

THE ROLE OF INFORMATION FOR IMPROVEMENT OF PATIENTS' TREATMENT IN BULGARIA

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SUMMARY

Purpose: This issue is an attempt to assess patients' role as regards their compliance, respectively their non-compliance. The authors try to elucidate the factors concerning the patient-physician interrelation and patient-pharmacist interrelation that influence the non-compliance in order to increase the compliance rate.

Methods: Standard individual questionnaires and interviews were developed and applied to study an attitude to compliance and non-compliance among different categories of patients, suffering from chronic diseases.

Results: The obtained results show that the main reasons, influencing the patients' non-adherence to physicians' advice are: the high price of the drugs, the overburdened daily regimen, negligence, distrust towards the treatment and others. The insufficient information in the patient's leaflet together with the inappropriate drug form appears to be the main factors that cause non-compliance. This happens especially in the cases, when the patients are treated with more than one drug in different drug forms and particularly it concerns elderly people.

Even though the compliance among the patients investigated was comparatively high (50% to 92%), possibility for improvement still exists if the treatment that have to be initiated could be individualised. Thus the level of compliance will be improved and increased.

Discussion: The results from the data analysis show a great variation in the level of compliance among the chronic patients in Bulgaria. It ranges from 50 to 92%, depending on the type of the chronic disease and on the age of the patients. This fact shows the necessity for improvement of the different factors that has to begin as soon as possible.

Key words: medication, compliance, non-compliance, patient-pharmacist interrelation, patient-physician interrelation, information

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INTRODUCTION

This study was aimed to assess whether the chronic patients in Sofia, Bulgaria were compliant with their prescribed treatment and if not, what were their reasons for non-compliance?

Compliance is taking the correct amount of the correct medicine at the correct time and the problem of noncompliance is gaining more and more attention both within the pharmacy community as a part of the pharmaceutical care and among other health professionals as well.

Compliance is everyone's obligation. Non-compliance is a problem that has plagued medicine since its advent. Non-compliance occurs when a patient does not follow the advice of his or her physician. On the other hand nobody wants compliant patients who blindly obey the physician. The best decision is to have patients who understand better their conditions and both comprehend and agree with the advice of the pharmacists, e.g., patients who can be classified as "concordant". It is estimated that lack of concordance costs the health care industry over a billion dollars in hospital expenditure, loss of productivity at work and medico-legal issues. Concordance itself is a wide-ranging scope of possibilities. Non-concordance on the other hand ranges from a patient who does not take one aspirin a day to a patient who fails to continue with triple therapy for HIV treatment (1).

Non-adherence can manifest as either over- or under-dosing of medication and might be intentional, where patients refuse to follow advice through informed choice and argue that doing so is in their best interests, or unintentional, where informed choice is not exercised. Unintentional non-adherence can also be associated with problems in communication between patients and professionals; patients might have a poor understanding of what they are supposed to do or underestimate the severity of their illness (2).

It was elucidated that there are many factors that influence the level of compliance:

Physician's information

Perhaps there is a lack of effort on the part of the physicians to explain the treatment to the patient which consequently leads to ignorance of the doctor's advice. If the patient is unable to grasp the full extent of the disease he/she is less likely to be motivated and this will lead to non-compliance (1).

The Drugs

The implementation of new modern technology approaches for the creation of such contemporary drug forms like the microspheres, drug forms with controlled release and others, illuminates the role of the drug as a factor for the improvement of the level of adherence among the patients. The decrease in the drug release rate

by application of modified-release preparations allows drugs with short half-lives to be administered less frequently. Polypharmacy is often a factor and the number of drugs should be reviewed and reduced to a minimum before considering modified-release preparations. Patients' understanding of their condition and treatment should also be addressed if compliance is a problem (3).

Information Defect in the Patient Leaflets

The lack of information or the existence of inappropriate information is also a factor for unsatisfactory level of compliance. Patients do not retain all of the information that is given to them. In fact, it is reasonable to say that they will retain about half of it. That is why information included in the patients' leaflet is so important for literate patients. For any patient, the information must be reinforced and supportive. Also the information leaflets are an excellent way to provide patients with additional information. Patients should be told whether the side effects will appear, when they will appear, will they go away in time and if so, what is a reasonable period of time.

But at the same time some experiments revealed that patients who read complex drug information leaflets are significantly more confused, doubtful and overwhelmed than people who read simple or intermediate-level materials. Multifolded leaflets on thin paper, which contain large amounts of information, in small type and inserted in the pack do not invest the importance in the leaflet that professionals assume. There are also long and quite complex leaflets and an expectation that most patients will read them all on receipt may be unreasonable (4).

According to Bulgaria legislation and the corresponding regulations in force, that are in conformity with the WHO's directives, the main sections of the patient leaflets should contain information about the composition of the drug, therapeutic category, indications, contraindications, special warnings, precautions, interactions, adverse effects, dosage and storage conditions. Thus the leaflets should reinforce the information given by the physician and pharmacist. They should be written in clear, common language and printed in easily legible print.

Place of the Pharmacist

It is widely recognized that a combination of verbal information from health professionals and good quality of written information maximizes the benefits that patients get from medicines. Many researches studied what part pharmacists could play in effort to increase the level of compliance. Health care professionals, including pharmacists, do not maintain a systematic documentation. Lack of documentation had been shown to hinder effective information transfer between health care professionals, which could affect at large degree the patient care (5).

According to the Requirements of Board Regulations: "the pharmacists shall maintain patient confidentiality at all times. Confidential information shall include information maintained by the pharmacist in the patient's records or information which is communicated to the patient as part of patient counseling. As the latter is privileged it may be released only to the patient or to those practitioners and other pharmacists where, in the pharmacist's professional judgment, such release is necessary to protect the patient's health and well being; and to such other persons or governmental agencies authorized by law to receive such confidential information" (6).

The above-mentioned facts show the importance of the physician-patient-pharmacist relation and the role of information for the correct implementation and realization of the patient treatment.

MATERIAL AND METHODS

The aim of the study is to elucidate the factors, concerning the patient-physician and patient-pharmacist interrelation and also the role of information that influence the chronic patient's non-compliance in Sofia, Bulgaria.

The study was an inquiry survey, preceded by an interview (four different questionnaires are developed and applied). Four different categories of patients, suffering from chronic diseases are observed. Only patients suffering from chronic disease, with sufficient knowledge of Bulgarian for being interviewed and with corresponding writing and reading proficiency to fill in a questionnaire were included.

Cancer Patients

120 cancer patients on drug therapy from the National Oncological Center-Sofia were observed during the period 21.04-21.07.1998. A 22-itemed questionnaire was applied as a tool for assessment. The questions can be grouped in three groups:

- Patient's characteristics: age, sex, education, profession, and marital status.
- Factors, influencing the level of compliance: degree of family support, number of the daily administered drugs, changes in the daily regimen of the patient.
- Patients' information supply: received information about the drug treatment; information about the adverse drug reactions; availability of a good communication with the physician.

Recoverability of the questionnaires was 100%.

Asthma Patients

65 asthma patients from the Allergic clinic, University hospital "Alexandrovska" -Sofia were observed during the period 15.03-15.10.1999. A 37-itemed questionnaire was applied as a tool for assessment. The questions can be grouped in four groups:

- Patient's characteristics: age, sex, education, profession, and marital status.
- Factors, influencing the level of compliance: permanence of the disease, degree of family support, number of the daily administered drugs, changes in the daily regimen of the patient.
- Patients' information supply: received information about the drug treatment; information about the adverse drug reactions.
- Patient-physician and patient-pharmacist interrelation: availability of a good communication with the physician and with the pharmacist.

Recoverability of the questionnaires was 93%.

Melting Pot of Pharmacy Patients

200 patients from two private and two municipal pharmacies from Sofia, suffering from one or more chronic disease like diabetes, depression, hypertension, coronary heart disease and arthritis, were observed during the period 01.11.1998-01.02.1999 and the second group of 60 patients was observed during the period 01.06.2001-01.09.2001. These chronic diseases require the regular administration of one and more drugs, the compliance is very

important for the achievement of good therapeutic results and that is why these patients were chosen as a object of the research. A 17-itemed questionnaire was applied as a tool for assessment. The questions can be grouped in four groups:

- Patients' characteristics: age, sex, education, and marital status.
- Factors, influencing the level of compliance: permanence of the disease, degree of family support, number of the daily administered drugs, changes in the daily regimen of the patient.
- Patients' information supply: information in the drug leaflet, the information and appearance of the drug package, the prize of the drug.
- Patient-physician and patient-pharmacist interrelation: availability of a good communication with the physician and with the pharmacist.

Recoverability of the questionnaires was 63% in 1998-1999, and 100% in 2001 respectively.

Elderly Patients

Pharmaceutical therapy is the most common medical intervention used to treat the elderly. The variations in response to medications among the elderly result in part from wide differences in numbers and patterns of coexisting conditions, organ function, frailty, cognitive ability, and capacity to perform activities of daily living. Since these factors differ by age, drug therapy requirements and problems may differ across "younger-old" (ages 65-75), "older-old" (76-85), and "oldest-old" (86+) age cohorts (7). By the seventh decade of life, three out of four people suffer from at least one chronic disease and more than half have two or more diseases (8).

40 elderly patients from "House for elderly people"- Sofia, that belong to the groups "younger-old" and "older-old" and that suffer from one or more chronic disease, such as arthritis, high blood pressure, depression, heart disease and other, were studied during the period 01.12.1998-08.02.1999. A 10-itemed questionnaire was applied as a tool for assessment. The questions can be grouped in four groups:

- Elderly patients' characteristics: age and sex.
- Factors, influencing the level of compliance: permanence of the disease, number of the daily-administered drugs.
- Patients' information supply: information in the drug leaflet, the information and appearance of the drug package, the prize of the drug.
- Patient-physician and patient-pharmacist interrelation: availability of a good communication with the physician and with the pharmacist.

Recoverability of the questionnaires was 100% for the elderly patients.

Thanks to the answers in the questionnaire the main factors that influence the compliance were determined and especially the role of the information. For the statistical work up of the collected data percentage /%/ as a generalized characteristic (± 1.96 SD) was used. Standard error of the percentage (SEp) is calculated by the formula:

$$\text{SE percentage} = \sqrt{\frac{p(100-p)}{n}}$$

p - percentage

n - number in the sample

The procession of the received database was performed by application of contemporary computer programs –Excel, Statistica.

RESULTS

The 406 interviewed patients suffer from different types of chronic diseases: 120 (30%) – from variations of drug-treated cancer, 60 (14.8%) – from asthma, 186 (45.8 %) – from hypertension, diabetes, depression and other chronic diseases and 40 (9.4%) – from one or more chronic diseases typical for the elderly patients (Fig 1).

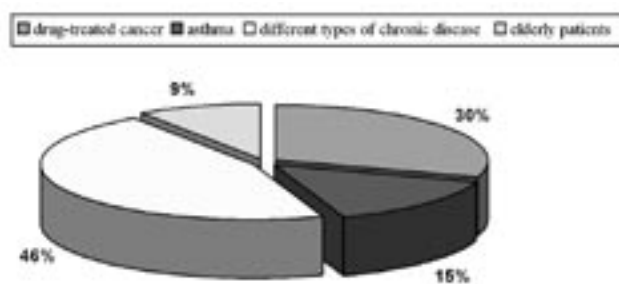


Fig. 1. Distribution of patients by disease.

Cancer Patients

About 7% of the cancer patients (SEp=2.32) are not satisfied with information on the drug they can read in the patients' leaflet. There is not enough information about the possible adverse drug reactions (ADR) that can appear in the process of the treatment or if such information is available it makes them feel more confused and doubtful about their treatment. Patients need to be told whether the ADR will go away in time and if so, what is a reasonable period of time. Unfortunately such an information is not available in the leaflets and this fact leads to non-adherence because of the sever ADRs that are unexpected and too complicated for this group of chronic patients (Fig 2).

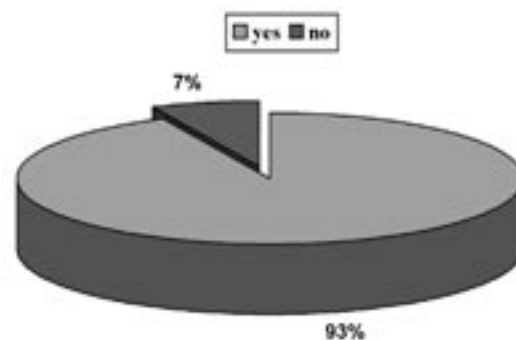


Fig. 2. Satisfaction of cancer patients with the information in the drug leaflet.

The cancer patients are to some degree satisfied with regards to their opportunity to communicate with their physician every moment they have doubts about their treatment. Only 5% (SEp=1.99) of them rarely get information from their physician about the way of treatment, while 63% (SEp=4.4) are satisfied with their physician's attitude (Table 1).

Table 1. Patient-physician interrelation (cancer patients)

	Always	Often	Sometimes	Rare	Never
Percentage	63%	22%	10%	5%	0%

There is no information about the patient-pharmacist interrelations, because the interviewed patients were hospitalized and obtained their medication in the hospital ward and had therefore no direct contact with the hospital pharmacists.

Asthma Patients

More than one third of the asthma patients 39% (SEp=6.29) are not satisfied with the information provided in the patients' leaflet. They do not find the necessary information about the application of the drug form, which is more complicated especially for the inhalation drug forms. The use of these drug forms need to be explained more in details, thus preventing their misuse, improper dosing and consequently not achieving the expected treatment effect. According to the patients, there is not enough information in the sections "contraindications, special warnings, precautions, interactions, adverse effect" about the possible ADR that can appear in the process of the treatment. This leads to therapy non-compliance because improper use of drug and fear from appearance of unexpected drug reaction could lead to worsening of the patient's physical status (Fig. 3).

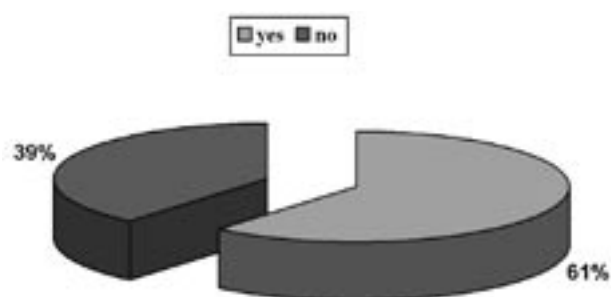


Fig. 3. Satisfaction of the asthma patients with the information in the leaflet.

As regards interrelation of asthma patients with their physicians it appears satisfactory. Only 29% (SEp=5.85) of them do not get information from their physician about the way of treatment, while 43% (SEp=6.39), almost one half, is not satisfied with the information about the possible ADR (Table 2).

Table 2. Patient-physician interrelation (asthma patients)

	Way of treatment	ADR
Satisfied	71%	57%
Not satisfied	29%	43%

The asthma patients' opinion about the patient-pharmacist interrelation is that only 14% (SEp=4.48) of the patients are not informed about the way of treatment with the drug they obtain in the pharmacy and 29% (SEp=5.85) do not receive information about the possible ADR that can accompany the treatment (Fig. 4).

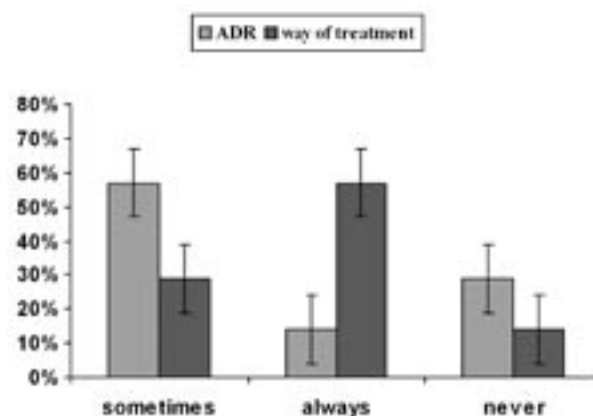


Fig. 4. Information given by the pharmacists to the asthma patients.

Pharmacy Patients

More than one third of the pharmacy patients, 36% (SEp=3.52), are not satisfied with the information in the patients' leaflet. This group includes patients that suffer from different chronic diseases, so this fact concerns a wide group of drugs – antihypertensive, psychotic, antidiabetic drugs and many others. As in the two groups before, these patients do not find enough information in the leaflets sections about the way of drug application, the frequency of drug use and details about possible ADR that could appear in the process of the treatment and whether the side effects would go away in time and if so, what is the expected period of time for that. This ill information is one of the main factors that lead to non-compliance (Fig. 5).

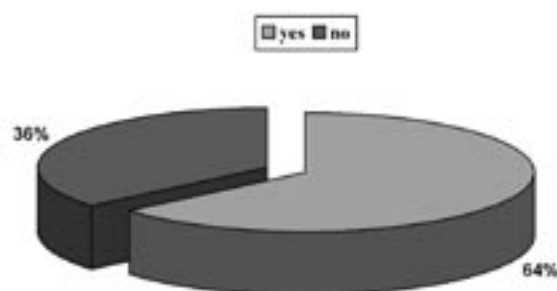


Fig. 5. Satisfaction of the pharmacy patients with the information in the leaflet.

The pharmacy patients are to some degree satisfied with the information they get from the physician, concerning their medication. Only 24% (SEp=3.13) of them do not get enough information from their physician about the way of the treatment, about one third 27% (SEp=3.25) do not have a free access to their physician when they need any additional information about the treatment and almost one half 46% (SEp=3.65) do not get exact information about the possible ADR (Table 3).

Table 3. Patient-physician interrelation (pharmacy patients)

	Drug application and way of treatment	Contact	ADR
Positive	76%	73%	54%
Negative	24%	27%	46%

The patient-pharmacist interrelation in this group is more thorough. About 36% (SEp=3.52) do not get information about the drug – way of application, frequency of use or possible ADR. And 45% (SEp=3.64) are not contented with the time the pharmacist has spend to talk with them about the treatment (Fig. 6).

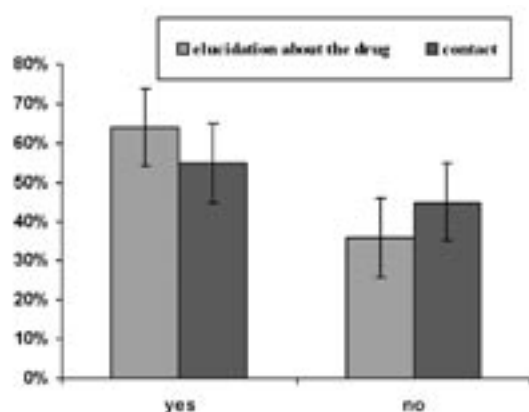


Fig. 6. Satisfaction of the pharmacy patients with the information obtained from the pharmacist.

Elderly Patients

About one forth of the elderly patients 17% (SEp=5.94) have a negative attitude towards the information in the patients' leaflet. This group of people is unable to read drug labels and patients leaflets, because of the small letters. Most of them declare that because of that fact they very rarely open and read the leaflet. This fact leads to appearance of: ADR because of a lack of information about the proper dosage regimen; inappropriate way of application of the drug form, improper combination with other drugs and unacceptable storage conditions, that bring about non-adherence among these patient (Fig. 7).

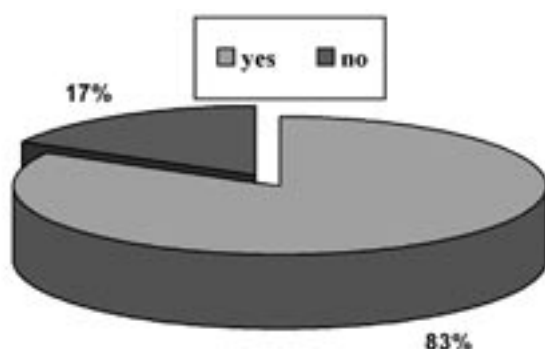


Fig. 7. Satisfaction of the elderly patients with the information in the drug leaflet.

The elderly patients are satisfied with their interrelation with physician, concerning their medication. Only 10% (SEp=4.74) of them do not get enough information from their physician about the way of the treatment (Fig. 8).

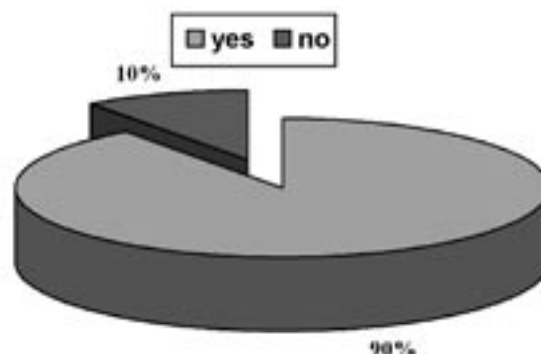


Fig. 8. Satisfaction of the elderly patients with their contact with the physician.

Their attitude towards the patient-pharmacist interrelation is a little bit more negative – 15% (SEp=5.65) are not totally contented with the time spent in the pharmacy and with the completeness of the pharmacist's answers (Fig. 9).

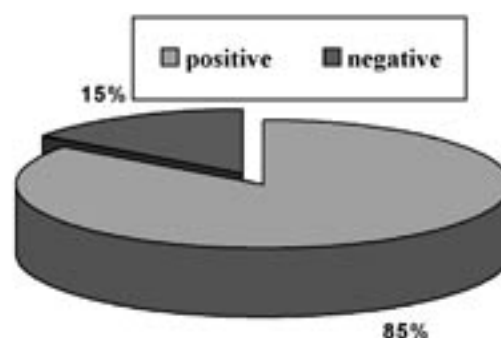


Fig. 9. Attitude towards patient-pharmacist interrelations.

The level of compliance among the studied groups of patients is as follows:

- 92% for the cancer patients;
- 86% for the asthma patients;
- 69% for the pharmacy patients
- 59% for the elderly patients (Fig. 10).

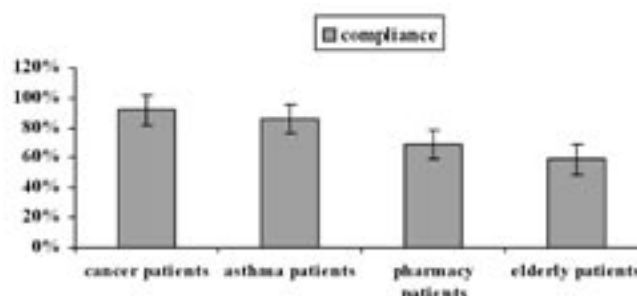


Fig. 10. Level of compliance among the different group of patients.

DISCUSSION

From the above-mentioned results we can conclude that the chronic patients in Sofia, Bulgaria, that suffer from one or more of the most common chronic diseases are to some degree compliant with their prescribed treatment. The level of compliance among the studied groups of patients ranges from 92% for the cancer patients to 59% for the elderly patients, depending on the type of the chronic disease, the age of the patients and on the number of the applied drugs. The obtained data confirm the results from other studies, according to which the level of compliance varies from 92% to 50% for patients, suffering from different chronic diseases (9). The level of compliance among the elderly patients in the other countries varies from 50-60% and even sometimes to 25% according to them (10). These results show that the situation in Bulgaria is similar to that one in other countries as to chronic patients' attitude toward their drug treatment. But it can be hard to point out the main reason for their non-compliance.

The results from the survey show that one of the main factors that has an influence on the level of non compliance seems to be the information – obtained from the leaflets, from the physician or from the pharmacist. The different attitude of the interviewed patients toward these sources of information shows the possible spheres, which have to be improved in order to achieve a better level of compliance and better treatment.

The long and quite complex leaflets make most patients non-compliant (4). This concerns especially those ones aged above 65 years. Special decree, concerning the leaflets for older patients, targeting this sector of population will certainly help since its size increases every year and elderly people are the consumers of a great part of drugs because of their multi-morbidity.

As health-care professionals, the pharmacists are those who can increase the benefits from the drug treatment by application of the pharmaceutical care, thus combining the written information with the verbal one. In the practice of pharmaceutical care,

it is the pharmacist's responsibility to identify whether a patient would comply or would not and try to identify any cause or reason for noncompliance. When the pharmacist takes the time to counsel patients and explain the purpose and appropriate use of each medication, patient compliance tends to improve (11). The building up of a monitoring system on the treatment is necessary for the pharmacists in Bulgaria, in order to learn that the given information was well understood and would lead to good compliance of the patients with their prescribed treatment.

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