Interventions on the principle of Pulmonary Medication Profiles
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Summary

Samenvatting
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This thesis describes a patient intervention study which is named the IPMP study (Interventions on the principle of Pulmonary Medication Profiles). The IPMP study is based on a specific strategy in pharmaceutical care. The interventions were administered by Dutch community pharmacists in 2001 and 2002. The study was designed as a randomized controlled trial on patient level, including an observational study and three opinion surveys.

In the Dutch health care system community pharmacists document patient medication records of all prescriptions dispensed in their pharmacies in their computerized pharmacy information systems. Pharmacists generally instruct, inform and motivate patients to use their medication as prescribed. In addition, pharmacists are the health care professionals, who could support patients with long-term medication use by optimizing their treatment as agreed upon between physicians, patients and pharmacists and as described in evidence-based guidelines.

The IPMP study was performed aiming at improving patients’ drug use by providing pharmaceutical care to patients at risk of suboptimal pulmonary drug therapy and investigating the efficacy of tailored interventions administered to individual patients by their community pharmacists. Consequently this thesis is about collaboration involving patients, physicians and pharmacists.

Part I of the thesis focused on the preparations for the investigation.

In the introduction (chapter 1) former studies concerning pharmaceutical care interventions in patients with pulmonary diseases were described. At the start of the IPMP study (in 2000), an intervention study in a randomized controlled trial design on patient level aiming at improving drug treatment and medication use by administering individualized and enhanced interventions to pulmonary patients by community pharmacists had not been carried out. The motive for this scientific research in pulmonary patients was to demonstrate the long-term efficacy of the provision of tailored pharmaceutical care in daily pharmacy practice.

In chapter 2 the contents, the structure and the sequence of the different parts of the IPMP study were explained and justified. In the study the principle was assumed that drug treatment recommended in evidence-based pulmonary guidelines should lead to optimal clinical outcomes for asthma and COPD patients (chronic obstructive pulmonary disease). All
steps of the complex intervention strategy aiming at improving patients’
drug treatment and medication use were described.

The interventions were performed by Dutch community pharmacists in their
daily pharmacy practice. Five educational meetings were scheduled to
educate the participating pharmacists and to implement the intervention
strategy extensively.

Patients at risk of suboptimal drug therapy were invited for a consultation in
the pharmacy. The intervention strategy comprised patient consultations,
six pharmaceutical care modules and an evaluation of the results of the
intervention with the patient. Participating pharmacists advised changes in
the medication treatment by contacting the prescribing physicians. The
follow-up period was one year, in which the same pharmacists reviewed the
patients’ medication records every three months. If necessary, the
pharmacists could start a new intervention. After one year participating
pharmacists invited the patients for a final consultation.

To start the IPMP intervention patients at risk of suboptimal drug therapy
were identified by the use of patients’ medication records. Chapter 3
describes the construction of the IPMP algorithmic computer instrument to
select patients having theoretically deviant drug use compared with the
different prescription levels of the Dutch pulmonary guidelines. The
identification procedure of nine deviant-treatment profiles was tested and
validated in four community pharmacies.

In Part II of the thesis the results of the complex IPMP intervention strategy
were investigated.

The process of the intervention and the resulting professional satisfaction of
the participating pharmacists are described in chapter 4. Pharmacists in 24
community pharmacies invited selected patients (aged 13-70 years) with
current deviant drug use to a consultation in their pharmacies. In structured
consultations, tailored at the current drug use, patients’ coping behaviour
and specific problems with their medication were identified. Based on this
identification process, a tailored intervention (Type I intervention) was
constructed for each individual patient that could comprise one or more of
the six pharmaceutical care modules. These modules were: inhaler
technique (1), evaluation of drug use (2), knowledge of medication and
disease, and adherence to correct drug use (3), device change (4),
medication change (5) and self-management (6). Informed consent to
document all details of their intervention and the periodical medication
reviews was given by 199 patients. Pharmacists documented these interventions in great detail. They administered 813 pharmaceutical care modules and contacted physicians concerning 100 patients. The intervention strategy was well implemented. Participating pharmacists reported to be successful in improving medication use and drug treatment of their patients. Pharmacists were satisfied with the pro-active pharmaceutical care approach and considered it worthwhile.

In the final consultation (chapter 5) pharmacists observed increased knowledge about medication and improved inhaler technique in the patients described in chapter 4 (response rate 76%) compared with the results and observations in the same patients before the pharmaceutical care interventions. At this point of time patients reported fewer drug-related problems and fewer adverse effects compared with their opinions in the first consultation.

In an opinion survey (sent to the same patients by the researchers, response rate 76%) patients were satisfied with the intervention provided by their pharmacist and considered it important. The majority (67%) reported that they had learned more about their medication or the inhaler technique, resulting in significantly improved coping behaviour with their pulmonary medication compared with patients who valued the intervention only as a nice conversation with their pharmacist. Patients with improved coping behaviour reported statistically significantly fewer symptoms compared with patients reporting no change in behaviour (Chi-square test, \( P<0.05 \)).

Chapter 6 describes the results of the randomized controlled trial in which 999 patients were involved. Within each pharmacy identified patients were randomly allocated to an intervention or a reference group. Patients of the intervention group, who accepted the invitation of their pharmacists for a consultation (\( N=219 \), response rate 53%), received Type I interventions, as described in chapters 4 and 5. Additionally, physicians were advised on optimal prescribing for all individual patients of the intervention group, if necessary (Type I and Type II interventions). Patients of the reference group received care as usual.

After one year patients’ medication records were assessed again to study a possible change in deviant-treatment profiles, indicating a change in medication use either more or less in concordance with the pulmonary guidelines. A profile change algorithm was developed to value changes in these profiles.
The change in profiles on an ‘intention-to-treat’ principle differed statistically significantly between the intervention and the reference group (P=0.009). The overall relative risk (RR) of improvement compared with the reference group was 1.25 (95% CI 1.08-1.46) for all patients in the intervention group and nearly doubled (RR=1.43, 95% CI 1.20-1.71) for Type I intervention patients. Type II interventions as such did not result in statistically significant changes in profiles.

In general, it could be concluded that pharmaceutical care provided to pulmonary patients resulted in significant and sustainable improvement of their drug therapy.

After sending the invitation to the patients of the intervention group pharmacists were confronted with patients not responding to the invitation. In chapter 7 a non-respondents survey was performed to investigate the reasons why they did not participate in the IPMP study. Compared with the results of the participating patients’ opinion survey, described in chapter 5, non-participating patients were significantly less satisfied – on non-defined aspects - with their pharmacies, had fewer experiences in earlier consultations with their pharmacists and preferred to ask the family doctor questions about medication instead of the pharmacist. However, there were no differences concerning professional aspects such as expert knowledge, accuracy and information provision.

Although non-participating patients were identified as being at risk of suboptimal drug therapy, they did not notice any drug-related problem and/or were satisfied with their medication. Therefore they had no special reason to see their pharmacist.

Barriers concerning the provision of pro-active pharmaceutical care by community pharmacists were surveyed during the IPMP study and discussed in a structured discussion meeting. They were defined in chapter 8. The general barriers such as lack of time, money, knowledge or motivation to counsel patients were not mentioned. At the start of the IPMP study all participating pharmacists reported in structured questionnaires that they had implemented the good pharmacy practice standard into practice and were familiar and experienced with pharmaceutical care interventions in pulmonary patients. The largest reported barrier consisted of patients who did not respond to the invitation themselves and could not be contacted by the pharmacists. In general, pharmacists valued the communication with patients’ physicians positively. Only a few contacts...
were frustrating. Recommendations were developed to facilitate the communication with patients and with physicians.

In Part III of the thesis, the general discussion (chapter 9), the consistency between the three research techniques was demonstrated.

In the randomized controlled trial statistically significantly improved drug therapy of patients of the intervention group was shown. Pharmacists observed increased knowledge and improved inhalation technique in patients after the intervention, and adherence to agreed medication. In the patients’ opinion survey intervened patients were satisfied with the intervention and mentioned an improved coping behaviour with their medication resulting in significantly fewer symptoms. In this way the efficacy of the tailored pharmaceutical care interventions was proven and confirmed by pharmacists and patients in observation and opinions. The best results were obtained by collaboration of patients, physicians and pharmacists in the so called Type I interventions.

**Concluding remarks**
Because a pharmaceutical care process as described in the IPMP study resulted in socially relevant outcomes such as optimal drug treatment and medication use, this tailored pharmaceutical care strategy should be upscaled to daily pharmacy practice. The pro-active approach was feasible in daily community pharmacy practice. Participating patients and pharmacists were satisfied with the provided interventions.

Searches in the pharmacy database to identify patients at risk of suboptimal drug use were an appreciated start of pro-active pharmaceutical care and should be available on a regular basis.

Extensive implementation of the complex intervention strategy using clear and plain protocols is a condition for an efficacious result. Firm establishment is necessary to demonstrate effectiveness in daily practice.

In the IPMP study not all identified patients were aware of suboptimal drug use and possible drug-related problems. As a consequence, these patients did not respond to the pharmacists’ invitation. Pharmacists and other health care professionals should sensitize patients at risk so that they will be treated well.

By expanding pharmaceutical care interventions pharmacists will market their patient oriented capacities to patients and physicians.