Estimating the economic effects of pharmaceutical reimbursement scheme reform by microsimulation

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Estimating the effects of reforms in advance is an important part of evidence-based and transparent legislative processes. The aim of this study was to describe a microsimulation method created to produce ex ante estimates of pharmaceutical pricing and reimbursement policy reforms. As a case example, the estimates for the 2016 pharmaceutical reimbursement scheme reform, including, e.g., the introduction of a €50 annual deductible, are presented. A static microsimulation model was developed based on the reimbursed purchases of 380,931 individuals drawn at random (10% sample) from the prescription register. The 2016 reform was projected to create savings of \in 44 million/year for the National Health Insurance (NHI). For patients, the median annual out-of-pocket costs increased from \in 78 to \in 96 (by + \in 18). For 97%, the estimated change was less than €50/year. The majority of patients whose out-of-pocket costs increased had relatively low prior costs. However, >€50/year increases predominantly affected patients entitled to higher reimbursements based on chronic or severe illnesses, among whom older and lower-income individuals were overrepresented. Increases of $\geq \in 100$ were rare (0.003%) and derived from exceptional circumstances. The microsimulation produced prompt but versatile estimates of the effects of legislative reforms by factoring in the entire spectrum of individual situations among affected patients.

Keywords: Microsimulation, fees and charges, health care costs, pharmaceutical preparations, health equity, health insurance.



Introduction

Social inequalities in health have been described in numerous studies from many countries (e.g., Mackenbach et al. 2008). These systematic differences in health status between socioeconomic groups have been linked to complex mechanisms that include factors related to societies, communities and individuals (Dahlgren & Whitehead 1991; WHO 2010a). In particular, the social gradient of health and the higher representation of social problems and health inequality within societies that have higher income inequality have

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been widely studied in the international literature (e.g., Marmot 2004; Wilkinson & Pickett 2011). In this context, the relatively high health inequality in Finland seem paradoxical because of the low income inequality (OECD 2014; Tarkiainen et al. 2013). Health inequality in Finland has thus been commonly linked to structural inequities in access, influenced by the dual financing of health care and the large role of occupational health care (Kangas & Blomgren 2014; OECD 2005; Vuorenkoski et al. 2008). The institutional approach is supported by the observed socioeconomic differences in the use of many health services and the relatively inequitable distribution of doctor visits in Finland (Häkkinen & Alha 2006; van Doorslaer et al. 2006; OECD 2011; Vuorenkoski et al. 2008).

The idea behind inequitable access is determined by the Inverse Care Law: "The availability of good medical care tends to vary inversely with the need for it in the population served" (Hart 1971). Access barriers stem from a variety of reasons, of which economic barriers are among the most recognised and studied (e.g., Dahlgren & Whitehead 1991; Penchansky & Thomas 1981; Sabaté 2003; Piette et al. 2006). Much the previous research on access has focused on doctor visits (e.g., van Doorslaer et al. 2006). However, access barriers may be different for different health care services. Based on international comparisons, patients in Finland rarely encounter cost-related barriers to doctor visits, but barriers from waiting list are common (Eurostat 2016; OECD 2005). Doctor visits alone are nevertheless insufficient if the patient is not able to afford the prescribed treatment.

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In terms of economic access, prescription medicines are important since they are one of the most common health care interventions and, in many countries, also represent a large part of the overall health care user charges (e.g., Avorn 2010; OECD 2015). According to the literature, implementations of and increases in patient co-payments have reduced third-party payer expenditures but simultaneously have been associated with a decreased use of necessary medicines (Austvoll-Dahlgren et al. 2008; Goldman et al. 2007; Lexchin & Grootendorst 2004, and Martikainen 2012). User charges can have detrimental effects on equity, which can lead to poor health outcomes and an ineffective use of resources (Remler & Greene 2009; WHO 2010b). Previous research has also shown that increased cost sharing can lead to an increased rate of adverse events, e.g., hospitalisation, nursing home admission and mortality (Dormuth et al. 2009; Tamblyn et al. 2001).

The Finnish reimbursement system for medicines has been previously criticised for relatively high co-payments for medicines (Mossialos & Srivastava 2008). Additionally, patients in Finland pay a higher share of costs than patients in many other Nordic and European countries before reaching the annual co-payment ceiling¹, which acts as a safety net against a high burden of costs (Vogler 2008). According to surveys of the general population conducted in Finland between 2000 and 2015, economic problems in buying prescription medicines were reported by 11-17% of respondents (Aaltonen et al. 2013; Lindholm 2001; Rikala et al. 2016). Low income and less-than-good self-assessed health have been associated with a higher likelihood to report access barriers to medicines and other health care services (Aaltonen et al. 2013; 2014). In the 2015 survey, 56% considered the level of reimbursement for medicines inadequate (Rikala et al. 2016).

In response to the financial crisis in recent years, shifting the costs for medicines from public payers to patients has been a common measure used in European countries (Vogler et al. 2011). Additionally, the Finnish government has sought savings from the pharmaceutical reimbursements by introducing several reforms that have increased patients' share of costs (Government Proposals 113/2012; 330/2014; 106/2015 and 128/2015). However, Finnish reforms have also included measures with counterbalancing effects for patients, e.g., price cuts and decreases in the level of the annual ceiling.

A transparent and evidence-based legislative process requires that the effects of reforms be evaluated in advance and that enough information be readily available for decisionmakers, different stakeholders, the media and the public, including those potentially impacted by the reforms, to enable equal participation in the political debate (De Agostini et al. 2016; Tuomisto et al. 2014). In the context of pharmaceutical policy, a challenge is the complexity of the reimbursement scheme, due to which macro-level evaluations easily lead to misleading conclusions from the perspectives of both cost containment and equity.

In this article, we describe the *ex ante* microsimulation method, developed for use in the science-policy interface, to

provide prompt and timely analyses of the effects of pricing and reimbursement policy reforms.

As a case example, we present the results of the estimates produced for the 2016 reform. In practice, the described microsimulation method was also used to simulate the alternative reform scenarios during the policy-making process prior to the 2016 reform (Government proposals 330/2014; 106/2015; 128/2015). Overall, since 2010, over one hundred microsimulations, of which only a fragment has ended up in published documents, have been produced by Kela for regulators and stakeholders to use in the planning and preparation of pharmaceutical pricing and reimbursement reforms implemented between 2013-2016 (e.g., Government proposals 113/2012; STM 2012a; 2012b).

The Finnish reimbursement system for medicines in 2015 and the 2016 reform

Under the Health Insurance Act (1224/2004), all permanent residents in Finland are entitled to reimbursements for medicines from the National Health Insurance (NHI).

The basic reimbursement (35% of the retail price in 2015) applies to all reimbursable medicines. Higher reimbursements are paid based on a needs test (disease-based reimbursements) or high annual out-of-pocket costs (annual ceiling). Non-reimbursed medicines are paid in full by the patient without an annual ceiling.

The severe and chronic diseases that entitle a patient to higher disease-based reimbursements (65% or 100%) are set by a Government Decree. The 65% reimbursement applies to, e.g., cardiovascular diseases, asthma and rheumatic diseases, and the 100% reimbursement applies to, e.g., diabetes, epilepsy and cancer. For 100% reimbursed medicines, a fixed prescription fee applies (€3.00/item/purchase for max 3 months' supply in 2015). Disease-based reimbursements apply only to products used in treatment of a specific disease; the patient's other medicines can be reimbursed at different rates.

Reimbursements can be restricted by prior authorisation to a specific patient group. Reimbursement restrictions apply to expensive treatments, and their purpose is to control prescribing and public expenditure. Restrictions may apply to products reimbursed at any rate (35%/65%/100%).

The annual co-payment ceiling is a safety net designed to protect patients from very high out-of-pocket expenditure. After patients' cumulative co-payments exceed the ceiling (indexed, $\in 613$ in 2015), they become eligible for fully reimbursed medicines for the rest of the calendar year. However, a fixed prescription fee applies ($\in 1.50$ /item/purchase for max 3 months' supply in 2015).

The reform in 2016 increased patients' share of costs by several mechanisms. First, an annual deductible² was implemented. This means that all adults (over 18 years) pay the full price of their medicines for the first \in 50 within the calendar year, after which the aforementioned reimbursements apply based on patients' entitlements and cumulative co-payment expenditure (Figure 1). Furthermore, the fixed

prescription fees were increased (for disease-based 100% reimbursement from $\in 3.00$ to $\in 4.50$ and after annual ceiling from $\in 1.50$ to $\in 2.50$). Additionally, to partly counterbalance the negative effects of the reform on patients, the basic reimbursement rate was raised from 35% to 40%.

Materials and methods

Microsimulation method in the pharmaceutical pricing and reimbursement setting

Microsimulation is a commonly used method in planning, monitoring and assessing legislative changes. In the context of the effects of social security benefits and taxation reforms on income distribution, comprehensive tax-benefit microsimulation models have been developed nationally and internationally (De Agostini et al. 2016; Statistics Finland 2016; Sutherland et al. 2002; Sutherland & Figari 2013). Microsimulation has also previously been used in the planning of pharmaceutical reimbursement reforms (Dormuth et al. 2005). In the pharmaceutical pricing and reimbursement setting, microsimulation is needed to factor in the interactions between simultaneous changes within the complex reimbursement schemes. In the Finnish context, the effects of cumulative mechanisms^{1–2} are particularly difficult to estimate without micro-level data.

Microsimulation is a modelling technique that operates on micro-level data by applying a set of rules on each record. The main types of microsimulation are static and dynamic models. In static models, behavioural effects are not modelled, and thus, the applied rules are executed with no variation. Static models are usable in predicting the detailed effects of changes on a short time-frame. Dynamic models use probabilistic techniques to allow variation and have been used to model, e.g., demographic development (Zhou 2013).

In this study, we used a static microsimulation model, since our aim was to model detailed short-term effects. Additionally, in the *ex ante* setting, it is relevant to know the impact of the reform on individuals *in their current situation*. The estimates thus form the basis for a value judgement of whether the projected economic consequences are fair and reasonable. From the budgetary perspective, our main goal was to find combinations of parameter changes that generated the necessary savings, in comparison to *if the reform was not implemented*. Therefore, we used a *ceteris paribus* assumption, under which it is envisaged that other changes, related to e.g., product range and price levels, would affect the compared situations equally.

It is known that changes in patient payments affect utilisation of medicines via price elasticity. Previously published estimates of price elasticity for medicines have ranged between -0.2 and -0.6; i.e., a 10% increase in co-payments has been associated with a 2–6% decrease in use and costs (Goldman et al. 2007; Martikainen 2012). However, small changes in prices may not affect use at all, and the effects may vary by country and by population subgroup (Briesacher et al. 2007; Gemmill 2008; Martikainen 2012; Piette et al. 2006). Therefore, a single estimate of price elasticity is not likely to be valid across different population subgroups. For the same reasons, from the budgetary perspective, results from a dynamic model would be subject to higher uncertainty.

Data

The microsimulation model is based on patient- and purchase-level register data of reimbursed purchases of medicines, supplemented with information on morbidity as well as the socioeconomic and demographic characteristics of patients. The data are updated annually so that they reflect as reliably as possible the current prescribing patterns as well as the rapidly changing pharmaceutical market. At the time when the Government Proposal regarding the 2016 reform was prepared, the most current were from 2014. In this article, we present updated results based on 2015 data.

Data were extracted from the nationwide registers at Kela, including the Prescription Register, the Pharmaceutical Product Register, the Special Refund Entitlement Register and the Tax Register. Patient identifiers (pseudonymised ID code) and the product code of the medicine (Nordic article number, VNR) were used to link data across registers.

A 10% simple random sample (N=380,931) of the patients in the Prescription Register in 2015 formed the simulation population. For these patients, all reimbursed prescription medicine purchases during the respective year were drawn from the Prescription Register.

Purchase data: Information on purchases and purchased products were collected from the Prescription Register, supplemented with variables from the Product Register. For each purchase, the extracted information included 1) product information: brand name, product code (VNR), strength, package size, Anatomical Therapeutic Chemical (ATC) code, according to the classification system maintained by the WHO Collaborating Centre for Drug Statistics Methodology (2015); 2) information on price and reimbursement: wholesale price, retail price (incl. and excl. VAT), reference price³, NHI reimbursements, reimbursement codes (restricted or disease-based reimbursements); 3) information about the patient: patient identification, age (end of year), gender; 4) information about the dispensing: dispensed quantity, date, pharmacy, generic substitution; and 5) information about the prescription: prescriber identification, prescription date.

Morbidity: To assess morbidity, entitlements for restricted and disease-based reimbursements were used from the Special Refund Entitlement Register (Fimea & Kela 2016, 87-91). The entitlements are commonly used as proxies for morbidity in pharmacoepidemiological research (e.g., Tolppanen et al. 2013; Vehko et al. 2013). Information on entitlements that were valid at least one day during 2015 were used. Altogether, 149 different entitlements were identified. In the analyses, patients with entitlements for different types of cancer (38 different entitlements) were grouped together as one group, as were patients with cardiovascular diseases (12 different entitlements). In this article, only the results for the 10 patient groups that were largest among each gender are presented.

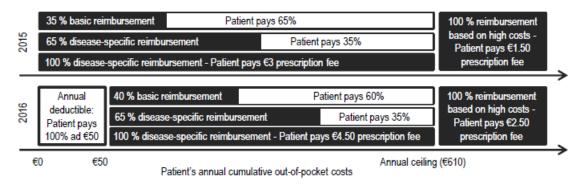


Figure 1. Pharmaceutical reimbursement scheme in Finland in 2015 and 2016.

Income: In this study, taxable personal income was used as a proxy of socioeconomic position. It must be noted, though, that personal income is less sensitive than household income because, e.g., a person without personal income can benefit from high incomes of other household members, or a person with high personal income may have several dependants with no income. However, registers available at Kela did not include direct information on household income or indirect information based on which household income could be reliably assessed, and data linkages across registers outside Kela were outside the scope of this study.

To partly overcome the sensitivity problems related to using personal income, especially those related to children and young adults, analyses by income included only patients aged 30 years or older (N=291,343; 76% of the sample), who were divided into deciles. Notably, since the sample was drawn from the prescription register, which encompasses approximately 70% of the population (in 2015, 65% of the male and 74% of the female population), the deciles are not directly generalisable to the general population (Fimea & Kela 2016, 110). It is likely that the 30% of the population not represented in the register has a different income distribution and different sociodemographic characteristics than the population within the register. Thus, the results related to income are to be considered crude estimates.

Case example simulation - 2016 reform

For the baseline, discrepancies in the raw data were solved, e.g., unclaimed reimbursements after reaching the annual ceiling. In the 2016 simulation, the reimbursements for each purchase and each person were re-calculated using the reform parameters, taking into account the effects of cumulative reimbursement mechanisms – the annual deductible and the annual ceiling – on the annual level. The simulated reform parameters are presented in Table 1.

Statistical analyses

The effects of the reform for patients and for the NHI were calculated as the difference between the 2016 simulation and the baseline. The results were multiplied by 10 to extrapolate the findings of the 10% sample to the population level. The

population level, in this study, represents all patients with reimbursed purchases (70% of the Finnish population). The effects of the reform were estimated in total and by population subgroup (by gender, age and income decile), by prior outof-pocket costs and for the 10 most common disease groups by gender, based on entitlements to disease-based and restricted reimbursements (in total, 11 patient groups in total are presented).

In this study, the NHI reimbursements refer to the costs for medicines covered by the NHI, including reimbursements paid after the annual ceiling was exceeded. Patient out-ofpocket costs refer to the difference between the total cost and NHI reimbursements, including the reference premiums³.

The microsimulation and all analyses were performed using SAS software version 9.4 (SAS Institute Inc., Cary, North Carolina). All costs are in Euros, 2015 currency level.

Ethical considerations

The data sampling was conducted at the statistical unit of Kela, where the data were pseudonymised for research purposes. The Finnish legislation on data protection allows using sensitive administrative data for scientific research purposes. No permission from an ethical board is required for a study that is solely based on registers. Kela has a statutory obligation to conduct research that serves the development of the social security system (Act on the Social Insurance Institution 731/2001).

Results

The projected savings for the NHI were \in 44 million per year (-3% of the total reimbursement expenditure), and this sum was shifted to the patients (Table 2). For patients, the median change in annual out-of-pocket expenditure was $+\in$ 11 (IQR $+\in$ 3 $+\in$ 17). For 44% of patients, the annual change in out-of-pocket costs year was $\pm\in$ 10 at most and for 90% $\pm\in$ 30 at most. An increase of over \in 50 per year affected 3% of patients. The maximum increase in the simulation was \in 185 per year and the maximum decrease \in 47 per year. The number of patients whose annual out-of-pocket costs exceeded the annual ceiling decreased by 2%.

Table 1

The reimbursement system parameters at the baseline and in the 2016 simulation.

	Baseline	2016 simulation
Annual deductible	€0	€50 (€0 for ≤18 yrs)
Basic reimbursement	35% (co-payment 65%)	40% (co-payment 60%)
Disease-based reimbursement (lower)	65% (co-payment 35%)	65% (co-payment 35%)
Disease-based reimbursement (higher)	100%, €3 fixed prescription fee	100%, €4.50 fixed prescription fee
Co-payments after reaching the after reaching the annual ceiling ($\in 613$)	€1.50 fixed prescription fee	€2.50 fixed prescription fee

Table 2

Descriptive statistics at the baseline and in the 2016 simulation. All figures are based on simulation data (N=380,931), extrapolated to population level (x10).

	Baseline	2016 simulation	Difference (%)
Total NHI reimbursements	€1.401 Million	€1.357 Million	-€44 Million (-3%)
Total sum of patient out-of- pocket payments	€569 Million	€613 Million	+€44 Million (+8%)
Median out-of-pocket payments/patient/year	€78	€96	+ €18 (+23%)
Median NHI reimbursements/patient/year	€54	€42	- €11 (-20%)
Mean out-of-pocket payments/patient/year	€147	€159	+€12 (+8%)
Mean NHI reimbursements/patient/year	€368	€356	-€12 (-3%)
Number (%) of patients exceeding the annual ceiling	179.700 (5%)	175.300 (5%)	-4,400 (-2%)

At the baseline, the distribution of out-of-pocket costs was strongly skewed; 56% of patients paid under €100 per year and 74% paid under €200 per year, while 7% of patients paid €500 or more per year. Increases in out-of-pocket costs occurred predominantly among patients at the lower end of the cost distribution (Figure 2). The share of patients with increases of €10 or more was 58% among patients who paid less than €200 at baseline and 37% among those who paid €200 or more at baseline. Increases of over €30 were most common (13–14%) among patients who paid \in 100–249 at baseline and among those who paid $\in 650$ or more (55%). Increases of over €50 were most common among patients who paid less than €250 (3%) at baseline and those who paid $\in 650$ or more (11%). Increases over $\in 100$ were rare (0.003%) and mainly affected patients who paid €650 or more at baseline. The large increases for these patients were caused by the multifold effects of the increased fixed prescription fee due to the notable amount of purchases after exceeding the annual ceiling. Approximately 4% of patients benefitted from the reform by a decrease of $\in 10$ or more in annual out-of-pocket costs. This was most common (38–54%) among patients who paid $\in 400-599$ per year at baseline. The patterns were similar for the two genders (data not shown).

Older individuals were slightly more likely to experience larger increases in out-of-pocket costs than younger age groups (Figure 3). This was because nearly all (99%) patients with increases of over €30 were eligible to diseasebased reimbursements, and the entitlements are more common among older individuals. Increases of over €30 affected 17% of male patients and 14% of female patients aged 65–74 years and 16% of male and 13% of female patients aged 75 years or older. In the younger adult age groups (19–64 years), the shares were between 7% and 13% among male patients and between 4% and 9% among female patients. Children and adolescents (0–18 years) were exempt from the annual deductible; therefore, increases in their out-of-pocket costs were rare and derived from the increased fixed co-payments.

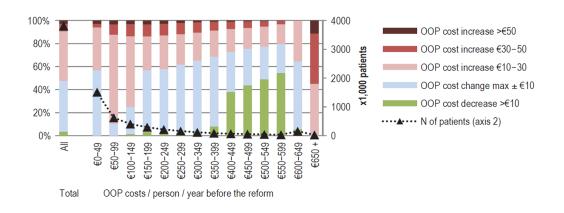


Figure 2. Annual change in out-of-pocket (OOP) costs, by annual out-of-pocket costs paid before the reform.

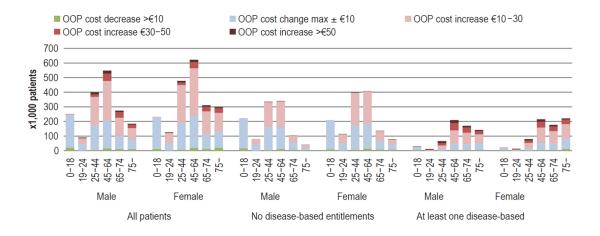


Figure 3. Annual change in out-of-pocket (OOP) costs, by gender, age and disease-based entitlements.

Patient groups that were most affected by the reform were those entitled to 100% reimbursements. The proportions of male and female patients facing increases of \in 50 per year were, respectively, 34% and 28% with severe mental disorders, 23% and 20% with epilepsy, 21% and 16% with glaucoma, and 15% and 13% with diabetes (Figure 4).

Higher increases were slightly more common at the lower end of the income distribution (Figure 5). Increases of over \in 30 affected 19% of male and 14% of female patients in the lowest income decile and 8% of male and 5% of female patients in the highest income decile.

Discussion

This article presents a microsimulation method developed for producing estimates of the economic effects of various pharmaceutical pricing and reimbursement scheme reforms. As a case example, 2016 reform effects are presented. The strength of the microsimulation methods is that the entire spectrum of individual situations among affected patients can be taken into consideration instead of hypothetical cases. The method also enables targeted analyses of impacts on specific population and patient subgroups. Therefore, the

THE ECONOMIC EFFECTS OF PHARMACEUTICAL REIMBURSEMENT SCHEME REFORM

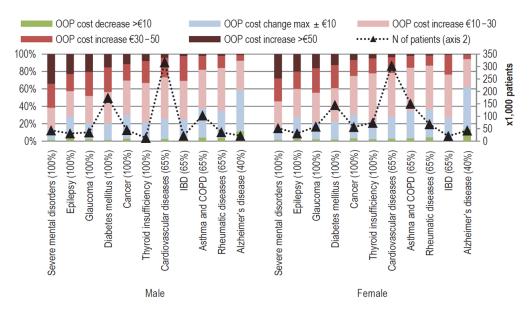


Figure 4. Annual change in out-of-pocket (OOP) costs among patients with entitlements (reimbursement rate) based on severe/chronic diseases, by gender.

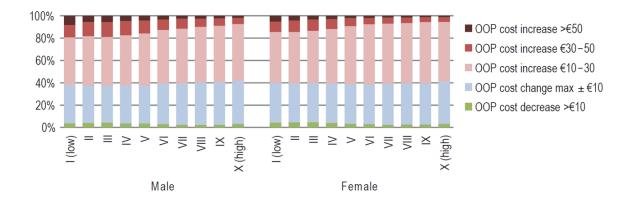


Figure 5. Annual change in out-of-pocket (OOP) costs, by gender and income decile (I-X). Patients aged 30 years and older are included.

method can be used flexibly in various situations to provide estimates on what can be expected from the reform in relation to the sought policy goals. Furthermore, the method allows identifying unexpected cumulative effects.

The focus of the 2016 reform was on reducing public pharmaceutical spending; therefore, it was expected that most patients would experience increasing out-of-pocket costs. One of the original aims of Prime Minister Jyrki Katainen's government programme was to ensure that costs do not act as a barrier to necessary medicines for low-income people (Finnish Government 2011; Government proposal 330/2014). The implementation of the annual deductible derived from the proposals of a working group set by the Ministry of Social Affairs and Health in 2011. The working group suggested a deductible, along with increases in reimbursement rates and a decrease in the annual ceiling, as a response to the government goals of targeting reimbursements to patients with higher medicine use (STM 2012a).

According to the simulations, the increases in annual outof-pocket costs were relatively small for most and affected a large majority of patients at the lower end of the out-ofpocket cost distribution. However, the largest increases affected mainly patients with severe and chronic conditions as well as patients with a very high number of purchases. Older and low-income patients were also affected by the reform.

It appears that the implementation of the annual deductible largely conformed to the aims of targeting the effects of the saving measures to patients who previously paid relative little for their medicines. For patients with occasional and rare or very low cost purchases with the basic reimbursement rate (40%), the reform had mostly small effects. The increase of the basic reimbursement rate from 35% to 40% also lessened the effects of the deductible on patients who had moderately high out-of-pocket costs for medicines in this reimbursement category. Child and adolescent patients benefitted the most from the increased reimbursement rate as they were exempt from the annual deductible.

However, in the 2015 scheme, patients who almost only used 100% reimbursed medicines, based on a severe or chronic condition, also had low out-of-pocket costs despite using expensive treatments. For them, the increases in out-of-pocket costs due to the annual deductible (0% reimbursement for the first \in 50) were larger than they were for patients who previously paid 65% or 35% out-of-pocket. They were also affected by the increased fixed prescription fees. Furthermore, 100% reimbursements are most common among people with low incomes (Aaltonen 2015). In this respect, the reform seems to act contrary to the original goals.

Increases in fixed prescription fees after patients exceeded the annual ceiling also led to notable increases in out-ofpocket costs for few patients with high out-of-pocket costs and a very high number of purchases. It was outside the scope of this study to examine in detail the specific cases where these changes occurred and whether the large number of medicines was clinically justified. Nevertheless, the protective effect of the annual ceiling was weakened by the reform.

To confirm the effects of the reform and to evaluate the sensitivity and accuracy of the used method, ex post analyses are needed. Previously, the effects of the 2013 pharmaceutical pricing and reimbursement reform have been estimated using ex ante (2010 data, 10% sample) and ex post (2013 data, total population) microsimulations. Despite the differences in the data coverage and the changes in prices and the range of products over time, the two simulations resulted in closely similar estimates. According to both simulations, the mean change in patient out-of-pocket costs was $+ \in 9$. In the ex ante simulation, the share of patients for whom the change was a maximum of $\in 10$ per year was 64%, and in the *ex post* analyses, it was 63%. The effect of the 5% price cut on the NHI expenditure was €57 million based on both analyses (Saastamoinen et al. 2016; Government Proposal 113/2012). The overall effect of the 2013 changes for the NHI expenditure was €92.7 million based on the *ex ante* analyses, and in the ex post analyses, it was €91.2 million (Aaltonen, unpublished simulation results; Saastamoinen et al. 2016). Hence, the reliability of the ex ante simulation was relatively good at the population level and in predicting changes to patients.

The simulations in both *ex ante* and *ex post* settings, however, represent only the direct effects of legislative changes on prices and out-of-pocket costs. In reality, the effects of the reforms are mingled with behavioural effects and other changes related to the supply side and, e.g., economic circumstances. In addition to behavioural effects due to price elasticity, reforms may affect the behaviour of prescribers, the pharmaceutical industry and pharmacies. From the equity perspective, the effects of the reforms need to be examined in terms of the outcomes related to access to necessary medicines, households' economic burden and health.

Medicines also represent only a part of overall health care user charges. Within the overall health care system, separate co-payment ceilings also apply to public health care services and travel costs. Although exceeding all three ceilings is rare, the burden of costs may become notable for heavy users of health care services (Mikkola et al. 2009). Individuals also respond differently to cost pressures. While some defer medicine use or other treatments, others may go without other necessities, e.g., nutrition, which may have even more detrimental effects on health (Heisler et al. 2005; Kinnunen 2009; Kruunari 2009). Increases in co-payments may also have effects on social assistance (means-tested last resort minimum income assistance) expenditure and use.

Cost containment and efficiency are important goals in health care and pharmaceutical policy in order to ensure that maximum health and quality of life are achieved with available resources. However, user charges are not an optimal method to achieve these goals, since they are difficult to allocate equitably (WHO 2000; WHO 2010b). Therefore, shifting the focus from influencing patients by user charges to promoting rational prescribing is encouraged.

Conclusions

Microsimulation provided a prompt and flexible method to produce various estimates of the effects of pharmaceutical pricing and reimbursement reforms. The 2016 reform increased the out-of-pocket costs for most patients. Increases were most common among patients at the lower end of the out-of-pocket cost distribution. However, the largest increases affected patient groups with high health needs and a large number of purchases. The aims of targeting the cost containment measures to patients with lower medicine use were therefore not entirely successful. Further research is needed to assess the impact of the reform on equitable access to and use of medicines.

Endnotes

¹Ceiling: Patients pay the full price or part of the cost up to a ceiling, after which medicines are available at reduced cost for the rest of the calendar year (Austvoll-Dahlgren et al. 2008).

²Deductible: Initial expense up to a fixed amount, which must be paid out-of-pocket for medicines over a calendar year; then, all or a percentage of the rest of the cost is covered by the NHI (WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies 2017).

³Reference price system: Within the reference price system, identical medicines are clustered, and within the cluster,

reimbursement is paid based on the lowest, i.e., reference, price. If a patient refuses to switch from the prescribed product to a cheaper substitutable alternative, the patient pays the difference (referred here as reference premium) between the reference price and the retail price (WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies 2017).

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References

- Aaltonen, K. (2015). Lääkekorvaukset. In J. Blomgren, K. Aaltonen, J. Tervola, & L. Virta (Eds.), *Kelan sairaanhoitokorvaukset tuloryhmittäin* (pp. 18–26). Sosiaali- ja terveysturvan selosteita 93. Helsinki: Kela.
- Aaltonen, K., Miettinen, J., Airio, I., Martikainen, J. E., Saastamoinen, L. K., Bell, J. S., ... Norris, P. (2014). Cost-related barriers to use of health services and prescription medicines in Finland: a cross-sectional survey. *The European Journal of Public Health*, 25, 368–372.
- Aaltonen, K., Miettinen, J., Saastamoinen, L. K., & Martikainen, J. (2013). Kenellä ei ole varaa lääkkeisiin? In I. Airio (Ed.), *Toimeentuloturvan verkkoa kokemassa. kansalaisten käsitykset ja odotukset* (pp. 232–247). Teemakirja 9. Helsinki: Kela.
- Austvoll-Dahlgren, A., Aaserud, M., Vist, G., Ramsay, C., Oxman, A. D., Sturm, H., ... Vernby, A. (2008). Pharmaceutical policies: effects of cap and co-payment on rational drug use. *Cochrane Database of Systematic Reviews*, 1.
- Avorn, J. (2010). Medication use in older patients: better policy could encourage better practice. *Journal of American Medical Association*, 304, 1606–1607.
- Briesacher, B. A., Gurwitz, J. H., & Soumerai, S. B. (2007). Patients at-risk for cost-related medication nonadherence: a review of the literature. *Journal of General Internal Medicine*, 22, 864– 871.
- Dahlgren, G., & Whitehead, M. (1991). *Policies and strategies to promote social equity in health*. Stockholm: Institute for future studies.
- De Agostini, P., Paulus, A., & Tasseva, I. V. (2016). The effect of changes in tax-benefit policies on the income distribution in 2008-2015 (Tech. Rep.). EUROMOD at the Institute for Social and Economic Research.
- Dormuth, C. R., Burnett, S., & Schneeweiss, S. (2005). Using policy simulation to predict drug plan expenditure when planning reimbursement changes. *Pharmacoeconomics*, 23, 1021–1030.

- Dormuth, C. R., Neumann, P., Maclure, M., Glynn, R. J., & Schneeweiss, S. (2009). Effects of prescription coinsurance and income-based deductibles on net health plan spending for older users of inhaled medications. *Medical Care*, 47, 508–516.
- Eurostat. (2016). EU-SILC Database. Self-reported unmet needs for medical examination by sex, age, detailed reason and income quintile. Luxembourg: Eurostat. Retrieved 2017-02-28, from <http://appsso.eurostat.ec.europa.eu/nui/ submitViewTableAction.do>
- Fimea & Kela. (2016). Finnish statistics on medicines 2015. Helsinki: Fimea & Kela.
- Finnish Government. (2011). Pääministeri Jyrki Kataisen hallituksen ohjelma. Helsinki: Finnish Government.
- Gemmil, M. (2008). *The price elasticity of demand for prescription drugs: an exploration of demand in different settings*. London: London School of Economics and Political Science.
- Goldman, D. P., Joyce, G. F., & Zheng, Y. (2007). Prescription drug cost sharing: associations with medication and medical utilization and spending and health. *Journal of American Medical Association*, 298, 61–69.

Hart, J. T. (1971). The inverse care law. The Lancet, 297, 405-412.

- Heisler, M., Wagner, T. H., & Piette, J. D. (2005). Patient strategies to cope with high prescription medication costs: who is cutting back on necessities, increasing debt, or underusing medications? *Journal of Behavioral Medicine*, 28, 43–51.
- Häkkinen, U., & Alha, P. (2006). Health Service Utilization and its Socioeconomic Determinants. Health 2000 Survey. Kansanterveyslaitoksen julkaisuja B10. Helsinki: National Public Health Institute.
- Kangas, O., & Blomgren, J. (2014). Socio-economic differences in health, income inequality, unequal access to care and spending on health: a country-level comparison of Finland and 16 other European countries. *Research on Finnish Society*, 7, 51–63.
- Kinnunen, K. (2009). Sairaus mukana ahdingossa (Sickness and distress). In K. Kinnunen (Ed.), Sairas köyhyys (pp. 198–229). Suomen ev.lut. kirkon kirkkohallituksen julkaisuja 7. Helsinki: Church Council.
- Kruunari, A. (2009). Medicine or food: the sufficiency of basic social security based on the experiences of the long-term ill. Master's thesis in Social work. Tampere: University of Tampere.
- Lexchin, J., & Grootendorst, P. (2004). Effects of prescription drug user fees on drug and health services use and on health status in vulnerable populations: a systematic review of the evidence. *International Journal of Health Services*, 34, 101–122.
- Lindholm, H. (2001). *Changes in the well-being of the Finnish population 19952000.* Studies in social security and health 63. Helsinki: Kela.
- Mackenbach, J. P., Stirbu, I., Roskam, A.-J. R., Schaap, M. M., Menvielle, G., Leinsalu, M., & Kunst, A. E. (2008). Socioeconomic inequalities in health in 22 European countries. *New England Journal of Medicine*, 358, 2468–2481.

- Marmot, M. (2004). The status syndrome: how social standing affects our health and longevity. London: Bloomsbury.
- Martikainen, J. (2012). Uusien lääkkeiden markkinoille tulo ja lääkekustannuksiin vaikuttaminen. Sosiaali- ja terveysturvan tutkimuksia 119. Helsinki: Kela. Retrieved 2017-07-20, from https://helda.helsinki.fi/handle/10138/29431
- Mikkola, H., Kapiainen, S., Seppälä, T., Peltola, M., Tuominen, U., Pekurinen, M., & Häkkinen, U. (2009). *Tutkimus terveydenhuollon maksukattojen yhdistämisestä*. Helsinki: Terveyden ja hyvinvoinnin laitos.
- Mossialos, E., & Srivastava, D. (2008). *Pharmaceutical policies in Finland: challenges and opportunities*. Copenhagen: European Observatory on Health Systems and Policies.
- OECD. (2005). Reviews of health systems: Finland. Paris: OECD.
- OECD. (2011). Health at a glance 2011. Paris: OECD.
- OECD. (2014). Society at a Glance 2014. Paris: OECD.
- OECD. (2015). Health Statistics 2015. Online database. Retrieved 2016-04-11, from <http://stats.oecd.org/index .aspx?DataSetCode=HEALTH_STAT>
- Penchansky, R., & Thomas, J. W. (1981). The concept of access: definition and relationship to consumer satisfaction. *Medical Care*, 19, 127–140.
- Piette, J. D., Heisler, M., Horne, R., & Alexander, G. C. (2006). A conceptually based approach to understanding chronically ill patients' responses to medication cost pressures. *Social Science & Medicine*, 62, 846–857.
- Remler, D. K., & Greene, J. (2009). Cost-sharing: a blunt instrument. Annual Review of Public Health, 30, 293–311.
- Rikala, M., Enlund, H., Hämeen-Anttila, K., & others. (2016). Medicines, reimbursement of medicines and decision-making on treatment – a population view. Kuopio: Finnish Medicines Agency.
- Saastamoinen, L. K., Ahola, E., Tervola, J., Tillman, P., & Tuominen, U. (2016). Sairausvakuutuskorvauksista leikattiin 125 miljoonaa euroa vuonna 2013. Miten leikkaukset kohdentuivat? *Yhteiskuntapolitiikka*, 81, 551–558.
- Sabaté, E. (Ed.). (2003). Adherence to long-term therapies: evidence for action. Geneva: World Health Organization.
- Statistics Finland. (2016). Microsimulation. Web page. Retrieved 2016-09-08, from <https://www.stat.fi/tup/ mikrosimulointi/index_en.html>
- STM, a. (2012). Lääkekorvausjärjestelmän kehittäminen. Lääkekorvausjärjestelmän kehittämistyöryhmän loppuraportti. Sosiaalija terveysministeriön raportteja ja muistioita 33. Helsinki: Ministry of Social Affairs and Health.
- STM, b. (2012). Lääkekorvausjärjestelmän kehittäminen. Lääkekorvausjärjestelmän kehittämistyöryhmän väliraportti. Sosiaali- ja terveysministeriön raportteja ja muistioita 6. Helsinki: Ministry of Social Affairs and Health.

- Sutherland, H., & Figari, F. (2013). EUROMOD: the European Union tax-benefit microsimulation model. *International Journal* of Microsimulation, 6, 4–26.
- Sutherland, H., Taylor, R., & Gomulka, J. (2002). Combining household income and expenditure data in policy simulations. *Review of Income and Wealth*, 48, 517–536.
- Tamblyn, R., Laprise, R., Hanley, J. A., Abrahamowicz, M., Scott, S., Mayo, N., ... Perreault, R. (2001). Adverse events associated with prescription drug cost-sharing among poor and elderly persons. *Jama*, 285, 421–429.
- Tarkiainen, L., Martikainen, P., & Laaksonen, M. (2013). The changing relationship between income and mortality in Finland, 1988–2007. *Journal of Epidemiology and Community Health*, 21–27.
- Tolppanen, A.-M., Taipale, H., Koponen, M., Lavikainen, P., Tanskanen, A., Tiihonen, J., & Hartikainen, S. (2013). Use of existing data sources in clinical epidemiology: Finnish health care registers in Alzheimer's disease research-the medication use among persons with Alzheimer's disease (MEDALZ-2005) study. *Clinical Epidemiology*, 5, 277.
- Tuomisto, J. T., Pohjola, M., & Pohjola, P. (2014). Avoin päätöksentekokäytäntö voisi parantaa tiedon hyödyntämistä. *Yhteiskuntapolitiikka*, 79, 66–75.
- Van Doorslaer, E., Masseria, C., Koolman, X., Group, O. H. E. R., & others. (2006). Inequalities in access to medical care by income in developed countries. *Canadian Medical Association Journal*, 174, 177–183.
- Vehko, T., Sund, R., Arffman, M., Manderbacka, K., Ilanne-Parikka, P., & Keskimäki, I. (2013). Monitoring the use of lipidlowering medication among persons with newly diagnosed diabetes: a nationwide register-based study. *Brittish Medical Journal Open*, 3.
- Vogler, S. (2008). PPRI report. Pharmaceutical pricing and reimbursement information. Vienna: Project Commissioned by European Commission, Health and Consumer Protection Directorate-General and the Austrian Ministry of Health, Family and Youth.
- Vogler, S., Zimmermann, N., Leopold, C., & de Joncheere, K. (2011). Pharmaceutical policies in European countries in response to the global financial crisis. *Southern Medical Review*, 4, 69–79.
- Vuorenkoski, L., Mladovsky, P., & Mossialos, E. (2008). Finland: health system review. *Health Systems in Transition*, 10, 1–168.
- WHO. (2000). The world health report 2000: health systems: improving performance. Geneva: World Health Organization.
- WHO, a. (2010). A conceptual framework for action on the social determinants of health. Geneva: World Health Organization.
- WHO, b. (2010). *Health systems financing. The path to universal coverage. The world health report.* Geneva: World Health Organization.
- WHO Collaborating Centre for Drug Statistics Methodology. (2015). ATC/DDD Index 2015. Retrieved from <http://www.whocc.no/atcddd/>.

WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies. (2017). *Glossary*. Web resource. Retrieved 2017-02-23, from <http://whocc.goeg .at/Glossary/About>

Wilkinson, R., & Pickett, K. (2011). The spirit level: why greater

equality makes societies stronger. USA: Bloomsbury.

Zhou, M. (2013). *Microsimulation: statistical methodology and assessment of uncertainty*. Working papers 44. Helsinki: Kela.