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A PRACTICAL APPROACH FOR OVER-THE-COUNTER DRUGS AVAILABILITY AND AFFORD ABILITY ASSESSMENT - Primer with analgesics

RECETESİZİLAÇLARIN BULUNABİLİRLİK VE ERİŞİLEBİLİRLİK DEĞERLENDİRİLMESİNE YÖNELİK UYGULAMALI BİR YAKLAŞIM

(örnek: ağrı kesici)

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ABSTRACT

Assessing the availability and affordability of over-the-counter (OTC) drugs is a vital component of information on pharmacies issues and important for implementing the Good Pharmacy Practice. The main study question is to investigate the availability, levels of serving in ambulatory pharmacies and affordability of OTC analgesics. The used basic design was observational prospective (follow-up) study. We collected the data from 40 outpatient pharmacies in Bulgaria for all registered OTC analgesics in 2003. The results show that approximately 61% in winter and 59% in summer of all OTC analgesics are available in the pharmacies and only 42% of trademarks are available in all observed subjects. These facts describe relatively low level of serving for nonprescription drugs. In winter months registered sales data is greater with 18-20% than in summer. The average ceiling retail price of OTC analgesics is 76% of the lowest government daily wage ILGDWI. The price of 11 products exceeded this value and ibuprofen-containing products are with lowest affordability.

Presented figures indicate that availability, affordability and serving levels with OTC analgesics are relatively low. There is a lack of opportunity for consumers to choice them according the efficacy and safety, and determined factors are existed habits and prices.

Key words: *OTC analgesics, availability, affordability, ambulatory care (outpatients' pharmacy)*

ÖZET

Recetesiz olarak satılan ilaçların bulunabilirlik ve erişilebilirlik bakımından değerlendirilmesi eczanelerin karşı karşıya geldikleri sorunlar ile ilgili bilgilerin bir unsuru oluşturup iyi eczacılık uygulamalarında önemlidir. Araştırmanın esas amacı recetesiz olarak satılan ağrı kesicilerin bulunabilirliği, klinik eczanelerindeki hizmet seviyesi ve benzeri ilaclara erişilebilirliğin incelenmesidir. Kullanılan araştırma yöntemi gözetmeli muhtemel(kontrol) inceleme yöntemidir. Bulgar eczanelerinin 40'indan recetesiz olarak satılan 2003 yılında tescil edilen bütün ağrı kesiciler hakkında bilgi topladık. Yapılan inceleme sonuclarına göre reçetesiz olarak satılan bütün ağrı kesicilerin yaklaşık % 61 'ı kış mevsiminde, % 59'u ise yaz mevsiminde eczanelerde bulunmakta, ticari markaların yalnız % 42'si bütün *eczanelerde bulunmaktadır. Bu hususlar reçetesiz ilaçların orantılı ise düşük kullanım seviyesini gösterdi. Yaz aylarına kıyasla kış aylarında kaydedilen satış düzeyi % 18-20 oranında daha yüksektir. Reçetesiz olarak satılan ağrı kesicilerin perakende ortalama sınır fiyatı devletçe garantilenen asgari günlük ücretinin % 76'sini oluşturmaktadır. 11 ağrı kesicinin fiyatları bu bedeli aşmakta, ibuprofen içeren ilaçlara erişim imkanları en sınırlıdır. Elde edilen sonuçlara göre reçetesiz olarak satılan ağrı kesicilerin bulunabilirlik, erişilebilirlik ve hizmet seviyesinin oldukça düşük olduğu görülmektedir. Tüketicilerin ağrı kesme kuvveti ile insan sağlığına zararsızlık açısından seçim imkanları yok denecek kadar azdır. Bu doğrultuda alışkanlık ile fiyat, belirleyici etkenlerdir.*

Anahtar kelimeler: *Reçetesiz ağrı kesici; bulunabilirlik; erişilebilirlik; klinik bakım (poliklinik eczane)*

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INTRODUCTION

One of the majör achievements of twentieth century is the large approval of the idea that everyone has rights for healthcare and access to healthcare services without any invincible hindrances (1). To make these guidelines real, it is necessary to provide an access to ali types of medicinal aid and/or products and assuming obligation of government to ensure optimal structure, financing the healthcare system and keeping high quality of service (2). At the end of 2002 in Bulgaria there are totally 4195 community pharmacies that are allocated as follows: in capital Sofia - 993; in regional cities 2836 and the rested 366 in small villages and resorts.

The manufacturers of OTC products are supporting the enlargement of the market and considering that making studies of economic savings and affordability, and supporting the self-care will bring optimum effect över the quality and quantity of provided products and services (3). 46 trademarks (TM) with OTC analgesics (from ATC therapeutic subgroup N02B) are authorized in the Bulgarian market. Their INN is acetylsalicylic acid (ASA), paracetamol/acetaminophen (APAP), metamizole/dipyrone and ibuprofen. The registered combinations are containing vitamin C, caffeine and B vitamins. As percentage OTC analgesics are 1% of ali authorized medicinal products, whereas they are 13,7 % of ali OTC products.

The products that are containing active ingredient ASA are 39% (18), these with APAP are 46% (21) and the part with metamizole is 11% (5). The products with ibuprofen are only 2 or 4% and they are monoproducts. in accordance with the origin about 1/3 of the drugs are local produced (15) and double more - 31 (67%) are import.

The Tablets Are Most Widespread Drug Form - 23 Products, On The Second Place İs The Effervescent Tablet (11), Following After Liquids - Syrups And Suspensions (5). As Suppositories, Chewing (Oral Dispersible) Tablets And Powders Are Totally 7 Medicines And Ali Of Them Are Containing Apap.

MATERIALS and METHODS

The survey can be defined as prospective and descriptive, including as objects of supervision generally 40 community pharmacies /every 107^{th}/ - 5 in each of five different regional cities and 15 in the capital Sofia. The used selection criteria are locality (type of the city, traffic and/or market center and hospital closeness, etc.) ownership and number of the served patients per one month. The study covers 2003, separate in two sub periods: February/March; July/August.

The survey is conducted in following main steps:

- Collecting a data for supported available quantity and sold OTC analgesics from the pharmacies during the both of sub periods according to TM, INN and form.
- Determination of level of service through *availability,* as a basic measure of access to drugs, and analysis of the selling data (4). This step needed to; check which of the OTC analgesic listed are available at everyone facility during two sub periods.
- Determination of *affordahility* through analysis of ceiling retail prices.

By defining the affordability we modified the WHO definition and our purpose was to measure affordability as an indicator of access to essential drugs like OTC analgesics. Affordability is expressed as the ratio of the costs of treatment (ceiling retail price) and the lowest daily government salary/wage (5).

The affordability of *a drug without prescription* might be expressed as ratio of the maximum (ceiling) price of any product (TM) and the lowest daily government salary/wage. The analysis and discussion are based on indicated lowest government salary (LGS) in Bulgaria - 110 BGN and lowest daily government wage (LDGW) - 3.66 BGN for year 2003.

RESULTS and DISCUSSION

The research reveals that during the winter the average value of available OTC analgesics in pharmacies is 61%. 42% of TMs (the number of local and imported trade marks is the same) are available in **all pharmacies.** Actually all domestic TMs are available in all pharmacies instead of relatively small number of imported products in contrast of their higher number in the list. This shows relatively high availability of products belonging to only one ATC group, Figure 1. By analysis according to active substance the most of products are with APAP and combinations, following by monoproducts with ASA. There is missing important difference between observed regions and this is indication for existed consumer habits.

The general mount average INN selling in pharmacy shows that in the winter they are about 18-20% higher. The OTC analgesic leader in Bulgarian market is metamizole under different TMs of the domestic manufacturers, following by APAP - localproduced and imported ASA in combination with vitamin C. An explanation of these facts is the price of the products, which is lower than the average price of therapeutic group, consumer's habits, the advices of pharmacists and market activity of marketing authorization holders /___s/. Preferred drug form is tablets for metamizole and APAP, and effervescent tablets for ASA + Vitamin C. The quantitative data for sales of the metamizole are two times higher then APAP and 32% smaller then all drug and dosage forms containing ASA.

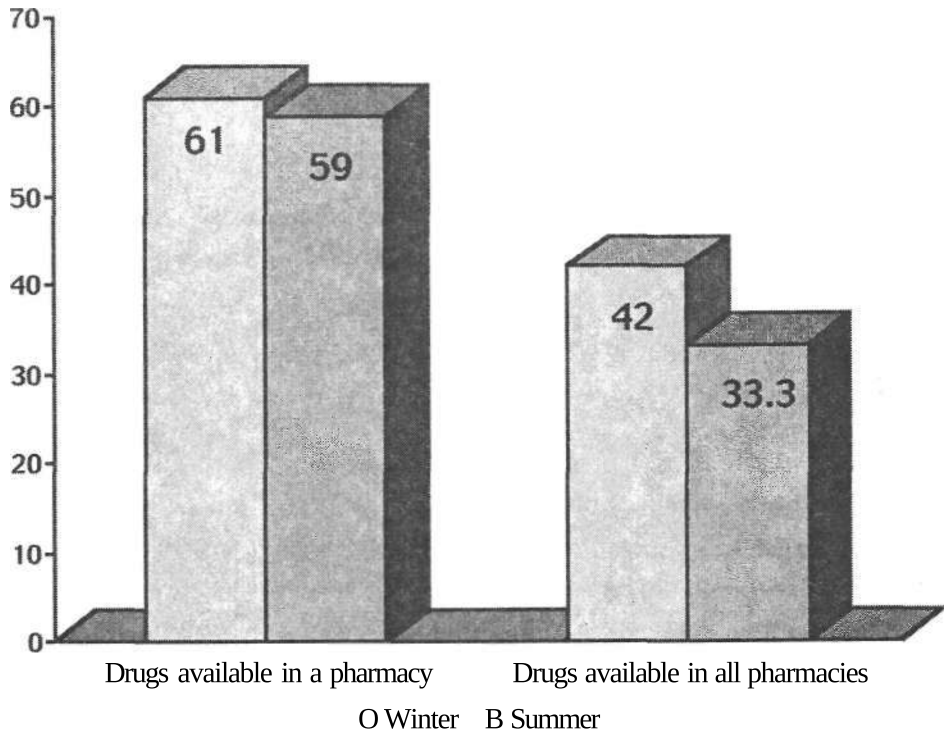
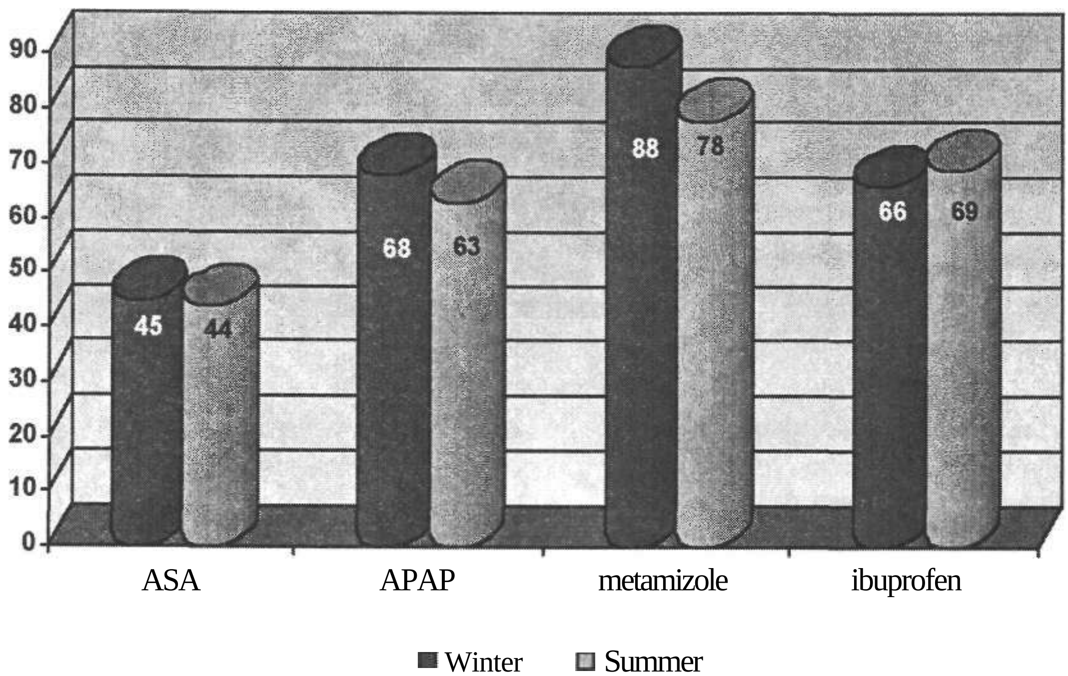


Figure 1. Serving level - mean, over study periods (%)

In the summer (July and August) the average part of available products in pharmacies is 59%, while the ratio between local and import is 5:3. A bigger difference is reported by the drugs, which are available in all pharmacies (33.3%) and that is good example for the seasonable marketing of OTC analgesics.

The comparison of availabilities by INN is shown in Figure 2. The data shows that average reported availability during both of periods is varying in narrow borders. There are no differences about the ASA products - their availability is constant. The difference between APAP products is small, but the decrease by metamizole is considerable. A season ranges are detected by the selling. The average mount number of sold packages in the winter in one pharmacy is 1615, while in the summer it is 16% lower (1364).

In Bulgarian pharmacies prevail OTC analgesics from import in different drug and dosage forms. The quantities of OTC analgesics domestic production are higher because of there sustainable sales all over the year. The seasons' variations are insignificant and the regional differences might be expressed in higher availabilities and sales of imported and relatively expensive TM in capital Sofia and bigger regional cities. All these facts illustrate the good level of serving with OTC analgesics, shaped consumers' habits and higher availabilities över the other ATC groups. The stable consumer's demand defines the size and diversity of the OTC analgesics availabilities in Bulgarian pharmacies.



Figüre 2. Comparison of the OTC analgesics' availability by INN and sub periods (%)

For affordability evaluation we used the registered ceiling retail price. By 11 (25%) of them the price is higher than LDGW, when ali of them are imported and this shows their low affordability. The average ceiling retail price of ali authorized OTC analgesics is 76% of LDGW. This indication is high and it sets relatively low affordability. The evaluation explains the estimated high use of local generic drugs, while there is wide variety of products.

The affordability data by INN reveals that the average price for:

- ASA is 2,4% of LGS; 71% of LDGW
- APAP is 3% of LGS; 88% of LDGW
- Metamizole is 1,5% of LGS; 46% of LDGW
- Ibuprofen is 4,3% of LGS; 130% of LDGW

The least affordable drugs are those containing ibuprofen. The ratio between local and import drugs, based on average price in the market is exposed in Table 1. The local drugs are significantly cheaper and affordable than the imported. The average price of import products is higher than LDGW. That means that MAHs has not conformed the registered product prices with local competitors from the same market segment. They rely mainly on promotional activities for good remunerated patients. The newly approved local drugs are following the same logics and are presented with affordability about 90%.

Table 1. Affordability of the OTC analgesics by origin

Origin of the drugs	Share of LGS (% on average)	Share of LDGW (% on average)
Local production	1,55	53,4
From import	3,2	**101,9**

On the Table 2 are presented data for affordability according to drug form. The results show that the most affordable are tablets, following by suppositories, whereas powders and suspensions have low affordability. The average ceiling price according to the drug form is higher than 1/2 of LDGW.

Table 2. Affordability of the OTC analgesics by drug form

Drug's form	Tablets	Efferves.tablets	Oral dispersible tablets	Powders, syrups, suspensions	Suppositories
Brand names	23	11	4	5	3
Share of LGS (%)	1,9	2,5	3	4,1	2,3
Share of LDGW(%)	62,3	81,2	98,1	155,9	76,1

CONCLUSION

The presented method and the analyses are good describing the level of service in the pharmacies with OTC products (analgesics). The results show that the use and the habits of consumers are well shaped. By the variety of brand names the searching is turned mainly on local products, which are cheaper and common in the practice. This profile of consumer searching is modifying the size and variety of supported availabilities in the pharmacies. The estimated indications reveal low level of affordability to OTC analgesics in Bulgaria and lack of possibility for patients to choose the drugs according at their quality and effectiveness. The factors, which define the choice and consumer habits, are the price and the type of drug form and package.

The applied modified WHO methodology give us possibility for monitoring, evaluation and comparing the performance of facilities, districts, provinces and the overall situation in the country and seeing trends over time. The results of the study can be used:

> to be aware of the institutional problems and identify strategies to improve the situation;

> to assess the structure and capability of regional and national pharmaceutical sector when developing projects and changes in the future;

> to assess the progress and accomplishment of current projects;

> to focus the activities of the professional groups and/or bodies, NGOs and academia on advocacy activities and information campaigns for rational drug use.

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