Clinical pharmacology in health care service

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Introduction

The discipline of clinical pharmacology was founded in the second half of the 20th century. The American pharmacologist Harry Gold was the first to recognize the need for new experts in medicine, saying something like the following: “...the special kind of investigators is needed, who are familiar not only with the techniques and the basics of laboratory pharmacology, but also with clinical medicine...” (1). Clinical pharmacologists should use their profound understanding of the mechanisms of drugs action and pharmacokinetics in solving health problems of the patients in the real life.

However, from its beginnings, clinical pharmacology has developed differently in the various parts of the world, mostly being more research-oriented than health care-oriented (2). In the United States of America, where clinical pharmacology was born, it has never reached the patients: recent surveys of the American Society for Clinical Pharmacology showed that the majority of around 800 clinical pharmacologists work in the academia, industry, Contract Research Organisations (CRO), or government. Their main work area is the drug development process, but not the usage of drugs in health care (3). The majority of American clinical pharmacologists are doctors of medicine and the rest of them are either pharmacists or doctors in biology (3, 4). On the other hand, clinical pharmacology in Europe focuses both on research and health care services. One of the doyens of clinical pharmacology, professor Folke Sjoqvist, has recently said: “Clinical pharmacology is not only a research discipline, but also a clinical specialty in its own right with functions in health care that focus on the rational use of drugs by physicians and patients” (5). Finally, there are parts of the world where clinical pharmacologists did not find their place among other specialties or researchers, and their role remained unclear to others (6).

The role of clinical pharmacology in health care should be viewed from the standpoint of health care services provided to patients, i.e. consumers. The reason for this is a prosaic one – the majority of Health Insurance Funds from all over the world pay for the given services (7–10). Therefore, if clinical pharmacologists want to be the part of a health care system, they have to offer well-defined services, which are needed either by patients, other medical doctors, or a medical facility management. However, these three categories of potential users of clinical pharmacologists’ services have first to become aware of the extent of the help they could get from clinical pharmacologists. It is not surprising that well-established Clinical pharmacology units exist mostly at University hospitals or other state-of-art medical facilities, where health care and scientific culture is sufficiently high (6).

What are the most important services clinical pharmacologists could offer? It is difficult to determine, and it depends heavily on the local health care needs (2). Highly developed health care system would need highly sophisticated services; the less developed one would ask for the basic help in rationalization of drug utilization. In this article the scope of possible services is given, using the activities of the Department of Clinical Pharmacology in the Clinical
Advising patients after clinical evaluation. Within any health care system, there are patients to whom various drugs are prescribed by several specialists, who are often not informed properly (or do not care) about the drugs the patient is already taking. In the majority of the cases, general practitioners are able to synchronize drug therapy for a patient, but when the problems of a patient are complex, he or she is referred to a clinical pharmacologist (11). The clinical pharmacologist then has to take a history and examine a patient, as well as to study his or her medical documentation, in order to understand the patient’s problems and give the appropriate advice.

The DCP-K gave 154 such advices to 136 patients in the first 6 months of the year 2004.

Giving drug information to the patients directly, by phone, SMS-messages or e-mail. Giving drug information to the patients or to the public is not a service uniquely offered by clinical pharmacologists. In the majority of health care facilities, pharmacists who run the units offer such service, too, probably due to the small number of clinical pharmacologists available (12). However, whenever possible, the drug information units are best led by pharmacists, and supervised by clinical pharmacologists; such organization gives the high quantity of services combined with the high reliability, as we can learn from the experience of the Department of Clinical Pharmacology in the Huddinge Hospital, Stockholm (13). Sometimes, the drug information service is specialized for only one area, like “anti-doping hot line”, also operating in the Huddinge Hospital (14).

During the first 6 months of the year 2004, in DCP-K 86 drug informations were given. The majority of the questions asked by the patients were those concerning adverse drug reactions, concomitant drug use and the use of drugs during pregnancy and lactation.

The services offered directly to the patients

Advising hospital and primary care physicians, if possible, after clinical evaluation of their patients. Medical doctors have often to deal with the patients who have complex health problems, and require several drugs which could interact with each other, so the help of a clinical pharmacologist is needed. This help could be offered in the form of a detailed report with references (15), when a clinical pharmacologist(s) studies the literature, evaluates published studies according to the principles of the evidence-based medicine, and gives advice to the colleagues. A whole team usually considers the problem, and stores the case data on the accessible database, which could be used as a reference for a similar case. Another option is to examine a patient, give an advice immediately, and make additional literature search, if needed. This option may be less reliable, but it has the advantage of the direct contact with a patient, and getting the true impression about his/her case, which could differ from the impression of a clinician in charge of that patient.

In DCP-K, 187 advices for 135 patients were given in the first 6 months of the year 2004. All the advices were given according to the second option.

Giving drug information to other medical doctors directly, by phone, SMS-messages or e-mail. The same staff which usually gives drug information to patients does it to the colleagues, too (16,17). Actually, the service is similar to the one for patients, only the information is much more extensive. Most questions asked by other medical doctors are in relation with the adverse drug reactions, the choice of therapy/drug, and the therapy during pregnancy or breast feeding (18). Some studies have shown that over 70% of the colleagues consider such services important for their practice (15).

In DCP-K, 129 items of drug information were given to clinicians for the first 6 months of the year 2004. Around 80% of the items were about the choice of a drug.

Reporting adverse drug reactions. For the majority of developed countries, the rate of spontaneous reporting of adverse drug reactions (ADR) is at the satisfactory level (more than 250/1000000 inhabitants); however, the same is not true for undeveloped or developing countries, or countries in socio-economic transition, like Serbia & Montenegro. Clinical pharmacologists should run the Regional Centers for adverse drug reactions, but they should also work on ADR reporting the rate increasement. The colleagues who suspect an ADR should be able to call a clinical pharmacologist, who will evaluate the causality of suspected ADR and help with its reporting. Availability of such a service makes the reporting easier for a busy clinician, and also increases the reporting rate significantly (19).

After offering such a service in DCP-K, the reporting rate of ADR in the hospital increased from 10/year to 40/year.

Therapeutic drug monitoring is one of the most important services that a clinical pharmacologist can offer. The measurements of drug concentrations in serum are done in the hospital biochemical laboratories, but the interpretation of the measured values is reserved for a clinical pharmacologist (20). Accurate dose titration could only be made if all the factors influencing pharmacokinetics of a drug are taken into account; and only clinical pharmacologists have sufficient knowledge and the skills to do so.

In DCP-K, the concentrations of both antiepileptics and antibiotics are measured in serum. The request from a clinician for the therapeutic drug monitoring first has to be approved by a clinical pharmacologist, and after the meas-
urement, the result is followed by the comment of a clinical pharmacologist. In the first 6 months of the year 2004, 147 patients underwent the therapeutic drug monitoring.

Design of post-marketing studies. Post-marketing drug studies are often initiated by either medical doctors or pharmaceutical companies, with various purposes. According to the existing regulations, such studies do not need an approval of a drug agency, but only a notification. It is only a clinical pharmacist who is able to make an appropriate design of such studies, and ensure an ethical verification. However, clinicians can hardly expect from clinical pharmacologists in pharmaceutical companies to make the design for them – this would simply cost too much; but clinical pharmacologists working in a health care facility can offer such a service within the cost limits set by health insurance funds.

During the first 6 months of the year 2004, the clinical pharmacologists from DCP-K designed 1 post-marketing case-control study.

Providing continuing medical education. Continuing medical education (CME) has become obligatory for each practicing physician in the majority of the countries. Health care facilities, especially those of tertiary care, which have a competent staff could also provide CME (21). Clinical pharmacologists could offer courses in rational pharmacotherapy, which could satisfy both primary and secondary care physicians. The DCP-K has held two CME courses in the first half of the year 2004.

The services offered to the management

Serving in Drugs and Therapeutics Committee (DTC) of a hospital. The DTC is a body through which clinical pharmacologists may influence drug prescribing in a hospital. It combines the local guidelines and drug lists development, and through it clinical pharmacologists have both time and an opportunity to actively create the drug policy of a hospital (22). Unfortunately, due to the lack of clinical pharmacologists in practice, more than half of the DTCs are chaired by pharmacists, who, although knowledgeable, lack the skills of physicians (12).

A clinical pharmacist has chaired the DTC in the Clinical Hospital Center “Kragujevac” since its establishment in 1999. A total of 63 local guidelines and three versions of local drug formulary were produced as a result of the DTC activity.

Pre-dispensing control of expensive drug prescribing. Due to insufficient training in clinical pharmacology at medical schools and postgraduate education in the majority of countries (23), it becomes necessary to impose control on prescribing of expensive drugs. Drug utilization and cost analysis in the Clinical Hospital Center “Kragujevac” has shown that only 1 drug (antibiotic ceftriaxone) consumes around 15% of the drug budget (24)! By imposing pre-dispensing control on prescribing in the Clinical Hospital Center “Kragujevac” by a clinical pharmacist, the consumption of expensive drugs was decreased by 30% in the year 2003. This service performed 4150 pre-dispensing chart controls during the year 2003. The prescriptions were changed in 21% of the cases, but only after the consensus reached with a prescribing physician.

Periodic auditing of prescribing practice in the hospital. In order to test whether prescribers follow the local guidelines and the treatment standards, clinical pharmacologists should prepare and conduct the audits periodically. This role of clinical pharmacologists was identified indirectly by the American College of Clinical Pharmacology, which stated that “a clinical pharmacist should serve as an ombudsman in all the hospitals to track possible medication errors and to educate the medical and nursing staffs on how to mitigate such errors” (25). The audits are the only way to spot the irrational or erroneous behavior of prescribers, and to have the basis for planning the corrective actions (26). It is important to perform auditing according to the internationally agreed methodology (27).

The clinical pharmacologists from DCP-K perform on average, 1–2 audits of prescribing practice in the Clinical Hospital Center “Kragujevac” per year.

Ninety percent drug utilization analysis. Analysis of drug utilization focusing on the number of drugs constituting 90% of the volume (DU 90%) is very useful for revealing prescribing profiles in a health care facility (28). The DCP-K follows drug utilization in the Clinical Hospital Center “Kragujevac” according to the WHO methodology (expressed in the number of defined daily doses per 1000 patient-days) from the year 1997, and with the emphasis on the utilization of 90% of the volume from the year 2003. The management of the hospital uses these data for the basis of the corrective actions (e.g. initiating an audit), if the drug utilization pattern does not follow the agreed local guidelines, as well as for planning drug purchase.

Preparation of a hospital’s drug formulary and drug procurement list. Although a drug formulary of a hospital is negotiated and accepted by its DTC, someone has to prepare the first draft of the list. This is the unique responsibility of a clinical pharmacist and in DCP-K this process is repeated each year. As noted by Feely: “Clinical pharmacologists are uniquely positioned to determine the cost benefit and utility of modern therapy and give impartial advice on safe, effective and economic patient care” (29). Besides the preparation of the draft, clinical pharmacologists participate actively in the process of the formulary negotiation.

Starting from a drug formulary, clinical pharmacologists of DCP-K prepare the drug procurement list draft, too. They negotiate the draft with all the relevant clinicians, and estimate the necessary drug quantities based on drug utilization data. Finally, the draft is discussed and agreed with the chief hospital pharmacist, and handed over to the procurement committee (30). Participation of a clinical pharmacist in this process is important, since no other expert profile is competent enough to negotiate the drug purchase with clinicians (prescribers).
Serving in local Ethics Committee. The Ethics Committee of a health care facility is necessary for reviewing of and deciding on the proposals for clinical trials. It should be organized and it should function according to the internationally agreed standards, set by WHO (31). Clinical pharmacologists are familiar with the standards, and educated enough to discuss the therapeutic options in all the clinical areas. The president of the Ethics Committee of the Clinical Hospital Center “Kragujevac” (established in 1997) is a clinical pharmacologist.

Conclusion

The services mentioned above are the direct response of clinical pharmacologists to the needs of patients, medical doctors and hospital management. However, if clinical pharmacologists are not available, clinical pharmacists take over these services, as observed in the USA (32, 33). Whether this is acceptable or not, remains to be seen, although some studies have demonstrated that “system using pharmacists as independent practitioners to promote primary care has achieved high-quality and cost-effective patient care” (32, 34, 35). What clinical pharmacology as a discipline should perform, are the well-designed studies which would investigate the impact of services of clinical pharmacologists to prescribing and health care in general. This is the only way to exactly define the position of clinical pharmacology in health care system and clinical pharmacologists from all over the world should be encouraged to conduct such studies.

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