. In the long run one main aim is for community pharmacies to integrate their concepts/programmes to initiatives provided by professionals in primary care. A focus will be put on improving IT and contractual arrangements.[8]

In Germany cognitive pharmaceutical services[III] are being implemented[9] and the role of pharmacists only supplying medicines is changing. In 2003 the way towards cognitive pharmaceutical services started with family pharmacy contracts between community pharmacists representatives and the largest sickness fund that include remuneration of pharmacists when providing pharmaceutical care. These contracts were extended in 2004 and since then general practitioners have been integrated. Most of the community pharmacies in Germany are part of this initiative.[10]

In Spain pharmaceutical care and the responsibility of providing pharmaceutical care services by pharmacists is regulated by law.[11] Pharmacy practice research is limited in Spain despite many community pharmacies. Besides services such as compounding, measurement of blood pressure and weight or testing of cholesterol, some advanced cognitive services were in place in 2005, however only a few were being remunerated.[12]

In the Baltic States pharmaceutical care has not been implemented as in some other European Union states. In Estonia for example the government has not put the focus on the pharmaceutical care issue so far. However, overall, for the last two decades pharmacists have acted in a more patient-oriented way.[13] In Lithuania a study showed that only two percent of the pharmacies are prepared to implement comprehensive pharmaceutical care services. But most of the pharmacies have introduced components of pharmaceutical care such as measurement of blood pressure or written information to patients.[14]

In Croatia a high quality pharmacy system is in place, however no network between relevant actors in health care or pharmaceutical care initiatives is in place. The same applies to the Hungarian system. In general eastern European countries have a very good education at university level, however the main focus is put on pharmacy logistics. Areas such as pharmaceutical care, networking or patient counselling have potential to be improved.[15]

The literature survey has shown a long tradition in pharmaceutical services and care in some European countries, in particular in the Nordic countries, UK, the Netherlands, Germany, but also in a few Mediterranean countries. However, in Central and Eastern European countries the implementation of pharmaceutical care has not proven to be as advanced as in Western European countries.

[III]In contrast to the pharmaceutical care concept the concept of cognitive pharmaceutical services (CPS) puts the focus on the role of community pharmacists providing clinical and professional assistance to patients and other health care professionals. Definition of CPS: "The use of specialised knowledge by pharmacists for the patient or health care professionals for the purpose of promoting effective and safe medicine therapy."

3 International Projects

3.1 Pharmaceutical Care Network Europe

In the year 1994 the Pharmaceutical Care Network Europe (PCNE) was founded by pharmaceutical care researchers with the aim "to help to develop pharmacy along the lines of pharmaceutical care in the involved European countries through:

» stimulating pharmaceutical care and pharmacy related outcome research in Europe;

» stimulating research and implementation projects carried out in more countries simultaneously;

» organising a bi-annual working conference around pharmaceutical care and pharmacy practice research;

» all other possible activities that serve the aim of the association"[16].

PCNE started some joint pharmaceutical care initiatives. The therapeutic outcome monitoring (TOM) and the elderly medication analysis (OMA) projects are briefly described below.

3.1.1 Therapeutic Outcome Monitoring (TOM)

The aim of this controlled intervention study was the evaluation of effects of a TOM programme for asthma patients. The programme was a community-based pharmaceutical care programme to detect, prevent and resolve drug related problems in patients with asthma. The results of this study showed positive effects on asthma symptoms status, health-related and asthma-related quality of life and days of sickness. Furthermore knowledge of asthma and medication thereof increased and inhalation errors, medicine use and medicine therapy problems decreased. The authors of the study concluded that TOM for asthma patients by community pharmacists improves the quality of medication therapy for patients with asthma.[17] Participating countries in this joint project included Austria, Belgium, Canada, Denmark, Florida (US), Germany, Iceland, Northern Ireland and the Netherlands.[18]

3.1.2 Elderly Medication Analysis (OMA)

In seven European countries (Sweden, Portugal, Northern Ireland, Ireland, Denmark, Germany, the Netherlands) the effect of a structured pharmaceutical care programme provided to elderly patients (≥65 years) was measured in a randomised, controlled, longitudinal, clinical trial. The patients who visited the pharmacies that offered a structured pharmaceutical care programme received the following interventions:

- „Technical medication check-up. All the patients' drugs were checked to identify and discard outdated and useless drugs. At the same time, the elderly patients were instructed in practical use and handling of the medicines.
- Medicines regimen assessment and identification of drug-related problems
- Diary for self-monitoring at home
- Medication overview. The elderly patients regularly received an updated overview of all their medicines. The medication overview was a help to the patients and, furthermore, served as a means of communication to other health professions
- Individual patient counselling on problems connected with the use of medicines
- A check of the medicine cabinet in the home"[19]

The results showed significant health-related improvements and better control of signs and symptoms in elderly people involved in the pharmaceutical care programme in some countries. Also costs related to pharmaceutical care provision were reduced in most participating countries. The structured pharmaceutical care service provision improved patient satisfaction and compliance and also pharmacists and general practitioners seemed to have a positive opinion of the new structured pharmaceutical care approach. [20, 21]

3.2 Other international initiatives

EuroPharm Forum, a World Health Organisation (WHO) collaborating centre, initiated a campaign called "questions to ask about medicines" back in 1993. Since then the campaign has been implemented in several countries in different ways (e. g. single campaigns, repeated campaigns, platform for the continuous process of patient education and communication). The campaign aimed at encouraging patients and pharmacy customers to proactively gather information (e. g. asking health care professionals specific questions before treatment start) about treatment in order to get the maximum therapeutic benefit out of medicines. In 2004 a guideline for the implementation of campaigns has been introduced and twinning projects have started

where countries with experience with this campaign help countries that just start to implement them. Also an evaluation of the project has been taken into consideration.[22]

The Pharmaceutical Group of the European Union (PGEU), the European association that represents community pharmacists, is active in pharmaceutical care-related projects. PGEU is a project partner in the European Union Network for Patient Safety (EUNetPaS) that is funded by the European Commission with the aim to establish a network of all 27 EU Member States and relevant stakeholders to enhance and encourage collaboration with regard to patient safety.[23] Also a paper on patient medication adherence was released in 2008. The main objective of the study was to explore the potential of pharmacists to improve rates of patients' adherence to therapies in general and to long-term therapies that are used in treating chronic conditions and their risk factors. A special focus is collaboration with other health care professionals (teamwork and communication).[24]

The former Expert Group on Safe Medication Practices of the CoE emphasised in their report on medication safety that a patient-focused approach to increase medication safety is of upmost importance. It was also pointed out that coordinated Europe-wide pharmaceutical care activities, taking into account multi-professional cooperation, would positively influence the safe and effective use of medicines.[25]

4 Case studies – Pharmaceutical care in selected countries

In the course of the scoping exercise interviews with stakeholders from the Austrian Chamber of Pharmacists[26] and the Portuguese Association of Pharmacies[27] were conducted. The aim of these interviews was to learn more in detail about pharmaceutical care practices as well as other pharmacy-related initiatives in those two selected countries.

4.1 Pharmaceutical care in Austria

The definition of pharmaceutical care by Hepler & Strand is well known in Austria. In general pharmaceutical services, especially counselling of patients in the pharmacy has a long tradition in Austria. Several initiatives have been undertaken in this respect, however documentation was missing for a long time. The development of pharmaceutical care in Austria started around 12 years ago when first studies were conducted with questionnaires. Those studies showed that documentation was not feasible for most of the pharmacists at that time as there were no time resources for that. As a result IT-supported programmes with training for pharmacy staff were implemented including, for example, disease management of diabetes or asthma.

4.1.1 Case study I: Pharmaceutical Safety Belt (Arzneimittel-Sicherheitsgurt)

The introduction of the Pharmaceutical Safety Belt (PSB) was first discussed in the year 2005 as from this year onwards pharmacies in Austria have been obliged to settle the accounts with the sickness funds electronically. The official political decision was made in July 2006 when the start of a pilot project was agreed. The pilot project then started in February 2007 with the participation of 71 out of 76 pharmacies in the province Salzburg and ended on the 30 June 2008.

The main objectives of the PSB are

» 1) prevention of adverse drug reaction,
» 2) prevention of multi-prescribing and
» 3) improvement of compliance (surveillance).

The practical implementation of the PSB envisages the pharmacist to ask the patient for permission to include the data of what medication he/she is taking into the database. This data include, on the one hand, prescribed medicines from dispensing doctors, specialists or hospitals and, on the other hand, over-the-counter medicines. This allows for a complete personal medication profile. However, the patient needs to voluntarily give the requested information due to data protection issues. The computer safety software in the participating pharmacies verifies possible interactions and shows a warning. Then the pharmacist assesses whether this alert is relevant or not. In case the warning is relevant the pharmacist consequently records if and how the problem could be solved and also may consult the prescribing doctor.[28] Throughout the entire project more than 12,000 adverse reactions and/or interactions related to 8,500 patients and in more than 3,000 cases double medication could be prevented. Furthermore in 5,000 cases errors related to the regular intake of medicines could be avoided.[29]

According to a survey undertaken with pharmacy customers in 2007, data protection issues do not seem to be an issue with regard to the implementation of the PSB.[30] However, on a political level data protection concerns have been raised.

A next step of the pilot project included the involvement of doctors in the project, being aware of the fact that the prescribing doctors play a major role in the pharmaceutical care process of the patient. Due to reasons that were not known, the participation of doctors in this project failed. [31]

After the successful end of the pilot project and its evaluation[32] it is at the time of the survey (autumn 2009) planned to include the PSB, renamed as e-medication database (E-MD), into the Electronic Health Record (Elektronische Gesundheitsakte, ELGA). The ELGA includes all relevant multi-media and health-related data of a clearly identifiable person. These data are provided from different health care providers and the patient him-/herself and is stored in one or more information systems (virtual health record). Wherever a patient is treated, these data are available, irrespective of place and time to authorised persons considering data protection.[33]

4.1.2 Case study II: Pharmacy days

The Austrian Chamber of Pharmacists regularly initiates a “pharmacy day” (Tag der Apotheke), which is dedicated to specific topics related to pharmaceutical care. The previous pharmacy day was themed “10 minutes for my medication” with the aim to check interactions of medicines and direct patient counselling. Other topics in the past included “magistral preparations”, “get rid of quicksilver”, “10 minutes for your health” and “home pharmacy check”.[34]

4.1.3 Case study III: Clinical pharmacy in Austria

In Austria pharmaceutical care is an important element in clinical pharmacy. The hospital pharmacist's education consists of three main modules one of them being pharmaceutical care. It has been proven for many years that the involvement of the hospital pharmacist in the therapeutic team is of advantage for all parties concerned such as doctors, nurses and patients. The model of clinical pharmacy established in Great Britain and United States of America is not applicable one-to-one in Austria due to the different staff situation. However many successful projects and current activities show that patient-related clinical pharmacy is very important in terms of the safe and effective use of medicine. As a member of the therapeutic team, the clinical pharmacist contributes to quality assurance with regard to prescription, distribution and administration of medicines starting from the point of admission and hospital stay to the point of discharge of the patient. The regular participation in ward rounds, team meetings and access to clinical patient records allows the clinical pharmacist to directly apply his/her knowledge concerning doses adjustment, interactions, incompatibility as well as decisions on medicines and dosage forms. The consultation of clinical pharmacists is documented in the clinical patient records. The clinical pharmacist is also very important when it comes to interface management. He/she can inform chronically ill patients, for example, on continued medication therapy after discharge. This positively influences the compliance of patients.[35]

4.2 Pharmaceutical care in Portugal

The pharmaceutical definition by Hepler & Strand underlies the pharmaceutical care programmes in Portugal.

In Portugal the National Association of Pharmacies (ANF) has been responsible for the pharmacy development of the last 20 years. After securing the economic sustainability of pharmacies, the investment in communication technologies and information software as well as improving the architecture of pharmacies was an important step. Pharmaceutical care services such as point-of-care measurements, medicine waste management and needle exchange services were developed in a next step. Later the methadone substitution programme was introduced. Comprehensive pharmaceutical care programmes including disease management programmes were also implemented.[36] Since the late nineties (some) pharmacies in Portugal have offered a mix of pharmaceutical care and diseases management programmes (DMP), which were basically focused on three areas:

» Hypertension
» Diabetes
» Asthma (in the late nineties extended by COPD)

Starting with a pilot phase in the late nineties, pharmaceutical care projects officially started in 2000. In 2007 a new law allowed pharmacies to offer a wider range of services (e. g. nutrition counselling, vaccinations), which supplemented the pharmaceutical services that (some) pharmacies had already provided before (e. g. some point-of-care measures).

4.2.1 Case study I: Pharmaceutical care programmes

The ANF developed a methodology and tools for pharmacists in order to offer these pharmaceutical care services (e. g. tools for documentation, tools for better communication with patients and doctors). The pharmacists who wish to offer a specific pharmaceutical care programme need to receive training, provided by the ANF school. The pharmaceutical care programme can only be offered in a pharmacy if at least one pharmacist has completed a training, for which the pharmacist needs to pay him/herself. The training consists of four compulsory modules (diseases, drug-related problems, communication with doctors, marketing) which last one day each. More training can be completed on a voluntary basis. Interest in providing pharmaceutical care is not only shown by pharmacists in the cities but also pharmacists in rural areas participate in the training.

Documentation, monitoring and evaluations

The ANF cooperates with the Centre for Health Studies and Evaluation (CEFAR), which is a research centre owned by one of the ANF companies. CEFAR monitors the pharmaceutical care programmes.

» Monitoring on how (many) pharmacists implemented the programme(s) (mainly process indicators)

» Impact assessment monitoring (e. g. blood measurement, respiratory tests, as indicators – "Did the health status improve?")

Pharmacists need to submit data to the ANF in written form. ANF is working on implementing an electronic submission tool.

The issue of data protection caused a long discussion with the Data Protection Agency. Originally, ANF wanted to receive the patient records including patient history, adverse drug reactions, etc., but this was not permitted. The patient file is kept locally in the pharmacies.

The patient has to give his consent before entering the programme.

Communication

After implementation of a pharmaceutical care programme the communication between pharmacists and doctors has considerably improved which has two reasons: first, pharmacists are trained to better communicate with the doctors. A check-list guiding the communication with a doctor is one of the tools provided. Second, doctors now better accept pharmacists and their work. Sometimes doctors refer patients to a pharmacy for a pharmaceutical care programme. These patients have the highest rate of acceptance and compliance as they get advice by two health professionals. To allow an exchange of information and lessons learned among pharmacists, the ANF organised meetings for pharmacists who offer pharmaceutical care programmes. Cases are presented and discussed with colleagues. This meetings proved to be very successful.

Workload for pharmacists

Workload depends on whether an interaction occurs and/or further counselling is needed. The hypertension programme, for example, is the least time-consuming one, needing 20 minutes for the first patient counselling and further 10 minutes for each follow-up talk.

Management of the time is an important element and it is taught in the training. Elderly people seem to be very time consuming as sometimes they want to talk about everything but the pharmaceutical care programme. Pharmaceutical care related counselling (also methadone programmes, vaccinations) need to be carried out in a separate room which seems to be a further incentive for the patients to never stop talking. It is compulsory for (new) pharmacies in Portugal to have a separate room of minimum 15 m^2.

Remuneration

Some pharmacies charge for the pharmaceutical care programmes, some offer those programmes for free. ANF considers charged amounts as not cost-effective.

The diabetes programme now gets supported by the Portuguese National Health Service (SNS). Patients who register in this programme pay a monthly fee of € 15, the SNS covers 75% thereof.

For the hypertension programme and asthma programme it is up to the pharmacies how much they charge.

Changes over the course of time

» Classification: Pharmacies now classify drug-related problems (DRP) according to the already implemented and tested Spanish classification (the DRP classification of 2nd consensus of Grenada). In the beginning, they used the classification of the Pharmaceutical Care Network which was considered as too academic and not suitable for practical use.

» Training: Pharmacists complained that the trainings were too long. At the beginning all modules needed to be done at once. Now a more flexible training programme was introduced allowing pharmacists to attend models whenever they want. ANF ensures that there are enough training sessions (not only in the big cities, but also decentralized, even organized if wished by the pharmacists).

» Documentation: Pharmacists considered it as too complex, as a result it was simplified. It is a compromise because now fewer data for evaluation are available. Online documentation is planned.

Pharmaceutical Services

In Portugal, pharmaceutical care is seen as an important part of pharmaceutical service. The reason behind this was, according to ANF, that "pharmacists understand that there is a shift from product-centred care to patient-centred care".[37]

ANF differentiates between

» essential services (e. g. dispensing, point of care measures, waste collection, counselling, providing leaflets to the patients) and

» advanced services (pharmaceutical care, methadone substitution). Advanced services usually need specific training and are provided in consultations with appointments.

Today, 90% of the pharmacies provide point-of-care measures (blood pressure measurement and weight measurement is done by nearly 100%). With the new law of 2007 allowing further services, more pharmacies are likely to invest and offer a broader range of services.

4.2.2 Case Study II: Campaigns

ANF is very active in launching large-scale campaigns with high media coverage. These campaigns include:

» Polypharmacy: In one week patients had the possibility to bring all their medicines to the pharmacist and get advice on possible interactions. This campaign mainly aimed at elderly people.

» Campaign on cardio vascular diseases

» Smoking cessation campaign

» Vaccination programmes (flue vaccination, HPV vaccination campaign is starting): This is possible thanks to a change in pharmacy law in 2007 allowing pharmacists to undertake vaccinations.

These campaigns often were developed together with professors from the medical society, which has also contributed to pharmacists being now better accepted by the doctors.

5 Specific diseases and pharmaceutical care

The literature review and personal talks with relevant stakeholders have shown that pharmaceutical care is in particular carried out in specific disease areas. In this section we explore which diseases pharmaceutical care programmes usually focus on and why specific diseases are more commonly addressed in pharmaceutical care.

5.1 Coronary heart disease

In many countries pharmaceutical care programmes include coronary heart disease programmes.

A systematic review of randomised trials that evaluated the effects of pharmacists in the care of patients with heart failure was undertaken by a Canadian study group and showed that the risk of all-cause and heart failure hospitalisations could be reduced by almost one third through intervention, e. g., information to patients, patient support programmes, self-monitoring, and medicine education. Therefore the authors of the study concluded that the incorporation of pharmacists into multidisciplinary heart failure care teams should definitely be considered.[38] Also another study on congestive heart failure resulted in improved outcomes (better compliance with medicine therapy, significantly improved knowledge of medicine therapy, fewer hospital admissions for patients in a pharmaceutical care programme).[39] Another systematic review showed that community pharmacy-based services (including patient education and medication management) contribute to the reduction of risk behaviours and risk factors of coronary heart diseases.[40]

5.2 Hypertension

Pharmaceutical care in the field of hypertension is rather common and has, according to the literature, proven to be useful.[41] A systematic review and meta analysis on the sensitivity of patient outcomes to pharmacist interventions shows that pharmacists' interventions significantly reduce systolic blood pressure.[42]

5.3 Asthma

As already mentioned in section 3.1.1, joint studies on the effect of pharmaceutical care for asthma patients in a community setting including several countries have been carried out, most of the time using the therapeutic outcome monitoring approach. The mainly positive outcomes of asthma studies related to pharmaceutical care show that pharmaceutical care in this respect can be useful.

5.4 Others

Further diseases where pharmaceutical care programmes are common include diabetes, chronic obstructive pulmonary disease (COPD), migraine and instable angina pectoris.

Regarding pharmaceutical care for specific diseases, a positive influence on a patient´s health has been evidenced in different studies.

Some diseases are considered more appropriate for pharmaceutical care programmes since in countries where customer retention in pharmacies is usually not very high patients with specific diseases tend to use one pharmacy. Also specific diseases tend to be more present in specific age groups (e. g. elderly people). Due to the clear focus on a specific group of patients (usually not too large) disease-specific pharmaceutical care can be given and evaluated.[43]

6 Indicators

As mentioned in Section 1, the EDQM project on pharmaceutical care aims to improve patient safety and quality through pharmaceutical care. In order to achieve an improvement, the pharmaceutical care concept should be spread in the CoE countries by means of developing indicators that should be tested and implemented in those countries. For this reason indicators that were suggested in the literature were collected and presented in an expert workshop on 19 November 2009, forming a basis for the further development of indicators.

6.1 Indicators proposed in literature

As a result of the literature research and interviews with experts, the following indicators, which are listed in Table 6.1, have been identified. The indicators are commented on according to the lessons learned during the scoping exercise.

Table 6.1:
Pharmaceutical care indicators proposed in literature and interviews

Indicator	Discussion
Performance / Medicines substitution	This indicator measures how often, out of a total, pharmacists substitute medicines in accordance with doctors in order to prevent medicines interactions (e. g. adverse drug reactions) in patients. This indicator would show the impact and success of pharmaceutical care, however, in practice it is rather difficult and time-consuming to measure.
Hospital admission, frequency and duration (after pharmacy/nurse-led interventions)	The implementation of this indicator would be possible in disease specific pharmaceutical care programmes with good documentation. Measurements could be taken before and after the pharmacy-led intervention. However, measurements across countries are not possible.
Number of interventions (pharmacy led interventions, nurse led interventions)	This indicator would be relatively easy to measure. However, there is large room for interpretation.
Number of drug related problems / medication errors	This is a classical indicator with regard to pharmaceutical care, however the possibility of measurement depends on the vigilance systems in the countries. One option could be to measure a possible reduction of drug related problems / medication errors in a disease specific pharmaceutical care with a rather small group of people.
Patient satisfaction	Patient satisfaction has been regularly evaluated together with pharmaceutical care programmes. A difficulty of this indicator is its large room for interpretation and its different understanding in different countries. Therefore, it is not recommended for cross country comparisons.
Regular customers / trust / patient-pharmacist relationship	Similar arguments as for patient satisfaction. It is also considered as very subjective therefore it is difficult to measure and compare it between countries.
Process indicators (on key elements of pharmaceutical care, e. g. counselling, documentation)	Proposed indicators is questions on the process: "Is electronic documentation available?" "Is clinical pharmacy implemented?" "Are there indications having intensive programmes?" Such questions could be answered, and rather easily included in an evaluation of pharmaceutical care.
Health status indicators, e. g. morbidity rates	Such indicators are well measurable and standard indicators in the health systems of many countries. The problem is rather the interpretation, as it is difficult to attribute an improvement in health to pharmaceutical care only, as it is no "clinical trial situation", as one expert said, but there may be a number of many other factors.

Source: Bell et al. (2007), interview with Mag. Max Wellan (Austria), Cristina Santos and Ema Paulino (Portugal); Koshman et al. (2008), Machado et al. (2007); Pharmazeutische Gehaltskasse (2007); Rossing et al. (2005); Søndergaard et al. (2002); van Mil (2005); Vermeire et al. (2005); Westerlund & Bjork (2006); GÖG/ÖBIG survey

6.2 Expert opinions on indicators

In the course of the interviews with experts from the Austrian Chamber of Pharmacists and the Portuguese Association of Pharmacies, the following concerns were raised especially with regards to outcome indicators.

» In order to get high quality evaluations a large amount of data is needed which results in time-consuming documentation work for pharmacists (cf. Section 4.2.1). Small patients groups are considered to be more appropriate for evaluations (cf. Section 5).

» The question of comparability was raised. How can a situation be assessed and/or compared (before/after) that is real life, and not a clinical trial? (see also the argument on health status indicators in Table 6.1). For possible pharmaceutical care indicators there are several factors that influence outcome.

In addition, the implementation and further development of evaluation tools for existing pharmaceutical care programmes was considered as non-priority, since countries and institutions with a long tradition in pharmaceutical care have already developed advanced instruments for documentation and evaluation.

Hence, it was seen important that pharmaceutical care is disseminated and promoted in those countries which are not as advanced. In order to promote it, information on existing pharmaceutical care initiatives (good practice models) and tools for a successful implementation of pharmaceutical care was considered to be of high relevance. For that reason it was proposed that in a first step focus should be given to process indicators. A suggested model could be the development of a check-list including several, mainly process, indicators (e. g. documentation, tools for communication, etc.). Countries which are not as advanced would clearly see which areas need to be developed, and could then better plan their pharmaceutical care initiatives.

7 Conclusion

Across Europe several projects and initiatives aiming at a responsible provision of pharmaceutical therapy are being carried out in different manners. They range from counselling in community pharmacies via specific disease-oriented programmes (e. g. asthma, hypertension) to projects including electronic documentation of drug-related problems. Among countries there is a different understanding when or from what point on an initiative/project is considered as pharmaceutical care.

In general, pharmaceutical services can be distinguished into essential and advanced services with pharmaceutical care programmes being part of the latter. With regard to pharmaceutical care, two types might, according to the experts, be distinguished: 1) basic pharmaceutical care projects which are aimed at many patients or 2) a "deluxe approach" which allows for valid research data to be obtained, and which can be systematically evaluated based on well-defined indicators. However, the "deluxe approach" needs to focus on a rather small number of patients. The first approach has the advantage to reach many patients, but high quality data are much more difficult to get.

An overall pharmaceutical care approach according to the definition of Hepler & Strand for all CoE countries is considered to be quite difficult to implement also due to the underlying different health care as well as pharmaceutical systems. Cultural and traditional differences might be barriers to the implementation of an identical pharmaceutical care approach. The authors understand that suggested pharmaceutical care actions need to be adapted for each country.

A major aim of the EDQM project is to spread the concept of pharmaceutical care and its use in the CoE Member States. The proposed tool is the identification of indicators in a first step and its practical implementation in the countries in a second step. This scoping exercise has explored possible pharmaceutical care indicators. The authors have identified a few, however some of them have certain limitations. Pharmaceutical care related outcome indicators (e. g. number of drug related problems, health status indicators) are good to measure, particularly in specific disease-related programmes such as asthma or hypertension (cf. section 4) where smaller patient groups are targeted. But it is not clear if the improvement measured is a result of the pharmaceutical care initiative, or may also be attributable to other factors. The larger the patient group, the more difficult is the measurement and a grounded interpretation of the indicators.

Compared to outcome indicators, pharmaceutical care process indicators seem to be more appropriate to implement, and might be more appropriate with regard to the

goal of the CoE project. A suggested way is to provide a check-list of key elements of pharmaceutical care including several process indicators. This check-list would allow countries to identify their needs and areas for further development in pharmaceutical care. Based on the experience from the literature research and expert opinions, the authors of the present scoping exercise believe that for disseminating the pharmaceutical care concept in the CoE countries, especially in those not so advanced, such a check-list could support the implementation of pharmaceutical care while taking into consideration cultural and historical country characteristics.

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