EXPERT WORKSHOP

INDICATORS OF THE QUALITY OF PHARMACEUTICAL CARE: DEVELOPMENT APPROACHES & PRELIMINARY RESULTS

PROCEEDINGS

10 December 2010
European Directorate for the Quality of Medicines & HealthCare (EDQM)
7 allée Kastner, CS 30026
F-67081 Strasbourg
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>I – PROGRAMME</th>
<th>Pages</th>
</tr>
</thead>
<tbody>
<tr>
<td>II – KEYNOTE ADDRESS</td>
<td>11</td>
</tr>
<tr>
<td>Mr Nico KIJLSTRA</td>
<td>13</td>
</tr>
<tr>
<td>Quality of pharmaceutical care – How to reconcile patients' rights and demands with healthcare system’s missions and goals</td>
<td>13</td>
</tr>
<tr>
<td>III – ABSTRACTS AND PRESENTATIONS</td>
<td>17</td>
</tr>
<tr>
<td>Session theme: Selected Quality of Pharmaceutical Care Indicators: Development approaches and preliminary pilot results</td>
<td>19</td>
</tr>
<tr>
<td>1.1 UNDERSTANDING THE PHARMACEUTICAL CARE CONCEPT AND APPLYING IT IN PRACTICE</td>
<td>21</td>
</tr>
<tr>
<td>Dr Sabine VOGLER</td>
<td>22</td>
</tr>
<tr>
<td>1.2 PHARMACEUTICAL CARE: THE KEY ROLE OF PATIENT PARTICIPATION</td>
<td>29</td>
</tr>
<tr>
<td>Ms Marlies GEURTS</td>
<td>30</td>
</tr>
<tr>
<td>1.3 PROMOTION OF MEDICATION SAFETY THROUGH DATE LINKAGE &amp; MONITORING</td>
<td>35</td>
</tr>
<tr>
<td>ABSTRACT: Data Linkage &amp; Health Information Exchange</td>
<td>36</td>
</tr>
<tr>
<td>Professor Christian LOVIS, Dr Hanna Marita SEIDLING, Ms Carla MEYER-MASSETTI</td>
<td>39</td>
</tr>
<tr>
<td>1.4 COMMUNICATION AND INTERDISCIPLINARY COOPERATION</td>
<td>47</td>
</tr>
<tr>
<td>Professor Afonso CAVACO, Dr Paula FERREIRA</td>
<td>48</td>
</tr>
<tr>
<td>1.5 ADHERENCE TO TREATMENT GUIDELINES</td>
<td>57</td>
</tr>
<tr>
<td>Ms Iryna MUKOMEL</td>
<td>58</td>
</tr>
<tr>
<td>1.6 PHARMACEUTICAL CARE: SPECIAL NEEDS OF REGIONS</td>
<td>67</td>
</tr>
<tr>
<td>Abstract - Presentation: Expert survey &amp; pharmacy survey in ALBANIA</td>
<td>69</td>
</tr>
<tr>
<td>Professor Dr Afrim Tabaku</td>
<td>69</td>
</tr>
<tr>
<td>Expert survey &amp; pharmacy survey in Georgia</td>
<td>77</td>
</tr>
<tr>
<td>Mr Zaza CHAPICHADZE</td>
<td>77</td>
</tr>
<tr>
<td>Development quality of pharmaceutical care indicators on the national and professional level (pharmacist's self-assessment tool) in Republic of Moldova</td>
<td>82</td>
</tr>
<tr>
<td>Dr Zinaida BEZVERHNI</td>
<td>82</td>
</tr>
<tr>
<td>Expert survey &amp; pharmacy survey in Ukraine</td>
<td>88</td>
</tr>
<tr>
<td>Ms Olga GRINTSOVA</td>
<td>88</td>
</tr>
<tr>
<td>1.7 METHODOLOGY</td>
<td>93</td>
</tr>
<tr>
<td>Dr Martin HENMAN</td>
<td>94</td>
</tr>
<tr>
<td>Ms Gudrun BUSCH</td>
<td>97</td>
</tr>
<tr>
<td>Session theme: Conclusions - The Way Forward</td>
<td>101</td>
</tr>
</tbody>
</table>
I – PROGRAMME

Background and objectives

Pharmaceutical care is an indispensable element of patient centred healthcare. Patient expectations and desired quality of life are important factors to ensure the best possible medication outcome, and to possibly prevent recurrence of disease.

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

The Committee of Experts on quality and safety standards for pharmaceutical practices and pharmaceutical care (CD-P-PH/PC) contributes to the mission of the EDQM through providing policies and model approaches for the safe use of medicines in Europe, including guidelines on pharmaceutical care. Among other activities the Committee of Experts CD-P-PH/PC has been entrusted with supporting the quality assessment of pharmaceutical care through indicators.

The Committee of Experts CD-P-PH/PC published in 2009 the report “Pharmaceutical Care: Where do we stand - where should we go?”[1]. The report analysed the current awareness of the concept of pharmaceutical care in Europe, approaches for the quality assessment of pharmaceutical care, the extent to which pharmaceutical care is implemented in practice, and the competences and skills required.

The report was launched at the expert workshop “Assessing the quality of patient-centred pharmaceutical care in Europe – where do we stand, where should we go?”, Strasbourg, 19 November 2009, organised by the EDQM – Council of Europe. The participants, officials, scientists, representatives of national and European associations/professionals boards of doctors, pharmacists, nurses, and independent patient associations, supported fully the report findings and conclusions and developed key elements of a forward-looking programme for the development of quality assessment indicators in 2010. The participants urged the development of indicators for pharmaceutical care that are acceptable to a wide range of countries in Europe, and target the prerequisites of appropriate medicine therapy such as patient participation, commitment and medication-related health literacy, and multidisciplinary communication and cooperation.

In 2010, a network of twelve scientists from nine academic institutions, has developed about fifteen indicators for the quality assessment of pharmaceutical care in Europe and started pilot projects in the following areas:

- self-assessment for health professionals to promote understanding of the pharmaceutical care concept and applying it in practice,
- linking data & information to improve the safe and effective use of medicines,
- patient counseling, personalised written information, and doctor’s communication to foster patient participation, active communication and inter-professional cooperation,
- attaching key importance of patient needs, beliefs, values and self-management: achieving patient concordance from start to the end of the medication,
- implementation of pharmaceutical care in regions with special needs.

Healthcare systems should take into account pharmaceutical care as an approach and working method to improve professional standards and provide an essential basis for health policymaking that ensures the best possible outcome of medication in the patient whilst improving the patient’s quality of life.

Aim of the expert workshop

The expert workshop is aimed at:

- discussing the development approaches and preliminary pilot results of the quality of pharmaceutical care indicators which had been developed by the scientific collaborators in the frame of the EDQM hosted collaboration platform;

- enlarging the network between public authorities, international relevant institutions and organisations, collaborators from scientific institutions and health care professionals’ associations with a view to developing, adapting and piloting in the frame of the EDQM hosted collaboration platform a basic set of pharmaceutical care indicators suitable for many countries of Europe;

- establishing a roadmap for providing the network with validated pharmaceutical care indicators based on a structured needs’ analysis,

- a platform for the exchange of information about the utility of the indicators when applied for policy-making and improvement of professional standards,

- relevant publications and support tools,

- promoting awareness that quality assessment of pharmaceutical care through indicators care is needed to improve the outcomes of medicines therapy.

Target audience

The target audience comprises:

- Scientific collaborators of the Committee of Experts on quality and safety standards for pharmaceutical practices and pharmaceutical care (CD-P-PH/PC) in the field of pharmaceutical care,

- delegations of the European Committee on Pharmaceutical and Pharmaceutical Care (CD-P-PH) and its Committee of Experts on quality and safety standards for pharmaceutical practices and pharmaceutical care (CD-P-PH/PC),

- nominees/participants in the expert workshop “Assessing the quality of patient-centred pharmaceutical care in Europe – where do we stand, where should we go?”, Strasbourg, 19 November 2009, and the Pharmaceutical Care Workshop, co-organised by the EDQM with the Gesundheit Österreich GmbH (GOG), Vienna, 28 June 2010;

- representatives of relevant international and European organisations and institutions.

A good mix of different professions and of member countries is desired. The number of workshop participants is limited to 50 in total. As the expert workshop will be held in English, participants need to be fluent in that language.
Speakers

The speakers have relevant expertise and profound working experience dealing with pharmaceutical care/development of indicators in healthcare/pharmaceutical care. They come from public authorities, and from academia (List of speakers, see Appendix).

Working methods

Presentation and discussion of scientific individual indicator development approaches and follow up activities. At the adoption of the workshop conclusions, the chair will invite all participants. The Chair will invite the participants to come up with concrete suggestions on the next steps for going forward, and on how to achieve enlarged participation in the project by countries and stakeholder associations.
Welcome address and opening

9.00 a.m. Ms Susanne KEITEL, Director, EDQM

Keynote address

9.10 a.m. Quality of pharmaceutical care – how to reconcile patients' right and demands with healthcare system’s mission and goals

Speaker: Mr Nico KIJLSTRA, Chair of the Committee of Experts CD-P-PH/PC, Dutch Health Care Inspectorate

Session theme: “SELECTED QUALITY OF PHARMACEUTICAL CARE INDICATORS: DEVELOPMENT APPROACHES AND PRELIMINARY PILOT RESULTS”

Chair: Mr Nico KIJLSTRA

Understanding the pharmaceutical care concept and applying it in practice

9.30 a.m. Pharmacists' self-assessment tool

Speaker: Ms Sabine VOGLER, Gesundheit Österreich GmbH, Geschäfts bereich Österreichisches Bundesinstitut für Gesundheitswesen/Austrian Health Institute (GÖG/ÖBIG)

9.45 a.m. Discussion of the indicator development approach & follow-up and the way forward

10.00-10.30 a.m. Coffee break

EDQM Foyer

Pharmaceutical care: the key role of patient participation

10.30 a.m. Concordance and chronic conditions: indicators for patient involvement

Speaker: Ms Marlies GEURTS, University Groningen, the Netherlands

Speaker: Ms Christiane RITSCHEL, University Jena, Germany

10.45 a.m. Discussion of the indicator development approach & follow-up and the way forward

Promotion of medication safety through data linkage & monitoring

11.00 a.m. Indicators of implementation of data linkage & health information exchange

Speakers: Mr Christian LOVIS, Ms Hanna Marita SEIDLING, University Hospital of Geneva, Service of Medical Informatics, Geneva, Switzerland; Ms Carla MEYER-MASSETTI, Swiss Patient Safety Foundation, Zürich, Switzerland
11.30 a.m.  **Discussion of the indicator development approach & follow-up and the way forward**  
*Communication and interdisciplinary cooperation*

11.45 a.m.  Patient counseling, personalised written information, communication with the physician  
Speakers: Mr Afonso CAVACO, Ms Paula FERREIRA, Faculty of Pharmacy, University of Lisbon, Portugal

12.00 noon  **Discussion of the indicator development approach & follow-up and the way forward**  
*Adherence to treatment guidelines*

12.15 p.m.  Presentation of a interdisciplinary study protocol  
Speaker: Ms Iryna MUKOMEL, University National of Pharmacy, Ukraine

12.30 p.m.  **Discussion of approach & follow-up and the way forward**

12.45 – 1.45 p.m.  *
Lunch*

Chair:  Mr Nico KIJLSTRA

**Pharmaceutical care: special needs of regions**

1.45 p.m.  Studies: development quality of pharmaceutical care indicators on the national and professional level (pharmacist's self-assessment tool) in Albania, Georgia, Moldova, Ukraine  
Speakers: Mr Afrim TABAKU, Public Health Institute, Albania  
Mr Zaza CHAPICHADZE, Ministry of Health, Georgia  
Ms Zinaida BEZVERHNI, University Chisinau, Moldova  
Ms Olga GRINTSOVA, University Kharkov, Ukraine

2.45 p.m.  **Discussion of the indicator development approach & follow-up and the way forward**  
*Methodology*

3.15 p.m.  Development of quality of pharmaceutical care indicators: decision tool for policy-makers and professional associations  
Speaker: Mr Martin HENMAN, School of Pharmacy, Trinity College Dublin, Ireland

3.30 p.m.  **Discussion of approach & follow-up and the way forward**

3.45 p.m.  Standard Operating Procedure (SOP): testing of quality of pharmaceutical care indicators  
Speaker: Ms Gudrun BUSCH, Federal Office of Public Health, Switzerland
4.00 p.m. 
**Discussion of approach & follow-up and the way forward**

4.15 - 4.30 p.m. 
Coffee break

**Session theme: “CONCLUSIONS - THE WAY FORWARD”**

4.30 p.m. – 5.00 p.m.

Chair: Mr Nico KIJLSTRA, Panelists: all speakers

The speakers will present key conclusions of the discussion. The Chair will invite the participants to come up with concrete suggestions on the next steps for going forward, and on how to achieve enlarged participation in the project by countries and stakeholder associations. The workshop conclusions will be adopted by the audience.

Closing address

5.15 p.m. 
Speaker: Mr Jean-Marc SPIESER, DBO, EDQM
II – KEYNOTE ADDRESS
Mr Nico KIJLSTRA  
Chair of the Committee of Experts CD-P-PH/PC, Dutch Health Care Inspectorate  

Quality of pharmaceutical care – How to reconcile patients’ rights and demands with healthcare system’s missions and goals

Dear Ladies and Gentlemen,

Protection of our health is a fundamental human right. Therefore access to healthcare is a fundamental right. Healthcare of good quality, which is relatively safe and not only accessible but also affordable, and which is sustainable is a core asset of every developed society. We, every single one of us will exercise this right, sooner or later in our lives.

As obvious as these words may sound, we only have to look at the situation in Haiti and in Pakistan to realise that well organised healthcare is not something we can take for granted. To care is about taking responsibility, working together, using organisational skills and providing for the necessary means.

But be aware: the disaster of failing quality and safety management in healthcare is closer to you, to me, to our beloved, than we in Western Europe think. Let me make a comparison: a research report of last month shows that in the Netherlands each year almost two thousand (1960) preventable deaths occur in Dutch hospitals. That is the equivalent in victims of the crash of five fully loaded Jumbo jets. Healthcare is a silent killer whose damage we seem, but must not, accept. Primary cause: mistakes and errors during surgical procedures. On a close second place: medication related preventable mortality. Since the previous monitor in 2004 this number has not been reduced, it even increased slightly, despite concerted efforts of many involved.

In addition each year about 1700 preventable deaths due to medication errors and side-effects in first-line healthcare occur. With these staggering numbers you might ask: are those numbers right? Is this a proper scientific investigation? Well, it is. For example, the clinical teams which reviewed the random cases consisted of medical specialists, nurses and pharmacists with good professional reputation. Every case was reviewed by two independent review teams, who were blinded to each other's findings. Every case which was not rated as preventable by both teams was discarded.

This is the situation in the Netherlands, ten years after the publication of To Err is Human. Looking at the consistently high rankings of Dutch healthcare in the Eurobarometer benchmark, I fear that there is no reason to believe that the situation in other European countries is much better. If you know that we have a population of 16.6 million, it is easy to calculate the theoretical equivalent for your country.

Surprisingly, still few decision makers in politics and in our healthcare community seem to acknowledge that preventable damage from medical and pharmaceutical practice, the silent ongoing killing, is a problem for them. I am convinced the moment will come that the general public will not any longer accept this.

Public opinion will demand accountability and transparency from both professionals and authorities. We as policy makers and regulators have a special responsibility towards the public. The responsibility to organise healthcare

2 Hospital Admissions Related to Medication (HARM) study 2006, Division of Pharmacoepidemiology & Pharmacotherapy, Utrecht Institute for Pharmaceutical Sciences, and HARM-wrestling 2008; concrete interventions to increase short-term medication safety in primary care.
structures, to assess performance and expenditure and to facilitate professions in such a way that the healthcare system is really delivering. Performance in terms of quality and safety, efficacy and efficiency.

The Council of Europe is the body for human rights and social cohesion in the European territory. It voices the rule of law, as well as the principles of humanity and equality for all citizens. And therefore it has an excellent position to develop healthcare policies and strengthen professionalism by issuing guidance, tools and resolutions. This is an approach reaching well beyond the economic principles governing the European Union.

The many quality of life surveys carried out among consumers and patients, come to the same conclusions: once our stomachs are filled, we consider our health as the most precious asset in life, just before friends, children, partners and our families (usually in this order).

Coming from the nineteenth century and deep into the last century, the professional qualification of individual caregivers sufficed as a societal mandate for providing responsible healthcare, at least in most cases. But: things have changed.

The population has grown, new technology became available, medical specialisations evolved and the complexity of healthcare increased significantly. Certainly in the last two decades, possibilities for individuals to communicate and travel increased dramatically. The mandate to care responsibly is not any longer maintained by titles and qualifications alone. Healthcare professionals have to prove what they’re worth of; have to demonstrate their performance, what their treatments cost and what they contribute to society.

A fortiori, for authorities who are usually considered much less trustworthy and admirable to the man in the street, than are the medical and pharmaceutical professionals, we should take extra efforts to ensure a smoothly operating and well performing healthcare system. And it is just that, what this meeting is about.

Who is in charge to meet this challenge? Nobody and everybody. Authorities will never be able to do this alone.

- Authorities should assume leadership, create awareness and provide direction.

- Scientists are needed to develop reliable measures.

Before policy makers, civil servants and regulators are able to assess what is needed in healthcare, reliable data and a robust data collection structures are needed. They (we!) must be made aware that they need steering information, a wheel and handles before really taking a drivers’ seat. So, awareness comes first. Posing the right questions.

- Professionals are essential to help designing and implementing safety and quality strategies and to provide real-life data.

- Consumers and patients are needed to give feedback about quality and safety and to help raising awareness. I am convinced that the public is willing to pay for quality, as soon as it matters to them.

This workshop is set up as a meeting platform for everyone involved in the pharmaceutical care indicators project. For you, the group of forerunners on this topic in Europe, today will be an opportunity for exchanging views and to demonstrate the first results of early indicator pilots.

In the past three years this project has taken off slowly, but steadily. We established the working principles, agreed on concepts within pharmaceutical care, on definitions and a working plan. We started several multinational indicator pilots. We needn’t be ashamed of that. It is a very complex multifaceted, multistakeholder field. If we look at the five years’ and ten years’ goals of the medication safety initiatives in the USA: none of the targets has been realised.
However, we must make sure that we keep focus that we do not leave it with surveys and descriptive statistics, but that we really devise and field-test European pharmaceutical care indicators.

Supported by the EDQM organisation we are encouraged to improve our networking structure, ensure that progress is made.

We are not the only ones. Indicators as a method for quality assessment are ‘en vogue’ throughout the healthcare community. Especially in the domain of hospital care and medical specialties, progress has been significant, due to the adoption of the indicators concept by quality assurance organisations, departments and individuals in healthcare institutions. A new branch of consulting industry is emerging. When authorities require transparency and accountability, people are being paid for collecting, managing and presenting the quality and safety data.

But still, within the pharmaceutical care domain and regarding the use of medicines, you are today in a unique position to help solving serious problems caused by using high quality medicines, of vital relevance for everyone.

As a chair I will try to support you in getting as much feedback as possible. I wish you a fruitful meeting.
III – ABSTRACTS AND PRESENTATIONS
Session theme: Selected Quality of Pharmaceutical Care Indicators: Development approaches and preliminary pilot results
Chair:

Mr Nico KIJLSTRA

Chair of the Committee of Experts CD-P-PH/PC
Dutch Health Care Inspectorate
1.1 UNDERSTANDING THE PHARMACEUTICAL CARE CONCEPT AND APPLYING IT IN PRACTICE

Speaker:

Dr Sabine VOGLER

Gesundheit Österreich GmbH
Geschäfts bereich Österreichisches Bundesinstitut für Gesundheitswesen/
Austrian Health Institute (GÖG/ÖBIG)
Dr Sabine VOGLER
Pharmacists' self-assessment tool

Understanding the pharmaceutical care concept and applying it in practice
Pharmacists' self-assessment tool

Dr. Sabine Vogler
Expert Workshop: Indicators of the Quality of Pharmaceutical Care
10 December 2010

Topic group: Objectives and tasks

➢ Aim
  - to better understand the integration of pharmaceutical care within the health system,
  - by identifying concrete practices of pharmaceutical care,
  - which could serve as good practice models for other countries

➢ What did we do?
  - Scoping Exercise 2009
  - Development of a Pharmaceutical Care Indicators Check-list 2019

Scoping Exercise 2009

➢ Pharmaceutical Care in Europe
  - Overview in Europe: literature review
  - Case studies: Austria, Portugal
  - Exploring possible indicators

➢ GOG report
  - Different understanding
  - Different progress across Europe
  - Focus on specific diseases
  - Several initiatives / projects (e.g. PCNE, EuroPharm Forum)

Lessons learned

➢ Key findings & concerns on indicators
  - Documentation - number of data
  - Is attributable to pharmaceutical care?
  - Comparability
  - Cultural behavior
  - Level of pharmaceutical care is different in countries
  - Outcome vs. process indicators

The idea of a Pharmaceutical Care check-list for self-assessing the work of pharmacists was raised

controversial
Conclusions at Strasbourg Workshop, Nov. 2009
(Max Wellan, Sabine Vogler)

Pharmaceutical Care Indicators Check-list

- An Austrian initiative?
- Which stakeholders to involve?
  - Pharmacists?
  - Others?
- Development of a draft by GOG/OBIG
  - Major issues or
  - Draft version?

Vienna Workshop, 28 June 2010

25 participants, mostly pharmacy background; 50 percent from Austria

Organised by Gesundheit Österreich and EDQM

Different perspectives
Proceedings of Expert Workshop “Indicators of the quality of Pharmaceutical Care: Development approaches & preliminary results”, Strasbourg, 10 December

Dr. Sabine VOGLER
Pharmacists’ self-assessment tool

Aims of the Pharmaceutical Care Indicators Check-list

- Check-list for pharmacies
  - Self-checking tool for individual pharmacies on their progress in Pharmaceutical Care
  - List of questions to be checked

- Survey tool
  - Survey for countries (regions) to assess their implementation of Pharmaceutical Care
  - List of indicators to be measured

Draft Pharmaceutical Care Indicators Check-list

- Background
- Pharmaceutical services incl. Pharmaceutical Care
- Counselling and patient information
- Documentation and monitoring
- Safety
- Qualification and training
- Communication and involvement of further health professionals
- Patients’ perspective

Vienna Workshop, Group Work tasks – 3 parts

- Common understanding
  - Definition of Pharmaceutical Care
  - Which health professionals (e.g. hospital pharmacists)?
  - Need for such a check-list?

- Review of the check-list
  - Outline
  - Missing issues, supplementary information

- Discussion about implementation
  - Feasibility
  - Data availability

Vienna Workshop, Group Work – 3 groups
Proceedings of Expert Workshop “Indicators of the quality of Pharmaceutical Care: Development approaches & preliminary results”, Strasbourg, 10 December

Dr. Sabine VOGLER
Pharmacists’ self-assessment tool

Vienna Workshop, Group Work – outcomes

- Practical recommendations
  - Section on quality to be included
  - Country background information
  - Awareness of Pharmaceutical Care

- Focus on care concept instead of supply concept
  - “If the list is one of Pharmaceutical Care it must be oriented to Care provision rather than services.”

- Integration of Pharmaceutical Care aspects as mainstream concept

Follow-up activities

- Topic group „Special needs of regions“
  - Development of their pharmacist’s self-assessment tool
    - see presentation in the afternoon

- Pharmaceutical Care Indicators Check-list
  - Implementation in Austria?

The way forward?

Contact

Dr. Sabine Vogler
Head of Pharma Team
WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies
Health Economics Department
Stockenring 6
1010 Vienna
T: +43 1 515 81 147
F: +43 1 515 81 72
E: sabine.vogler@parac.at
www.parac.at

Thanks go to:
Austrian Federal Ministry of Health
Further slides for information

Outline of the Draft Pharmaceutical Care Indicators Check-list, discussed at the Vienna Workshop, June 2010

Draft Pharmaceutical Care Indicators Check-list/1

- Background
  - Indicators on role/work of pharmacies
  - Code of conduct
  - Indicators on whether and how pharmaceutical care is
    statutorily regulated in a country

- Pharmaceutical services incl. Pharmaceutical Care
  - Extent of essential pharmaceutical services besides
    dispensing medicines (i.e. point of care measures)
  - Extent of advanced pharmaceutical services (excl. Pharm.
    Care)
  - Extent of Pharmaceutical Care initiatives
  - Extent of disease-oriented Pharmaceutical Care
    initiatives
  - Extent of patient group specific Pharmaceutical Care
    programmes
  - Extent of theme programmes

Draft Pharmaceutical Care Indicators Check-list/2

- Counselling and patient information
  - Average time spent on counselling per patient’s visit
  - Share of pharmacies with separate rooms for counselling
  - Share of pharmacies that provide Ph. Care related
    information to patients

- Documentation and monitoring
  - Share of pharmacies in a country that perform
    documentation
  - Share of pharmacies that perform evaluations & analyses
  - Measurement of patient’s compliance
  - Indicators on implementation of data protection needed
    for performing Pharmaceutical initiatives
  - Average time spent on documentation per patient’s visit

Draft Pharmaceutical Care Indicators Check-list/3

- Safety
  - Role of pharmacies in relation with detection of drug-
    related problems, e.g. ADR, interactions, contraindications, etc.
  - Extent of detected detection of drug-related problems,
    e.g. ADR, interactions, contraindications, etc.

- Qualification and training
  - Average number of staff per pharmacy and indication on
    qualification
  - Training offers for pharmacy staff
  - Indicators on content and framework of trainings for
    Pharm. Care
  - Share of trainings for Pharmaceutical Care reimbursed
  - Indicators on incentives for trainings for Pharmaceutical
    Care
  - Share of pharmacies offering themselves training for
    specific Pharmaceutical Care programmes
Draft Pharmaceutical Care Indicators Checklist/4

» Communication and involvement of further health professionals
  - Indicator on involvement of other health care professionals in the Pharmaceutical Care process
  - Indicator on communication with other health care professionals

» Patients’ perspective
  - Share of pharmacies per country that carry out patient surveys
  - Indicators on perception of Pharmaceutical Care by patient (understanding, acceptance)
  - Share of regular customers
1.2 PHARMACEUTICAL CARE: THE KEY ROLE OF PATIENT PARTICIPATION

Speakers:

Ms Marlies GEURTS
University Groningen, the Netherlands
Ms Marlies GEURTS
Concordance and chronic conditions: indicators for patient involvement

Indicators for patient involvement in the process of pharmaceutical care
Up-date and preliminary results of a feasibility study

Background & Introduction
- Patient counseling essential for determining expectations and concerns
- High degree patient involvement \(\rightarrow\) improve medication adherence
- Patients who are explicitly invited to ask questions ask significantly more questions (Beinert GW et al.)
- Most consultations take less than 20 minutes (Geurts MME et al.)

Indicators
- INDICATOR 1: Use of a patient self-completion concordance form (SCCF) during a consultation at the start of new chronic treatment
- INDICATOR 2: Use of a documentation system for registration of consultations
- INDICATOR 3: Use of a structured clinical medication review in the provision of pharmaceutical care to target groups of patients

<table>
<thead>
<tr>
<th>Patient's expression</th>
<th>Drug therapy problems</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Understanding</td>
<td>Additional drug therapy</td>
<td>28</td>
</tr>
<tr>
<td></td>
<td>Unnecessary drug therapy</td>
<td>6</td>
</tr>
<tr>
<td>Expectations</td>
<td>Ineffective drug</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>Dosage too low</td>
<td>20</td>
</tr>
<tr>
<td>Concerns</td>
<td>Adverse drug reaction</td>
<td>14</td>
</tr>
<tr>
<td></td>
<td>Dosage too high</td>
<td>5</td>
</tr>
<tr>
<td>Behavior</td>
<td>Noncompliance</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>100</td>
</tr>
</tbody>
</table>

Drug Therapy Problems (DTP)
(N=26,238 Patient Encounters) (Cipolle RJ et al.)
Methods

- Study material
  - Self-completion concordance form (SCCF)
    1. What would you like to know about this medicine (or medicines)?
    2. What are your expectations of the effects of this medicine or medicines?
    3. Have you experienced problems using this medicine the first weeks?
    4. If you have concerns about taking this treatment for long term, what are your concerns?
    5. What would be a reason for you to stop using this medicine?

- First dispensing
  - Hand out SCCF and make appointment for consultation / second dispensing

- Second dispensing
  - Consultation based on SCCF
  - Patient questionnaire

- After all consultations
  - Pharmacist questionnaire
  - Sent back study material

Partners

- Bulgaria (Valentina Petkova, Velislava Vachanova)
- Finland (Marja Airaksinen, Anna Buljareva, Marika Pohjanpysä)
- Portugal (Afonso Miguel Cavaco, Ana Tereza Moreira Neres, Susete Costa)
- Scotland (Steve Hudson, Ian Miller, Alan Clee)
- The Netherlands (Han de Gier, Marlies Geurts, Iris Zuydgoest)
Proceedings of Expert Workshop “Indicators of the quality of Pharmaceutical Care: Development approaches & preliminary results”, Strasbourg, 10 December

Ms Marijke GEURTS
Concordance and chronic conditions: indicators for patient involvement

(Preliminary) Results

<table>
<thead>
<tr>
<th>Country</th>
<th>Letters send out</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bulgaria</td>
<td>500 (random)</td>
<td>41 (8.2%)</td>
</tr>
<tr>
<td>Finland</td>
<td>3 (not random)</td>
<td>3</td>
</tr>
<tr>
<td>Portugal</td>
<td>600 (random)</td>
<td>?</td>
</tr>
<tr>
<td>Scotland</td>
<td>?</td>
<td>?</td>
</tr>
<tr>
<td>The Netherlands</td>
<td>500 (random)</td>
<td>46 (9.2%)</td>
</tr>
</tbody>
</table>

Time Schedule

<table>
<thead>
<tr>
<th>Month</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>November 2010</td>
<td>Study period</td>
</tr>
<tr>
<td>December 2010</td>
<td>Collect study material from pharmacies</td>
</tr>
<tr>
<td>January 2011</td>
<td>Enter results in data sheet / send data sheet to the Netherlands</td>
</tr>
<tr>
<td>February – May 2011</td>
<td>Analysis final results and write final report (the Netherlands)</td>
</tr>
</tbody>
</table>

References

- Barnett CW et. al., Patient-guided counseling in the community pharmacy setting, J Am Pharm Assoc 2000;40(6):765-772
- Cox K et. al., A Systematic review of communication between patients and health care professionals about medicine taking and prescribing, Medicines Partnership, London, 2004
- Geurts MME et. al., The evaluation of an intervention based on the application of patient self-completion concordance forms in Dutch community pharmacies and the effect on adherence to chronic medication, Patient Educ Couns 2010; 78(1):85-90

Indicators for patient involvement in the process of pharmaceutical care

Review of a pre-test and discussion among nursing professionals in Germany and Switzerland
Main Findings

- SCCF form is feasible and easy to apply
- Can be used by different health care providers (physicians, pharmacists, nurses)
- Understanding and involvement into the process of pharmaceutical care is required
- Form is a practicable assessment but we also have to focus on the general conditions

Issues To Be Discussed

- “High risk” groups of patients
  - Frail elderly
  - Multimorbidity
  - Polypharmacy
  - Dementia
  - Psychiatric diseases
- Discrepancies in discharge medications
- Responsibility in the process of pharmaceutical care
- Multidisciplinarity and team approach
1.3 PROMOTION OF MEDICATION SAFETY THROUGH DATE LINKAGE & MONITORING

Speakers:

Professor Christian LOVIS, Dr Hanna Marita SEIDLING
University Hospital of Geneva, Service of Medical Informatics, Geneva, Switzerland

Ms Carla MEYER-MASSETTI
Swiss Patient Safety Foundation, Zürich, Switzerland
ABSTRACT: Data Linkage & Health Information Exchange

Prof. Christian Lovis, MD MPH; Dr. Hanna Seidling, PhD; Carla Meyer-Masseti, MS pharm / FPH

BACKGROUND
In the 21st century, patients and providers have to navigate through an increasingly complex health care system. Various providers in numerous settings are collecting a wide variety of patient-related data, leading to therapeutic decisions often involving drug therapy.

It is estimated, that up to 18% of the patient safety errors in general and as many as 70% of adverse drug events could be eliminated if the right information about the right patient is available at the right time. In order to provide safe and comprehensive pharmaceutical care, a new magnitude of decision support is required. This can be achieved with data from various sources, linked and made readily available to all healthcare providers involved in direct patient care or to decision makers taken care of populations.

OBJECTIVES
1. Data Linkage and Health Information Survey
The primary aim of “Data Linkage and Information Exchange” was to develop a set of indicators in the format of a survey and subsequently obtain feedback on its ability to assess the current status of data linkage.

2. Safety and quality indicators for the use of “Antibiotics” and “Anticoagulants
The secondary aim was the development of indicators for the high-risk drugs antibiotics and anticoagulants as an example and to assess how accessible health information can be used for quality assessment in daily practice.

METHOD
1. Data Linkage and Health Information Survey
The development of the indicator set “Data Linkage & Information exchange” is based on a systematic literature review (Pubmed, Embase & Scopus) in order to identify established indicators in the field of electronic data linkage and information exchange. Eighty-five indicators were initially considered for inclusion into the indicator set “Data Linkage & Information Exchange”.

The final 15 indicators were chosen among experts according to the following criteria:
- Universally applicable to different health care providers and types of institutions
- Representing important, universal aspects of data linkage and information exchange

For the international distribution, the EDQM working party network was used as a “snowball system”. For the distribution in Switzerland, the IHE-CH organization, the Network of the Swiss Hospital Association H+ as well as the network of the Swiss Medical Informatics Association (SGMI) were used.

2. Safety and quality indicators for the use of “Antibiotics” and “Anticoagulants
As a practice oriented example for the use of accessible health information data, the topics “Antibiotics” and “Anticoagulants” were chosen.

A thorough literature research in the databases Pubmed and Embase was done for the identification of indicators assessing the quality of antibiotic or anticoagulation therapy.

RESULTS
1. Data Linkage and Health Information Survey
Eight experts from Albania (2), Portugal (1), Switzerland (1) and The Netherlands (4) answered to our request. Several adjustments to the format of the survey were recommended:
- Addition of definitions regarding demographic information.
- Introduction of an additional choice “Does not apply” to every question.
- Clear distinction of single- and multiple-answer questions.

Regarding the content, additional choices were requested in order to obtain more in-depth information on several topics of the survey:
Medication history: additional information on information available in the record
Staff using e-Health tools: addition of “pharmacists” and “pharmacy technicians”
Impact of e-Health tools: measurement of “medication errors” and “patient outcome”
Barriers to implementation: addition of “legal constraints on data exchange”

Overall the acceptance and understanding of the survey was considered good and valuable.
Thirty-two respondents from Albania (1), Portugal (3), Switzerland (18) and Ukraine (10) from various practice sites (hospitals, public pharmacies, physician’s offices) participated in the survey.

2. Safety and quality indicators for the use of “Antibiotics” and “Anticoagulants

Antibiotics

Literature search identified 42 indicators that measured quality of antibiotic treatment. Indicators could be allocated to structure (N=9), process (N=15), and outcome (N=18). Of those indicators, we selected 2 as pilot indicators to be evaluated in an inpatient setting using electronic prescription data: (1) ratio intravenous prescriptions/per oral prescriptions and (2) appropriate treatment with regard to available antibiograms.

Indicator (1): Ratio intravenous prescriptions / per oral prescriptions

Indicator (1) was evaluated as longitudinal measurement over a 4-year period in one geriatric clinic of the Geneva University Hospitals. Included were only antibiotics which are available both as oral and parenteral preparations. The ratio was calculated as: Number of intravenous prescriptions / (Number of per oral prescriptions + Number of intravenous prescriptions). All prescriptions which lasted longer than 1 day were included.

The ratio increased over time from 0.18 to 0.31.

Indicator (2): Appropriate treatment with regard to available antibiograms.

Because the results of antibiograms are usually only available after antibiotic treatment has been started, we considered the following conditions to be inappropriate:

(1) Treatment started, germ found to be resistant against antibiotic and treatment NOT changed to a sensible substance (=inappropriate treatment)
(2) Treatment started, negative microbial culture test and treatment NOT stopped (=overuse)

Over a five year period, 3300 patients were treated with antibiotics before they received microbial culture test results. Of those, 1109 (33%) were considered to be treated inappropriately, most often because antibiotic treatment was not stopped after negative test results (N=1069).

Anticoagulants

Literature search identified 42 indicators that measured quality of anticoagulation therapy. Twelve indicators assessed structural and organizational aspects of an institution, best suited for a survey in the format of a questionnaire.

Of the 30 indicators addressing individual patient health data, two were selected for electronic data mining. Selection criteria were (1) feasibility of indicator assessment in 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:
Indicator: Anticoagulant 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 anticoagulant therapy:
Indicator: Anticoagulant AND vitamin K

Pilot testing for those 2 indicators is planned for 2011.

A template for manual collection of data on the quality of anticoagulation therapy in regular intervals was developed.

CONCLUSION / OUTLOOK

1. Data Linkage and Health Information Survey

Computerisation of processes are major pre-requisites in order to implement efficient, large-scale and sustainable monitoring systems and to replace obsolete, unsatisfactory and expensive manual reporting. Data linkage and
information exchange are an important prerequisite for a transparent and connected healthcare system. The pilot phase for the application of the “Data Linkage & Information Exchange” indicator set showed clearly, that the status of implementation and use of e-Health tools varies widely – not only all over Europe, but also in one country. The questionnaire was capable of catching a diverse range of implementation.

2. Safety and quality indicators for the use of “Antibiotics” and “Anticoagulants

Antibiotics

Two indicators were evaluated with electronic prescription data linked to laboratory test results obtained from a tertiary care hospital over a 5 year period. We defined scenarios under which these indicators might be applied. Both indicators can be used to compare quality of antibiotic treatment over time within the same institution as well as to compare different institutions.

Anticoagulants

A set of 12 indicators for the assessment of institutional factors possibly influencing quality of anticoagulation therapy was compiled. Thirty indicators for assessing individual data of patients under anticoagulation therapy were identified. A manual data collection sheet for repeated manual assessment of the quality of anticoagulation therapy was proposed. In addition, two indicators for electronic data mining were suggested, about to be tested in 2011.

Further development of additional indicators about the same or additional medication therapy topics might be considered for the future. Availability of valid and up-to-date individual patient health data is a prerequisite for such projects. In addition, data needs to be available in a structured way in order to be electronically useable.

Reference List


Mattison ML, Afonso KA, Ngo LH, Mukamal KJ. Preventing potentially inappropriate medication use in hospitalized older patients with a computerized provider order entry warning system. Arch Intern Med 2010;170:1331-1336.

Professor Christian LOVIS, Dr Hanna Marita SEIDLING, Ms Carla MEYER-MASSETTI
Indicators of implementation of data linkage & health information exchange

Data linkage and health information exchange
Topic group 3

- under-use, overuse, misuse of the health care system...
  - IOM Roundtable on Quality (JAMA 1998)
- "To Err is Human": building a safer Health System
  - 2.5-5.7% inpatients have complications
  - 0.6-13.0% lead to death, 50% evitable
  - 8th mortality cause in the USA
  - drug errors > 7'000 deathly in the USA
  - (workers: 6'000)

According to a research at Cambridge University, it doesn't matter in what order the letters in a word are, the only important thing is that the first and last letter be at the right place.

The rest can be a total mess and you can still read it without problems. This is the main reason why we have no problem decoding every letter by itself, but the word as a whole.

Amazing huh?
Proceedings of Expert Workshop "Indicators of the quality of Pharmaceutical Care: Development approaches & preliminary results", Strasbourg, 10 December

Professor Christian LOVIS, Dr Hanna Maria SEIDLING, Ms Carla MEYER-MASSETTI

Indicators of implementation of data linkage & health information exchange

Objectives

1. To develop and evaluate a survey as paper-based tool to assess the current status of data linkage and health information exchange in Europe

2. Demonstration of opportunities for quality assessment of drug treatment enabled by data linkage:
   - Antibiotics
   - Anticoagulants
Proceedings of Expert Workshop “Indicators of the quality of Pharmaceutical Care: Development approaches & preliminary results”, Strasbourg, 10 December

Professor Christian LOVIS, Dr Hanna Marta SEIDLING, Ms Carla MEYER-MASSETTI
Indicators of implementation of data linkage & health information exchange
Results – Data Linkage

Availability of software

Electronic prescribing
N=21

Clinical decision support
N=11

Availability of drug information

National drug information
N=32

International drug information
N=24

Conclusion – Data Linkage

- Validity of the first results
- Revision of the questionnaire
- Further modes of distribution and analysis

Results – Data Linkage

Individual patient health record
N=21

- Electronic record (N=21)
- Combination of paper and electronic records (N=18)
- Paper-based record (N=3)

Information exchange provider-provider

- Phone (N=21)
- Mail (N=18)
- Fax (N=12)
- Email/electronic messaging (N=12)
- Machine interpretable data (N=6)

Barriers for implementation

<table>
<thead>
<tr>
<th>Barriers for implementation</th>
<th>Provider’s office</th>
<th>Hospital pharmacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>The local IT knowledge of the staff is very limited</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Implementation is overall very cost intensive</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>Implementation is staff personnel-intensive</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Vendor is not offering satisfying products</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Available products are not certified, making a choice difficult</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Available systems are fragmented and therefore hard to link</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Legal restrictions in other countries are not endorsed or allowed by regulatory bodies who are not in place for implementation</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Technical and financial barriers for the implementation of available solutions</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Standardisation for data exchange is lacking</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Other healthcare providers don’t use electronic technologies, therefore, no data exchange is possible</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Information about patient information with competing pharmacies</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Malfunction of equipment is frequent and often of unknown reason</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>The benefits for my own practice are not evident</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>
Anticoagulants - Background

- So-called „high-risk drug”
- US National Patient Safety Goals
  [www.jointcommission.org](http://www.jointcommission.org)
- Institute for Healthcare Improvement
  [www.ihi.org](http://www.ihi.org)
- Narrow therapeutic window
  ⇒ Necessity to balance the risk of bleeding and clotting
  ⇒ Through standardisation and regular assessment of the quality of anticoagulation management

**FOCUS: Vitamin K Antagonists** (interfaces / interfaces)

---

Anticoagulants – Part 1: Survey

Baseline organisational information (12 indicators / questions)

- FORMAT: SURVEY / QUESTIONNAIRE
  - Geographic location
  - Profession
  - Anticoagulation therapy related activities
    - P&T committee
    - Availability of guidelines
    - Availability of specialists
  - Hospital Process:
    - Medication reconciliation
    - Discharge teaching / Discharge materials for patients

---

Anticoagulants – Part 2: Medication Use Evaluation

**Patient Individual health information**

**FORMAT: ELECTRONIC DATA MINING**

1. Clinical event
   Number of patients treated with a vitamin K antagonist AND suffering from a major bleeding
   **INDICATOR 1:** Anticoagulant AND major bleeding
   (ICD-10 AND Haemoglobin decrease >2g/dl AND INR>3)

2. Use of antidotes
   Number of patients treated with a vitamin K antagonist AND receiving vitamin K during their anticoagulation therapy.
   **INDICATOR 1:** Anticoagulant AND use of vitamin K

---

Anticoagulants – Part 2: Medication Use Evaluation

**Patient Individual health information**

**FORMAT: MANUAL ASSESSMENT**

- Use of a manual form for data collection
- Study subjects:
  - Analysis of 20 patients treated with anticoagulants / institution
- Study interval:
  - at least every year
- Objectives:
  - Indication
  - Quality of Prescribing
  - Dosage / Dosage intervals
  - Monitoring (type of lab, intervals, reaction time)
  - Concomitant drug therapy / interactions
  - Discharge teaching / Discharge materials

---

Proceedings of Expert Workshop "Indicators of the quality of Pharmaceutical Care: Development approaches & preliminary results", Strasbourg, 10 December
Antibiotics – Pilote indicators

- Appropriate treatment – Appropriate treatment on resistencies

* Setting: Geneva University Hospital
  * Study period: 5 years (06/2005-05/2010)
  * Population: 36,641 patients receiving antibiotic treatment (38,383 treatment episodes)

2015 patients with one microbiological culture per treatment period (4080 treatment episodes)

- 25% Patients were admitted at home
- 35% Antibiotics ordered in 24h
- 85% Appropriate treatment in 24h

Antibiotics – Conclusion

* The literature suggests a vast number of quality indicators for antibiotic treatment

* Selection of two indicators that
  * Are straightforward to calculate,
  * And are independent of setting specific differences such as availability of drugs or specific guidelines

The way forward

- Revision of the survey on data linkage
- Redistribution in a broader sample
- Testing of indicators for antibiotics and anticoagulants according to available resources

Mayer-Modesti, Seidl, Leuven, 2013 + DSM, Council of Europe, All rights reserved.
1.4 COMMUNICATION AND INTERDISCIPLINARY COOPERATION

Speakers:

Professor Afonso CAVACO, Dr Paula FERREIRA

Faculty of Pharmacy,
University of Lisbon, Portugal
Professor Afonso CAVACO, Dr Paula FERREIRA

Patient counseling, personalised written information, communication with the physician

APPLICABILITY STUDY OF COMMUNICATION INDICATORS IN PHARMACEUTICAL CARE

- Council of Europe and the development of a better medication safety culture
- European Directorate for the Quality of Medicines and Healthcare (EDQM) project on the development of quality indicators: assessment and improvement of pharmaceutical care
  - Higher awareness and practical guidance for healthcare professionals
  - Data for decision and policy-makers; harmonisation of practice involving pharmaceutical usage
- Few validated indicators for the quality of pharmaceutical care available

APPLICABILITY STUDY OF COMMUNICATION INDICATORS IN PHARMACEUTICAL CARE

Ignorance is the leading cause of illness. Non-adherence is the leading cause of treatment failure. Communication is part of the cure.

- Pharmacists’ communication skills: central role in practice
- Knowledge sharing: extract, interpret, evaluate, confirm, clarify and summarise information on symptoms, diseases, lifestyles, treatments, etc.
- Communication essential to detect and reduce medication-related problems, increasing rational use of medicines
- Communication essential to patient-centred care: patient involvement and participation in therapeutic decisions

APPLICABILITY STUDY OF COMMUNICATION INDICATORS IN PHARMACEUTICAL CARE

Study Aim
- Pilot development and testing of the applicability of 3 communication indicators in different European pharmaceutical practice realities

Study Objectives
- Evaluate the relevance of the 3 proposed communication indicators within each country pharmaceutical practice
- Evaluate the adequacy of the proposed observation methodology
- Data collection: recruitment, study period, registration forms for each specific communication event
- Contribute to establish the construct and content validity, as well as the reliability of the proposed indicators
APPlicability study of communication indicators in Pharmaceutical care

- Proposed initial communication indicators
  - With patients and caregivers
  - Interdisciplinary communication and cooperation
- Process type indicators (Donabedian) for community pharmacy practice
  - C1: Initial Counseling indicator
  - C2: Personalized written information indicator
  - C3: Pharmacist-Pharmacist communication indicator

Materials and Methods
- Pilot study implementation and feedback
  - Two phases:
    1. Comments and suggestions provided by the collaborative country, after a first contact with the study manual and field materials
    2. Field work in 3-5 selected pharmacies, the application of indicators forms during communication events observation

C1: Initial counseling
- Oral advice given by the pharmacy professional (pharmacist or technician) to the patient that receives a new prescribed medication

C2: Personalized written information
- On paper information (handwritten, printed) produced and given by the pharmacy professional to the patient that has asked specifically for that information
- Not based on a prescription, but on a request for medication information made by the patient and not corresponding to package inserts or other standardized patient bulletins

C3: Pharmacist-Pharmacist communication
- Any contact made by the pharmacy professional to the pharmacist in relation to identified drug-related problems (0%) which needs pharmacy professional-pharmacist communication to be solved
- Retrospective event analysis
General portrait of Pharmaceutical Care in

1. Total number of pharmacies;
2. Number of medication per pharmacy;
3. Number of prescription per pharmacy;
4. Number of non-prescription per pharmacy;
5. Prescriptions costs per medication;
6. Prescription services required:
   - Home drug delivery;
   - Home support;
   - Prescription administration;
   - Health education program;
   - Pharmaceutical care programs (please specify);
7. Medication review;
8. Other;

What is the current role of the community pharmacist in healthcare and society? Future perspectives?

Additional comments:

Registeration document for C2

1. What type of medical problems did you experience in the last 6 months?
2. How many healthcare professionals did you consult for your problems?
   - Doctor
   - Pharmacist
   - Physical therapist
   - Other

Registration document for C2

1. What was the name of the patient who presented the patient after the patient request?
2. What type of information was provided to the patient after the patient request?
   - Written (e.g. medication leaflet)
   - Telephone (e.g. 3 days to 1 week)
   - Face-to-face (e.g. 3 days to 1 week)
   - Other

Registration document for C2

1. How did you obtain written information?
   - Patient's request
   - Healthcare professional
   - Other

Registration document for C2

1. What type of disease was treated by the pharmacist?
   - Acute
   - Chronic

Registration document for C2

1. What type of disease was treated by the pharmacist?
   - Acute
   - Chronic
Proceedings of Expert Workshop “Indicators of the quality of Pharmaceutical Care: Development approaches & preliminary results”, Strasbourg, 10 December

Professor Afonso CAVALCO, Dr Paula FERREIRA
Patient counseling, personalised written information, communication with the physician

<table>
<thead>
<tr>
<th>Registration statement for C9 (Pharmaceutical Communication Indicator)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. What is the average time between the prescription notification and supply to the patient?</td>
</tr>
<tr>
<td>Response: 0 minutes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Field researcher questionnaire</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Background information</td>
</tr>
<tr>
<td>Public authority or organization:</td>
</tr>
<tr>
<td>Average number of clients per day:</td>
</tr>
<tr>
<td>Number of employees:</td>
</tr>
<tr>
<td>Number of other staff:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. Equipment and services</th>
</tr>
</thead>
<tbody>
<tr>
<td>Displaying software</td>
</tr>
<tr>
<td>Therapeutic management (tacrolimus, immunosuppression) access</td>
</tr>
<tr>
<td>Individual health record</td>
</tr>
<tr>
<td>Other services:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. Communication issues available in the pharmacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phone:</td>
</tr>
<tr>
<td>Other:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4. Are there phone services available in the pharmacy?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5. How many clients are served by the pharmacist per consultation?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>6. Staff members available in the pharmacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicine</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>7. What are the patient’s access to the pharmacy?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequently</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>8. Communication skills training</th>
</tr>
</thead>
<tbody>
<tr>
<td>Online</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>9. How well does the pharmacist communicate with patients?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very well</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>10. What are the overall impressions of the pharmacy?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excellent</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>11. Are there any suggestions?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>12. Are there any comments or suggestions?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>13. What are the suggestions?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improvements</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>14. Are there any comments or suggestions?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>15. What are the suggestions?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improvements</td>
</tr>
</tbody>
</table>
APPLICABILITY STUDY OF COMMUNICATION INDICATORS IN PHARMACEUTICAL CARE

Results. Participating countries feedback and major protocol changes
- C3 Indicator: prospective analysis of information until 30 C3 forms or a maximum of 90 days
  - Introduction of a new DIN classification
  - Rational due to generalized limited documentation related to contacts with physicians: it is proposed to use the indicator prospectively (even if introducing testability bias)
- DIN classification extension
- Inclusions of negative/positive feedback from the physician
- Additions to Field Researcher Questionnaire – Annex D
  - Opening hours, pharmacy team description

APPLICABILITY STUDY OF COMMUNICATION INDICATORS IN PHARMACEUTICAL CARE

Results. Partner countries
- Albania: Afrim Tlaku
- Georgia: Zaza Chapichadze
- Ireland: Martin Henman
- Moldova: Zinaida Buzhverdi
- Netherlands: Han de Gier, Marije Geurts
- Portugal: Afonso Cavaco, Paula Sousa Ferreira
- Spain: Flor Alvarez Toledo
- Switzerland: Carla Meyer
- Ukraine: Olga Grinstova

APPLICABILITY STUDY OF COMMUNICATION INDICATORS IN PHARMACEUTICAL CARE

Results. Participating countries preliminary results
- Albania: Afrim Tlaku
  - First prescription: information commonly provided orally, concerns dosage, frequency, period of use, and also precautions and side effects
  - Personalized written information: OTC medicines, in general counseling rarely occurs
  - Pharmacist communication: there is no O/R patient and pharmacies are not aware of this issue, so communication nonexistent (except for the near hospital located pharmacies)
  - No quantitative description

APPLICABILITY STUDY OF COMMUNICATION INDICATORS IN PHARMACEUTICAL CARE

Results. Participating countries preliminary results
- Georgia: Zaza Chapichadze
  - First prescription: oral counseling common, concerning dosage, frequency and period of use
  - Personalized written information: rarely happens, but some written in box related to dosage, frequency and period of use
  - Pharmacist communication: no form of contact with prescriber
  - No quantitative description
Proceedings of Expert Workshop "Indicators of the quality of Pharmaceutical Care: Development approaches & preliminary results", Strasbourg, 10 December

Professor Afonso CAVACO, Dr Paula FERREIRA
Patient counseling, personalised written information, communication with the physician

APPLICABILITY STUDY OF COMMUNICATION INDICATORS IN PHARMACEUTICAL CARE

Results. Participating countries preliminary results
- Moldova: Zinaida Bezeverhi
  - First prescription: information commonly provided in verbal and written form; includes dosage, frequency, period of use and also precautions or side effects; patient mentions 17 prescriptions and request for information
  - Personalized written information rarely happens, most information verbally provided
  - Pharmacist-prescriber communication: rare contact; pharmacies do not have DRPs registration
  - No quantitative description

- Netherlands: Han de Gier, Marlies Geurts
  - First prescription: patient records first prescription and alerts to information giving, concerning dosage, precautions and side effects in oral and written form
  - Personalized written information: patient information requests rare
  - Pharmacist-prescriber communication: great concern about DRPs; records made in prescriptions not on software/documentation; common contact with the prescriber
  - No quantitative description

APPLICABILITY STUDY OF COMMUNICATION INDICATORS IN PHARMACEUTICAL CARE

Results. Participating countries
- Portugal: Afonso Cava, Paula Sousa Ferreira
  - First prescription: counseling provided in 80-90%; information commonly given in verbal and written form; concerning dosage, frequency and period of use; rarely precautions and side effects
  - Personalized written information: OTC written information (handwritten on the package) approx 30%; limited to dosage, frequency and period of use
  - Pharmacist-prescriber communication: most pharmacies do not have DRPs; record if detected DRI is solved through patient or by phone contact with the pharmacist (contact with hospital physician rare)
  - Limited quantitative data

- Spain: Flor Alvarez Toledo
  - First prescription: pharmacy professional questioning and provided information spontaneously orally concerning dosage, frequency and period of use; sometimes precautions
  - Personalized written information: handwritten in paper/package, concerning dosage, frequency and period of use
  - Pharmacist-prescriber communication: occasionally by phone, mostly about safety related DRPs

Afonso Cava, Paula Sousa Ferreira, 2008/2009. Council of Europe. All rights reserved.
Proceedings of Expert Workshop “Indicators of the quality of Pharmaceutical Care: Development approaches & preliminary results”, Strasbourg, 10 December

Professor Afonso CAVACO, Dr Paula FERREIRA
Patient counseling, personalised written information, communication with the physician

APPLICABILITY STUDY OF COMMUNICATION INDICATORS IN PHARMACEUTICAL CARE

Results. Participating countries
- Spain: Flor Alvarez Toledo
  - Asturias
    - First prescription: counseling provided in 75%, mostly spontaneously and orally, concerning dosage, frequency and period of use, as well as side effects.
    - Personalised written information: handwritten in paper/package, concerning dosage, frequency and period of use, as well as precautions, side effects and administration route.
    - Pharmacist prescribing medication: mostly safety D90, with physician contact predominantly by phone and positive feedback. 25% were not reported since pharmacists suggested further patient/physician visit.

APPLICABILITY STUDY OF COMMUNICATION INDICATORS IN PHARMACEUTICAL CARE

Results. Participating countries
- Switzerland: Carla Meyer
  - Mainly missing information in C3 formulary and Annex D, among others comments.

APPLICABILITY STUDY OF COMMUNICATION INDICATORS IN PHARMACEUTICAL CARE

Preliminary conclusions
- Participants feedback was very important to improve field methodology as well as formularies.
- New study protocol is now ready to be tested in collaborating countries.
- Strong heterogeneity in study application, initial results difficult to compare.

Thank you for your attention!
1.5 ADHERENCE TO TREATMENT GUIDELINES

Speakers:

Ms Iryna MUKOMEL
University National of Pharmacy, Ukraine
Ms Iryna Mukomel
Presentation of an interdisciplinary study protocol

Study Protocol proposal
Improving the adherence to clinical practice guidelines with pharmaceutical care

Evidence based medicine takes time
- The volume of medical literature doubles every 10 years
- 10,000 citations added to MEDLINE/day
- Keeping up with relevant primary literature is a challenge (understatement?) or futile (overstatement?)
- Quality shortcuts are valuable and necessary

What are Clinical Practice Guidelines?
«Clinical practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances»
Institute of Medicine, 1990

Clinical Practice Guidelines
What are their purpose?
- Attempt to distill a large body of medical knowledge into a convenient, readily usable format.
- PGs are not simply an efficient resource for practitioners:
  - promote rational, evidence-based practice;
  - reduce inappropriate variations in care;
  - identify gaps in knowledge (future research);
  - educate individuals or groups.

- 855 different guidelines in the U.K.
- This produced a pile of 68 cm and weighing 28 kg.
- 160 were more than 10 pages and 25 were presented as booklets or large folders.

The mass of paper represents a large amount of information, but it is in an unmanageable form that does little to aid decision making.

The implementation problem

- Many patients (estimated 30-45%) do not receive recommended (evidence based) care.
- 20-25% of tests ordered or medications prescribed are not evidence based, unnecessary and potentially harmful.
- Many patients harmed because of adverse events, partly caused by not using evidence based guidelines.
- Large, unexplained differences in the use of guidelines between sites and providers.

Barriers to Adherence to Practice Guidelines in Relation to Behavior Change

<table>
<thead>
<tr>
<th>Barriers to Adherence</th>
<th>Knowledge</th>
<th>Attitude</th>
<th>Behavior</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lack of Knowledge</td>
<td>Risk of injury</td>
<td>“I do not have experience in treating hyperthyroid patients and only see a few of them per year. Think this is not sufficient to build up expertise.”</td>
<td></td>
</tr>
<tr>
<td>Lack of Awareness</td>
<td>“Can I really be honest to you? I have never read the guideline.”</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lack of Support</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Barriers related to

- Knowledge: “Can I really be honest to you? I have never read the guideline.”
- Attitude: “I do not have experience in treating hyperthyroid patients and only see a few of them per year. Think this is not sufficient to build up expertise.”
- Behavior: “This recommendation is obsolete.”
Implementation of guidelines: the evidence

- Overviews of systematic reviews show (Grol/Grimshaw 2003, Grimshaw 2004): no evidence that one of many many approaches to change is superior in all situations; most are useful in some settings for some guidelines
- Change even after well-planned interventions usually moderate (6-10%); however such a change may be (clinically) relevant
- Not clear why some strategies and change interventions are effective for some guidelines in some settings and not for others
- We lack research on new, interesting approaches

Factors associated with the effective implementation of Clinical Practice guidelines

<table>
<thead>
<tr>
<th>Probability of being effective</th>
<th>Development strategy</th>
<th>Dissemination strategy</th>
<th>Implementation strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>Internal</td>
<td>Specific educational intervention</td>
<td>Patient-specific reminder at time of consultation</td>
</tr>
<tr>
<td>Above average</td>
<td>Intermediate</td>
<td>Continuing education</td>
<td>Patient-specific feedback</td>
</tr>
<tr>
<td>Below average</td>
<td>External local</td>
<td>Nailing target groups</td>
<td>General feedback</td>
</tr>
<tr>
<td>Low</td>
<td>External</td>
<td>Publication in journals</td>
<td>General reminder</td>
</tr>
</tbody>
</table>

based on Grimshaw, 1994

Two issues

- Creating a structure and context for implementation of guidelines and changes in patient care
- Engaging professionals in using guidelines and improving practice

Pharmaceutical care

- direct involvement of the pharmacist in the design, implementation, and monitoring of a therapeutic drug plan to produce a specific therapeutic outcome
- Evidence based pharmacy or evidence based practice
Rate of antimicrobial resistance in S. pneumoniae

What does it mean?

Participants of pharmaceutical care

Hypothesis of the study

- pharmaceutical care can improve the adherence to Clinical Practice Guidelines for mild pneumonia, acute bacterial bronchitis, bacterial tonsillitis, acute media otitis and cystitis
Objectives

Primary objective
- To improve the adherence to Clinical Practice Guidelines with pharmaceutical care

Secondary objective
- Costs of antibiotic therapy

Methods

Study design

The study is a prospective, randomized controlled trial.
Sample size

- In study will recruit 120 physicians to detect a difference of 0.5% with 90% power, significance level 0.05, probability of drop-outs 20%. The number of patients is 1380; a significance level of 5% and 90% power, probability of drop-outs 20%.
- In Ukraine we will recruit PGs, otolaryngologists, urologists.
- In Germany we will be focus to General Practitioners
- Other country are invited to participate

Study inclusion and exclusion criteria

<table>
<thead>
<tr>
<th>Inclusion criteria of the patient</th>
<th>Exclusion criteria of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>age of 318 years patient with diagnosis of mild pneumonia, acute bacterial bronchitis, bacterial tonsillitis, an acute urogenital tract infection (cystitis) consult for the first time within these illnesses</td>
<td>any of the following comorbidities asthma chronic obstructive pulmonary disease, diabetes, HIV, congestive heart failure chronic ischemic heart disease</td>
</tr>
</tbody>
</table>

Procedure

The study will be divided into two phases:

Phase I – pre-intervention phase (three month)
- Randomisation
- Visiting active group by the clinical pharmacist

Phase II – post-intervention phase (three month)

Pre-Intervention Phase

Data collection:
- prescribed antibiotics;
- costs of antibiotic treatment;
- age, gender and diagnosis of the patients according to ICD-10
Intervention

- The aim is to increase awareness and to increase the efficiency of antibiotics therapy.

The chart with first-, second-line antibiotics

Post-Intervention Phase

**Data collection:**

- prescribed antibiotics;
- costs of antibiotic treatment;
- age, gender and diagnosis of the patients according to ICD-10

Data collection: overview

- Consent Form
- Physician information leaflet
- Patient Registration Form
- Approval of the ethic committee

Post-detailing period

Prescribing data will be compared from both phases will be the effects of the therapeutics adviser’s visit
Analysis and conclusion

Comparing pre-intervention period and post-intervention period regarding:

- Prescriptions of antibiotics,
- number of prescriptions per physician,
- costs of prescribed antibiotics.

The prescribed antibiotics will be analysed in comparison with clinical practise guidelines, and the costs of antibiotic therapies in active and control groups will be calculated to evaluate pharmacist influence to improve the adherence to guidelines.

Thank you for your attention
Any Questions?
1.6 PHARMACEUTICAL CARE: SPECIAL NEEDS OF REGIONS

Speakers:

Professor Afrim TABAKU
Public Health Institute, Albania

Dr Zaza CHAPICHADZE
Ministry of Health, Georgia

Dr Zinaida BEZVERHNI
University Chisinau, Moldova

Ms Olga GRINTSOVA
University Kharkov, Ukraine
Studies: development quality of pharmaceutical care indicators on the national and professional level (pharmacist’s self-assessment tool) in Albania, Georgia, Moldova, Ukraine
Abstract - Presentation: Expert survey & pharmacy survey in ALBANIA

Professor Dr Afrim Tabaku

Background: Pharmaceutical care has been proposed as the mission for pharmacy practice and, in numerous studies, has been shown to improve patients' health outcomes and decrease costs. Although a number of articles about pharmacy practices in European countries have been published, few reviews compare pharmacy and pharmaceutical care practices throughout Europe, especially in developing countries.

There are several reasons why it is difficult to get a clear picture of pharmacy and pharmaceutical care practices in Europe.

Although the European Union has now existed for many years, there has yet to be any harmonization in the field of primary health care even though a number of recommendations have been made. As a result, there still are major differences in health care policies and practices among European countries. Furthermore, it is not very common to describe current practices or professional developments in pharmacy; most articles focus on commercial and professional threats to pharmacy or future challenges.

The aim of this survey was to describe the status of implementation of pharmaceutical care practice in Albania, as well as to analyze the factors that have limited the process of implementation of pharmaceutical care.

Material and methods: This survey involved a short term observation period at twenty pharmacies allocated in urban and suburban area of Tirana city, and is based on analyses of self assessment and expert survey questionnaires. The questionnaires were distributed in different continuing professional development events for pharmacists during second half part of November 2010 (20 questionnaires for pharmacist self assessment, 5 questionnaires for expert survey, and 5 questionnaires for pretest evaluation). The rate of responders was 100%. Through questionnaires we have collect data for some indicators, like number of population of the zone where pharmacy is allocated, qualification of pharmacy staff in pharmaceutical care, medicines dispensing, inter-professional collaboration, patient counseling and education, on self care, extent of diagnostic pharmaceutical services, knowledge of concept of pharmaceutical care, concerning of pharmaceutical care in the program of undergraduate, postgraduate or continuous education, as well as number of prescriptions per day, years of practice of staff, declaration and documentations of drug related problems, etc. Statistical processing of data is carried out by using Statistical Package for Social Sciences (SPSS 15).

Results it has resulted from this survey that 80% of experts have no knowledge of concepts of pharmaceutical care, 80% were unfamiliar about the implementation of pharmaceutical care in the country, 60 % have no knowledge about the National Good Pharmacy Standards. Pharmaceutical care is not included in curricula of undergraduate or post graduate students. Also, it is yet not included in the continuous education curricula.

The majority of pharmacies are allocated in zone with up to 10 000 inhabitants. There are small private pharmacies in general with one pharmacist, while some of these have employed and one technician. The rate between pharmacists and technicians have resulted 1.9: 0.3

About 90 % of pharmacists had not completed university education in pharmaceutical care

Regarding drug related problems, only 60% of pharmacies have documented ADRs. Collaboration with physicians and other medical staff, in point of view of reporting ADRs, is to be desired because in the country yet does not exist the pharmacovigilance law, which will oblige all medical staff to declare the ADRs.

Total score of the survey was 38.60

Conclusion: Results of this survey, according evaluation of self assessments have shown that in Albania yet is not implemented pharmaceutical care.
Professor Afrim TABAKU

Pharmaceutical care Project
TG4: Expert survey & pharmacy survey in ALBANIA

Prof. Dr. Afrim Tabaku*, MSc. Aurora Napuce**,
MSc. Kleva Shpati***
* Public Health Institute, Tirana-Albania
** U.F.O University, Tirana-Albania

INTRODUCTION

Pharmaceutical care has been proposed as the mission for pharmacy practice(1) and, in numerous studies, has been shown to improve patients' health outcomes and decrease costs.

An accepted definition of pharmaceutical care is "the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life." However, because the pharmaceutical care concept is so comprehensive, it will take a number of years for the profession to achieve its mission.

MATERIAL AND METHODS

This study involved a short term observation period at twenty pharmacies allocated in urban and suburban area of Tirana city, and is based on analyses of self-assessment and expert survey questionnaires. The questionnaires were distributed in different continuing professional development events for pharmacists during second half part of November 2010 (30 questionnaires for pharmacy self-assessment, 8 questionnaires for expert survey, and 5 questionnaires for pretest evaluation)

Statistical processing of data is carried out by using Statistical Package for Social Sciences (SPSS 15).

The aim of this study was to describe the current status of pharmaceutical care practice in Albania, as well as to analyze the factors that influence in the process of implementation of pharmaceutical care in country.
Proceedings of Expert Workshop “Indicators of the quality of Pharmaceutical Care: Development approaches & preliminary results”, Strasbourg, 10 December

Professor Dr Afrim Tabeku
Expert survey & pharmacy survey in ALBANIA
Proceedings of Expert Workshop “Indicators of the quality of Pharmaceutical Care: Development approaches & preliminary results”, Strasbourg, 10 December

Professor Dr Afrim Tabaku
Expert survey & pharmacy survey in ALBANIA

<table>
<thead>
<tr>
<th>ITEMS</th>
<th>% of respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>yes</td>
</tr>
<tr>
<td>Is there any legal basis, health strategy or policy document for the implementation of the concept of pharmacy care</td>
<td>100%</td>
</tr>
<tr>
<td>Do you have national Good Pharmacy Practice Standards</td>
<td>100%</td>
</tr>
<tr>
<td>Is the current education in the field of pharmaceutical care sufficient for pharmacist</td>
<td>100%</td>
</tr>
<tr>
<td>Are there any professional publications concerning pharmaceutical care</td>
<td>100%</td>
</tr>
<tr>
<td>Are there any public information campaigns concerning rational use of medicine</td>
<td>100%</td>
</tr>
</tbody>
</table>

WORKING STAFF IN PHARMACY

Descriptive Statistics

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Mean</th>
<th>Std. Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacists</td>
<td>20</td>
<td>1.00</td>
<td>4.00</td>
<td>1.500</td>
<td>.55224</td>
</tr>
<tr>
<td>Technicians</td>
<td>20</td>
<td>.00</td>
<td>2.00</td>
<td>.300</td>
<td>.57124</td>
</tr>
<tr>
<td>Others</td>
<td>20</td>
<td>.00</td>
<td>1.00</td>
<td>.500</td>
<td>.22381</td>
</tr>
<tr>
<td>Valid N (Raw/ES)</td>
<td>20</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

TIME SPENT PER PATIENT

<table>
<thead>
<tr>
<th></th>
<th>Mean ±SD</th>
<th>Median</th>
<th>95% C.I</th>
</tr>
</thead>
<tbody>
<tr>
<td>Counseling</td>
<td>35.000 ± 20.207</td>
<td>40.000</td>
<td>25.260 – 44.739</td>
</tr>
<tr>
<td>Dispensing</td>
<td>65.000 ± 20.207</td>
<td>60.000</td>
<td>55.260 – 74.740</td>
</tr>
</tbody>
</table>
PROCEEDINGS OF EXPERT WORKSHOP “INDICATORS OF THE QUALITY OF PHARMACEUTICAL CARE: DEVELOPMENT APPROACHES & PRELIMINARY RESULTS”, STRASBOURG, 10 DECEMBER

Professor Dr Afrim Tabaku
Expert survey & pharmacy survey in ALBANIA

QUALIFICATION OF STAFF

<table>
<thead>
<tr>
<th>Qualification</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacists completed university education in</td>
<td>10.34%</td>
</tr>
<tr>
<td>Pharmaceutical care</td>
<td></td>
</tr>
<tr>
<td>Pharmacists not completed university education in</td>
<td>89.66%</td>
</tr>
<tr>
<td>Pharmaceutical care</td>
<td></td>
</tr>
</tbody>
</table>

MEDICATION REVIEW

<table>
<thead>
<tr>
<th>Frequency</th>
<th>% of respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>60%</td>
</tr>
<tr>
<td>Occasionally</td>
<td>40%</td>
</tr>
</tbody>
</table>

DO YOU HAVE COMPUTER IN YOUR PHARMACY

<table>
<thead>
<tr>
<th>Response</th>
<th>% of Pharmacies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>90%</td>
</tr>
<tr>
<td>No</td>
<td>10%</td>
</tr>
</tbody>
</table>

Services offered by pharmacies

<table>
<thead>
<tr>
<th>Service</th>
<th>% of Pharmacies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood pressure</td>
<td>80%</td>
</tr>
<tr>
<td>Weight control/BM</td>
<td>70%</td>
</tr>
<tr>
<td>Blood glucose testing</td>
<td>60%</td>
</tr>
</tbody>
</table>
Proceedings of Expert Workshop “Indicators of the quality of Pharmaceutical Care: Development approaches & preliminary results”, Strasbourg, 10 December

Professor Dr Afrim Tabeiu
Expert survey & pharmacy survey in ALBANIA

<table>
<thead>
<tr>
<th>Service</th>
<th>N</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measurement of blood pressure</td>
<td>20</td>
<td>3.00</td>
<td>3.00</td>
<td>2.100</td>
<td>0.968</td>
</tr>
<tr>
<td>Weight control/BMI</td>
<td>20</td>
<td>3.00</td>
<td>3.00</td>
<td>1.850</td>
<td>1.424</td>
</tr>
<tr>
<td>Blood glucose testing</td>
<td>20</td>
<td>3.00</td>
<td>3.00</td>
<td>1.850</td>
<td>1.137</td>
</tr>
</tbody>
</table>

Patient Assessment (Usually offered services)

<table>
<thead>
<tr>
<th>Service</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>On patients initiative, as a measurement without risk factors assessment</td>
<td>50</td>
</tr>
<tr>
<td>On pharmacists initiative, as a measurement without risk factors assessment</td>
<td>10</td>
</tr>
<tr>
<td>On patients initiative, as a component of health risk factors assessment service</td>
<td>35</td>
</tr>
<tr>
<td>On pharmacists initiative, as a component of health risk factors assessment service</td>
<td>5</td>
</tr>
</tbody>
</table>

Patient Assessment cont

<table>
<thead>
<tr>
<th>Question</th>
<th>Not discussed or explained</th>
<th>Occasionally discussed or explained</th>
<th>Always discussed or explained</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are the results discussed in the context of the patient’s overall health</td>
<td>0 %</td>
<td>90 %</td>
<td>10 %</td>
</tr>
<tr>
<td>Is the need of the refer to a physician explained to the patient, when necessary</td>
<td>20 %</td>
<td>70 %</td>
<td>10 %</td>
</tr>
</tbody>
</table>

% of PHARMACIES THAT DOCUMENTED ADRs

<table>
<thead>
<tr>
<th>PHARMACIES</th>
<th>% of Documented ADRs in pharmacy</th>
<th>% of Not documented ADRs in pharmacy</th>
</tr>
</thead>
</table>
Proceedings of Expert Workshop “Indicators of the quality of Pharmaceutical Care: Development approaches & preliminary results”, Strasbourg, 10 December

**INTERPROFESSIONAL COLLABORATION**

<table>
<thead>
<tr>
<th>% of PHARMACIES</th>
<th>Interprofessional collaboration</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No interprofessional collaboration</td>
</tr>
<tr>
<td>10</td>
<td></td>
</tr>
<tr>
<td>20</td>
<td></td>
</tr>
<tr>
<td>30</td>
<td></td>
</tr>
<tr>
<td>40</td>
<td></td>
</tr>
<tr>
<td>50</td>
<td></td>
</tr>
</tbody>
</table>

**OVERALL EVALUATION**

<table>
<thead>
<tr>
<th>SCORE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Qualification of staff</td>
</tr>
<tr>
<td>Medicines dispensing</td>
</tr>
<tr>
<td>Self care</td>
</tr>
<tr>
<td>Point of care testing</td>
</tr>
<tr>
<td>Total Score</td>
</tr>
</tbody>
</table>

**Score** | **Level of Pharmaceutical Care implementation**
--- | ---
< 52 | No implementation
53 - 72 | Low level of implementation
73 - 88 | Medium level of implementation
89 - 103 | High level of implementation

**BARRIERS**

- Lack of specific training
- Lack of doctor co-operation
- Lack of pharmacists’ competency
- Lack of communication skills with health team
- Non-conducive structure of the local health care system
- Lack of specific software/technological resources
- Lack of reimbursement
- Lack of time available
- Lack of support staff
- Lack of access to medical information
- Unsatisfactory physical layout of pharmacy

**BARRIERS cont**

- Occasional patients
- Lack of documentation skills
- Difficulties to access drug information
- Commercial profile
- Lack of motivation/compromise
- Lack of acceptance of a need for a pharmacist by health system and other clients
CONCLUSIONS

- In Albania is not implemented Pharmaceutical Care
- By our opinion, there are many factors that have influenced in non implementation of Pharmaceutical Care, such as Pharmaceutical Care is not included in undergraduate, postgraduate or in continuous education curricula, lack of law on pharmacovigilance, lack of institutional collaboration between pharmacists and other medical staff.
EXPERTS’ SURVEY V.3. PHASE 1 FOR PHARMACEUTICAL CARE

Piloting in Georgia

- Do you think the concept of “pharmaceutical care” is known and understood in your country?
  part or no

- What does the term “pharmaceutical care” mean in your country? Please describe
  Pharmaceutical care is a process of improving patient's quality of life.

- Is there a legal basis, health strategy or policy document for the implementation of the concept of pharmaceutical care in your country?
  no or do not know

- Is the concept of pharmaceutical care, actively implemented or accepted as part of professional practice by the health care professional bodies in your country?
  partially accepted or unfamiliar

- Please describe the barriers for implementing in practice the concept of pharmaceutical care in your country?
  No legislation. No recourses.

- Do you have national Good Pharmacy Practice standards, related to quality of care?
  no or do not know

- Is there education concerning pharmaceutical care in your country?
  no or do not know
  Undergraduate or postgraduate university curricula, continuous education programs, sponsored by Industry or Professional organisations

- To your opinion, is the current education in the field of Pharmaceutical Care sufficient for pharmacists?
  No
  What do you think is needed to improve the education in the field of Pharmaceutical Care in our country?
  Specialised educational and training programs are needed.
Proceedings of Expert Workshop “Indicators of the quality of Pharmaceutical Care: Development
approaches & preliminary results”, Strasbourg, 10 December

Dr Zaza CHAPICHADZE
Expert survey & pharmacy survey in Georgia

- Is it mandatory for pharmacist to complete Pharmaceutical Care education before starting to work in a pharmacy?
  No

- How many pharmacists in your country complete pharmaceutical care education annually:
  University education, Continuous education, sponsored by industry or professional organisations
  What is total number of registered pharmacists in your country?
  3000

- Are there any public or independent medicines information sources in national language available in your country:
  a. for patients/consumers no or do not know
  b. for prescribers and pharmacists yes, internet
  Are any of them in on-line version? yes, please specify

- Are there any professional periodical publications concerning pharmaceutical care available in your country?
  yes, but not independent

- Are there any public information campaigns concerning rational medicines use conducted in your country?
  no or do not know

I INFORMATION ABOUT THE RESPONDENT

- Is your pharmacy situated in a community having:
  - less than 10,000 inhabitants
  - 10,000-20,000 inhabitants
  - 20,000-50,000 inhabitants
  - 50,000-100,000 inhabitants
  - 100,000-200,000 inhabitants
  - 200,000-500,000 inhabitants
  - more than 500,000 inhabitants

- How many patients/visitors is your pharmacy supplying counseling per day?
  100-300

- How many staff work in your pharmacy:
  pharmacists 2-5; pharmacy technicians 0

- Is customer retention measured in your pharmacy? no

- If yes, how high is the proportion of regular (loyal) customers of all customers per year? no
  Please define, what a regular customer means for you?
  Patients regularly visiting the pharmacy
Proceedings of Expert Workshop “Indicators of the quality of Pharmaceutical Care: Development approaches & preliminary results”, Strasbourg, 10 December

Mr Zaza CHAPICHADZE
Expert survey & pharmacy survey in Georgia

II. QUALIFICATION OF STAFF

- Share of pharmacists completed university education in Pharmaceutical Care?
- Share of pharmacists completed continuous education in Pharmaceutical Care?
- How often your pharmacists complete the continuous education courses in Pharmaceutical Care?
- Who are the providers of the continuous education courses in Pharmaceutical Care for your pharmacists.

III. MEDICINES DISPENSING

1. Is professional assessment of prescription before medicines dispensing conducted in your pharmacy?
   - not done or occasionally performing professional assessment
2. When dispensing medicines, according to prescriptions, what kind of information and how often is offered in your pharmacy?
   - Medication name, description and/or purpose if considered necessary
   - Route, dosage, dosage form, and administration schedule if patient requests or if considered necessary.
   - Precautions to be observed if patient requests or if considered necessary
   - How to identify and to report adverse reactions to pharmacist/doctor, Techniques for self-monitoring, proper storage, Potential drug-drug, drug-food interactions. Prescription refill information, Action to be taken in the event of a missed dose - not offered

3. On average, how much time is spent per patient visit:
   - a. on dispensing ___0.00___%  
   - b. on counselling ___0.00___%

4. When counseling during medicines dispensing, is the medication regimen discussed taking into consideration patient’s lifestyle and quality of life?
   - Not or occasionally

5. Is written drug information regarding dispensed medicines provided for the patients in the pharmacy?
   - Patient Information leaflet (package leaflet) with every prescription
   - Dispensing label based upon patient profile if patient requests

6. Is medication review conducted in your pharmacy?
   - not performing MR (or not being able to do it) or occasionally performing MR when indicated by professional experience, knowledge

7. Is there a separate counseling room assigned for pharmaceutical care in your pharmacy?

8. Do you have computer (IT support?) in your pharmacy?
   - Yes, used for drug accountability and sell

9. Are patient medication records maintained in your pharmacy?
   - No

10. How many of adverse drug reactions are documented in your pharmacy during last three month? 0-5 ADRs

11. Is patient follow-up (by phone or in the pharmacy) after interventions or correction of ADR performed in your pharmacy?
   - never or occasionally performing a patient follow-up after a DRP related intervention

12. How many health-related interactions (calls, visits, etc.) with other health professionals do you have per month?
   - No communication with doctors or with other health professionals
IV. SELF CARE
1. Is the appropriateness of the OTC medicine for the concrete patient assessed before deciding whether or not to dispense the medicine?
   never, occasionally or always assessed before dispensing
2. Are the symptoms which require mandatory physician intervention detected before supplying OTC medication?
   never, occasionally or always assessed before dispensing
3. How many referrals to the physician have you made during last three months concerning OTC medicines in use? 0-5
4. Do you have a system for the documentation of those referrals? No
5. Is the advice on the treatment of symptoms and the appropriate use of OTC medicines provided when supplying medication?
   occasionally or always provide verbal advice
6. Is inappropriate use of OTC Medicines by the patient monitored?
   never or occasionally monitored

V. POINT OF CARE TESTING (HEALTH SCREENING)
1. What kind of services and how often do you offer?
   measurement of blood pressure several times a week, weight control (BMI), blood glucose, cholesterol, respiratory and other tests not performed
2. Above mentioned service is usually offered on patients' initiative, as a measurement without risk factors assessment
3. Are the results discussed in the context of the patient's overall health and lifestyle, desired quality of life, needs and expectations?
   occasionally discussed
4. Is the need of the referral to a physician explained to the patient, when necessary?
   occasionally explained
5. Is the patient provided with a report outlining the results and recommendations arising from the screening test?
   not provided

VI. EVALUATION OF SELF-ASSESSMENT
Total Score Level of Pharmaceutical Care Implementation
< 55 No implementation of Pharmaceutical Care

VII. RECOMMENDATIONS FOR IMPROVEMENT
A. No implementation of Pharmaceutical Care
   Major improvement needed in:
   Staff qualification and education, in special continuous education;
   Ensuring evidence-based informational support for staff;
   Implementation of standard operational procedures for:
   Medicines dispensing, Self-care, Health screening, patient counseling, dangerous symptoms detection in case of self-care, ADR detecting and documentation procedure.
Thanks you for attention
Development quality of pharmaceutical care indicators on the national and professional level (pharmacist’s self-assessment tool) in Republic of Moldova

Dr. Zinaida BEZVERHNI

---

**Pharmaceutical care concept**

Pharmaceutical services delivered to patients, e.g. medicines dispensing, blood pressure measurement, self-care, services, etc.

---

**Pharmaceutical care**

= Patient counseling + education

\[ \text{Interprofessional collaboration} \]

\[ \text{Patient involvement, desired quality of life, need and expectations} \]

\[ \text{Follow-up of medication decision (to stop, to go on, modify medication)} \]

\[ \text{Documentation of interaction (medication decision)} \]

---

**Pharmacists’ self-assessment tool**

- A questionnaire based on the above-mentioned concept of pharmaceutical care.

- 7 main compartments:
  1. Information about respondent
  2. Qualification of staff
  3. Medicines dispensing
  4. Self care
  5. Point of care testing (health screening)
  7. Recommendations for improvement

---

**Compartments “Medicines dispensing”, “Self care” and “Point of care testing (health screening)”**

- 5 subsections:
  1. Patient assessment
  2. Patient counseling and education
  3. Documentation
  4. Follow-up
  5. Interprofessional collaboration
Compartment
“Evaluation of self-assessment”

- a grid to assess the level of pharmaceutical care implementation according to the obtained total score.
- 4 levels:
  1. No implementation of pharmaceutical care (less than 52 points)
  2. Low level of implementation of Pharmaceutical care (53-72 points)
  3. Medium level of implementation of Pharmaceutical care (73-88 points)
  4. High level of implementation of Pharmaceutical care (89-105 points)

In Republic of Moldova
- 40 recipients
- a deadline for reply on 22 October 2010.
- 35 replies received by 29 October 2010.
- The survey data were tabulated using MS Office software.

Respondents’ information
- 21 (60%) are pharmacies situated in urban areas (more than 150,000 inhabitants)
- 14 (40%) rural area pharmacies.
- The average number of visitors per day is varying from 50 to 500, mean value is about 200.
- Number of pharmacists and pharmacy assistants working into a pharmacy is varying from 1 to 7; average number is 3 pharmacists per pharmacy.
- More than half of pharmacies (N=22) are measuring customer retention, share of loyal customers varying from 10% to 50%.

Qualification of staff
- 50% of pharmacists have university education concerning pharmaceutical care
- 50% of pharmacists have completed continuous education programmes, which they attending once in 5 years or less.
- The only provider of continuous education in pharmaceutical care is Pharmacy Faculty of State Medical and Pharmaceutical University.
Information offered during medicines dispensing

- 40% of time is spent on dispensing and 60% on counseling per patient visit.
- Only one pharmacist reported that medication regimen is not discussed taking into consideration patient’s lifestyle and desired quality of life, need and expectations, others reported doing this occasionally (12) or permanently (22).
- 50% (26) pharmacists provide information leaflet (package leaflet) with every prescription.
- 43% of pharmacists never provide dispensing label based upon patient profile.
- 77% (27) of pharmacists are never performing medication review or are doing this occasionally.
- 42% (16) pharmacists report that there is a separate counseling room in their pharmacy.

Patient counseling and education during medicines dispensing

Documentation, follow-up and interprofessional collaboration

- All pharmacies have a computer, which is used for logistics and stock control.
- No pharmacist reported about using computer for patient medication records.
- 11 pharmacists have patient medication records for 10-20% of their customers.
- Reporting of ADR is mandatory for pharmacists in Republic of Moldova. There are 3 ADR reported by 35 pharmacies during last 3 months.
- 65% (30) of respondents never or occasionally perform patient follow-up after interventions.
- 26 from 35 pharmacies have no health-related interactions with other health professionals.

Self-care

- 83% (29) of respondents consider that appropriateness of the OTC medicine for the concrete patient is always assessed before dispensing.
- 20 from 35 pharmacies always detect the symptoms which require mandatory physician intervention before supplying OTC medication.
- But only 7 from 20 pharmacies had at least one referral to the physician during last 3 month and only 2 occasionally document these referrals.
- 80% (28) of pharmacists reported that always provide verbal and occasionally (21) or always (7) written advice, when supplying OTC medication.
- 42% (15) pharmacies never monitor use of OTC medicines by the patients and others do this occasionally.
Dr. Zinaida Bezverghi
Development quality of pharmaceutical care indicators on the national and professional level (pharmacist's self-assessment tool) in Republic of Moldova
Conclusions

- Both surveys suggest a low level of awareness of pharmaceutical care concept and no implementation in community pharmacies’ practice in the Republic of Moldova. The major challenges are: lack of education in the field of pharmaceutical care, lack of medicines information sources, lack of legal basis and lack of interprofessional collaboration.

- Despite some limitations, the pharmacists’ self-assessment tool has shown a good application to have an overview on pharmaceutical care implementation in community pharmacies’ practice. After some revision, it can be used for evaluation of pharmaceutical care implementation in the Republic of Moldova.

Pharmacists’ opinion about pharmaceutical care implementation

- to improve professional education in the field of pharmaceutical care;
- to ensure the access to evidence-based medicines information sources;
- to improve collaboration between health care professionals;
- to have necessary software for documentation etc.

Recommendations

- to raise the awareness regarding pharmaceutical care between decision-makers and pharmacies, as well as other health care professionals in the Republic of Moldova;
- to develop relevant university and postgraduate curricula in the field of pharmaceutical care;
- to prepare specialists in the field of pharmaceutical care (train-the-trainers approach);
- to develop and to disseminate methodical literature concerning pharmaceutical care implementation among practicing pharmacists.

regarding self-assessment tool

- to revise the pharmacists’ self-assessment tool, in special compartments dealing with qualification of staff and patient counseling and education. It is considered more relevant measurement of communication parameters via external observation;
- to reconsider the scores offered for each compartment;
- to revise the recommendations for improvement, having regard to the development of pharmacy practice in the concrete country.
Dr. Zinaida Bezverkhna
Development quality of pharmaceutical care indicators on the national and professional level (pharmacist's self-assessment tool) in Republic of Moldova

Thank you for attention!
Expert survey & pharmacy survey in Ukraine

Ms Olga GRINTSOVA

PHARMACEUTICAL CARE QUALITY INDICATORS DEVELOPMENT
TG 4 Regions of Europe with specific needs

PILOT STUDY RESULTS UKRAINE

Ms Olga Grinetska
Department of clinical pharmacology with pharmaceutical care
National University of Pharmacy
Kharkiv

Aim
- To study the current awareness of the concept of pharmaceutical care (Helper&Strand definition) and to determine the preconditions for pharmaceutical care implementation in Ukraine (expert survey):
  - understanding and legal regulation;
  - undergraduate and postgraduate education;
  - independent information sources concerning the rational medicines use for patients; healthcare professionals;
  - pharmaceutical care periodic editions for healthcare professionals;
  - rational medicines use information campaignes for patients;
- To pilot the pharmacy self-assessment tool for their progress in pharmaceutical care (pharmacy survey)

EXPERT SURVEY
10 experts, representing:
- Ministry of Health of Ukraine
- Expert Committee of the Ministry of Health of Ukraine
- Pharmacist Professional Board (Pharmacists's Association of Ukraine)
- Universities
  National University of Pharmacy
  National Medical University Lviv
  State Medical University Donetsk
- Institute for professional development of pharmacist

Concept of Pharmaceutical Care
- is known (5/10) and is known partly (5/10)
- other terms, used to define the concept are mostly the variations of Helper & Strand definition
- definition in Pharmaceutical Encyclopedia
- strong focus on the CTC-medicines supply

GPP national standards
- do not exist (4/10)
- partly (6/10), reference to the 32 protocols (SOP) for the CTC-medicines supply (adopted by the Ministry of Health in 2010)

development of national GPP standards is one of the aspects of further development of pharmacy practice (Concept of Pharmacy Branch Development 2011-2020)
Pharmaceutical care curricula

Undergraduate education (10/10 experts):
- mandatory since 2000
- include OTC-medicines dispensing by different symptoms and rational choice of OTC-drugs for different groups of patients/customers (newborn, pregnant, elderly, smokers, diabetes patients)
- Pharmacy students — 120 training hours, part of clinical pharmacy course
- Clinical pharmacy students — 240 training hours, Rx dispensing as part of clinical pharmacology course

2/10 experts - pharmaceutical care education in Ukraine is sufficient for pharmacists.
8/10 experts - there are improvements needed in the university and continuous education curricula:
- to increase the training hours of medical subjects, clinical pharmacy for pharmacy students;
- to involve the principles of GPP as part of education of pharmacists;
- to develop SOP for Rx drug dispensing and include them into the undergraduate curricula;
- to include information concerning the safe prescription drug use;
- to increase of study hours on the postgraduate level;
- to include the principles of pharmaceutical care assessment in the pharmacies.

Ms Olga GRINTSOVA
Expert survey & pharmacy survey in Ukraine

Pharmaceutical care curricula

Postgraduate (continuous education) (10/10 experts):
- mandatory to be completed every 5 years
- is provided only by State Medical Universities (2) and Institute for professional development (1)
- 48 training hours
- basic elements:
  - OTC-medicines supply
  - Rational OTC-medicines choice for different groups of patients: newborn, pregnant, elderly

* no available statistics of number of pharmacists (7/10 experts)
** ca. 10 000 pharmacists complete continuous education per year
*** ca. 10 000 pharmacists complete pharmacy faculties (3/10 experts)

Public / independent medicines information sources in national language

For customers/patients:
- there are public and independent information sources in national language for customers/patients (8/10 experts). As examples were provided:
  - manual for OTC-drug use (7/9 experts);

For doctors and pharmacists:
- there are public and independent information sources in national language for doctors and pharmacists (10/10 experts):
  - national register of medicines (10/10 experts);
  - State reference book - Formulary of Ukraine (10/10 experts);
  - clinical protocols (2/10 experts),
All of them are available in on-line format.
Proceedings of Expert Workshop “Indicators of the quality of Pharmaceutical Care: Development approaches & preliminary results”, Strasbourg, 10 December

Ms Olga GRINTSOVA
Expert survey & pharmacy survey in Ukraine

Professional periodical publications concerning pharmaceutical care

10/10 experts referred to following sources:

- All-Ukrainian scientific journal "Clinical Pharmacy" (Kharkiv);
- Journal "Pharmaceutical practice" ( Kiev, ukrpharm.com.ua);
- Journal "Pharmacy" (Kiev, www.prozor.com.ua);
- Other information sources (journals and magazines):
  - Health (www.ought.com.ua);
  - Pharmaceutical Bulletin (www.bulap.org.ua);
  - National pharmaceutical (www.npharm.com.ua);
  - Ukrainian medical journal (www.ukrmed.com.ua);
  - Your health (www.ukr.gov.ua);

There were no public information campaigns concerning the rational drug use conducted in Ukraine (10/10 experts)

Customer retention was measured in 30% (6/20) pharmacies.

As a regular customer respondents identified a person:

- who is satisfied with the care provided 15% (1/6).

Qualification of staff

<table>
<thead>
<tr>
<th>Share of pharmacists, completing education in pharmaceutical care</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-10%</td>
</tr>
<tr>
<td>University education</td>
</tr>
<tr>
<td>Continuous education</td>
</tr>
</tbody>
</table>

PHARMACEUTICAL CARE SELF-ASSESSMENT TOOL PILOT STUDY PHARMACY SURVEY

- There are 12,787 big pharmacies, 5,159 medium-size pharmacies and 4,047 pharmacy clinics in Ukraine.
- 373 pharmacies in Ukraine are licensed for the manufacturing of medicines.
- 45% of all pharmacies are situated in cities and towns (population 100,000 inhabitants and more)

Pilot study in Ukraine:

- 20 pharmacies (10 community pharmacies and 2 hospital pharmacies) from 5 regions
- Response rate 100% (5/5).
- 11/20 pharmacies from cities with >1,000,000 inhabitants
- 373 ± 247 average number of patients/customers per day (from 50 to 650)
- 3 ± 2 pharmacists (from 2 to 8 in one pharmacy)
- 3 ± 3 pharmacy technicians (from 0 to 6)

Olga Grinsova, 10/12/2010 EOM, Council of Europe, All rights reserved

MEDECINES DISPENCING

- professional assessment is always (65%) and occasionally performed (40%) in pharmacies

Olga Grinsova, 10/12/2010 EOM, Council of Europe, All rights reserved
MEDICINES DISPENCING

Time distribution:
40% 17 for dispensing
60% 17 for counseling

Medication regimen adjustment
15% not adjusted
70% occasionally adjusted
15% always adjusted

Written drug information

Patient information provided:
5% in writing
30% verbally
55% both

Customer rate:
5% satisfaction
30% neutral
65% dissatisfaction

SELF CARE

Appropriateness of the OTC-medication:
always (40%) or occasionally (55%) assessed

Symptoms (mandatory physician intervention):
always (35%) or occasionally (55%) detected

Referrals to doctor: 50% do it; average 1% of daily customers

85% pharmacies do not document the referrals

Patient counseling: 40% always provide verbal and 45% provide verbal and written advice. Inappropriate use of OTC-drugs is never (75%) or occasionally (25%) monitored

Point of care testing (health screening)

Basic diagnostic services are:
- measurement of blood pressure (offered with different frequency in 80% of pharmacies)
- weight control/BMI (offered with different frequency in 35% of pharmacies)

Only 15% testings are offered on pharmacist's initiative

Result discussed always (45%) or occasionally (35%)

Need of the referral explained always (75%)

Report not provided (75%) or occasionally provided (25%)

No documentation (100%) and no follow-up (20%)
TOTAL SCORE

Average score of Ukrainian pharmacies
44 ± 8
Minimal score 29
Maximal score 57
Only 3 pharmacy have got more 52 points — low level of pharmaceutical care implementation

CONCLUSION:
- Quality of pharmaceutical care indicators are needed in Ukraine;
- The pharmaceutical care self-assessment tool piloted in this study is a feasible tool for evaluation of the implementation level of pharmaceutical care;
- The national survey using this tool will help to evaluate the implementation level of pharmaceutical care in Ukraine and help to define the directions for further improvement;
- Pharmaceutical care self-assessment tool after some modifications can be used both for quality assessment on the national level and on the level of pharmacies;
- There are also needed the pharmaceutical care quality indicators for the hospital pharmacies, that can be developed on the basis of the self-assessment tool, piloted in this study.

RECOMMENDATIONS

Pharmacy practice regulation
- Staff qualification and education, in particular continuous education;
- Ensuring evidence-based informational support for staff;
- Implementation of standard operational procedures for: medicines dispensing; health screening; Rx medicines patient counseling

National level
- Action plan for the national GPh standards development for pharmacy practice;
- Adoption of the Pharmaceutical care concept by the Ministry of Health of Ukraine;
- Promotion of the Pharmaceutical care concept between all involved stakeholders.

RECOMMENDATIONS

Education
- Basic and continuous education curricula should be improved in the field of patient-oriented care;
- Adoption of the EDCM guidelines "Creating better medication culture in Europe" into the educational curricula;
- The pharmaceutical care quality indicators must be included into the university and continuous education curricula for pharmacist.

Patient involvement
- Public information campaigns for promotion of the rational drug use;
- More independent information sources concerning the rational drug use for patients.
1.7 METHODOLOGY

Speakers:

Dr Martin HENMAN
School of Pharmacy, Trinity College Dublin, Ireland

Ms Gudrun BUSCH
Federal Office of Public Health, Switzerland
Dr Martin HENMAN

Development of quality of pharmaceutical care indicators: decision tool for policy-makers and professional associations

Flow Chart of Indicator Development User Grid

Indicators Development Log Book

INDICATOR DEVELOPMENT FORM

Part 1: IDENTIFICATION OF AN INDICATOR

1. What is the specific name of this indicator?

2. What structure, process, or outcome does this indicator measure or represent?

3. What is the rationale for this indicator? Why has this indicator been selected? What is the purpose of the indicator? Are there external/internal stakeholders who have influenced the selection?

4. List the organizational unit(s), department(s)/function(s), or teams to which the indicator applies (Emergency, CCG Teams, Department Name, System-Wide, Healthcare Providers, etc.)

5. Indicate how this indicator will satisfy the core strategic objectives: Medication safety, Quality of pharmaceutical care/guidelines, Professional excellence or leadership, Multidisciplinarity, professional co-operation.
Proceedings of Expert Workshop “Indicators of the quality of Pharmaceutical Care: Development approaches & preliminary results”, Strasbourg, 10 December

Dr Martin HENMAN
Development of quality of pharmaceutical care indicators: decision tool for policy-makers and professional associations

Workshop with International Collaborators & Structured Discussions
- Structural Indicators of Pharmacists & Pharmacies & of Medicines Supply
- Pharmacy Process Indicators not widely accepted outside pharmacy except Patient Safety Indicators
- Pharmacist's activities do not fit well into standard methods
- Pharmacist-patient interactions are affected by many other - confounding - factors
- It is difficult to measure outcomes of professional-professional interaction
- Pharmacists considered indicators as research tools rather than practice tools

Structure
- Structure indicators address system design, organisational characteristics, systems functioning and the adequacy of resources.
- Supply of meds usually measured as a part of structure (prescriptions dispensed/items provided/cost per item)
- But, we know that supply & reimbursement policies affect patient's use of medicines
- We know that both short-term & long-term compliance/adherence with prescribed medicines is not a consistent proportion of prescribing

Process indicators
- Describe the interaction between the pharmacist & another stakeholder, usually the recipient of care, the patient, or between the pharmacist & the prescriber or the health authority when these interactions are relevant to issues of health service delivery
- They include how accessible care is to patients
  - What proportion of prescriptions written are dispensed
  - But also how care is provided - such as a standardised brief intervention for smoking cessation
  - and what is provided - such as a medication use review (MUR) or a pharmaceutical care plan

Outcome indicators
- Assess the effects on the patient's health, health status and quality of life of the care delivered
- Final outcomes such as death & disability may be the result of multiple factors
- High HbA1c levels in patients with diabetes mellitus. Is an intermediate outcome but these are only valid if evidence links them to a Final Outcome
- Pharmaceutical Care as defined by Hepler and Strand & as applied in the EDOQM Project, explicitly states that the pharmacist provides medicines in order to achieve ‘definite outcomes that improve a patient’s quality of life’
**Prescription Medicines Supply**

- Research in many countries shows that there are frequently legal, administrative & pharmaceutical form issues with prescriptions
- Pharmacists frequently address & resolve these issues
- But there is evidence of drug-related admissions to hospital & of drug-related problems
- We collect information about costs & payment of medicines not patient care
- We measure the processes but not how well they are done
- Ofen we cannot ‘follow’ the patient to the outcome

**Next Steps**

- **Short-term**
  - Complete piloting of Indicator Development User Grid Flowchart & validation
  - Complete refinement of Indicator Development Log Book
- **Intermediate to Long term**
  - Validate methodologies for development Indicators of Quality of Pharmaceutical Care
  - Dissemination of methodologies, research basis, & potential use among stakeholders as per EDCM
  - Develop & validate the theoretical & methodological basis of Indicators of Pharmaceutical Care

---

**Conclusion**

- In order to take account of the unique aspects of pharm pract some development of the theoretical basis for the indicators is needed, specific methods for their development and deployment may be needed, and a dissemination and education process within pharmacy and with the other stakeholders will be required
Ms Gudrun BUSCH

Standard Operating Procedure (SOP): testing of quality of pharmaceutical care indicators

Monitoring indicator projects in Europe

within the scope of the overall project "Quality of Care - Indicators" initiated by the Committee of Experts on quality and safety standards in pharmaceutical practice and pharmaceutical care (CD-P-PH/PC)

Gudrun Busch
Travel facilitator "EVALUATION OF THE QUALITY OF PHARMACEUTICAL CARE - DEVELOPED APPROACHES & PRELIMINARY RESULTS"

©2010 EDQM, Council of Europe. All rights reserved

Overall goal

- Improving the patient’s quality of life by measuring outcome of pharmaceutical care through indicators

Monitoring Process - Roles

- Submission electronically via the e-Platform of the "Quality of care - indicator project"

- Roles of Actors:
  Administrative Office EDQM, national Project leader, Expert group, Working party, Working party PL, CD-P-PH/PC, CD-P-PH, GR-SOC ...
Monitoring – Eligibility Check

- further Criteria to be respected:
  - Ethic issues
  - Intellectual property (IPR)
  - Language
  - Timetable
  - Resources
  - Documentation and templates

How to monitor indicator projects in Europe focusing on the overall goal: Improving the patient’s quality of life?
Session theme: Conclusions - The Way Forward
Session Chair:
Mr Nico KIJLSTRA

Panellists:
All Speakers
In their conclusions, the participants of the expert workshop ‘Indicators of the Quality of Pharmaceutical Care: Development Approaches & Preliminary Results”, held in Strasbourg on 10 December 2010, used the definition of pharmaceutical care from Hepler and Strand\(^3\), and also as referred to in the working mandate of the body overseeing this programme of activities, the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH).

The workshop participants called on the Member States of the Council of Europe to support awareness of the pharmaceutical care model by appropriate legal provisions, practical guidance, training and education for health professionals including pharmacists, doctors, pharmaceutical technicians, and nurses.

The workshop participants called on the Member States of the Council of Europe and the European Directorate for the Quality of Medicines & HealthCare (EDQM) to continue and strengthen their support for improvements in the quality of pharmaceutical care in Europe through the development, validation and wide-spread use of indicators.

Below, we set out the conclusions of the workshop participants on the establishment and progress of the indicator development and piloting projects presented by the speakers on individual areas.

The workshop participants commended the speakers on the quality of their project approaches and the reports presented at the event.

1) **Area: “Methodology”**

The development, piloting and implementation of indicators should be based on the utilisation of scientifically proven methods and approaches, validated in practice and with a clear conceptualisation of all the steps involved.

The theoretical basis of the pharmaceutical care indicators needs to be further developed in order to take account of the unique aspect of pharmaceutical practice.

Specific methods for the development and deployment of pharmaceutical care indicators are needed, and a dissemination and education process within all stakeholders of pharmaceutical care will be required.

The workshop participants:

- endorsed the concept of the **indicator development user grid**, as presented, as an essential quality assurance tool for the development of all indicators in the framework of the Committee of Experts CD-P-PH/PC\(^4\) co-ordinated project, supported by the EDQM. This will ensure that harmonised approaches are used for the development of indicators which are public health focused;
- before wide-spread use, they recommended to pilot the indicator development user grid and to publish it together with instructions for use on a EDQM-restricted web portal dedicated to pharmaceutical care activity;
- in this context, and for on-going quality assurance, they recommended applying the indicator development user grid to the pharmaceutical care indicators presented, or that it is developed within the framework of this project and that it is included in an updated version of the project documentation maintained by the EDQM;
- they appreciated the options presented for standardised and pragmatic procedures to **pilot** all indicators developed in the framework of this project, which will ensure that the data obtained are comparable;

---

\(^3\) “Pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve or maintain a patient’s quality of life”. In: Hepler CD, Strand L. Opportunities and responsibilities in pharmaceutical care. Am J Hosp Pharm. 1990; 47:533-43.

they considered as essential the consolidation of both the development and piloting procedures into one procedure.

2) **Area: ‘Understanding the pharmaceutical care concept and applying it in practice’**

The workshop participants recognised that the implementation of the pharmaceutical care model in practice has not yet been fully accomplished. Self-assessment by individual professionals of their knowledge and use of the pharmaceutical care model is an important step towards increasing awareness and closing information gaps. The workshop participants endorsed the concept of a pharmaceutical care self-assessment tool, as introduced by the speaker on this topic, and as developed further by the speaker on the topic of “Special needs of special regions”.

There was consensus that self-assessment needs to focus on the comprehensive model of pharmaceutical care, instead of pharmaceutical services or supply logistics.

Considering the multi-stakeholdership of pharmaceutical care, it was recommended that an adapted assessment tool be also piloted among other health professionals e.g. doctors and nurses.

The workshop participants encouraged those countries that had expressed their interest in the implementation and regular, periodic, re-use and re-evaluation of self-assessment to participate in a specific pilot study. In particular, they recommended further development of the recommendations of the self-assessment tool in terms of the different levels of scores obtained (e.g. providing selected literature references for the different score levels, and/or links to e-learning training modules to be developed). This will effectively facilitate the understanding and application of the pharmaceutical care model by health professionals involved in pharmaceutical care.

3) **Area: “Pharmaceutical care - the key role of patient participation”**

As highlighted by the pharmaceutical care model, which puts patient participation, involvement in treatment decisions and pharmacotherapy at its’ center, the workshop participants considered the identification of patients’ knowledge, expectations and concerns as a pre-requisite for the best possible medication outcome.

As opposed to traditional ‘top-down’ counselling by health professionals, the workshop participants supported the development and refinement of specific tools that actively engage the patient in a chosen therapy from its outset. Therefore, the application of the pharmaceutical care model can help to translate patient needs and expectations in a problem-solving format and to optimise care.

The participants also endorsed regular reviews of clinical medication for high-risk patients.

In support of the above, the workshop participants recommended to the EDQM to support the provision of guidance on best practices for reviews of clinical medication and educational material.

4) **Area: “Promotion of medication safety through data linkage & monitoring”**

Pharmaceutical care, particularly the area of multi-sectorial, e-supported communication between healthcare professionals, helps avoid adverse drug events caused by a lack of information about the right drug for the right patient at the right time. Electronic data linkage and health information exchange are valuable tools for implementing the pharmaceutical care model and to assist in closing information gaps occurring at the prescription, transcription, distribution and use of medication.

Representative and comprehensive data collection should be based on automatic data acquisition.
Quality indicators in the field of pharmaceutical care all face common challenges: how to get the information in a sustainable, affordable and reliable way? The only response is that these data, usually collected during daily clinical activities, are computerised. Thus, in order to avoid transformation of a huge amount of data that are unusable, the computerisation of this data should be standardised through a regulatory framework that specifies technical, semantical, legal and privacy aspects, thereby building a framework for co-operation in the area of e-supported data linkage and health information exchange across Europe.

The workshop participants supported the development and validation of indicators of effective, e-supported data linkage and health information exchange.

5) **Area: “Communication and inter-disciplinary co-operation”**

The workshop participants:

- encouraged feedback from the national stakeholders in pharmaceutical care on the proposed field methodology and, in particular, on the templates for the survey questionnaires “Communication and inter-disciplinary co-operation” to be directed to the speaker (A. Cavaco);

- endorsed the revision of the indicator development and piloting concept to include not only processes, but also structural indicators (e.g. average time dispensing);

- called for greater participation of countries in piloting the revised study protocol.

The workshop participants appreciated that EuropharmForum and Pharmakon would co-operate in this indicator project.

6) **Area: “Special needs of regions as regards pharmaceutical care in Southern and East Europe”**

The workshop participants endorsed the self-assessment form that has been adapted to the special needs of regions as an effective tool for the initial contribution of pharmacists to the promotion and implementation of pharmaceutical care throughout Europe and not just limited to Southern and East Europe.

The self-assessment tool needs to be augmented by available sources for information and education, such as selected literature, model training and curricula.

The workshop participants recognised that the adapted self-assessment tool had been well-accepted in the five pilot countries, and had proven valid and effective for a situation analysis and for the development of further approaches.

The workshop participants concluded that the wide implementation of the self-assessment tool among all concerned health professionals in Europe was needed in order to sustain efforts to improve the quality of pharmaceutical care in Europe.

7) **Area: “Adherence to treatment guidelines”**

Pharmaceutical care is an effective instrument for ensuring adherence to clinical practice guidelines that are aimed at improving the rational use of medicines, patient safety, efficiency and the responsible management of healthcare costs. Their implementation requires the inter-disciplinary co-operation of all healthcare professionals.
The participants endorsed, in principle, a study concept that would provide an indicator for measuring the value of inter-disciplinary interaction among prescribers and pharmacists, with a view to ensuring adherence to clinical treatment guidelines, for example, with regard to the prescription of antibiotics.

As observed in practice, the interaction of pharmacists with prescribers on pharmaceutical care issues will enhance compliance with treatment guidelines, resulting in improved medication outcomes.
APPENDIX 1: LIST OF SPEAKERS/ POSTER PRESENTERS

Ms Zinaida BEZVERHNI  
State Medical and Pharmaceutical University  
"Nicolae Testemitanu"  
Str. Testelitanu 22  
MD2025 Chisinau  
Moldova

PD Dr Michael HARTMANN  
University Hospital Jena, Pharmacy  
Erlanger Allee 101  
07743 Jena  
Germany

Ms Gudrun BUSCH  
Federal Office of Public Health  
Seilerstrasse 8  
3013 Bern  
Switzerland

Dr Martin HENMAN  
Trinity College Dublin - Center for the practice of Pharmacy  
Trinity College Dublin  
Dublin 2  
Ireland

Assistant Professor Dr Alfonso CAVACO  
FFUL - Faculty of Pharmacy, University of Lisbon  
Av. Prof Gama Pinto  
1649-003 Lisbonne  
Portugal

Dr Susanne KEITEL  
Director  
European Directorate for the Quality of Medicines and HealthCare (EDQM)  
7 Allée Kastner  
67100 Strasbourg  
France

Dr Zaza CHAPICHADZE  
State Regulation Agency for Medical Activities, Ministry of Health of Georgia  
144 Ak Tseretelli Ave, 0119 Tblisi  
Georgia

Mr Nico KIJLSTRA  
Dutch Health Care Inspectorate  
P.O. Box 392  
8000 AJ Zwolle  
The Netherlands

Mr Alan CLEE  
Strathclyde University  
51aHareleeshill Road  
ML92RB Larkhall  
Scotland

Professor Christian LOVIS  
University Hospitals of Geneva  
4 Gabrielle Peret Genil  
1211 Geneva  
Suisse

Dr Paula FERREIRA  
FFUL - Faculty of Pharmacy, University of Lisbon  
Av. Prof Gama Pinto  
1649-003 Lisbon  
Portugal

Ms Pharm/ FPH Carla MEYER MASSETTI  
Swiss Patient Safety Foundation  
Asyl Strasse 77  
CH – 8032 Zurich  
Switzerland

MSc (Pharm D) Marlies GEURTS  
Groningen Research Institute of Pharmacy  
Antonius Deusinglaan 1  
9713 Groningen  
The Netherlands

Ms Iryna MUKOMEL  
National University of Pharmacy  
Heroev Truda St, 47 apt.  
61129 Kharkov  
Ukraine
ORGANISING COMMITTEE

Project coordinators: Mr Nico KIJLSTRA, Dutch Health Care Inspectorate (Vice-Chairman Committee CD-P-PH), Dr Keith RIDGE (Committee CD-P-PH delegation, United Kingdom).

Mr Zaza CHAPICHADEZE (Committee CD-P-PH/PC, Georgian delegation), Ms Eva HOFBAUER (Committee CD-P-PH; Austrian delegation), Ms Caroline HOGG (Committee of Experts CD-P-PH/PC; Irish delegation), Dr Christian KALCHER (Vice-Chair Committee of Experts CD-P-PH/PC, Austria), Ms Marita KINSELLA (Committee CD-P-PH; Irish delegation) Ms Carla MEYER-MASETI (Committee CD-P-PH/PO; Swiss delegation).

Secretariat / Organising team

Responsible for the organisation of the Expert workshop:

Ms Sabine WALSER, Administrative Officer, Biological Standardisation, OMCL Network & HealthCare Department (DBO), European Directorate for the Quality of Medicines & HealthCare (EDQM)

Tel.: + 33 3 (0) 90 21 42 25; E-mail: sabine.walser@edqm.eu

Ms Yema ONWUZURUMBA, Assistant and CONTACT, Biological Standardisation, OMCL Network & HealthCare Department (DBO), European Directorate for the Quality of Medicines & HealthCare (EDQM)

Tel.: + 33 3 (0) 90 21 54 36; E-mail: yema.onwuzurumba@edqm.eu
APPENDIX 2: SPEAKERS' CURRICULA VITAE

Dr Zinaida Bezverhni
Dr Zinaida Bezverhni is an assistant at Social Pharmacy department, State Medical and Pharmaceutical University “Nicolaе Testemitanu”, Chisinau, Moldova. She graduated from the mentioned university in 2002 and joined the social pharmacy department in same year. She completed her PhD research in 2010. She is actively involved in the developing of national Good Pharmacy Practice standards and education programs for pharmacist and pharmacy students in this area. She is a Member of the Executive committee of Association of Pharmacists from Republic of Moldova since 2007. Since 2005 she is the secretary in charge of the Pharmaceutical Journal of Moldova. Since November 2009 she is actively involved in EDQM research project regarding pharmaceutical care in Europe. She is the author of 15 scientific papers in international and national scientific journals and conference proceedings.

Ms Gudrun Busch, Pharmacist
Gudrun Busch is Deputy Head of Therapeutic Products Law Section at the Federal Office of Public Health FOPH since 2006. Before she joined the Regulatory Authority in Switzerland for pharmaceutical products, Swissmedic,

She worked in Regulatory Affairs for Biotechnology from 2004-2006. She has been involved in the organisational development of the restructuring process, too. In addition she analysed the Vigilance activities, import controlling and wrote reports on complementary medicines being subjects to criminal procedures. Prior to that she worked in business management of pharmacies and wholesale trade for four years.

Assistant Professor Dr Afonso Miguel Cavaco
Born in March 1966 and has one son. He graduated from the University of Lisbon (Portugal) as a pharmacist in 1990, obtained an MSc in Community Pharmacy from the same University and a PhD in Pharmacy Practice and Policy from the University of London (UK) in 2006, under the supervision of Prof Ian Bates. In the last trimester of 2007, he was a post-doctoral Fulbright fellow at Johns Hopkins Bloomberg School of Public Health (USA), working with Prof Debra Roter. Afonso holds a position as Assistant Professor at the Faculty of Pharmacy, University of Lisbon. He is responsible for the undergraduate teaching unit Pharmacy Lab, as well as pharmacy students’ internship. He is also involved in post-graduate courses on communication skills for pharmacists and pharmacy management. His main research interest at the moment is patient-provider interaction/communication studies, using the Roter Interaction Analysis System (RIAS method), in particular for medical and pharmaceutical consultations.

Dr Zaza Chapichadze, MD, PhD
Dr Zaza Chapichadze is Deputy Head of Pharmaceutical Department of State Regulation Agency for Medical Activities of Ministry of Labour, Health and Social Affairs of Georgia. He holds a PhD (1986) in pharmacology from the Tbilisi State Medical University (PhD confirmed by UK NARIC in 2010). He was trained in pharmacotherapy in Saarbrücken, Germany, in 1995 and at the Radcliff Infirmary, St. John’s College, Oxford, UK. He has served on the Working Group of Pharmacotherapy of the Georgian Association of Cardiology and Scientific Secretary of Georgian Society of Pharmacology. He is a member of European Society of Cardiology. He has been extensively involved in the development of clinical research programmes across Georgia as National Coordinator and Scientific Consultant. He is Editor-in-Chief of several pharmacological text and reference books: “Georgian Pharmacological Formulary”, “Pharmacological Reference book”, “International Clinical Trials- A Guidebook and Compendium of National Drug Laws”, Interpharm Press, USA, etc. He is an author of more than 50 scientific papers published also in European Journal of Heart Failure, European Respiratory Journal, European Heart Journal, New England Journal of Medicine, International Journal of Clinical Pharmacology and Therapeutics.

Ms Marlies Geurts, MSc. PharmD
Marlies Geurts studied pharmacy at the University of Groningen, the Netherlands. In 2007 she finished her master and retrieved her PharmD-degree. In 2007 she started her PhD, her PhD-project is entitled “Integrated Pharmaceutical Care” where she focuses on the cooperation between pharmacists, general practitioners and,
and patients. Secondly she studies the implementation of a web-based pharmaceutical care plan in the Netherlands.

Ms Olga Grintsova, MPharm
Ms Olga Grintsova is an assistant (lecturer) in the department of clinical pharmacology with pharmaceutical care at the National University of Pharmacy, Kharkiv, Ukraine. She holds a Master degree (2007) in clinical pharmacy and Specialist degree in clinical pharmacy (2006) from the National University of Pharmacy. From 2007 till 2010 she did her PhD studies at the National University of Pharmacy and in January 2011 is planned the PhD Thesis defense. She is a Member of the Pharmacist's Board of Ukraine. She was actively involved in development of curricula and research programs in pharmaceutical care and social pharmacy in Ukraine. She is author of scientific papers in pharmacology, clinical pharmacy, and international conference proceedings in social pharmacy.

Dr Martin Henman, BPharm, MA, PhD, PG Cert (Health Econ), MPSI
Dr Martin Henman is a Lecturer in Pharmacology and Co-ordinator of the Centre for the Practice of Pharmacy in Trinity College Dublin. After completing his Pharmacy degree in the UK, Dr Henman practised as a hospital pharmacist before undertaking a PhD in Pharmacology. He then started in University practice where he has remained ever since, and, following his move to Trinity College, he became Co-ordinator of the Centre for the Practice of Pharmacy in 1997. In 2006, Dr Henman was presented with one of the Provost's Teaching Awards in recognition of the excellence of his contribution to teaching and learning in Trinity College. He is a Member of the Pharmaceutical Society of Ireland. His main research interest is Pharmaceutical Care and Dr Henman is a founder member of a research grouping, Pharmaceutical Care Network Europe. In September 2003 he became its Chairman. Dr Henman was a member of the Pharmaceutical Care Task Force of the European Association of Faculties of Pharmacy that proposed the introduction Pharmaceutical Care in the undergraduate syllabus. Dr Henman is Medical Editor of 'The Irish OTC Directory', the Primary Care Guide to Non-Prescription Medicines, and of the website, ‘yourmedicines.ie’.

Dr Susanne Keitel, Director, EDQM
Dr Susanne Keitel is a licensed pharmacist with a Ph.D. in pharmaceutical technology. Her work experience includes 10 years in pharmaceutical development in industry, with five years as Department Head of “Pharmaceutical Development/ORal Dosage Forms” at the former Schering AG, Berlin. From 1997 to 2005, she held the position of Division Head Pharmaceutical Quality at the Federal Institute for Drugs and Medical Devices (BfArM), Germany. She additionally served as Acting Head of the Division European Procedures from November 2003.

From July 2005 to October 2007, Susanne Keitel was Head of EU, International Affairs at BfArM. During her time with BfArM, she represented the agency in a number of EU committees, including the Joint CHMP/CVMP Quality Working Party (QWP), the EMEA Paediatric Working Party and the European Commission’s Notice to Applicants Group. She was actively involved in the International Conference on Harmonization (ICH), where she acted as the EU topic leader and rapporteur for the ICH guidelines on stability testing and pharmaceutical development. On a national level, she was, from 2001 to 2007, Chair of the German Pharmacopoeia and the German Homeopathic Pharmacopoeia. Since October 2007, Susanne Keitel is Director of the European Directorate for the Quality of Medicines & HealthCare (EDQM) of the Council of Europe in Strasbourg.

She also lectures in the postgraduate course “Master of Drug Regulatory Affairs“ at Bonn University, where she is responsible for the module on the quality dossier. In 2009, Dr. Keitel was elected as corresponding Foreign Member at the French Académie Nationale de Pharmacie.

Mr Nico Kijlstra, Health Care Inspectorate, Ministry of Health, Welfare and Sport, the Netherlands
Pharm.D., senior inspector, Health Care Inspectorate, scientific project leader
He (1962) studied pharmacy and public administration. He has working experience in public and hospital pharmacy and was part-time assessor of applications for marketing authorisations for the Medicines Evaluation Board. In 1996 he joined the Health Care Inspectorate, the public service responsible for supervision and enforcement of healthcare in the Netherlands.
As a senior inspector his main responsibility is supervision of quality and safety of the use of medicines and of pharmaceutical care, based on relevant legislation and guidance. He led several projects in the field of medication safety and performance measurement in healthcare, all related to the safe and effective use of medicines. He has been involved in the subject of medicines and Internet since 2002, e.g. as a member of the Ad hoc working group on mail-order of medicines of de Council of Europe. He regularly inspects e-pharmacies. Currently he is vice-chair of the European Committee on Pharmaceuticals and Pharmaceutical Care, and Chair of the Committee of Experts on quality and safety standards in pharmaceutical practices and pharmaceutical care, under the aegis of the European Directorate for the Quality of Medicines and Healthcare, Council of Europe, Strasbourg.

Professor Christian Lovis, MD MPH
Christian Lovis is professor of clinical informatics at the University of Geneva and leading the Division of Medical Information Sciences at the Geneva University Hospitals.

Prof Lovis is a medical doctor trained in Internal Medicine with special emphasis on emergency medicine. In parallel, he studied Medical Informatics at the University of Geneva focusing on clinical information systems. In 1998, Prof Lovis developed a natural language entry system for the CPOE in the Veterans Affairs’s Vista computerized patient record in Seattle. In 2000, he graduated with a Master in Public Health from the University of Washington.

Christian is the author of a large number of peer-reviewed papers and an editorial board member of major journals in medical informatics, such as the Journal of the American Medical Informatics Association, Methods of Information in Medicine and The International Journal of Medical Informatics. Christian is the president of the Swiss Medical Informatics Association; the secretary of the European Federation of Medical Informatics. He is chairing the Health Information System working group of the International Medical Informatics Association and the Traceability working group of the European Federation of Medical Informatics. He is co-chairing the “standard and architecture” working group of the Swiss eHealth federal coordination committee. Christian is member of several working groups at the European Union for ICT activities, such as impacts of health records, policies around secondary usage of clinical data, or regulation for the usage of RFID in healthcare. He is the clinical leader of the DebugIT Eu project of the 7th framework that intend to develop a distributed pan-European network around infectious disease surveillance using clinical information systems.

Ms Carla Meyer-Massetti, MS pharm/ FPH
Carla Meyer-Massetti holds a master of pharmacy degree from the University of Basel, Switzerland (2001). Through positions in hospital and public pharmacies as well as in the pharmaceutical industry, she obtained her specialization in hospital pharmacy (FPH) in 2006. In 2008 and 2009, she completed a medication safety fellowship at the University of California San Francisco, USA. Subsequently, she accepted a position with the Swiss Patieny Safety Foundation as a project manager of the Drug Event Monitoring Project, focussing on the development of medication safety indicators. She is a co-examiner in the yearly extemporaneous formulation exams at the University of Basel and supervises master’s thesis. To keep informed about medication safety developments in hospitals in Europe and abroad, she is a member of the Swiss Society of Public Health Administration and Hospital Pharmacists (GSASA), FIP, ESCP and ACCP. She will complete her PhD in medication safety at the University of Basel, Switzerland in 2011.

Ms Iryna Mukomel, Student
Iryna Mukomel is Student of the National University of Pharmacy of Kharkov. From 2008 she has been a Member of the Students Scientific Society of a Clinical Pharmacology with Pharmaceutical Care Department. She was a participant of All-Ukrainian scientific-practical conferences of students and young scientists «Actual questions of new drug formation » with reports of researching work:

- 21-22.04.2008- the topic of report was: “The influence Korvalol on the rat’s respiratory system”
- 6-7.10.2008 - the topic of report was: "The use of angiotensine II receptor antagonists in the treatment of Hypertensive encephalopathy" (was awarded the Diploma degree II)
- 24.03 2010- the topic of report was: "The use of combined cardioprotectors in the treatment of coronary heart disease" (was awarded the Diploma degree I).
Ms Aurora Napuce, MSc
Academic: I graduated Master of Science (MSC)
2010 I graduated from the Faculty of Dentistry and Pharmacy at U.F.O University

Professional Experience:
2009-2010 Professional training in "Pharmacy Daja" Tirana, Albania
2008-2009 Professional training in "Vinipharma", Tirana, Albania

Scientific Work:
2009-2010 Indicators of Pharmaceutical Care

Presentation of scientific work
Pharmaceutical care indicators, Albania, 2nd Scientific Conference of Department of Pharmacy
Faculty of Dentistry and Pharmacy, June 5, 2010, Tirana, Albania

Dr Hanna M. Seidling, pharmacist, PhD
Dr Hanna M. Seidling is currently a postdoctoral research fellow at the Geneva University Hospitals in the Service of Medical Information Sciences and the Hospital Pharmacy. She completed her studies of Pharmacy at the University of Heidelberg (2006) and accomplished her dissertation entitled "Prevention of excessive doses in electronic prescribing systems" in the Department of Clinical Pharmacology and Pharmacoepidemiology at the University of Heidelberg in February 2010. Her focus areas of research include the development, implementation, and evaluation of clinical decision support systems and electronic prescribing platforms as well as the assessment of prescription quality.

From February 2010 to May 2010 she was visiting research fellow in the Division of General Internal Medicine and Primary Care at the Brigham and Women’s Hospital in Boston, USA where she deepened her knowledge on strategies to reduce medication errors and worked on modulators of alert acceptance in electronic decision support systems.

Professor Dr Afrim Tabaku
Professor Dr Afrim Tabaku is graduated in Pharmacy by Faculty of Natural Science, University of Tirana, Albania in 1966, and since that time he is working at the Public Health Institute. Also, in the same time he is engaged as a lecturer of toxicology in the Faculty of Medicine Sciences, Department of Pharmacy at U.F.O University, Tirana. He holds a PhD degree in 1985 in environmental toxicology, in 1994 he graduated as an associate professor and in 1999 he graduated as professor. He mentored some PhD thesis in field of environmental toxicology, adverse drug reactions, and recently he is mentoring one thesis in the field of drug-drug interactions. Prof. Dr Tabaku has served as member of executive committee of international society of built environment from 1997 up to 2003.

He has been extensively involved in the development of curricula and research programmes in Department of Pharmacy at U.F.O University.

He is an author of some graduate textbooks as well as more than 90 scientific papers published in, international and national scientific journals, as well as in conference proceedings.
Last year he was included in the project of pharmaceutical care indicators in collaboration with EDQM. Actually he is dealing with adverse drug reactions and drug-drug interaction in hospital and ambulatory settings in Albania.

Dr Sabine Vogler
Dr Sabine Vogler is a senior researcher in the field of health economics, in particular on the analysis of health care systems (Europe and beyond) with a focus on medicines, i.e. pricing and reimbursement, rational use of medicines, distribution of pharmaceuticals. She is Head of the Pharma Team in the Health Economics Department at Gesundheit Österreich GmbH / Austrian Health Institute which is a well-known research institute in Austria, and she is Head of the WHO Collaborating Centre for Pharmaceutical Pricing and
Reimbursement Policies which was designated in summer 2010 at the Health Economics Department of Gesundheit Österreich. She has in-deep knowledge due to more than 15 years of research experience in these areas. She has been the project coordinator of various projects at national and at EU level (including PPRI, http://ppri.goeg.at and PHIS, http://phis.goeg.at). Furthermore she has been invited to various high level workshops and meetings as an expert in the field of pharmaceutical pricing and reimbursement. She has published several studies and is an appreciated speaker at conferences.
APPENDIX 3: LIST OF PARTICIPANTS

PhD PharmD Linda AAGAARD THOMSEN
Pharmakon – Danish College for Pharmacy Practice
Slagslunde bygade 12
3660 Stenloese
Denmark

Dr Zsuzsanna CSAKURDA-HARMATHY
Országos Gyógyszerészteti Intézet Hungarian Institute of Pharmacy
Zrínyi utca 3
1051 Budapest
Hungary

Mr Miguel Angel GASTELURRUTIA
General Directorate for Pharmacy and Healthcare Products- External expert.
Paseo de Larratxo, 98
San Sebastian 20017
Spain

Cand. Pharm Agnes GOMBOS
Norwegian Pharmacy Organisation
Postboks 5070, Majorsteun
0301 Oslo
Norway

Dr Nina GRIESE
ABDA - Federal Union of German Associations of Pharmacists
Jaegerstr. 49/50
10117 Berlin
Germany W1W 6UW London
United Kingdom

Ms Maria Jesus GUILLÓ
General Directorate for Pharmacy and Healthcare Products- Ministry of Health, Social Policy and Equality
Paseo del Prado, 18-20
20017 San Sebastian
Spain

PD Dr Michael HARTMANN
University Hospital Jena, Pharmacy
Erlanger Allee 101
07743 Jena
Germany

Ms Caroline HOGG
PSI - Pharmaceutical Society of Ireland
PSI, 18 Shrewsbury Rd, Ballsbridge
Dublin 4
Ireland

Dr Attila HORVATH-SZIKLAI
Hungarian National Committee of Pharmaceutical Care
Dózsa Gy. út 86/b
H-1068 Budapest
Hungary

Ms Caroline HOGG
PSI - Pharmaceutical Society of Ireland
PSI, 18 Shrewsbury Rd, Ballsbridge
Dublin 4
Ireland

PhD Blzenka JURISIC
Agency for Medicinal Products and Medical Devices
Republic of Croatia
Ksaverska c. 4
10000 Zagreb
Croatia

Dr Joao MARTINS
INFARMED, IP
Parque da Saude, Av do Brasil 53
1749-004 Lisboa
Portugal

Ms Maria MORAIS
INFARMED, IP
Ave Brasil 53
1749-004 Lisboa
Portugal

Ms Maria Jesus GUILLÓ
General Directorate for Pharmacy and Healthcare Products- Ministry of Health, Social Policy and Equality
Paseo del Prado, 18-20
20017 San Sebastian
Spain

Prof. Dr Helder MOTA FILIPE
INFARMED, IP
Ave Brasil 53
1749-004 Lisboa
Portugal

Dr Jan SAEVELS
APB (Association Belgian Pharmacists)
Rue Archimède 11
B-1000 Brussels
Belgium
Ms Kristine SALMINEN
Finnish Medicines Agency, FIMEA
Mannerheimintie 103b
FI-00301 Helsinki
Finland

Prof. Gyöngyvér SOOS
Hungarian National Committee of Pharmaceutical Care
Dózsa Gy. út 86/b
H-1068 Budapest
Hungary

Dr Theodorus Frans Johan TROMP
Europharm
Lelystraat 80,
8265 BE Kampen
The Netherlands

Ms Kristine VRUBLEVSKA
Pharmacists' Society of Latvia
Skolas 3
LV-1010 Riga
Latvia

Dr Tommy WESTERLUND
Medical Products Agency
SHIP, Att Läkemedelsverket, Rönnowsg. 8
SE-252 25 Helsingborg
Sweden

BSc Iris ZUYDGEEST
University of Groningen
Damsterdiep 3a
Groningen 9711 SG
The Netherlands