



IMPACTS OF POLICY CHANGES AND THE ROLE OF INSTITUTIONAL STRUCTURES IN HEALTHCARE

Exploring outcomes related to the pharmacological care of type 2 diabetes

Hanna Rättö

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ABSTRACT

Health and social protection systems offer care and security in times of need. A wellfunctioning system can also help mediate the consequences of unequally distributed determinants of ill -health. However, the structures of a system may also invite nonclinical factors such as the socioeconomic status of a patient influence the receipt of care. The capability of the system to provide for those in need is thus a complex whole, with policy interplays and interconnected institutional structures further hampering the possibilities for evaluating the role of distinct features in provision of care and security.

Using prescription medicines as an example of healthcare service, the four articles in this dissertation examine policies and institutional structures affecting healthcare. The articles utilise study designs arising from policy reforms and structures of healthcare system that affect patients with type 2 diabetes, a chronic disease that requires long-term pharmacological treatment. The first and second articles examine the effects of a reform within the affected system by studying the impacts of increased medicine co-payment on medicine use on all affected patients and on patients from different socioeconomic backgrounds. The third article concentrates on institutional interplays and studies the impact of increased co-payment on the receipt of social assistance, a last-resort financial aid. The fourth article focuses further on the role of institutional structures and analyses the medicine prescribing patterns for patients using services in public, private and occupational healthcare.

The first three articles use nationwide Finnish register data from 2010–2019 and exploit a quasi-experimental setting caused by the introduction of a reform that increased the co-payment for non-insulin type 2 diabetes medicines. Population-level impacts on medicine use are investigated with interrupted time-series analysis and segmented regression. Analysis of socioeconomic differences in take-up of insulin after the reform utilises proportional hazard method. Insulin is often a less optimal but from the patients' perspective a cheaper treatment alternative. The impact of co-payment increase on social assistance receipt is studied using difference-in-differences analysis. The fourth article uses descriptive methods and logistic regressions with comprehensive regional level register data from 2013–2018 to evaluate the prescribing patterns reflecting clinical guidelines of care in patients receiving prescriptions for novel non-insulin type 2 diabetes medicines in different healthcare sectors.

The results showed that after the reform increasing the co-payment for noninsulin type 2 diabetes medicines, the total consumption of these medicines declined. However, the consumption of insulins did not increase. There were also no differences in the development of insulin initiation patterns between patients with different socioeconomic position after the reform. The effects of the reimbursement system reform seemed, however, to spread to the social assistance system, as the probability of social assistance receipt rose in patients using type 2 diabetes medicines. This also suggests an impact on the affordability of the affected medicines. The likelihood of insulin initiation in patients with type 2 diabetes was found to be declining during the study period, reflecting novel type 2 diabetes medicines entering the reimbursement system. The characteristics of patients initiating novel medicines in different healthcare sectors aligned with the known socioeconomic differentiation of Finnish primary care, but the prior prescribing patterns in all sectors reflected the clinical guidelines of type 2 diabetes care. The higher likelihood of prior insulin use in patients initiating novel medicines in public sector compared to patients initiating them in occupational care implied the possibility of initiation at a later stage or unaccounted differences in patient characteristics.

Overall, the study demonstrates how implemented reforms can be utilised to enhance our understanding of policy connections in a system of health and social protection. It also increases our understanding of the role of institutional structures in providing care for individuals in different socioeconomic positions. Finally, the findings on impacts of the co-payment increase of non-insulin antidiabetic medicines directly contribute to the assessment of the varied effects of this particular reform in Finland.

To conclude, this study showed that in an interconnected health and social protection system, reforms can have unintended consequences. Due to system-level complementarities, outcomes can also realize in other parts of the system than the one directly affected by the reform. The increased medicine co-payment affected the use of targeted medicines but did not lead to unintended effects in the use of less optimal treatments. The effects were not, however, contained within the reimbursement system. Due to complementarities between the medicine reimbursement and social assistance systems, the probability of social assistance receipt increased after the increase in medicine co-payment. Overall, the prescribing patterns of antidiabetic medicines reflected the changing treatment practices and reimbursement policies. With respect to initiation of novel non-insulin antidiabetic medicines, characteristics of patients in different healthcare sectors paralleled the known cross-sector differences of the Finnish healthcare system. Nevertheless, prior medicine use indicated similar adherence to clinical guidelines of care in all sectors. As such, policy changes of a system that provides care for patients in need should be made only after careful consideration. A deeper understanding of structures, effects, and interplays within the overall health and social protection system can help guide future polices.

KEYWORDS: policy change; policy interplay; healthcare system; type 2 diabetes

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TIIVISTELMÄ

Terveys- ja sosiaaliturvajärjestelmät tarjoavat hoivaa ja turvaa niitä tarvittaessa. Hyvin toimiva järjestelmä voi myös auttaa tasoittamaan seurauksia, joita huonoon terveydentilaan yhteydessä olevien tekijöiden epätasaisella jakautumisella on. Järjestelmän rakenteet voivat kuitenkin myös edesauttaa muiden kuin hoitoon liittyvien tekijöiden, kuten potilaiden sosioekonomisen aseman, heijastumista hoidon saamiseen. Järjestelmän kyky vastata tarpeisiin onkin monimutkainen kokonaisuus, jossa politiikkojen väliset yhteydet vähentävät mahdollisuuksia arvioida järjestelmän yksittäisten ominaisuuksien yhteyttä hoivan ja turvan tarjoamiseen.

Tämä väitöskirja käyttää reseptilääkkeitä esimerkkinä terveydenhuollon palvelusta. Väitöskirjan neljä artikkelia tarkastelevat terveydenhuoltoon vaikuttavia politiikkoja ja institutionaalisia rakenteita. Artikkelien tutkimusasetelmat ovat lähtöisin politiikkamuutoksista ja terveydenhuollon rakenteista, jotka vaikuttavat tyypin 2 diabetesta, pitkäaikaista lääkehoitoa vaativaa kroonista sairautta, sairastaviin potilaisiin. Ensimmäinen ja toinen artikkeli tarkastelevat politiikkamuutoksen vaikutuksia järjestelmässä, johon se on kohdennettu. Ne tarkastelevat lääkkeiden omavastuuosuuden noston vaikutusta lääkkeiden käyttöön ensin kaikilla niillä potilailla, joihin muutos kohdistui ja sitten erikseen potilaiden sosioekonomisen aseman suhteen. Kolmas artikkeli keskittyy järjestelmätason yhteyksiin ja tutkii omavastuun noston vaikutusta toimeentulotuen, viimesijaisen taloudellisen avun, käyttöön. Neljäs artikkeli syventää institutionaalisten rakenteiden roolien tarkastelua ja analysoi lääkkeiden määräämistä potilaille, jotka käyttävät terveydenhuollon palveluita julkisessa terveydenhuollossa, yksityisessä terveydenhuollossa tai työterveyshuollossa.

Kolme ensimmäistä artikkelia hyödyntävät kansallisen tason suomalaisia rekisteriaineistoja vuosilta 2010–2019 sekä muiden tyypin 2 diabeteksen hoidossa käytettävien lääkkeiden kuin insuliinien omavastuuosuutta nostaneen politiikkamuutoksen voimaan tulosta syntynyttä kvasi-kokeellista asetelmaa. Väestötason vaikutuksia lääkkeiden käyttöön tarkastellaan keskeytetyn aikasarja-analyysin ja segmentoidun regression avulla. Sosioekonomisia eroja insuliinin, hoidollisesti usein vähempiarvoisen mutta potilaiden näkökulmasta edullisemman hoitovaihtoehdon, aloittamisessa politiikkamuutoksen jälkeen tarkastellaan suhteellisen riskin menetelmää käyttäen. Omavastuuosuuden noston vaikutusta toimeentulotuen käyttöön tarkastellaan erot eroissa (diffrenecs-in-differences) -analyysin avulla. Neljännessä artikkelissa käytetään kuvailevia menetelmiä ja logistisia regressiomalleja sekä kattavaa alueellista rekisteriaineistoa vuosilta 2013–2018 arvioimaan kliinisten hoitosuositusten heijastumista lääkkeen määräämiseen potilailla, jotka aloittavat uuden tyypin 2 diabeteslääkkeen terveydenhuollon eri sektoreilla.

Tulosten mukaan tyypin 2 diabeteslääkkeiden omavastuuosuutta nostaneen politiikkamuutoksen jälkeen näiden lääkkeiden kokonaiskulutus laski, mutta insuliinin kokonaiskulutus ei noussut. Insuliinihoidon aloittamisen kehityksessä muutoksen jälkeen ei myöskään ollut eroa eri sosioekonomisessa asemassa olevien potilaiden välillä. Lääkekorvausjärjestelmään kohdennetun muutoksen vaikutukset kuitenkin näkyivät toimeentulotukijärjestelmässä, sillä toimeentulotuen saamisen todennäköisyys tyypin 2 diabeteslääkkeitä käyttäneillä potilailla nousi muutoksen jälkeen. Tämä kertoo vaikutuksesta näiden lääkkeiden taloudelliseen saavutettavuuteen. Insuliinin aloittamisen todennäköisyys potilailla, jotka olivat käyttäneet tyypin 2 diabeteslääkkeitä, laski tarkastelujakson aikana, mikä heijastaa uusien tyypin 2 diabeteslääkkeiden tuloa korvausjärjestelmään. Uusia tyypin 2 diabeteslääkkeitä eri terveydenhuollon sektoreilla aloittaneiden potilaiden ominaisuudet vastasivat aiempia tietoja suomalaisen perusterveydenhuollon sosioekonomisesta eriytymisestä, mutta aiempi lääkehoito heijasteli tyypin 2 diabeteksen hoitosuosituksia kaikilla sektoreilla. Verrattuna työterveyshuoltoon, julkisessa terveydenhuollossa uuden diabeteslääkkeen aloittaneilla potilailla oli korkeampi todennäköisyys aiempaan insuliinin käyttöön, mikä saattaa liittyä uuden lääkkeen aloittamiseen myöhemmässä vaiheessa, tai havaitsemattomiin eroihin potilaiden ominaisuuksissa.

Tutkimus havainnollisti, kuinka politiikkamuutoksia voidaan käyttää lisäämään ymmärrystämme eri politiikkojen yhteyksistä terveys- ja sosiaaliturvajärjestelmässä. Tutkimus myös tuotti tietoa siitä, miten institutionaaliset rakenteet ovat yhteydessä hoivan tarjoamiseen erilaisessa sosioekonomisessa asemassa oleville henkilöille. Tyypin 2 diabeteslääkkeiden omavastuuosuuden nostoa koskevat tulokset ovat lisäksi suoraan hyödynnettävissä kyseisen muutoksen vaikutuksia arvioitaessa.

Yhteenvetona, tämä tutkimus havainnollisti, että terveys- ja sosiaaliturvajärjestelmään liittyvien politiikkamuutosten vaikutukset voivat ilmetä järjestelmän eri osien keskinäisten yhteyksien takia myös sellaisissa järjestelmän osissa, joihin muutokset eivät suoraan kohdennu. Lisäksi suomalaisen terveydenhuoltojärjestelmän rakenteet heijastuvat eri sektoreilla hoitoa saavien potilaiden erilaisuutena. Lääkkeiden omavastuun nosto vaikutti kohteena olleiden lääkkeiden käyttöön, mutta ei ilmennyt tahattomina vaikutuksina hoidollisesti vähempiarvoista lääkehoitojen aloittamisessa. Vaikutuksia ei kuitenkaan ilmennyt vain kohteena olleessa järjestelmässä. Lääkekorvausjärjestelmän ja toimeentulotukijärjestelmän yhteyksien vuoksi toimeentulotuen saamisen todennäköisyys kasvoi omavastuuosuuden noston jälkeen. Yleisesti ottaen diabeteksen hoitoon käytettyjen lääkkeiden määrääminen heijasteli muuttuvia hoitokäytäntöjä sekä muutoksia korvattujen lääkkeiden valikoimassa. Uusia tyypin 2 diabeteslääkkeitä aloittaneiden potilaiden ominaisuudet heijastelivat tunnettuja eroja terveydenhuollon eri sektorien välillä, mutta aiempi lääkekäyttö heijasteli kliinisiä hoitosuosituksia kaikilla sektoreilla. Kun politiikkamuutoksia tehdään järjestelmässä, joka tarjoaa hoivaa sen tarpeessa oleville, tulisi käyttää huolellista harkintaa. Ymmärryksen lisääminen rakenteista, vaikutuksista sekä yhteyksistä terveys- ja sosiaaliturvajärjestelmässä auttaa ohjaamaan tulevia politiikkoja.

ASIASANAT: politiikka muutos; politiikkojen väliset yhteydet; terveydenhuoltojärjestelmä; tyypin 2 diabetes

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Table of Contents

Ac	knowle	edgements	7
Tal	ble of (Contents	8
Lis	t of Or	iginal Publications	11
1	Intro	duction	12
2	Healt 2.1 2.2 2.3 2.4 2.5	hcare systems and medicines Healthcare provision in welfare states Financial protection Pharmaceutical coverage Different provider sectors Policy changes, complementarities, and institutional structures in an interconnected system of health and social protection	17 17 19 21 22
3	Study	y aims	30
4	Data 4.1 4.2 4.3	and methods Register data Statistical methods Ethics statement	32 32 35 38
5	Resu	Its from the sub-studies	40
	5.1 5.2	Impact of increased co-payment for non-insulin antidiabetic medicines on the utilisation of affected medicines and insulins Impact of increased co-payment for non-insulin antidiabetic medicines on insulin initiation among patients in different	. 40
	5.3	socioeconomic groups Impact of increased co-payment for non-insulin antidiabetic	. 41
	5.4	medicines on the use of social assistance Prescribing patterns reflecting the guidelines of care in type 2 diabetes before the initiation of novel antidiabetic medicine in public, occupational, and private healthcare settings	. 41
	5.5	Main findings	. 43

6	Discu	45	
	6.1 6.2	Interpretation of the results Lessons to welfare policy literature	
	6.3	Methodological considerations	50
	6.4	Policy implications	51
	6.5	Conclusions	
List	t of Re	eferences	54
Ori	ginal l	Publications	65

Table 1. Summary of the research designs.	34
Table 2. Summary of main findings.	44

List of Original Publications

This dissertation is based on the following original publications, which are referred to in the text by their Roman numerals:

- I Rättö, H., Kurko, T., Martikainen, J. E., & Aaltonen, K. (2021). The impact of a co-payment increase in the consumption of type 2 antidiabetics – A nationwide interrupted time series analysis. *Health policy (Amsterdam, Netherlands)*, 125(9), 1166–1172.
- II Rättö, H. (2022). Socioeconomic inequalities in insulin initiation among individuals with type 2 diabetes – A quasi-experimental nationwide register study. SSM – population health, 19, 101178.
- III Rättö, H., & Aaltonen, K. (2021). The effect of pharmaceutical co-payment increase on the use of social assistance – A natural experiment study. *PloS* one, 16(5), e0250305.
- IV Rättö, H., Nurminen, M., & Aaltonen, K. Prescribing patterns before the initiation of novel antidiabetic medicine in public, occupational and private healthcare: a register study reflecting the guidelines of care in type 2 diabetes. Upcoming.

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1 Introduction

Healthcare systems provide care and security in times of need. Besides maintaining and restoring health, they aim at offering protection against the financial consequences of ill health (United Nations [UN], 2023; World Health Organization [WHO], 2005). Nevertheless, socioeconomic differences in distribution of health and ill health are widely reported even in countries that have comprehensive health and social protection systems (Commission on Social Determinants of Health, 2008; Lahelma et al., 2019; Machenbach & Kunst., 1997; Machenbach et al., 2008; Marmot 2004). The distribution of the use of healthcare services has also been found often to inequitably favour those who have a higher socioeconomic status, even when needs are accounted for (Blomgren & Virta, 2020; Manderbacka et al., 2009; Van Doorslaer et al., 2006; Van Doorslaer et al., 2000). Even if healthcare cannot directly affect many of the underlying factors driving socioeconomic health disparities, a well-functioning health system can help mediate their consequences (Commission on Social Determinants of Health, 2008).

Of late, healthcare expenditure has been rapidly growing in many countries, leading to the introduction of policies aimed at curbing such increase. The measures taken have, among others, included reforms increasing the share of healthcare costs patients must pay themselves out-of-pocket. (Keehan et al., 2015; Stadhouders et al., 2019.) Cost sharing, referring to third-party payers requiring that patients pay directly a share of the costs for service, product, or care received is, however, known to be a regressive form of financing (Van Doorslaer et al., 1999; Wagstaff et al., 1999). Cost-containment policies targeted at healthcare systems can also have unintended effects on, for example, clinical outcomes or the use of necessary services (Arcà et al., 2020; Lavikainen et al., 2020a). In case the burden is disproportionate for those in economically vulnerable positions, the capability of the system to provide equal access to care can be affected. Moreover, in an interconnected system of health and social protection, measures targeted at one part of the system can also have spillover effects on other parts of the overall system. Complementary effects and complex institutional structures can thus make it even more difficult to anticipate all impacts of introduced changes.

Affordable medicines are acknowledged as an important requirement of functional healthcare (European Commission, 2020). Affordability in general is one of the key dimensions of access to healthcare (Penchansky & Thomas, 1981) that also the WHO (2005) mentions when describing prerequisites of equitable access. Besides affordability, other dimensions of access (Penchansky & Thomas, 1981) such as availability of services can affect healthcare utilisation. Disparities in, for example, the timeliness of access or the content of care accessed, can also be associated with maintaining or exacerbating disparities in health.

Recent developments in the Finnish system of health and social protection offer a unique possibility to study the implications of introduced changes and system-level structures in varied aspects of receipt of care. Using reimbursed outpatient medicines as an example, this dissertation explores the unintended impacts of a costcontainment policy introduced in the Finnish healthcare system. Furthermore, it analyses the complementary effects within the overall system of health and social protection and explores how the institutional structures of healthcare system are reflected in care provided. The dissertation aims to reach these main aims with four sub-studies utilising settings arising from the Finnish healthcare system and affecting patients with type 2 diabetes. Diabetes is one of the important public health priorities among non-communicable diseases and its increasing costs form a significant part of the overall healthcare spending (Cho et al., 2018; Seuring et al., 2015; WHO, 2023). It has even been called 'a defining disease of the 21st century' (The Lancet, 2023).

Type 2 diabetes is a chronic disease that requires long-term pharmaceutical treatment. This dissertation first examines the effects of a policy change increasing the co-payment for non-insulin antidiabetic medicines on medicine utilisation of all affected patients (Sub-Study I) and on the take-up of insulin, often less optimal but from the patient's perspective a cheaper treatment alternative, in patients with different income levels (Sub-Study II). The viewpoints in the dissertation are broadened from the reimbursement system to the effects on the receipt of last-resort social assistance (Sub-Study III). The dissertation concludes by analysing the prescribing patterns reflecting the clinical guidelines of diabetes care in patients being prescribed novel, typically more expensive, non-insulin antidiabetic medicines for the first time in public, private, and occupational healthcare (Sub-Study IV).

In Finland, outpatient medicines that are assessed as reimbursable based on national criteria are reimbursed on universal basis as part of the national health insurance (NHI). In 2017, the Finnish government implemented a series of austerity policies, including savings measures targeted at the public pharmaceutical budget that aimed to curb the increasing expenditure on outpatient medicine reimbursements. Among the introduced policies was a reform increasing the share patients paid out-of-pocket as co-payment for their non-insulin antidiabetic

medicines used for type 2 diabetes. Between 2010 and 2016, the reimbursement expenditure on non-insulin antidiabetic medicines had more than doubled in Finland, from \notin 50 million to \notin 108 million (from approximately 4% to 8% of the total reimbursement expenditure); (Statistical Database Kelasto, 2023). The reform aimed to create savings from the public pharmaceutical budget, by decreasing reimbursement expenditure by \notin 20 million annually and increasing patients' co-payment expenditure with the corresponding amount.

Compared with previous policy measures targeted at pharmaceutical expenditure in the 2010s, the reform in 2017 only affected one relatively high-need patient group. Diabetes patients often have co-morbidities that also require pharmaceutical treatment and even before the reform, they paid higher than average annual medicine co-payment (just over \in 300, compared to the average of \notin 200) (Kurko et al., 2018). In addition, even the other healthcare related co-payments of diabetes patients have been found to be higher than average, due to their more frequent use of services (Peltola & Vaalavuo, 2018).

On average, the reform in 2017 was expected to increase the annual co-payment expenditure of the affected patients by over \notin 70. For almost one third of patients with type 2 diabetes, the increase was expected to be at least \notin 100. (Government Proposal 184/2016; Kurko et al., 2018.) Due to the expected increases, concerns were raised before the reform over affected patients' ability to afford their necessary medicines or even having to switch to less optimal pharmacological treatments due to increased cost of care (Government Proposal 184/2016). In addition, the possibility of increased use of social assistance to pay for medicine co-payments was brought up during the parliamentary process (Government Proposal 184/2016, StVM 30/2016).

Evidence fairly consistently shows that increases and introductions of cost sharing for medicines reduces their utilisation and that these effects extend to necessary medications and particularly affect vulnerable groups. Studies on cost sharing have most typically examined public pharmaceutical spending and medicine utilisation as outcomes. (Austvol-Dahlgren et al., 2008; Gemmil et al., 2007; Goldman et al., 2007; Kolasa & Kowalczyk, 2019; Lexchin & Grootendorts, 2004; Luiza et al., 2015; Mann et al., 2014; Sinnot et al., 2013.) Relatively few studies have, however, assessed the impacts on system level outcomes or outcomes related to more intrinsic goals such as health or equal access. Furthermore, the effects of policy changes targeted at healthcare are likely to be context-dependent to at least some extent, with institutional structures and complementary effects within the overall system of health and social protection complicating the interpretation of the findings in comparative settings.

Besides cost sharing, access to and content of healthcare services can also impact prescription medicine use, because it is a healthcare professional who prescribes the required medicines to patients. In Finland, the use of primary care has demonstrated relatively large socioeconomic disparities (Blomgren & Virta, 2020; Manderbacka et al., 2009; Van Doorslaer et al., 2006; Van Doorslaer et al., 2000). A suggested contributor to these disparities is the existing system of primary care, where public, occupational, and private options are available. Public healthcare offers primary and specialist healthcare services for all residents – however, waiting times can be long and usually at least some service fees apply. Occupational healthcare offers primary and some specialist-level care for the employed, often with short waiting times and no service fee at the time of the service. Private healthcare offers primary and a variety of specialist-level services, mostly in an outpatient setting. Waiting times to private care are often short, but availability of the services can differ between regions. In addition, though a small share of the cost of private care is reimbursed from NHI, patients have to cover most of the cost of private care themselves. (Keskimäki, 2022; Koponen & Tynkkynen, 2023; Manderbacka et al., 2019.)

Available evidence on service use in public, occupational, and private healthcare demonstrates socioeconomic differences between patients using services in different sectors, with patients in public sector having on average a less prestigious position (Blomgren et al., 2022; Blomgren & Virta, 2020). Studies on service use have mostly analysed numbers and distributions of contacts, with less attention on the type or content of the service received. However, existing evidence implies that patients in public sector are less likely to receive prescriptions for newer medicines (Aaltonen et al., 2018; Jussila et al., 2022). Nevertheless, evidence on use and content of care in occupational healthcare is relatively scarce, as the availability of high-quality individual-level data on service use in occupational healthcare is limited.

This dissertation contributes to the timely conversation on varied, sometimes unintended effects of increased cost sharing in healthcare. It likewise elucidates the connections that the structures of healthcare system and the receipt of pharmacological care have. Findings regarding patients' socioeconomic position and the use of last-resort financial aid further add to the topics of equal access and financial protection in the healthcare system. Moreover, the dissertation advances the discussion on the role of policy interplays and complementary effects between parts of the overall health and social protection system that has lately surfaced in the literature on welfare policies and systems (e.g. Nelson et al., 2022). The possibility of interconnected policies implies that focusing solely on the targeted policy field when examining policy impacts might overlook spillover effects on other fields in the overall health and social protection system.

From a comparative perspective, the findings of this dissertation offer evidence on the impacts of increased cost sharing in a country with comprehensive and universal health and social protection system in place. Moreover, as features such as privatisation and public-private mix are increasingly present in all healthcare systems, the findings on service use in different settings provide evidence also for an international discussion on the consequences of this trend.

The studies included in the dissertation use high-quality, comprehensive register data and established statistical methods suitable for analysing such material. Methodologically, Sub-Studies I–III utilise nationwide register data and quasi-experimental setting resulting from the introduction for increased co-payment of non-insulin antidiabetic medicines. In analysing the effects of increase in co-payment increase, the setting also allows considerations of causality. In Sub-Study IV, extensive regional register data, including individual-level information on the use of occupational healthcare services are used to analyse the prescribing patterns for patients using healthcare services in different provider sectors.

From a policy perspective, results from the dissertation directly address concerns raised over the unwanted impacts on medicine utilisation and social assistance receipt expressed before the co-payment increase of non-insulin antidiabetic medicines in 2017. Insights into the complementarities as well as the content and receipt of care in different healthcare sectors inform the planning and implementation of large-scale reforms of the Finnish health and social protection system. Finally, varied findings regarding the impacts of increased co-payment on patients contribute to the constantly resurfacing discussions on the repercussions of introducing austerity measures on healthcare systems.

The dissertation is structured as follows: Chapter 2 focuses on the previous literature on healthcare systems and medicines as part of healthcare, including discussions on the affordability of care in terms of medicine use. The aims and methodologies of the four included sub-studies are presented in Chapter 3 and Chapter 4, respectively. The results of the sub-studies are presented in Chapter 5. Discussion of the findings and conclusions of this dissertation are considered in Chapter 6.

2 Healthcare systems and medicines

2.1 Healthcare provision in welfare states

Welfare states have traditionally aimed to provide for needs that are not met adequately through markets. Examples of the situations where these needs arise include interruptions of income because of old age or illness. (Taylor-Gooby, 2004; Titmuss, 1974; Zutavern & Kohli, 2010.) Public provision has also been widely recognised as desirable in meeting the needs related to high-value, high-cost services such as education or healthcare (Taylor-Gooby, 2004). These needs still apply. In addition, new kinds of societal needs have risen from, for example, changes in family and gender roles, increased insecurities in labour markets, and sustainability concerns (Greve 2023; Greve & Paster, 2022; Rhodes, 1997; Schoyen et al. 2022; Taylor-Gooby, 2004).

The established structures and funding arrangements of welfare states have in recent decades faced pressures from several directions. Demographic changes due to rising life expectancy and decreasing birth rates imply substantial financial pressures on welfare provision systems, as the high needs of old age are met primarily with contributions from the working-age population. Concurrently, low economic growth and high unemployment rates limit the resources available for meeting the increasing needs. In addition, external shocks such as the COVID-19 pandemic have challenged the capability of welfare systems to respond to the rising needs. Moreover, sustainability challenges such as climate change increasingly threaten the ecological foundations of modern welfare states. (Gori & Luppi 2023; Pierson, 1998; Rhodes, 1997; Schoyen et al. 2022; Taylor-Gooby, 2004.) As a response to these developments, policy reforms of varying extents have been implemented in many welfare states (Greve, 2020; Pierson, 2001; Pierson, 1994). Reforming existing systems to react to increasing pressures and changing risks have however turned out to be difficult, as the systems are built on long-standing commitments, with vested interest, and also tend to have high legitimacy (Pierson, 2000; Rhodes, 1997; Varjonen, 2021).

The need for funding has increased also in healthcare due to, for example, the greater needs of aging populations and technological advances such as new, often expensive, medicines (Chandra & Skinner, 2012; Greve, 2020; Keehan et al., 2015;

Rome et al., 2022; Soppi et al., 2018). This has led many countries to introduce costcontainment policies targeted at healthcare (Mossialos & Le Grand, 2019; Pierson, 1998; Stabile et al., 2013; Stadhouders et al., 2019). Attempts to improve the efficiency in care provision have in essence meant delivering more welfare output with at most marginally increasing budget (Pierson, 1998), with introductions of market principles and competitive pressures used to control spending (Kettunen, 2011; Taylor-Gooby, 2004). In addition to efficiency measures, policies increasing the cost sharing between patients and the public payers have been introduced (Stadhouders et al., 2019). Cost sharing aims to diminish the risk of overuse that arises from patients not being required to meet the full cost of their care. However, it also unloads part of the cost of care received to the patient. (Chandra et al., 2011; Luiza et al., 2015.) This, in turn, can have implications on the affordability of care and the financial protection the healthcare system offers in case of ill health.

In general, public perceptions of European healthcare systems have been found to be positive (AlSaud et al., 2018; Missinne et al. 2013; Wendt et al, 2010). However, in the intersection of growing needs and limited resources to meet them, identifying best practices and learning from the experiences of others has become increasingly important in healthcare. Comparative studies on healthcare systems have aimed to capture and characterise the institutional structures and available resources in different systems and to examine and compare their performance in providing care (Organisation for Economic Co-operation and Development [OECD], 1987; Reibling, 2010; Wendt, 2014; Wendt, 2009).

Attempts to apply methods and concepts from other fields of comparative social policy to characterise healthcare systems have utilised particularly the concept of decommodification and related welfare regime categorisations, derived from the influential work of Esping-Andersen (1990); (Bambra, 2007; Bambra, 2005a). Welfare regimes do not, however, specifically focus on healthcare. Rather, they examine the broader spectrum of welfare provision that healthcare is a part of. (Alber, 1995; Bambra, 2005b; Wendt, 2009; Wendt et al., 2009.) Furthermore, the categorisation proposed by Esping-Andersen (1990) is mostly concerned with decommodification of monetary benefits: pensions, sickness benefits and unemployment benefits and extends their implications to all forms of social policy provision (Bambra, 2005a; Bambra, 2005b; Kautto, 2002; Kasza, 2002). However, in functions such as education or health and social care, the role of cash transfers can be marginal compared to the role of service provision and delivery, complicating directly applying welfare regimes to healthcare system comparisons (Bambra, 2005b; Wendt, 2009; Wendt et al., 2009). Thus, for comparative purposes, healthcare system typologies, reflecting the varied properties and outcomes of the systems providing for health needs have been created (e.g. OECD, 1987; Reibling 2010; Reibling et al., 2019; Wendt 2014; Wendt, 2009). In addition to the roles of actors and structures related to

healthcare systems, the importance of understanding outcomes of different systems has been emphasised (Marmor & Wendt, 2012; Wendt 2022).

Based on their main form of financing, healthcare systems have traditionally been categorised as tax-based national health systems (NHS), social health insurance (SHI) systems, and systems relying on private insurance. The provision of care is most often classified using public and private dimensions. (OECD, 1987; Wendt et al., 2009; WHO, 2018.) Categorisations based solely on modes of financing and provision of care have, however, been found lacking in their ability to distinguish different types of healthcare systems and possibilities, for example, to access care or the relative importance of primary care have been suggested to be much more important in identifying different types of healthcare systems (Reibling, 2010; Reibling et al., 2019). Moreover, different healthcare systems have even been implied to have different consequences with regard to the more intrinsic outcomes, such as health or equality of access to and utilisation of services (Murrey & Fenk, 2000; Reibling & Wendt, 2011; Van Doorslaer et al., 2006). For example, equality of healthcare utilisation has been found to be higher in systems with stronger access regulation (Reibling & Wendt, 2011; Van Doorslaer et al., 2006) and access to care has even been considered the main mediator of healthcare system effects on health and health equality (Schneider et al., 2021).

2.2 Financial protection

Financial protection against consequences of ill health is a common goal of societies (UN, 2023). Most European countries have healthcare systems providing services on a universal basis, meaning that a set of services is provided for all. However, even in universal systems, coverage also depends on the range of covered services and the share of costs patients must pay themselves out-of-pocket. (OECD, 2021.) Economic access or affordability of care is a key dimension in providing equitable access to healthcare (Penchansky & Thomas, 1981; WHO, 2005). For example, in Reiblings (2010) healthcare system categorisation emphasising access, affordability is directly implied in the share of costs that patients need to cover themselves (cost sharing) and also reflected in distinguishing who and for what care receives financial protection (i.e. universality and the package of covered benefits).

Studies have assessed financial protection and the affordability of healthcare using measures such as dropping below poverty line (impoverishment) due to costs of care or spending more than a specific share of income on care (catastrophic spending) (Thomson et al., 2019; Wagstaff & Van Doorslaer, 2003; Wagstaff & Van Doorslaer, 2001). Findings imply that health-related cost sharing can be a significant economic burden and may be so also in countries that have a well-developed health and social protection system in place. Health-related expenditure can even create a

barrier in access to care, resulting in unmet need. (Thomson et al., 2019.) Furthermore, cost sharing is a regressive form of financing (Van Doorslaer et al., 1999; Wagstaff et al., 1999), and the burden may thus be especially emphasised in the financially less well-off (Aaltonen et al., 2014; Aaltonen et al., 2013a; Israel 2016). For example, in the European Union (EU), 33% of residents reported in 2017 that costs related to medical care were somewhat of a financial burden for their households. In addition, 11% reported such costs as a heavy burden. An even higher share of people in households below 60% of the median equivalised income reported experiencing financial difficulty: 34% reported some burden and 19% high burden with regard to medical care. (Eurostat 2019.)

Evidence fairly consistently shows that people with lower socioeconomic status have worse health than those with higher status, even in countries with comprehensive health and social protection systems in place (Álvarez-Gálvez & Jaime-Castillo, 2018; Bambra, 2011; Lahelma et al., 2019; Marmot, 2004). The reasons for such prevailing disparities have been explored from different angles (Bambra 2011; Machenbach, 2012). It can be postulated that social standing affects health status (Marmot, 2004) or that differences in health lead to differences in socioeconomic status (Blaine et al., 1993), with studies demonstrating evidence in both directions (Marmot, 2004; Schuring et al., 2007; Vaalavuo, 2021). In general, the relationship between socioeconomic status and health has been implied to be complex and often likely bi-directional (Goldman, 1994; Kröger et al., 2015). Healthcare cannot directly affect the variety of health determinants. A system that functions well can, however, help mediate the consequences of determinants of ill health between people in different socioeconomic positions. (Commission on Social Determinants of Health, 2008.) Disparities in access can strengthen existing or even translate to health disparities, if people with lower socioeconomic status have more challenges in accessing healthcare due to, for example, cost of care.

In general, studies have demonstrated that cost sharing reduces healthcare utilisation (Chandra et al., 2010; Luiza et al., 2015). Highly developed healthcare systems are, however, made even more complex by complementarities and interplays within the overall system of health and social protection (Wendt, 2022). The distinction between health and social protection is often artificial, as in many cases the needs are common or intertwined. Other forms of social protection such as pensions may buffer the negative effects of out-of-pocket healthcare costs by increasing vulnerable households' ability to pay (Israel, 2016; Reeves et al., 2017), whereas in systems where there are last-resort schemes covering health expenses, a higher level of out-of-pocket payment might lead to increased utilisation of these schemes. Moreover, in case of the care of old people or people with disabilities, health needs are often met within the wider structures of social protection (Halmetoja et al., 2023; Vaalavuo, 2020).

2.3 Pharmaceutical coverage

Pharmaceutical coverage systems represent arrangements and instruments regulating 'who pays which drugs under which circumstances' (Seiter, 2010, p.4). They aim to secure patients' access to important medicines and to reduce the risk of heavy economic burden on people in need of pharmacological care (Luiza et al., 2015; Seiter, 2010). In European countries with well-developed welfare systems, pharmaceutical coverage systems are typically embedded in public healthcare systems. However, the coverage for pharmaceuticals is often not as comprehensive as the coverage for inpatient and outpatient care (OECD, 2021). In the EU, the households' financial burden due to expenditure on medicines has been reported to be higher than the burden due to medical care (Eurostat, 2019).

The systems for pharmaceutical coverage typically include policies targeted at patients, physicians and the pharmaceutical industry. These policies aim to guarantee access to safe and efficient medicines, while simultaneously limiting pharmaceutical expenditure. (Luiza et al., 2015; Mossialos & Oliver, 2005.) Pharmaceutical policies targeted at patients are typically intended to disincentivise the overuse of medicines, the use of medicines with limited value and medicines for conditions where other, more cost-effective treatments are available (Luiza et al., 2015). The perceived risk of unnecessary use derives from the possibility of moral hazard, when the coverage system insulates patients from the full cost of care and supplies economic incentives to purchase more medicines than necessary (Luiza et al., 2015; Rice et al., 2004). Direct cost sharing policies shift part of the financial burden of medicines from thirdparty payers to patients, thus increasing patients' financial responsibility. There is, however, a wide variation in the ways cost sharing policies have been designed and implemented. Differences exist in, for example, how much patients are expected to pay or the mechanisms the payments are determined. (Luiza et al., 2015; Vogler et al. 2019.)

In Finland, outpatient medicines are reimbursed on a universal basis as part of the NHI system, with reimbursements applying to medicines assessed as reimbursable based on national criteria. The reimbursement is usually provided directly at the pharmacy. In 2020, the expenditure on reimbursable outpatient medicines accounted for approximately 9.5% of the total health expenditure (Finnish Institute for Health and Welfare, 2023). In addition to the basic reimbursement category that applies to all reimbursed medicines (40% of the retail price), the system includes two disease-based reimbursement categories covering either 100% (with fixed co-payment of €4.50/purchase) or 65% of retail price. These categories apply to certain severe and chronic illnesses, such as cancer and diabetes. Until 2017, all antidiabetic medicines were reimbursed in the 100% category. In 2017, non-insulin antidiabetic medicines were moved to the 65% category, while insulins remained in the 100% category. Reimbursements for new and expensive medicines are often restricted for patients fulfilling certain diagnostic criteria. Entitlements to diseasebased and restricted reimbursement can be granted to patients based on a doctor's certificate. The reimbursement categories only apply after patients meet an initial annual deductible (\notin 50, children and youth are exempt). (Health Insurance Act; Kastarinen, 2020; Social Insurance Institution of Finland 2023.) Increased level of reimbursement or otherwise less restricted access has been associated with increased medicine consumption in Finland (Martikainen et al., 2007; Martikainen et al., 2010).

The Finnish medicine reimbursement system also includes an annual co-payment ceiling mechanism (\notin 592.16 in 2023) that aims to protect patients from high medicine co-payment. After meeting the ceiling, patients pay a fixed fee of \notin 2.50/purchase for the rest of the calendar year. (Social Insurance Institution of Finland 2023.) Nevertheless, the private expenditure on outpatient medicines has been deemed high compared to comparable countries such as other Nordic countries (Keskimäki et al., 2019). Together with user fees in other areas of healthcare, out-of-pocket payments have even been criticized for undermining the progressivity of the Finnish healthcare funding (Keskimäki et al., 2019). Previous studies have also implied patients' sensitivity to medicine co-payment in Finland (Hamina et al., 2020; Tervola et al., 2021).

2.4 Different provider sectors

Results from several studies have indicated that even when needs are accounted for, healthcare use can be biased towards those who have a higher socioeconomic status also in affluent countries (Blomgren & Virta, 2020; Manderbacka et al., 2009; Van Doorslaer et al., 2006; Van Doorslaer et al., 2000). Besides the cost of care, other factors not necessarily associated with need can affect the use of healthcare services or prescription medicines. For example, the characteristics of the patient, the characteristics of the physician, or the decision-making processes of the service provider can affect the provision or receipt of care. (Chandra et al., 2011; Hajjaj et al., 2010; Suleman & Movik, 2019.) Patients' socioeconomic status can be associated with the resources available to acquire treatment, or patients' preferences for certain treatments over others can lead them to ask for these treatments (Chandra et al., 2011; Hajjaj et al., 2010). Physicians' characteristics or financial incentives can affect their behaviour in, for example, prescribing medicines. In settings where patients are free to choose their physicians, the latter may try to accommodate patients' demands to keep them from choosing another physician. (Chandra et al., 2011; Dulleck et al., 2011; Jussila et al., 2022.) Moreover, as medical care is an area often characterised by substantial involvement of either private or public insurance, insurance coverage can also influence the care that is provided. Factors reflecting more system-level structures such as guidelines of care or internal decision making processes of organisations where the physicians work can have an impact as well. (Chandra et al., 2011, Hajjaj et al., 2010.)

The use of primary healthcare services has demonstrated relatively large socioeconomic differences in Finland (Blomgren & Virta 2020; Van Doorlaer et al., 2006; Van Doorslaer et al., 2000). One of the suggested explanations for this is the Finnish healthcare system, where public, occupational and private options are available and receive at least some public funding. Though the range of available services differs across sectors, primary care services are available in all three settings. Prescriptions for outpatient medicines are reimbursed similarly from the NHI regardless of the sector where the prescriber operates. Furthermore, physicians are not differentially financially rewarded for prescribing certain pharmaceutical products over others.

Public healthcare provides comprehensive services from primary to highly specialised tertiary care for all residents in Finland. Until 2022, municipalities were responsible for organising public healthcare for their residents. In 2022, the responsibility was shifted to the newly established wellbeing services counties, which are larger regional operators. Most hospital inpatient and highly specialised outpatient services are provided in public healthcare, with primary care acting as a gate-keeper to specialist care. Services are mainly tax-funded, though user fees also apply to most services. Regardless of their relatively small size and a ceiling mechanism applying, user fees can limit the access to care for those with lowest incomes. However, it is particularly the long waiting times that restrict the access to public healthcare, and the problem has become even more pronounced in the aftermath of the COVID-19 pandemic. (Keskimäki et al., 2019; Rissanen et al., 2023.)

In most cases, employers have the responsibility of arranging preventive occupational healthcare services for their employees. However, in addition to mandatory services, a large share of the occupational care schemes also offers curative services at primary care level, with possibilities for specialist level consultations sometimes included. Employers are entitled to reimbursements for a share of costs of arranging occupational care for their employees. The reimbursements are financed through contributions from employers and employees, and the direct financing with government expenditure is very small. However, as employers are entitled to tax reductions from the costs remaining after the reimbursement, government participates indirectly in the financing of occupational care. Occupational healthcare covers most (89%) of the employees in Finland. For those entitled to it, occupational healthcare often has short waiting times and is free at the point of service delivery. Occupational healthcare services are mostly purchased from private companies (in 2020, for 86% of the recipients). (Keskimäki

et al., 2019; Koponen & Tynkkynen, 2023; Social Insurance Institution of Finland, 2022.)

Private healthcare offers primary and a large selection of specialist care, mostly in outpatient settings. Waiting times to private care are typically short, and patients can access the range of available specialists directly, without referral. The availability of services, however, has regional differences. Though the use of private healthcare receives some funding through the NHI, particularly after the 2010s users have been required to bear most of the costs themselves. (Keskimäki et al., 2019.) The popularity of voluntary private health insurances covering, among other things, out-of-pocket costs for private healthcare, has been growing in the last decade (Finance Finland, 2023).

Especially in the working-age population, the use of primary healthcare in Finland is heavily differentiated by sector according to socioeconomic (Blomgren & Virta, 2020) and labour market status (Blomgren et al., 2022). The patients from higher socioeconomic status are more likely to use services in occupational and private healthcare, whereas patients from lower socioeconomic status rely on the public healthcare. As per the well-documented association between ill health and low socioeconomic status (Lahelma et al., 2019; Mackenbach et al., 2008; Mackenbach & Kunst, 1997; Marmot et al., 2012), the selection of patients with lower socioeconomic status to public healthcare suggests on average worse health in patients receiving care in public primary care compared to patients in occupational and private healthcare. As differences in access between sectors have been implied (Aalto et al., 2023), this also suggests that patients with worse health might be subject to longer waiting times. In addition, the possible cross-sector differences in, for example, the content of care might also result in socioeconomic differences in the care received. Available studies on service use in different settings have, however, mostly concentrated on the number of primary care contacts and their distribution across healthcare sectors and among different socioeconomic groups (Blomgren et al., 2022; Kestilä et al., 2019; Rinne & Blomgren, 2023), with less attention on the content of service provided.

Regarding prescription medicines, previous studies have demonstrated that private and occupational healthcare have important positions in prescribing reimbursable medicines, though the majority of prescriptions are written in public healthcare (Aaltonen et al., 2018; Jussila et al., 2022; Kari et al., 2022; Rättö et al., 2022). Available studies have also suggested differences in prescribing patterns of newer medicines across healthcare sectors, with patients in public healthcare less likely to receive prescriptions for newer medicines than patients in other sectors (Aaltonen et al., 2018; Jussila et al., 2022). Taking into account the socioeconomic differentiation of the Finnish primary care, these findings parallel the general evidence on socioeconomic differences in the utilisation of newer pharmacological treatments (Härkönen et al., 2015; Ohlsson et al., 2009; Rantsi & Hyttinen, 2020; Weiss et al., 2018). Findings from international settings also imply that socioeconomic differences in prescribing patterns are not limited to new medicines, as differences have also been suggested in the use, for example, of guideline-recommended medications (Hyun et al., 2017; Ohlsson et al., 2010).

2.5 Policy changes, complementarities, and institutional structures in an interconnected system of health and social protection

From the point of view of empirical analyses, a policy change offers a possibility to assess the varied effects of the implemented policy, as it creates a theoretical counterfactual situation where circumstances with and without the change can be compared. The policy reform increasing the co-payment for non-insulin antidiabetic medicines in 2017 aimed to create savings from public pharmaceutical budget, but already before the implementation, the possibility of unintended impacts was discussed (Government Proposal 184/2016; StVM 30/2016). The empirical analyses exploiting the setting that arose from the implementation of the reform explore the effects on medicine utilisation and the receipt of social assistance. From a more theoretical perspective, the findings add to the literature on the varied impacts of policy measures targeted at healthcare. In exploring the complementarities between medicine reimbursement system and the system of last-resort financial aid, the dissertation also contributes to the timely discussion on policy interplays between various policy fields (Wendt, 2022; Yerkes et al., 2022). The quasi-experimental design of the analyses allows the consideration of causality, further adding to the evidence. Moreover, the empirical analysis utilising detailed information on prescribing patterns and healthcare service use in public, occupational and private healthcare further informs of the association of the institutional structures in healthcare and the receipt of care. In examining these connections, the dissertation contributes to the discussion on how system-level factors are associated with care provision in an interconnected system of health and social protection.

Policy changes and complementary effects

Healthcare systems consist of multiple interconnected policies and institutional structures that aim to protect the health of their beneficiaries and provide care for those in need. Providing financial protection in case of ill health is also a common objective. Other often acknowledged objectives include efficiency, quality, responsiveness, equity and access. (Papanicolas 2012; UN, 2023.) The objectives can be met with a variety of policies and instruments. However, measures targeted

at an individual objective may not always produce outcomes aligning with other objectives. Measures increasing access can, for example, require increases in available resources, contradicting the overall goals related to cost-containment and efficiency. Conversely, requirements of increased efficiency or cost-containment can result in decreases in access or equity. Thus, implemented policy changes can have contrasting results, when outcomes reflecting different objectives of the healthcare system are evaluated.

Policies introducing or increasing cost sharing of medicines have repeatedly shown to reduce utilisation of even necessary medicines (Kiil & Houlberg, 2014; Luiza et al., 2015; Sinnot et al., 2013). The finding of decreased utilisation after increased cost aligns with the observed behavioural effects of cost sharing in healthcare in more general terms (Kiil & Houlberg, 2014), including evidence from randomised controlled trial settings: the Rand Health Insurance Experiment conducted in the US in the 1970s found that higher cost sharing was associated with decreased use of all types of healthcare services, including medicines (Leibowitz et al., 1985; Newhouse et al., 1981). The burden of increased cost sharing may be especially emphasized in vulnerable populations, such as individuals with lower socioeconomic status (Chernow et al., 2008; Kiil & Houlberg, 2014). Increased cost of pharmacological care may also lead to unmet medicinal need or substituting more expensive products with less costly alternatives when they are available (Saito et al., 2010; Thomson et al., 2019). The latter might be a problem, if the therapeutic values of the switched treatments are not equal, and patients are left with suboptimal treatment due to financial reasons. Evidence reflecting the system-level or more intrinsic goals such as health or equity is, however, rarer (Luiza et al., 2015), though a recent study implied medicine cost sharing having negative health effects (Chandra et al., 2023). Nevertheless, a Cochrane review on the effects of medicine cost sharing policies (Luiza et al., 2015) identified no studies fulfilling their inclusion criteria of assessing health outcomes, though some measured outcomes in terms of healthcare utilisation.

The effects and effectiveness of an individual policy measure may also be dependent on other, interconnected policies or the overall context in which the policy is implemented (Bakker & Van Vliet, 2022; Coe & Snower, 1997; Orszag & Snower, 1999). Complementarities in policies or institutions imply that they or their outcomes are to some degree mutually dependent. Institutions or policies can be complementary, when they reinforce each other's returns (Coe & Snower, 1997). However, complementarities also rise when different parts of an overall system compensate for each other's deficiencies (Buntin et al., 2011; Crouch et al., 2005; Hemerijick et al., 2023). Thus, limiting the assessment of the impacts of a reform to a single part of the system may overlook the role of complementary features or spillover effects.

Policy connections have most often been studied within a particular field, but complementarities may also be found between multiple policy fields (Bakker & Van Vliet, 2022; Dewilde & Haffner, 2022; Orszag & Snower, 1999; Yerkes et al., 2022). Within policy fields, complementary effects have been suggested, for example, in housing policies and labour markets, where multiple policies targeted at the same outcome such as unemployment are suggested to have mutually reinforcing returns (Coe & Snower, 1997; Dewilde & Haffner, 2022). In healthcare, there is some evidence of decreased access to preventive or chronic care manifesting as increased demand for other services such as hospital care (Chandra et al., 2010; Hsu et al., 2006; Trivedi et al., 2010) and increased cost of outpatient pharmaceuticals reflecting as increased demand for healthcare services (Buntin et al., 2011; Luiza et al., 2015). Across policy fields, complementarities have been suggested, for example, in employment policies with care and education policies or housing policy and other welfare state policies (Bakker & Van Vliet, 2022; Dewilde & Haffner, 2022; Plavgo, 2023). Evidence on interplays between healthcare and other policy fields is, however, limited.

The co-payment reform in 2017 decreased the public pharmaceutical reimbursement expenditure as expected, by €20 million annually, by increasing the patients' co-payment expenditure (Kurko et al., 2018; Talka et al., 2019). However, already before the implementation of the reform, concerns were voiced over patients' ability to afford their necessary medicines after the increase in co-payments and also over the possibility of negative consequences on clinical outcomes due to patients having to switch to less optimal treatments because of higher costs (Government Proposal 184/2016; StVM 30/2016). From a clinical perspective, concerns were raised over the increased use of insulin for economic rather than clinical reasons, as the reimbursement rate of insulins was not affected in the reform. The clinical justifications for preferring non-insulin treatments in non-insulin-dependent diabetes include insulin being associated with an increased risk of hypoglycaemia and weight gain. In addition, practical requirements related to insulin treatment such as more frequent need for blood glucose monitoring or the intramuscular administration route may cause difficulties compared with oral antidiabetic medicines and negatively influence treatment adherence. (Barnett, 2013; Chatterjee et al., 2017; Type 2 Diabetes. Current Care Guidelines, 2018.)

The risk of increased cost sharing translating into increased use of social assistance was also brough up during the parliamentary process (StVM 30/2016). In Finland, medicine co-payments are not sensitive to a patient's income. They can, however, be covered by social assistance, a last-resort financial aid in the Finnish system of social protection, for those who pass a strict means test. The increased use of social assistance would indicate that the affected patients experienced serious economic consequences due to increased cost of care. It would also demonstrate

complementary effects between the medicine reimbursement system and the social assistance system. Moreover, at system-level, it would indicate that a measure aiming to reduce public expenditure in one part of the system resulted in increasing expenditure in another part of the system.

Institutional structures of healthcare system

During the last decades, growing expenditure on prescription medicines has posed a major challenge for healthcare financing (Luiza et al., 2015). Among the factors driving the growth are the increasingly high prices of new medicines that enter the markets and treatment practices. New medicines have offered potential health gains, but they tend to enter the markets with higher prices than those of the existing alternatives. Inappropriate patterns in the prescribing of newer medicines can thus result in increased pharmaceutical expenditure, with marginal or no added health benefits. (Mossialos & Oliver, 2005; Soppi et al., 2018; Suleman & Movik, 2019; Vogler et al., 2016.)

Institutional structures of healthcare system can affect the receipt or content of care, including but not limited to medicine utilisation (Chandra et al., 2011; Rinne & Blomgren, 2023). If institutional structures encourage non-clinical factors such as income level or labour market position to have an impact in the receipt of care, these factors can also be reflected in patterns of medicine utilisation, such as compliance with clinical guidelines of care or initiation of newer medicines.

Type 2 diabetes is one of the key public health priorities among noncommunicable diseases (Cho et al., 2018; The Lancet 2023). It is associated with cardiovascular complications that are also a marked factor in diabetes mortality (Cosentino et al., 2020; Dal Canto et al., 2019; Davies et al., 2022; Visseren et al., 2022). Thus, in addition to balanced glycaemic control, maintaining low blood pressure and cholesterol level are important parts of comprehensive care of type 2 diabetes. Accordingly, cholesterol-lowering medicines are recommended in most national guidelines for the comprehensive care of type 2 diabetes. In the OECD collection of health-related indicators, prescribing of cholesterol-lowering medicines is used as an indicator of the quality of prescribing in primary care for diabetic patients. (OECD, 2015.)

The increasing costs related to care of diabetes form a significant part of overall healthcare spending (Riddle & Herman, 2018; Seuring et al., 2015). Of late, the expenditure on, for example, pharmacological treatment of type 2 diabetes has grown. In Finland, the total reimbursement expenditure for non-insulin antidiabetic medicines more than doubled between 2010 and 2016, from 4% to 8% of the total reimbursement expenditure (from \notin 50 million to \notin 108 million) (Statistical Database Kelasto, 2023). In addition to increasing use of these medicines, the growth was

driven by the uptake of newer (novel), typically more expensive non-insulin antidiabetic medicines (Soppi et al., 2018).

Accumulating clinical evidence of novel antidiabetic medicines implies additional cardiovascular and renal benefits for those at high risk (Davies et al., 2022; Marx et al., 2021). Novel medicines have been adopted relatively quickly in the Finnish national Current Care Guideline that guides the choice of pharmacological treatment for type 2 diabetes (Järvinen et al., 2016). However, novel medicines are not usually recommended as the first-line pharmacological antihyperglycaemic treatment in type 2 diabetes. In most cases the clinical guideline recommends metformin (an older non-insulin antidiabetic medicine) as the first-line treatment. If metformin is not tolerated or the response is insufficient, another antihyperglycaemic agent can be used instead of or in combination with metformin. The choice between available treatment options, including novel antidiabetic medicines, is guided by the patient's clinical condition. However, in the context of non-insulin-dependent diabetes, insulin is in most cases recommended only in the later lines of treatment, for example, to control difficult hyperglycaemia or for patients showing signs of insulin deficiency. (Type 2 Diabetes. Current Care Guidelines, 2018; Davies et al., 2018.)

In 2023, approximately 7% of the Finnish population purchased reimbursable non-insulin antidiabetic medicines (Statistical Database Kelasto, 2024). In the Finnish health and social protection system, patients can receive prescriptions to reimbursable outpatient medicines from any healthcare sector. The guidelines of care also apply similarly regardless of sector where the prescriber operates. Nevertheless, available studies have suggested disparities in prescribing patterns of newer medicines between patients who have different socioeconomic positions (Aarnio et al., 2016; Härkönen et al., 2015; Rantsi & Hyttinen 2020; Salonsalmi et al., 2021) and also between healthcare sectors (Aaltonen et al., 2018; Jussila et al., 2022). However, due to the limited availability of high-quality individual-level data on service use in occupational healthcare, few studies have been able to investigate prescribing patterns in settings that are able to distinguish prescriptions written in occupational care. Furthermore, evidence on the adherence to clinical guidelines of care across sectors is lacking. Evidence on care patterns across healthcare sectors would add to the scarce knowledge on the content of care provided in the different settings of the Finnish healthcare system.

3 Study aims

The aim of this dissertation is to examine various impacts of a policy change introduced in the Finnish healthcare system. The impacts of a policy reform targeted at patients and aiming to create savings are first studied in the affected part of the system, after which complementary effects impacting an interconnected part of the overall system of health and social protection are examined. In addition, the dissertation aims to explore how the institutional structures of the healthcare system are reflected in the receipt of care. The overall aims of this dissertation are met through four sub-studies utilising study settings that resulted from the introduction of policy reform and structures of healthcare system that affected patients with type 2 diabetes, a chronic disease requiring long-term pharmacological treatment.

Sub-Study I and II examine the effects of the co-payment increase on non-insulin antidiabetic medicines on the medicine utilisation. In Sub-Study I, the impact of copayment increases in the utilisation of affected medicines as well as insulins is studied at the societal level. Sub-Study II examines if the co-payment increase affected the insulin initiation of individuals in different socioeconomic position in a different manner. More specifically, the research questions in Sub-Study I and II are as follows:

- Did the increased cost sharing in non-insulin antidiabetic medicines affect the average monthly utilisation of the affected medicines and insulins? (Sub-Study I)
- Did the increased cost sharing in non-insulin antidiabetic medicines affect differently the insulin initiation of patients with different income levels? (Sub-Study II)

Sub-Study III explores the complementarities between different parts of the overall system for health and social protection and examines if the increased cost sharing in non-insulin antidiabetic medicines increased the use of social assistance, a last-resort financial aid. The research question in Sub-Study III is as follows:

3. Did the increased cost sharing in non-insulin antidiabetic medicines increase the probability of using social assistance to pay for the co-payment of the affected medicines? (Sub-Study III)

Sub-Study IV investigates the connections between the institutional structures in the Finnish healthcare system and the receipt of pharmacological care. More precisely, the study investigates if the earlier prescribing patterns reflecting clinical guidelines of care differed between patients who were prescribed novel, typically more expensive non-insulin antidiabetic medicines for the first time in public, occupational, and private healthcare. The research question in Sub-Study IV is as follows:

4. Did the prior prescribing patterns reflecting clinical guidelines of diabetes care differ between patients initiating novel non-insulin antidiabetic medicines in public, occupational, and private healthcare? (Sub-Study IV)

This dissertation thus contributes to the conversation on the unintended impacts of policy changes targeted at patients and aiming to create savings from a healthcare system. As the impacts of a reform increasing medicine co-payment are also examined in the social assistance system, the dissertation also advances the timely discussion on complementary effects and policy interplays within the overall system of health and social protection. From the perspective of institutional structures in healthcare, the dissertation expands the current understanding of how the structures of an overall healthcare system are reflected in the receipt and content of care, adding also to the discussion on access to care. Moreover, in examining the outcomes related to the socioeconomic status of patients and the use of social assistance, the findings further add to the discussion on equal access and the affordability of care.

From a policy perspective, the findings of this dissertation directly address concerns over the unwanted impacts on medicine utilisation and social assistance receipt that were expressed before the implementation of the co-payment increase of non-insulin antidiabetic medicines in Finland in 2017. Finally, insights into system-level complementarities and reflections of structures of the healthcare system offer information to the ongoing reforms in the Finnish health and social protection system.

4 Data and methods

4.1 Register data

All four sub-studies use individual-level register data (Table 1). Analysis sets for all sub-studies are based on the register of dispensations reimbursable under the NHI scheme maintained by the Social Insurance Institution of Finland. The register contains information on all reimbursed outpatient prescription medicine purchases in Finland. It includes information on, for example, the anatomical therapeutic chemical (ATC) classification group (WHO Collaborating Centre for Drug Statistics Methodology [WHOCC], 2023) of the medicine purchased and the date of the purchase, as well as the age, sex, and pseudonymised identification for the patient purchasing the medicine. Information on whether the co-payment for the purchase was paid by social assistance, the date the prescription for the medicine was written, and the pseudonymised identification for the prescriber are also included in the register. (For further details on the register, see Data Resource Catalogue, 2023.)

Sub-Studies I–III are based on nationwide register data on all individuals purchasing reimbursed antidiabetic medicines in Finland during the study period. For Sub-Study III, information on purchases of specially reimbursed medicines for chronic hypertension or chronic coronary artery disease were also collected. Furthermore, data on (possible) time of death (Sub-Study II), eligibility for special rate of reimbursement (Sub-Studies II and III), and taxable income of patients (Sub-Studies II and III) from respective registers were included. Analysis set for Sub-Study I included the period 2014–2018, for Sub-Study II the period 2011–2019, and for Sub-Study III the period 2016–2017.

Sub-Study IV is based on regional register data on all reimbursed antidiabetic medicine purchases made by individuals living in the city of Oulu during 2013–2018. This sub-study also includes information on the use of healthcare services. Information on the use of public healthcare services was collected from the registers the city of Oulu and the Care Registers for Health Care maintained by the Finnish Institute for Health and Welfare. Information on the use of occupational healthcare was collected from the patient registers of four large occupational healthcare providers in the Oulu area, and information on the use of private healthcare was collected from the register maintained by the Social Insurance Institution of Finland.

As the register of dispensations reimbursable under the NHI scheme does not include information on the healthcare sector where the prescription for the dispensed medicine originated, prescriptions were allocated to healthcare sectors by adapting a method developed by Miettinen et al. (2016) that utilises information on healthcare service use. In addition, information on demographic variables (i.e. age, sex), eligibility for special rate of reimbursement, and taxable income of the patient was collected from the respective registers. The register data are described in greater detail in a report by Blomgren and Jäppinen (2020).

Method	Interrupted time series analysis with segmented regression	Cox proportional hazard analysis	Difference-in-differences – analysis with linear probability model	Logistic regressions, with the healthcare sector as an independent variable
Outcome measure	Average monthly per patient medicine purchase in defined daily doses (DDDs)	Insulin initiation (Yes/No)	The use of social assistance in paying co- payment for non-insulin antidiabetic medicine (Yes/No)	Prior use of non-insulin antidiabetic variable (Yes/No), statin (Yes/No) and insulin (Yes/No)
Study period	2014–2018	2011–2019	2016–2017	2013–2018
Data	Nationwide register	Nationwide register	Nationwide register	Regional register
Research question	Did the increased cost sharing in non-insulin antidiabetic medicines affect the average monthly utilisation of the affected medicines and insulins?	Did the increased cost sharing in non-insulin antidiabetic medicines affect differently the insulin initiation of patients with different income levels?	Did the increased cost sharing in non-insulin antidiabetic medicines increase the probability of using social assistance to pay for the co- payment of the affected medicines?	Did the prior prescribing patterns reflecting clinical guidelines of diabetes care differ between patients initiating novel non-insulin antidiabetic medicines in public, occupational, and private healthcare?
Sub-study	_	=	Ξ	≥

Hanna Rättö

Table 1. Summary of the research designs.

4.2 Statistical methods

Interrupted time series analysis with segmented linear regression

Sub-Study I utilised a quasi-experimental setting arising from the introduction of increased co-payment for non-insulin antidiabetic medicines in 2017. In the study, interrupted time-series analysis with segmented linear regression (Bernal et al., 2017; Jandoc et al., 2015; Wagner et al., 2002) was used to investigate the impact of co-payment increase in medicine utilisation. As an outcome measure, the study used the mean monthly per person purchase in defined daily doses (DDDs) which is a statistical measure used to inform the theoretical number of days the purchased medicine lasts if used in adult patients for the main indication of the medicine (WHOCC, 2023).

Interrupted time series analysis compares the level and trend of the outcome measure before and after a known change point to examine if they are affected by the intervention implemented at this known change point. It has been considered a practical method for evaluating population-level impacts of health interventions that have taken place at a clearly defined point in time (Bernal et al., 2017). The method, however, requires a sufficient number of data points (typically at least 12) before and after the examined change (Wagner et al., 2002) to reliably consider, for example, seasonal variations. In this analysis, monthly data from 2014–2018 were used, translating into monthly data points for 36 months before and 24 months after the co-payment increase.

The final specification of the model considers the seasonal variation typical for the Finnish medicine reimbursement system (Soppi et al., 2019; Verho, 2012) and autocorrelation up to 12 months, taking the following form:

 $\begin{array}{l} Y_t \!\!=\!\!\beta_0 \!\!+\! \beta_1 \mbox{ time } \!\!+\! \beta_2 \mbox{ intervention } \!\!+\! \beta_3 \mbox{ time after intervention } \!\!+\! \beta_4 \mbox{ December } \!\!+\! \beta_5 \mbox{ January } \!\!+\! v_t \!\!, \end{array}$

where Y_t is the mean purchase of medicine in DDDs in month t. *Time* is a continuous variable reflecting time from the start of the observation period in months. *Intervention* is a binary variable taking the value 0 before the reform and 1 after the reform. *Time after intervention* is a continuous variable indicating time after the reform in months. *December* and *January* are binary variables taking the value 1 for December and January and 0 otherwise. β_0 estimates the baseline mean purchase and β_1 is the estimate of monthly change in purchase before the reform. β_2 is the estimates the monthly change in purchase after the reform, compared with the monthly trend before the reform. Finally, v_t is the error term that consists of an autoregressive error part and a random error part ε_t .

Survival analysis and Cox proportional hazard model

Survival analysis and Cox proportional hazard model were applied in Sub-Study II. The method evaluates the share of followed-up units 'at risk' of the event of interest at any given time. With the method, it is also possible to inspect the impact of several factors simultaneously. (Zwiener et al., 2011.) In the study, the sub-hazard of insulin initiation was estimated with death as a competing risk (Austin et al., 2016), using hazard ratios (HR) with their 95% Wald confidence limits.

The study also utilised the quasi-experimental setting that was caused by the introduction of reform that increased the co-payment for non-insulin antidiabetic medicines in 2017. To examine whether the impact of the reform in insulin initiation varied with a patient's income level, two patient groups were defined. All insulinnaïve patients purchasing non-insulin antidiabetic medicines in 2017 were affected by the co-payment reform and served as the treatment group while the control group comprised all insulin-naïve patients who purchased these medicines in 2014, at which time no co-payment increase had been implemented. In the study, insulin-naïve patient is defined as a patient who had not purchased insulin at least for three years. Both groups were then followed for a maximum of three years (2017–2019 and 2014–2016 for the treatment and control groups, respectively) to investigate insulin initiation. Individuals who do not initiate insulin therapy during the three-year follow-up were marked as right-censored.

To study the impact of the reform by income level, individuals were grouped into income quintiles based on their personal taxable income at the beginning of the follow-up. The analysis of interaction between the patient groups (treatment and control) and income quintiles was used to compare the change in risk of insulin initiation in patients with different income levels after the co-payment increase of non-insulin antidiabetic medicines in 2017. Wald's test was used to test the statistical significance of the included interaction term. To account for patient characteristics, information on age, sex and co-morbidities was also included in the analysis.

Difference-in-differences --analysis and linear probability model

Sub-Study III also exploits the quasi-experimental setting that resulted from the introduction of reform that increased the co-payment for non-insulin antidiabetic medicines in 2017. It uses the difference-in-differences approach and linear probability model (Angrist & Pischke, 2009; Gomila, 2021) to estimate the effect of the co-payment increase on social assistance receipt. A patient who had at least one reimbursed medicine purchase in the examined medicine class directly paid by social assistance is defined as a patient receiving social assistance. The outcome of interest is the share of social assistance receipts in a calendar year.

In the analysis, the change in the share of social assistance recipients among a group affected by the co-payment increase and a group not affected by the co-payment increase was compared. The compared groups were defined based on entitlement for a special reimbursement for medicines. The group affected by the co-payment increase (treatment group) was defined as all patients diagnosed with diabetes (based on special reimbursement codes 103 and 215) who purchased non-insulin antidiabetic medicines in 2016 or 2017, or both. Correspondingly, the group not affected by the increase in co-payment (control group) was defined as patients who did not belong to the treatment group, were diagnosed with chronic hypertension or chronic coronary artery disease and dyslipidaemia associated with chronic coronary artery disease (based on special reimbursement codes 205 and 206), and also purchase medicines reimbursed with the respective codes in 2016 or 2017, or both.

The main rationale behind the choice of the control group was that the risk factors for chronic hypertension and hyperlipidaemia are largely the same as those for type 2 diabetes. Both are also known to be related to the metabolic syndrome, the symptoms of which include, for example, overweight, dyslipidaemia, hypertension, and hyperglycaemia (Alberti et al., 2006). Furthermore, in the Government Proposal for the reimbursement rate reform, it is noted that life-style changes are very important to the prevention and treatment of type 2 diabetes, which is also true for coronary artery diseases and arterial hypertension, and that medicines for cardiovascular diseases (such as coronary artery diseases and arterial hypertension) are already reimbursed in the lower special reimbursement rate (65%) category (Government Proposal 184/2016).

The average treatment effect on the affected patients is estimated with the general framework comparing group means in two groups at two different time points with the equation given below:

 $Y_{it} = \beta_0 + \beta_1 After_t + \beta_2 Treat_i + \beta_{DID} (After_t * Treat_i) + \beta_{char} X_{it} + \varepsilon_{it},$

in which i refers to a patient and t to the time when that patient was observed. Y is the outcome of interest (the probability of social assistance receipt). *After* takes value 1 if the patient was observed after the reform and 0 otherwise. *Treat* is an indicator taking the value 1 if the patient belongs to the group subject to the copayment increase and 0 if not. X is a vector of patient characteristics (age, sex, comorbidity, and taxable income), and ε represents random error. The parameter of main interest, the difference-in-differences estimator, is given by the coefficient of interaction term *After* * *Treat* (i.e. β_{DID}). It estimates the change in the probability of social assistance receipt in the treatment group relative to the control group.

Logistic regression models and odds ratios

Logistic regression models were used in Sub-study IV to define odds ratios (ORs) and their 95% confidence intervals to compare the preceding medicine use reflecting clinical guidelines of care in patients initiating novel non-insulin antidiabetic medicine in public, occupational and private healthcare settings. Novel antidiabetic medicines were defined based on the reimbursed purchase of a medicinal product belonging to ATC (WHOCC, 2023) classification categories A10BJ (Glucagon-like peptide-1 [GLP-1] analogues), A10BK (Sodium-glucose co-transporter 2 [SGLT2] inhibitors), or a product containing a combination of oral blood glucose lowering drugs (ATC category A10BD), that included a SGLT2-inhibitor as part of the combination. A new patient initiating novel medicine was defined as a patient who had not purchased these medicines during the previous 365 days.

Prior use of another non-insulin antidiabetic medicine (ATC A10B, excluding categories for novel antidiabetic medicines), statin (ATC C10AA) and insulin (ATC A10A) were used as binary outcome measures and studied in separate models. The prior use of aforementioned medicines was examined based on whether the individual had at least one reimbursed purchase of these medicines during the 365 days before the initiation of the novel antidiabetic medicine. In addition to all new patients initiating novel antidiabetic medicines, separate models were used to study working-age (25–64 years) patients.

With respect to all studied outcomes, the independent variable of the most interest was the healthcare sector (public, occupational, or private) where the patient received the first prescription for novel antidiabetic medicine. For controlled models, information on age, sex, diabetes-related hospital-level healthcare service use, existence of a comorbidity, taxable income, and the initiation year were also used.

4.3 Ethics statement

The study was based solely on administrative, secondary register data and thus, by Finnish law no Ethics Board approval was required (Finnish National Board on Research Integrity TENK, 2019). All data used in the study were fully pseudonymised before it was accessed, and all data preparation and linkages in all sub-studies were done with pseudo-identifiers. As the register holder, the Social Insurance Institution of Finland approved the use of the data for the Sub-Studies I, II, and III. The City of Oulu, the Social Insurance Institution of Finland, National Institute for Health and Welfare, the included occupational healthcare providers, Statistics Finland, the Finnish Tax Administration and the Health and Social Data Permit Authority Findata approved the use of the data for the Sub-Study IV as a part of the project 'Sosiaaliturvan etuuksien ja palveluiden käyttö Oulussa 2013–2018'.

Legal restrictions prevent from openly sharing the data supporting the sub-studies. Individual-level health data are considered highly sensitive, and access is strictly regulated by law in Finland (Act on the Secondary Use of Social and Health Data). Permission to access the data can be sought from the register holders.

5 Results from the sub-studies

5.1 Impact of increased co-payment for non-insulin antidiabetic medicines on the utilisation of affected medicines and insulins

Sub-Study I examined how an increase in the share patients pay out-of-pocket for their necessary medicine affects medicine utilisation. The study first examined the effect of the increased co-payment for non-insulin antidiabetic medicines on the utilisation of the affected medicines. The effect on the utilisation of insulins was then examined for spillover effects in insulin utilisation. The co-payment for insulins was not affected, but, before the reform, concerns were raised over increased use of insulin for economic rather than clinical reasons.

The result from Sub-Study I showed that the pre-existing decreasing trend of 0.2 DDDs per month (p < 0.001) in average monthly purchase of non-insulin antidiabetic medicines was not significantly affected by the increase in co-payment. However, a significant decrease (p < 0.001) in the level of mean purchase was detected after the reform. It indicates that patients purchased on average 5.6 fewer DDDs (approximately 5% less) per month than would have been expected based on the preceding months. No increase in insulin utilisation was found; instead, a small but significant (p < 0.001) decrease of 2.2 DDDs (approximately 1.5%) in the mean monthly per person purchase was detected. There was also a pre-existing declining trend of 0.3 DDDs per month (p < 0.001) in the average monthly purchase of insulin. After 2017, a slight but significant upward turn (0.06, p < 0.05) in the trend was found, implying that the decrease became slightly less pronounced.

The findings indicate that increases in medicine co-payment can have significant effects on the purchasing behaviour of affected patients even in the presence of ceiling mechanisms that aims to protect patients from high cumulative out-of-pocket expenditures on medicines. However, no evidence of increased insulin utilisation among patients using non-insulin antidiabetic medicines was found. Detected effects on insulin utilisation are likely due to patients using both non-insulin antidiabetic medicines and insulin applying the changed pattern to all their purchases.

5.2 Impact of increased co-payment for non-insulin antidiabetic medicines on insulin initiation among patients in different socioeconomic groups

Insulin use was further investigated in Sub-Study II that examined if the co-payment increase of non-insulin medicines affected differently insulin initiation of patients with different income levels. The findings indicated that the risk of insulin initiation was significantly lower with patients who began to use insulin at later time points of the study period. Results also implied that, compared to the highest income quintile, the risk of insulin initiation was significantly higher in the lower quintiles throughout the study period. However, no differences in how the reform affected the risk of insulin initiation between patients with different income levels were found (Wald's test, p = 0.7).

The lower risk of insulin initiation in later years of the study period most likely reflects the changing treatment practices for type 2 diabetes and novel non-insulin antidiabetic medicines entering clinical treatment practice even in Finland. In type 2 diabetes, initiation of these novel medicines is typically recommended before recommending the use of insulin. This in turn likely reflects as a lower risk of insulin initiation in later years. The prevailing risk differences between income quintiles probably reflect, at least partly, the general socioeconomic stratification in health, as in type 2 diabetes, insulin is typically recommended in conditions often associated with obesity, for example, to control difficult hyperglycaemia or if patients show signs of insulin deficiency (Kahn et al., 2016; Type 2 Diabetes. Current Care Guidelines, 2018). Differences between income quintiles were not, however, affected by the increasing co-payments for non-insulin antidiabetic medicines. This indicates that at least regarding insulin initiation, there were no disparities between patients with different income levels in the impact of the reform in 2017.

5.3 Impact of increased co-payment for non-insulin antidiabetic medicines on the use of social assistance

The relationship between increased medicine co-payment and financial difficulty as well as policy connections within the overall system of health and social protection were investigated in Sub-Study III. It examined if the increased co-payment for noninsulin antidiabetic medicines led to an increased use of last-resort social assistance to pay for the affected medicines.

Results from Sub-Study III showed that after the reform the share of social assistance recipients increased a little less than 1 percentage point more among type 2 diabetes patients than among a patient group not affected by the co-payment

increase (p < 0.001). The change is notable in terms of policy effect, as the probability of social assistance receipt was small to begin with (2.2 percent among patients affected by the reform). The effect was more pronounced among patients who were aged under 65 -years (approximately 2 percentage points, p < 0.001), likely reflecting the fact that in Finland social assistance receipt is more common among younger age groups (Jauhainen & Korpela, 2019).

These findings show that the reform targeted at the medicine reimbursements system increased the use of social assistance among patients the reform affected. This indicates that increases in patients' out-of-pocket expenditure on medicines can lead to serious financial difficulties and challenges in the economic access to necessary care even in well-developed healthcare systems. The results of Sub-Study III also demonstrate complementary effects between different parts of the overall health and social protection system. Moreover, they indicate that the effects of a reform aiming to curb the increase in the public pharmaceutical budget had a spillover effect on other part of the overall health and social protection system, culminating in the increased use of social assistance.

5.4 Prescribing patterns reflecting the guidelines of care in type 2 diabetes before the initiation of novel antidiabetic medicine in public, occupational, and private healthcare settings

Sub-Study IV examined the prescribing patterns reflecting the clinical guidelines of diabetes care among patients being prescribed novel non-insulin antidiabetic medicines (SGLT2 inhibitor or GLP-1 analogue) for the first time in public, occupational, and private healthcare. In non-insulin-dependent diabetes, clinical guidelines recommend in most cases metformin (an older non-insulin antidiabetic) as the first-line treatment, and insulin only at later stages for insulin deficiency or in case of severe hyperglycaemia. Using a cholesterol-lowering medicine is typically recommended for all.

Findings from this sub-study indicate that the use of novel non-insulin antidiabetic medicines as first-line treatment was rare in all healthcare sectors, with over 90% of initiators having used another non-insulin antidiabetic medicine before. After accounting for patient characteristics, no significant differences between the sectors were found in prior statin use. Prior use of insulin was not significantly different in public and private care; however, patients initiating novel antidiabetic medicines in the public sector were more likely to have used insulin than patients in the occupational healthcare. Though most of the prescriptions to initiate novel antidiabetic medicine originated from public healthcare settings (76%), especially occupational sector also had an important role (18%). Differences in the

characteristics of initiators across sectors reflected the known socioeconomic distribution of patient populations in different healthcare sectors: initiators in public healthcare had on average lower income than patients initiating with prescriptions from the other sectors. Patients in public healthcare were also more likely to have used hospital-level specialist care, suggesting higher morbidity. Findings of working-age patients largely mirrored findings on patients of all ages.

5.5 Main findings

The results of the four sub-studies included in the dissertation are summarised in Table 2. They demonstrate that in addition to impacts within the targeted sector, the impact of co-payment increase on necessary medications had a spillover effect on the system of social assistance, implying complementarities within the overall system of health and social protection. The increase in co-payment for non-insulin antidiabetic medicines resulted in decreased utilisation of the affected medicines. However, no increase in either the overall insulin utilisation or the initiation of insulin treatment was observed among patients affected by the reform. In addition, in the development of the initiation of insulin treatment, no differences between individuals with different income levels were found after the co-payment increase. This implies that regarding insulin initiation, individuals with lower income were not disproportionally affected. However, the detected increase in the use of social assistance suggests some of the effects of the increased cost of care were mitigated via social assistance. This, in turn, suggests that not all financial difficulty due to increased out-of-pocket costs resulted in decreased use or other changes in use patterns.

Furthermore, the findings imply that the structures of the overall Finnish healthcare system are reflected in the care provision in different healthcare sectors and in the development of use patterns of antidiabetic medicines. The characteristics of patients initiating novel non-insulin antidiabetic medicine in public, occupational, and private healthcare paralleled the previously established general differences in the socioeconomic position and the morbidity of the individuals receiving care in different settings. Prescribing patterns reflecting the clinical guidelines of care before the initiation of novel antidiabetic medicine imply equal adherence in public, occupational and private healthcare, with regard to the prior use of non-insulin antidiabetic medicines in public healthcare were more likely to have used insulin before than patients in occupational healthcare suggesting initiation at more advanced stage, undetected differences in patient characteristics, or both. Finally, the changes in treatment practices and the range of reimbursed medications for non-insulin diabetes were reflected in the use patterns of insulin and

non-insulin antidiabetic medicines. The decreasing patterns of insulin use and initiation likely reflect the entrance of novel non-insulin antidiabetic medicines into treatment practices and the reimbursement system, as these medicines are typically initiated before insulin in non-insulin-dependent diabetes.

Research questions	Main findings		
Did the increased cost sharing in non-insulin antidiabetic medicines affect the average monthly utilisation of the affected medicines and insulins?	 After the co-payment increase, patients purchased less of the affected medicines than before. No corresponding increase in insulin utilisation was detected. 		
Did the increased cost sharing in non-insulin antidiabetic medicines affect differently the insulin initiation of patients with different income levels?	 No differences between patients with different income levels were found in the effect on insulin initiation. The risk of insulin initiation was lower in later periods, and patients with lower level of income had a higher risk throughout the study period. 		
Did the increased cost sharing in non-insulin antidiabetic medicines increase the probability of using social assistance to pay for the co- payment of the affected medicines?	 The reform increased the probability of using social assistance to pay for the co-payment of the affected medicines. The effect was more pronounced among patients who were aged under 65 -years. 		
Did the prior prescribing patterns reflecting the clinical guidelines of diabetes care differ between patients initiating novel non-insulin antidiabetic medicines in public, occupational, and private healthcare?	 No differences were detected in prior use of other non-insulin antidiabetic medicine, with novel medicines seldom being initiated as a first-line treatment in any healthcare sector. 		
	 No differences across healthcare sectors in prior use of statins were detected, after accounting for patient characteristics. 		
	 Patients in public sector were more likely to have used insulin before than patients in occupational sector. 		

Table 2. Summary of main findings.

6 Discussion and conclusions

This dissertation studied the effects of a policy change aiming to create savings from the healthcare system by increasing cost sharing. Moreover, it examined system-level complementarities and institutional structures in an interconnected system of health and social protection. The policy reform that increased the outof-pocket costs for patients on non-insulin antidiabetic medicines was used to study the effects of increased cost sharing in medicine utilisation and in the use of social assistance. The role of healthcare systems institutional structures in providing access to medicines was further examined with regard to patients receiving prescriptions for novel non-insulin antidiabetic medicines in public, occupational, and private healthcare.

6.1 Interpretation of the results

First, the results from the dissertation demonstrate that the co-payment increase in non-insulin antidiabetic medicines in Finland led to a decrease in the average monthly purchase of the affected medicines. The findings align with those from previous studies which have concluded that increases in and introductions of medicine cost sharing reduce utilisation, with effects extending even to necessary medications (Austvol-Dahlgren et al., 2008; Gemmil et al., 2007; Goldman et al., 2007; Kolasa & Kowalczyk, 2019; Lexchin & Grootendorts, 2004; Luiza et al., 2015; Mann et al., 2014; Sinnot et al., 2013). There might be several reasons for the diminished utilisation after the co-payment increase. For example, in case of prior overuse, decreased use might indicate a more appropriate use of medicines (Rojas García & Antonanzas Villar, 2020). However, possible reasons for the decreased utilisation also include deferred or otherwise suboptimal use of necessary medicines for financial reasons, as the policy change transferred part of the cost of care to patients. Overall, the results demonstrate significant effects on the purchasing behaviour, even in the presence of ceiling mechanisms aiming to protect patients from high cumulative medicine expenditures. However, effects reflecting health more directly were beyond the scope of this study, and, especially, long-term effects on health and healthcare service use remain an important subject for future studies.

In addition to cost savings, previous studies on cost-containment measures targeted at increasing health budgets in high-income countries have reported unintended clinical outcomes (Arcá et al., 2020; Lavikainen et al., 2020a). However, contrary to the concerns expressed for possible spillover effects on less optimal treatments for financial reasons, the results showed no increase in the average monthly purchase of insulin among patients affected by the co-payment increase. Instead, a slightly decreasing trend present already before the co-payment increase was found.

Within the observations of averages, the risk of unwanted effects might have been higher with some patients than others. The effects of increased medicine copayment have been found to especially affect vulnerable populations (Kiil & Houlberg, 2014), and the potentially inequitable impact of medicine co-payments has also been recognised in Finland (Hamina et al., 2020; Tervola et al., 2021). Furthermore, in individuals with type 2 diabetes, early insulin initiation has previously been associated with lower socioeconomic position (Abu-Ashour et al., 2017; Reach et al., 2013). Nevertheless, no differences in the development of the risk of insulin initiation after the policy change was detected in patients with different income levels, implying the insulin initiation of individuals in lower socioeconomic status was not disproportionally affected by the co-payment increase. However, a survey study (Lavikainen et al., 2020b) found responders reporting increased insulin use, with cost considerations among reasons to initiate the treatments. Some spillover effect on insulin use thus remains possible, though the impact in initiation does not seem to vary systematically according to income level.

Consistent with previous studies (Abu-Ashour et al., 2017; Reach et al., 2013), the risk of insulin initiation was found to be higher in patients with lower socioeconomic status. There are likely several reasons for this. Nevertheless, in Finland, insulin is typically recommended in type 2 diabetes, for example, to control difficult hyperglycaemia or if patients show signs of insulin deficiency (Type 2 Diabetes. Current Care Guidelines, 2018). These conditions are often associated with obesity (Kahn et al., 2006). Lower income, in turn, is associated with several lifestyle-related risk factors (e.g. smoking or habits related to eating and physical activity). Thus, the risk differences between patients with different income levels likely reflect, at least partly, the general socioeconomic stratification in health (Lahelma et al., 2019; Marmot, 2004; Tarkiainen et al., 2013).

Moreover, the risk of insulin initiation was found to decrease with time, paralleling the detected decreasing trend of average utilisation. The lower risk of insulin initiation at later time points in the study and the decreasing trend in average insulin utilisation are likely to reflect the changing treatment practices of type 2 diabetes and novel non-insulin antidiabetic medicines entering clinical practice and reimbursement system in Finland (Järvinen et al., 2016; Niskanen & Laine, 2020).

Novel antidiabetic medicines are in most cases recommended before insulin in the treatment of non-insulin-dependent diabetes, their entrance thus pushing insulin to even later treatment lines.

Second, the introduction of increased co-payment for non-insulin antidiabetic medicines increased the use of social assistance in paying the out-of-pocket costs of the affected medicines. Social assistance is a form of last-resort financial aid in the Finnish system of social protection. It is subject to a strict means-test, and the receipt implies serious difficulties in the ability to cover essential living costs. The recipients are at high risk of experiencing poverty and are considered among the least well-off in society. The increased use of social assistance due to increased cost of care thus indicates that increases in out-of-pocket expenditure on medicines can lead to serious financial difficulties and even threaten the affordability of care even in countries with a well-developed healthcare system in place. The findings on the relationship between increased medicine co-payment and social assistance receipt in Finland are consistent with previous findings on ill health and social assistance receipt (Vaalavuo, 2016), with the quasi-experimental setting offering additional evidence on the direction of this association.

However, likely not all who experienced financial difficulty due to the increased co-payment were eligible or received social assistance. Social assistance is subject to a means-test, and serious financial difficulty might have taken place also among those who were not eligible. In addition, social assistance is known to be a form of financial benefit where marked non-take-up exists. Reasons for those who are eligible for not claiming the benefit can be related to, for example, the demanding application process and stigma associated with social assistance (Currie, 2006; Kuivalainen 2007; Matikka & Paukkeri, 2016).

Third, from a system-level perspective, the increased use of social assistance as a result of increased out-of-pocket payments for outpatient medicines indicates complementarities between different parts of the overall system of health and social protection. In the Finnish system, medicine reimbursements are the primary institutional feature aiming to provide access to outpatient medicines. From the perspective of the overall system of health and social protection, however, the complementary role of social assistance implies that at the system-level, more than one institutional feature participates in securing economic access to outpatient medicines. Furthermore, the results showed that policy measures aiming to create savings in one part of the overall health and social protection system can increase the use of other forms of social protection. This, in turn, implies that in considering the impact of a policy measure implemented in an interconnected system of health and social protection, policy interplays and complementary features should be carefully considered. Fourth, the preceding prescribing patterns of non-insulin antidiabetic medicines and cholesterol-lowering medicines did not differ between patients initiating novel non-insulin antidiabetic medicine in public, occupational, and private healthcare. However, patients initiating novel medicines in public healthcare were more likely to have used insulin before than patients in occupational healthcare. Patients initiating a novel medicine in public healthcare had on average lower income, and also had higher morbidity, than patients in other healthcare settings. This likely reflects the general differentiation of patients using healthcare services in different sectors of the Finnish primary care (Blomgren et al., 2022; Blomgren & Virta, 2020).

Non-clinical factors such as the socioeconomic position of the patient or the healthcare sector where the prescriber operates can impact the patterns of prescription medicine use (Chandra et al., 2011; Hajjaj et al., 2010; Weiss et al., 2018). Nevertheless, no differences were found in the use of another non-insulin antidiabetic medicine or cholesterol-lowering medicine before the initiation of novel medicine, implying similar adherence to guidelines of care across sectors regarding these treatments. Most notably, almost all patients in all sectors had used another non-insulin antidiabetic medicine before the initiation of novel medicine. This is as per the Finnish Current Care Guidelines (2018) for type 2 diabetes, where novel antidiabetic medicines are seldom recommended as a first-line antihyperglycaemic treatment. The higher likelihood of prior insulin use in patients in public sector compared to patients in occupational care suggests undetected differences in patient characteristics, the initiation of novel medicine at later stages in public healthcare, or both. Clinical characteristics that would affect the choice of antidiabetic medication, such as weight or glycaemic control, could not be accounted for in this dissertation. Future research should study the timing of the treatment intensification in different healthcare sectors, accounting for these factors.

With regard to the institutional structures of the Finnish healthcare system, the results corroborate the previous findings of the differentiated nature of primary care system (Blomgren et al., 2022; Blomgrem & Virta, 2020) and show that it extends to the initiation of novel medicines. This adds to the previous findings suggesting socioeconomic and cross-sector differences in patterns of medicine utilisation in Finland (Aaltonen et al., 2018; Härkönen et al., 2015; Jussila et al., 2022; Rantsi & Hyttinen, 2020).

6.2 Lessons to welfare policy literature

In several countries, the share of gross domestic product spent on healthcare has increased, leading to cost-containment policies targeted at healthcare (Pierson, 1998; Stadhouders et al., 2019). Measures aiming to create savings or increase the efficiency in healthcare can, however, have a negative impact on other healthcare

system objectives. This dissertation demonstrated that even in welfare systems with universal healthcare and ceiling mechanisms protecting patients from very high copayments, targeting the cost-containment measures at patients' out-of-pocket expenditure can decrease the utilisation of even necessary medicine. In addition, the receipt of social assistance implies effects on financial protection and affordability, one of the key dimensions of access to healthcare (Penchansky & Thomas, 1981).

The effect of increased medicine co-payment on the use of last-resort social assistance also demonstrates complementarities in an overall health and social protection system. Though the complementary effects have been suggested previously within policy fields (Coe & Snower, 1997) and in some cases across fields (Bakker & Van Vliet, 2022; Orszag & Snower, 1999), evidence on the interplay between healthcare and last-resort financial aid is limited. In general, the findings on complementary effects add to the timely discussion on policy interplays between various policy fields (Yerkes et al., 2022).

Finally, welfare states have faced many pressures in the last decades, and learning from the experiences of others has become increasingly important also in healthcare. From an international perspective, the findings on impacts of implemented changes and system-level complementarities advance the discussion on identifying best practices in healthcare provision in the presence of complementarities. Nevertheless, the heterogeneity of applied welfare policies complicates generalising evidence across healthcare systems or welfare states. Medicine cost sharing can take many forms and different cost sharing policies might give arise to different responses (Luiza et al. 2015; Vogler et al. 2019). Last-resort financial aid schemes also differ across countries, which can affect comparability (Frazer & Marlier, 2016; Tervola et al., 2023). In addition, specific features of policies in place can affect the connections between interacting policies. For example in Finland, a previous study found that the average amount of social assistance used to pay for medicines decreased towards the end of the year, implying that annual copayment ceiling decreases the need for social assistance at the end of the year (Aaltonen et al., 2013b). Furthermore, social assistance receipt is known to be more common in younger age groups in Finland (Jauhiainen & Korpela, 2019), as there are pension schemes and entitlements especially protecting people at or close to retirement age. Thus, from comparative perspective, accounting for the role of system-specific features requires rigorous consideration.

Besides financial incentives, decisions related to sensitive subjects like health are also affected by other factors. Societal conditions, such as trust in the healthcare system or attitudes towards receipt of last-resort financial aid, can also be reflected in these decisions. In future, striving for a more comprehensive understanding of underlaying societal conditions would help to further account for the differences between healthcare systems.

6.3 Methodological considerations

This dissertation was based on high-quality, individual-level register data covering several years. Studies exploring the effects of increased medicine co-payment used nationwide data and a quasi-experimental setting allowing considerations of causality. In exploring the role of institutional structures in the Finnish healthcare system on receipt of pharmacological care, regional data were used. Notably, the information on the use of occupational care was included in these data, permitting the detailed examination of the Finnish primary care system.

The data used in the dissertation allow comprehensive, nationwide description of the utilisation of reimbursed medicines, including information on entitlement for disease-based special reimbursements and paying out-of-pocket costs from social assistance. However, the register data are based on information on the reimbursed outpatient medicines dispensed from community pharmacies. Thus, based on the available data, observations on whether the dispensed medicines were used appropriately or used at all cannot be made. Furthermore, information on medicines used in inpatient setting or on outpatient medicines not reimbursed from the NHI, is not included in the data. Regarding antidiabetic medicines, this is unlikely to bias the results as the outpatient medicines used in pharmacological care of diabetes are for the most part reimbursed (Nurminen et al., 2023). Future studies should, however, consider including this information to further describe the development of antidiabetic medicine utilisation.

The Finnish health register data is a rich source of information for research purposes (Furu et al., 2010; Laugesen et al., 2021). However, patient-level information on the use of occupational care is often lacking, even though occupational care has an important role in the Finnish healthcare system (Blomgren et al., 2022; Rättö et al., 2022). This dissertation was able to utilise individual-level register data on service use in occupational care in Oulu, the fifth largest city in Finland. Medicine prescriptions were allocated to healthcare sectors to identify the healthcare sector in which the specific prescription originated, by adapting a method developed by Miettinen et al. (2016). Only a few studies in Finland have previously examined the sector where a prescription was written (Aaltonen et al., 2018; Jussila et al., 2022; Kari et al. 2022) and, in most cases, it has not been possible to identify prescriptions written in occupational care. Moreover, the rich data on patients socioeconomic position, use of healthcare services and entitlement to medicine reimbursements allowed accounting for patient characteristics with exceptional detail in examining the prescribing patterns.

The implementation of the co-payment increase for non-insulin antidiabetic medicines introduced to the Finnish system a quasi-experimental design that allowed a theoretical comparison of situations with and without the co-payment increase. However, quasi-experimental settings do not automatically generate untreated

control groups, if, for example, the introduced change is targeted at all potentially impacted individuals simultaneously. As the co-payment increase in non-insulin antidiabetic medicines in 2017 affected similarly all patients purchasing these medicines, this dissertation used several methods to employ the setting for comparative purposes. The effect of the co-payment increase on antidiabetic medicine use was examined by comparing the observed post-change use patterns to the contrafactual use patterns estimated based on the observed pre-change patterns (Jandoc et al., 2015; Wagner et al., 2002). The effect on the risk of insulin initiation in individuals with different socioeconomic position was investigated by comparing similar patient populations at different time points (e.g. Nurminen & Rättö, 2022; Vaalavuo, 2021) drawn from before and after the co-payment increase. Finally, in investigating the impact of the co-payment increase in the use of social assistance, a patient group with similar risk factors (Alberti et al., 2006) was used as a comparison group.

6.4 Policy implications

Overall, this dissertation showed that policy changes targeted at healthcare system can lead to contrasting results with regard to different goals of the system. It also demonstrated how complementary effects embedded in the overall system of health and social protection can result in spillover effects in parts of the system other than the one originally targeted. This implies that in considering the savings potential of policy measures targeted at necessary care, system-level dependencies and complementary roles of other forms of social protection should be considered very carefully. As several countries have of late introduced cost-containment policies aiming to curb the increasing health expenditures (Stadhouders et al., 2019), these insights are of interest also in international perspective.

Before the implementation of the co-payment increase in non-insulin antidiabetic medicines, concerns were raised over patients' ability to afford their necessary medicines. Concerns for possible negative consequences on clinical outcomes, for example, due to patients' having to switch to less optimal treatments for financial reasons, were also presented. In addition, the risk of the co-payment increase translating into increased use of social assistance was brought up during the parliamentary process. (Government Proposal 184/2016; StVM 30/2016.) Findings of this dissertation thus directly inform the public discussion in Finland. Together with studies suggesting economic difficulties, negative developments in satisfaction with care, impacts related to the consumption antidiabetic medicines and reduced glycaemic control among individuals affected by the co-payment increase (Aaltonen et at., 2022; Lavikainen et al. 2020a; Lavikainen et al. 2020b; Suviranta et al., 2019), the findings of this dissertation demonstrate that the co-payment increase also had

unintended impacts. Thus, in the planning and implementation of health and social protection system reforms, attention should be given to access to care and financial protection.

The dissertation also showed that the socioeconomic differences in patient populations receiving care in different primary care settings in the Finnish healthcare system also extend to patients being prescribed novel, typically expensive medicines for the first time. As novel non-insulin antidiabetic medicines are an important example of the growing gap between technological and fiscal possibilities in healthcare, factors related to their uptake and appropriate use should be carefully considered. Furthermore, the findings indicate that policy measures targeted even at specific interventions at primary care may impact very different populations in different settings. As well-being service counties take their first steps as operators responsible for providing healthcare in Finland, any contribution to the scarce knowledge of content of care in different healthcare sectors is valuable.

6.5 Conclusions

The increase in the co-payment for non-insulin antidiabetic medicines resulted in decreased utilisation of the affected medicines. However, no increase in either the overall insulin utilisation or the initiation of insulin treatment was observed among the affected patients. Furthermore, in the development of the initiation of insulin treatment, no differences between individuals with different income levels were observed after the co-payment increase. This implies that regarding insulin initiation, individuals with lower income were not disproportionally affected. However, the increased use of social assistance indicated that some of the effect of increased cost of necessary medications was mitigated through increased use of social assistance. This suggests that not all financial difficulty due to increased cost of care resulted in decreased use or other changes in use patterns.

The characteristics of patients initiating novel non-insulin antidiabetic medicines in public, occupational, and private healthcare mirrored the previously established differences in the socioeconomic position and the morbidity of patients receiving care in the different settings of primary care. However, prescribing patterns reflecting the clinical guidelines of diabetes care before the initiation of novel antidiabetic medicine implied equal adherence in public, occupational, and private healthcare with regard to the prior use of a non-insulin antidiabetic medicine and cholesterol-lowering medicines. However, compared to patients initiating novel antidiabetic medicines in occupational healthcare, patients in public healthcare were more likely to have used insulin before, suggesting undetected differences in patient populations, initiation at more advanced stage, or both. Overall, the changes in treatment practices and in the range of reimbursed medications for non-insulindependent diabetes were reflected in the use patterns of antidiabetic medicines.

In conclusion, this dissertation demonstrated that in addition to intended outcomes, policy measures targeted at healthcare can also have unintended consequences. Furthermore, due to the system-level complementarities, the spillover effects of the implemented policy measures can be felt in other parts of the overall health and social protection system than the one originally targeted. Institutional structures and the de facto tiered nature of the Finnish primary care system were also reflected in the characteristics of patients initiating novel non-insulin antidiabetic medicines in different healthcare sectors. Thus, in addition to the features of the medicine reimbursement system, the institutional structures of healthcare system as well as the complementary effects within the overall system of health and social protection can influence the access to pharmacological care.

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