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MiniReview

The Impact of Clinical Pharmacists on Drug-Related Problems and Clinical Outcomes

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Abstract: Drug-related problems are frequent and may result in reduced quality of life, and even morbidity and mortality. Many studies have shown that clinical pharmacists can effectively identify and prevent clinically significant drug-related problems and that physicians acknowledge and act on the clinical pharmacist's suggestions for interventions to the drug-related problems. A pro-active rather than a reactive approach on the part of the pharmacists seems prudent for obtaining most benefit. This includes participation of pharmacists in the multidisciplinary team discussions – at the stage of ordering and prescribing – where all types of drug-related problems, including also potential problems, should be discussed. In addition, counselling by pharmacists about medication on discharge and follow-up after discharge resulted in better outcomes. Furthermore, clinical pharmacists can positively influence other outcomes, such as improvement of levels of markers for drug use (e.g. optimization of lipid levels, anticoagulation levels and blood pressure). Some studies have reported positive effects on hard clinical outcomes, such as reduced length of stay, fewer re-admissions and fewer disease events (e.g. heart failure events and thromboembolism). However, more studies should be undertaken with larger patient populations, including patients from multiple sites. More knowledge about patient-specific factors that predict improved care is also needed. In conclusion, there is increasing evidence that participation and interventions of clinical pharmacists in health care positively influence clinical practice.

Drugs are an important input factor in the Western healthcare system. However, it has been shown that drugs may give negative health outcomes, such as increased morbidity and mortality [1–3] and reduced quality of life [4]. Moreover, lack of effect of the chosen drug can also be a challenge in the management of patients, and often optimal levels of blood glucose, cholesterol or blood pressure are not reached during drug treatment [5]. The reason could be the choice of drug or dosage, or patient factors such as drug-disease interactions or adherence problems.

A cornerstone of clinical pharmacy is the identification, solving and prevention of drug-related problems. A drug-related problem is defined as 'an event or circumstance involving drug therapy that *actually or potentially* interferes with desired health outcomes' [6]. Drug-related problems have been categorized by different research groups into different classification systems. In short, these problems deal with choice of drug, drug dosages, adverse drug reactions, drug interactions, lack of monitoring of drug effects/toxicity, and adherence problems. Drug-related problems include both actual and potential problems. An actual problem has resulted in clinical manifestations (e.g. a drug-related rash, an adverse drug reaction), or therapy failure due to incorrect dosage. A potential problem is not manifest, but if left unresolved, it may lead to drug-related harm to the patient. Examples are the administration of a non-steroidal anti-inflammatory drug (NSAID) to a patient with renal failure, or erythromycin to a patient taking warfarin or simvastatin. Often the most cost-effective pharmacotherapy focuses on the prevention of illness. The same preventive focus is relevant when dealing with drug-related problems, as their occurrence is connected to negative health outcomes. Hence, a main objective should be to prevent drug-related morbidity.

A clinical pharmacist may assess drug-related problems in different settings: in hospital multidisciplinary teams, in nursing homes and in primary care. The pharmacist's contribution to the optimization of drug therapy may be evaluated by ascertaining the number of drug-related problems addressed or prevented, or by assessing the clinical outcomes for the patients. These are *indirect* and *direct* measurements, respectively, the latter providing the most conclusive evidence.

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Interventions on drug-related problems and acceptance by the prescriber

Studies have shown that the majority (50–80%) of drug-related problems can be prevented [7–9], which strongly supports that these problems should be addressed.

Interventions suggested by clinical pharmacists to solve or prevent drug-related problems are to a large degree accepted and acted on by the prescribers. An acceptance rate of 41–96% has been reported [10–17]. Furthermore, in European countries where clinical pharmacy is still under development, similar acceptance rates are found, as shown in recently published studies from Norway, Denmark, Sweden and Belgium [18–22]. The highest acceptance rates were obtained when pharmacists were attending the rounds with the physicians and when making proposals for interventions at the stages of ordering or prescribing (i.e. a pro-active approach). The low acceptance rate found by Patel et al., 41%, was explained by the method used, namely, that communication was solely indirect by written comments and not by oral notifications during team discussions (i.e. the approach was reactive) [17]. Also Douchette's finding of a low acceptance rate, 47%, was explained by the fact that the pharmacist had reduced access to patient-specific information, besides the fact that the proposals for interventions were given as written reactive notifications [15].

Other terms related to the drug-related problems concept – such as inappropriate prescribing and suboptimal prescribing – have been used as outcome measurements. A randomized controlled study by Hanlon et al. among outpatients at Veteran Affairs Medical Center showed that medication review by clinical pharmacists followed by discussions with the physicians resulted in less inappropriate prescribing. This was maintained at the 12-month follow-up [23]. The intervention group had fewer adverse drug reactions than the control group. The quality of life, however, was not affected. In a comparative, prospective study, Buck et al. found that a clinical pharmacy service resulted in a reduction in suboptimal prescriptions among hospitalized patients in orthopaedic wards in Denmark [19].

A review including 14 randomized controlled studies provided evidence that clinical pharmacist interventions reduced the occurrence of drug-related problems in the old patients [24]. There is, however, still a need for large multicenter studies to test cost-effectiveness.

It is interesting to elucidate the clinical significance of drug-related problems identified by the clinical pharmacist. Although the scoring system for clinical significance is not consistent between the studies, it can be concluded that the majority of the interventions are of high clinical significance for the patient [12,22,25–29].

The identification and suggestions for interventions by clinical pharmacists on clinically significant drug-related problems, and further, the acceptance of the interventions by the prescribers, are evidence of the major contribution of clinical pharmacists in reducing the frequency of drug-related problems, thus implying better pharmacotherapy for the patient. Interventions to reduce the occurrence of these problems are principally an *indirect* measure of their effects on patients.

Effects of pharmacist interventions on different clinical outcomes

The studies described above deal with circumstantial evidence of an important role of the clinical pharmacist. A more *direct* measurement of the influence of clinical pharmacists is based on observations of the patient's clinical outcomes. Preferably, hard end-points should be evaluated, these being mortality, disease events and prevention of disease. These end-points are for practical reasons difficult to assess in clinical practice and research. Therefore, surrogate end-points are often used, for instance fewer hospital admissions, reduced length of stay or fewer admissions to emergency rooms. Other surrogate markers could be the level of serum concentration of various drugs, or the achievement of optimal drug effects as assessed by monitoring, such as optimal levels of anticoagulation (INR), lipids, blood glucose or blood pressure. Furthermore, adherence to a drug regimen could be assessed, as well as reduction in the frequency of adverse drug reactions. Another aspect of clinical outcome is to increase or maintain the individual's quality of life. Different studies have focused on different outcomes.

Interventions on adherence.

Given that the prescribing is optimal for the individual patient, efforts should be made to enhance adherence to medications. In studies where this is addressed, both the terms *adherence* and *compliance* have been used, often synonymously, although they have different definitions. Adherence, in addition to the aspect of following the recommendations of the physician, also includes the agreement of the patient to the recommendations. In this review, the term, which corresponds to the term used in each paper, is used. In a prospective, randomized, controlled study among patients with *Helicobacter pylori*, Al-Eidan et al. showed that patients in the clinical pharmacist intervention group had significantly higher compliance to the medication regimen compared to the control group (92.1% versus 23.7%, $P = 0.02$) [30]. In another clinical pharmacist intervention study among patients with chronic reactive airways disease, Weinberger et al. did not find significant differences with regard to medication compliance between the intervention and control groups [31]. Both studies are included in the Cochran's review 'interventions for enhancing medication adherence' [32]. The authors concluded that it is difficult to increase adherence among patients with chronic health problems. However, interventions to increase short-term adherence are relatively successful. This was the result regardless of which health professional carried out the interventions.

Indicators of drug use.

The achievement of the optimal drug effect (e.g. a satisfactory INR during anticoagulation), implies a reduction in the risk

of negative clinical outcomes (e.g. stroke, acute myocardial infarction or bleeding events). Pharmacist-led anticoagulation services improved the anticoagulation of the patient and reduced warfarin complications as shown in a comparative study among hospitalized patients commencing warfarin, where the intervention group – with daily consultation by a hospital pharmacist – had INR in the relevant medical range for significantly more days and in significantly more patients than the control group without pharmacist counselling. Furthermore, the patients in the pharmacist group used fewer medications known to significantly interact with warfarin ($P = 0.02$) [33]. On the other hand, Poon et al. who studied old outpatients did not find significant differences with regard to the percentages of therapeutic INR values between the control group and the intervention group, the latter having medication chart review and counselling by a clinical pharmacist (48.1% in the pharmacist group versus 46.4% in the conventional group). However, patients with both sub- or supratherapeutic INR values received quicker follow-up by pharmacists than by physicians [34]. In these studies, the pharmacists were especially trained to perform this service.

Pharmacists have also been involved in lipid-monitoring clinics. In Till's retrospective study among patients with dyslipidaemia, the intervention group, which had a clinical pharmacist actively adjusting the drug therapy, achieved a better reduction in low-density lipoprotein than the control group ($P = 0.049$). The author concluded that inclusion of a trained pharmacist in the multidisciplinary team resulted in improved treatment [35]. In another randomized study of patients with dyslipidaemia, the intervention group had a medication review by an ambulatory care clinical pharmacist, and achieved a significantly greater change in total cholesterol (17.7 versus 7.4 mg/dl, $P = 0.028$) and low-density lipoprotein cholesterol (23.4 versus 12.8 mg/dl, $P = 0.042$) compared to the control group [36]. In a prospective, randomized, controlled study, Peterson et al. evaluated the impact of pharmacist-conducted home visits on the outcome of lipid-lowering therapy. They found a significant reduction in total cholesterol compared to the control group [37].

Also important to monitor are blood pressure and blood glucose. Reid et al. studied the implementation of a pharmacist-led clinic for hypertensive patients in primary care and found that interventions by the pharmacist led to better blood pressure control and better drug prescribing [38]. Choe et al. performed a prospective, controlled, randomized study on how guidance by a clinical pharmacist would influence glycaemic control in patients with type II diabetes [39]. Patients in the intervention group achieved greater reduction in haemoglobin A_{1c} (HbA_{1c}) than the control group.

Disease-specific clinical end-points.

As already stated, the gold standard for evaluating drug effects should be related to hard clinical end-points (e.g. disease events). Although Poon et al. did not find differences between the intervention and control groups with regard to INR values, more thromboembolic events occurred in the control group ($P < 0.01$) [34]. The intervention group had, however, more minor bleedings such as bruising and nose-bleeds than the control group. The results of this study demonstrate the importance of not only concentrating on surrogate markers, but also measuring disease events.

In another randomized, prospective study, the benefit of adding a clinical pharmacist to the heart failure management team was investigated, and comparison was made with a group receiving usual care [40]. The intervention group had significantly lower all-cause mortality and fewer heart failure events than the control group after 6 months follow-up ($P = 0.005$). It is also of interest that significantly more patients in the intervention group reached the target dose for the angiotensin-converting enzyme inhibitor (ACE-I) ($P < 0.001$). In another prospective study among old patients with chronic stable heart failure, patients in the intervention group, which received an intensive counselling programme for 3 months by a pharmacist, had less peripheral and pulmonary oedema than the control group ($P < 0.01$), and showed better improvement in exercise tests ($P < 0.005$) [41].

As mentioned above, Al-Eidan et al. showed that compliance to a *Helicobacter pylori* drug regimen was significantly improved by introducing counselling by a clinical pharmacist, but an even more important finding was that higher eradication frequency was obtained in the intervention group compared to the control group (94.7% versus 73.7%, $P < 0.001$) [30].

Disease management end-points.

Hospitalization, re-admissions and length of hospital stay are other surrogate markers for disease. In a randomized study among patients discharged from general medical departments, the intervention group had follow-up counselling by a clinical pharmacist [42]. New drug-related problems that were identified in the post-discharge phase were solved or the patients were referred to their primary physician. The overall result was fewer admissions to emergency rooms within 30 days in the intervention group compared to the control group ($P = 0.005$). Another study among old patients with focus on discharge counselling by a clinical pharmacist, showed that the intervention group had significantly fewer unplanned visits to their primary physician as well as significantly fewer re-admissions to hospital than the control group, which had no pharmacist counselling ($P < 0.05$) [43].

An Australian prospective multicentre study showed that pharmacist interventions reduced the re-admission rate [44]. In contrast, the study by O'Dell et al. among hospitalized patients with acute coronary syndrome did not show any significant differences in re-admission rates between the control group and the intervention group. In the latter, a clinical pharmacist participated in rounds and had therapy discussions with physicians [10]. A subgroup of patients with unstable angina had, however, significantly fewer re-admissions during the study.

In the study by Dagers et al. among warfarin users, the intervention group was counselled by a hospital pharmacist,

and reduced re-admissions due to bleeding or recurrent thrombosis were documented. In addition, the length of stay was significantly shorter in the intervention group compared to the control group (6.8 versus 9.5 days, $P < 0.009$) [33].

The role of the pharmacist has been explored in different settings. A Cochrane's review published in 2000 looked at the role of the *outpatient* pharmacist and the effects on health services utilization, costs and patient outcomes [45]. Generally, the intervention groups – involving a pharmacist – had decreased use of unscheduled health services and fewer visits to specialist physicians than the control group. In one study, scheduled visits were increased, whereas hospital and emergency room admissions were decreased. It was not possible to draw conclusions about pharmacist services compared to other health professional services, as there had been too few studies performed. The authors concluded that since some of the studies included in the review had poorly defined interventions and also lacked patient outcome data, making generalization difficult, more rigorous research should be undertaken to document the outpatient pharmacist's role. In addition, the cost-savings should be explored in further studies. Kaboli et al. have recently published a review about clinical pharmacist services and *inpatient* medical care [46]. A total of 36 studies including more than 17,000 patients were evaluated in the review. They found that clinical pharmacist service reduced adverse drug reactions or medication errors, and further, medication adherence, knowledge and appropriateness were improved. They also found reductions in the length of stay. None of the studies included in the review gave negative health outcomes, but one of the studies showed increased healthcare use. The authors asserted that most of the interventions discussed could be implemented by re-allocation of existing resources; however, cost-effectiveness could be explored further. Kaboli et al. [46] concluded that, in general, clinical pharmacist service improved care in inpatients and there was no evidence of harm to patients. The participation of the clinical pharmacist together with other health professionals on rounds, reconciling medication and counselling patients on discharge medication and follow-up, all resulted in better outcomes. This review also stated that more research should be undertaken with larger patient populations from multiple sites, with reproducible interventions. In addition, more research to identify patient-specific factors that predict improved care should be performed.

Comments

For some of the drug-related problems discussed above, it could be questioned whether other health professionals than clinical pharmacists, could carry out the tasks equally efficient. 'Extended care' providers (e.g. nurses) who provide education, social support for behavioural changes and activation (e.g. taking medication regularly) are shown to improve outcomes for patients with chronic illness [5]. However, there is a lack of studies comparing different health professional on this issue. As stated in a Cochran's report, 'whether pharmacists can manage drug therapy as well as physicians remains unanswered due to a shortage of studies' [45].

Another question is what help the drug prescriber (physician) could obtain from support systems as for example computer programmes for drug interactions or adverse drug reactions. Could they provide much of the needed assistance and thus make the pharmacist redundant? It has been shown, however, that many of the adverse drug reactions alerts are of more theoretical than practical relevance for the individual patient [47]. Furthermore, computer systems provide too many false positive drug–drug interaction alerts with the consequence that the prescribers turn off the alert system [48]. Therefore, computer decision support systems have limitations and should be used together with other clinical judgement.

The economic aspects of the participation of the clinical pharmacist in the healthcare team have not been specifically addressed in this *MiniReview*. In addition, in the studies referred to, which mainly are clinical studies, the economic topic is absent or has been superficially dealt with. However, in general, an economic benefit has been reported, related to studies of various tasks performed by clinical pharmacists (e.g. reconciliation of drug lists, follow-up of guidelines, logistic and distribution tasks) [49,50]. Furthermore, the cost for one hospital stay is so high that prevention of hospitalization and re-admissions – which were outcomes in some of the studies referred to in the review – would be expected to turn out to be cost-effective. But still, more studies are needed to explicitly elucidate whether the discussed approach to prevent drug-related problems is cost-effective.

Conclusion

Studies have shown that clinical pharmacists effectively can identify, solve and prevent clinically significant drug-related problems. A proactive rather than a reactive approach seems prudent for obtaining the greatest benefit from the interventions. This includes pharmacist participation in the multidisciplinary team discussions – at the stage of ordering and prescribing – where all types of drug-related problems, including potential problems, should be discussed.

Furthermore, it has been shown that interventions by clinical pharmacists improve clinical outcomes, such as improvement in levels of markers for drug use and disease, for example, more optimal lipid levels and INR levels, reduced length of hospital stay, fewer re-admissions and fewer disease events such as heart failure events or thromboembolism. In conclusion, there is increasing evidence that participation and intervention of clinical pharmacists in health care have a positive influence on clinical outcomes.

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