Medication interest in pregnant women

Interes za zdravljenje z zdravili pri nosečnicah

Rok Antolič,[1] Marko Polič,[2] Lovro Stanovnik,[3] Živa Novak Antolič[4]

[1] *Lekarna, Univerzitetni klinični center Ljubljana*

[2] *Filozofska fakulteta Univerze v Ljubljani*

[3] *Inštitut za farmakologijo, Medicinska fakulteta Univerze v Ljubljani*

[4] *Klinični oddelek za perinatologijo, Ginekološka klinika, Univerzitetni klinični center Ljubljana*

Korespondenca/ Correspondence:
mag. Rok Antolič, mag. farm.
rok.antolic@gmail.com

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Izvleček

Izhodišča: Komplianca zdravil je jemanje zdravil v skladu z navodili zdravnika in farmacevta. Izraz komplianca označuje pasivnost, izraz adherenca za zdravila pa vključuje še aktivno sodelovanje bolnika. Strokovnjaki uvajajo izraz interes za zdravljenje z zdravili (*angl.* medication interest). Nizek interes za zdravljenje z zdravili (v nadaljnjem besedilu interes za zdravljenje) vodi v neučinkovito zdravljenje in dodatne zdravstvene zaplete, če pri tem slabe finančne učinke povsem zanemarimo. Med študijem farmacije in med študijem medicine interes za zdravljenje (komplianca, adherenca) obravnavamo zelo skromno. Prepričevanje odraslega, ki je razvil negativen odnos do jemanja zdravil, je manj uspešno. Pravilen odnos do zdravil začnemo razvijati s pravilnim pristopom pri otrocih, mladostnikih in nato pri odraslih. Tako kot na primer razvijamo odnos do prometa in učimo prometna pravila. Farmacevtska industrija nezadržno prepričuje zdravnike in farmacevte o čim večji uporabi zdravil; delavnic, na katerih bi se zdravniki in farmacevti naučili, kako zviševati interes za zdravljenje pri bolnikih ter za preventivno jemanje, ni. Vrzel je vsekakor potrebno zapolniti. V Sloveniji porabimo za zdravila na leto kar 600 milijonov evrov, od katerih jih veliko sploh ne uporabimo. Tu so velike rezerve: vendar je treba ugotoviti, zakaj je interes za zdravljenje nizek, nato pa zdravnike, farmacevte in bolnike o tem podučiti.

Pravilno jemanje zdravil je izredno zahtevna naloga za mnoge bolnike in za zdravnike, farmacevte, medicinske sestre ter vse, ki skrbijo za bolnike. Po nam znanih in dostopnih podatkih v Sloveniji ni poročil o sistematičnem preverjanju interesa za zdravljenje. Nikakor pa ne smemo predpostavljati, da v Sloveniji problema nizkega interesa za zdravljenje ni.

Razlogi za nizek interes za zdravljenje so raznoliki: medicinski, psihološki in okoljski. Med seboj se prepletajo.

Za skupino nosečnic v Sloveniji ne poznamo podatkov o interesu za zdravljenje, razen za preventivno jemanje folne kisline. Preventivno jemanje folne kisline je zaradi nizkega interesa za zdravljenje po mnenju strokovnjakov največji neuspeh javnega zdravstva nasploh. Res je neverjetno, da tako preproste, učinkovite in poceni primarne preventive zelo hudih prirojenih napak nevralne cevi ne upošteva niti šestina bodočih nosečnic. Z ugotavljanjem interesa za zdravljenje in preventivo ter razlogov za morebiten nizek interes lahko pri nosečnicah začnemo z izboljševanjem tega perečega problema.

Metode: Raziskati smo skušali interes za zdravljenje pri nosečnicah. V raziskavo smo vključili otročnice, ki so v Porodnišnici Ljubljana rodile ob pričakovanem dnevu poroda (več kot 37 tednov) zdravega enojčka. Raziskavo je odobrila Komisija za medicinsko etiko RS (št 27/07/09). Anonimno smo anketirali otročnice v prvih nekaj dneh po porodu. Januarja 2010 je potekala pilotska raziskava pri 50 otročnicah, od 1.2.2010 do 14.4.2010 pa glavna raziskava pri 263 otročnicah.

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Spraševali smo jih, katera zdravila so jim predpisali v nosečnosti in v kolikšni meri so zdravila jemale; povprašali smo jih o njihovem odnosu do jemanja zdravil na splošno ter o jemanju folne kisline.

Rezultati in razpravljanje: Na vprašalnik je odgovorilo 259 udeleženk. Zdravila na recept so v nosečnosti predpisali v 71,9 %, zdravila brez recepta pa je dobilo 75,7 % nosečnic. Tako je 57 % nosečnic dobilo zdravilo na recept in tudi zdravilo brez recepta; 19,8 % je dobilo samo zdravilo brez recepta in 16,3 % samo recept za zdravilo. Samo 7 % nosečnic ni dobivalo zdravil. V prvem delu raziskave smo ugotavljali interes za zdravljenje. Za zdravila zoper akutne težave (antibiotiki, analgetiki, vagitorija) je bil po samooceni udeleženk interes 61,4 % pri 57 nosečnicah, ki so jim bila ta zdravila predpisana. Interes za kronično zdravljenje (inzulin, antihipertenzivna zdravila in drugo) je bil pričakovano visok: 17 od vseh anketiranih so bila ta zdravila predpisana in 12 (70,6 % od 17) je ta zdravila tudi pravilno jemalo. Ta skupina je zelo majhna, tako da je ugotovitve potrebno preveriti še na večjem številu udeleženk. Interes za zdravljenje s pripravki železa (predpisano 86 udeleženkam) je bil 47,7 %. Glavni razlog za nizek interes za zdravljenje je bil pozabljivost. Ostali razlogi so bili slabost, slaba razlaga in različna navodila zdravnika in farmacevta.

V drugem delu raziskave smo spraševali o splošnem odnosu do zdravil. Ugotovili smo, da udeleženke zaupajo zdravnikom, zaupanje farmacevtom pa je bilo opisano kot nekoliko manjše kot zaupanje zdravnikom. Pisna navodila uporabnic niso prestrašila. Motivacija za jemanje zdravil s strani zdravnikov je bila dobra. Zaznava tveganja za neželene učinke zdravil je bila visoka. V tretjem delu smo ugotavljali pravilnost preventivnega jemanja folne kisline. Preventivno je pravilno jemalo folno kislino samo 19 % od 259 udeleženk, kar je s stališča javnega zdravja izjemno zaskrbljujoče. Udeleženke smo povabili, naj na koncu napišejo komentar; odzvalo se jih je 68. Predvsem je udeleženke begalo dejstvo, da dobijo lahko določena zdravila brez recepta in to, da je nekatera zdravila treba plačati tudi v nosečnosti. Včasih je veljalo, da je zdravilo tista snov, ki jo zdravnik predpiše na recept in je (na videz, saj Zavodu za zdravstveno zavarovanje zavarovanci plačujemo) zastonj. Zdravil na recept večinoma ni dovoljeno oglaševati. So pa zdravila, ki so v prometu že dlje, dobijo se brez recepta ter jih je dovoljeno oglaševati. Zaradi obilice reklam je veliko nosečnic prepričanih, da se da večino bolezni pozdraviti s t. i. naravnimi sredstvi. Veliko udeleženk je menilo, da bi bilo smiselno zdravila, ki jih bolnik ne potrebuje več, vendar so še uporabna, uporabiti. Skrbelo jih je tudi onesnaževanje okolja z nepravilno odvrženimi zdravili. Želele so, da bi zdravniki predpisovali manj zdravil oz. da zdravila predpišejo le takrat, ko je to res potrebno. Zaskrbljene so bile zaradi slabe osveščenosti prebivalstva glede jemanja zdravil.

Zaključki: Interes za zdravljenje z zdravili je primerljiv s podatki iz literature. Zdravila so bila predpisana večini nosečnic. Večina nosečnic je ob tem nabavljala tudi zdravila, ki so na voljo brez recepta. Preventivno so folno kislino nosečnice pravilno jemale le v 19 %. Izrazito nizek je interes za zdravila, ki se jemljejo preventivno. Kako je mogoče, da obveščena populacija zaradi pozabljivosti ne jemlje edine poceni nenevarne snovi, za katero je dokazano, da značilno primarno prepreči hude anomalije nevralne cevi?

Interes za zdravljenje z zdravili lahko povečamo. Najprej moramo nujno vedeti, kolikšen je interes in kakšni so razlogi za nizek interes, da bi bili lahko ukrepi učinkoviti.

V slovenski strokovni literaturi nismo našli izraza interes za zdravljenje z zdravili, zato smo, kot je nam znano, prvi vnesli izraz »interes za zdravljenje z zdravili« v slovenski strokovni prostor.

Abstract

Background: Low medication interest leads to insufficient treatment, additional hospitalisations and complications, even if we do not consider financial burden. Appropriate attitude regarding medication interest should be taught from young age on: just as we do with traffic education. The problem of medication interest is mentioned in medical school and taught in pharmacy school. Persuading adults, who already have developed low medication interest, is difficult. Pharmaceutical companies continuously "work on" physicians and pharmacists promoting drug use. There are no workshops to teach the same people how to increase medication interest. We did not find any publication regarding systematic surveillance of medication interest in pregnant women in Slovenia. It should not be supposed that the problem of low medication interest does not exist.

Methods: 50 women in a pilot survey and 263 in the main survey were anonymously questioned about drug treatment in pregnancy, their attitude regarding medication and preventative folic acid use.

Results: Responses were obtained from 259 women: 57 % pregnant women were prescribed drugs and bought non-prescription drugs; 19.8 % only bought non-prescription drugs, and to 16.3 % women drugs were prescribed only. Medication interest for acute treatment among 57 participants, who were prescribed such drugs, was 61.4 %, for chronic (out of 17 prescribed) 70.6 %, and 47.7 % (out of 86 prescribed) for treatment with iron. Pregnant women trust their physicians and pharmacists and are not frightened by written instructions for drug use. Motivation by physicians is good. The main reason for low medication interest is forgetfulness. Risk perception is high. Only 19 % of pregnant women took folic acid properly.

Conclusions: Medication interest is comparable to literature data: relatively high for acute problems, relatively low for iron supplementation and extremely low for preventative folic acid intake. As to our knowledge, we were the ones to introduce the term »medication interest« into professional literature in Slovenia.

Introduction

To achieve correct medication is quite a difficult task for many physicians, patients, pharmacists, nurses, family members and all the others who take care of patients. Medication costs comprise direct cost of drugs and also financial burden of non effective treatment and complications.[1] Of course, the first step is to know what medication interest is like.

The terms compliance and adherence to drug use should be substituted by a term that does not have a negative connotation and that also tells something about patient motivation. Trust should be built from the first encounter of the patient with physician: the patient should feel that they are both allies against the patient's illness. This alliance among physician/ pharmacist, patient and his relatives, nurses, social workers and others is best described by a positive expression medication interest. Medication interest is on average 50 % and varies from 15 to 93 %.[1,2] On average half of all patients with chronic therapy stops taking medication in one year; at least one third of the patients are thus endangering their lives seriously.[2] Low medication interest is the most important single factor determining the outcome, effectiveness and cost of treatment.[3]

Slovene authors have published many articles regarding medication of psychiatric patients, menopause patients and data on drug prescribing, but there are no systematic data regarding medication interest. It is supposed to be similar to the literary data. In one year approximately 600 million Eur are used for drugs and, after some estimates, about 20 % of drugs are directly thrown away. In 2004, in the population over 65 years of age, 53094 people were prescribed 8 or more different groups of drugs. The standardised index rose from 100 to 182 (almost doubled) from 2004 to 2009 for those being prescribed 15 drugs or more.[4]

Medication interest is difficult to measure. The most used methods are subjective as is self-reporting of the patient. Visual analogue scale is one of the methods used,[5] interviews and questionnaires are others. Invasive methods like drug level in blood or urine are as subjective as the former because patient may not take the drug for a long period and then take it just before the check-up. Indirect methods as e.g. electronic device measuring how many times the bottle was opened do not tell if the drug was really taken. In conclusion, prescription of drug does not mean the patient will go to pharmacy and get the drug and getting the drug from the pharmacy does not mean the patient will take the drug. Regarding the use of questionnaire, i.e. the most widely used method, many questions are still open. When should we ask the patient? In the case of acute illnesses, the appropriate time is when the patient returns for a check up. Should physician or pharmacist, when there are many patients waiting, inquire about medication interest? Although it is difficult, it is most feasible. Or give the patient the questionnaire to answer at home and send it back? There is always possibility that the patient would want to please the physician or the pharmacist and write ideal answers, not real ones. Visiting patients at home and asking them questions does not necessarily give more

accurate results. In one study in Slovenia it was checked how many drugs people have at home;[6] it is not possible, however, to conclude how many drugs were properly used in that way.

Causes for low medication interest are intertwined and are medical, psychological and environmental.

Among medical are: severity of the disease, medical condition, long-term medication, disease itself precludes proper intake (blindness, immobility, dementia etc). Severe or frequent side effects lower the interest. The perception of risk is more a psychological entity, and so are low motivation, low trust in physician, denial of disease (taking drug itself means that the disease exists), different perception of disease by the patient, complicated drug intake, and others. Environmental causes are: foreign language, affordability, lack of time, difficult accessibility, difficulties to open the drug box or bottle etc. Insufficient explanation when the drug is prescribed can thus be intertwining of all three causes. When physician, in a limited time s/he has, makes the diagnosis and is satisfied with that, s/he decides which treatment is necessary; less time is available to persuade the patient of necessity to take the prescribed drugs. If the patient has severe problems, s/he will start taking drugs. If not, and not having the opportunity to discuss the medication at length, s/he will search information from others, often lay people. Not knowing the details, it is only a small possibility that the information s/he gets is appropriate. Focusing on unwanted side effects described in the leaflet accompanying the drug, which might not have been mentioned by the physician, further decreases the probability that the drug will be taken. Even if a patient starts taking the medication, the perception of the "high price" of side effects in comparison to improvement of the illness demotivates the patient from continuing the medication.[7] Patients perceive drugs that could be bought without prescription as completely safe, which of course is not true.[8]

Pregnant women represent a group where medication interest is a special problem. Only healthy or properly treated pregnant women can deliver a healthy newborn. But pregnant patients are afraid that the drug might harm the baby; so sometimes they do not take the drug. Because of not taking antibiotics for urinary tract infection preterm delivery might occur. On the other hand, pregnant women take different non-prescription drugs and nutritional supplements without asking physician or pharmacist about risks – which might be real, as only drugs are strictly controlled. Perception of teratogenic risk is higher than real risk.[9] Counselling decreases the perception of risk in those pregnant women who were exposed to non teratogenic agents; in those exposed to teratogenic agents the perception of risk did not decrease.[10,11]

Projections of WHO show that from 2012 onwards depression is going to be the most frequent disease. The number of women, future pregnant women, taking antidepressants is increasing. In spite of assurance that the chosen drugs are not teratogenic, 15 % of pregnant women stopped taking antidepressants.[12] The percentage is much higher compared to those pregnant women who stopped taking antibiotics (1 %).

Neural tube defects (NTD) are second largest group of congenital anomalies, the first being heart anomalies. Closing of the neural tube takes place from 16th to 27th day of embryonal life. One of the main causes is relative deficiency of folic acid together with genetic factors. Extremely grave congenital anomalies can be prevented by a simple and cheap method of primary prevention. It was shown[13] that 400 µg (4000 µg for women with chronic diseases) of folic acid, taken from conception until the 8th week of pregnancy, prevents more than 70 % of NTD. Primary prevention possibilities – except for vaccinations – are relatively scarce. Low levels of folic acid were found also in other complications in pregnancy.[14-18]

We do not know medication interest in the group of pregnant women in Slovenia; there are some data on low medication interest for preventative folic acid consumption – only 15 % of pregnant women used folic acid properly.[19] The aim of the present survey was to establish the medication interest for acute, chronic, iron and preventative drug intake in a group of pregnant women.

The study was approved by the Ethical Committee of the Republic Slovenia (No 27/07/09 from 2.9.2009).

Methods

The anonymous survey took place at the University Medical Centre, Department of Obstetrics and Gynecology, Division of Perinatology. In the pilot survey carried out in January 2010, 50, and in the main survey, which took place from February 1 to April 14, 263 women in the first days after delivery were given questionnaires regarding drug intake during the pregnancy that had just ended with delivery. Inclusion criteria were: delivery of a healthy child after 37 weeks of singleton pregnancy. All women consented to participate in the survey.

The first author himself developed the questionnaire with 58 questions. The first part of the questionnaire comprised questions regarding the use of drugs in pregnancy, while the questions in the second part referred to attitudes regarding drug use in general. Participants answered on the 5-point scale ranging from "I strongly agree" to "I strongly disagree". The third part of the questionnaire included questions regarding the preventative use of folic acid. The questionnaire was first tested in a pilot study and some corrections were made for the main survey.

Statistical analysis

For statistical analysis, SPSS program for Windows version 17 was used. Categorical data were analysed with the chi-squared test; for multivariate analysis of factors affecting proper drug intake a logistic regression was used. P-values < 0.05 were deemed significant.

Results

The age of participants was 19–42 years, mean 31.0 years (SD = 4.418). We achieved a very high response rate: only 4 questionnaires out of 263 were not filled in. With the help of the first part of the study, we found out that drugs were prescribed to 71.9 % of all women, and 75.7 % of all pregnant women bought additional drugs that can be obtained without prescription; besides that, 54.4 % of all women took nutritional supplements. In that way 57 % pregnant women were prescribed drugs and also bought drugs without prescription; 19.8 % only bought drugs without prescription, and 16.3 % were given prescription for drugs only. Only 18 (7 %) of pregnant participants did not get any drugs. Regarding all drugs, only 56 % of pregnant women declared that they took the drugs as they were advised. Proper drug use was statistically significantly higher ($p = 0.045$) in the group with good explanation.

The main reason for not taking drugs as prescribed was forgetfulness in 53.8 % of cases, nausea in 20.9 %, insufficient explanation in 13.2 % and different explanation of physician and pharmacist in 9.9 %. The main reasons for not starting the prescribed drug were the following: in 22.4 % other pregnant women told them they had problems after taking that drug; in 19.1 % they were not given assurance that the drug would not harm the baby; in 16.9 % physician did not convince them it is necessary to take the drug; in 11.5 % it was that other pregnant women told them the drug did not help them; in 10.1 % friends and relatives told them the drug would harm the baby; and some gave other reasons. Multivariate analysis showed there were no correlations between proper drug intake, age, education or number of pregnancies. When drugs were studied separately, medication interest for acute treatment was 61.4 % (Table). As acute treatment the following drugs were evaluated: antibiotics, analgesics, vaginal antimycotics. Medication interest for chronic treatment was relatively high: 12 out of 17 (70.6 %) of pregnant patients self reported proper drug use; the number of pregnant patients taking these drugs was however very small. Medication interest for treatment with iron was 47.7 % out of 86 participants who were prescribed these drugs.

In the second part of the study, we evaluated attitudes towards drug use in general. Almost one half (47.9 %) of participants declared they were afraid of adverse effects of drugs and one third of participants declared

Table: Medication interest for various indications

Indication for drug use	No. of participants in specific indication group	Medication interest*
Chronic disease	17	70.6 %
Acute problem	57	61.4 %
Iron replacement	86	47.7 %
Preventative use of folic acid	259	19.0 %

**Medication interest is expressed as self-assessment of the correct drug use.*

that different physicians gave different instructions for the same drug.

Participants responded that folic acid use was precisely explained to them in 21.7 % and many were convinced it did not matter when folic acid was taken. Patients with chronic diseases did not know they should use 4 mg of folic acid (ten times as much as healthy women).

At the end of the questionnaire participants were asked to give their comments; 25.9 % of participants volunteered. They expressed interest for more adequate information regarding drugs and reliable information about side effects. Many were convinced that most of diseases could be cured by so called herbal medicines. In general, participants expressed trust in their physicians and pharmacists; however they thought physicians were too quick prescribing and prescribing too many drugs.

Discussion

The high response rate means that the bias of non-responding was not relevant. It was obtained by meticulous oral explanation of aims of the study and personal invitation into the study.

It was shown that the reported drug use in pregnancy depends on the pregnancy outcome; a less than optimal outcome might provoke over-reporting. It was for this reason that the inclusion criterium was delivery of a healthy child after 37 weeks of singleton pregnancy. It was obvious that most of participants in the study did not know the exact difference between prescription drugs, drugs obtainable without prescription and nutritional supplements. The difference between the first two and the latter is very big regarding efficiency, safety and quality. Drugs must pass through many procedures to prove all mentioned properties before registration; this is not necessary for nutritional supplements. For the latter the producer should not attribute any healing properties by law.

Generally speaking, when we ask someone about proper drug intake, and the answer is affirmative, much is in fact unknown; even if computer databases are used[20] the answers are not more accurate. In this survey it is shown how many additional questions are necessary to find out relatively accurately how the drug was really taken by the patient. In fact, always when the improvement does not occur as planned we should ask ourselves: "Did the patient believe me that it was necessary to take the drug? Did s/he take it properly? Did s/he take it at all? Did s/he take it in the right dosage?" It is important to build on patient's intrinsic motivation by increasing understanding why taking drugs is important and by increasing trust even more.

Among many interesting observations one was expected for the population of pregnant women:[21] the perception of risk was much higher than the real risk.

The majority (78.1 %) declared that the use of folic acid was not explained precisely to them and did not know that folic acid should be taken from conception until the 8th week of pregnancy for NTD prevention. Other authors found almost the same percentage of preventative intake of folic acid,[22] while others found over reporting of folic acid use.[23] It might be that participants heard also of folic acid use for other indications.[24] The answers revealed that patients with chronic diseases did not know they

should use 4 mg of folic acid (ten times as much as healthy women). Folic acid must be paid; maybe that is why the population of women about to become pregnant thinks it is not a very important drug. If the state does not pay for it then it is not necessary. Many participants expressed their belief that appropriate nutrition is sufficient for folic acid supplementation. In Great Britain one--hour workshops were organised; participants calculated folic acid intake in the food they ate. In a very practical way participants were shown that it is almost impossible to get enough folic acid in this way. Before the workshop, 42 % participants thought they can get enough folic acid from food; after the workshop, only 1 % thought so, and they were better in advising women afterwards.[25] Not taking folic acid at the time of conception some call the major defeat of public health.[26] The problem is that almost half of pregnancies is not planned, which means women are not taking folic acid during the period in which neural tube is being developed. Other factors for not taking folic acid are the same as for other preventative drug use. Patients do not have symptoms and taking drugs is hypothetical as they do not feel it is helping them. Lack of motivation and not being informed enough are the main causes of low intake. Some countries already decided to add folic acid to staple food, nevertheless, counselling about proper nutrition and folic acid supplementation remain important.[27] It is to be hoped that soon it will be common knowledge that women in reproductive years not using contraception should take folic acid. With constant motivation this information should pass from generation to generation. In September 2010 FDA approved oral contraceptives with added folic acid to assure high folate levels as high percentage of pregnancies are not planned. On the other side, of course, all side effects should be constantly observed.[28]

To increase medication interest is important from the standpoint of individual as well as from the standpoint of the state. A lot of effort is necessary to assure appropriate medication interest in the patient. We must find what his/ hers pros and cons are and try to explain, when necessary. The final decision is, of course, on the patient him/ herself. The interactions between patients' personal knowledge and convictions regarding disease, motivation to fight the disease and trust in their capability to take part in disease eradication should be known. One of the participants in the study gave a political (that is, easy to say and difficult to realise) advice what to do to overcome the main reason for not taking drugs properly, forgetfulness: "Taking drugs should be as simple as possible for drug users and should change one's habits as little as possible". Regarding state, motivation is important as well. In Slovenia there is constant dispute how to decrease the enormous amount of money used for drugs. On the other hand, many drugs are not used; they are kept at home or thrown away, leading to more complications because of non-use of drugs and, contradictory, to more drug use. Evaluation surveys should be performed regularly. We showed in 2001, that the proper intake of preventative folic acid was only 15 %.[19] In 2010, the proper use is almost as low; we have done nothing efficient in between to improve folic acid preventative use. So this tells us we should do something else or differently to achieve better results. Pharmacists should not be forced to sell cosmetics but rather do what they studied for: that is to use their knowledge to improve pharmacotherapy.

We should establish workshops for physicians and pharmacists about improving medication interest and continuously perform evaluations. Throwing drugs away also poses an ecological risk.

Conclusions

To our knowledge, this is the first survey of medication interest regarding all drugs used by pregnant women in Slovenia. It has shown that on average medication interest is comparable to literature data. It is extremely low for preventative use of folic acid. With increased motivation, patients realize that their own medication interest is very important. Well educated physicians and pharmacists can help change patients' behaviour. As we showed, increasing medication interest could also improve cost/ effectiveness

of health care. Editors should suggest that authors may only use the word "prescribed" in their articles and not the phrase "taking drugs" unless medication interest was also checked.

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