1 INTRODUCTION

1.1 Introduction

This work concentrates on patient education about drugs. It’s general objectives focus on the question how to develop patient education in community pharmacies, especially the verbal information about drugs.

Definitions of patient education in literature vary, but mostly include a patient related objective (knowledge, attitude, skills, behavior) and ‘communication’, being the instrument to realize these objectives. We have defined patient education about drugs as the communicative activities addressed to the patient, with the main objective to realize patients’ proper drug use. In this view patient education activities about drugs may concern efforts to influence patient’s knowledge, attitude or skills, as the ultimate objective of all these different activities concentrates on patients’ drug use. For example a demonstration of a drug inhaler primarily emphasizes patients’ skills, but the ultimate objective focuses on proper drug use.

Patient education nowadays gets a lot of attention in the different professions and institutes within the health care system, among which community pharmacies. This interest in patient education may have different backgrounds. One could advocate the necessity to practice patient education from several points of view, such as patients’ rights to be informed, or patients’ needs to have information, but also because patient education may contribute to patient compliance. These different backgrounds for patient education about drugs will be discussed in section 1.2. Patient education in community pharmacy is an innovation, perhaps in a stronger sense than it is in other professions. For this reason the (young) history of patient education in this field will be discussed in section 1.3. Attention is given to the support from the professional association of pharmacists to practice patient education in community pharmacy and the initiatives of individual community pharmacists in this respect, while also the basic and postgraduate education provided by universities and technicians’ schools are discussed. This brief historical view offers some background knowledge to evaluate the current level of patient education in community pharmacies. Finally in 1.4 an introduction is given of the objectives of this study and the contents of this work.
1.2 The necessity of patient education about drugs

1.2.1 Introduction

Patient education is an instrument to support people to solve their health related problems. In this respect governments, professionals and patients are involved in patient education, each of them with different backgrounds. These different backgrounds to advocate patient education about drugs, will be discussed briefly. Successively attention will be given to patients’ right to receive information (1.2.2), patients’ informational needs about drugs (1.2.3) and patients’ noncompliance with drug treatment (1.2.4).

1.2.2 Patients’ right to receive drug information

In the Netherlands legal requirements concerning patient information about drugs proceed from different regulations: the Medicine Supply Act, the Medical Service Contract Bill and the product liability regulations such as formulated in the Civil Code [1-3].

Until 1993 the Medicine Supply Act gave only a limited number of rules concerning the responsibility of pharmacists to inform patients about their drugs. These rules concerned pharmacist’s duty to put drug label instructions on all prescription drugs and to enclose a patient package insert, when a complete manufactured package was delivered to the patient [1]. The Dutch Medicine Supply Act however was recently changed, as the European Economic Commission decided that from January 1993 in all drugs marketed in European Community a user leaflet should be enclosed or clear instructions should be printed on their packages [2]. In interpreting the consequences of this rule one should take into account that Dutch community pharmacies also deliver pharmacy prepared drugs, which do not have to be delivered with a patient package insert. The Medicine Supply Act describes in detail the contents of the patient package inserts of drug manufactures. All drugs produced by drug manufacturers should enclose a patient package insert or equivalent information on the package of a drug [1].

In addition to the Medicine Supply Act, one may expect pharmacists to be faced with the consequences of the Medical Service Contract Bill, which has been introduced in april 1995 [3]. This bill embodies several patients’ rights, among which the right to receive information and the right to consent to a treatment. However, the Medical Service Contract Bill is explicitly not applicable to community pharmacists and concentrates on the relations between doctors and patients. This limitation has been experienced as rather disappointing by pharmacists [3].

With respect to patient education, the product liability regulations of the Civil Code have serious consequences for pharmacists. These regulations state that the pharmacist who
supplies drugs may be held liable for drug induced injuries that are related to the failure to provide complete and adequate drug information. To prevent this liability the pharmacists should include the manufacturer’s patient package inserts, when supplying industrially manufactured drugs. Regarding drugs prepared in the pharmacy, community pharmacists should be conscious of the necessity to deliver adequate drug information in order to prevent product liability risks [1].

In conclusion one may state that in the Netherlands neither the Medicine Supply Act nor the Medical Service Contract Bill, but the product liability regulations of the Civil Code seem to have the most far reaching consequences for practicing patient education in community pharmacy.

The legislation regarding patient education about drugs in the Netherlands and in Europe concentrates on written drug information. In the United States of America however legal rules have also been formulated about the verbal information about drugs and the trend seems to be towards patient counseling as a standard of care in pharmacy practices [4]. Pharmacists’ duty to counsel patients has been an issue in USA court cases since the 1930s. At least 40 states in the United States of America now have either a statutory or a regulatory requirement that pharmacists should counsel patients about outpatient prescriptions [5]. Since 1974 pharmacists of the state Washington have been required to explain orally and if necessary in writing to the patient or the patient’s agent directions to assure proper utilization of the medication prescribed [6].

1.2.3 Patients’ informational needs

Different instruments may be used to find out whether patients want to be informed about drugs. One could ask patients about their drug interests or perceived lack of drug information, or ask health professionals about the perceived informational needs of their patients. Another possibility is to look at patients’ drug informing behavior and to study the extent to which patients read patient package inserts and drug labels and what kinds of questions they ask about drugs. In interpreting the results of these studies one has to bear in mind that patients’ interests may not always result in drug related questions addressed to health professionals. For different reasons patients may not ask questions when they meet their doctors or pharmacists. For example patients may feel anxious or reluctant to ask questions, or do not have any questions at the moment they receive their prescription drug or Over The Counter medication (OTC). So patients’ informational needs may only partly result in drug questions in their contacts with doctors, pharmacists and drug information centers (as will be discussed in detail in chapter 2). In this section we will review studies about the knowledge, interests and priorities of patients concerning the different drug information aspects.
Patients’ knowledge

Patients’ lack of drug knowledge has been shown in several studies. Ascione interviewed 187 patients who used cardiovascular drugs for at least 1 month and found the highest scores for knowledge of the drug regimen and of the drug purpose. Fewer patients were correct about the appropriate action for a missed dose and only 10% reported correct side effect information about the drugs they were taking [7]. A national pharmacy survey in the United Kingdom among 8831 patients who were handed out prescriptions drugs, revealed that 55% did not know exactly how they should take their medicines while 42.5% did not know how to cope if adverse reactions occurred [8]. Among 85 patients receiving cardio-respiratory drugs, only 16% remembered having been told about the duration of use and 8% about the adverse effects [9]. Among 99 chronic patients with advanced chronic lung disease, only 17% gave correct answers to the questions about the name, indication, appearance and dosage schedule of the prescribed drugs. In addition, nearly one third of all the patients could not properly answer any of these questions about their medication [10]. Patients’ incorrect drug knowledge may be due to different kinds of failures of their communication with health professionals, which are listed in figure 1.1.

- Information has not been given
- Information has not been noticed
- Information has been forgotten
- Information has been misunderstood
- Information was contradictory

Figure 1.1 Communication failures

Patients’ interests

There is considerable evidence that patients want to be informed about their drugs. Consumer surveys concerning pharmaceutical services almost all indicate that the respondents desire counseling from their pharmacists [11-13]. Patients want to be informed about the different drug aspects, including the drug adverse effects [14]. Most patients like to be informed both orally and written about their drugs [8,15,16]. Studies among Dutch populations also conclude that patients want to be informed written and verbally about several aspects of OTCs and prescription drugs, such as the dosage schedules and other instructions about drug use, the effects and adverse effects [17-21]. Studies among visitors of community pharmacies in the USA have shown that the public is even willing to pay for pharmacist’s services in patient counseling [22]. Patient’s interests in drug information is also demonstrated in reviews of patient satisfaction studies [23].
1.2.4 Patient compliance

Patient compliance about drugs may be defined as the extent to which patients follow the drug instructions given to them by different health professionals. Patient education is also advocated after examining the results of studies that report about the frequencies and consequences of patient noncompliance, which could have been prevented by patient education. Reviews of compliance studies conclude that failure to take medications properly occurs in more than 50% of the cases [24-31]. The drug errors made most frequently are patients’ use of fewer or more than the prescribed drug dosages. Other frequently made drug errors are improper dosing intervals and wrong drug administrations [25,27,29-32]. Some drug applications, such as inhalers or eyedrops, in particularly can cause drug errors [33-35]. Boyd found that 31% of the 380 prescriptions studied were misutilized in a manner that posed a serious threat to the patients’ health [31]. Others found that 4-7% of all hospital admissions are the result of people’s failure to follow the instructions about drugs [36-37].

Compliance studies frequently report the importance of patients’ correct drug knowledge in preventing noncompliance [30-31,38-42]. Patients’ incorrect drug knowledge and lack of motivation to comply with the drug instructions given to them, could be due to different pitfalls in their communication with health professionals such as listed in figure 1.1. Patient compliance requires patients’ knowledge about drug instructions as well as patients’ agreement with the necessity to treat their disease, but patients are found to disagree frequently with the prescribed drug treatment [38]. They have to be convinced of the necessity and benefits of the drug treatment in order to be able to be compliant [43]. This requires patients’ involvement in the decisions about their drug therapies, which may be realized by communicating with patients about the different aspects of the proposed drug therapy.

1.2.5 Conclusion

For different reasons pharmacists and pharmacy technicians should be involved in patient education about drugs. Firstly, pharmacists will meet product liability problems if they dispense drugs without delivering the accompanying drug information. Secondly, patients nowadays want to be informed about the different aspects of the drugs they have to use and they want to receive written and verbal drug information. After all patient education is important in order to effect proper drug use and prevent noncompliance, as it is known that a lack of drug knowledge and motivation are the major reasons for noncompliance. In other words patients have to be informed about the drug instructions, their disease, the drug effects and drug adverse effects. Therefore, patients should be provided with information about their diseases and the necessity of drug therapy, while they also have to be informed about the drug instructions. The provision of drug information may however not be sufficient to overcome the
potential barriers for proper drug use and a personal contact may be needed to support patients in solving their drug problems.

1.3 Patient education: a new task of community pharmacists

1.3.1 Introduction

We will briefly describe the young history of patient education in Dutch community pharmacies, in order to provide some background information that may facilitate the understanding of the actual level of patient education in Dutch community pharmacies.

Pharmacists’ primary activity has always been oriented towards preparing and dispensing drugs rather than providing drug information to patients, which situation lasted until 1975. Before the year 1975 pharmacists were not allowed to deliver the package inserts of industrial drug packages to patients [1]. The introduction of pharmacists’ duty to deliver the enclosed patient package inserts with industrial drugs in 1975, may be viewed as a starting point for patient education in community pharmacy. From 1975 on individual pharmacists as well as different organizations who are involved in drug production, drug distribution and pharmacists’ education, have developed several activities and tools to support patient education in community pharmacy. We provide a short overview of these activities addressed to community pharmacists and about the educational activities of pharmacy schools and technicians’ schools with respect to pharmacists’ and technicians’ expertise on patient education.

1.3.2 The professional organization of pharmacists

One of the first activities of the Royal Dutch Association for the Advancement of Pharmacy (the KNMP) addressed to patient education has been the development of patient education materials about drugs. Several written patient information materials have been developed to support pharmacists in their patient education activities, which are continuously kept up to date. In addition, audiovisual drug information has been developed with the objective to educate pharmacy visitors about drugs while they are waiting in the pharmacy [44]. Another patient education activity of the professional organization of pharmacists is the Drug Information Telephone Center for patients, which started in 1990 [45-46].

The professional association of Dutch pharmacists provides her members with professional standards about pharmaceutical care. These standards have been updated recently and include several patient education statements. Figure 1.2 lists the statements about the objectives of patient education and about the kind of drug information pharmacists should provide [47].
Patient’s interest and own responsibility are the basics of patient education
- The pharmacist supports the patient to take well-considered decisions about drug use
- The pharmacist creates real opportunities to provide a personal advice to the patient
- Advice about selfmedication are based upon standards about selfcare
- Verbal and written drug information are given about the characteristics of drugs and advice about proper drug use and other aspects which are related with patient’s health

Figure 1.2  Pharmacists’ standards about patient education [47]

The listed standards demonstrate pharmacist’s responsibility in providing drug information about both prescription drugs and selfmedication. The standards also include aspects about the correctness, clearness and concreteness of the information given to patients. These kind of quality aspects of written drug information given to patients have also been discussed in the weekly magazine addressed to practicing pharmacists [48-49]. Also the quality of the verbal drug information given to patients in a community pharmacy has received attention in the pharmacists’ magazine [50]. The standards listed in figure 1.2 have been developed recently and are to be introduced in pharmacy practice in the near future, by using peer review and accreditation.

In 1992 the association of Dutch pharmacists has described her views and planned activities with respect to pharmacists’ position in the near future and emphasized the necessity of patient education in community pharmacy [51]. In 1994 the professional organization of pharmacists started a campaign which has the objective to improve pharmacists’ image among the general public. This campaign was needed as it was found that consumers were not aware of pharmacists’ activities in drug education [52]. In addition a working group developed standards about how to communicate with patients at the counter in community pharmacies [53].

Next to these activities of the professional association of pharmacists, groups of pharmacists have developed individualized drug letters in connection with their computerized medication control systems. These drug letters concern readable patient leaflets which include the selected information addressed to the individual patient. For example the letters addressed to male drug users do not contain extensive information about drugs and pregnancy or breast feeding, in contrast to the letters addressed to the female drug users [21,54].

1.3.3 Pharmacy schools and technicians’ schools
At the two faculties of pharmacy in the Netherlands patient education was introduced in the curricula in the mid 1980s [55]. One may state that at the moment about 10% of the practicing community pharmacists were taught about patient education during their university period. The technicians’ schools nowadays pay attention to patient education in their lessons about drug dispensing or in their lessons about people’s behavior [56]. In addition to technicians’ basic education, technicians’ schools have developed drug information courses for practicing technicians, which include patient education subjects [57]. No results have been published about the percentage of technicians that has been taught about patient education during their school period or after they left school.

In 1985 the pharmacy schools have started postgraduate courses about patient education for practicing community pharmacists [55]. These one-day postgraduate courses concentrate on different patient education subjects and since 1993 on these courses are also available for technicians. Figure 1.3 lists the patient education courses which have been provided to practicing pharmacists and pharmacy technicians at the university of Utrecht in 1995 [58].

![Figure 1.3. Postgraduate courses in patient education [58]](image)

At the moment about 300 out of the 1500 practicing community pharmacists have followed one of these postgraduate courses about patient education. In addition to these postgraduate courses, pharmaceutical companies provide courses about patient education to pharmacists and technicians.

### 1.3.4 Conclusions

Several initiatives have been developed to support pharmacists and pharmacy technicians in their efforts to practice patient education in community pharmacy. Pharmacists and technicians are nowadays taught about patient education during their educational period, while their colleagues who received school education at an earlier date may attend the patient education courses which are provided by pharmacy schools, technicians’ schools or by other organizations. In addition, patient information leaflets have been developed about individual drugs as well as about several drug groups, while the introduction of a computerized
prescription drug delivery system has realized a standardization of the drug instructions written on the drug labels. To what extent have these different activities been sufficient to support pharmacists and technicians in practicing patient education as one of their daily activities in community pharmacy practice? This question will be answered in chapter 2, which concentrates on the actual level of patient education about drugs in community pharmacies.

1.4 This thesis

This work deals with the development of patient education about drugs in community pharmacies. The first question to be discussed is whether there is a need for increased attention on patient education in community pharmacies. Therefore chapter 2 starts with an overview of the current level of patient education about drugs in relation with patients’ drug questions and the effects on patients’ drug use. Besides this, studies about the determinants and development of patient education behavior will be reviewed. Based upon this review the general research questions of this study will be presented in the last section of chapter 2.

Chapter 3 concentrates on behavioral and organizational change processes described in literature, in order to find out which individual and organizational variables are expected to play a role in pharmacists’ and technicians’ patient education behavior and how these variables can be influenced. Chapter 4 presents the research questions and research methodology of our study. As a quasi-experimental design was used, this chapter includes a description of an intervention program that was used to develop patient education in community pharmacies. We studied the effectiveness of this intervention program, while we also studied the determinants of patient education behavior. Chapter 4 also describes the dependent and independent variables that were studied and what kind of data collecting methods were used to answer our research questions.

The results of our study are presented in chapter 5. This chapter starts with the collected data about patient education activities in community pharmacies. Results are presented about the frequency and quality of the observed patient education activities. Chapter 5 also presents information about the pharmacy technicians who participated in our study. This chapter reveals the results about the determinants of technicians’ patient education behavior and the results of the intervention program on patient education in community pharmacies. Finally chapter 6 presents the conclusions of our study, which are discussed subsequently for their consequences regarding pharmacy practice and research into patient education about drugs.
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