Abstract

Charles University in Prague, Faculty of Pharmacy in Hradec Kralove
Department: Social and Clinical Pharmacy
Candidate: **Josef Maly**
Supervisor: **Jiri Vlcek**
Tittle of Doctoral Thesis: **Analysis of possibility of applying clinical pharmacy to pharmaceutical care**

Introduction and Aim

Clinical Pharmacy (CP) is a modern, scientific, and multidisciplinary oriented medical field located on the border between pharmacy and medicine. CP follows the patterns and factors affecting the rational selection and use of drugs, dietary supplements, and medical devices used to health protection and the disease prevention and treatment. CP utilizes the methods and research outputs of other disciplines (e.g. pharmacology, pharmacoepidemiology, pharmacoinformatics, pharmacoeconomics, social pharmacy, or medical disciplines). The principles of CP may involve all pharmacists working in various types of health facilities. Furthermore, in practice the ideas of PC are developed by pharmaceutical care (PC). The aim of PC is to promote the optimal therapeutic value of prescribed drugs and OTC (over-the-counter), i.e. to reduce drug related problems (DRP) in the sense of maximization effect and minimization risk of therapy at optimal health care costs. DRP is defined as an event or circumstance associated with drug therapy that actually or potentially impedes the achievement of the intended health outcomes. As DRP are classified inappropriate prescription due to patient´s age, clinical condition, or his/her comorbidities or conversely, lack of drug with a significant impact on mortality or underlying disease, then clinically relevant drug-drug interactions, risk of non-adherence, or adverse drug reactions. Medication review realized by pharmacists or clinical pharmacists in inpatients, pharmacy, or home care represents the appropriate method for drug risk management and optimization of intended results by way of detection, prevention, and solution of DRP. The aim of the dissertation project was to analyse the possibilities how to apply CP in PC. The project consists of the following four sections:

1) analysis of the role of pharmacist in identifying and solving DRP,
2) analysis of medication record review as a tool to identify DRP,
3) analysis of counselling providing to patients in pharmacy,
4) analysis of the opinions, attitudes and experiences of selected groups of health professionals with generic drugs and generic substitution.

Methods

1) Community and hospital pharmacists recorded during 40 days all potential DRP which were identified during drug dispensation or other follow-up activities when patients collected their prescribed drugs. Data were collected using printed or web form included among others description of DRP, drugs for which DRP occurred, proposed interventions of pharmacist, characteristic of faulting entity, information sources used for solving DRP, or other data about the patient (age, gender, medical history, other drugs, etc.). Subsequently, obtained DRP were classified and their clinical significance and the accuracy of proposed interventions of pharmacist were evaluated.
2) Two pairs of pharmacists conducted in November 2011 a pilot medication record review of randomly selected inpatients from the rehabilitation centre in the Czech Republic. Using forms

the following data were collected: identification number of medication record, patient´s characteristics (age, gender, diagnoses or morbidities in patient´s anamnesis, drugs used in the day of data collection including dose and dosage regime), and description of DRP. All DRP were classified according to the modified Pharmaceutical Care Network Europe Classification V5.01. Clinical relevance of the identified drug interactions was evaluated using two drug databases. Data were processed by frequency analysis.

3) Data were collected from individual counselling provided to patients in community pharmacies in Poděbrady and Moravská Třebová and hospital pharmacy in Prague. Data collection was conducted in the period from June 2006 to December 2012. Counselling was provided by trained pharmacists and pharmacy students on their six-month practice. It was carried out in the separated consultation room. Each counselling was recorded in writing. In an interview with the patient important information from the patient history were obtained: demographic data (gender, age, etc.), data from patient and family history, life style, risk factors of patient´s diseases, all drugs and dietary supplements. Selected parameters such as height, weight, blood pressure, blood glucose, or total cholesterol were obtained from the patient or were measured directly in the pharmacy. Medication and dietary supplements review and identification of potential DRP were held directly during counselling or after that. The data were analysed, classified, and evaluated using frequency analysis. Identified DRP were classified according to the modified Pharmaceutical Care Network Europe Classification V5.01. Relationships and correlations were tested by the chi-square test, generalized linear model (GLMz), method of regression trees (CHAID analysis), always with a significance level of $p < 0.05$.

4) All members of the Czech Chamber of Pharmacists and all general practitioners who took part in the annual and regional professional conferences of the Society of General Practice ČLS JEP were asked to participate in a questionnaire survey. Data collection was conducted in period from November 2008 to March 2009. The questionnaire was divided into 5 sections and consisted of 28 questions concerning the issue of generic drugs, generic substitution and prescribing. Obtained data were analysed using descriptive statistics and correlations were tested by selected parametric and non-parametric tests. Statistically significant results were considered those assuming $p < 0.05$.

Results

1) A total of 66 pharmacists (21.2% males, median age of 30 years; 63.6% having a specialization, median 6 years of practice, 51.5% community pharmacists) identified 2,280 DRP during the drug dispensation or prescription checking. Out of those, nearly 50% were problems with dosing, 8.9% were drug interactions, and 8.4% duplications in therapy. Incorrect or inappropriate intervention of pharmacist was found in 1.7% of cases. In 7.5% of cases DRP was directly touched the patient but no patient had to be hospitalized or life-threatened, respectively. 38.9% of cases involved patients older than 65 years. 93.7% DRP did a prescriber (physician) and solution of 74% of cases required five minutes of pharmacist´s time at maximum. Drug dispensation in the pharmacy represented an activity in which pharmacist was able to fulfil the control function and hence was able to be considered as a fuse in the health care system.

2) 70 medical records were revised (42 males, median age of 59 years) and 141 potential DRP were identified. Almost 80% of patients had at least one DRP. Most DRP were classified as a "Drug choice problem" (47.5%), of which almost one half of the cases involved non-prescription of drug

even if there was a clear indication, and "Dosing problem" (34.0%) where more than one half of the cases were related to too low dose. 10.6% of drug interactions were also found. The investigation pointed out that the medication record review is an instrument by which the pharmacist is able to identify and evaluate relevant DRP.

3) Counselling focusing on overweight and obesity was attended by 41 patients (32 females, median age of 54 years, 32 patients with BMI ≥ 28), of which 12 came repeatedly. 44 potential DRP were identified and mostly involved non-adherence, dosing problems or drug interactions. 44 drugs potentially inappropriate in respect of metabolic syndrome were found in therapy of 56% patients. Counselling focusing on patients with the risk of hypertension was attended by 323 patients (102 males, median age of 60 years, 64.8% of patients with BMI > 25, 50.5% of patients with hypertension). Suspected hidden hypertension was expressed in 25% of patients. 186 DRP were identified, i.e. 0.57 DRP per patient. Most DRP involved drug choice problem (indication of inappropriate drug or lack of drug).

4) A total of 615 completed questionnaires were returned from pharmacists (return rate of 8.0%). The demographic characteristics of pharmacists were: 76.4% females, mean age of 37.5 years (SD = 10.4), 69.6% having a specialization. General practitioners returned 263 questionnaires (14.3% of respondents). Their demographic characteristics were as follows: 177 females, mean age of 52.2 years (SD = 13.7), 94.3% having a specialization. 61.5% of pharmacists considered generic drugs as bioequivalent to the respective brand name drugs. In the opinion of 16.1% (11.2%) pharmacists generic drugs were of lower quality (had more adverse drug reactions) than the brand name drugs. Generic substitution (prescription) was perceived as a positive tool by 77.4% (63.6%) pharmacists. Our results demonstrated that confidence in generic drugs and substitution were related to the age, level of knowledge and awareness of generic drugs as well as generic substitution ($p < 0,05$). Comparing the opinions and attitudes of pharmacists and general practitioners on generic drugs, substitution and prescribing the difference between these groups was statistically significant.

Conclusion

The present project is one of the first publications of this type in the Czech Republic discussing on the models of the revision of pharmacotherapy at the counter in the pharmacy, in the hospital, in counselling in the pharmacy, and in the implementation of GS or generic prescribing, respectively, how is able to utilize the knowledge of CP by providing FC in the early 21st. The pharmacist or clinical pharmacist can actively participate in the development of safe medication practice, particularly by identifying, solving and preventing DRP.