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Time Series Analysis on the Impact of Generic Substitution and Reference Pricing on Antipsychotic Costs in Finland

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ABSTRACT

Objectives: To analyze the medium- to long-term impact of generic substitution and the reference price system on the daily cost of antipsychotics in Finland. The additional impact of reference pricing over and above previously implemented generic substitution was also assessed. **Methods:** An interrupted time series design with a control group and segmented regression analysis was used to estimate the effect of the implementation of generic substitution and the reference price system on the daily cost of antipsychotics. The data have 69 monthly values of the average daily cost for each of the studied antipsychotics: 39 months before and 30 months after the introduction of reference pricing. For one of the studied antipsychotic, the time before the introduction of reference pricing could be further divided into time before and after the introduction of generic substitution. **Results:** According to the model, 2.5 years after the implementation of reference pricing, the daily cost of the studied antipsychotics was 24.6% to 50.6% lower than it would have been if reference pricing had not been implemented. Two and a half years after the implementation of the reference price system, however, the additional impact of reference pricing over and above previously implemented generic substitution was modest, less than 1 percentage point. **Conclusions:** Although the price competition induced by reference pricing decreased the prices of antipsychotics in Finland in the short-term, the prices had a tendency to stagnate or even to turn in an upward direction in the medium- to long-term. Furthermore, the additional impact of reference pricing over and above previously implemented generic substitution remained quite modest.

Keywords: cost-containment policy, generic substitution, reference pricing, segmented linear regression analysis.

Introduction

In most European countries, prescription medication costs are subsidized by public or private health insurance schemes. Because patients do not bear the full cost of their consumption, prices have limited effect on their choice between different treatments. This and the rising public pharmaceutical expenditures have created a need for governments to regulate medicine prices and demand in various ways [1,2]. One attractive steering and cost-containment policy option for many governments has been the promotion of the use of generic medicines through generic substitution and a reference price system.

In generic substitution, pharmacies have the right or obligation to substitute the prescribed medicine with a cheaper equivalent medicine [3]. Reference-based pricing, however, is a reimbursement mechanism in which a third-party payer sets a ceiling price for interchangeable pharmaceuticals belonging to the same cluster. The clusters are based on generic groups, related drug groups, or groups for drugs with similar therapeutic effects. The ceiling price, or reference price, is based on, for example, the lowest or the average price of products in that cluster. Products priced at or below the reference price are subsidized, whereas products above the reference price require the patient to pay the excess in part or in total [2].

Although it is known that reference price systems are in the short-term generally associated with decreases in prices covered by the policy, studies examining the impact beyond the first year of implementation are lacking [2,4,5]. Furthermore, to our knowledge, there is only one previous study that has been able to differentiate between the impact of generic substitution and the reference price system on prices. In that study from Finland, a substantial decrease, ranging from 29.9% to 66.3%, was seen in the daily cost of antipsychotics after 1 year of implementing the reference price system. Because one of the studied antipsychotics was already included in generic substitution over a year before the reference pricing, it was observed that 75.3% of the total decrease of 43.3% in the daily cost was generated by generic substitution [6].

The aim of this study was to analyze the medium- to long-term impact of generic substitution and a reference price system on the daily cost of antipsychotics in Finland. The additional impact of reference pricing over and above previously implemented generic

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substitution was also assessed. We also report on the price developments of one of the studied antipsychotics.

Pricing and Reimbursement of Pharmaceuticals in Finland

Finland adopted a reference price system in April 2009, whereas generic substitution was introduced 6 years earlier, in April 2003. Concurrent with the adoption of a generic reference price system, the range of medicinal products available for generic substitution was also extended. In Finland, it was not possible to grant product patents for medicinal substances before 1995; only so-called analogy process patents were possible. Although products protected by an analogy process patent in Finland were initially included in generic substitution, this decision was changed in 2006 when the Finnish Medicines Act was amended so that pharmaceuticals were excluded from the generic substitution system if they were protected by an analogous process patent in Finland and had product patent protection in at least five other European Economic Area countries. When a generic reference price system was approved by the Finnish government, however, the decision was again changed and it was decided that pharmaceuticals protected by an analogous process patent would again be included in the sphere of generic substitution (Amendment 803/2008 on Medicines Act [395/1987]). This meant that products protected by an analogy process patent could be included into generic substitution in Finland even while the products were still under patent protection in many other countries.

In the generic substitution system in Finland, pharmacies are obligated to substitute a prescribed medicine with the cheapest or close to the cheapest product containing the same active substance. Substitutable products contain the same active ingredient, the same quantity, have the same route of administration, and must be sold in comparable package sizes. The reference price groups are based on the list of substitutable medicinal products compiled by the Finnish Medicines Agency Fimea. The reference prices are determined quarterly, and they are calculated by adding €1.50 to the price of the most inexpensive product within the group if the cheapest product is priced below €40.00. If the cheapest product is priced at €40.00 or more, a sum of €2.00 is added. When a product is included in a reference price group, however, a maximum wholesale price for the product is confirmed. This price is often around 40% lower than the price of the originator product but generally higher than market prices [7]. That is to say that the actual market prices and thus the reference prices are typically lower than the confirmed maximum wholesale prices.

When only generic substitution was in effect, either the physician or the patient could veto the substitution without affecting the reimbursement rate of the product. In the reference price system, stronger monetary incentives for patients were implemented. Patients who do not wish to switch to a cheaper medicine are reimbursed according to the reference price, and they must pay the excess themselves. If the substitution is vetoed by the prescribing doctor, the reimbursement is calculated according to the purchase price of the dispensed product [8]. In Finland, there are three reimbursement categories: the basic refund category (42% during the study years), lower special reimbursement category (72% during the study years), and higher special reimbursement category (a fixed co-payment of €3.00 per purchase and the rest is reimbursed at 100%).

Besides the implementation of generic substitution and reference pricing, the reimbursement system in Finland remained substantially unchanged through the study period.

Antipsychotic Medication

Antipsychotics are primarily indicated for the treatment of psychotic disorders such as bipolar disorder and schizophrenia and schizoaffective disorder. They were not originally included in generic substitution in Finland because of concerns about compliance [9]. This decision was later changed and from 2006 onward antipsychotics were considered to be substitutable, provided they otherwise meet the criteria for substitutability.

In 2008, three antipsychotics—olanzapine, quetiapine, and risperidone—accounted for 82% of the total reimbursed spending on antipsychotic medications and more than 5% of the total reimbursed pharmaceutical expenditure in Finland [10,11]. Two of these antipsychotics—olanzapine and quetiapine—were protected by an analogy process patent. They were included into generic substitution alongside the introduction of reference pricing in April 2009, whereas the third, risperidone, had been included in generic substitution already in January 2008. Aripiprazole is also an antipsychotic but in contrast to the three other antipsychotics it was not included in the reference price system because of its patent status during the study period.

In Finland, prescription drugs used in ambulatory care are reimbursed under the National Health Insurance Scheme, which covers all permanent residents in Finland. Antipsychotics can be reimbursed either under the basic reimbursement category or under the higher special refund category. To be entitled to receive reimbursement under the higher special refund category, the patient must be diagnosed with severe psychotic disorder [8]. On average, the antipsychotic reimbursement rate was 92% in 2008.

Antipsychotics were chosen for this study because of their high total costs and because different active substances within the drug group were included in generic substitution and reference pricing at different times during the study period. More specifically, olanzapine, quetiapine, and risperidone (the most used atypical antipsychotics) were selected for this study, whereas aripiprazole was used as a control group.

Methods

The Social Insurance Institution of Finland maintains a national register that contains information on medicine purchases that have been reimbursed under the National Health Insurance Scheme. About 94% of the antipsychotic medication consumption sold by Finnish pharmacies is covered by the register. The data extracted for this study consisted of reimbursed purchases of olanzapine (Anatomical Therapeutic Chemical classification [12] code N05AH03), quetiapine (N05AH04), risperidone (N05AX08), and aripiprazole (N05AX12) from January 1, 2006, to September 31, 2011. The data include information on the date of dispensing, the Anatomical Therapeutic Chemical code of the product, total cost of the purchase, and the number of defined daily doses [12] purchased. The concept of DDD was developed for drug consumption statistics, and it represents the assumed typical daily dose for a drug when used for its main indication in adults. Because we had no information on actual daily doses of the medication, we used DDD as a proxy for daily dose. Monthly sums of costs and DDDs were calculated for each of the antipsychotics, and these sums were further calculated into monthly average costs per DDD. The costs used are retail prices exclusive of value-added tax, and they include both the National Health Insurance Scheme's reimbursement part of the price and the patient's own contributions.

To assess the effect of the implementation of generic substitution and the reference price system on the daily cost of antipsychotics, we used an interrupted time series design with a control group. Segmented regression analysis was applied to this design. An interrupted time series is a strong quasi-experimental design in which data are collected at multiple time points before and after the intervention. The advantage of this design is that it detects a possible underlying secular trend that could wrongly