Common Data Model for Interoperability of Observational Health Data: Bulgarian Diabetes Register Pharmacology Case Study

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Main Topics

1. Introduction
2. Objectives
3. Methods and Materials
4. Results
5. Discussion
6. Conclusion
1. Introduction
The need for a Pharmacology case study for diabetes treatment.

Assessment of expenses for prescribed drugs:
- provides evidence for regulatory decision making
- identifies trends in using different classes of drugs

Requires patient-centric approach for data analysis:
- outpatient records are collected from disparate and heterogeneous data sources
- serious interoperability issues

Solution:
- employ a Common Data Model for representation of observational health data
- Map to a CDM all the outpatient records (6,887,876) issued in Bulgaria to patients with diabetes (501,065)
- the BDR published in the EHDEN Portal allows sharing EHR data across clinicians, patients and communities
2. Objectives

- What is the share of modern drugs for treatment of diabetes in the Total costs?
- What is the share of costs for drugs prescribed for treatment of diabetes comorbidities (cardiovascular, nervous system, ophthalmological disorders etc)?
- What are the relative shares of costs for treatment of these disorders with respect to the overall expenses for treatment of diabetes comorbidities?
- What is the average yearly cost for prescribed drugs for diabetes treatment and how it relates similar expenses in other EU countries?
3. Methods and Materials

### Table 1. Drug classes for treatment of Diabetes

<table>
<thead>
<tr>
<th>Code</th>
<th>Drug class</th>
<th>International Nonproprietary Name (INN)</th>
</tr>
</thead>
<tbody>
<tr>
<td>T1</td>
<td>Insulin</td>
<td>Insulin unique analogues and combination regimens</td>
</tr>
<tr>
<td>T2</td>
<td>Sulfonylureas</td>
<td>Glyburide, Glipizide, Glimepiride, Glimepiride, Tolbutamide, Chlorpropamide, Tolazamide</td>
</tr>
<tr>
<td>T3</td>
<td>Biguanides</td>
<td>Metformin</td>
</tr>
<tr>
<td>T4</td>
<td>Alpha-Glucosidase Inhibitors</td>
<td>Acarbose, Miglitol, Voglibose</td>
</tr>
<tr>
<td>T5</td>
<td>Thiazolidinediones</td>
<td>Troglitazone, Rosiglitazone, Pioglitazone</td>
</tr>
<tr>
<td>T6</td>
<td>Incretin-Dependent Therapies</td>
<td>Incretin, Exenatide, Liraglutide, Dulaglutide, Albiglutide&quot;,Lixisenatide, Semaglutide, Sitagliptin, Saxagliptin, Linagliptin,Alogliptin</td>
</tr>
<tr>
<td>T7</td>
<td>Meglitinides</td>
<td>Nateglinide, Repaglinide</td>
</tr>
<tr>
<td>T8</td>
<td>Sodium-Glucose Cotransporter Type 2 Inhibitors</td>
<td>Canagliflozin,Apagliflozin,Empagliflozin, Ertugliflozin</td>
</tr>
<tr>
<td>T9</td>
<td>Statin-Dependent therapies</td>
<td>Simvastatin, Lovastatin, Ravastatin, Fluvastatin, Atorvastatin, Cerivastatin, Rosuvastatin, Ppitavastatin</td>
</tr>
</tbody>
</table>

### Table 2. Drug classes for Diabetes comorbidity treatment

<table>
<thead>
<tr>
<th>Code</th>
<th>Drug class for comorbidity treatment</th>
<th>ATC code prefix</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Cardiovascular drugs</td>
<td>C01, C03, C07, C08, C09, C10</td>
</tr>
<tr>
<td>A1</td>
<td>Antithrombotic agents</td>
<td>B01</td>
</tr>
<tr>
<td>N</td>
<td>Nervous system disorders</td>
<td>N01-N07</td>
</tr>
<tr>
<td>G</td>
<td>Urological disorders</td>
<td>G04</td>
</tr>
<tr>
<td>S</td>
<td>Ophthalmotological disorders</td>
<td>S01</td>
</tr>
<tr>
<td>L</td>
<td>Endocrine disorders</td>
<td>L02</td>
</tr>
<tr>
<td>M</td>
<td>Treatment of bone diseases</td>
<td>M05</td>
</tr>
<tr>
<td>R</td>
<td>Asthma drug categories</td>
<td>R03</td>
</tr>
</tbody>
</table>

The costs are evaluated both at **patient-centric level** and at **high level** in terms of **cost distributions** among the drug classes in each one of the two groups **using a OHDSI OMOP CDM database (BDR)**.
4. Results

✓ The Bulgarian Diabetes Register is a public Common Data Model implementation allowing to overcome poor interoperability issues.

✓ It contains the latest and complete dataset of outpatient records of 501,065 distinct patients with diabetes in Bulgaria in 2018. Compared to data from 312,223 diabetic patients in Italy (2014).

✓ The pharmacology case study reports new results for better assessment of the cost burden created by prescribing drugs for diabetes.

✓ Two major groups of drugs are considered—drugs for treatment of diabetes and related comorbidities.

✓ Novel drug diabetes therapies are just evolving in 2018, while the Metformin prescriptions prevail significantly.

✓ The costs are evaluated both at patient-centric level and at high level in terms of cost distributions among the drug classes in each group.

✓ Average 675 euros yearly per diabetic patient expenses for prescribed drugs in Bulgaria in 2018, compared to average 1,044 euros yearly per diabetic patient in Italy in 2014.
Notes

**Biguanides** (T3 class), *Metformin* drugs are the most frequently prescribed

**Modern classes of drugs** (T8 class) *Sodium-Glucose Cotransporter Type 2 Inhibitors*, are among the least frequently prescribed in 2018.

Other rarely prescribed drugs are (**T5 & T7 class**), Thiazolidinediones and Meglitinides because they have undesirable side effects.
The largest share of expenses is attributed to the insulin (T1 class) drugs, although it is the third most prescribed class of drugs.

Besides, the average price in Bulgaria for the insulin drug class has been about 60 euros against 16 euros for the Metformin drug class in 2018.
Drugs for **cardiovascular disorders** and drugs with **antithrombotic agents** (coded A and A1) together have the greatest weight (70.10%) in the Total Costs for treatment of comorbidities.

Total costs of drugs for treatment of diabetes comorbidities
5. Discussion

Novel results:

✓ Nationally-representative observational health data of patients with diabetes in Bulgaria from 2018 mapped to an OMOP CDM in the BDR (501,065 distinct patients).

✓ Population-based pharmacology studies of the drug cost burden for treatment of socially significant diseases like diabetes are rarely public available.

✓ Public access to the BDR enables transparency in accessing data and verifying the integrity and consistency of the pharmacology case study results.

✓ The reported results confirm public data for the shares on expenses on distinct drug classes used for diabetes treatment established in Italy (312,223 patients).

✓ The pharmacology study results are consistent with data in official governmental financial reports for diabetic's drugs reimbursement expenses.
6. Conclusion and Future Work

✓ This paper provides results from a population-based study of the burden of pharmacology costs for treatment of diabetes in Bulgaria (501,065 distinct patients with diabetes).

✓ Popular CDM are critically analyzed in relation to the objectives of this study.

✓ The study uses observational health data from heterogenous, disparate datasets that is transformed to OMOP CDM and persisted in the BDR.

✓ The results indicate the trends and effects in using different classes of drugs for diabetes treatment in comparison with public data from other countries.

✓ The results allow to conclude that the shares on expenses per drug classes used for diabetes treatment in Bulgaria are similar to those established in other EU countries (average 675 euros yearly per diabetic patient expenses for prescribed drugs).

✓ The study provides evidence that the treatment of comorbidities accompanying the diabetes illness is almost as expensive as the treatment of the diabetes itself.

✓ The pharmacology case study makes public lot of new and rarely found in the literature evidence-based results that are useful for regulatory decision making as well as for drug suppliers in planning their market strategies.

✓ The inherent interoperability of the OMOP CDM allows extending the research work to data analysis across a federated network of OMOP CDM databases by participating in the MegaStudy entitled “Studying Drug shortages in Europe: A Multinational, Multidatabase Network Study” as EH DEN Data partner.
Acknowledgment

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Thank you for your attention!

Questions?

Comments?