

1. Task Number

123 Tomsk: Rational Pharmacy Management

Developing of Medicines' Formular to Treat Ulcer

2. Name of the Task

Continuous Quality Improvement in Inpatient Departments of  
Siberia

Municipal Hospital # 3

3. Developed by

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The problem of rational, effective and safe use of medicines in the present socio-economic conditions of our country acquires special importance and requires new approaches to solve it.

Based on WHO recommendations to provide rational use of medicines comprehensive national policy in the field of pharmacy has been developed and implemented in many countries and it as a rule includes:

- adequate legislation to provide safety and quality of medicines and regulate their realisation and use;
- program to improve pharmaceutical procurement based on the lists of main medicines;
- provision of specialists and the public with objective and timely information regarding medicines;
- strategy in educational activities to rationally use medicines.

Pharmaceutical procurement of an inpatient department in Russia as one of the services is included into the program of mandatory medical insurance (MMI). Three years of working experience in the conditions of MMI revealed a number of problems and the most important of them is the provision of health care facilities with medicines. The practice shows that as a rule health care facilities can not guarantee the necessary amount of pharmaceutical care envisaged by medical economic standards even in case when considerable expenses are spent for medicines.

One of the most difficult problems of health care facilities is the deficite of financial resources and impossibility to provide normal operation of a facility due to the constant growth of prices for medicines, utilized material and technical resources, tariffs for communal services etc.

One of the reasons for insufficient and ineffective provision of health care facilities with medicines is also the fact that the use of allocated financial resources for pharmaceutical care is not regulated, there is no rational scheme of relationships between organisation that handles financing, health care facility and pharmacy.

Expanding the assortment of pharmaceutical goods from vitally important to super fashionable and fairly often the “prestigeous” use of them by physicians creates the ever growing demand for medicines, the increase in share of expenses to pay for them and limited financial resources.

The money allocated for the purchase of medicines usually make up a significant share of expenditures in the budget of a health care facility. And herewith the important step to increase the therapeutic feedback in the purchase of medicines is the rational approach to their selection, use of the most effective remedies to achieve positive effect in treatment within the shortest period of time.

The most effective method to rationally use the medicines is the creation of a formular.

**The formular** is a special list of medicines of restrictive nature, it permits to make use of only those medicines that are included into this list, establishes the rules of adequate substitution based on their cost and affordability.

Applying the formular in a health care facility significantly reduces the nomenclature of the medicines used, increases their therapeutic feedback, makes it easier to purchase them, allows to exercise quality control regarding the medicamentous provision.

Development and introduction of the formular system in health care facilities is carried out within the project “Rational Pharmaceutic Management in Russia” which is financed by the USA Agency for International Development and is implemented under the aegis of intergovernmental program “ZdravReform”.

- The objective of the *Rational Pharmaceutical Management Program* is to render assistance in the improvement of medicamentous therapy by perfecting the methodology, rational selection and use of medicines in clinical practice, establishing and expanding the information services including the data regarding the pharmacologic and clinical properties of medicines.

### **Creation the formular in a health care facility enables to solve the following problems:**

- restricted allocation of resources to purchase the medicines;
- ever growing number of therapeutic alternatives;
- erroneous prescription and use of medicines;
- availability of hazardous and ineffective remedies on the market;
- lack of objective pharmaceutic information;
- high cost regarding provision, storage and purchase of big quantity of medicines and medical items;
- availability of questionable quality medicines on the market.

### **Prerequisites to Formular Creation:**

1. Significant increase of the cost of medicines.
2. Limited allocation of financial resources to purchase medicines.
3. Questionable effectiveness of some of the medicines entering the russian market.
4. Great number of wholesale companies. It caused the import of considerable quantity of medicines unknown before in the region as well as great variety of prices for medicines.
5. Insufficient knowledge of medical workers as far as new medicines are concerned.

### **Rational Use of Medicines**

At present about 70% of medicines on the world market are duplicates or not vitally important remedies. Many of them do not give any advantages as compared to the already known medicines. Some other medicines demonstrate too high toxicity as compared to their therapeutic effect and are brought on to the market without any sufficient information regarding their effectiveness. Almost always new medicines are more expensive than the existing ones. As it is seen from the experience sometimes it is very difficult to eliminate the problems caused by medicines prescribed by physicians (polypragmazia - prescription of medicines that can hardly be combined), selling of medicines by pharmacutists (wrong substitution, absence of any contacts with physicians) and taking medicines by patients (non-observance of the the scheme of taking the medicine, lack of information for the patients).

It is possible to solve these problems with the help of the formular by means of eliminating of low effective medicines from the list of those which are allowed to be used in the inpatient department and by teaching the specialists to make use of some specific medicines.

### **Establishing and Development of Information Services Concerning Medicines**

To rationally prescribe, purchase and use safe and effective medicines it is necessary to have complete, objective, updated information that answers it's purpose and contains reliable data concerning medicines. At the present time more and more new, not known before medicines break into pharmaceutical market from the whole world because centralized deliveries were stopped and many new wholesale commercial structures appeared. The information which usually accompanies a medicine and originates from the producer is rarely objective because it's of a commercial nature and does not possess full data concerning contraindications, side-effects and interaction with other medicines. Fairly often new drugs hardly ever have any difference from already existing on the market old tested remedies but they are sold at a higher price. Doctors and pharmacutists experience difficulties when making decisions concerning the prescription of a medicine due to the insufficient information.

Creation the formular will limit the list of medicines used and give a chance to specialists to deeply study the therapeutic effect of medicines listed in the formular. Well-organized work concerning information in the field of pharmaceutics contributes not only to optimal choice and correct application of medicines, decrease of their unfavourable effects but is also justified from the economic point of view. Unfortunately Russia lacks professional objective versatile information regarding medicines.

### **Results Expected from Introduction of the Formular**

- reduction in the length of treatment and stay of the patients in the inpatient department;
- leaving out of hazardous and ineffective medicines from the assortment of applied medicines;
- reducing the number of names of the purchased medicines which enables to purchase more medicines with the same money;
- implementing purpose-oriented programs helping the medical staff to improve their skills and deepen the knowledge;
- collection of more complete and objective information regarding medicines used in the inpatient department.

### **Stages of Work Regarding Creation of Medicamentous Formular to Treat Ulcer**

#### *1. Administrative Stage*

The project "Rational Pharmaceutic Management" was presented to the oblast health care authorities, the leaders of Mandatory Medical Insurance Territorial Fund, leading specialists of the oblast and the city, to chief doctors from central rayons' hospitals. And the concept of formular system application in a health care facility was approved and found their support. Municipal hospital # 3 has become an experimental site to carry out the work connected with creation of the formular. Minicipal hospital # 3 - is the largest in the city multidisciplinary medical-preventive association comprising the

polyclinic with the catchment area of 39,5 thous. people and meant for 350 visits in a shift and the hospital for 515 beds. There are 10 medical departments in the hospital:

- ⇒ therapeutic
- ⇒ gastroenterologic
- ⇒ pulmonologic
- ⇒ neurologic
- ⇒ infectious
- ⇒ surgical I and II
- ⇒ urologic
- ⇒ stomatologic
- ⇒ ear, nose and throat

Besides there are support and paraclinical services which help to examine and treat the patients. Within the hospital there is a pharmacy. There is no clinical pharmacist there.

To create the formular of medicines to be used by all the wards of the hospital within such a short period of time given in the Contract does not seem possible. So to create the limited list of the medicines that are made use in gastroenterologic ward was chosen with regard to the fact that one of the subprojects of “ZdravReform” program concerning the quality of care “Decrease of the Length of Stay in the Inpatient Ward of the Patients with Ulcer” has been under way there. Creation of the medicines’ formular in this ward enables to use the most effective and less costly medications and consequently to increase the quality of care and to decrease the economic expenses.

Gastroenterologic ward is meant for 40 beds. Patients are admitted according to the existing plan 3 times a week from the city’s polyclinics as well as from the rural areas of Tomsk oblast.

The ward closely cooperates with biochemical laboratory, departments of endoscopy, X-ray diagnosis, ultrasound diagnosis.

Prior to the beginning of work with the formular there were meetings with medical staff devoted to the advantages of formular system, the volume of the forthcoming work concerning it’s implementation.

There was issued an order on establishing Formular-Therapeutic Committee (FTC) and it’s main objective was the professional selection of medicines, their evaluation, safe and effective use.

Besides the following amount of work was supposed to be the *FTC functions*:

- considering the opportunity of including medications in the formular;
- giving advice to medical staff concerning the issues related to the use of medicines in the hospital;
- provision of optimal therapeutic treatment in the wards;
- clinical data evaluation regarding new medicines not yet inserted in the formular;
- recommendations concerning entry into or elimination of some medicines from the list;
- study the data regarding side-effects.

**Members of Pharmacologic-Therapeutic Committee of the Municipal Hospital # 3:**

- |  |                   |
|--|-------------------|
| 1. Chairman - Medical Director                                     | - Kolosova I.P.   |
| 2. Secretary - Pharmacy Director                                   | - Leiman Y.L.     |
| 3. FTC member - Director in Economics                              | - Fomina T.I.     |
| 4. Head of Therapeutic Ward  | - Savchenko Y.P.  |
| 5. Head of Surgical Ward   | - Portnyagin M.P. |
| 6. Head of Internal Diseases Chair in the State Medical University | - Volkova L.I.    |

To create the limited formular related to gastroenterology there was established a team of 4 members in the department.

None of the PTC members has any business relationships with the producers or distributors of medicines. All the specialists have undergone the course of training to improve their skills and competence in the field of clinical pharmacology and issues of rational purchase of medicines (Pharmacy Director).

### **PTC followed certain rules in it's activities:**

- ⇒ Medicines entered the formular list bearing their generic names. Pharmacy has the right to make therapeutic substitutions when supplying medicines to the wards;
- ⇒ There existed the justified demand in a certain medicine to be included into the the formular;
- ⇒ The cost of medicine is justified by it's effectiveness;
- ⇒ Medicine must be always accessible to be purchased from the suppliers.

The use of generic names in the formular is due to the fact that it is more informative than the company's name and shows that it belongs to a definite group of medications. Besides assigning generic names enables the pharmacy to make generic substitutions while the firm's nomenclature imposes to deliver only the indicated in the department's order medicine. And generic medications are much cheaper and make it easier to purchase them from various suppliers.

Thus, despite the fact that medical specialists are well aware of famous brand names of medicines the use of international non-patented (or generic) names of medications allows to extent the choice of medicines independent of their specific brand name, lessens the expenses as for pharmaceutic therapy without any decrease in the quality of treatment not taking into account the cost aspects of medicines.

## *2. Development of Medicines Formular List*

### **Information regarding medications**

In order to select medicines into the formular the following sources were made use of:

1. Register of Medicines permitted for use in Russian Federation. 1994
2. Handbook "Bidal". 1995, 1996.
3. Register of Medicines (1993, 1994, 1995). Edited by Y.F.Krilov
4. Remedies. Edited by M.D.Makovsky
5. Monographs on Various Medicines
6. B.K.Lepakhin, G.V.Shakova Synonyms of Medicines. M., 1995
7. Medicines of Foreign Producers in Russia. 1993.

### **Classification of Medicines**

To arrange the work in a proper way there was chosen the classification of medicines according to pharmaco-therapeutic principle which is based on therapeutic use of medicines and is easily understood by medical personnel, pharmacutists and pharmacologists.

The list of medicines used in gastroenterologic department for the period of January-May 1996 has been analysed. 134 names of medications from various pharmaco-therapeutic groups entered this list (Table #1).

The total sum amounted to 31.624.489 roubl.

Prices for medicines were not indicated in the table due to the fact that they have greatly changed during the period under consideration. So for analysis was taken only the amount of money spent for buying the medicine.

The major part of expenses in the department was itemized between the following groups:

- antacids, astringent, medicines with coating effect;
- antibiotics;
- repairants;
- spasmolytics;
- cholagogic medicines.

#### **Distribution of Medicines according to Pharmaco-Therapeutic Groups**

<b>Pharmacologic-Therapeutic Groups</b>	<b>Amount (thous.roubl.)</b>	<b>% to the total sum according to the group</b>
Antacids	6.396.061	20
Histamin and antihistamin	3.082.699	12.6
Spasmolytics	2.112.836	6.7
Hepatoprotector	2.256.153	7.2
Cholagogic medicines	579.349	1.8
Fermental medications	811.878	2.6
Sulfanilamides	2.132.078	6.74
Antibiotics	2.668.382	8.4
Medicines belonging to other groups	10.685.048	33
<b>TOTALLY:</b>	<b>31.624.489</b>	<b>100</b>

Thus, medicines' consumption analysis shows that major part of the expenses in the department constitute medications intended for ulcer treatment (53,5%), among them considerable part is taken by H-2 receptors blocks as well as repairants, antibiotics and fermental remedies.

### **Use of Hospital Budget**

One of the most important moments in determining the quality of care is determination of the share of expenses spent for medicines among the total expenses in a health care facility.

	19 95		1996 1 quarter	
	in the amount (thous.roubl.)	in % to total expenses	in the amount (thous.roubl.)	in % to total expenses
Total expenses in the hospital	8773,2	100	15366,4	100
Including costs for medicines and medical instruments	2483,1	28	3291,4	21

Costs for medicines in gastroenterologic department for the period under study made up 4,5%.

No medicines were charged off in the department due to the termination of the period of their application.

### **Analysis of Morbidity Structure in the Department**

Morbidity structure has been studied in the department during the year (Table #2). The analysis shows that cases of gastric and duodenal ulcer occur most often and consequently, length of stay of the patients with such pathology takes most of bed days.

The problem of gastric ulcer and duodenal ulcer at the present time is still topical in theoretical as well as in practical sense. It is caused by the fact that ulcer belongs to the most widely spread diseases in all parts of the world. Absolute number of ulcer patients is still rather considerable in our country. So in 1986 in USSR there were 620 thous. patients with gastric and duodenal ulcer who received care in the inpatients departments and wards of the hospitals (Alekseyev B.F., Soboleva N.P. 1991). Gastroduodenal ulcers are diagnosed in 305 thous. of cases in gastroenterologic departments. Gastroenterologic department of the municipal hospital # 3 is not an exception. The percentage of patients with ulcer there constitutes accordingly 43,5% in 1993, 45,9% in 1994, 44,4% in 1995, 52,6% for the 1 quarter of 1996. As the patients are mostly young and able-bodied people and complications of the process often take many weeks and months causing serious consequences and premature invalidism of the patients it is necessary to search for new, more effective ways of treatment. It in its turn can lead to the reduction of the patients' length of stay in the hospital and decrease of the expenses for patients' treatment.

Comparison of the number of ulcer cases and the amount of money allocated for medicines spent for specific treatment of this pathology enables to come to the conclusion that expenses regarding medications and the number of ulcer cases are directly related.

### **Conducting VEN and ABC Analysis**

VEN analysis is distribution of medicines according to the category and their vital importance.

Vitally important medicines are those that are important for saving the patient's life.

Essential medicines are those that are effective in the treatment of less dangerous but still serious diseases.

Non-essential medicines are those that are used for treatment of non-serious diseases as well as costly medicines with symptomatic indications.

System EXCEL was used to make the analysis. Making the distribution according to the system VEN (Table # 3) 16 medicines for the amount of 3.078 thous. rouble. were included into the group of vitally important. It makes up 9,7% - these are antibiotics, hormonal, cardio-vascular medicines, remedies influencing blood coagulability. 74 medicines for the amount of 15.964 thous. rouble. - 53% were included into the group of essential medicines. The group of non-essential drugs is represented by 51 medicines for the amount 12.611 rouble. - 40%.

<b>VEN analysis of medicines</b>	<b>Amount spent for medicines (thous.roubl.)</b>	<b>% from the total amount</b>
Vitally important	3.078	9.7
Essential	15.964	53
Non-essential	12.611	40

To analyse expenditures and check the effectiveness of the medicines used there was carried out ABC analysis (Table # 4).

ABC analysis is a technique of medicines' distribution according to 3 groups in conformity with their consumption.

*Class A* - 20 % of medicines for which 70-80% of the budget resources are allocated in the department.

*Class B* - average level of consumption.

*Class C* - most of medicines with low frequency of consumption. 25% of the medicines' budget are spent for them.

The ranking of medicines is made according to the cost of purchases. Medicines for the amount of 31.624.489 rouble. were spent in the department for the period of investigation.

Analysis shows that the main amount of financial resources - 75% was spent to purchase 20 medicines, among them vitally important drugs (ampicillin), for remedies intended for treatment of serious diseases - 39% of the budget and for non-essential - 27%. The biggest amount was spent for the medicine salophaloc used in the treatment of non-specific enterocolitis. Though this medicine is very expensive it's therapeutic effect is very high.

The conducted analysis shows the structure of expenses in the department for the purchase of medicines. The decrease in use of less effective drugs such as carsill, namagel (more expensive than almagel) enables to allocate more money to buy more essential medicines.

### **Analysis of Medicines' Therapeutic Classes to Be Selected and Included into the Formular List**

Creation of the formular in the department was carried out the following way: all medicines used in the department were considered to be the initial formular. In the process of analysis some of them were left out from the list, in some cases new ones entered the list.

From the group of antacids, remedies creating coating and astringent effect *almagel* and expensive but more effective *maalox* were listed into the formular. It was recommended to reduce the purchase of *namagel* due to it's rather high cost but as for therapeutic effect it has almost no difference from *almagel*.

Besides it was decided to leave medicine *de-nol* in this group which along with astringent properties possesses antimicrobial activity regarding helicobacter - bacteria causing the development of ulcer and gastritis.

Medicines from H-2 group with blocking effect - in the department in 1996 *cimetidin* was not practically used so it was decided to include into the formulary *ranitidin*, which is taken 1-2 times in 24 hours and it reduces the expenses in the course of treatment and does not influence the hormonal status of young men. This group also entered *pirenzepin* (*gastril*, *gastrozepin* and others) because this medicine is a bit different from medicines of this group as for its mechanism of acting - it blocks acetylcholine receptors and quite often can be combined with H-2 blocking remedies. *Omeprazol* is used in the department not so often (23 packs in 5 months) due to its high cost but short clinical experience of its application especially on the background of low effectiveness of other H-2 blocking remedies it proved to be rational when used in the course of treatment.

Among antiemetic medicines it was chosen *metoclopramid*. This remedy along with antiemetic effect has positive influence upon dyskinesia of gastrointestinal tract, eliminates zophagitis-reflex and gastritis-reflex which often complicate the process of ulcer.

Out of repairants was chosen *glunat* (produced by pharmacologic enterprise in Tomsk) as well as *metronidazol* and *metilurazil*.

Cytoprotector - *sucralfat* (venter) which along with antacid properties is also cytoprotector and prevents the destructive effect of pepsin, hydrochloric acid and taurocholic acids.

Out of fermental drugs the list entered *festal* and *panzinorm*. *Mezimforte* must be left out as it is low effective.

Cholagogic remedies - *allochole* and *oxaphenamid* are traditionally well-known medicines, effective and are produced by Tomsk Chemical Pharmacologic Enterprise.

Diuretics - the formulary list entered the most effective and cheapest remedies as *furosemide* and *hydrochlorothiazide*. Being potassium storing medicines combined *triampur* as well as *spironolacton* were left in the list. The latter is the only one out of all diuretics that eliminates portal hypertension, so it is effective in the treatment of hepatic cirrhosis.

Remedies influencing blood coagulation - *vicazol* and *aminocaproic acid* - native inexpensive rather effective medicines are included into the list of vitally important remedies of RF Ministry of Medical Industry.

Medicines for parenteral feeding - *panangin* and *aspacam*.

Tranquilizers and sedative medicines - *diazepam* was chosen as the drug having maximum antialarming effect; *oxazepam* is better for elderly people, has not lengthy period of action, low toxic. Also in the list were left *leonurus tincture*, *corvalol*, *valocordin*.

Non-narcotic analgetics - the list entered *sodium metamyzolum (analginum)*, *acetylsalicylic acid* and *paracetamol* that are produced in Tomsk, and also *spazgan* and *trigan*.

Spazmolytics - *no-shpa* and *papaverin* remained in the list as traditionally effective medicines, recommended for use by the Ministry of Health as vitally important medicines.

Group of antibiotics - *ampicillin*, *cephazolin*, *lincomycin*, antimycotic - *nistatin*.

Purgative medicines - *senocides (glaxena)*.

Adsorbing remedies - activated charcoal.

Remaining groups of medicines are represented by one or two names and are used in the department as accompanying means and for this reason entered the formular list as they are without any changes.

Thus, the formular list of gastroenterologic department entered medicines from 39 pharmacologic therapeutic groups.

Besides due to the fact that ulcer occupies the first place in the morbidity structure of the department separately is proposed formular of medicines to treat ulcer.

#### 1. Gastric secretion block

- histamins x receptors block - *ranitidin* in tablets
- acetylcholine x receptors block - *pirenzepin (gastrozepin)* in tablets
- inhibitor H+K+ATphaz - *omeprazol (omez)* in tablets

#### 2. Antacides, astringent, creating coating

- *almagel* in bottles
- *biscalcitrat (de-nol)* in tablets
- cytoprotector *sucralfat (venter)* in tablets

#### 3. Repairants

- *methyluracil* in tablets
- *glunat* in amp.
- *metronidazole*

#### 4. Cholinolytics and spazmolytics

- *platyphyllin* in amp.
- *drotaverin hydrochloride (no-shpa)* in tabl., amp.

#### 5. Antiemetics

- *methoclopramide* in tabl., amp.

#### 6. Tranquilizers

- *diazepam* in tabl., amp.

### **Main difficulties in making up the formular**

1. The short period of time assigned for the task fulfillment. It did not enable to make the analysis for the longer period. But the most important thing is that at this stage it is impossible to calculate the efficiency of the proposed formular application.
2. Insufficient software concerning the creation of medicines' formular, so data processing as regards some sectors was carried out manually. At present PC has been installed in the pharmacy, the program for the account of purchases and spending the medicines in the hospital as a whole and in the departments in particular was prepared and is operating now. It considers the requirements for making up the formular.
3. There is no sufficient information concerning medicines with the exception of above mentioned handbooks and manuals about medications offered by the companies which deliver or produce medicines.

However the objectives set up prior to the development and introduction of the formular were achieved. The list of medications used in the department was considerably reduced (from 77 names as regards the results of the order to the oblast pharmacologic warehouse up to 15 names). In the future it will be easier to purchase medicines from suppliers.

It is planned to evaluate economic effect from the introduction of medicines' formular in gastroenterologic department by the end of 1996.