

Usefulness of the patient information leaflet (PIL) and information on medicines from professionals: A patients' view. A qualitative study

Uporabnost pisne informacije o zdravilu (pmil) in informacije o zdravilih, ki jih poda strokovnjak: pogled bolnikov. Kvalitativna študija

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Izvleček

Izhodišče: Informacija o zdravilu za bolnika (PMIL) je pomemben vir informacij o zdravilih. Manj je znano, ali bolniki ta navodila berejo in, ali pri tem dobijo potrebne informacije. Bolniki dobivajo ustrezne informacije tudi od strokovnjakov (zdravnik, farmacevt, medicinska sestra). Informiranje bolnika o zdravilu je pomemben dejavnik, ki pozitivno vpliva na komplianco.

Namen študije je preveriti uporabnost PMIL z vidika bolnika in ugotoviti, katerim drugim virom informacij o zdravilih bolniki zaupajo ter predlagati izboljšave, ki bodo pri bolnikih povečale informiranost in s tem komplianco.

Metode: 4 fokusne skupine so bile oblikovane v različnih zdravstvenih zavodih v severovzhodni Sloveniji. Udeleženci, skupaj 20, so bili naključni bolniki, ki so bili pripravljene izraziti svoja stališča o PMIL, o drugih virih informacij o zdravilih in o možnih spremembah. Pogovori so bili posneti in po prepisu je bilo besedilo analizirano po kakovosti.

Rezultati: Bolniki berejo PMIL selektivno: najbolj jih zanimajo stranski učinki, kontraindikacije in namen, zakaj se zdravilo uporablja. Bolniki so poudarili, da je jezik v PMIL preveč strokoven. Če ne razumejo prebranega ali prepoznajo stranski učinek, se večina bolnikov odloči poiskati izbranega zdravnika in precej manjkrat medicinsko sestro ali farmacevta. Zdravnik jim je najbolj zanesljiv vir informacij. Menijo pa, da

bi farmacevti lahko zavzemali bolj dejavno vlogo pri poučevanju o zdravilih.

Zaključek: PMIL nudi zadosti delnih odgovorov, vendar bolniki v njem ne dobijo celovite informacije o zdravilu glede na svoje zdravstveno stanje, zato ga nimajo kot zadostni vir informacij. V PMIL pogrešajo večji poudarek ključnim informacijam in boljšo čitljivost besedila. Najbolj zanesljiv vir informacij o zdravilih je zanje družinski zdravnik. Farmacevti bi lahko prevzeli dejavnejšo vlogo pri poučevanju bolnikov.

Abstract

Background: The Patient information leaflet (PIL) is an important source of information for every patient. Little is known about whether patients read the PIL and whether it contains useful information. Other sources of drug-related information are professionals (a family practitioner, a pharmacist and a nurse). Informing patients on drugs improves their compliance.

The aim of the study was to identify the usefulness of PIL from the perspective of the patient, to assess professionals as a source of drug-related information and to suggest changes that can improve informing and therefore patients' compliances.

Methods: Four focus group interviews were conducted across different primary health care centres in the North East of Slovenia. Focus groups were composed of randomly selected patients (in total 20) who were willing to express their views

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on PILs, on other drug information sources and on possible improvements. A qualitative analysis of the data was based on the transcription of the audiotapes.

Results: Patients read the PILs selectively. They were most interested in side effects, contraindications and the purpose of the prescribed drug. Participants reported that the language in PILs is too scientific. In the case they do not understand PILs or they recognise some of the side effects, a majority of participants decide to contact a family physician first, and less frequently a pharmacist or a nurse. A family physician is considered

to be the most trustworthy source of information and patients think that pharmacists could play a more active role in patients' education.

Conclusion: Current PILs offer enough partial information to patients but need some improvements in terms of better legibility and access to the most crucial information. PIL does not enable a comprehensive information with respect to patient's health status. Most reliable source of information is considered to be a family practitioner. Pharmacists could play a more active role in the education of patients.

Introduction

Modern medicine is based on treatment with medications. The majority of prescription drugs are prescribed in family practices, therefore great responsibility for effective and rational prescribing lies with family doctors.¹ In Slovenia, 16,242,776 prescriptions were used in a population of 2 million in 2012, and patients received on average two prescription drugs each time.^{2,3} 75 % of family practice patients kept prescription drugs and 64 % kept over-the-counter (OTC) drugs stored at home and used them for self-medication in 83.6 %.^{4,5} The use of OTC drugs in the Slovenian student population for self-medication is even higher (92.3 %) and also higher than what is reported in studies from other cultures and populations.⁶⁻⁸ Therefore, communicating with patients effectively and educating them about drugs contributes to better knowledge of drugs, which is assumed to enhance patient adherence to treatment.^{9,10}

Written materials extend communication beyond the time of the actual consultation time and enables patients to become more familiar with all aspects of the drug taken. Patient information leaflets (PILs), which are attached to each packaging of drugs, are an important source of information for every patient. They are derived from the Summary of Product Characteristics (SmPC) and tailored to the needs of patients but often the terminology is too vague to be helpful for patients.^{11,12}

Findings from Israel show that 51.5 % respondents read PILs, which in 34.9 % caused some doubts and could have diminished their adherence to treatment.¹³ In the USA, when a new drug was prescribed, 56.2 % of patients who read PMIL understood the provided information well and in 63.8 % evaluated it as useful.¹⁴ PIL must be designed in such a way that 90 % of adult population can understand the information provided.¹⁵ User-friendly design improves patient adherence.¹⁶ Patients in the UK have some difficulties in understanding PILs' chapters on the interaction of drugs and contraindications.¹⁷ The same is true also when pictograms and illustrations are added to PILs, especially when patients over 65 years read them.¹⁸

Family practitioners are considered to be a very trustworthy source of drug-related information for patients and they influence patients' decision on medicine taking.¹⁹⁻²¹ Communication with patients and their inclusion in the treatment improves health outcome. In Slovenia, a time for doctor-patient consultation in family practice is very limited and it is not known whether patients obtain the information sought.

However, we currently have no account of the actual attitude of patients towards PILs, how they use and understand them and from who do they get useful information on drugs.

Aim of the study

The aim of the study was to discover the patients' views on the usefulness and quality of PILs and to investigate who is considered to be the most important source of information on medications for patients in Slovenia. On the basis of these findings, improvements will be suggested.

Methods

Family doctors from different regions (rural, urban) in the north-east of Slovenia recruited patients on a preselected day in a week by asking each fifth patient to take part in the study (random selection). The inclusion criteria were ability to communicate one's own views (targeted selection), absence of psychiatric illnesses and drug/alcohol dependence, adequate hearing ability and adequate mobility. 42 patients were asked to participate and 20 of these responded. Each patient received a written information leaflet on the study protocol and the approval of the National Ethics Committee. Participants signed a consent form. They were informed by phone of the time and location of a group meeting.

We formed four focus groups: 6 women (30–45 years old), 5 women (45–60 years old), 2 men and 2 women (30–45 years old) and 3 men and 2 women (58–73 years old).

The participants neither knew the moderator or the observer nor did they know each other. Each discussion lasted approximately 50 minutes. Participants were asked the following questions: "Do you read medication leaflets?", "Do you take into account the information you have read?", "Is the provided information useful and clear?" "Who offers you the most reliable information about drugs?", "Who else do you think can also inform you about drugs?", and "Are there any other issues we might have missed?"

After each discussion, which was audio-taped and then transcribed for qualitative analysis, the moderator and the observer met and exchanged information on the process. When the views began to repeat in the focus group and no new ideas on the subject

were offered, we stopped running new groups.^{22,23}

The content was analysed by two researchers and monitored by a supervisor experienced in qualitative analysis. Coding was performed with the aim of getting as many analytical categories and theoretical explanations from the transcripts as possible. The analysis followed the usual five-step process: information gathering, theme identification, coding/indexing, structuring and interpretation.²⁴

Results

After reviewing the data, identifying a thematic framework, indexing, charting, mapping and interpretation, three categories of statements with a subset of 10 themes were identified.

Attitudes of patients to PIL

Participants usually read PILs. A majority only read specific parts of PILs, which mainly depended on their focus of interest. Patients are interested in side effects, contraindications and how the medicines function. Some of them are interested in the chemical composition of the drug. All of them stressed that in case of drugs for children they read PILs in total.

Patients who wish to know the medicine and in case of dissatisfaction with a doctor's explanation were the most interested in reading PILs. Patients were convinced that bad experiences reported by other patients raised the necessity of reading PILs. In case of OTC drugs, the majority of patients paid greater attention to PILs. They shared the opinion that using more medicines would make them read PILs.

There was an interesting common statement that respecting the PILs depends on the prescribed medication. Antibiotic PILs are well respected. Some of the patients also respected PILs in order to get the desired treatment outcomes.

Quality of PILs

A majority of patients agreed that the information in PILs was not easy to un-

derstand and were too complex for a non-professional readership. There was a lot of criticism regarding the font size and paper quality. The majority of proposals were made regarding the writing style. Some proposed a change of the size of the sheet. All the interviewed patients agreed that the most important information should be marked in

bold. The general opinion was that PILs do not offer useful information to majority of patients.

Surprisingly, patients shared a satisfaction with the PILs in case that they do not have possibilities to get information elsewhere.

Table 1: Results of the qualitative analysis

Categories	Themes	Patients' quotations
First category: Patients' attitude to reading PIL	Theme 1: Reading PILs	"I read the contraindications section."; "I read the side effects section.; "...if I do read them, then I read the whole PIL."
	Theme 2: Relevant part of PILs	"I read about side effects."; "...always but contraindications."; "I am interested in how it (drug) works..."; "...for sure for kids, I always read in total."; "I check the composition, then if there are any allergies..."; "I check if there is anything new."; "I am interested in what the drug is for and if it is safe when driving a car or operating machinery."; "I always check expiry date. Seriously..., yes, same as in sausages."
	Theme 3: Factors influencing decision to read PILs	"...if I understood my doctor well, I would not read (PILs) anymore..."; "My doctor's advice is a rule for me ..."; "I went to a pharmacy, explained my needs, and they gave me the wrong thing ... yes, so in my experience, you must sometimes read (PILs)."; "...if the medicine is new, of course you read..."; "I would read due to my knowledgeable character..."; "...I check a little bit more, if I buy an OTC drug ... what medicine you can combine it with."; "...if I were to take more medicines at the same time, I would certainly read if they are compatible."
	Theme 4: Adherence to the PIL	"I always adhere to the information when using antibiotics... with other drugs I am probably less strict."; "...depends on the medication."; "I follow (advice) when I must, when taking antibiotics, I am very careful in following advice."
Second category: Quality of PILs	Theme 1: Usefulness of data in PILs	"They (PILs) do not mean anything to me."; "...not meant for a lay readership. They are more appropriate for healthcare professionals."; "...when you read, you start to imagine, hey, hey, I am really dizzy."; "The usefulness is minor, but it makes people unsecure a lot.;"
	Theme 2: Legibility of PILs	"A very small font size, the elderly are very pissed..."; "The paper is of low quality."; "A lot of information on a small sheet of paper."
	Theme 3: Satisfaction with PILs	"This kind of information should stay attached to the drugs."; "I agree that it is structured well, considerably satisfying."; "If something happens during the night, good Lord, why should I be worried... PILs are always there to read..."
	Theme 4: Views and proposal for the improvement of PILs	"It should be in bold, if it should be taken before a meal, on an empty stomach or... those items should be in bold."; "It must be stressed, how to take medication, with how much liquid... some take drugs with 'caffe au lait'."; "...less complicated, easier understandable, less text..."; "What really matters should be in bold."; "...paper size should be A4..."
Third category: Getting the most reliable information on medicines	Theme 1: Actions taken in case of unclear information in PILs	"I call the doctor..."; "My doctor is a low..."; "I stop medication and make an appointment with my family doctor."; "I will not take medication; if I was on a sick leave, then I would take it..."; "I continue until there is something critical."; "Let's say, if I have some specific question, I ask pharmacist or maybe a nurse."; "...I surf the Internet, there is much more information.;"
	Theme 2: Other professionals who can offer useful information	"Let's say, if I have some specific question, I ask pharmacist."; "Information point with somebody who knows medications very well would be useful."; "...abroad, clinical pharmacists are counsellors to patients and to physicians."; "In hospital, there are clinical pharmacists."

Getting the most reliable information on medicines

The patients were sharing common views on seeking additional information with a family doctor. Many also mentioned other sources such as the Internet and magazines. A majority of patients were critical regarding unclear information in PILs, but only a few of them stopped taking prescribed drugs. Some of them expressed complete trust in what their doctors had prescribed and pointed out the necessity of additional information in the area of consumerism. Patients told that they sometime get information on a drug from the nurse or the pharmacist and considered that (clinical) pharmacists should be more important counsellors regarding the use of medicines as they experienced abroad.

Discussion

Methods

We have chosen focus groups (FGs) to elucidate patients' views and their attitudes because group interactions provide more responses and convey more views than a simple interview or a questionnaire.²² FGs consisted of 6, 5, 4 and 5 participants, respectively and achieved the required number of 4–12 participants.²² We finished recruiting new focus groups when no new ideas arose during the discussion. The sample size was not determined by statistical rules but by others factor, such as representativeness of the participants (they know the scope, know how to express their own views) and data saturation. However, a sample of 20 participants was representative for the aim of the research and focus group study was concluded with the saturation of data.^{22–24} Further, different ideas could be gathered if some special social group were included in the research i.e. homeless people or members of a Roma community.

Analysing the data

Text analysis was integrated with the observer's notes (non-verbal communication, emphasis of specific topics, clarity of the

views expressed) and triangulation during analysis was performed. Patients responded with short sentences, which can indicate that they were unfamiliar with some of the topics discussed in the study. The researchers have found that patients emphasised the necessity of individual communication with the family doctor much more frequently than with e.g. a pharmacist or a nurse. Although the frequency of a specific answer is not important in a qualitative analysis, we can deduce that individual communication is important for patients.

The patient information leaflets (PILs)

Our findings confirmed the results of previous studies that patients read different parts of PILs.⁹ In Slovenia, patients are mostly interested in the purpose of a prescribed drug, about the regimen of medication and the side effects. In fact, patients seem to ignore the information in the PIL, which they do not understand. Generally, patients express satisfaction with specific parts of PIL which they had read and they did not highlight any new item compared to other studies.^{25,26} This general view indicates a rather low degree of patients' awareness that PILs offer much more information and that they can do more for safety of medication by adhering to instructions.

Surprisingly, they pay much more attention to PILs for antibiotics than those for more potent drugs which have more side effects. This could be the result of a well-designed social media campaign about the rational use of antibiotics in recent years or the result of the patients' belief that the use of antibiotics is linked to a serious disease.

Patients, who did not get adequate information about a prescribed drug from their doctor, were more often forced to read PILs. On the other hand, patients seek detailed information from their family doctors when the information in PILs is not understandable. This is in line with the findings of other studies, which reported that some PILs confuse patients' understanding.¹³ We can anticipate that patients who fail to obtain satisfactory answers from either source

would stop taking the prescribed medication. Moreover, health-care professionals,²⁷ the Internet²⁸ and other media²⁹ are consulted in case of ambiguous information in PILs, which supports the view of patients that PILs should include more understandable phraseology for lay readers.^{13,14} Also, the design, i.e. use of font and bold text can guide patients to read the most important parts of PILs.²⁶ Therefore, being advised to read PILs by their physicians would not improve patients' knowledge on drugs.

In spite of the general opinion that the PILs are difficult to understand, the majority of patients find the information they need. That may denote a low level of pretentiousness of patients to the content of PILs; patients can find out partial information in every PIL but they are usually unable to understand the content in its entirety. Therefore, encouraging patients to pay attention to PIL would not improve their understanding of medicine. Conversely, it can confuse patients or arise a number of questions that need to be discussed with a family doctor. According to this study, PILs do not render a time consuming doctor-patients communication on drug more efficient, and therefore other options have to be sought to improve patients' knowledge on drugs. The role of family doctors in informing patients regarding medication is stressed in each PIL by directing patients to consult their doctors in case they need any further information ('In case you need any further information, consult your doctor'), thus referring patients to communicate with them.^{27,30,31} The lack of family practitioners and the huge frequency of patients' visits a day makes it impossible to inform patients successfully.^{2,3}

Trustworthy information

Good information on drugs enables better adherence of patients to the directions and continuity of intake of medicines. In Slovenia, patients mainly asked the family physicians for more detailed information, therefore doctor-patient communication time should be extended and GPs also have to adjust their communication skills to the patients' expectations.

In practice, the number of daily GP-patient contacts is very high and spending more time with every patient in an already busy timetable is impossible.³ Currently, an increase in the workload is unacceptable for GPs. Due to the lack of doctors it is not possible to recruit new ones and the only way to solve this problem would be by involving an additional expert to do the consultancy on drugs.

The pharmacists

In Slovenia, there are no clinical pharmacists on the primary health care level yet although their presence would be very helpful and, according to the studies, the following services for this setting can be suggested: medication reconciliation, medication review, patient education, promotion of compliance, and involvement in the treatment.^{32,33} Some studies have also indicated a significant impact of pharmaceutical care on health outcome improvements, knowledge, medication adherence, medication beliefs and significant reduction in hospital admission rates.³⁴ Also, GPs could contact them while prescribing medicines. A health care team (e.g. a GP, a nurse, a clinical specialist and a pharmacist) could be more efficient at educating people about the importance of regular medical treatment, while the role of pharmacists and inter-professional collaborative practice in patient care from the economic, humanistic, efficacy, and safety perspectives remains a subject for future research.^{35,36}

Conclusion

The results of this study indicate that patients most appreciate information on drugs that are given by the experts in personal contact. Although PILs seemed to be a good source of information, patients do not consider them as sufficient. Additionally, reading PILs often results in patients' concern and therefore triggers further questions that require additional GP's time, otherwise intended for treatment and consultation. That could be a reason why physicians do not en-

courage patients to read written information on medicines.

To date, the most reliable source of information on the use and effect of medicines have been doctors themselves. The obstacle of the doctors' lack of time could be reduced by using an effective computer programme on medicines and their interactions, and by the decision to supplement the health care team at the primary care level with additional experts. The study has shown that health care policy in Slovenia could foster more ac-

tive involvement of a pharmacist as an important additional consultant on medication and education of patients in the primary care setting.

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