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Nauka i studia
2012



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PHARMACOECONOMIC EVALUATION OF MEDICINES WITH CONSIDERATION FOR ADVERSE REACTIONS

Resume

In the article the importance of questions of medicines safe consumption and rational pharmacotherapy, an estimation of side effects losses has been marked. The complex of researches directed on studying of risks, connected with drug side effects has been carried out, and methodical approaches to their estimation has been proved. The calculations of side effects losses an example of antibacterial drugs has been offered with the help of algorithm of it's estimation.

Key words: medicines, adverse reaction, risks, pharmacoeconomic evaluation, losses.

I. Introduction

Recently, the problem of drug safety becomes more actual. Analysis of literature shows that the increase in side effects of used drugs depends on many factors, including lack of information about the new capabilities of effective pharmacotherapy, polypharmacy, low use of the achievements of evidence-based medicine, unethical promotion, self-healing problems, inadequate monitoring of drugs side effects. According to various sources 2 to 6% of the human population suffer from adverse reactions, while 6-15% of patients having serious adverse reactions required adjustments. Mortality from drugs adverse reactions (DAR) came in the 4th place in the world, give place to only the cardiovascular diseases and oncology [1, 5-8].

Risks arising from the use of medicines, including adverse reactions, lead to serious economic losses from eliminating the consequences of irrational therapy.

II. Formulation of the problem

In connection with the above the purpose of the research was studying the risks associated with the occurrence of DAR (in Ukraine) and methodical approaches to their assessment.



III. Results

Investigation of the specific risks associated with the DAR development allowed to classify risks into separate groups according to the objects to which they apply.

Thus, the following risks can occur in a person receiving medical agents: development of adverse reactions; adverse outcome (disability, the emergence of new disease, invalidity, death); moral damage; prolongation of treatment duration; increased cost of treatment.

For insurance company: increase payments.

For employing organizations arise: labor expenses; increase payments for list of temporary disability; shortfall in revenue.

For health care settings is a threat to these risks: increase in financial expenses in the event of changing the drug that caused the DAR; increase in financial costs for treatment of DAR; increase in the financial costs of emergency medical manipulation in case of DAR; reduced confidence in medical staff and clinic in general; increase in bed- days and annual average bed occupancy rate; pecuniary penalties and litigation; irrational list of drugs recommended for the procurement budget.

For manufacturers in this situation there are risks: identify the negative drugs consequences; return of the batch of goods; prohibition of the sale of the drug; pecuniary penalties; risk of legal costs; deterioration of the company's image.

Economic and social costs associated with the above listed risks are significant enough. Estimation of these costs provides an understanding of risk in case of DAR and improves, in particular, the rationality of budgetary and extrabudgetary funds to purchase drugs.

Usually, the costs for removing the effects of DAR are divided into direct and indirect[2 – 4]. Direct cost includes the cost of medical and pharmaceutical care patient (cost of services provided and the cost of medicines, materials used, equipment, etc.). Also there is the impact of indirect costs that appears after a period of time and is quite significant in its social and economic structure. The structure of indirect costs are those associated with temporary disability in case of DAR, non-produced product by patient as a result of his disability, associated with disability or death, increase of payments for sick- lists, an increasing number of bed- days and annual average bed occupancy rate , with an ineffective formation of drugs assortment , which are purchased by medical institutions.

We composed an algorithm (Fig. 1), which is proposed to calculate the direct costs of removing the effects of DAR. Calculations should be carried out using data on dosage, basic diagnosis, duration of drug therapy, the number of cases of DAR, information about cancellation of a particular drug. Next, the calculations take into account the costs on diagnosing the symptoms of the DAR manifestation, the average cost of AR symptoms pharmacotherapy, duration of treatment, cost per bed- day.

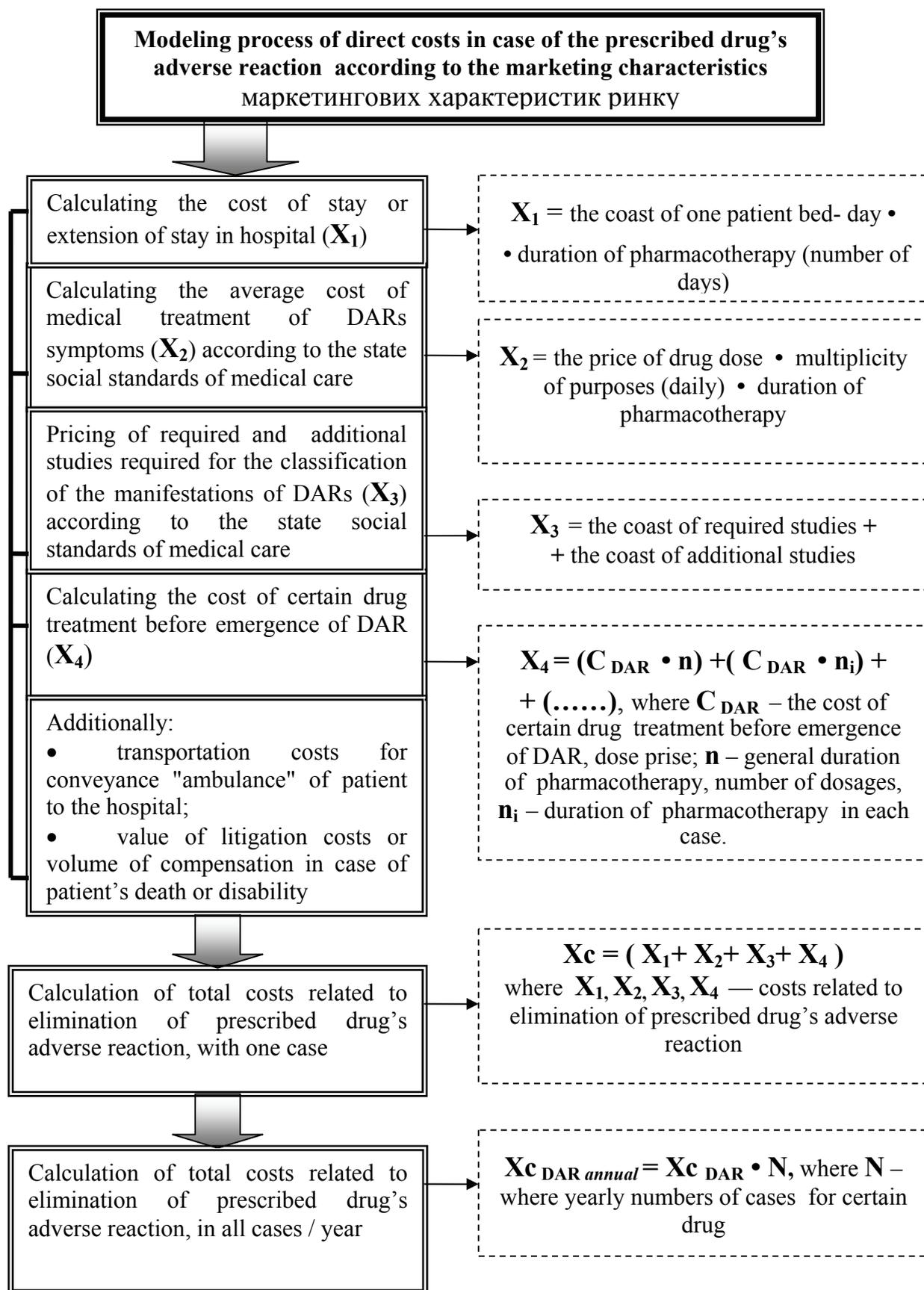


Fig.1 The process of direct costs modeling in case of the prescribed drug's adverse reaction according to marketing characteristics

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Using this algorithm we have calculated the direct costs to remedy the effects of PR through the use of antibacterial drugs. Calculations were carried out using a database of cases of DAR in the Kharkiv region, Ukraine, during few years. Cost measures of care was evaluated based on the minimum purchase prices for drugs (at the time of research) and minimum rates for medical manipulations which were on the health insurance market.

The amount of drug therapy was calculated according to standards of medical care for adult population in Ukraine (Ministry of Healthcare of Ukraine № 507 from 28.12.2002 «On the approval of medical care and quality of medical care standards»).

The analysis shows the need for careful selection of drugs in terms of «quality – safety,» because amounts received as costs to eliminate the effects of DAR in some cases can be reduced to zero rationality and optimization of pharmacotherapy, significantly increase the duration and cost of treatment.

The proposed analysis algorithm allows to assess the level of costs for elimination of AR, promotes cost-effective methods of drug use, improve the quality of medical and pharmaceutical care, rational use of available resources, including budgetary and extra-budgetary funds allocated for drugs purchasing.

IV. Conclusions

1. It is shown that importance of safe consumption of medicines and rational pharmacotherapy causes the need for the mechanism of cost calculation of the adverse events manifestation and choice of medical product development, that allow, on the one hand, to optimize the cost of medical care, and on the other – to achieve the most effective treatment results.

2. Investigation of the specific risks associated with the occurrence of adverse reactions when using drugs, allowed to classify risks into the following groups: for the person receiving medical product, for company-employer, for health care setting; for drug manufacturer.

3. The expediency of conducting pharmacoeconomic analysis considering direct costs in case of DAR. The method for calculating the direct costs to determine more effective (safe) and less expensive drugs for rational drug therapy and expediency of the inclusion of appropriate drugs in the forms of any level was developed and scientifically proved.

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