QUALITY INDICATORS
FOR PHARMACEUTICAL CARE:
OUTCOMES OF THE EDQM PROJECT
AND NEXT STEPS

REPORT

VENUE: EDQM, STRASBOURG (FRANCE)

DATE: 26 NOVEMBER (ALL DAY) AND 27 NOVEMBER 2015 (MORNING ONLY)

Workshop Principal Conclusions and Recommendations

The workshop "Quality Indicators for Pharmaceutical Care: Outcomes of the EDQM Project and Next Steps" brought together national public health authorities, international organisations operating in the public health field, European and national associations of healthcare professionals, health insurance providers and experts from academia to share views on policies and strategies to improve public health performance, discuss the outcomes of the EDQM Pharmaceutical Care Quality Indicators Project and elaborate concrete suggestions for the practical implementation and use of the above quality indicators.

The following is a summary of the main points raised by speakers and participants during the workshop plenary and breakout sessions.

Effectiveness and cost-effectiveness evaluations

Pharmaceutical care can improve the good and safe use of medicines, leading to the best possible medication outcome for the patient, efficient use of resources and reduction of health inequality.
Yet the clinical and economic impact of pharmaceutical care should be assessed (via, for instance, cost-effectiveness analysis of pharmaceutical care interventions) to clearly demonstrate that the implementation of pharmaceutical care in healthcare systems provides value for money and reduces health care budgets.

IT tools

The availability of proper IT tools and dispensing databases at hospital and community pharmacy level is essential for the implementation and use of the EDQM quality indicators. Patient owned health records, health data sharing practices, tools for decision support and patient empowerment are examples of new developments that could facilitate the implementation and evaluation of pharmaceutical care activities. Legal and ethical frameworks should be developed to ensure proper data protection and privacy.

Education

Pharmaceutical care is provided for the direct benefit of 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 healthcare professional, and the healthcare professional gives competence and commitment to the patient (accepts responsibility)[1].
With a view to encouraging the practice of pharmaceutical care in a responsible and competent manner, postgraduate and continuing education in clinical pharmacy, medication therapy management services, patient communication and counselling should be delivered to provide healthcare professionals with the knowledge, skills, and attitudes they need to achieve the above goal.

Interprofessional cooperation

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 (in line with his/her expectations and needs)[1]. In other words, the medication use process involves other healthcare professionals, including physicians and nurses, who possess unique expertise and play an important role in delivering patient-centred care. Regular interaction

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[1] Hepler C.D. and Strand L.M. Opportunities and Responsibilities in Pharmaceutical Care. Am. J. Hosp. Pharm. 1990; 47: 533-543

of the pharmacist with physicians, nurses, carers and patients should be promoted and encouraged with the aim of optimising the delivery of pharmaceutical care and improving health outcomes for patients.

Accreditation systems

Accreditation programmes for the delivery of pharmaceutical care activities could be considered. Accreditation should be issued by an independent body, consist of assessments carried out at regular intervals, provide a comprehensive evaluation of the entire pharmaceutical care process, and make use of validated indicators. Accreditation could be used to stimulate reflection on one's own practice and promote the improvement of pharmaceutical care practices on national and individual pharmacy level.

Incentives

Pharmaceutical care provision often relies on pharmacists' goodwill rather than on remuneration. Given the investment in time and intellect in the pharmaceutical care process, remuneration of pharmaceutical care activities could be considered. Provided that pharmaceutical care is delivered in a systematic, consistent and appropriate manner, compensation could be offered to pharmacists in the form of a direct monetary payment or incentives such as continuing pharmacy education points, discounted rates for training courses and/or conferences, and support for professional certification.

Role of policy-makers

Policy-makers and stakeholders with responsibility for pharmaceutical and pharmacy policy are invited to acknowledge that pharmaceutical care could be a key element for the promotion of the safety and quality of medication use. Therefore, they are encouraged to promote and implement the pharmaceutical care philosophy and working methods in their national healthcare systems. A policy framework could be created in this respect, and the following recommendations could be considered: a. establish a legal basis for removing current barriers to the implementation of pharmaceutical care; b. provide financial commitment to activities fostering the efficient and safe use of medicines (e.g. medication therapy management services); c. promote initiatives that support active engagement of all key players in the medication use process and put patients at the centre of the medication process; d. engender a collaborative approach with national and international organisations to set harmonised standards and best practices for the safety and quality of the medication process.

EDQM

The EDQM is encouraged to seek cooperation with other intergovernmental organisations, national authorities and professional bodies to join forces and work together on initiatives to promote better health outcomes, provide patient-centred care, deliver high quality of care, and ensure the efficient use of healthcare resources.
In particular, given that the EDQM is a quality standard setting organisation, the EDQM is advised to liaise with other stakeholders in the public health field in efforts to provide harmonised provisions and model approaches for the safe and efficient use of medicines in Europe, such as a guidance document on good pharmaceutical care practices (including the EDQM quality indicators), a terminology manual on pharmaceutical care concepts and definitions, a set of principles on data collection methods and data sharing processes, validated methodologies for the development of pharmaceutical care quality indicators and quality indicator logbooks.

Introductory Note

This report provides a short summary of the workshop organised by the Council of Europe's European Directorate for the Quality of Medicines and HealthCare (EDQM) on 26-27 November 2015.

The workshop was held in Strasbourg (France) and was attended by a wide range of participants, representing European and national associations of healthcare professionals, national public health authorities, experts from academic institutions, health insurance providers, and European and international organisations active in the field of quality of care.

The workshop was designed to enable participants to expand their knowledge and familiarise themselves with policies and strategies that are currently in place to improve public health and health system performances at international and national level, and to discuss the outcomes of the EDQM Pharmaceutical Care Quality Indicators Project which aimed to design indicators to assess the quality of pharmaceutical care in Europe.

Workshop Background

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

Sometimes the benefits of medications are not fully realised (e.g. due to lack of medication adherence) or, even worse, considerable mortality and morbidity could be associated with inappropriate use of medicines.

According to the definition established by C.D. Hepler and L.D. Strand, pharmaceutical care is: "the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life". Pharmaceutical care involves the process through which a pharmacist cooperates with a patient and other healthcare professionals in designing, implementing and monitoring a therapeutic plan that will produce specific therapeutic outcomes for the patient[2].

The activities of the European Directorate for the Quality of Medicines and HealthCare (EDQM) in the field of pharmaceutical care are carried out in line with Hepler and Strand's definition of pharmaceutical care.

The EDQM's pharmaceutical care activities are overseen by the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH) and carried out with the support of one of its subordinate bodies, the Committee of Experts on Quality and Safety Standards in Pharmaceutical Practices and Care (CD-P-PH/PC). This latter is entrusted with improving pharmaceutical care and practices in community care homes and in ambulatory and hospital care services through specific programmes and policies.

Since 2008, the CD-P-PH/PC has been carrying out a project to develop, test and validate basic sets of quality indicators, feasible for authorities in different countries in Europe, covering 4 key areas of the pharmaceutical care process for continuous improvement of health outcomes and quality of life for patients (EDQM Pharmaceutical Care Quality Indicators Project). The project has been carried out with the support of the Quality of Pharmaceutical Care Working Party, which consists of scientific collaborators from different academic institutions in Europe.

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[2] Hepler C.D. and Strand L.M. Opportunities and Responsibilities in Pharmaceutical Care. Am. J. Hosp. Pharm. 1990; 47: 533-543

Workshop Aims

The workshop was aimed at:

- Mapping policies and strategies that are currently in place to improve public health and health system performance at international and national level in Europe;

- Presenting the outcomes of the EDQM Pharmaceutical Care Quality Indicators Project;

- Obtaining feedback and guidance as to the implementation and use of EDQM pharmaceutical care quality indicators;

- Creating awareness regarding pharmaceutical care as a successful strategy to enhance the responsible use of medicines within healthcare systems and by healthcare professionals and patients;

- Providing a platform for sharing experiences and advancing the efficient and safe use of medicines, leading to the best possible medication outcome for the patient.

Workshop Working Methods

Plenary speakers, representing different stakeholder groups (international organisations; national health authorities; academia; healthcare professional associations; health insurance), presented policies and strategies currently in place to improve public health and health system performance at European and national level, and shared their point of view on how quality of care and responsible use of medicines could be effectively measured.

Two breakout sessions took place on the first day of the workshop. The aim of the breakout sessions was to present and discuss the outcomes of the EDQM indicators multinational validation studies, and to exchange views and elaborate concrete suggestions for the practical implementation and use of the EDQM pharmaceutical care quality indicators. The main outcomes from the breakout sessions were summarised in the plenary.

Key outputs from the workshop were summed up on the closing day.

Workshop Presentations

The workshop presentations are available on the EDQM's website, under Publications, Products and Services; Publications; Proceedings of International Conferences; 26-27 November 2015, Strasbourg, France - Quality Indicators for Pharmaceutical Care: Outcomes of the EDQM Project and Next Steps (link: https://go.edqm.eu/proceedings).

Summary of Breakout Sessions

Topic Group (TG) 1 - Adherence to nationally agreed clinical practice guidelines

Moderators: Prof Dr Michael HARTMANN (TG1 leader) and Dr Tommy WESTERLUND

Aim of TG1 study: to validate 1 quality indicator focusing on the impact of interprofessional collaboration on adherence to antimicrobial prescribing guidelines in ambulatory care settings.

Main conclusions:

Interprofessional cooperation

Interprofessional collaboration is a partnership that includes all involved healthcare professionals working together to carry out an individualised therapeutic plan in order to produce specific therapeutic outcomes for the patient and deliver the highest quality of care.

With a view to implementing and using TG1 indicator, interprofessional collaboration in ambulatory care settings should be promoted and fostered.

The following approaches could be used to improve interprofessional cooperation: a. promote continuous professional development (via, for instance, postgraduate courses supporting the need for healthcare professionals to focus on interprofessional collaboration in the healthcare setting); b. increase trust between general practitioners and pharmacists by sharing of positive outcomes of interprofessional cooperation; c. include interprofessional training at university (integrated in curriculum for master's degrees); d. educate patients to choose healthcare professionals who have well established cooperation with each other; e. promote the approach currently in place in some European countries (e.g. the Netherlands) where general practitioners and pharmacists are located in the same health centre and are used to holding regular consultations with each other.

State-of-the-art guidelines and electronic tools

With the increased availability and use of IT tools in daily practice, it seems crucial to ensure that clinical practice guidelines reflect the current state-of-the-art scientific work, are based on the principles of evidence-based medicine, and are made available to healthcare professionals in electronic format.

In addition, given the heavy workload of healthcare professionals, it is advised to make TG1 data collection tools available in electronic format in order to reduce the amount of effort required to gather TG1 data and motivate healthcare professionals to provide the requested data.

Indicator implementation

Implementation could be carried out in partnership with other international and/or national organisations and could start on a small scale before implementing the indicator across several countries in Europe.

If needed, further piloting, involving more countries as well as other organisations working in the field of quality of care, could be considered, too.

In addition, implementation could be supported by incentives for healthcare providers to encourage collaboration and high-quality care. Incentives could either be financial (e.g. additional payments or bonuses) or non-financial (e.g. access to/support for training and education).

Finally, implementation could be complemented by cost-effectiveness studies to determine the broader benefit of pharmaceutical care and further support its implementation in daily practice.

TG2 - Monitoring of therapeutic plans and medication safety by pharmacists through data linking and exchange of information about therapy and patient's medical condition in anticoagulant and antibiotic therapy

Moderators: Prof Dr Agnieszka SKOWRON (TG2 leader) and Prof Dr Roland BAL

Aim of TG2 study: to validate 2 quality indicators focused on the access to individual patient's medical and prescription data (patient health record) at hospital pharmacists' level in case of antibiotic and anticoagulant therapy.

Main conclusions:

IT tools

On the one hand, the high availability of IT equipment in physicians' offices and pharmacies facilitates smooth exchange of patient health data between healthcare professionals, but, on the other hand, data sharing between physicians and pharmacists remains rather limited at the moment.

Generally speaking, health data sharing should be further promoted and encouraged, especially at physicians' level where reluctances to disclose patient data to pharmacists have often been reported.

The use of TG2 indicators could help evaluate and improve data exchange practices. Nevertheless, indicator templates should be available in electronic format and the burden of data collection should be limited.

Personal health records, such as the French "Pharmaceutical Record", envisioned as a portable, patient-controlled electronic record derived from various sources, could be used to facilitate and improve the health data sharing process.

Barriers to health data sharing

A wide variety of patient-related data is currently collected in health systems. Proper health data linkage and health information exchange could facilitate the timely availability of patient-specific health information to all members of the healthcare team.

The proposed indicators help promote data sharing and assess health data sharing practices in hospital settings. Nevertheless, their implementation and use in daily practice could be hindered by the following barriers to data sharing: technical (e.g. lack of standardisation, varying data quality, incompatibility between databases); motivational (lack of incentives to share data, additional time and effort to be made to ensure proper data sharing); economic (lack of financial resources); political (lack of political will and commitment to promote data sharing, lack of guidelines, lack of trust); legal (data protection laws) and ethical (protection of privacy and confidentiality).

Indicator implementation

The proposed indicators exclusively focus on hospital pharmacy settings. Since hospital pharmacies differ considerably from community pharmacies, health information exchange in these two settings could be rather different and, as a consequence, TG2 indicators might not be suitable for implementation and use

in ambulatory care settings. Development and validation of indicators for the quality of health data sharing in community pharmacy settings should be considered.

TG3 - Structured Pharmacist-Patient Consultations via "My CheckList"

Moderators: Prof Dr Han de GIER (TG3 leader) and Prof Dr Martin HENMAN

Aim of TG3 study: to validate 2 quality indicators, which aim to measure the level of patient involvement and, hence, the quality of pharmaceutical care by evaluating the following items: 1) documented counselling provided by a pharmacist during a patient-pharmacist consultation based on the so-called "My CheckList" at the start of a new chronic treatment; 2) provision of documented medication reviews following the needs that arose during the so-called "My CheckList" consultations, in the case of elderly patients who are suffering from multi-morbidity and receiving polypharmacy.

Main conclusions:

Facilitators for patient involvement

Patient involvement and participation in care decision-making can be challenging and progress towards achieving meaningful and effective patient involvement can be slow.

The following approaches were suggested to facilitate patient involvement: a. ensure that both patients and pharmacists understand the added value of structured pharmacist-patient consultations: this will probably facilitate the consultation process and help overcome barriers; b. telephone-based interventions could be a solution to barriers in daily practice (e.g. lack of privacy in the pharmacy; lack of time for counselling at the moment of the pharmacy visit); c. patient follow-up after intervention should also be considered: this could help further address patient's concerns and establish an ongoing dialogue about the patient's health and needs; d. data analysis using prescription entry could be used to help pharmacists with patient selection and ensure that patients who need such intervention are identified and included in the consultation process (e.g. patients with complex medication regimens; patients receiving polypharmacy; elderly and frail patients).

Role of policy-makers

The impact of pharmacist-patient consultations to improve adherence with prescribed medications should be measured and robust independent evaluation, including a health economic assessment, should be carried out. The results, in turn, could be translated into a number of recommendations to guide policy makers to create a policy framework for responsible and safe use of medicines.

Pharmacist-patient consultations could be costly for individual pharmacies and often require additional workforce; therefore, financial incentives should be considered to support the pharmacists' proactive role in the improvement of the medication use process and in the provision of patient-centred care.

Indicator implementation

TG3 indicators seem to be simple and helpful for assessing the quality of pharmaceutical care activities; nevertheless, it should be kept in mind that, in some countries, their implementation and use might imply a change in community pharmacy practice and not just a simple assessment of an intervention. Changing daily practice often requires political will and support from all key actors in the medication use process; therefore, the implementation of TG3 indicators in everyday practice might not be straightforward and actually take some time.

In addition, in spite of the encouraging results obtained in the validation phase, potential and actual barriers could hinder the implementation and use of TG3 indicators in daily practice. These barriers could be related, for instance, to pharmacists' workload, need for postgraduate training in clinical pharmacy, lack of patient records, lack of communication skills, lack of a dedicated room in the pharmacy to perform consultations.

TG4 - Implementation of Pharmaceutical Care Philosophy and Working Methods

Moderators: Dr Zinaida BEZVERHNI (TG4 leader) and Dr Charlotte ROSSING

Aim of TG4 study: to develop and validate a tool aiming at evaluating, monitoring and improving the implementation of the pharmaceutical care philosophy and working methods in the European countries.

Main conclusions:

Barriers to use of self-assessment tool in daily practice

TG4 self-assessment tool could support the implementation of pharmaceutical care especially in countries where pharmaceutical care is not well advanced yet and community pharmacy practice is mainly focused on medicines sales.

Yet, given that the use of the self-assessment tool relies on pharmacists' good will, it is important to motivate them to make good use of it. Possible strategies to encourage pharmacists to use the tool could include: a. where possible, support the statements and activities that are reported in the tool with reference to evidence-based research outcomes; b. promote the use of the self-assessment tool as a starting point to teach healthcare professionals pharmaceutical care principles and working methods; c. encourage the use of the self-assessment tool as a means of continuous professional development in pharmaceutical care and improve daily practice; d. use the self-assessment tool for accreditation purposes.

Implementation of self-assessment tool

The following facilitators could support the implementation of TG4 self-assessment tool in daily practice: a. integration of the tool in the pharmacy quality system as an integral and substantial part of the quality assurance process; b. development of a quality manual to be distributed together with the self-assessment tool; c. provision of individual feedback to pharmacists to help them quickly see their strengths and highlight areas that need work; d. outcomes to be made available to health authorities to permit benchmarking to identify weaknesses and strengths, and offer directions for improvement at national level.

The way forward

Additional steps are recommended before implementing TG4 tool in daily practice: a. perform a psychometric test in different countries to evaluate the sensitivity of the tool and define indicators; b. involve more countries with different experiences in pharmaceutical care in the evaluation of the self-assessment tool; c. define intervals at which the assessment should be performed in daily practice.

With a view to ensuring the implementation of the self-assessment tool across Europe, the EDQM is advised to join forces and establish a collaborative approach with national health authorities and professional bodies.

Annex

Workshop Speakers

Mr Menno AARNOUT, Executive Director, International Association of Mutual Benefit Societies (AIM) - Brussels, Belgium

Prof Dr Roland BAL, Professor of Healthcare Governance, Erasmus University Rotterdam - Rotterdam, the Netherlands

Mr Luc BESANÇON, General Secretary and CEO, International Pharmaceutical Federation (FIP) - The Hague, the Netherlands

Dr Zinaida BEZVERHNI, TG4 Leader, Associate Professor, State University of Medicine and Pharmacy - Chisinau, Moldova

Dr Ian FORDE, Policy Analyst, Organisation for Economic Co-operation and Development (OECD) - Paris, France

Ms Maggie GALBRAITH, Project Manager, French National Authority for Health (HAS) - Saint-Denis La Plaine, France

Prof Dr Han de GIER, TG3 Leader, Professor of Pharmaceutical Care, University of Groningen - Groningen, the Netherlands

Mr Olivier GROSS, Director of Professional Practice, National Chamber of Pharmacists - Paris, France

Prof Dr Michael HARTMANN, TG1 Leader, Hospital Pharmacist, Jena University Hospital - Jena, Germany

Prof Dr Martin HENMAN, Associate Professor of the Practice of Pharmacy and Co-ordinator of the Centre for the Practice of Pharmacy, Trinity College Dublin - Dublin, Ireland

Dr Blaženka JURIŠIĆ, Senior Scientific Adviser, Croatian Agency for Medicinal Products and Medical Devices (HALMED) - Zagreb, Croatia

Dr Susanne KEITEL, Director, European Directorate for the Quality of Medicines and HealthCare (EDQM) (Council of Europe) - Strasbourg, France

Mr Nico KIJLSTRA, Scientific Project Leader EDQM Pharmaceutical Care Quality Indicators Project, Senior Health Inspector, Health Care Inspectorate, Ministry for Health, Welfare and Sport - Utrecht, the Netherlands

Ms Joan PEPPARD, President, European Association of Hospital Pharmacists (EAHP) - Brussels, Belgium

Dr Paul De RAEVE, General Secretary, European Federation of Nurses Associations (EFN) - Brussels, Belgium

Dr Charlotte ROSSING, Head of Research and Development, Pharmakon - Hilleroed, Denmark

Prof Dr Agnieszka SKOWRON, TG2 Leader, Head of Social Pharmacy Department, Jagiellonian University Medical School - Kraków, Poland

Dr Stephan SPAT, Technical Officer, World Health Organization (WHO) Regional Office for Europe - Copenhagen, Denmark

Dr Tommy WESTERLUND, Researcher, Medical Products Agency - Helsingborg, Sweden

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