### **VILNIUS UNIVERSITY**

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# USING NATIONAL HEALTH INSURANCE FUND DATABASE FOR THE ASSESSMENT OF PRESCRIBING QUALITY AND EFFICIENCY

Summary of doctoral dissertation

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### **VILNIAUS UNIVERSITETAS**

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#### BACKGROUND

Health care is to enter its third revolution in the first decades of the 21<sup>st</sup> century, which follows the revolution of the provision of public services (clean water and sewage systems at the beginnings of the 20<sup>th</sup> century) and the revolution of the health science (vaccines, pharmaceuticals, devices in the 20<sup>th</sup> century). The third revolution will be driven by information: the key question is how we can optimize the use of health care recourses on the basis of existing information and knowledge. The rational use of resources includes the spread of global best practices based on available evidence, reduction of variability within the health care system and tackling errors and mistakes in applying the existing technologies.

The key challenge in terms of rational use of medicines for health care systems can be identified as: the assurance of giving the right medicine in right dose for the right patient under the right conditions at lowest cost for society and patient, the reduction of fatal and non-fatal adverse reactions of pharmaceuticals, the avoidance of unnecessary medical treatments.

In the past decades, the most European countries have developed administrative databases to monitor drug utilization, by measuring volume and expenditures of medicines on a national scale. For international comparisons, a drug classification system was elaborated by the World Health Organization, namely the Anatomical Therapeutic and Chemical Classification with standardization of the expression of drug utilization in Defined Daily Doses (the ATC/DDD system). A number of cross-national studies, comparing volume and expenditures of different countries have been published. Meanwhile, national drug utilization monitoring systems have been increasingly used for measuring not only volume and expenditures of prescribing, but also the quality of prescribing.

Hence, it is now time to pay attention to the opportunities and pitfalls in measuring prescribing quality by using indicators derived from drug databases.

Future challenges and opportunities require that policy makers implement successful strategies to guarantee rational use of medicines. Efforts to improve value for money in public spending on pharmaceuticals could do a lot to save resources that could be better spent enhancing the availability, accessibility and appropriate use of effective innovative medicines.

The administrative databases, which capture information about drug utilization in "real world", are required for measuring prescribing quality and efficiency.

**THE AIM** of this thesis is to evaluate to what extent the National Health Insurance Fund (NHIF) database is a relevant and reliable (applicable) tool for the assessment of drug utilization, prescribing quality and efficiency.

#### **OBJECTIVES**

- 1. To assess to what extent the NHIF database is a relevant and reliable database to conduct drug utilization studies.
- 2. To assess prescribing patterns in the various therapeutic areas using NHIF database data:
  - 2.1. To evaluate prescribing quality of antibiotic treatment for infants in outpatient setting.
  - 2.2. To evaluate the prevalence of antidiabetic drugs use for type 2 diabetes in different regions of Lithuania.
- 3. To evaluate applicability of NHIF database for evaluation of prescribing efficiency:
  - 3.1. Assessment of prescribing efficiency evaluating price reductions for generics.
  - 3.2. Assessment of prescribing efficiency using comparison with Western European countries.

#### SCIENTIFIC NOVELTY

The comprehensive investigation on NHIF database data on reimbursed medicines was carried out in this work. That enabled to assess the suitability of NHIF data for evaluation of prescribing patterns, quality and efficiency.

Although few studies on medicines utilization using NHIF data has been published, this database was not comprehensively evaluated and described.

For the first time the medicines prescribing prevalence, quality, as well as regional differences in medicines utilization were assessed using NHIF population based electronic administrative database data. For the first time in Lithuania some widely used

quality indicators have been applied evaluating quality of prescribing of antibacterial drugs for infants. The NHIF data were used in crossnational comparative drug utilization studies. This work has comprehensively demonstrated applicability of different tools for evaluation of prescribing quality and efficiency.

#### THE DEFENSIVE STATEMENTS

- 1. NHIF database data is suitable and reliable for drug utilization studies.
- 2. NHIF database data is suitable for assessing the prescribing quality and rational drug use.
- 3. NHIF database data is suitable for assessing the prescribing efficiency.

#### LITERATURE REVIEW

The literature review covered different the most relevant references on the topic under investigation from pier reviewed medical journals. The increasing drug utilization and rapidly growing expenditure on new drugs is seen as a major challenge to continued equitable and comprehensive healthcare in Europe. This unsustainable growth has resulted in increasing urgency among governments, health authorities and health insurance companies to introduce reforms to improve prescribing efficiency for both new and existing drugs. The measures to evaluate prescribing quality and efficiency were compared. Different experiences in performing drug utilization studies, using administrative and commercial databases were analysed. A recognized problem – the validity of the data in drug utilization studies was discussed.

#### MATERIALS AND METHODS

# The assessment to what extent the NHIF database is a relevant and reliable to conduct drug utilization studies

Data from three different databases were included in this study: NHIF database, Intercontinental Marketing Services (IMS) database, Soft Dent database.

NHIF database

The compulsory health insurance system in Lithuania is a public insurance that constitutes the basis for financing the Lithuanian health care system, covering 98% of the population. Reimbursed drugs accounted for approximately 63% of Lithuanian

prescription pharmaceutical costs in 2009. All reimbursement data are centralized in a single NHIF database.

The NHIF database contains information about patients including their date of birth, gender, sex, place of living, information on prescribed medicine (including the drug name, dose and number of doses in each prescription), the diagnosis, prescriber and pharmacy data. The reimbursement claims are submitted when prescriptions are filled in pharmacies. Unreimbursed drugs and hospital medicines are not included in the NHIF database.

As a result, the NHIF database contains all reimbursed prescriptions for the population of Lithuania. Robustness and validity of the NHIF database is assured by that fact that computerized dispensing records are subject to frequent financial audits, as they are basis of reimbursement. The NHIF database includes data on each prescription at each pharmacy, which has an agreement with NHIF. Data from pharmacy to NHIF data base is trasfered according to the rules of an agreed protocol. NHIF uses the captured data to provide audits to pharmacies and health care institutions.

#### IMS database

IMS is a commercial company, which collects drug utilization data at many different levels of complexity and time periods within and between countries. These data are sold to pharmaceutical companies and governments, and are sometimes provided free of charge for academic research. IMS data are usually based on wholesaler returns and, hence, cover all utilization (reimbursed and unreimbursed drugs). IMS Pharmaceutical Market Audit reports retail pharmaceutical sales in volumes and in number of DDDs (for products which have DDDs defined by WHO).

The Soft Dent database is a commercial database. It contains data (sales and volumes) from wholesale companies on distribution of medicines, including OTC medicines, to pharmacies, with wholesale prices without VAT.

Data on all reimbursed prescriptions for Proton pump inhibitors (PPIs, (ATC group A02BC), statins (C10AA), renin-angiotensin inhibitors (ACEIs – C09AA, ARBs – C09CA), as well as any SSRIs or newer antidepressants, such as venlafaxine, mirtazepine, reboxetine and duloxetine (N06AB and N06AX), from 2004 to 2009 were taken from NHIF database.

IMS data on total number of DDD soled for PPIs, statins, ACEIs and ARBs, SSRIs or newer antidepressants – venlafaxine, mirtazepine, reboxetine and duloxetine from 2004 to 2009 were supplied directly from IMS Health Inc., Lithuania.

Data from these databases were collected only on single preparations of ACEIs and ARBs in a view of the difficulties with recording combination products within IMS data. However, this represented from 83% to 92% of total renin-angiotensin utilization on a DDDs basis during the study period.

Statin utilization data in 2005-2007 from the Soft Dent database were taken directly from the publication.

The PPIs, statins, ACEIs and ARBs, SSRIs or newer antidepressants reimbursement policy description was made performing the orders' of Ministry of Health analysis.

ATC/DDD methodology and ATC/DDD index (2010), were used in line with recommendations. The results were expressed as a number of DDD for Thousand Inhabitants per Day (DDD/TID). Average annual percentage change (AAPC) was calculated on each group, separately on utilization data (DDD/TID) for NHIF database and IMS database. NHIF database utilization figures were subsequently compared with the utilization rates derived from the IMS and the Soft Dent respectively.

# The assessment of prescribing patterns in the various therapeutic areas using NHIF database data

The evaluation of prescribing quality of antibiotic treatment for infants in outpatient setting

The quality of antibiotic prescribing for infants (0-12 months of age) in outpatient setting was analyzed using NHIF data. It was assumed that the number of infants each year is roughly equivalent to the number of children born that year. The birth data for years 2003-2008 was obtained from the Department of Statistics. NHIF prescription data on antibiotics dispensed for infants during the period 2003-2008, were selected. The study included all infants, who claimed at least one dispensing for any systemic antibacterial (ATC group J01).

Infants' antibiotic utilization was expressed as a number of courses of antibiotic treatment (prescriptions) per 1000 infants born in the year. The prevalence rate of

infants treated with antibiotics was expressed as the number of infants treated with antibiotics per 1000 infants.

Prescription quality was assessed using the following quality indicators: prevalence of antibiotic prescription in infants, the ratio of narrow and broad-spectrum penicillins, the ratio of oral and injectable formulations, and indications (according International Classification of Deseases 10 version (ICD-10)) for antibiotic prescribing. These indicators were determined and compared in different regions (counties) of Lithuania.

Statistical analysis was performed using StatsDirect (version 2.7.8.) and MS Excel software. The parameters of the mean and standard error were calculated. Antibiotic utilization and prevalence rate changes were calculated on the AAPC.

The assessment of the prevalence of the use of antidiabetic drugs for type 2 diabetes in different regions of Lithuania

The the prevalence of the use antidiabetic drugs prescribed for type 2 diabetes in different regions of Lithuania (counties) was analyzed using NHIF data. This observational study included all patients who had type 2 diabetes mellitus (ICD-10 code E11), and was assigned to at least one prescription of medicines from ATC groups A10A and A10B in 2008-2010. Information on the annual average population Statistics in Lithuania and in individual 10 different regions (counties) were obtained from the Department of Statistics.

The prevalence and patterns of the use of antidiabetic drugs (including oral antidiabetic drugs (biguanides, sulphonylureas, thiazolidinediones), combination of oral antidiabetic drugs and insulin, and only insulin) in Lithuania and in different regions (counties) in 2008-2010 was analyzed. Assignement of patients to specific region was done using patient sign-in to the primary health-care provider of health care facilities area. Prevalence of the use of antidiabetic drugs was expressed by a number of patients treated with antidiabetic drugs per 1000 inhabitants.

Patients were divided to three groups according the following criteria:

- those, who received only oral antidiabetic drugs during a year period,
- those, who received a combinations of oral antidiabetic drugs and insulin during a year period,

• those, who received only insulin during a year period.

Statistical analysis was performed using StatsDirect (2.7.8.version) and MS Excel software. The parameters of the mean and standard error were calculated. Changes in the prevalence of drugs were estimated using AAPC.

#### Evaluation NHIF database data applicability for prescribing efficiency assessment

Assessment of prescribing efficiency evaluating price reductions for generics

Prescription data for period (2000-2001 and 2009) were obtained from the NHIF database.

The study included all patients who were dispensed at least one reimbursed prescription for any PPI (A02BC), statin (C10AA), ACE inhibitor (ACEIs – C09AA), or SSRI (N06AB) in 2000/2001 and in 2009. ATC/DDD index (2010) was used for the study.

The prices (reimbursed expenditure/DDD) of generics of PPI, statin, ACE inhibitor, SSRI groups in 2009 were compared with prices of originator in 2000 or 2001 (reimbursed expenditure/DDD). The percentage prices reduction was calculated for the various generics during period 2000/2001-2009.

The percentage price reduction for various generics in Lithuania was compared with percentage price reduction for generics in other European countries (data taken from publications).

Assessment of prescribing efficiency using comparison with other European countries

This is a cross-national retrospective observational study involving the analysis of reimbursed utilization and expenditure on a yearly basis for the PPIs(A02BC) and statins(C10AA) among European countries.

Data from nineteen European countries and regions databases were used in this study.

The following definitions have been used to classify the different pricing approaches for generics across Europe:

 Prescriptive pricing (PP) – mandated price reductions for generics for reimbursement compared with, for instance, pre-patent loss prices for the originator;

- Market forces (MF) no prescriptive pricing approaches; price reductions left to market forces with typically patients paying an additional co-payment for a more expensive drugs, including branded generics;
- Mixed approaches (MA) typically prescriptive pricing for the first generic or generics; market forces after that.

Information about country generic policy was obtained from the study participants.

Only administrative databases data were used to ensure standartization across countries.

Utilization rates for the different molecules in each class were computed using ATC/DDD index (2010) with utilization patterns in 2007 generally compared with 2001.

The data sets collected to compare prescribing efficiency for the PPI and statin among the European countries included:

- Total DDDs in 2001 and 2007
- DDD/TID
- Reimbursed expenditure in 2001 and 2007
- Reimbursed expenditure (Eur)/1000 inhabitants/year in 2007

Table 1. Principal measures used to evaluate changes in prescribing efficiency for both the PPIs and statins during the study period

Objective	Measure	Efficiency criteria/comment
Assessment of	The increase in utilization	Three efficiency criteria
overall prescribing	rates versus the increase	No efficiency – rate of increase in expenditure
efficiency	in reimbursed expenditure	exceeds utilization
	over time	Efficient countries – rate of increase in utilization
		more than double the rate of increase in
		expenditure
		Considerable efficiency – reimbursed expenditure
		decreasing over time despite increasing utilization
Extent of potential	Overall utilization in 2007	Data treated with caution as different co-payment
savings from	(DDD/TID) compared	levels for the PPIs and statins in addition to any
increasing	with overall expenditure	co-payment for the package
prescribing	(Eur/1000	
efficiency	inhabitants/year), with	
	both measures adjusted	
	for population sizes	

#### **RESULTS**

# Assessment to what extent the NHIF database is a relevant and reliable database to conduct drug utilization studies

In order to perform an accurate comparison between databases specific drugs reimbursement conditions should be described.

- 1) Prescribing restrictions and co-payment issues during the study period
- PPIs

PPIs have a 50% co-payment for reimbursement. In addition, reimbursement is currently restricted to patients with reflux oesophagitis, duodenal ulcers, or for *Helicobacter pylori* eradication. Alongside this, until 2006 omeprazole, rabeprazole and esomeprazole were reimbursed. However, from 2006 only omeprazole was reimbursed in a view of the high cost of the other essentially similar PPIs.

#### Statins

There is currently a 20% co-payment for reimbursed statins. In addition, statins are only reimbursed for secondary prevention. Up to 2006 statins were reimbursed only for 6 months period. Alongside this, up to 2006 statins could only be prescribed by cardiologists for reimbursement. Since 2006, the first prescription must still be issued by a cardiologist although GPs are subsequently allowed to continue prescribing, which is enforced through an active gatekeeper system in Lithuania. Restrictions though have recently been lifted for generic statins.

#### ACEIs and ARBs

There is a 20% co-payment for reimbursed ACEIs and ARBs. There are currently no prescribing restrictions for ACEIs in patients with hypertension, although there are prescribing restrictions for original ARBs (for active substance without generic analogue).

#### • Selected antidepressants

There is a 20% co-payment for reimbursed antidepresants. Similar to ACEs and ARBs, there are currently no prescribing restrictions. However, after 3 months, GPs are obliged to refer patients to psychiatrist if they are not responding to the initial course of treatment.

#### 2) Utilization comparisons between the commercial and NHIF databases

#### PPIs

Total PPIs utilization in the IMS database increased from 4.9 in 2004 to 17.6 DDD/TID in 2009, representing an AAPC of 53% (Table 2). Reimbursed PPIs utilization increased from 0.7 in 2004 to 2.8 DDD/TID in 2009, representing a similar AAPC of 60% during the same period.

Table 2. Utilization of PPIs from 2004 to 2009 among NHIF and IMS databases

DDD/TID	2004	2005	2006	2007	2008	2009	AAPC
IMS total DDD/TID	4.9	7.0	10.4	13.8	18.7	17.6	52%
NHIF reimbursed DDD/TID	0.7	1.4	2.0	2.3	2.9	2.8	60%
% reimbursed DDD/TID vs. IMS	14.5	20	19	16.5	16	16	

Overall, there was a 5 to 7 fold difference (Table 2) between utilization rates in the IMS versus NHIF databases, with the utilization rates in the administrative database (NHIF) varying from 14.5% to 20% of commercial database rates during the study period.

#### Statins

Statin utilization increased by just over 3 fold from 2.4 DDD/TID in 2004 to 7.7 DDD/TID in 2009 in the IMS database, with a similar rate of increase in the NHIF averaging approximately 44% per year (Table 3). The utilization rates in the two commercial databases containing OTC and self purchases were similar when utilization was converted to 2010 DDDs (Table 3).

Table 3. Utilization of statins from 2004 to 2009 among NHIF, Soft dent and IMS databases

			_	,			
DDD/TID	2004	2005	2006	2007	2008	2009	AAPC
IMS total DDD/TID	2.4	2.3	3.1	4.5	7.1	7.7	44%
NHIF reimbursed DDD/TID	0.6	0.6	0.7	0.8	1.1	1.8	40%
Soft Dent database DDD/TID	n.d.	2.7	3.0	4.4	n.d.	n.d.	
% of NHIF database DDD/	23	27	21	18	15	24	
TID vs. IMS	23	21	21	10	13	24	
% of NHIF DDD/ TID vs. Soft	n.d.	23	23	18	n.d.	n.d.	
Dent database	11.0.	23	23	10	11.0.	n.a.	

NB Data on Soft Dent database only available 2005 to 2007

Utilization rates in the NHIF database were low when compared with the IMS database, mirroring the results seen with the Soft Dent database. Overall utilization in the

administrative database ranged from 15% to 27% of total IMS utilization during the study period, i.e. 3 to 6 fold differences between 2004 and 2009.

#### ACEIs and ARBs

Total utilization of single ACEIs and ARBs in the IMS database grew steadily from 99.7 in 2004 to 147.3 DDDs/TID in 2009 (Table 4). Utilization rates appeared similar between IMS and NHIF database, with reimbursed rates at between 83% and 89% of total IMS utilization (Table 4) 2005 to 2009.

Table 4. Utilization of single ACEIs and ARBs from 2004 to 2009 among NHIF and IMS databases

DDD/TID	2004	2005	2006	2007	2008	2009	AAPC
IMS total DDD/TID	99.7	100.8	117.3	131.4	147.5	147.3	10%
NHIF reimbursed DDD/TID	75.4	83.6	97.2	111.3	128.2	131.8	15%
% of reimbursed vs. IMS	76	83	83	85	87	89	

The AAPC of 15% between 2004 and 2009 was greater in the administrative database (NHIF) compared to IMS database, which was only 10% per year during the study period.

#### Selected antidepressants

The utilization of selected antidepressants grew from 7.7 in 2004 to 13.7 DDD/TID in 2009 in the IMS database (Table 5). Again, limited differences between NHIF and IMS databases, with reimbursed utilization between 83% and 88% of IMS utilization (Table 5).

Table 5. Utilization of selected antidepressants from 2004 to 2009 among NHIF and IMS databases

DDD/TID	2004	2005	2006	2007	2008	2009	AAPC
IMS total DDD/TID	7.7	8.1	10.0	11.7	13.4	13.7	16%
NHIF reimbursed DDD/TID	5.4	6.5	7.9	8.9	11.0	12.1	26%
% of reimbursed vs. IMS	71	80	79	76	83	88	

Overall, the AAPC in the IMS database was lower than in the NHIF database, 16% versus 26%, respectively.

# • Assessment of prescribing pattern in the various therapeutic areas using NHIF database data

2.1 Evaluation of prescribing quality of antibiotics' treatment for infants in outpatient setting

During the period 2003-2008 utilization of antibiotics in infants decreased with an AAPC of -6.3% (Table 6).

Table 6. Antibiotic utilization in infants in Lithuania in 2003-2008

Year	Number of treatment courses	Number of infants, treated with antibiotic	Antibiotic utilization in infants (number of courses per 1000 infants)	Prevalence rate of infants treated with antibiotics (The number of infants treated with antibiotics per 1000 infants)
2003	32022	18247	1047	59.6
2004	37490	20073	1232	66.0
2005	32798	17911	1074	58.6
2006	26498	15851	848	50.7
2007	29887	17038	924	52.7
2008	25210	15346	719	43.8

The prevalence rate of infants treated with antibiotics – decreased with an AAPC of -5.3% during the period 2003-2008.

Fourteen different antibiotics were prescribed during the study period (Table 7).

Table 7. Antibiotics prescribed for infants in 2003–2008

Group of antibiotics	ATC-code	Drug name
Broad spectrum penicillins	J01CA04	Amoxicillin
Narow spectrum penicillins	J01CE01	Benzylpenicillin
	J01CE02	Fhenoxymethylpenicillin
Combinations of penicillins, incl. beta-	J01CR02	Amoxicillin and clavulavic acid
lactamase inhibitors	J01CR04	Sultamicillin
First-generation cephalosporins	J01DB05	Cefadroxil
Second-generation cephalosporins	J01DC02	Cefuroxime
	J01DC10	Cefprozil
Sulfonamides and trimethoprim	J01EE01	Sulfamethoxazole and trimethoprim
Macrolides	J01FA01	Erythromycin
	J01FA09	Clarithromycin
	J01FA10	Azithromycin
Aminoglycoside antibacterials	J01GB03	Gentamicin
Nitrofuran derivatives	J01XE01	Nitrofurantoin

The majority of infants received broad spectrum penicillins (J01CA) and broad-spectrum penicillins with β-lactamase inhibitors (J01CR). Each year these two groups of antibiotics made up around 65% of all courses. Macrolides (J01FA) were the third mostly prescribed group of drugs (about 14% of all courses). Cephalosporins (J01D) made up about 9% annually. Narrow-spectrum penicillins (J01CE) accounted only for 7.4% in 2003 and 5.4% in 2008 (Figure 1). Broad and narrow spectrum penicillins ratio was 9.2 in 2003 and 12.9 in 2008. In the most of the cases infants have been treated with amoxicillin. Five antibiotics, amoxicillin, amoxicillin with clavulanic acid, cefadroxil, clarithromycin, and azithromycin, made up 85% of all antibiotic treatment courses in 2003-2008.

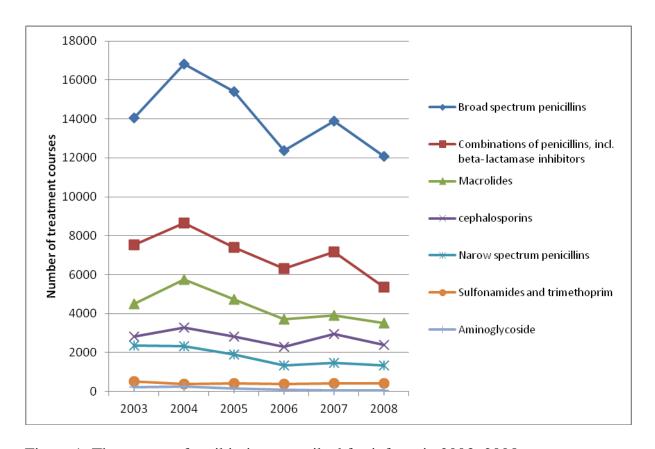


Figure 1. The groups of antibiotics prescribed for infants in 2003–2008

Oral antibiotics accounted for 97-99% of all courses. Injectable antibiotics were rarely prescribed for infants in outpatient setting; they made up only 1-3%.

Every year, about 83% of antibiotic courses were prescribed for treatment of various respiratory diseases. The most common diagnoses were acute bronchitis (J20),

acute pharyngitis (J02) and acute nasopharyngitis (J00) (Figure 2). Each year, only 3% of antibiotic courses were prescribed for treatment of pneumonia in infants.

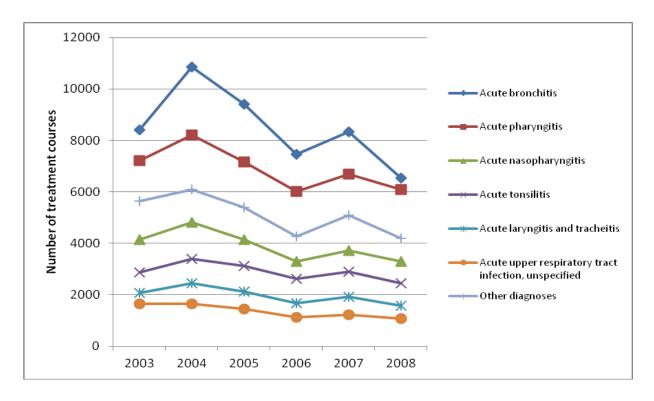


Figure 2. Indications for antibiotic prescribing in infants 2003-2008

Table 8. Antibiotics utilization in infants in 2003-2008

Year	The number of treatment courses per 1000 infants			The prevaler antibiotics (The antibi	e number o		ated with	
	Average +/- standar error	Min	Max	Ratio max/min	Average +/- standar error	Min	Maks	Ratio max/min
2003	1199 +/-97	652	1551	2.4	68.9 +/- 6.2	38.9	99.4	2.6
2004	1419+/-117	764	1889	2.5	73.6 +/- 4.7	46.0	88.9	1.9
2005	1233+/-107	673	1746	2.6	68.4 +/- 6.4	39.4	99.8	2.5
2006	979 +/- 98	537	1370	2.6	59.5 +/- 5.1	33.3	83.4	2.5
2007	1093+/- 98	554	1596	2.9	62.1 +/- 5.5	31.4	89.2	2.8
2008	846 +/- 79	418	1233	3.0	62.6 +/- 5.3	28.1	79.0	2.8

Comparison of the use of antibiotics in infant in different counties of Lithuania showed that the number of courses per 1000 infants varied up to three fold in different counties during the study period (Table 8).

Antibiotic utilization in different counties of Lithuania varied up to 2.8-fold (Figure 3). The lowest prevalence rate was in Kaunas county,  $38.2 \ (+/-2.6)$ , while the highest in Alytus county,  $89.0 \ (+/-3.6) \ (p < 0.05)$ .

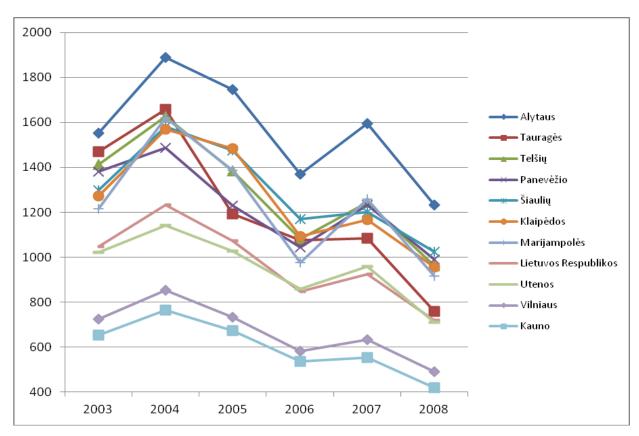


Figure 3. Antibiotic utilization in infants in different counties in 2003-2008

# 2.2 Assessment of prevalence of the use of antidiabetic drugs for type 2 diabetes in different regions of Lithuania

Prevalence (a number of patients treated with antidiabetic drugs per 1000 inhabitants) of the use of antidiabetic drugs for type 2 diabetes increased from 21.7 in 2008, to 25.5 in 2010. The AAPC in prevalence of the use of antidiabetic drugs was 8.7% during 2008-2010.

During the study period, the most of the patients were treated with oral antidiabetic drugs, which accounted for 73%, insulin preparations made up 16%, and combination of insulin and oral antidiabetics -11%.

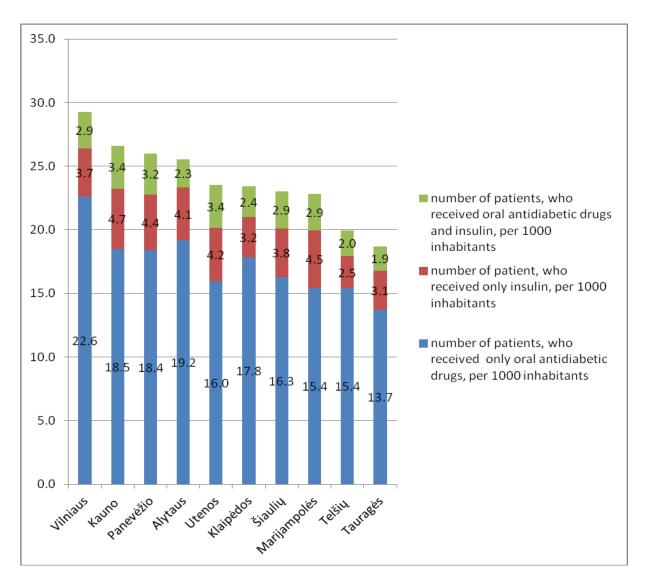


Figure 4. Prevalence of the use of antidiabetic drugs for type 2 diabetes in counties of Lithuania in 2010

The prevalence of the use of antidiabetic drugs is shown in Table 9. The highest value of prevalence was in Vilnius, and the lowest was in Tauragė (Table 9).

Table 9. Prevalence of the use of antidiabetic drugs (number of patients treated with antidiabetic drugs per 1000 inhabitants)

Year	Average +/- standart error	Min	Max	Ratio max/min
2008	20.21 +/-0.98	15.52	25.21	1.62
2009	22.14+/-1.01	17.35	27.32	1.57
2010	25.46+/-1.05	18.71	29.25	1.56

Prevalence of the use of oral antidiabetic drugs is shown in Table. 10. The highest prevalence of the use of oral antidiabetic drugs prevalence was seen in Vilnius, and the lowest was in Tauragė (Figure 4).

Table 10. Prevalence of the use of oral antidiabetic drugs (a number of patients treated with only oral antidiabetics per 1000 inhabitants)

Year	Average +/- standart error	Min	Max	Ratio max/min
2008	14.66 +/-0.75	11.38	19.43	1.71
2009	16.05+/-0.77	12.70	21.07	1.66
2010	17.33+/-0.80	13.72	22.63	1.65

The prevalence of insulin monotherapy is demontrated in Table 11. The highest value of prvalence was in Marijampolė in 2008, and in Kaunas in 2009-2010, the lowest was in Telšiai county (Table 11).

Table 11. Prevalence of the use of insulins (a number of patients treated with insulin only per 1000 inhabitants)

Year	Average +/- standart error	Min	Max	Ratio max/min
2008	3.39 +/-0.19	2.37	4.11	1.73
2009	3.65+/-0.21	2.33	4.36	1.87
2010	3.82+/-0.23	2.50	4.75	1.90

The prevalence of the use of combination of oral antidiabetics and insulins is shown in Table 12. The highest prevalence of the use of combination of oral antidiabetic drugs and insulins was in Utena county in 2008 and in Kaunas county in 2009-2010, the lowest prevalence was in Tauragė.

Table 12. Prevalence of the use of combination of oral antidiabetics and insulins (a number of patients treated with oral antidiabetics and insulins per 1000 inhabitants)

Year	Average +/- standart error	Min	Max	Ratio max/min
2008	2.17 +/-0.16	1.46	2.89	1.98
2009	2.45+/-0.17	1.62	3.19	1.97
2010	2.73+/-0.17	1.92	3.37	1.76

# Evaluation NHIF database data applicability for the assessment of prescribing efficiency

3.1 Assessment of prescribing efficiency evaluating price reductions for generics

#### • Generic omeprazole

The percentage prices reduction for generic omeprazole was 56%, e.g. generic omeprazole price (reimbursed expenditure/DDD) in 2009 was 56% below originator price in 2000.

This compares with price reductions for generic omeprazole in 2007 (between 52% and 85%) versus originator prices in 2001 among a range of European countries. These included Austria, France, Germany, Italy, Portugal, Spain, Sweden and the UK.

Seven manufacturers of generic omeprazole were included in the Price List in 2008 and 7 in 2009 in Lithuania.

#### • Generic simvastatin

In the first year of generic availability the percentage of price reduction for generic simvastatin was 83% below the originator price in 2000, i.e. this makes up only 17% of the originator price in 2000. As a consequence of this price erosion, the manufacturer of originator simvastatin left the market place in 2004.

These findings again compare well with price reductions of between 53% and 97% for generic simvastatin in 2007, versus typically originator prices in 2001, among a range of European countries. These again included Austria, France, Germany, Italy, Portugal, Spain, Sweden and the UK.

The price of generic atorvastatin in Lithuania in 2009 was 87% below of the price of originator in 2001 (Figure 5). However, generic atorvastatin was not typically available among Western European countries during the study period.

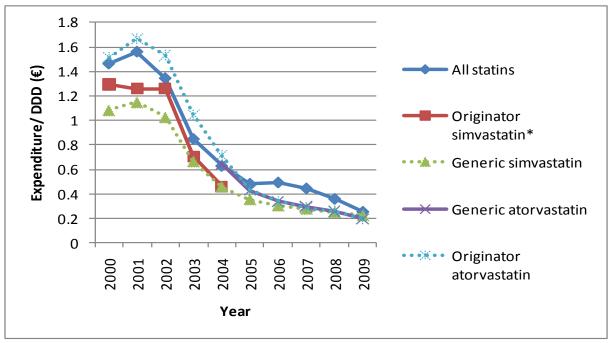


Figure 5. Reimbursed expenditure/DDD for selected statins in Lithuania (Eur) \*NB There was limited or no utilization of originator simvastatin after 2003

Four manufacturers of generic simvastatin were included in the Price List in 2008 and 5 - in 2009 in Lthuania.

#### ACEIs

There were similar reductions in the reimbursed prices of generics ACEIs over time (Table 13).

Table 13. The percentage reduction in price (reimbursed expenditure/DDD) for selected generic ACEIs versus originator prices in 2001 over time in Lithuania

ACEI	Year of availability of the first	% reduction versus originator prices in	
	generic	2001	
Generic enalapril	1997	52%	
Generic ramipril	2004	65%	
Generic quinapril	2006	50%	
Generic fosinopril	2006	63%	

Our data compare with the following (on expenditure/DDD basis):

- Austria 44% reduction for generic enalapril in 2007 vs. originator prices in 2001, 77% reduction for generic ramipril in 2007 vs. originator prices in 2001.
- Portugal 40% reduction for generic enalapril in 2007 vs. originator prices in 2000.

- Scotland 50% reduction for generic enalapril in 2007 vs. originator prices in 2001.
- Spain (Catalonia) 62% reduction for generic enalapril in 2007 versus originator prices in 2003.
- Sweden 87% reduction for both generic enalapril and generic ramipril in 2007 vs. originator prices in 2001.

Six manufacturers of generic enalapril were included in the Price List in 2008 and 5 in 2009 in Lithuania. Similarly, there were 6 manufacturers of generic ramipril in 2008 and 7 in 2009.

#### SSRIs

Table 14 depicts the percentage reduction in prices of generic SSRIs over time in Lithuania.

Table 14. The percentage reduction in prices of selected generic SSRIs (reimbursed expenditure/DDD) in 2009 vs. originator prices in 2001 in Lithuania

Generic SSRIs	% reduction generic vs. originator	Generics available in 2001	
	prices in 2001		
Fluoxetine	55%	Yes	
Citalopram	59%	No	
Sertraline	73%	No	

Similar reductions were also seen among other European countries with the possible exception of Sweden (Table 15).

Table 15. The percentage reduction in prices of selected generic SSRIs in 2007 vs. originator prices in 2001 (on expenditure/DDD basis)

Country	% reduction	% reduction citalopram	% reduction sertraline
	fluoxetine		
Austria	55%	59%	73%
Portugal	48%	NA	40%
Scotland	87%	83%	87%
Spain	65%	47%	47%
(Catalonia)*			
Sweden	92%	94%	95%

\*Spain: 2007 vs. 2003

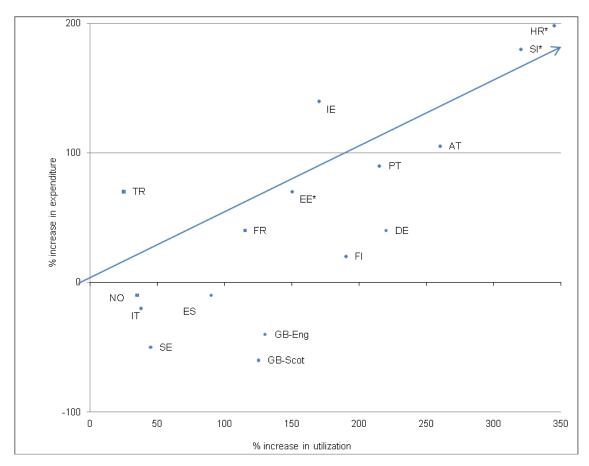
Overall, 4 manufacturers of generic fluoxetine were included in the Price List in 2008 and 3 in 2009, 6 manufacturers of generic citalopram in 2008 and 6 in 2009, and 6 manufacturers of generic sertraline in 2008 and 7 in 2009 in Lithuania.

3.2 Assessment of prescribing efficiency using comparison with other European countries

Figure 6 demonstrates the influence of the various supply and demand-side measures on PPIs prescribing efficiency among the different European countries and regions as measured by the rate of change in utilization (DDDs) versus reimbursed expenditure principally between 2001 and 2007. The countries have been broken down by:

- Geography into Central and Eastern European countries.
- Different approaches to pricing of generics: Prescriptive PP, Market Forces MF,
  Mixed MA

In both Lithuania and Poland, there was approximately a two fold difference in the rate of increase in utilization (DDD basis) versus the rate of increase in reimbursed expenditure for the PPIs between 2001 and 2007, e.g., in Lithuania utilization increased 10.8-fold between 2001 and 2007 and in Poland over 150-fold between 2002 and 2007. This appreciable increase in utilization following reimbursement, which was considerably greater than seen in the other European countries, led to their exclusion from Figure 8. In Lithuania, increase in PPIs utilization was from 0.12 DDD/TID in 2001 to 2.28 DDD/TID in 2007; increase in expenditure was from 10 Eur per 1000 inhabitants per year in 2001 to 100 Eur per 1000 inhabitants per year in 2007. Because of considerable PPIs utilization (1800%) and expenditure (900%) growth Lithuanian data were excluded from Figure 6. It may be said that expenditure for PPIs reimbursement in Lituania was used efficiently, since the rate of increase in utilization more than double the rate of increase in expenditure.

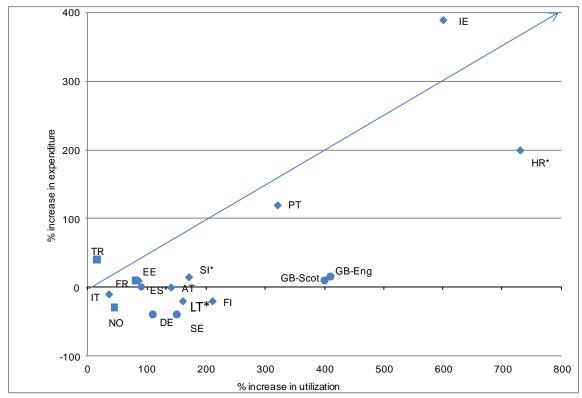


Generic pricing: ■ - PP, ● - MF, ◆ - MA. \* - CEE countries

Figure 6. Rate of increase in expenditure versus the rate of increase in utilization (DDD based) for the PPIs principally from 2007 versus 2001 among European countries (unless stated), with generic pricing approaches divided into three categories. Standard country abbreviations have been used. ES = Catalonia (2007 versus 2003), EE = 2007 versus 2004, HR = 2007 versus 2000, IT = 2008 versus 2006, NO = 2007 versus 2004, TR = 2009 versus 2007.

In Lithuania increase in statins utilization was from 0.3 DDD/TID in 2001 to 0.8 DDD/TID in 2007. The expenditure for statins reimbursement decrease from 171 Eur/1000 inhabitants per year in 2001 to 128 Eur/1000 inhabitants per year in 2007.

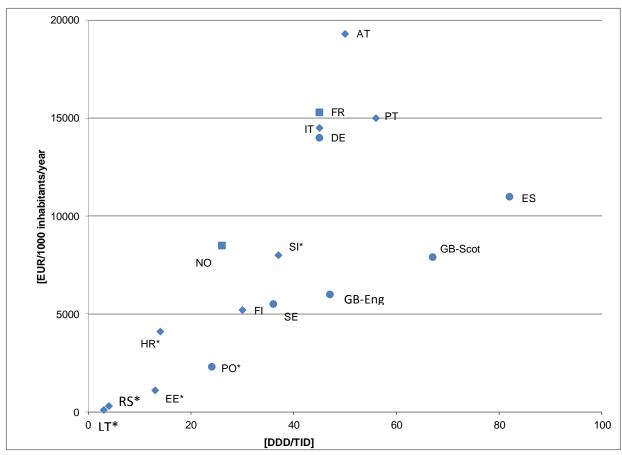
The expenditure for statins reimbursement was used considerable efficiently in Lithuania, because reimbursed expenditure decreasing over time despite increasing utilization (Figure 7).



Generic pricing: ■ - PP, ● - MF, ◆- MA. \* – CEE countries

Figure 7. | Percentage change in utilization (DDDs) versus the percentage change in reimbursed expenditure for the statins principally from 2001 to 2007 among European countries. The countries again divided into former Central and Eastern European countries (CEE) with the approaches to generic pricing divided into three categories. Standard country abbreviations have been used. ES = Catalonia (2007 versus 2003), EE = 2007 versus 2004, HR = 2007 versus 2000, IT = 2008 versus 2006, NO = 2007 versus 2004, TR = 2009 versus 2007.

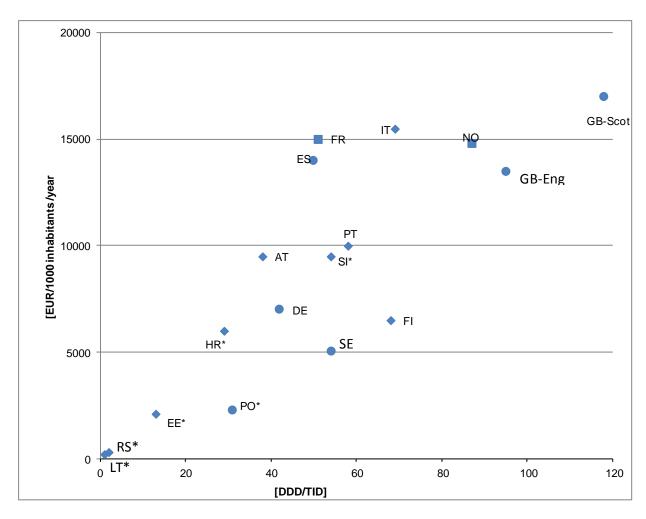
Significantly lower PPIs utilization rates were found in Eastern and Central European countries than in Western European countries. Lithuania has the lowest PPIs intake (2.28 DDD/TID). Among Western European countries significant PPIs cost differences at exactly the same utilization rates were seen. England, Scotland and Sweden spend significantly less money than France, Portugal, or Italy for PPIs reimbursement (Figure 8).



Generic pricing: ■ - PP, ● - MF, •- MA. \* - CEE countries

Figure 8. Utilization (DDD/TID) and overall expenditure (Eur/1000 inhabitants/year) for PPIs among European countries in 2007 (Italy 2008, Serbia 2008). Standard country abbreviations have been used. ES = Catalonia. Republic of Ireland not included as the GMS population has greater morbidity than the general population.

Study shows much lower rates of statins utilization in Eastern and Central European countries than in Western European countries. The lowest intake of statins is in Lithuania (0.8 DDD/TID). Among Western European countries significant cost differences at exactly the same utilization rates were seen. Sweden, Finland spent significantly less money France, Portugal for statins reimbursement (Figure 9).



Generic pricing: ■ - PP, ● - MF, ◆- MA. \* - CEE countries

Figure 9. Utilization (DDD/TID) and overall expenditure (Eur/1000 inhabitants/year) for the statins among European countries in 2007 (Italy 2008, Serbia 2008). Standard country abbreviations have been used. ES = Catalonia. Republic of Ireland not included as the GMS population has greater morbidity than the general population.

#### **CONCLUSIONS**

- NHIF database data is suitable for drug utilization studies. NHIF database data on drugs with prescribing restrictions represents only a part of the total drugs utilization in Lithuania.
- 2. NHIF database data can be used to assess prescribing quality to analyse prevalence of drugs utilization, variations in prescribing in different Lithuanian regions.
  - 2.1. During the first year of life, half of the infants are treated with systemic antibiotics. Antibiotic utilization in infants has decreased during study period. Broad spectrum antibiotic were the mostly prescribed antibiotics for the first year children. The most of antibiotics were prescribed for viral infections.

- 2.2. Wide variations were observed between regions for prevalence of use of all antidiabetic drugs (1.6 fold). The highest variability was observed in prevalence of the use of insulin monotherapy (1.9 fold).
- 3. NHIF database data is applicable for the evaluation of prescribing efficiency:
  - 3.2. NHIF expenditure of PPIs, statins, ACEIs and selected antidepressants had been used effectively for the period 2000-2009. The reimbursed price reduction of these drugs was the same as in other European countries.
  - 3.3. NHIF expenditure for PPIs reimbursement during period 2001-2007 had been used efficiently; the growth rate of utilization of this drug class was two times higher than the expenditure growth rate. NHIF expenditure for statins reimbursement during the period 2001-2007 had been used considerably efficiently. The utilization of these drugs increased by 2.7 fold, when expenditure for reimbursement of statins decreased. Utilization rates of reimbursed statins and PPIs are the lowest among 19 European countries.

#### RECOMMENDATIONS

NHIF database is a valuable tool for the analysis of drug utilization, quality of care, prescribing efficiency and drug policy. It have been shown that in the drug utilization studies, particularly in cross-national comparative drug utilization studies, it is important to describe in detail a database, and drug reimbursement policy (including any prescribing restrictions).

NHIF database should be accessible for scientific research, in order to facilitate analysis of the data and make these available for further improvement of health care system.

NHIF captured data should be used for evaluation of prescribing quality. Ministry of Health should promote development of prescribing quality indicators and implement procedures of prescribing quality evaluation. Prescribing quality indicators, based on NHIF data, should be implemented in the national system for feedback to individual prescribers. Prescribing quality indicators should be used in payment for extra services on activity based results.

NHIF captured data could be used for evaluation of drug use prevalence variation in different regions of Lithuania. The regional prescribing variation indicates the need for a more detailed analysis of the causes of regional variation, introduction of interventions or academic detailing in order to improve prescribing.

NHIF data could be used for evaluation of prescribing efficiency.

The Ministry of Health should use the evaluation of prescribing efficiency for assessment of generic drug policy to continue funding comprehensive and equitable healthcare. Effective generic medicines policy allows introduction of high-priced innovative drugs into the reimbursement system.

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- 2. Garuoliene K, Godman B. Gulbinovič J, Wettermark B, Haycox A. European countries with small populations can obtain low prices for drugs: Lithuania as a case history. Expert Review of Pharmacoeconomics and Outcomes Research. ISSN 1473-7167. 2011;11(3):343-9.
- 3. Garuolienė K, Basys V, Gulbinovič J. Kūdikių gydymo antibiotikais kokybės vertinimas. Lietuvos bendrosios praktikos gydytojas. ISSN 1392-3218. 2011; 15(5):397-403.
- 4. Garuoliene K, Godman B. Gulbinovič J, Wettermark B. Care needed when comparing utilization rates between commercial and administrative databases in cross national comparative studies? Advances in Pharmacoepidemiology and Drug Safety. Pateikta spaudai.

#### **PRESENTATIONS**

#### Posters:

- Garuoliene K, Gulbinovic J. Quality of antibiotic prescribing in infant in ambulatory care. Basic and Clinical Pharmacology and Toxicology. 2010; 107:S2352. Poster presentation at the 16 World Congress of Basic and Clinical Pharmacology, 17-23 July, 2010, Copenhagen, Denmark.
- 2. Garuoliene K. Impact of recent reforms in Lithuania on pharmaceutical utilization. 7th Baltic policy dialogue on Ensuring access to medicines: harnessing health policies in face of the crisis: 2010, 2-3 Sept, Tallinn, Estonia.
- 3. Garuoliene K, Gulbinovic J, Godman B, Wettermark B. Care needed when evaluating the impact of health policies using different databases. Book of Abstracts Health Technology Assessment International. 2011, M-260 (759). Poster presentation at the 8th Annual Meeting Health Technology Assessment International, 27-29 June, 2011, Rio de Janeiro, Brazil.
- 4. Garuoliene K, Gulbinovic J, Godman B, Wettermark B. Haycox A. European countries with small populations cannot obtain appreciable price reductions or generics: fact or fiction? Book of Abstracts Health Technology Assessment International. 2011, M-259 (760). Poster presentation at the 8 th Annual Meeting Health Technology Assessment International, 27-29 June, 2011, Rio de Janeiro, Brazil.

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### **Experience**

A member of Piperska group, Rational Prescribing group, Pharmaceutical Pricing Reimbursement Information network, European Drug Utilization Research group, International Society for Pharmacoepidemiology, Health Technology Assessment International, participate in the WHO and the European Commission activity.

# VAISTŲ SKYRIMO VERTINIMAS, NAUDOJANT VALSTYBINĖS LIGONIŲ KASOS INFORMACINĘ SISTEMĄ

### Disertacijos reziume

#### **DARBO AKTUALUMAS**

Nedaug yra žinoma apie nuolat vykstantį tyrimą – vaistų vartojimą "realiame gyvenime". Todėl ne tik Lietuvoje, bet ir kitose šalyse norima sužinoti, ar vaistai yra tinkamai skiriami ir vartojami, ar kasdienėje klinikinėje praktikoje jie yra tokie pat efektyvūs ir saugūs kaip buvo nustatyta klinikiniuose tyrimuose, ar vaistai yra finansiškai prieinami pacientams, ar skiriant vaistus yra optimaliai naudojami sveikatos apsaugos sektoriaus finansiniai resursai.

Optimalus lėšų vaistų kompensavimui panaudojimas tapo ypač aktualus, nes net pačių turtingiausių šalių vaistų politikos formuotojai susiduria su dilema, kaip užtikrinti inovatyvių brangių vaistų prieinamumą pacientams.

Dėl šios priežasties, skatinamas racionalus vaistų vartojimas, kuris suteikia galimybę parinkti tinkamiausią gydymą pacientui, optimaliai naudoti lėšas vaistams, sudaryti galimybę kompensuoti naujus vaistus. Aktualūs tampa tyrimai, kurie vertina ir analizuoja įprastinę vaistų skyrimo praktiką, nustato vaistų vartojimo problemas ir jų priežastis, vertina intervencijų, gerinančių vaistų skyrimo praktiką, efektą.

Nacionalinės administracinės duomenų bazės, kaupiančios informaciją apie vaistų suvartojimą ir išlaidas visos šalies populiacijos mastu, yra laikomos tinkamiausiais duomenų šaltiniais vaistų skyrimo kokybei ir efektyvumui vertinti

#### **TIKSLAS**

Nustatyti VLKIS sukauptų duomenų apie išduotus kompensuojamuosius vaistus tinkamumą vaistų suvartojimui, vaistų skyrimo kokybei ir efektyvumui vertinti.

#### UŽDAVINIAI

- 1. Įvertinti VLKIS duomenų tinkamumą vaistų suvartojimo tyrimams atlikti.
- 2. Įvertinti atskirų vaistų grupių vartojimą, naudojant VLKIS sukauptus duomenis apie išduotus kompensuojamuosius vaistus:
- 2.1. Įvertinti kūdikių gydymo antibiotikais ambulatorinėje praktikoje kokybę.

- 2.2. Įvertinti 2 tipo cukrinio diabeto gydymui skiriamų antidiabetinių vaistų paplitimą skirtinguose Lietuvos regionuose.
- 3. Nustatyti VLKIS duomenų tinkamumą vaistų skyrimo efektyvumui vertinti:
- 3.1. Nustatyti kompensuojamųjų vaistų išlaidų panaudojimo efektyvumą, analizuojant generinių vaistų kompensuojamųjų kainų mažėjimą.
- 3.2. Palyginti kompensuojamųjų vaistų išlaidų panaudojimo efektyvumą Lietuvoje su kitų šalių rodikliais.

#### **MOKSLINIS NAUJUMAS**

Šiame darbe kompleksiškai įvertinti VLKIS kaupiami duomenys apie išduotus kompensuojamuosius vaistus ir jų panaudojimo tinkamumas vaistų skyrimo kokybės, vaistų išlaidų panaudojimo efektyvumui ir vaistų politikai vertinti. Iki šiol, naudojant VLKIS sukauptus duomenis apie vaistus yra atlikti keli autorių tyrimai, tačiau ši ADB nebuvo išsamiai ištirta ir aprašyta, kaip yra ištirtos ir aprašytos analogiškos administracinės duomenų bazės kitose šalyse.

Pirmą kartą naudojant administracinės duomenų bazės duomenis apie vaistus buvo vertinta gydymo kokybė, vaistų vartojimo paplitimas, tyrinėjami regioniniai vaistų vartojimo netolygumai. Vaistų skyrimo rodikliai bei vaistų vartojimo paplitimas buvo palyginti skirtinguose Lietuvos regionuose. Taip pat pirmą kartą VLKIS duomenys buvo panaudoti tarptautiniuose vaistų suvartojimo tyrimuose, palyginti su analogiškomis kitų šalių duomenų bazėmis bei naudojant VLKIS vertinta vaistų politikos priemonių efektyvumas.

#### GINAMIEJI TEIGINIAI

- 1. VLKIS duomenų bazėje surinkti duomenys tinkami vaistų suvartojimui vertinti.
- 2. VLKIS duomenys tinkami vaistų skyrimo kokybei vertinti bei priemonėms racionaliam vaistui vartojimui parinkti ir pokyčiams vertinti.
- 3. VLKIS duomenų bazės duomenys tinkami vaistų skyrimo efektyvumui vertinti.

#### DISERTACIJOS STRUKTŪRA IR APIMTYS

Darbą sudaro struktūrinės dalys, 22 lentelės, 15 paveikslų.

Įvadiniame skyriuje bendrais bruožais aprašoma tiriamoji problema, darbo aktualumas, darbo tikslai ir uždaviniai, mokslinis naujumas, suformuluoti ginamieji teiginiai.

Literatūros apžvalgoje aprašomos pagrindinės racionalaus vaistų vartojimo problemos, aptariamos vaistų skyrimo kokybės vertinimo galimybės bei vaistų suvartojimo tyrimai. Aprašyti vaistų suvartojimo tyrimų duomenų šaltiniai – administracinės duomenų bazės, jų privalumai ir trūkumai. Aprašytos racionalų vaistų vartojimą skatinančios priemonės.

Tyrimo metodologija pateikiama kiekvienai daliai atskirai. Aprašytas duomenų statistinis apdorojimas. Tyrimų rezultatai pateikiami tekste, lentelėse, paveiksluose.

Rezultatų aptarime gauti tyrimų rezultatai lyginami su kitų autorių duomenimis, svarstomi darbo privalumai ir trūkumai.

Išvadose ir rekomendacijose apibendrinami tyrimų rezultatai, pateikiami galimi problemų sprendimo būdai.

Disertacija baigiama literatūros sąrašu, kuriame yra 253 bibliografiniai šaltiniai. Atlikus darbą ir išanalizavus rezultatus, padarytos šios IŠVADOS:

- 1. VLKIS kaupiami duomenys yra tinkami vaistų suvartojimo tyrimams atlikti. VLKIS sukaupti duomenys apie vaistus, kuriems nustatyti vaistų skyrimo ribojimai, atitinka tik dalį tos grupės vaistų suvartojimo Lietuvoje.
- 2. VLKIS kaupiami duomenys gali būti naudojami vaistų skyrimo kokybės vertinimui, vaistų suvartojimo paplitimo nustatymui bei analizuojant regioninius vaistų skyrimo netolygumus.
- 2.1. Lietuvoje pusei vaikų pirmaisiais gyvenimo metais yra skiriamas gydymas sisteminiais antibiotikais. Nors antibiotikų vartojimas buvo gana didelis, tačiau tiriamuoju laikotarpiu mažėjo. Dažniausiai kūdikiams gydyti skirta plataus spektro antibiotikų. Siauro spektro penicilinų vartojimas buvo labai mažas ir dar mažėjo. Dažniausiai antibiotikų kūdikiams buvo skirta virusinėms kvėpavimo takų ligoms gydyti.

- 2.2. 2 tipo CD gydymo skirtinguose Lietuvos regionuose tyrimo rezultatai rodo, kad antidiabetinių vaistų paplitimas skirtinguose regionuose skiriasi 1,6 karto. Didžiausias skirtumas nustatytas tik insulinu gydymo schemoje paplitimas skiriasi net 1,9 karto
  - 3. VLKIS kaupiami duomenys gali būti naudojami vaistų skyrimo efektyvumo vertinimui.
- 3.1. Išlaidos PSI, statinų, AKF, ARB ir pasirinktų antidepresantų buvo naudojamos efektyviai, nes 2000-2009 metų laikotarpiu šių vaistų kompensuojamųjų vaistų kainų mažėjimas buvo toks pat, kaip ir kitose Europos šalyse.
- 3.2. PSI kompensavimui 2001-2007 metų laikotarpiu PSDF išlaidos buvo panaudotos efektyviai, nes šios vaistų grupės vaistų suvartojimo rodiklis augo du kartus greičiau, nei išlaidų rodiklis.

Statinų kompensavimui 2001-2007 metų laikotarpiu PSDF išlaidos buvo panaudotos labai efektyviai, nes šios vaistų grupės vaistų suvartojimo rodiklis padidėjo 2,7 karto, o išlaidos sumažėjo. Kompensuojamų statinų ir PSI suvartojimo rodikliai yra patys mažiausi tarp 19 Europos šalių.

#### REKOMENDACIJOS

VLKIS yra vertinga priemonė vaistų suvartojimo, gydymo kokybės, išlaidų panaudojimo efektyvumo tyrimams. Atliekant tarptautinius palyginamuosius vaistų suvartojimo tyrimus, svarbu išsamiai aprašyti duomenų bazę bei vaistų kompensavimo politiką (aprašyti nustatytus vaistų skyrimo apribojimus), tam kad nebūtų klaidingai pateikti šalies vaistų suvartojimo rodikliai

VLKIS turėtų tapti lengviau prieinama moksliniams tyrimams. Turėtų būti sukurta VLKIS duomenų analizės posistemė, patogi ir prieinama moksliniams tyrimams.

VLKIS sukaupti duomenys gali būti naudojami vaistų skyrimo kokybės tyrimams. Sveikatos apsaugos ministerija turėtų diegti vaistų skyrimo kokybės gerinimo priemones, naudojant sukurtus vaistų skyrimo kokybės rodiklius, teikiant gydytojams grįžtamąją informaciją apie jų vaistų skyrimo veiklą. Valstybinė ligonių kasa vaistų skyrimo kokybės rodiklius gali naudoti atsiskaitymui už suteiktas paslaugas su pirmines sveikatos priežiūros paslaugas teikiančiomis gydymo įstaigomis: pasiekus numatytus rodiklius, taikomas papildomas mokėjimas už gerus darbo rezultatus.

VLKIS sukaupti duomenys gali būti naudojami vaistų vartojimo paplitimo skirtinguose Lietuvos regionuose netolygumams nustatyti. Darbe nustatyti regioniniai vaistų skyrimo (suvartojimo) netolygumai rodo, kad reikalinga atlikti išsamesnius tyrimus, išanalizuoti šių netolygumų priežastis bei numatyti priemones šių netolygumų mažinimui.

Vaistų skyrimo efektyvumas, naudojant VLKIS duomenis, gali būti vertinamas analizuojant procentinį vaistų kainų mažėjimą, vaistų suvartojimo bei vaistų išlaidų rodiklių palyginimą. Generinių vaistų politika, analizuojant vaistų skyrimo efektyvumą, laikoma labai efektyvia, kai vaistų suvartojimo rodikliai per nustatytą laikotarpį augo du kartus greičiau, o išlaidų rodikliai sumažėjo, efektyvia, kai vaistų suvartojimo rodikliai padidėjo daugiau bei vaistų išlaidų rodikliai ir neefektyvia, kai vaistų suvartojimas augo lėčiau nei išlaidų rodikliai. Efektyvi generinių vaistų politika sudaro galimybes šalies vaistų kompensavimo sistemai kompensuoti brangius inovatyvius vaistus.

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#### **Patirtis**

K. Garuolienė yra tarptautinių mokslinių draugijų, besidominčių racionaliu vaistų vartojimu (Piperska- racionalaus vaistų skyrimo grupės, (angl. – Piperska group Rational Prescribing), PPRI projekto (angl. Pharmaceutical Pricing Reimbursement Information network)) bei vaistų suvartojimo tyrimais DURG (angl. Drug Utilization Research group) narė, Tarptautinės farmakoepidemiologų draugijos (angl. International Society for Pharmacoepidemiology), Tarptautinės medicinos technologijų vertinimo draugijos (angl. Health Technology Assessment International) narė. Dalyvauja PSO ir Europos Komisijos organizuotose konferencijose vaistų kainodaros ir kompensavimo, racionalaus vaistų vartojimo klausimais. K. Garuolienė kartu su bendraautoriais publikavo daugiau nei 10 straipsnių ivairiuose moksliniuose žurnaluose.