Pharmaceutical Care

Policies and Practices for a Safer, More Responsible and Cost-effective Health System

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Policies and Practices for a Safer,
More Responsible and Cost-effective
Health System

European Directorate for the Quality of Medicines & HealthCare, EDQM

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Contents

Preface

The acceptation of the philosophy of pharmaceutical care throughout this publication and working programme is based on the definition established by Charles D. Hepler and Linda M. Strand.[1]

Definition of pharmaceutical care

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 (1) curing a disease, (2) elimination or reduction of a patients' symptomatology, (3) arresting or slowing down a disease process, or (4) preventing a disease or symptomatology.

Pharmaceutical care involves the process through which a pharmacist co-operates with a patient and other 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:

1. identifying potential and actual drug-related problems,[2]

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1 Hepler C.D. & Strand L.M. Opportunities and Responsibilities in Pharmaceutical Care. Am. J. Pharm. Educ., 53, 7S-15S (1989) and Hepler C.D. & Strand L.M. Opportunities and Responsibilities in Pharmaceutical Care. Am. J. Hosp. Pharm., 47, 533-543 (1990).

2 C.D. Hepler and L.M. Strand, 1989 and 1990: "... A drug-related problem is an event or circumstance actually interfering with the patient experiencing the optimum outcome of medical care (preventing best possible medication outcomes). The concept of drug-related morbidity includes both treatment failure and a new medical problem." Hepler and Strand defined categories of drug-related problems

2. resolving actual drug-related problems, and
3. preventing drug-related problems.

Pharmaceutical care is a necessary element of healthcare, and should be integrated with other elements. Pharmaceutical care is, however, provided for the direct benefit of the patient. The pharmacist is directly responsible to the patient for the quality of that care.

The fundamental relationship in pharmaceutical care is mutually-beneficial exchange, in which the patient grants authority to the provider and the provider gives competences and commitment (accepts responsibility).

The fundamental goals, processes and relationships of pharmaceutical care exist, regardless of practice-setting.

which go beyond safety-related aspects: untreated indications, improper drug selection, sub-therapeutic dosage, failure to receive drugs, over-dosage, adverse drug reaction, drug interactions and drug use without indication.

Executive summary

Medication is the most frequent intervention within healthcare systems worldwide. Achieving the best possible outcome of medication for the quality of life of patients should be *the primary aim of all health professionals involved in the medication process, as well as carers and patients, depending on their abilities and capacities*.

Often, the benefits of medication cannot be realised in patients (e.g. due to treatment failures), and even worse, considerable mortality and morbidity are related to the inappropriate use of medicine use, for example:

- inappropriate prescription ("prescribing errors"),
- inappropriate delivery ("dispensing errors"/"administration errors"),
- inappropriate patient behaviour ("non-adherence with treatment regimen"),
- inappropriate monitoring and reporting,
- patient idiosyncrasy,
- lack of (medication-related) health literacy in the public.

Pharmaceutical care is a quality philosophy and working method for professionals within the medication process. It is indispensable for helping to improve the good and safe use of medicines, thus realising the best possible outcome of medicines for the patient. It contributes to the optimisation of outcomes from medicines and the prevention of harm and inappropriate use. This is achieved through the promotion of medication-related health literacy, the involvement and participation of patients in their medication, and the assignment and acceptance of responsibilities in an appropriate manner within the medication process. Together, these factors improve the quality of life of patients and their families, the utilisation of resources and help reduce inequalities in healthcare. By increasing the cost-efficiency of medicine use, pharmaceutical care will contribute to efficient and effective consumption of existing resources.

In line with the definitions established by C.D. Hepler and L.M. Strand, 1989 and 1990, pharmaceutical care is the provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life, in a relationship where the patient grants authority and the provider gives competence and commitment. It involves the process through which a pharmacist co-operates with a patient and other professionals in designing, implementing, and monitoring a therapeutic plan and influencing patient behaviour. This involves engaging the patient in the treatment of his/her condition, and the identification, handling and prevention of drug-related problems in their broadest sense (e.g. treatment failure through inappropriate or missing medication, adverse drug reactions).

In 2008, the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH) (steering body) co-ordinated by the European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe, commissioned a survey on key concepts in pharmaceutical care and the performance indicators used to evaluate the quality of pharmaceutical care and pharmaceutical services in Europe (N. Kijlstra, K. Ridge and S. Walser, 2009). The survey used the pharmaceutical care philosophy as defined by C.D. Hepler and L.M. Strand (1989 and 1990), with a particular focus on patient concordance/involvement, monitoring (documentation) and multi-disciplinary co-operation between healthcare professionals within the medication process and was, *inter alia*, inspired by Council of Europe Committee of Ministers Resolution ResAP(93)1 on the role and training of community pharmacists.

The survey concluded, *inter alia*, that:

- **pharmaceutical care** is a quality philosophy and working method indispensable for realising the benefits of medicine use for the individual patient and at national levels. It emphasises the importance of the provision of care in a responsible manner, in addition to functions related to medicine quality and logistics of supply;

- **patient participation** and concordance should be enhanced to ensure best possible medication outcomes through, for example, increasing (medication-related) health literacy;
- **policy-makers** should include the implementation of pharmaceutical care into healthcare systems on the **political agenda**;
- internationally-applicable **practical guidance** on the quality of pharmaceutical care for **healthcare professionals** within the entire medicine process should be developed;
- **added-value** of activities inspired by the pharmaceutical care philosophy and working methods should be demonstrated; for example, through outcome-related measures that assess safety, efficacy and cost-effectiveness;
- a set of **basic indicators** (see Table 1, page 13) should be developed and tested that are equally applicable to low-, middle-income and industrialised countries. Co-operation between countries with different situation as regards the implementation of pharmaceutical care should be strongly encouraged. When developing indicators for pharmaceutical care, clearly defined activities relating to healthcare outcomes, acceptable to a wide range of countries, should be selected.

Based on the conclusions of the above report, the Committee CD-P-PH oversees a programme of activities comprising the development and implementation of a set of indicators, generally applicable and more specific, of the implementation of pharmaceutical care in Europe. These activities are carried out by a Committee of Experts, member state delegates, with the help of a network of academic institutions across Europe, which are co-ordinated by the EDQM.

In low-, middle-income and industrialised countries in Europe, the Committee CD-P-PH activity aims to support

health authorities to:

- evaluate the outcomes of national policies in the field of pharmaceutical care,
- assess the performance of the entire medication use process,

- identify needs for improvement,
- revise medicine-related healthcare priorities at the national level through availing common standards, data and experience in other countries in Europe,
- improve professional standards in collaboration with bodies/ associations of healthcare professionals (e.g. pharmacists, doctors, nurses).

healthcare professionals to:

- implement the pharmaceutical care concept in daily practice,
- provide standardised, reliable data on the outcomes of medication (pharmacotherapy),
- improve the evidence base and quality of their professional and practice standards, in the framework of the support provided by the relevant professional bodies/associations.

patients and patients' organisations to benefit from:

- increasing availability and accessibility of reliable information throughout the whole medication process,
- significantly enhanced involvement in the decisions regarding medication (pharmacotherapy) and commitment to therapeutic plans.

This report summarises on one hand the evidence for inappropriate and unsafe use of medicines, non-adherence to good prescribing practices, non-compliance with therapeutic plans, lack of documentation and monitoring of therapeutic plans, preventable adverse drug reactions arising from this use, and on the other hand the benefits of wide-spread implementation of the pharmaceutical care philosophy and working methods for the individual patient and national healthcare systems.[3]

3 C.D. Hepler and L.M. Strand 1989 and 1990: "… Pharmaceutical services like pharmacokinetic dosing, therapeutic monitoring, and drug information …".

In line with the conclusions of the afore-mentioned EDQM (Council of Europe) survey report on pharmaceutical care in Europe (N. Kijlstra, K. Ridge and S. Walser, 2009), this report recommends, *inter alia*, a basic set of pharmaceutical care indicators as outlined in Table 1 and proposes their further development and implementation at international level.

Table 1. Basic indicators for pharmaceutical care

No.	Indicator	Comment
1	Number of pharmaceutical care interventions delivered per standardised denominator, such as 1000 prescriptions dispensed or 1000 patients.	These interventions need to be formally documented and audited and are intended to improve the safe and effective use of medicines. Interventions can suggest a change in the way medicines are prescribed, dispensed, administered or monitored. They may also confirm treatment decisions, foster patients' agreement and adherence to therapeutic plans, promote medication-related health literacy in patients, and support the joint development, agreement and follow-up (monitoring) of treatment plans by patients and health professionals.
2	Number of patients counselled about their medicines per standardised denominator, such as 1000 prescriptions dispensed or 1000 patients.	Formally documented and audited. Counselling comprises information given to an individual patient as part of the medication process that is adequate to ensure his/her ability to use the medication and to adapt his/her lifestyle in such a way as to have the best possible medication outcome.
3	Number of formal written feed-back responses from patients during treatment per 1000 prescriptions or 1000 patients about patients' specific medication-related literacy, concerns, life-quality needs/expectations, and satisfaction.	Formally documented and audited. This feed-back should be preferably encouraged at an early stage of the therapeutic plan in order to better implement and monitor the therapeutic plan. For examples of this indicator, see Item 5.2.2.
4	Number of adverse drug event reports (to include both adverse drug reactions and medication errors) per year.	Formally documented and audited and reported to recognised regional/national organisations and there must be documented evidence of local learning and systems' improvement.

These indicators are equally appropriate for in-patient and community settings, for hospital and community pharmacists, and other healthcare professionals, as applicable, in low-, middle-income and industrialised countries in Europe and other regions of the world. The indicators provide information about the range, quantity and quality of pharmaceutical care interventions/services[4] delivered. The indicators also provide an opportunity to gather in-depth knowledge on pharmaceutical care practices regionally, nationally, and internationally that will permit the sharing and follow-up of experiences over time by professional disciplines and the health sector in general, regionally, nationally and internationally.

These indicators are rather broad, and can be further developed and refined over time, but they are easily understood and will help pharmacists, other healthcare providers, and professional regulators to formalise and develop the pharmaceutical care philosophy and its working methods.

In the conclusions, the report proposes elements of a specific health policy agenda, which promotes approaches to realise the benefits of responsible medicine use in the best interests of patients' quality of life and sustainable social cohesion, such as through the implementation of pharmaceutical care. Indicators provide information indispensable for policy-makers and professional regulators to steer this process. Furthermore, the attention of policy-makers is drawn to the importance of international co-operation as regards the establishment of quality indicators for pharmaceutical care, evaluation and follow-up for healthcare policies and best professional practices in this field.

Implementing pharmaceutical care as a necessary quality-enhancing element in healthcare requires innovative approaches to improve patient participation, inter-professional collaboration in terms of therapeutic planning and monitoring, and a better focus on improving

4 See footnote 3 on page 12.

medicine use through monitoring of outcome-related indicators of pharmaceutical care.

Governments and policy-makers are invited to:

- acknowledge that optimal health and development should be built on the core pillars of participation, promotion, protection, prevention and provision and that an appropriate healthcare approach must be patient-focussed and ensure patient participation in the healthcare decisions affecting them, fostering their medication-related health literacy;
- commit to take specific action against health damage, diminished quality of life, work force reductions, and wasted healthcare resources that arise from the inappropriate use of medicines and drug-related problems as understood in their broadest sense;
- acknowledge available evidence that the pharmaceutical care philosophy and working methods can help achieve the benefits of responsible medicine use for individual patients and healthcare systems at national and regional levels by addressing issues of inappropriate medicine use in a comprehensive manner and, thereby, improving patient outcomes;
- promote and implement the pharmaceutical care philosophy and working methods in their national healthcare systems;
- introduce in all countries of the world, generally applicable quality indicators for pharmaceutical care to provide themselves with valid information for policy-making and to set professional standards and best practices in the field;
- in this context, support the wide application of generally applicable quality indicators for pharmaceutical care, as included in Table 1, page 13 of this report, and to provide for a mid-term strategy to follow up on the results and measures taken in response to the data generated;
- support programmes and activities for international collaboration to further develop pharmaceutical care standards, guidelines and training for the implementation and monitoring of pharmaceutical

care using, *inter alia*, generally-applicable and specific quality indicators. Examples of such programmes are those being carried out or supported by international organisations such as the Council of Europe and its EDQM, the WHO and relevant professional associations of pharmacists (such as the International Pharmaceutical Federation, FIP), medical doctors, nurses and other relevant health professions;

- avail themselves of the professional expertise of public health institutions, relevant professional associations (notably of pharmacists, medical doctors, nurses and other relevant professions) and patient organisations.

1. Defining pharmaceutical care

Medication is the most frequent intervention within healthcare systems worldwide. Achieving the best possible outcome of medication for the quality of life of patients should be *the primary aim of all health professionals involved in the medication chain, as well as carers and patients depending on their abilities and capacities*.

Pharmaceutical care is a quality philosophy and working method for professionals within the medication chain. It is indispensable for helping to improve the good and safe use of medicines, thus realising the full potential of medicines available on the market to achieve the best possible outcome in patients. It contributes to the prevention or reduction of inappropriate medicine use by promoting (medication-related) health literacy, the involvement and participation of patients in their medication, greater equality in healthcare, and the balanced sharing of responsibilities. These factors serve to improve the quality of life of patients and their families and the cost-effective utilisation of resources and to reduce inequalities in healthcare.

This report uses the definition of pharmaceutical care as established by C.D. Hepler and L.M. Strand (1989 and 1990) (see Preface, page 7).

2. Council of Europe activities in pharmaceutical care

Committed to the promotion of human and social rights, notably through its European Convention on Human Rights and Fundamental Freedoms and the Social Charter, the Council of Europe adopted the following relevant legal instrument addressing recommendations to governments of member states in the context of a common policy with regard to pharmaceutical care:

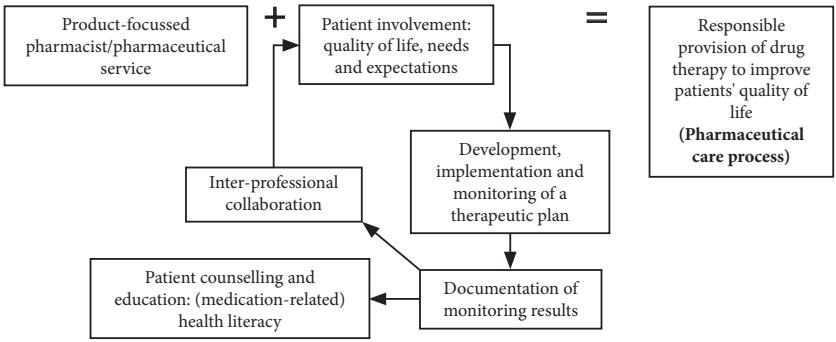
> Council of Europe Committee of Ministers Resolution ResAP(93)1 on the role and training of community pharmacists "*… considers that the primary focus of pharmaceutical care shall at all times be targeted towards patient advantage, either individually or collectively, whether directed at health promotion or maintenance, symptom relief, or maximising benefits and minimising risks from medication …*".

In accordance with the mission of the Council of Europe's European Directorate for the Quality of Medicines & HealthCare (EDQM), which includes "*… the development of policies for the safe use of medicines in Europe, including through pharmaceutical care …*", the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH), steering body, co-ordinated by the EDQM, was mandated to "… *contribute to improving public health and reducing health inequalities via developing harmonised provisions and practices including the rational use of medicines, implementing and promoting pharmaceutical care in Europe (having regard to the internationally recognised definition of pharmaceutical care by C.D. Hepler and L.M. Strand (1990) adopted and amended by WHO/FIP …*".

In 2008, the Committee CD-P-PH commissioned a survey on key concepts in pharmaceutical care and the performance indicators used to evaluate the quality of pharmaceutical care and pharmaceutical services in Europe (N. Kijlstra, K. Ridge and S. Walser, 2009). The survey used the pharmaceutical care philosophy and working methods established by C.D. Hepler and L.M. Strand (1989 and 1990), with a

particular focus on patient concordance/involvement, monitoring (documentation) and multi-disciplinary co-operation between healthcare professionals within the medication process (see Diagram 1).

Diagram 1



3. The case for pharmaceutical care

Often, the benefits of medication cannot be realised in patients (e.g. due to treatment failures or deficits), and even worse, considerable mortality and morbidity are related to inappropriate medicine use, for example:

- inappropriate prescription ("prescribing errors"),
- inappropriate delivery ("dispensing errors"/"administration errors"),
- inappropriate patient behaviour ("non-adherence with treatment regimen"),
- inappropriate monitoring and reporting,
- patient idiosyncrasy,
- lack of (medication-related) health literacy in the public.

3.1. Inappropriate and unsafe use of medicines

3.1.1. Medication error reports

A review of all incidents of medication errors reported to the National Reporting and Learning System (NRLS) in England and Wales between 1 January 2005 and 31 December 2010 was undertaken (Cousins *et al.*, 2012). The 526,186 medication error reports represented 9.68% of all patient safety incidents. Medication errors from acute general hospitals (394,951) represented 75% of reports. There was a relatively smaller number of medication error reports (44,952) from primary care, representing 8.5% of the total. Some 86,821 (16%) medication errors reported actual patient harm, with 822 (0.9%) of these errors resulting in death or severe harm.

Errors involving medicine administration 263,228 (50%) and prescription 97,097 (18%) were the process steps having the largest number of reports. Omitted and delayed medicine 82,028 (16%) and wrong dosages 80,170 (15%) represented the largest error categories.

Thirteen medicines or therapeutic groups accounted for 377 (46%) of the errors resulting in death or severe harm.

The National Patient Safety Agency (NPSA), United Kingdom, has issued guidance to help minimise errors with many of these medicines. Many recent errors could have been prevented if the NPSA guidance had been better implemented. It is recommended that healthcare organisations in all sectors establish an effective infrastructure to oversee and promote safe medication practice in the spirit of pharmaceutical care, including an annual medication safety report. In the future, preventable harm from medication can be further minimised by the continued use of the NRLS to identify and prioritise important actions for improving medication safety, continuing to issue medication safety guidance to the national healthcare providers via a central organisation and better methods to ensure that the NHS has implemented this guidance.

3.1.2. Prescribing errors

Hospital

A review was done of studies carried out between January 1985 and October 2007 on prescriptions for adult or child hospital in-patients that provided enough data to calculate an error rate. Electronic prescriptions and certain other types of prescribing errors were excluded from the review (Lewis *et al.*, 2009).

The median error rate (interquartile range [IQR]) was 7% (2-14%) of medication orders, 52 (8-227) errors per 100 admissions and 24 (6-212) errors per 1000 patient days. Most studies (84%) were conducted in single hospitals in the USA or the UK (72%). Most errors were intercepted and reported before they caused harm, although 2 studies reported adverse drug events.

Errors were most common with antibiotics and more common in adults (median 18% of medication orders [10 studies, IQR 7-25%]) than children (median 4% [6 studies, IQR 2-17%]). Incorrect dosage was the

most common error. Overall, it is clear that prescribing errors are a common occurrence, affecting 7% of medication orders, 2% of patient days and 50% of hospital admissions. However, the reported rates of prescribing errors varied greatly and this could be partly explained by variations in the definition of a prescribing error, the methods used to collect error data and the background of the study. Furthermore, a lack of severity scale standardisation for measuring harm to patients prevented any comparison of error severity across studies.

General practice

Avery, Barber *et al.* (2012) conducted a study of prescribing errors in general practice for 1,777 patients in the UK. Prescribing or monitoring errors were detected for one in 8 patients, involving around one in 20 of all prescribed medicines. The vast majority of errors were of mild to moderate severity, with one in 550 prescribed medicines being associated with a severe error. The following factors were associated with an increased risk of prescribing or monitoring errors: male gender, age less than 15 years or greater than 64 years, number of unique medication units prescribed, being prescribed preparations in the therapeutic areas of cardiovascular disease, infection, malignant disease, immunosuppression, musculoskeletal disease, and/or eye, ear-nose-throat (ENT) and skin disease. Prescribing or monitoring errors were not associated with the grade of general practitioner or whether prescriptions were issued as acute or repeat medication.

A wide range of underlying causes for the errors were identified, which were related to the prescriber, the patient, the primary care team, the working environment, the intervention, the computer system and the primary/secondary care interface. Many defences against errors were also identified, including strategies employed by individual prescribers and primary care teams, and making the best use of health information technology.

Conclusion

> Research studies indicate that prescribing errors in hospitals and in general practice are common. Not all prescribing errors cause harm, although a significant number do. Healthcare systems need to be re-designed to minimise the harm arising from prescribing errors. Using pharmaceutical care philosophy and methods enables pharmacists to work in collaboration with prescribers, patients and carers to identify and correct prescribing errors, minimise harm and achieve better healthcare outcomes.

3.1.3. Dispensing errors

Research publications from January 1966 to February 2008 were searched for studies indicating dispensing error rates (James *et al.*, 2009).

Sixty papers were identified that had investigated dispensing errors in Australia, Brazil, Spain and the USA. In general, the incidence of dispensing errors varied depending on the study setting, dispensing system, research method and operational definitions. The most common dispensing errors identified for community and hospital pharmacies were dispensing the wrong medicine, strength, form or quantity, or labelling medication with incorrect instructions for use.

Factors subjectively reported as contributing to dispensing errors were "look-alike, sound-alike" medicines, low staffing and computer software. High workload, interruptions/distractions and inadequate lighting were objectively shown to increase the occurrence of dispensing errors.

A comparison of the reviewed studies was confounded by differences in study settings, research methods, operational definitions for dispensing errors and error rates, and the classification of error types. The incidence of dispensing errors ranged between 0.01-3.32% in community pharmacies and 0.02-2.7% in hospital pharmacies.

Conclusion

> Research studies indicate that dispensing errors occur less frequently than prescribing errors. Not all these errors cause harm to patients, but some do. By requiring more knowledge of the clinical and quality of life needs of the patient and better communication, pharmacists providing pharmaceutical care services are in a better position to identify when a dispensing error has occurred, even before the medicine has been supplied to the patient, and to correct these errors, minimise harm and achieve better outcomes.

3.1.4. Medicine administration errors (MAE)

A research publication reported MAE rates in adult general wards in the United Kingdom between 1995-2009 of between 3-8% (Kelly and Wright, 2011).

What constitutes a medication administration error varies between studies, making comparisons difficult. Some studies include time errors (e.g. if a medicine is given one hour earlier or later than when it was prescribed for), whilst other studies ignore them. Time errors can have a significant effect on the MAE rate; for example, one study found that if they excluded time errors, their medication administration error rate dropped from 16.6% to 12.9%. The focus of MAE research on the number of errors can be misleading and over-estimate the problem. It is the severity of the errors that is important from the patient's perspective.

In 2011, a study of MAEs in older people in hospital wards in the UK (Kelly and Wright, 2011) found that the number and severity of medication administration errors was higher than in previous studies. During 65 medicine rounds observing 2,129 potential drug administrations made to 625 patients, 817 doses (38.4%) were given incorrectly (95% CI = 36.3-40.4). The overall mean harm score of the 35 incidents analysed was 4.1 (range 1.1-8.6, SD 1.8) on a scale of 0-10, where a score of 0 was given to an incident that was considered to have no effects on the patient and 10 given to an incident that would result in death.

Conclusion

> Medicine administration errors are the most frequent type of medication error in hospitals. Not all administration errors harm patients, but a significant number of these errors do. Pharmacists providing pharmaceutical care services outside the hospital pharmacy department, working collaboratively with prescribers, nursing staff and patients can proactively and reactively identify medicine administration error risks and take action to minimise these risks and their resulting harmful effects and improve healthcare outcomes.

3.1.5. Preventable adverse drug events (pADEs) in ambulatory care

Research publications between January 1966 and March 2007 were searched for studies indicating rates for preventable adverse drug events (pADEs) in ambulatory care (Thomsen *et al.*, 2007).

The median pADE incidence was 5.6 per 1000 person-months (1.1-10.1). The median pADE rate was 21% (11-38%). The median incidence of pADEs requiring hospital admission was 4.5 per 1000 person-months.

Cardiovascular medicines, analgesics and hypoglycaemic medicines together accounted for 86.5% of pADEs, and 77.2% of pADEs resulted in symptoms for the central nervous system, the electrolyte/renal system and the gastrointestinal tract.

Medication errors resulting in pADEs occurred in the prescription and monitoring stages. The most frequent medicine therapy problem reported in ambulatory-based studies of pADEs was the use of inappropriate drugs (42.7%, range 40.4-45%). For pADEs requiring hospital admission, the most frequent drug therapy problem reported was inadequate monitoring (45.4%, range 22.2-69.8%). Failure to prescribe prophylaxis to patients taking non-steroidal anti-inflammatory drugs or anti-platelet medicines frequently caused gastrointestinal toxicity, whereas lack of monitoring of diuretic,

hypoglycaemic and anti-coagulant use caused over- or under-diuresis, hyper- or hypoglycaemia and bleeding.

Adverse drug events are common in ambulatory care, with many being preventable and many resulting in hospitalisation. Quality improvement programmes should target errors in prescribing and monitoring medications, especially for patients using cardiovascular, analgesic and hypoglycaemic medicines.

Conclusion

> Preventable adverse drug events in ambulatory care (pADEs) cause harm to patients and admissions to hospital are relatively common. There are some high risk medicines that frequently cause harm. Community healthcare systems need to be re-designed to address the current high levels of preventable harm from medicine. By using pharmaceutical care philosophy and methods, pharmacists can work collaboratively with other healthcare professionals, patients and carers to identify actual and potential drug-related problems and suggest corrective actions to minimise harm and promote positive outcomes from medicine use.

3.1.6. Under-reporting of adverse drug reactions (ADRs)

A systematic literature search was carried out to identify studies providing a numerical estimate of under-reporting of adverse drug reactions (ADRs) (Hazell and Shakir, 2006). Studies from both hospitals and general practice were included. Estimates of under-reporting were either extracted directly from the published study or calculated from the study data. These were expressed as the percentage of ADRs detected from intensive data collection that were not reported to the relevant local, regional or national spontaneous reporting systems. The median rate of under-reporting was calculated across all studies and within sub-categories of studies using different methods or settings. In total, 37 studies using a wide variety of surveillance methods were identified from 12 countries. These generated

43 numerical estimates of under-reporting. The median rate of under-reporting across the 37 studies was 94% (interquartile range 82-98%). There was no significant difference in the median rates of under-reporting calculated for general practice and hospital-based studies. This systematic review provides evidence of significant and widespread under-reporting of ADRs to spontaneous reporting systems, including serious or severe ADRs. Further work is required to assess the impact of under-reporting on public health decisions and the effects of initiatives to improve reporting, including by pharmacists.

Conclusion

> Only a very small percentage of the ADRs that occur are reported via national spontaneous reporting systems. Currently, the majority of harm arising from medicine use goes unreported. As a result, the local, national and international actions required to minimise harm and maximise patient outcomes may be delayed or may not occur due to lack of information. By using pharmaceutical care philosophy and methods, pharmacists can work in collaboration with other healthcare professionals, patients and carers to identify actual and potential drug-related problems and report these to spontaneous reporting programmes. The number of ADR reports is included as one of the key indicators for pharmaceutical care services in this report.

3.2. Poor adherence to prescribed medicines and lack of effectiveness

Low adherence by patients to their prescribed treatments is very common (Haynes *et al.*, 2008). Typical adherence rates for prescribed medications are about 50%, but with a very broad range. Given that the response to treatment is related to the dosage and schedule of a therapy, non-adherence reduces treatment benefits and can bias assessment of the efficacy of treatments. With increasing numbers of efficacious self-administered treatments, the need is apparent for better understanding and management of non-adherence.

Of the 21 new randomised controlled trials in a Cochrane review update (an evidence-based medicine database) describing 24 interventions to improve adherence to prescribed medications, only 5 studies (21%) showed positive trends for both adherence and clinical outcome. Three of these studies involved allied health professionals, such as nurses and pharmacists, leading the adherence intervention. It may be feasible to expand the roles of nurses and pharmacists to include counselling with patients to enhance medication adherence. The effectiveness of these interventions should be further explored.

Conclusion

> Research indicates that only 50% of patients take their medicines as intended by the prescriber. This leads to sub-optimal healthcare outcomes. By using pharmaceutical care philosophy and methods, pharmacists can better inform patients and carers about their medicines and help tailor the medicine prescribed to meet the healthcare and quality of life needs of patients, with the aim of improving their adherence to their medicine treatment plan.

4. Evidence of the benefits of pharmaceutical care

4.1. Australian research on community pharmaceutical care interventions

In Australia, there has been extensive and on-going interest and research into community pharmacy pharmaceutical care interventions during the basic dispensing process (Peterson and Tenni, 2007; Reeve, Tenni and Peterson, 2007; Peterson *et al.*, 2010; Williams et al., 2011). This has prompted a wide range of reforms to improve the effectiveness and efficiencies of the healthcare system. Research findings identified 2 consistent themes as critical areas for reform to improve the quality, safety and sustainability of the Australian healthcare system. Firstly, the need to strengthen primary care and, secondly, the need to adopt a prevention focus (Peterson *et al.*, 2010).

The Australian government recognised that community pharmacists, as the most regularly visited primary healthcare providers, were integral to ensuring the quality of medicine use and in meeting broader healthcare agenda goals. The government concluded that they needed community pharmacists to provide timely, accurate and understandable information about medicines to their patients. However, only a small number of patients were accessing these pharmaceutical care services where they were available (Peterson *et al.*, 2010).

The Australian government clarified the need for community pharmacists to deliver pharmaceutical care as part of the basic dispensing service and provided computer documentation software that community pharmacists could use when providing pharmaceutical care to their patients. A study was carried out on 210 Australian community pharmacies. There were 6,230 pharmaceutical care interventions to address drug-related problems (DRPs) over a 12-week study period, for example 0.31 clinical pharmacy interventions per 100 prescriptions or one intervention for

every seventy patients (see also Table 1, Indicator No. 1, Interventions normally suggested a change in the way medicines were prescribed, dispensed, administered or monitored). The clinical significance of the pharmaceutical care interventions were judged as addressing a moderate or severe DRP in 43% of cases (Peterson *et al.*, 2010).

The research indicated that the adoption of pharmaceutical care interventions could have a combination of the following effects on healthcare utilisation, in terms of a change in the:

- number of visits to a general practitioner,
- number of visits to a hospital specialist,
- number of investigative tests performed,
- number of hospital admission days,
- cost of purchased medicines.

The above study (PROMISe III) found that 39% of pharmaceutical care interventions prevented or required a visit to the GP or hospital admission (Peterson *et al.*, 2010).

Conclusion

> Australian research has found that only a small number of patients accessed timely, accurate and understandable information about medicines from community pharmacists as part of the basic dispensing service. The Australian government clarified the need for community pharmacists to deliver pharmaceutical care as part of the basic dispensing service and provided computer documentation software for community pharmacists to use when providing pharmaceutical care to their patients. Following this initiative, there were improvements in clinical outcomes, hospital admissions and the cost of purchased medicines.

4.2. Preventing adverse drug events/medication errors in general practice in the United Kingdom

Medication errors are common in primary care and are associated with a considerable risk of patient harm. A pharmacist-led, information technology-based intervention was compared to a simple computer-generated feedback in terms of reducing the number of patients at risk of measures related to unsafe prescriptions and inadequate blood-test monitoring of medicines 6 months after this pharmaceutical care intervention (Avery, Rogers *et al.*, 2012).

Seventy-two general medical practices that provided care to 480,942 patients were allocated to either the simple computer-generated feedback for at-risk patients (control) or a pharmacist-led, information technology-based intervention (PINCER) composed of feedback, educational outreach and dedicated support.

Primary outcomes were measured in terms of the proportions of patients at 6 months after the intervention who had had any of 3 clinically-important errors:

1. non-selective, non-steroidal anti-inflammatory drugs (NSAIDs) prescribed to those with a history of peptic ulcer without co-prescription of a proton-pump inhibitor,
2. β-blockers prescribed to those with a history of asthma, and
3. long-term prescription of angiotensin converting enzyme (ACE) inhibitor or loop diuretics to those 75 years or older without assessment of urea and electrolytes in the preceding 15 months. The cost per error avoided was estimated by incremental cost-effectiveness analysis.

Patients in the PINCER group were significantly less likely to have been prescribed a non-selective NSAID without gastro-protection if they had a history of peptic ulcer (Odds-ratio OR 0·58, 95% CI 0·38-0·89), a β-blocker if they had asthma (0·73, 0·58-0·91), or an ACE-inhibitor or loop diuretic without appropriate monitoring (0·51, 0·34-0·78). PINCER has a 95% probability of being cost effective being cost effective if the decision-makers were willing to pay a maximum

of €95 per error avoided. The PINCER intervention is an effective method using computerised clinical records to reduce a range of medication errors in general practices.

Conclusion

> Medication errors in general practices were reduced by introducing regular visits by pharmacists, who provided pharmaceutical care interventions consisting of feedback, education and support to the general practice prescriber. This system is applicable to all general practice settings where medicines are prescribed, independently of whether the general practice is located in a low-, middle-income or industrialised country.

4.3. Pharmaceutical care for hospital in-patients

Research on pharmaceutical care for hospital in-patients published between 1 January 1985 and 30 April 2005 was evaluated by 3 independent assessors. In-patient pharmacist interventions were selected if they included a control group and objective patient-specific health outcomes. The type of intervention, study design and outcomes such as adverse drug events, medication appropriateness and resource use were extracted (Kaboli *et al.*, 2006).

Thirty-six studies met the inclusion criteria, including 10 that evaluated pharmacist participation on medical rounds, 11 medication reconciliation studies and 15 on drug-specific pharmacist services.[5] Adverse drug events, adverse drug reactions or medication errors were reduced in 7 of the 12 trials that included these outcomes. Medication adherence, knowledge and appropriateness improved in 7 of 11 studies, while the durations of hospital stays decreased in 9 of 17 trials. No intervention led to worse clinical outcomes and only one study reported more use of healthcare services by patients.

5 See footnote 3 on page 12.

Improvements in both in-patient and out-patient outcome measurements after discharge were observed.

Conclusion

> Research evidence demonstrates that the addition of pharmaceutical care services in the care of in-patients generally results in improved care, with no evidence of harm. Interacting with the healthcare team on patient rounds, interviewing patients, reconciling medications and providing patient discharge counselling and follow-up all resulted in improved outcomes.

4.4. Pharmaceutical care in community or ambulatory care settings

Research, published between January 1966 and March 2008, and using randomised controlled trials, was examined to compare:

1. pharmaceutical care services by a pharmacist targeted at patients versus services delivered by other health professionals,
2. pharmaceutical care services by a pharmacist targeted at patients versus the delivery of no comparable service,
3. pharmaceutical care services by a pharmacist targeted at health professionals versus services delivered by other health professionals, and
4. pharmaceutical care services by a pharmacist targeted at health professionals versus the delivery of no comparable service. Two authors independently reviewed studies for inclusion, extracted the data and assessed the risk of bias of the chosen studies (Nkansah *et al.*, 2010).

Forty-three studies were included, of which 36 were pharmacist interventions targeting patients and 7 studies were pharmacist interventions targeting health professionals. For comparison 1), the only included study showed a significant improvement in systolic

blood pressure for patients receiving medication management from a pharmacist compared to usual care from a physician. For comparison 2), in the five studies evaluating care outcomes, pharmacist services reduced the incidence of therapeutic duplication and decreased the total number of medications prescribed. Twenty-nine of the 36 studies reported positive clinical and patient outcomes.

Conclusion

> A review of published research has shown that pharmaceutical care interventions result in improvements in most clinical outcomes, although these improvements were not always statistically significant. A total of 8 studies reported patient quality of life outcomes; of these 3 studies showed improvement in at least 3 subdomains of recognised quality of life questionnaires. The other studies did not show statically significant difference. Details of the specific subdomains were not included in the paper.

4.5. Pharmaceutical care and antibiotic stewardship

A study examining the impact of an anti-microbial prescribing protocol for management of community-acquired lower respiratory tract infections reported both clinical and economic effects (Al-Eidan *et al.*, 2000). Clinical pharmacists were involved in the development of the protocol and encouraged its routine implementation on hospital wards. Patients treated using the protocol showed significantly reduced durations of hospital stays, reduced need and durations for intravenous drug therapies and a reduction in treatment failures.

A multi-centre study of guideline implementation for treating pneumonia was carried out at 23 hospitals and 60 out-patient clinics in the USA (Dean *et al.*, 2001). Pharmacists were part of the multi-disciplinary group that developed and implemented the guidelines and the study reported a significant reduction in 30-day mortality (odds ratio 0.69, 95% CI 0.49-0.97) for hospitalised patients treated by physicians who participated in the guideline programme.

A study reporting microbiological outcomes following implementation of a multi-disciplinary anti-microbial management team, which included pharmacists, reported significant and sustained reductions in Clostridium difficile-associated diarrhoea and resistant Enterobacteriaceae (Carling *et al.*, 2003).

Researchers at a tertiary university hospital in Scotland evaluated the impact of a restrictive policy on the use of anti-microbial medicines implemented by ward pharmacists. They reported a significant and sustained reduction in the use and cost of restricted agents in the 2 years following introduction of the policy. The cost of development, dissemination and implementation of the policy was fully evaluated and found to be 20% of the cost savings generated (Ansari *et al.*, 2003).

Information about the cost-effectiveness of employing specialist pharmacy staff in antibiotics is lacking, but savings of £10 per patient reviewed on multi-disciplinary ward rounds per day has been attributed to employment of an antibiotic pharmacist (Jones and Cheesbrough, 2005). Some hospitals have reported annual cost savings associated with antibiotic management activities of between £23,000 and £500,000 (Wickens and Jacklin, 2006).

Two anti-microbial stewardship strategies were implemented on an intensive care unit (K. Leichenberg, M. Hartmann, 2012) involving:

- pharmacist participation on ward rounds (prospective audit with intervention),
- monitoring of anti-microbial use (control of antibiotic consumption) and quarterly presentation of the data.

From January 2010 to December 2011, antibiotic consumption data were collected quarterly. The data were calculated on the basis of recommended daily dose (RDD) and application-dense (RDD per 100 patient's days) criteria. All interventions that were documented in the 2-year period were analysed for the cause of the intervention, the resulting action taken and the outcome. Over the 2-year period, 1,510 interventions were performed. Anti-microbial drugs were involved in 200 (13.3%) of these interventions. The reasons for

interventions included: no clear indication for the drug (n = 52/200 [26.0%]), incorrect dosage (n = 51/200 [25.5%]) and inappropriate drug prescription (n = 31/200 [15.5%]). In 55 (23%) of the interventions, the antibiotics were discontinued. In total, 146 (83%) pharmacist interventions were implemented. In 24 (12%) cases, information about antibiotic drugs was given to the physicians.

In July 2011, antibiotic consumption data for this study were reported and high consumption of broad-spectrum beta lactam- and linezolid-containing medicines was identified as problem within antibiotic therapy. However, following the introduction of quarterly reports on antibiotic consumption and new clinical approaches, the use of broad-spectrum antibiotics was reduced from 81.6% to 75.0% (RDD) and consumption decreased by 27.8% if RDD per 100 patient's days was chosen as criterion.

Conclusion

> Research evidence demonstrates that the addition of pharmaceutical care services can be beneficial to antibiotic stewardship and can reduce inappropriate antibiotic consumption, incorrect dosages and reductions in *Clostridium difficile*-associated diarrhoea and resistant *Enterobacteriaceae*.

4.6. Pharmaceutical care and adverse drug reaction (ADR) reporting

Hospital pharmacists can play a significant role in ADR reporting, many serious adverse drug events occur in hospitals, and ADRs account for a substantial proportion of hospital admissions. Community pharmacists can also play an important role in ADR reporting. For example, in the Netherlands, community pharmacists contribute substantially to ADR reporting, both in terms of numbers and quality. The contribution of pharmacists to pharmacovigilance

should not, however, be limited to ADR reporting. Input from the various pharmaceutical disciplines could also greatly enhance our understanding of the nature of ADRs (van Grootheest and de Jong-van den Berg, 2005).

Conclusion

> Using pharmaceutical care philosophy and methods enables pharmacists to work collaboratively with prescribers, patients and carers to identify and manage adverse drug reactions and to report these reactions to national spontaneous reporting programmes.

5. Indicators for pharmaceutical care as a tool to achieve the benefits of responsible medication use

5.1. Background to the EDQM indicator development programme

In line with the 2009 survey into pharmaceutical care recommendations, a project was carried out by the Committee of Experts on Quality and Safety Standards in Pharmaceutical Practices and Pharmaceutical Care (CD-P-PH/PC); subordinate to the Committee CD-P-PH, to develop and validate indicators for the quality of pharmaceutical care for use in Europe (see Item 2). In 2009, areas for the development of indicators were defined in scoping ("screening") studies and discussed and agreed with a wide audience composed of the relevant authorities from member states and stakeholder associations from the medication process at the expert workshop *Assessing the quality of patient-centred pharmaceutical care in Europe – where do we stand, where should we go*?, held in Strasbourg on 19 November 2009[6].

In 2010, the scientific rationale of model indicators was established on the basis of published literature and results of studies within the above project. These results were also discussed with a similar wide audience at the expert workshop *Development of indicators for the quality assessment of pharmaceutical care in Europe*, held in Strasbourg on 10 December 2010.

This pharmaceutical indicator research programme covers the development and implementation of generally-applicable and

6 Expert Workshop (Proceedings), http://www.edqm.eu/en/Quality-and-Safety-Standards-in-Pharmaceutical-Practices-Pharmaceutical-Care-1244.html (right column, Past Events).

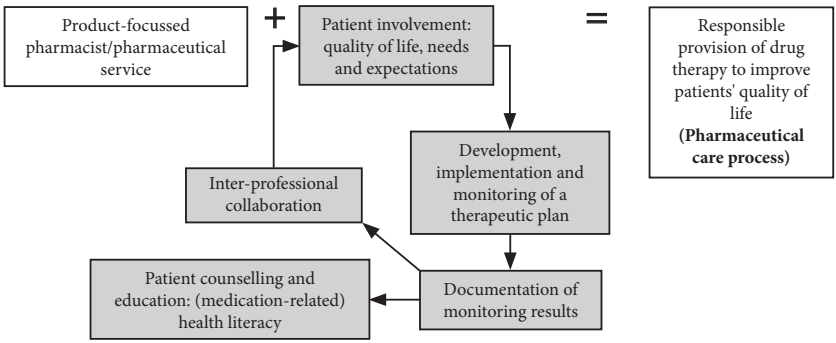
The Committee of Experts CD-P-PH/PC website "Programme results 2008-10" hosted by the EDQM, http://www.edqm.eu/en/Quality-and-Safety-Standards-in-Pharmaceutical-Practices-Pharmaceutical-Care-1244.html.

specific pharmaceutical care indicators, and the compilation, analysis and publication of the information obtained in the following areas: drug-related problems, ("medication safety – adherence to treatment guidelines"), monitoring of therapeutic plans ("medication monitoring and data linkage"), responsible provision of drug therapy to improve the quality of life of patients, interdisciplinary and patient communication, implementation of pharmaceutical care into the practices of healthcare professionals, and "patient involvement and self-management". These activities are being co-ordinated by the EDQM and are one element of the EDQM's mid-term strategy in the field of pharmaceutical care.

5.2. On-going research to develop indicators for the quality of pharmaceutical care

5.2.1. Pharmaceutical care interventions: monitoring and improving pharmacists' knowledge and implementation of the pharmaceutical care philosophy and working methods.

Diagram 2



Rationale

It is important to develop a set of pragmatic indicators of the level of knowledge and implementation of the pharmaceutical care philosophy and its working methods among community and hospital pharmacists.

In order to improve the acceptance and value of such indicators, they have been developed in the form of a questionnaire that permits, on the one hand, individual self-assessment and distance-learning for pharmacists and, on the other hand, monitoring of regional or national training programmes and other initiatives in the field of pharmaceutical care. Monitoring of the impact of initiatives/training is based on the evaluation of a representative number of questionnaires from the pharmacists that participate in the campaign/training. If desired, the evaluation can be anonymised. As follow-up, specific measures including education materials for pharmaceutical care can be developed and implemented.

The questionnaire including the indicators can be supplied together with a "user manual", which provides information and tools for distance learning for individual pharmacists. The recommendations for the improvement of pharmaceutical care working methods in practices depend on the scores obtained ("self-assessment tool").

Indicators: assess pharmacists' knowledge and implementation of the pharmaceutical care philosophy and its working methods.

The questionnaire fields "Medicines dispensing", "Self-care" and "Point of care testing (health screening)" contain questions on how pharmacists provide the above-mentioned essential services in line with the pharmaceutical care philosophy. These sections consist of five sub-sections:

- patient assessment,
- patient counselling and education,
- documentation,
- follow-up of the therapeutic plan,
- inter-professional collaboration.

The section "Evaluation of self-assessment" provides a tool to assess the level of pharmaceutical care implementation according to the total score obtained. It has 4 levels:

- no implementation of pharmaceutical care,
- low level of implementation of pharmaceutical care,
- medium level of implementation of pharmaceutical care,
- high level of implementation of pharmaceutical care.

"Recommendations for improvement" are provided in the form of an accompanying user manual which provides practical advice ("distance-learning") on how to improve pharmaceutical care working methods in community pharmacies, depending on the level of pharmaceutical care implementation by the individual respondents.

Indicator development and piloting

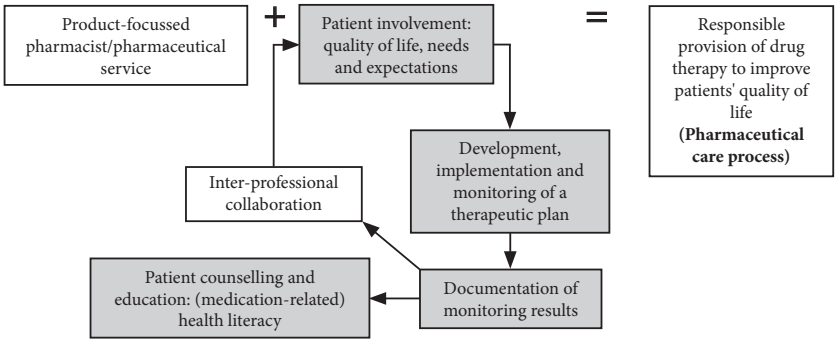
A specific working party of the scientific network co-ordinated by the EDQM and composed of Ms Zinaida Bezverhni (Moldova), Dr Zaza Chapichadze (Georgia), Ms Olga Grintsova (Ukraine), Professor Afrim Tabaku (Albania), and Ms Kristine Vrublevska (Latvia), established the rationale of the afore-mentioned indicators in 2011 and piloted them.

Interventions

Questionnaires containing the indicators (the "self-assessment tool") were developed and piloted in local language versions in community pharmacies in Albania, Latvia, Georgia Moldova and Ukraine. All replies could be scored.

5.2.2. Pharmaceutical care interventions: develop, agree, implement and monitor the therapeutic plan in co-operation with the patient, taking account of patient needs and expectations through patient involvement and promoting patient medication-related health literacy.

Diagram 3



Rationale

The pharmaceutical care philosophy considers patient involvement in the development, implementation and monitoring of a therapeutic plan a crucial element in the responsible use of medicines and, in particular, as regards chronic medication. Communication with patients is essential to understand his/her level of medication-related health literacy, and his/her needs, (social, professional, life-quality), expectations and concerns. Without recognising these important elements of patient's attitudes towards medication, doctors, prescribers and other professionals involved in the medication process will not succeed in tailoring the therapeutic plan to their patients. As a result, patient concordance with their therapeutic plan and vigilance towards unwanted effects will be reduced and the necessary close co-operation with their health provider will be diminished, leading to poor medication outcomes. The ability of patients to express their

needs, concerns and expectations as regards a new drug therapy can be measured with "Self-completion concordance forms" (SCCF forms).

Indicators

1. Number of SCCF forms completed by patients/1000 first prescriptions of a medicine for chronic treatment.
2. Number of SCCF forms recorded in a pharmacy/1000 prescriptions of a medicine for chronic treatment.
3. Number of clinical medication reviews carried out on the provision of pharmaceutical care to specific patient groups (e.g. elderly patients > 65 years, using > 5 medications for chronic medical conditions).

Indicator piloting and development

In 2010-2011, a specific working party of the scientific network, co-ordinated by the EDQM and chaired by Professor Han de Gier, Ms Marlies Geurts and Ms Iris Zuydgeest, the Netherlands, established the rationale and piloted the afore-mentioned indicators. These indicators were discussed provisionally with a peer group of nursing scientists as regards their relevance for use by nurses discharging patients from hospitals and in home/institutionalised care units.

A patient self-completion concordance form (SCCF) for consultation at the start of a new medicine for a chronic condition was developed and piloted.

A documentation system for the recording of consultations based on the use of the SCCFs was also established and piloted.

Finally, a structured clinical medication review for the provision of pharmaceutical care to target groups of patients (e.g. elderly patients > 65 years, using > 5 medications for chronic conditions) was elaborated and piloted.

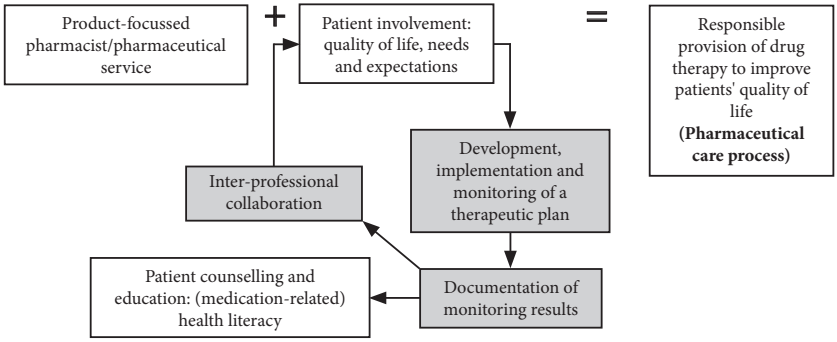
Intervention

The SCCF form comprised the following questions:

- What would you like to know about this medicine (or medicines)?
- What are your expectations of the effects of this medicine or medicines?
- Have you experienced problems using this medicine in the first weeks of use?
- If you have concerns about taking this treatment long-term, what are your concerns?
- What would be a reason for you to stop using this medicine?
- Please note here any questions or issues that you think will be important to discuss with your pharmacist as you continue to receive the treatment.

5.2.3. Pharmaceutical care interventions: monitoring of therapeutic plans and medicine safety by linking information about patients' medications and medical conditions from different entry points within the healthcare system

Diagram 4



Rationale

Linking information about patients' medications and medical conditions from different entry points within healthcare systems and the exchange of information on individual patients' therapeutic plans across the medication process are important prerequisites for efficient and integrated healthcare systems.

The pharmaceutical care philosophy essentially relies on a commonly developed, implemented and monitored therapeutic plan. This requires interprofessional co-operation and communication on individual patients' therapeutic plans across the entire medication process and linkage of patient-relevant therapeutic data. Thus, safe use of medicines, patient compliance and adherence to the clinical guidelines provided by health professionals is improved, all of which can be demonstrated by indicators.

Due to their education and competencies pharmacists have a key role in developing, implementing and monitoring therapeutic plans in concert with prescribers, including drug-safety aspects. The indicators should aim (a) to show the current status of the linkage of patient medication information in the setting of community pharmacies, and (b) should also consider the situation and needs of in-patient settings (hospitals), in particular for high-risk medication. The following criteria could be applied to the development and piloting of indicators on data linkage chosen by the scientists in the areas of antibiotic and anti-coagulant therapy:

- assess the implications of data linkage on the relevant safety parameters of pharmacotherapy,
- assess medication structures, both process and outcome,
- provide structured, objective data that can be processed with information technology (IT).

Indicators

a. Basic set of indicators on the linkage of patient medication information among community pharmacies

The proposed indicators help assess the current status of patient data linkage in community pharmacies for the purpose of medication safety monitoring (within an agreed therapeutic plan).

The indicators were chosen according to the following criteria:

- universally applicable,
- coverage of all relevant aspects of data linkage and information exchange between the pharmacist, other healthcare professionals and the patient.

The indicators measure the quality and/or availability of:

- hardware,
- drug information,
- individual patient health records,
- software,
- the means used for patient information exchange,
- the data exchanged,
- communication between the healthcare professionals involved in the treatment plan,
- patient information.

In addition, barriers for the implementation of e-Health tools were assessed in the pilot study.

b. Indicators of data linkage that enhance the safety and quality of antibiotic and anti-coagulant therapy in hospital settings

A literature search identified indicators that measured the quality of antibiotic treatments. These indicators could be classified into the categories of structure, process and outcome. Another literature search and a brain-storming event amongst experts yielded indicators that could measure factors influencing the quality of anti-coagulation therapies.

These latter indicators included basic organisational and structural information on healthcare institutions and institutional factors that could possibly influence the quality of anti-coagulation therapy. Indicators for assessing individual patients undergoing anti-coagulation therapy were identified (see below). A data collection sheet for repeated manual assessment of the quality of anti-coagulation therapy was proposed. In addition, 2 indicators for electronic data mining were identified.

STRUCTURE	Antibiotic policy/antibiotic stewardship programme.
PROCESS	Number of patients taking antibiotic drugs; number of antibiotic doses; form of dosage (iv/po medication); biological specimen collection; nosocomial infections.
OUTCOME	Appropriate therapy; adverse drug events.

The 30 indicators that assess individual patient health data could be used in the format of a form that, for example, assesses 20 patients every 12 months or for use in electronic data mining.

The selection criteria for indicator use were (1) feasibility of indicator assessment with regard to available information, and (2) feasibility for electronic screening.

1. **Clinical event**
   Number of patients treated with vitamin K antagonists and suffering from a major bleeding event.
   Indicator: anti-coagulant AND major bleeding (= haemoglobin decrease > 2g/dl AND INR > 6).

2. **Use of antidotes**
   Number of patients treated with vitamin K antagonists and receiving vitamin K during their anti-coagulant therapy.
   Indicator: anti-coagulant AND vitamin K.

Indicator piloting and development

In 2011, a specific working party of the scientific network, co-ordinated by the EDQM and chaired by Dr Carla Meyer-Massetti (Switzerland Foundation) and Professor Christian Lovis (Switzerland), established the rationale of the aforementioned indicators.

Intervention

a. Basic set of indicators for the assessment of the current status of patient data linkage in community pharmacies

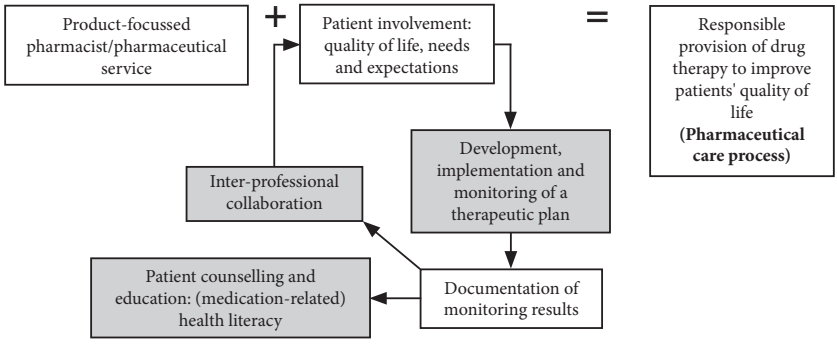
The indicator linking patient data, for the purpose of medication safety monitoring, was assessed in an ambulatory care setting.

b. Safety and quality indicators for the use of antibiotics and anti-coagulants in hospital settings

During the pilot phase, a limited set of electronic indicators was programmed and tested at the University Hospitals of Geneva (HUG). The indicators proposed in this section are mainly intended for use in in-patient settings.

5.2.4. Pharmaceutical care communication interventions: indicators for the availability of individualised information for patients about self-medication, and availability of pharmacist-prescriber co-operation on a possible/actual drug-related problem

Diagram 5



Rationale

Communication between the pharmacist and the patient, between the pharmacist and the prescriber, and between other health professionals is the catalyst within the pharmaceutical care process for the development of the therapeutic plan but, in particular, for the patient's ability to grant authority to the health provider and the provider's ability to accept that responsibility through competences and commitment.

The proposed indicators can be considered process indicators of communication: communication by a pharmacist with patients and care-givers, as well as inter-disciplinary communication and co-operation between pharmacists and prescribers on the drug-related problems of individual patients.

Indicators

- initial counselling indicator: oral and/or written advice given by the pharmacist to the patient who is supplied with a prescribed medication for the first time/1000 new prescriptions,
- personalised written information indicator: personalised written information by a pharmacist/1000 patients requesting self-medication and information about a medical condition/health issue suitable for self-medication,
- pharmacist-prescriber communication indicator: pharmacist's documented contact with the prescriber about identified drug related problems in an individual patient/1000 drug-related problems identified.

Indicator piloting and development

In 2011, a specific working party of the scientific network, co-ordinated by the EDQM and chaired by Dr Afonso Cavaco, Portugal, established the rationale of these afore-mentioned indicators.

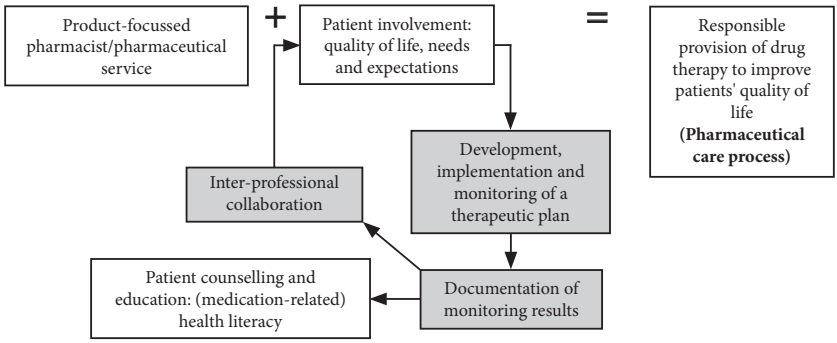
Intervention

- A pilot study was conducted in community pharmacies, assessing the feasibility of the above-mentioned indicators through simple and pragmatic overt observation for the identification and quantification of customised patient information with new medication prescriptions, counselling for non-prescribed medicinal products, and drug-related problems that required reporting and follow-up with the prescribers in the framework of a patient's therapeutic plan.

  Here, standard patient information leaflets ("medicine labelling") included in the medicine or supplied with the medicine that are not adapted/customised to an individual patient are not considered personalised written information.
- Pharmacist-prescriber communication consists of the reporting of adverse drug reactions and also the discussion of all drug-related problems; in particular, whether the medicine is appropriate (e.g. cases of over-medication) and effective in the patient.

5.2.5. Pharmaceutical care – a benefit for healthcare systems: indicators for the safe and effective use of medicines

Diagram 6



Rationale

All over the world, clinical practice guidelines are being developed in order to improve the quality of care, reduce adverse drug reactions including medication errors, and to control healthcare expenditure. Evidence shows that the development and availability of clinical practice guidelines does not necessarily ensure their use and implementation by healthcare practices. Means of communication which do not actively involve an individual, rarely induce a change in professional behaviour. The pharmaceutical care philosophy ("... process through which the pharmacists co-operates with … designing, implementing, and monitoring a therapeutic plan ...") can, through specific working methods (interventions) such as pharmacists providing information about drugs/medication practice guidelines and therapeutic follow-up, help to promote and implement best clinical practice and prevent inappropriate prescribing.

Indicator: pharmacist's interventions (information about drugs/medication practice guidelines and therapeutic follow-up)/100 prescriptions of a specific medicine for a specific indication for which a nationally/internationally agreed clinical practice guideline exists.

Indicator development and piloting

Currently, a specific working party of the scientific network, co-ordinated by the EDQM and chaired by Doz. Dr habil. Michael Hartmann (Germany), is validating the following pre-intervention/post-intervention indicators:

- prescriptions for antibiotics in line with established and agreed national or international clinical practice guidelines,
- number of prescriptions per General Practitioner (GP),
- cost of prescribed antibiotics.

Study inclusion and exclusion criteria:

Inclusion criteria for patients	• age ≥ 18 years • patient with diagnosis of mild pneumonia, acute bacterial bronchitis, bacterial tonsillitis, an acute media otitis, urinary tract infection (cystitis) • consultation with these illnesses for the first time
Exclusion criteria for patients	any of the following co-morbidities: • asthma • chronic obstructive pulmonary disease • diabetes • HIV • congestive heart failure • chronic ischaemic heart disease

Intervention

Pharmacists visit every GP in their intervention group and provide them with the nationally or internationally agreed and established clinical practice guidelines for first- and second-line antibiotic treatments for mild pneumonia, acute bacterial bronchitis, bacterial tonsillitis, acute media otitis and urinary tract infection, and then summarise/discuss them briefly. GPs in the control group are not visited or given the guidelines.

6. Conclusions and proposals for Health Ministers: beginning the journey – realising the added value of pharmaceutical care for the responsible use of medicines in all countries

Governments and policy-makers should note that, while significant regulatory structures have been put in place to ensure the quality and safety of medicines within Europe and worldwide, there is increasing evidence that the inappropriate use of medicines results in sub-optimal medication outcomes in patients, significant health damage and decreases the effectiveness of healthcare systems. Too often, patients do not benefit from the best achievable medication outcomes or even suffer preventable harm from inappropriate medicine use. Many patients feel that their needs and expectations are not sufficiently taken into account in treatment decisions or find it difficult to involve themselves in this process. Poor adherence by patients to prescribed medicines and by prescribers to treatment guidelines is common.

The pharmaceutical care philosophy and related working methods are a pivotal strategy in ensuring the appropriate use of medicines in a mutually beneficial way. It helps achieve the best possible outcome from the prescribed medication, thereby improving quality of life, utilisation of resources and reducing inequalities in healthcare. By increasing the cost-efficiency of medicine use, pharmaceutical care will contribute to more efficient and effective consumption of existing resources.

Implementing pharmaceutical care is a quality-enhancing element into the working methodologies of healthcare systems and requires innovative approaches to improve patient participation, inter-professional collaboration and a better focus on improving medicine use through the monitoring of outcome-related indicators.

In order to implement pharmaceutical care effectively in practice, this topic needs to be put high on the health and social political agenda by policy-makers and requires the continued support of all professionals involved in the medication process, such as pharmacists, medical doctors, nurses and patients.

In order to justify the expenditure of resources to payers and the public and steer health/social policies, reliable data on the impact of instruments, measures and practical initiatives should be available to policy-makers: indicators should be developed and validated that are useful for healthcare authorities and professional associations, and easy to use by healthcare providers. A limited number of robust, generally applicable indicators for community and hospital pharmacy sectors are therefore required. These can be supplemented by additional indicators, depending on regional needs.

Governments and policy-makers are invited to:

- acknowledge that optimal health and development should be built on the core pillars of participation, promotion, protection, prevention and provision and that an appropriate healthcare approach must be patient-focussed and ensure patient participation in the healthcare decisions affecting them, fostering their medication-related health literacy;
- commit to take specific action against health damage, diminished quality of life, work force reductions, and wasted healthcare resources that arise from the inappropriate use of medicines and drug-related problems as understood in their broadest sense;
- acknowledge available evidence that the pharmaceutical care philosophy and working methods can help achieve the benefits of responsible medicine use for individual patients and healthcare systems at national and regional levels by addressing issues of inappropriate medicine use in a comprehensive manner and, thereby, improving patient outcomes;
- promote and implement the pharmaceutical care philosophy and working methods in their national healthcare systems;

- introduce in all countries of the world, generally applicable quality indicators for pharmaceutical care to provide themselves with valid information for policy-making and to set professional standards and best practices in the field;
- in this context, support the wide application of generally applicable quality indicators for pharmaceutical care, as included in Table 1, page 13 of this report, and to provide for a mid-term strategy to follow up on the results and measures taken in response to the data generated;
- support programmes and activities for international collaboration to further develop pharmaceutical care standards, guidelines and training for the implementation and monitoring of pharmaceutical care using, *inter alia*, generally-applicable and specific quality indicators. Examples of such programmes are those being carried out or supported by international organisations such as the Council of Europe and its EDQM, the WHO and relevant professional associations of pharmacists (such as the International Pharmaceutical Federation, FIP), medical doctors, nurses and other relevant health professions;
- avail themselves of the professional expertise of public health institutions, relevant professional associations (notably of pharmacists, medical doctors, nurses and other relevant professions) and patient organisations.

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PHARMACEUTICAL CARE

Policies and Practices for a Safer, More Responsible and Cost-effective Health System

Medication is the most frequent intervention within healthcare systems. Often, the benefits of medication cannot be realised in patients, and even worse, considerable mortality and morbidity are caused by the inappropriate use of medicines. Pharmaceutical care is a quality philosophy and working method for professionals within the medication process, indispensable for the good and safe use of medicines. The Committee of Experts on Quality and Safety Standards for Pharmaceutical Practices and Pharmaceutical Care, coordinated by the EDQM, carries out activities comprising the development of generally applicable and specific indicators of the implementation of pharmaceutical care in Europe and beyond. Governments and policy-makers are invited to act against harm, reduced life quality, workforce reductions, and wasted resources that arise from the inappropriate use of medicines and drug-related problems.

The EDQM is a Directorate of the Council of Europe – an international organisation founded in 1949, now with 47 member states covering virtually the entire continent of Europe. The Council of Europe seeks to develop common democratic and legal principles based on the European Convention on Human Rights and other reference texts on the protection of individuals.

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