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Abstract

Aaltonen K. **Affordability of medicines from the pharmaceutical system perspective. Comparative analysis of Finland and New Zealand.** Helsinki: The Social Insurance Institution of Finland, Studies in social security and health 146, 2017. 189 pp. ISBN 978-952-284-019-6 (print), 978-952-284-020-2 (pdf).

In this study, the access-related features – conditions, disincentives, benefit level and universality – of the pharmaceutical systems in Finland and New Zealand were examined in conjunction to outcomes related to the distribution of out-of-pocket costs and cost-related access barriers. The studies were based on product and price listings, Household Budget Survey data, postal survey data and pharmacy sales registers. The systems had common features related to universal coverage and conditions. Both countries used ceilings and mechanisms to protect high need or vulnerable groups, and restricted reimbursements. The main differences were related to disincentives and benefit level: The Finnish system provided a wider choice between reimbursed therapeutic options, and a faster availability of new innovative medicines, but the general level of co-payments was higher. The New Zealand system had a high overall control of the reimbursed range, which included fully reimbursed medicines for most health needs. However, the range of reimbursed medicines was skewed towards older medicines. In Finland, out-of-pocket costs had regressive effects. Cost-related access problems were associated with lower income and higher health needs, as has been described for New Zealand in the previous literature. Based on the assessment of high out-of-pocket costs among older people in New Zealand, the use of medicines not included in the fully reimbursed range seemed rare and unrelated to socioeconomic deprivation. However, despite their higher health needs, high costs were less frequent among indigenous Māori and they coincided with a lower overall level of medicine use. Both systems have strengths and weaknesses related to different dimensions of affordability. The protective mechanisms in neither country seemed sufficient to counterbalance the negative effects of user charges entirely. Further research is needed on the causes and consequences of socioeconomic and ethnic differences in medicine use.

Key words: fees and charges, health care costs, cost sharing, pharmaceutical preparations, reimbursement mechanisms, affordability, health insurance, health services accessibility, health equity, Finland, New Zealand

Tiivistelmä

Tutkimuksessa tarkasteltiin lääkekorvausjärjestelmien lääkkeiden saatavuuteen vaikuttavia piirteitä, erityisesti korvattavuuden ehtoja, disinsentiivejä, korvattavaa valikoimaa ja universalismia, suhteessa lääkeomavastuiden jakautumiseen ja hoitojen käyttämättä jättämiseen kustannussyistä. Aineistoina käytettiin tuote- ja hinnastotietoja, kulutustutkimusaineistoa, postikyselyaineistoa ja apteekkien ostorekistereitä. Yhtäläisyydet liittyivät universalismiin ja korvattavuuden ehtoihin. Korvauksia kohdennettiin molemmissa maissa tarpeeseen liittyvillä mekanismeilla, omavastuukaton avulla sekä korvattavuusrajoituksilla. Erot liittyivät valikoimaan ja disinsentiiveihin. Suomessa korvattiin enemmän hoidollisesti toisiaan lähellä olevia vaihtoehtoja ja uusien lääkeinnovaatioiden määrä markkinoilla oli laajempi, mutta omavastuutaso korkeampi. Uudessa-Seelannissa kokonaan korvattavia lääkkeitä oli saatavissa useimpiin terveysongelmiin. Korvattava valikoima oli kuitenkin kontrolloidumpi ja sisälsi enemmän vanhempia lääkkeitä. Suomessa omavastuilla oli regressiivisiä vaikutuksia. Pienemmät tulot ja huonompi terveydentila olivat yhteydessä palveluiden käyttämättä jättämiseen kustannussyistä, mikä vastasi aiemmassa kirjallisuudessa Uudesta-Seelannista julkaistuja tuloksia. Omavastuiden jakautumisen perusteella Uudessa-Seelannissa ikääntyneet henkilöt käyttivät vain harvoin muita kuin kokonaan korvattavia lääkkeitä eivätkä korkeat omavastuut olleet yhteydessä potilaan sosioekonomiseen asemaan. Korkeammasta sairastavuudestaan huolimatta maoreilla (alkuperäiskansa) kuitenkin korkeat omavastuut olivat harvinaisempia, ja he myös ostivat vähemmän lääkkeitä eurooppalaistaustaisiin nähden. Kumpikin järjestelmä sisältää riittävyyteen liittyviä heikkouksia ja vahvuuksia eikä kumpikaan kykene täysin suojaamaan potilaita omavastuiden haitallisilta vaikutuksilta. Sosioekonomisten ja etnisten lääkkeiden käyttöön liittyvien erojen syiden ja seurausten selvittäminen vaatii vielä lisää tutkimusta.

Avainsanat: lääkekorvaukset, lääkkeet, lääkehoito, kustannukset, kustannusten jako, omavastuu, korvausjärjestelmät, terveyspalvelut, lääkkeiden saatavuus, eriarvoisuus, Suomi, Uusi-Seelanti

Sammandrag

Aaltonen K. **Tillräcklighet hos läkemedelsförmån. Komparativ analys av farmaceutiska system i Finland och Nya Zeeland.** Helsingfors: FPA, Social trygghet och hälsa, undersökningar 146, 2017. 189 s. ISBN 978-952-284-019-6 (hft.), 978-952-284-020-2 (pdf).

I denna studie, undersöktes åtkomstrelaterade faktorer, – villkor, motincitament, förmånens omfattning och universalitet – hos läkemedelsförmåner i Finland och Nya Zeeland i samband med resultaten av fördelningen av självrisker och kostnadsrelaterade problem. Studierna baserades på produkt- och prislistor, konsumtionsundersökning, postenkät och apotekens försäljningsregister. Gemensamma egenskaper var relaterade till villkor och universalitet. Båda länderna använder högkostnadskydd, mekanismer baserad av behov och begränsade ersättningar. De största skillnaderna gällde motincitament och förmånens omfattning: det finska systemet gav ett större urval mellan ersätts terapeutiskt likvärdiga läkemedel, och en snabbare tillgång till nya innovativa läkemedel, men den allmänna nivån på självriskerna var högre. Det nyzeeländska systemet hade en hög kontroll över förmånens omfattning, i vilken ingår läkemedel med full ersättning för de flesta hälsobehov. Emellertid var urvalen skeva mot äldre läkemedel. I Finland hade självriskerna hade regressiva effekter. Lägre inkomst och högre hälsobehov var associerade med högre frekvens av kostnadsrelaterade problem att få läkemedel och andra hälsovårdstjänster, som har beskrivits för Nya Zeeland i tidigare litteratur. Baserat på bedömningen av höga självrisker bland äldre personer i Nya Zeeland, var köp av läkemedel utan full ersättning ovanligt och inte associerat med socioekonomisk situation. Trots högre behov, var höga kostnader mindre frekventa bland Māori (urinvånare) och de sammanföll med en lägre total nivå av läkemedelsanvändning. Båda systemen har styrkor och svagheter med olika dimensioner av tillräcklighet. I ingetdera landet var skyddsmekanismerna tillräckliga för att motverka de negativa effekterna av självriskadelar helt. Ytterligare forskning behövs om orsaker till och konsekvenser av socioekonomiska och etniska skillnader i läkemedelsanvändning.

Nyckelord: läkemedelsersättningar, läkemedel, medicinering, kostnader, kostnadsfördelning, läkemedelsförmån, ersättningssystem, självrisk, hälsovårdstjänster, tillgång till läkemedel, ojämlikhet, Finland, Nya Zeeland

Acknowledge-ments

Contents

List of original publications

This dissertation is based on the following original publications:

I   **Aaltonen K, Niemelä M, Bell JS, Norris P, Hartikainen S.** Trends and income related differences in out-of-pocket costs for prescription and over-the-counter medicines in Finland from 1985 to 2006. Health Policy 2013; 110 (2–3): 131–140.

II   **Aaltonen K, Horsburgh S, Bell JS, Hartikainen S, Norris P.** Out-of-pocket costs for medicines among community dwelling older people in New Zealand. Submitted manuscript.

III   **Aaltonen K, Miettinen J, Airio I, Martikainen JE, Saastamoinen LK, Bell JS, Hartikainen S, Norris P.** Cost-related barriers to use of health services and prescription medicines in Finland. A cross-sectional survey. European Journal of Public Health 2015; 25 (3): 368–372.

IV   **Aaltonen K, Ragupathy R, Tordoff J, Reith D, Norris P.** The impact of pharmaceutical cost containment policies on the range of medicines available and subsidized in Finland and New Zealand. Value in Health 2010; 1 (13): 148–156.

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Terms, concepts and abbreviations

Terms are used as defined in Glossary by WHO CC for Pharmaceutical Pricing and Reimbursement Policies (2016).

Affordability of medicines: "The extent to which health insurance covers the (pharmaceutical) needs of patients in an adequate manner and at an affordable cost" (Kanavos et al. 2011, 55)

ATC: A classification system where the active ingredients are divided into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties. Medicines are divided into fourteen main groups (1st level, ATC 1 level), with pharmacological/therapeutic subgroups (2nd level – ATC 2 level). The 3rd and 4th levels (ATC 3 and ATC 4 level) are chemical/pharmacological/therapeutic subgroups and the 5th level (ATC 5) is the chemical substance. (WHO CC for Drug Statistics Methodology 2008)

Cost-sharing: "A provision of health insurance or third-party payment that requires the individual who is covered to pay part of the cost of health care received. This is distinct from the payment of a health insurance premium, contribution or tax, which is paid whether health care is received or not." (Rannan-Eliya and Lorenzoni 2010)

Country income grouping: Countries are grouped by, for example, the World Bank, to aggregate and compare key statistical data. The World Bank uses four income groups: low, lower-middle, upper-middle, and high, classified each year based on gross national income per capita. (The World Bank 2016)

CWF IHPS: Commonwealth Fund International health policy surveys

DDD (Defined daily dose): The assumed average maintenance dose per day for a drug used for its main indication in adults. (WHO CC for Drug Statistics Methodology 2008)

De-commodification relates to the strength of the systems to provide social protection and to emancipate individuals from market dependence (Esping-Andersen 1990)

DHB: District health board

EFPIA: European Federation of Pharmaceutical Industries and Associations

EMA: the European Medicines Agency

EU-SILC: the EU Survey of Income and Living Conditions

FDA: The United States Food and Drug Administration

Fimea: The Finnish Medicines Agency (formerly: the National Agency for Medicines)

FIP: International Pharmaceutical Federation

Health systems include "all the activities whose primary purpose is to promote, restore or maintain health"; vs. **Health care systems,** which include "the provision of, and investment in, health services". (WHO 2000)

Inequalities vs. Inequities in health: "Health inequality is the generic term used to designate differences, variations, and disparities in the health achievements of individuals and groups – – Health inequity refers to those inequalities in health that are deemed to be unfair or stemming from some form of injustice." (Kawachi et al. 2002)

Kela: The Social Insurance Institution of Finland

"Me-too" -product: New active ingredient with a comparable mode of action to an existing active ingredient (OECD 2008, 55)

Medsafe: New Zealand Medicines and Medical Devices Safety Authority

MOH: Ministry of Health

MSAH: Ministry of Social Affairs and Health

NHI: National health insurance

NHS: National health service

OECD: Organisation for Economic Co-operation and Development

PHARMAC: Pharmaceutical Management Agency of New Zealand

PHO: Primary health organisation

Price elasticity is the change (percentage) in the consumption of a medicine related to one percentage change in the price or charge that patients pay for that medicine (Austvoll-Dahlgren et al. 2008)

PPRI: Pharmaceutical Pricing and Reimbursement Information

Rational use of medicines: Patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community (WHO 1985)

SHARE: Survey on Health, Ageing and Retirement in Europe

WHO: World Health Organisation

WHO CC: World Health Organisation Collaborating Centre

1 Introduction

Inequalities in health have been explained by multifaceted mechanisms that include societal factors, material and social conditions, community-related and individual factors, as well as individuals' position in the society and the cumulative effects of different risk factors throughout life (Dahlgren and Whitehead 1991, 11; Marmot 2004; Wilkinson and Pickett 2010; WHO 2010a). Access to care is one determinant in this complex puzzle, and it can be further broken down into different dimensions, of which affordability is one (Penchansky and Thomas 1981; Whitehead and Dahlgren 2006; WHO 2010a). Affordability, i.e. economic access, itself also contains multiple dimensions: insurance strategies affect the population covered, internal health care markets affect the range of available and covered benefits, and direct user charges affect the utilisation (Dahlgren and Whitehead 1991, 36–38; OECD 2010a, 37; Reibling 2010).

Providing access to necessary care with affordable cost to patients and society is a key health policy goal globally (Declaration of Alma-Ata 1978; WHO 2005; European Commission 2010a; 2010b). Accordingly, most high-income countries have implemented health systems with financial protection on universal basis (OECD 2013). However, these health systems differ by their characteristics and performance (WHO 2000; Commonwealth Fund 2010a; OECD 2010a). The need to understand the mechanisms and incentives within these systems, and to learn from others, has resulted in a large body of comparative health care research (OECD 1987; Moran 1999; 2000; WHO 2000; OECD 2004; Wendt 2009; OECD 2010a).

In terms of affordability, prescription medicines are of special interest. Medicine use is one of the most common and important health care interventions (Avorn 2010). Adherence to medicines is thus critical in terms of economics and health outcomes (Tamblyn et al. 2001; Haynes et al. 2002; Sabaté 2003; Dormuth et al. 2009). Cost is one of the barriers that affect adherence negatively (Sabaté 2003; Piette et al. 2006). Prescription medicines also represent a large part of the overall health care user charges in many countries (Jones et al. 2008; OECD 2008, 38; Corrieri et al. 2010; Bock et al. 2014; OECD 2015a). There is, however, limited comparable information on the extent to which the reimbursement systems in different countries cover patients' pharmaceutical needs in terms of the adequacy of the covered benefits and affordable price (Kanavos et al. 2011).

Finland and New Zealand are high-income OECD countries of similar geographical and population size. They share relatively similar public health problems, relatively high health inequalities and have a similar level of health care spending per capita. Both countries have NHS (Beveridge) -type health care systems with universal coverage for prescription medicines (Klavus et al. 2012; Blank and Bureau 2014, 15; Lehto 2014). New Zealand has been able to keep the growth of public pharmaceutical spending at a lower level than many other high-income countries, and at the same

time, maintained low user charges (OECD 2011, 135, 155; Gleeson et al. 2013). Previous research has nevertheless revealed ethnic differences in cost-related barriers to prescription medicines (Jatrana et al. 2011). In Finland, high user charges have raised concerns over the equity in access to medicines (Mossialos and Srivastava 2008). International comparisons have ranked New Zealand among the countries with the least new medicines launched and Finland among the countries with a relatively high number of launches (Danzon et al. 2005; Cheema et al. 2012).

The purpose of this study was to evaluate and compare the features of the pharmaceutical systems that affect access and on how these features translate into affordability-related outcomes: distribution of out-of-pocket costs and cost-related access barriers. Finland and New Zealand were chosen for comparison because the two countries had several important differences in their pharmaceutical systems but similarities regarding the overall health care system, public health problems and market size. The results of this study provide a perspective through comparison to identify the relative strengths and weaknesses of each system. Further, the study provides methodological tools for the development of comparative pharmaceutical system analyses.

2 Review of the literature

2.1 Social inequalities in health

Social inequities in health are "systematic, socially produced (and therefore modifiable) and unfair" differences in health status between socioeconomic groups (Whitehead and Dahlgren 2006, 2). Lower levels of income, education and social hierarchy, lower labour position and socioeconomic disadvantage have been associated with higher morbidity and lower life expectancy in numerous studies from many countries (e.g. Whitehead and Dahlgren 2006; Mackenbach et al. 2008; Tarkiainen et al. 2013).

The causes behind health inequalities have been explained by the different determinants of health, conceptualised by e.g. Dahlgren and Whitehead (1991) and the WHO Commission on Social Determinants of Health (WHO 2010a). According to these models, health is linked to factors related to the socioeconomic and political context, to living and working conditions and to individual biological and behavioural factors. A large body of research has evolved around the social gradient of health, the *causes of causes*, i.e. the role of income inequalities and social structures in explaining health inequalities (e.g. Marmot 2004; Wilkinson and Pickett 2010). In public policy, the wider perspective in health inequalities has led to the Health in All Policies (HiAP) -approach, i.e. taking health implications into account in policymaking across sectors (WHO 2014).

Accordingly, scholars in the fields of social policy and health research have examined to what extent general societal-level determinants explain differences in health and health inequalities between countries. Diverse results have been found in studies that have examined the associations between health and different types of regimes, i.e. ideological aspects of and political traditions in welfare provision (e.g. Bambra and Eikemo 2009; Bergqvist et al. 2013; Kangas and Blomgren 2014). The diversity of the results is likely to be influenced by differences in defining welfare state models, changes in time and the variance in the used health-related outcomes (Bergqvist et al. 2013). Studies with a focus on the association between health and institutional aspects, e.g. access to health care, family or unemployment benefits, have found that more generous benefits seem to be associated with better health outcomes. However, people with higher socioeconomic position seem to benefit disproportionately, which may lead to widening or stable inequalities in health. (Borrell et al. 2006; Korda et al. 2007; Bergqvist et al. 2013.) Studies where the generosity of the system is measured as the level of public spending on health care and/or social services imply that higher spending is associated with better health and smaller health inequalities (Wu and Chiang 2007; Kangas 2010; Dahl and van der Wel 2012; Bergqvist et al. 2013; Kangas and Blomgren 2014). It seems likely, though, that after a certain level, the effect of higher spending on health levels off, as has been previously described between economic growth and life expectancy (WHO 2000, 9; Kangas 2010).

2.2   Affordability and access as policy goals

Inequity in access to healthcare is one of the determinants of social inequality in health (Whitehead and Dahlgren 2006, 8; WHO 2010a). The principal idea of inequitable access is determined by the Inverse Care Law: "The availability of good medical care tends to vary inversely with the need for it in the population served" (Hart 1971). Various reasons may cause inequities in access and use. Penchansky and Thomas (1981) defined the concept of access to health care in five dimensions: affordability, availability, accessibility, accommodation, and acceptability. Existing frameworks of access to medicines, reviewed by Bigdeli et al. (2013), have focused on developing countries. Depending on the framework, the domains are affordability, availability, accessibility, acceptability, adoption, rational use, sustainable financing and reliable health and supply systems. Previous research has also identified health system -related, physician-related, patient-related, disease-related and therapy-related factors, that affect the accessibility of health services and adherence to prescribed medicines (Andersen 1968; 1995; Sabaté 2003; DiMatteo 2004; Kardas et al. 2013).

Equitable access to health care is a key policy goal globally. According to WHO (2005), equity in access is achieved by universal coverage defined as "access to key promotive, preventive, curative and rehabilitative health interventions for all at an affordable cost". Access to affordable, sustainable and high quality healthcare is also a focus area within the Europe 2020 strategy, to ensure equal opportunities and ultimately to combat poverty (European Commission 2010a; 2010b). Social protection policies aim to increase the affordability of health care by facilitating financial access and by increasing the disposable income of poor households (Bambra 2005; Israel 2016).

Policy goals set the foundation for actual policies and for measuring their performance (Blank and Burau 2014). However, broad rhetorical goals need to be distinguished from specific programmatic goals that set frames to the actual policies. Especially broader policy goals tend to be difficult to measure. Marmor and Wendt (2011; 2012) presented a model of the ideas, interests and institutions that influence medical care arrangements and their performance (Figure 1, p. 19). This model can be used to conceptualise the processes that shape the ideas and broader policy goals of affordable medicines into actual policies and further to patient related outcomes.

Measuring and monitoring any aspects of policy requires collecting and evaluating relevant and reliable data on both *processes* and *outcomes* (Mossialos et al. 2004). Inputs, outputs and regulation are *processes*. Regulation includes both the *command-and-control approach*, i.e. "imposition of external constraints upon the behaviour of an individual or an organisation", and the *market approach*, which relies on incentives, i.e. "explicit or implicit rewards for performing a particular act" (Saltman 2002).

According to WHO (2000, 24), the fundamental, intrinsic objectives of health care are health, responsiveness and fair financing, of which the two latter are partly instrumental but also valuable on their own. Preferable *outcomes* are thus those related to patients, for example health status, quality of life, satisfaction and equity in access (Mossialos et al. 2004; Marmor and Wendt 2012). Using outputs (e.g. doctor visits, procedures, medicine use) as outcomes is common, although they do not necessarily correlate with health outcomes (OECD 2010a, 13).

Figure 1. Ideas, interests and institutions that shape affordability of medicines and its patient-related outcomes.[a]
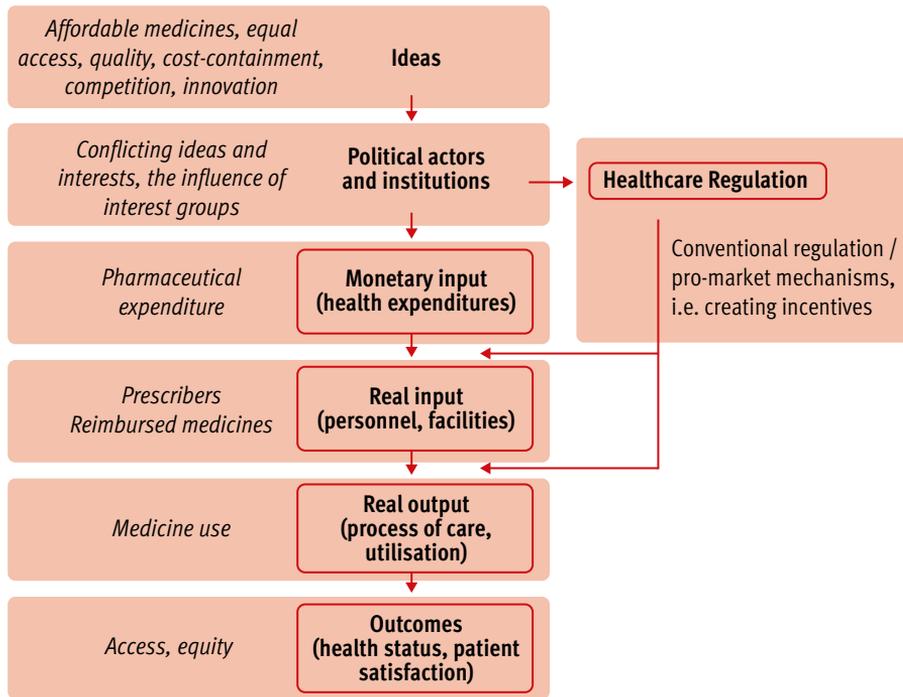
[a] Adapted from the model of the ideas, interests, and institutions in healthcare by Marmor and Wendt (2012).

Efforts to increase affordability often place pressure on other goals and ideas, especially cost-containment. Traulsen and Almarsdóttir (2005) have described the dynamic pharmaceutical policy process as evolution. Initially scientific or technical problems of ensuring quality, efficacy and safety result in sophisticated and costly medicines. Increasing use of these medicines leads to fiscal problems, and if used irrationally, to poor health outcomes and wasted resources. From the policy perspective, managing medicine use on the population level is referred to as *the problem of rational use of medicines* (Almarsdóttir and Traulsen 2005). WHO (1985) defined medicine use as being rational when "patients receive medications appropriate to their clinical needs,

in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their communities". Affordability, to both the system and the patient, is thus an essential part of rational use.

2.3 Pharmaceutical policy setting

Policy can be defined "as the conscious attempt of public officials or executives entrusted with public funds to achieve certain objectives through a set of laws, rules, procedures, and incentives" (Seiter 2010). The principles that guide policymaking, besides evidence, are based on values, ideology, and cultural, political, institutional and historical aspects (Immergut 1992; Traulsen and Almarsdóttir 2005; Seiter 2010; Leopold 2014, 10). Pharmaceutical policy, as defined by Almarsdóttir and Traulsen (2006), "deals with the principles guiding decision making in the field of pharmaceuticals. The goal of pharmaceutical policy is (similar to other social policy) to contribute on the overall health, welfare and well-being of society. It includes any policy that attempts to improve or regulate registration, reimbursement, and distribution of pharmaceuticals."

Pharmaceutical policy differs, to some extent, from health care policy. The three core objectives of health policy are equity/access, cost-containment/efficiency and quality/safety (Papanicolas 2012; Blank and Burau 2014, 109). These objectives are partly competing. Pharmaceutical policy includes a fourth core objective, promoting innovation (Jacobzone 2000, 5; Seiter 2010; Kanavos et al. 2011; Paris and Belloni 2013, 11). The most distinct difference is thus intertwinement with industrial policy, which derives from the importance of the pharmaceutical industry for the economies of many high-income countries (OECD 2008, 40–42; Kanavos et al. 2011, 19–21). The global pharmaceutical industry also has notable power in the national and international pharmaceutical policy arena (Traulsen and Almarsdóttir 2005; Seiter 2010).

While health care services typically have local markets, the market for pharmaceuticals is increasingly global, with few companies accounting for a large part of total global sales (OECD 2008, 52). Supranational bodies (the European Union) also influence the market and policies, directly and indirectly, e.g. by the harmonisation of patent and marketing authorisation processes and by incentives that facilitate the market entry of orphan medicines (OECD 2008, 115, 125; Morgane and Mondher 2012; Greer et al. 2013). The prices and consumption of pharmaceuticals nevertheless follow national patterns because of economic and political factors, national pricing and reimbursement policies as well as differences in guidelines and treatment traditions (OECD 2008, 30–38; Kanavos et al. 2011, 19). Countries also differ in the mechanisms related to inpatient and outpatient medicines (Paris and Belloni 2013, 20; Aho et al. 2017, 23). The industry therefore uses country-specific pricing and entry strategies to adapt to the differences and to avoid parallel trade (OECD 2008, 65–66, 170–174; Kanavos et al. 2011, 37). However, national pricing decisions also affect prices in other countries via international price benchmarking. As a result,

confidential rebate, clawback and risk sharing agreements between the industry and public payers have become increasingly popular (Espin et al. 2011; Carone et al. 2012, 29; Paris and Belloni 2013, 58; Vogler and Habimana 2014, 9).

The pharmaceutical policy framework is highly dynamic. Evolving new issues and market adaptation require policies to be constantly monitored, changed and adjusted (Traulsen and Almarsdóttir 2005; Seiter 2010; Leopold 2014). In the 1980s and 1990s, a high number of new medicines (active ingredients) were introduced globally and the pharmaceutical expenditure in many high-income countries grew more rapidly than total health expenditure and GDP (OECD 2008, 29–30, 54). In the 2000s, sales slowed down in many countries, due to a slight decline in the number of new medicines introduced and due to the increasing share of the generic market, spurred by the "patent cliff" – the expiring patents of medicines that reached blockbuster sales during the previous decades (OECD 2008, 54, 59; Song and Han 2016). Whereas the growth in spending in the 1990s was driven by medicines used in primary care, in the 2000s the growth has been rapid for medicines used in specialised care. The market has therefore concentrated and fewer very expensive medicines for small patient groups take up an increasing share of global sales. (OECD 2008, 59–60.) For example, between 2006 and 2015, the worldwide orphan medicine sales is estimated to have more than doubled and their share of total prescription medicine sales to have increased from 9% to 16% (EvaluatePharma 2015).

The unique and constantly changing mix of policies in each country is influenced by trade-offs between different policy objectives (Kanavos et al. 2011; Leopold 2014). However, although the mix is unique, similar policies are used by public payers and health insurance providers in different countries. Different sets of policies are used for different market segments, i.e. products with and without patent protection (Kanavos et al. 2011, 13–14; Carone et al. 2012, 33; Vogler and Habimana 2014, 6). Generic market policies include generic price links, internal reference pricing, generic prescribing and tendering (Kanavos et al. 2011, 35; Vogler and Habimana 2014, 10–11). Policies used for patent protected medicines include international price referencing, health-technology assessment, price and expenditure control mechanisms (Kanavos et al. 2011, 35; Carone et al. 2012, 20; Vogler and Habimana 2014, 10–11). Measures targeted to high-cost medicines include managed entry and risk-sharing agreements (Carone et al. 2012, 32; Paris and Belloni 2013; Vogler and Habimana 2014, 3).

Policy research methodology derives from political sciences, sociology and economics (Almarsdóttir and Traulsen 2006). Pharmaceutical policy analysis aims to study the performance and effects of implemented and changed policies on various outcomes, e.g. prices, expenditures, utilisation or health, and to predict the effects of future polices (Traulsen and Almarsdóttir 2005; Leopold 2014). In practice, policy analyses aim to provide evidence to guide or influence national pharmaceutical policymaking. The interest in learning from international experiences and gathering information

on the mechanisms of pharmaceutical policy measures has resulted in scientific research and in reports published by different organisations (e.g. OECD, WHO, European Commission, Commonwealth Fund) and networks (e.g. PPRI, Piperska Group, Matusewicz et al. 2015). Different stakeholders also conduct and fund policy research (e.g. EFPIA, FIP). The concurrent political debate and the interests of those who conduct and fund research influence topics chosen for policy research.

Commonly studied pharmaceutical policy topics in high-income European countries are efficiency, cost-containment, pricing and reimbursement (Bloor and Freemantle 1996; Bloor et al. 1996; Freemantle and Bloor 1996; Jacobzone 2000; Mossialos et al. 2004; Kanavos et al. 2011; Paris and Belloni 2013; Kanavos 2014; Leopold 2014; Leopold et al. 2014). Nevertheless, comprehensive and longitudinal studies of the impact of policies or policy mixes are still scarce (Carone et al. 2012, 47; Moreno-Serra 2013, 20–21). The pharmaceutical industry has pressed the issues of availability of new medicines and the restricting effects of cost-containment policies on market entries, profitability and innovation (Garattini and Ghislandi 2007). In the US, the political debate over universal coverage for medicines has led to a large body of research concentrating on access and affordability of medicines (Poisal and Chulis 2000; Heisler et al. 2005; Gruber 2006; Briesacher et al. 2007; Schoen et al. 2010). However, rising health-care costs, together with the economic downturn, have led to increased cost-sharing in many countries with extensive insurance coverage (Vogler et al. 2011; Leopold et al. 2014; Vogler and Habimana 2014, 14, 17). These trends may have raised public interest in studying affordability.

2.4 From policies to systems

The effects of policies are dependent on the joint effects of adopted policies rather than any one policy alone (e.g. Mossialos and Oliver 2005; OECD 2010a; Lehto et al. 2015). These complex entities of policies are referred to as systems, which, despite their uniqueness, represent variants or combinations of a limited number of types (Blank and Burau 2014, 13, 77). In policy research, the institutional context of different systems has been conceptualised by using ideal models and typologies (Blank and Burau 2014, 13). These typologies aim to differentiate countries based on indicators that reflect specific sub-systems of the overall system (Table 1, p. 23).

The main sub-systems used in comparative health policy research are funding, provision and governance (Blank and Burau 2014, 77). The OECD (1987) model used funding and provision as indicators to classify three types of health systems by the predominance of patient sovereignty (predominance of incentives) or social equity (predominance of control): the NHS-model (Beveridge), the social insurance -model (Bismarck) and the private-insurance-model (consumer sovereignty) (Table 1, p. 23).

Table 1. Health care system typologies/ideal models.

Source	Sub-systems & Indicators	(ideal) models / typologies	Examples
OECD 1987	Funding, coverage, ownership	National Health Service (Beveridge) model: Universal coverage, national ownership or control of production and general taxation.	the UK, Italy
		Social Insurance (Bismarck) model: Compulsory social security financed by employer and individual contributions, non-profit insurance funds, public/private ownership of production	Germany, France
		Private Insurance (Consumer sovereignty) model: Employer-based or individual private insurance, private ownership of production.	the US
Moran 1999; 2000	Governing the consumption, provision and production of heath care	Entrenched command and control states: Successful with resource scarcity: cost containment and equitable resource allocating. Weak at responding to increasing consumer demands.	Scandinavia and the UK
		Supply state: Successful at developing and diffusing innovation, weak in equitable access and cost containment.	the US
		Corporatist states: Successful at universal access to high-quality care, weak at change due to rigid institutions.	Germany
		Insecure command and control states: Inadequately resourced, and have not achieved equity, high co-payments lessen their universality	Greece, Portugal, Italy
Wendt 2009	Expenditures, financing, provision and access	Health service provision oriented type: High level and importance of provision, smooth access, modest cost-sharing, no gatekeeping, high patient choice, fee for service remuneration, high incentive to increase level of services	Austria, Belgium, France, Germany
		Universal coverage – controlled access type: Access to providers strictly regulated, equity in access, low cost-sharing, capitation remuneration, low incentives for doctors to increase the level of services	Denmark, the UK, Sweden, Italy, Ireland
		Low budget – restricted access type: Low expenditure per capita, restricted access, high cost-sharing which affects equity in access, salary remuneration, low doctor autonomy	Finland, Portugal, Spain
Reibling 2010	Regulation of access: Conditions (gatekeeping), disincentives (cost-sharing), benefit level (supply)	Financial incentive state: Mainly regulate access by cost-sharing	Austria, Belgium, Sweden, France, Switzerland
		Strong gatekeeping and low supply: No/low cost-sharing, extensive regulation and gatekeeping, low number of providers	Denmark, the Netherlands, Poland, Spain, the UK
		Weak regulation and high supply: Low/no gatekeeping and cost-sharing, high number of providers	Germany, Greece, Czech Republic
		Mixed regulation: Gatekeeping and cost-sharing	Finland, Italy, Portugal

In the assessment of access and affordability, the key dimensions in the different typologies and models are those related to regulating the demand for, and supply of, services. Moran (1999; 2000) examined the different roles of the state by examining the governance of consumption, provision and technology, and the relative weaknesses and strengths of different types of health-care states (Table 1, p. 23). Wendt et al. (2009) formed 27 ideal types by assessing relations between financing agents, providers and beneficiaries by the mixes of state, societal and private elements within the dimensions of regulation, financing and provision. By using data on health care expenditures, financing, provision and access from 15 European countries, Wendt (2009) used cluster analysis to construct three types of health care systems, 1) health service provision oriented, 2) universal coverage – controlled access and 3) low budget – restricted access. Reibling (2010) also used cluster analysis to type health care systems by the patient access dimension, by using gatekeeping, cost-sharing and supply as indicators (see Chapter 2.7).

Comparing and assessing the performance of health systems across countries and over time is a widely studied area of research (e.g. WHO 2000; OECD 2004; OECD 2010a; OECD 2011a). However, there is a large variation in the used outcomes and system indicators.

As population health is the defining health system goal, a common setting has been to assess system characteristics in relation to the level and/or distribution of health (WHO 2000; OECD 2010a). However, health and its equitable distribution are influenced by several other factors besides the health care system (see Chapter 2.1). Different measures used to measure overall population health include life-expectancy at different ages, infant mortality, disability-adjusted life-expectancy (DALE), health-adjusted life-expectancy (HALE), amenable mortality and premature mortality as potential years of life lost (PYLL) (WHO 2000, 28; OECD 2004, 20–24; OECD 2010a, 13–26).

Besides health, other health system goals used in performance assessments include responsiveness, quality and fair financing (WHO 2000; OECD 2004; OECD 2010a). Responsiveness is an indicator of quality and has been measured by surveys assessing patient experiences and satisfaction, more specifically e.g. patient choice, involvement and autonomy, confidentiality, waiting times, satisfaction and unmet needs (WHO 2000; Garratt et al. 2008; Schoen et al. 2010; OECD 2015b, 119–162). Fairness in financing implies that individuals and households contribute according to their ability to pay instead of need, do not face the risk of impoverishment and are not forced to go without necessary treatments due to the costs (WHO 2000; de Looper and Lafortune 2009). Measurements of fair financing are reviewed in more detail in Chapter 2.6.

Comparative studies have ranked or compared individual countries based on measures, indices or several measures of performance (e.g. WHO 2000; van Doorslaer et al. 2004; Schoen et al. 2010; OECD 2015b). In the WHO (2000) World health report, countries were assessed based on attainments, i.e. outcomes achieved, and relative performance, i.e. how well they could perform with the same resources.

The OECD (2010a) study combined system characteristics with performance outcomes to assess strengths and weaknesses of different types of systems. A set of 20 policy and institutional indicators were used to cluster the health care systems in 29 OECD countries into six groups. Within groups, the countries were benchmarked against each other, based on outcomes related to system efficiency and quality. Overall, efficiency varied more within groups than across them and therefore no specific type seemed to be preferential. Instead, well and poorly performing countries were identified in most institutional groups. The policy lessons from the benchmark were that similar reform approaches are unlikely to be efficient across systems, instead the areas for improvement were system-specific. Some countries could profit from reinforcing gatekeeping, others from increasing price signals for users. The reasons for inequalities in health also seemed to vary by country, and therefore it would be useful to examine whether inequities in access result from high out-of-pocket payments, from reliance on over-the-basic coverage or both.

Performance comparisons can also focus on a specific sub-sector (e.g. in-patient care, outpatient care, pharmaceuticals). Focusing has the advantage of examining similar activities thus enabling researchers to draw sector-specific policy recommendations. However, finding outcomes that only relate to one sub-sector may be challenging (OECD 2010a).

2.5 Pharmaceutical reimbursement systems

The reimbursement system refers to the institutional arrangements related to evaluating and deciding reimbursement status, mechanisms of funding as well as the eligibilities and conditions that define the circumstances under which reimbursements are paid (Seiter 2010, 4; Paris and Belloni 2013, 21–23). The features related to reimbursement eligibilities and schemes are described in more detail in Chapter 2.7.

Reimbursement systems may be public or private, compulsory or voluntary (Austvoll-Dahlgren et al. 2008). In high-income countries, the most common funding models are tax-funded systems (National Health Service, NHS or National Health Insurance, NHI) and social insurance, funded through insurance contributions by employers and employees as well as state subsidies. The role of private insurance varies by country, but it is typically supplemental or substitutive. (Kanavos et al. 2011; Paris and Belloni 2013, 17; WHO CC for Pharmaceutical Pricing and Reimbursement Policies 2016.) Conversely, in the US, health care is regulated, delivered and financed through various public and private institutions and programs, and there is wide variation in

coverage for prescription medicines. Also in Canada, the coverage for prescription medicines varies by province. (Commonwealth Fund 2010a; Paris and Belloni 2013, 17.)

In Europe, regulation regarding reimbursements usually falls under health and social legislation (Vogler 2008, 78; Seiter 2010, 4). The authorities responsible for reimbursement decisions in most European countries are the Ministries of Health or Social Affairs, Social Insurance Institutions, Medicines Agencies or specific institutions (Vogler 2008, 78). In several countries, the assessment of therapeutic value and/or price is conducted separately, based on which recommendations are given to decision makers (Paris and Belloni 2013, 22–23). The decision on price can be made in conjunction to the reimbursement decision, or separately, by a different body (Paris and Belloni 2013, 22–23).

Published *pharmaceutical system* comparisons have described in detail or classified different pharmaceutical systems by their sub-systems with or without macro-level indicators (e.g. Mossialos and Oliver 2005; Hutton et al. 2006; Garattini et al. 2007; Vogler 2008; Tele and Groot 2009; Paris and Belloni 2013). Comparisons have also focused on a single implemented policy, e.g. the reference-price system (Danzon and Kelcham 2004). A common measure of performance is comparing prices of medicines (Danzon and Chao 2000; Martikainen et al. 2005; Kanavos and Vandoros 2011). Kanavos (2014) compared the performance of generic markets by using several indicators. Few studies have studied countries as clusters in terms of e.g. by being more or less market-based (Matthews and Glass 2013), by economic stability (Leopold et al. 2014) or by WHO region (Cameron et al. 2009).

2.6   Dimensions of affordability

De-commodification has previously been used to address the protective strength of health insurance, both in terms of cash benefits and services provided (Kangas 1994; Moran 1999; Bambra 2005). Originally, de-commodification relates to the strength of social protection, i.e. "the extent to which individuals and families can maintain a normal and socially acceptable standard of living regardless of their market performance" (Esping-Andersen 1987, 86). Reibling (2010) operationalised four indicators of de-commodification to categorise dimensions of access to health care into: 1) *Conditions*, under which benefits may be received, which relate to eligibility criteria such as means or needs tests (e.g. gatekeeping); 2) *Disincentives* are measures that aim to reduce the take-up of benefits, i.e. to address moral hazards (e.g. cost-sharing); 3) *Benefit level* in health care, relates to the benefit package covered by the health system; 4) *Universality*, which is the degree of coverage of the system for the population. Reibling (2010) did not include the fourth indicator, universality, in the cluster analyses, since most high-income countries have universal coverage of health care services and the degree of coverage was thus not useful for differentiating system types.

Dimensions of access have also been used to compare pharmaceutical systems, but no standard methodology was identified in the literature (Cohen et al. 2007; Vogler 2008; Kanavos et al. 2011). The dimensions used for health insurance largely apply to pharmaceutical reimbursement systems, but also distinct differences exist, mainly because the focus of reimbursement systems is on products rather than services (Jacobzone 2000; Traulsen and Almarsdóttir 2005; Cohen et al. 2007; OECD 2010a, 27). The indicators of access to health care, operationalised by Reibling (2010) are thus examined below from the perspective of pharmaceutical systems.

Conditions: Pharmaceutical reimbursement systems typically include different levels of coverage, based on eligibility and exemption policies. The conditions, under which these policies apply, differ between systems. The Glossary by WHO CC for Pharmaceutical Pricing and Reimbursement Policies (2016), and respectively, also Vogler (2008) distinguish between four main types of reimbursement schemes regarding eligibility: disease-specific, product-specific, consumption-based and population group-specific. The most commonly used scheme in the EU is product-specific, where eligibility is considered based on an evaluation of different aspects of the pharmaceutical product (Vogler 2008). Disease-specific eligibility is linked to the treated condition and a certain pharmaceutical may be reimbursed at different rates for different conditions. Under population group-specific eligibility, specific groups, such as children, older persons or persons with low income are eligible while others are not. Finally, under the consumption-based eligibility scheme, the level of reimbursement depends on the patients' cumulative expenditure during a defined period. The reimbursement schemes can also be mixed with elements from several eligibilities. (Vogler 2008; WHO CC for Pharmaceutical Pricing and Reimbursement Policies 2016.) Another form of exemption within pharmaceutical systems is prior authorisation or restricted reimbursement, which limits the use of a product to specific (named) patients or circumstances (Austvoll-Dahlgren et al. 2008).

Disincentives: Cost-sharing is the most commonly used cost containment policy targeted at patients (Freemantle and Bloor 1996, Kanavos et al. 2011). Cost-sharing is used to reduce third-party payer expenditures but also as an incentive for the patient to deter overuse, use of ineffective and inappropriate medicines and thus limit the danger of moral hazard (Robinson 2002). Different forms of cost-sharing and patient payments are described in more detail in Chapter 2.4.1.

Benefit level: Assessments of benefit packages in the field of pharmaceuticals relates to the range of reimbursed products. Most European countries, as well as Australia and New Zealand, define reimbursable products on the national level by positive lists, i.e. lists of medicines that may be prescribed at the expense of a third party payer (Vogler 2008; Paris and Belloni 2013, 17). There is, however, some variation in whether the benefits are similar across different insurance schemes or regions and in whether the patients have a choice over the benefit packages (Cohen et al 2007; Paris and Belloni

2013, 17). In the UK covered medicines are decided on a county level and in Canada by public or private drug plans. In Germany and the Netherlands insurance providers may decide on coverage of different brands and include benefits above the national positive list (Paris and Belloni 2013, 17). One country may also have several positive lists with different reimbursement rates (Vogler 2008). Comparisons of the range of medicines available or reimbursed are reviewed in more detail in Chapter 2.4.2.

Universality: Most health systems in high-income countries are characterised by universal coverage for pharmaceuticals, with the exception of Northern America (Commonwealth Fund 2010a; Kanavos et al. 2011).

2.6.1 Cost-sharing for medicines

Different forms of patient payments for medicines have been determined and classified in the OECD Glossary of Statistical Terms (OECD 2001), in the Glossary of WHO CC for Pharmaceutical Pricing and Reimbursement Policies (2016), by Rannan-Eliya and Lorenzoni (2010), by Austvoll-Dahlgren et al. (2008) and by Rubin and Mendelson (1995). Patient payments include direct payments (also "out-of-pocket payments"), that are paid by private households directly to the provider, without the benefit of insurance (Figure 2, p. 29). Indirect payments, conversely, are paid irrespective of service use, and they may include insurance premiums and taxes, depending on the system.

Direct payments are classified into cost-sharing and other payments (Figure 2). Cost-sharing is the part of the cost that the health insurance or third party payer requires the covered individual to pay for received care. Rubin and Mendelson (1995) distinguish between direct and indirect cost-sharing. The former includes e.g. co-payments, coinsurances and deductibles, and the latter e.g. non-reimbursed/non-formulary medicines, tier payments and reference premiums. Non-reimbursed prescription medicines may also be regarded as self-medication, together with over-the-counter medicines and informal payments to medical care providers (OECD 2001).

Figure 2. Forms of patient payments.
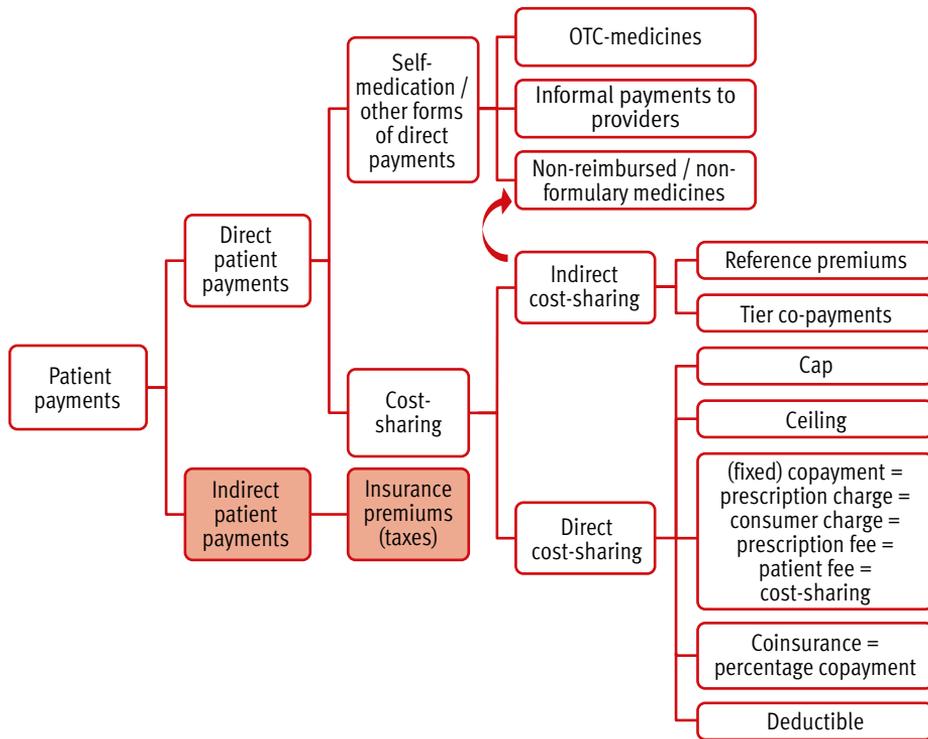
Red background = paid irrespective of service use, white background = paid for care received.
Abbreviation: OTC = Over-the-counter.

Cost-sharing can have negative effects on health, equity and efficiency (Remler and Greene 2009; WHO 2010; Hurley 2013; Smith 2013). Cost-sharing may deter people from using services, cause financial distress to those who use services and encourage overuse of services among those who can pay (WHO 2010b). The effects of cost-sharing policies on the (rational) use of medicines have been reviewed by Lexchin and Grootendorst (2004), Goldman et al. (2007), Austvoll-Dahlgren et al. (2008), Gemmill et al. (2008), Martikainen (2012) and Kiil et al. (2014). These systematic reviews show that the implementation of or increases in cost-sharing are associated with decreased use, especially in vulnerable populations. The decreases identified in the studies were not limited to discretionary and less necessary medicines and did not always lead to rational use. Previous research has also shown that increased cost-sharing can lead to an increased rate of adverse events, e.g. hospitalisation, nursing home admission and mortality (Tamblyn et al. 2001; Dormuth et al. 2009). In addition, self-reported non-adherence due to costs has been associated with adverse health outcomes (Mojtabai and Olfson 2003; Jatrana et al. 2015).

2.6.2 Range of reimbursed medicines

The priorities and resources available in each country define which therapies are reimbursed, and to what extent. However, the range of reimbursed medicines is also dependent on the range of medicines in the market. Availability is affected by pharmaceutical policies, together with market size, market structure, cultural and historic factors (Taylor 1992; Folino-Gallo et al. 2001; Cohen et al. 2007; Vogler 2008; Kanavos et al. 2011). According to several studies regarding price controls and entry strategies, launches of new medicines occur more often and with less delay in countries with higher expected price and volume and/or less price controls (e.g. Danzon et al. 2005; Kyle 2007; Danzon and Epstein 2008; Varol et al. 2010). Differences in prescribing patterns, in the role of industry promotion and in the use of generics or "me-too" products can influence the available range (Taylor 1992; Folino-Gallo et al. 2001). National policies can also affect availability in other countries, via external price referencing, parallel trade and global shortages, e.g. due to low profitability of older generic medicines and active ingredients (Kyle 2007; Kanavos et al. 2011; Link et al. 2012).

Examinations and comparisons of the overall range of medicines available or reimbursed across countries or systems are scarce and challenged by the complexity of such comparisons (Table 2, p. 32). Lack of uniform, standardised and comparable data has been a key methodological difficulty (Folino-Gallo et al. 2001; Vogler 2008; Ballem and Krause 2011). Identified challenges include e.g. incomplete or lacking national listings of products, and if listings have been available, differences in what products are included and excluded; differences in defining which products are medicines and lacking or variable assignment of ATC-codes.

Nevertheless, all identified comparisons have showed notable differences between countries. Differences have been found in the number and range of medicines available and reimbursed, the share of reimbursed products, the availability and reimbursement of newer and innovative products and in the active ingredients and suitable product formulations available and reimbursed for paediatric use (Folino-Gallo et al. 2001; Vogler 2008; Ragupathy et al. 2010; 2012). Comparisons focused on a certain illness or type of product found further differences across countries in e.g. authorised and reimbursed indications, distribution procedures (specialised centres only, second physician approval) and payer requirements (Blankart et al. 2011; Cheema et al. 2012).

In the most exhaustive of identified comparisons, conducted in 14 EU countries, only 7% of medicines (active ingredients) were available in all 14 countries and each country had exclusively available active ingredients. The most medicines were available in Germany and the least in Denmark. (Folino-Gallo et al. 2001.) In a comparison of four countries or systems – the UK, the US VANF (Veterans Affairs National Formulary), Australia and New Zealand – the UK had the most and New Zealand the

least available and reimbursed medicines as well as therapeutic groups with available or reimbursed medicines. The US had most innovative medicines available, and the US and UK had similar average age of available medicines. However, the UK had on average the newest reimbursed medicines and the highest number of reimbursed innovative medicines. New Zealand had fewer and older active ingredients and fewer innovative medicines available and reimbursed than the US VANF, UK and Australia (Ragupathy et al. 2012).

Due to the large number and variety of products available in different markets, several studies have focused on a basket of products. Based on a comparison of the 100 top selling medicines, France, the Netherlands, and the UK had approved fewer medicines than the US (Cohen et al. 2007). Of the medicines approved in all four countries, similar share was reimbursed in all countries. The Netherlands had the lowest cost-sharing but the most conditions on reimbursement, the USA had the highest cost-sharing and most variation in coverage across the population, but also the most choice over benefit schemes. In a comparison of five major therapeutic groups in three countries using therapeutic reference pricing – Germany, the Netherlands and New Zealand – Germany had the most and New Zealand the least active ingredients available (Danzon and Kelcham 2004). The difference between New Zealand and the other two countries was largest among active ingredients that were newest by global age.

Affordability is especially an issue in the case of new and expensive medicines. Accordingly, several studies have compared differences in access to expensive oncology medicines or orphan medicines. Ballem and Krause (2011) found provincial differences in the Canada in availability, coverage and cost-sharing of new oncology medicines. Wilson and Cohen (2011) observed a trade-off in access between the US Medicare and Australia: whereas the US Medicare covered a wider range of products, the cost-sharing and prices were notably higher. In neither system did all patients who could have benefited from new oncology medicines have access to them. Cheema et al. (2012) found large variation in the number of reimbursed indications for oncology medicines across 13 countries, regions or systems. Differences were influenced by e.g. the stringency of cost-effectiveness assessment and submissions. Blankart et al. (2011) compared access to orphan medicines in 11 countries and found differences in approved and reimbursed indications, prices and cost-sharing. In the US and Canada, patient co-payments were substantial. Matthews and Glass (2013) compared the adoption of orphan medicines in more and less market-based systems and found that less market-based systems may provide more efficient delivery of orphan medicines to patients. According to the authors, these results suggest that reimbursement mechanisms may be the primary factor affecting orphan medicine adoption.

Table 2. Review of studies comparing the range of available/reimbursed medicines.

Study	Countries/systems	Design / Data (Time)	Compared products; Outcomes	Methodological challenges	Key results
Folino-Gallo et al. 2001	Austria, Belgium, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden, the UK	Observational product-level analysis / Various regulatory data and documents (1998)	All medicines excl. food supplements, herbal and homeopathic products; Availability (N of medicines (ATC level 5) and trade names, overlap).	Varied quality and completeness of data, lack of standardisation in assigning ATC-codes, differences in the definition of medicine, licencing / distribution channel	Wide variation, only 7% of medicines available in all countries. Most medicines in Germany (1,974) and Austria (1,727), least in Denmark (1,016), Sweden (1,041) and Finland (1,130). The least variation in antineoplastic medicines and the most in alimentary and cardiovascular medicines.
Danzon and Kelcham 2004	Therapeutic reference price systems: Germany, the Netherlands and New Zealand	Observational product-level analysis / IMS price data Reimbursement data from national agencies (until 1998)	9 therapeutic groups (ATC: A02, A10, C10, N06, C01, C03, C07, C08, C09); Availability (country age vs. global age, N of competitors, prices) Affordability (reimbursement levels)	Possible selection bias due to low number of medicines in some of the assessed product subgroups.	New Zealand had the lowest number of medicines available but the highest share of and the lowest prices for reference priced medicines. New Zealand also had the lowest share of newer (post 1994 global launch date) medicines available. New Zealand reimbursement level (due to reference price) relatively low and reference classes the broadest.
Cohen et al. 2007	USA, France, the etherlands, the UK	Observational product-level analysis /Regulatory documents and data, IMS data, national informants (2004)	100 top selling medicines in the US; Access sub-dimensions (N with MA, time to MA, time between MA and reimbursement, % reimbursed, extent of reimbursement, % reimbursed with restrictions, patient choice, universality of coverage)	The relative importance and trade-offs between sub-dimensions.	Variation among the eight access sub-dimensions. The US approved most medicines. For medicines approved in all countries, the share of covered medicines was similar. The Netherlands: the lowest cost sharing but restrictions on a larger share of products. France: the slowest in time from MA to reimbursement. The US: the most flexible choice of benefit scheme but the least universal in evenness of coverage in the population.

Table 2 continues.

Table 2 continued.

Study	Countries/systems	Design / Data (Time)	Compared products; Outcomes	Methodological challenges	Key results
Vogler 2008	24 European countries	Observational product-level analysis / Literature (country profiles), local informants (2006–2008)	All products: Availability (N authorised/on the market/ Rx only/Reimbursable)	Various methods (e.g. different package sizes, formulations) with no standardised methodology or common inclusion/ exclusion criteria (e.g. homeopathic products).	Large differences in the number of products author-ised and on the market, partly due to varied methods of collecting information. The number of reimbursed pharmaceuticals (with various methods of calcula-tion) varied between 261 (Latvia) and 9,567 (Italy). The share of reimbursed medicines also varied between countries. The share of prescription only medicines tended to be higher than the share of reimbursed medicines.
Ragupathy et al. 2010	The UK, Australia, New Zealand	Observational product-level analysis / Prescribing refer-ences, reimburse-ment listings (1998, 2002, 2007)	Medicines for paediatric use: Availability/affordabil-ity (changes in N of avail-able/reimbursed medicines and formulations suitable for paediatric use.	Standardisation of data from different sources. All available products not listed in used sources. Clinical relevance of numeri-cal differences.	The number of entities indicated for children, suitably formulated and reimbursed was the highest in the UK throughout studied period but decreases were observed over time. Reversed pattern was found in Australia and New Zealand.
Ballem and Krause 2011	Canada: British Columbia (BC) and Ontario (ON) public plans	Observational product-level analysis / Provin-cial and national regulatory documents (2000–2011)	24 new oncology medicines; Availability (time from MA to reimbursement), cover-age (% of medicines with MA placed on formulary/ recommended; % of covered without restrictions, distri-bution of coverage across population), cost-sharing (degree of coverage)	Private insurance not assessed. Expan-sion of comparison to other provinces or countries is chal-lenged by the lack of availability (or public availability) and standard format of the documentation and data.	Medicines reviewed and available quicker in BC. BC had a higher share of medicines reimbursed but ON had fewer reimbursed with restrictions. All popula-tion groups were potentially covered. Both provinces have complex, but different, systems of cost-sharing.

Table 2 continues.

Table 2 continued.

Study	Countries/systems	Design / Data (Time)	Compared products; Outcomes	Methodological challenges	Key results
Blankart et al. 2011	Australia, Canada, England, France, Germany, Hungary, the Netherlands, Poland, Slovakia, Switzerland, the US Medicare	Observational product-level analysis / Regulatory documents and data (time not specified)	Orphan medicines (PAH, Fabry disease, HAE, chronic myeloid leukaemia): Availability (authorised indications, MA time, orphan status), access (outcomes of HTAs, extent of coverage, price)	Differences in approved indications and distribution. Restrictions on use. Prices not always public.	Wider range of authorised indications in the US than the EU. Faster MA in the EU and the US than smaller markets. Very high co-payments in the US and Canada. Lower prices in countries with centralised price controls (Australia, Canada, England) than in countries with free pricing (Germany and the US). After adjusting for purchasing power parities, the prices were the highest in Eastern Europe. Variation in authorised indications largest for PAH.
Wilson and Cohen 2011	The US Medicare (Part B and D) and Australia	Observational product-level analysis / Public documents and product registries, reimbursement information sources (2000–2009)	New oncology medicines excl. chemotherapeutics and hormonal treatments approved in the US: Availability (MA, reimbursement, time from MA to reimbursement, prices), coverage (% covered, restrictions), cost-sharing.	Only the Medicare health system was analysed in the US.	Of the 34 medicines approved by the FDA, 19 were approved in Australia. Prices were on average lower in Australia with wide intra-US variation. The US Medicare reimbursed more medicines with fewer restrictions than Australia. However, out-of-pocket costs were notably higher in the US due to safety net schemes in Australia.
Cheema et al. 2012	Australia, Canada (Ontario), England, France, Finland, Germany, Italy, Germany, Japan, New Zealand, the Netherlands, Scotland, Sweden, and the US Medicare Parts B and D	Observational product-level analysis / Survey of health authorities involved in reimbursement and public documents (2010)	10 oncology medicines (bevacizumab, bortezomib, cetuximab, erlotinib, imatinib, pemetrexed, rituximab, sorafenib, sunitinib, and trastuzumab); N of reimbursed indications, risk-management measures	Private insurance not assessed, complexity of reimbursement decisions, restrictions on reimbursement may limit access.	Finland, France, Germany, Sweden, and the US reimbursed the most indications (90%–100%). Canada (54%), Australia (46%), Scotland (40%), England (38%), and New Zealand (25%) reimbursed the least. Non-reimbursement was typically due to cost-ineffectiveness in countries that use CEA. In New Zealand, the main reason was excessive cost. New Zealand also had the fewest submissions for reimbursement from companies. Finland, Germany, Japan, the Netherlands had no risk-sharing-agreements.

Table 2 continues.

Table 2 continued.

Study	Countries/systems	Design / Data (Time)	Compared products; Outcomes	Methodological challenges	Key results
Ragupathy et al. 2012	The US Veterans Affairs National Formulary (VANF), the UK, Australia, New Zealand	Observational product-level analysis / Prescribing references, reimbursement listings (2007)	All medicines / innovative medicines: Access (MA, reimbursement status), by therapeutic group, global age	Only the VANF health system was included from the US. ATC codes not available in the data and thus assigned manually. Differing schedules for specific dosage forms (injectable medicines, vaccines).	The UK had the highest and New Zealand the lowest number of available/reimbursed unique medicines (ATC level 5), therapeutic groups (ATC level 4) with available/reimbursed medicines and number of reimbursed innovative medicines. The UK also had the newest and New Zealand the oldest reimbursed medicines. Australia and the US VANF generally fall between these systems, although the US VANF had the most available innovative medicines.
Matthews and Glass 2013	France, Germany, Spain, the UK, the US	Observational product-level analysis / Regulatory product listings, IMS price data (Analysis yr 2007, price data from 2010 also used)	13 orphan drugs: Adoption (number of patients with a rare disease using medicine) in more and less market-based countries	Possible selection bias of countries (not different enough). Lack of information on discounts (prices). Reimbursement mechanisms not included in analyses. Disease prevalence assumed similar in all countries.	A greater adoption of orphan medicines was associated with less market-based populations. No significant effect on adoption was found for disease prevalence, price or time on the market / market launch / being country of innovation. Therefore, it seems that the orphan medicine market differs from traditional market-based mechanisms.
Westerling et al. 2014	The UK, the Netherlands, West Germany, France, Spain, Estonia, Sweden	Observational product-level analysis / Various data: Registration documents, reports, sales statistics, questionnaire to national informants, literature (1977–2008)	Six pharmaceutical innovations (antiretrovirals for HIV, cimetidine, tamoxifen, cisplatin, oxaliplatin, cyclosporine); Market diffusion, introduction, peak sales, (yr)	Differences in the measures used in the sales data, lack of harmonised data (prescribing, DDD).	Variation between countries in introduction was shorter for most recent innovations (antiretrovirals, 8 yrs vs. cisplatin, 22 yrs). Delay in registration the shortest in the Netherlands (1.3 yrs), time lag until start of diffusion the shortest in France (2.2 yrs). Time from introduction to diffusion was similar between countries but diffusion periods varied (3–28 yrs). In Estonia, the introduction was delayed until the 1990s.

Abbreviations: MA = Marketing authorisation, CEA = Cost-effectiveness analysis, PAH = pulmonary arterial hypertension , HAE = hereditary angioedema , HTA = Health Technology Appraisal.

From the public health perspective, new medicines can bring therapeutic innovation and thus improve health outcomes and system efficiency. However, not all medicines have equal therapeutic value (Paris and Belloni 2013). Taking opportunity costs in account, non-rational use of medicines may also lead to inefficient use of scarce resources. As a consequence, assessments of therapeutic value have been developed academically and for regulatory purposes (Ahlqvist-Rastad et al. 2004; Motola et al. 2005; 2006; Prescrire editorial 2012; Vitry et al. 2013; Baird et al. 2014). Accordingly, comparison studies have focused on innovative medicines (e.g. Roughead et al. 2007, in price comparison). Westerling et al. (2014) retrospectively analysed the introduction and diffusion of pharmaceutical innovations first registered in the 1970–1980s and found that the between-country differences in introduction became shorter with innovations that are more recent. Further, time of registration was not always in line with time of start of diffusion.

2.7 Measuring affordability

The indicators of inequities used to measure health care access and use are share of population covered, out-of-pocket expenditure, health care utilisation and unmet care needs/forgone care (de Looper and Lafortune 2009; Allin and Masseria 2009a). Although all countries struggle with questions of affordability, the specific challenges, and the policies adopted in response to these challenges, are different for countries with different income levels (Seiter 2010). In general, medicines are more affordable in high-income countries than in low-income countries, when adjusted for national or individual income level (Machado et al. 2011). In many low and middle-income countries, treatments for acute and chronic illness are largely unaffordable, especially in the private health care sector, and they may be unavailable in the public sector (McIntyre et al. 2006; Cameron et al. 2009; van Mourik et al. 2010; Force 2012).

Wagstaff and Doorslaer (2001; 2003) have assessed affordability of health care by impoverishment (the proportion of population who drop below a defined poverty line due to costs for care) and catastrophic spending (proportion of population who spend more than a defined proportion of their income on care). These methods have been used prospectively, to quantify the proportion of people who would fall below or exceed the specified threshold due to the price of a specific service, or retrospectively, to quantify the proportion of people who in reality did exceed or fall below the threshold due to costs for care (Xu et al. 2003; Niëns and Brouwer 2013). However, the large variation in methods and used thresholds influences the comparability of results across studies (O'Donnell and Wagstaff 2008; Luczak and Garcia-Gomez 2012; Niëns and Brouwer 2013). The assessment of impoverishment is also not sensitive to the proportion of the population that already is below the poverty line and to whom the services are unaffordable at any price. Conversely, the cost is rated as affordable, however large it may be, for people who do not fall below poverty line. The method of assessing catastrophic spending does not take into account that the affordable level

might not be same for people with very low and very high incomes. (O'Donnell and Wagstaff 2008; Moreno-Serra et al. 2012; Niëns and Brouwer 2013.)

Facing catastrophic health expenses (e.g. over 40% of disposable income) is relatively rare in most high-income countries, due to exemptions and ceilings placed on patient payments (Xu et al. 2003). Nevertheless, the economic burden from cost-sharing is associated with the risk of delaying or forgoing needed medical care, also among insured populations (de Looper and Lafortune 2009; Schoen et al. 2010). The level and distribution of out-of-pocket costs for health care have been commonly used as indicators in evaluating reforms in the health care sector. National average estimates of out-of-pocket health expenditures are routinely reported in National Health Accounts (NHA) in many countries. Information on the share of household income or consumption spent on health care, i.e. burden of out-of-pocket spending, is regularly collected through household expenditure surveys (e.g. Household Budget Surveys, Living Standard Measurement Surveys, Income and Expenditure Surveys). However, the validity and comparability of these surveys varies between countries, and also within countries across measurement points. (Heijink et al. 2011.)

Purely considering costs of care does not provide a complete picture of affordability. Low realised out-of-pocket costs for poorer households may indicate a progressive financing mechanism or it may be the result of low access to and use of services (McIntyre et al. 2006; O'Donnell and Wagstaff 2008; Moreno-Serra et al. 2012). In low-income country settings, this has been address by Pradhan and Prescott (2002) by measuring catastrophic risk rather than realised payments. In high-income countries, commonly used indicators of unequal access are unmet need for care and service utilisation between low and high income groups (de Looper and Lafortune 2009; Hernández-Quevedo and Papanicolas 2012; Moreno-Serra et al. 2012).

Self-reported unmet medical needs or forgone care are a feature of a number of national and cross-national surveys, including the European Union Statistics in Income and Living Conditions Survey (EU-SILC), where individuals are asked whether they, during the previous 12 months, did not receive medical examination or treatment they thought they needed due various reasons e.g. cost, waiting time or availability (Allin and Masseria 2009a; de Looper and Lafortune 2009; OECD 2015b). The international health policy surveys conducted by The Commonwealth Fund have surveyed e.g. forgone care and medicines, out-of-pocket cost burden and insurance coverage in several countries, including the US, Australia, New Zealand, Canada and the EU countries (Schoen et al. 2007b; 2009a; 2009b; 2010; 2011; 2013; Osborn et al. 2014; Commonwealth Fund 2016). Unmet need and access barriers are examined in more detail in Chapter 2.5.2.

In health economics, inequity is assessed based on the interpretation of the principle of horizontal equity, which implies that individuals with similar needs have simi-

lar treatments. Empirically, horizontal inequity is measured by the degree of utilisation related to income, after adjusting for indicators of need (Bago d'Uva et al. 2009; Hernández-Quevedo and Papanicolas 2012). Generally, high-income countries tend to have rather equitable distribution of primary care service use but a "pro-rich" bias exists in the use of specialist care, especially when private health care options are available (van Doorslaer et al. 2004; 2006).

Assessing equity in utilisation is complicated by the multiple factors that affect use. A commonly used theoretical framework is Andersen's Behavioral Model, according to which health service use is a function of enabling and impeding factors, predisposition to use services and need for care (Andersen 1968; 1995). Within this model, access is equitable when demographic (e.g. age and gender) and need variables account for most of the variance in use, and inequitable when social structure (e.g., ethnicity, education, occupation), health beliefs, and enabling resources (e.g., income, insurance, waiting times) become dominant factors explaining differences. There is, however, wide variation in the operationalisation of the model (Babitsch et al. 2012).

The abovementioned methods used in measuring inequities in access to *health care* have also been applied to *medicines*. Catastrophic pharmaceutical out-of-pocket spending has been measured using various thresholds (e.g. McLeod et al. 2011; Luczak and Garcia-Gomez 2012). Cost-related non-adherence and equal use have been used as indicators of equal access to pharmaceuticals (Gemmill et al. 2008; Schoen et al. 2010; Mayer and Österle 2014). For low-income country settings, WHO and Health Action International (HAI) have developed a method where the prices of the medicines for selected chronic conditions are compared in relation to the wage of the lowest paid unskilled government worker in each country (WHO and HAI 2003; Gelders et al. 2006). This method is simple and straightforward, and requires only limited data. However, the method does not provide population-level information or take into account the overall range of medicines actually used. (Niëns and Brouwer 2013).

2.7.1 Distribution of out-of-pocket costs for medicines

A system-level approach of addressing patient payments is to examine the private components of spending on pharmaceuticals from national and international statistics (e.g. Kemp et al. 2011; Zare and Anderson 2013). However, this method disregards how the costs are distributed within the population. Overall, the distribution of costs for health care and pharmaceuticals is strongly skewed (Steinberg et al. 2000; Berk and Monheit 2001; Goulding 2005; Zuvekas and Cohen 2007; Saastamoinen and Verho 2013). Depending on the level and allocation of reimbursements, the skewed distribution may persist in patient payments and thus burden population subgroups inequitably (Poisal et al. 1999; Sambamoorthi et al. 2005; Corrieri et al. 2010; Bock et al. 2014). Nevertheless, since most countries have implemented mechanisms to protect patients from high burden of costs, the observed levels of private expenditure

are often lower than could be predicted from reimbursement arrangements (Paris et al. 2010).

An earlier systematic review of *health care* out-of-pocket payments found that among older people, low-income individuals paid most in relation to their income. Prescription medicines accounted for the largest share of health care payments. A lower level of education and female gender were associated with higher out-of-pocket payments and less comprehensive insurance coverage. (Corrieri et al. 2010.) However, the reviewed 29 studies included all types of health services (e.g. mammography) and, except from one study from Australia, derived from the US.

Using search methodology adapted from Corrieri et al. (2010), a comprehensive literature search was performed to examine income, ethnicity/race, education and gender-related inequalities in out-of-pocket payments for *medicines* in high-income countries. The search resulted in 25 research articles with data from 1995 onwards (Table 3, p. 40). Most studies (18) came from the US, where universal coverage for medicines has been a subject of political debate for decades (e.g. Poisal et al. 1999) but there is currently none. Evidence from other countries was relatively recent in comparison to the US. In 16 studies, the population was limited to older adults, typically individuals aged 65 and older.

The identified studies used a large variety of variables to assess out-of-pocket costs and cost burden (Table 3, p. 40). Absolute out-of-pocket costs for medicines were most commonly reported on annual level, but also per 3 months (Bock et al. 2014), monthly (Mojtabai and Olfson 2003; Safran et al. 2005; 2009; Neuman et al. 2007; Sanwald and Theurl 2014) and weekly (Jones et al. 2008; Searles et al. 2013). Relative costs were calculated with person-level income (Sambamoorthi et al. 2003; 2005; Wei et al. 2006; Bock et al. 2014), family income (Xu 2003) or total household budget/consumption (Jones et al. 2008; McLeod et al. 2011) as denominator. Sambamoorthi et al. 2003, 2005 and McLeod et al. 2011 used a threshold to define high/catastrophic out-of-pocket cost burden (> 10% of income). Two studies addressed primarily cost-related experiences: self-reported financial burden – from nil to extreme – (Searles et al. 2013) or categorised expenditures (Safran et al. 2005; 2009; Neuman et al. 2007). Two studies (Chen et al. 2010; Chen 2013) reported neither absolute nor relative costs, but the proportion of total costs paid out-of-pocket. Three studies assessed out-of-pocket costs for health care as the main outcome and only limited results regarding medicines were presented (Jones et al. 2008; Bock et al. 2014; Sanmartin et al. 2014).

Table 3. Overview of reviewed studies on cost sharing for medicines (in alphabetical order).

Study	Country	Population	Design (collection period); methods	Main objective and socio-demographic determinants (income/education/ethnicity or race/gender) with reported findings in relation to OOP cost	Variables related to OOP costs
Bock et al. 2014	Germany	3,124 respondents aged 57 to 84 years in Saarland. (Original sample 9,949 in 2000–2002)	Cross-sectional population-based prospective cohort study (ESTHER wave 8, 2008–2010), geriatric assessment incl. questionnaire on health care utilisation and OOP costs; multiple inferential statistic	OOP payments for health care (inpatient, nursing care, outpatient services, supplies, prostheses, pharmaceuticals (incl. combined Rx and OTC), by sociodemographic and health characteristics. Findings: Income, education, gender.	OOP OTC&Rx costs / person / 3 mo; Ratio of OOP costs and equivalised household disposable income.
Briesacher et al. 2003	The US	Medicare beneficiaries (≥ 65 yrs) 4,355 with heart disease, 1,568 with diabetes and 2,157 with hypertension	MCBS (1999); multiple inferential statistic	Effects of different types of Rx coverage on ethnic/racial differences in Rx use, prices and costs (total, OOP). Findings: Ethnicity/race (white/African American/Hispanic)	OOP Rx costs / person / yr
Chen 2013	The US	73,031 US-born citizens, 7,540 naturalised US-citizens (i.e. foreign-born US citizens) and 10,826 non-US citizens aged 18–64 yrs	MEPS (2002–2008) merged with National Health Interview Survey (NHIS); multiple inferential statistic	Factors associated with disparities in Rx use and costs (incl. OOP share) between US Citizens and immigrants. Findings: Citizenship (US-born/naturalised/non-US citizen)	OOP Rx costs as share of total Rx costs / person / year
Chen et al. 2010	The US	72,160 white and 30,509 Latino people aged 18–64 years.	MEPS (1999–2006) merged with National Health Interview Survey (NHIS); multiple inferential statistic	Factors associated with disparities in Rx use and costs (incl. OOP share) between non-Latino whites and Latino subgroups. Findings: Ethnicity (white/Puerto Rican/Mexican/Cuban/Central or South American/Other Latino)	OOP Rx costs as share of total Rx costs / person / year
Gaskin et al. 2006	The US	8,101 white, 816 African American and 642 Hispanic Medicare beneficiaries (≥ 65 yrs)	MCBS (1999); multiple inferential statistic	Effects of population characteristics and health on observed ethnic/racial disparities in Rx use and costs (incl. OOP costs). Findings; Ethnicity/race (white/African American/Hispanic)	OOP Rx costs / person / yr

Table 3 continues.

Table 3 continued.

Study	Country	Population	Design (collection period); methods	Main objective and socio-demographic determinants (income/education/ethnicity or race/ gender) with reported findings in relation to OOP cost	Variables related to OOP costs
Goulding 2005	The US	Community-dwelling Medicare beneficiaries (≥ 65 yrs)	MCBS (1992, 2001), bivariate inferential statistic	Trends in Rx use and costs (incl. OOP). Findings: Income, ethnicity/race (white/African American), gender	OOP Rx costs / person / yr
Jones et al. 2008	Australia	6,693 general population households.	Household Expenditure Survey (2003–2004); multiple inferential statistic	Variation of health-related OOP costs (incl. Rx and OTC medicines), by income and concession card status. Findings: Income	OOP Rx costs/ person (equivalised) / week
Mahmoudi and Jensen 2014	The US	26,109 Medicare beneficiaries (65 + yrs) and 19,354 adults (aged 55–63 yrs) as comparison group	MEPS (2002–2009); multiple inferential statistic	Effects of Medicare Part D (Rx insurance, effective 2006) on racial/Ethnic disparities in Rx use and costs (incl. OOP). Findings: Ethnicity/race (white/African American/ Hispanic)	OOP Rx cost / person / yr; OOP Rx costs as share of total Rx costs
McLeod et al. 2011	Canada	3,048 senior (≥ 65 yrs), 1,291 social assistance (< 65 yrs) and 10,091 general population households (< 65 yrs)	Survey of Household Spending (2006); bivariate descriptive statistic	Financial burden of Rx OOP costs for different types of households. Findings: Income.	OOP Rx costs as a share of total house-hold expenditure.
Mojtabai and Olfson 2003	The US	10,413 community-dwelling Medicare beneficiaries (≥ 65 yrs).	Health and Retirement study (HRS, wave 2000); multiple inferential statistic	Association of Rx coverage and adherence, and of adherence and health outcomes. Findings: Income, education, race/ethnicity (white/African American/ Hispanic/other), gender.	OOP Rx costs / month / person
Neuman et al. 2007	The US	16,072 non-institutionalised Medicare beneficiaries (≥ 65 yrs).	National Survey of Seniors and Prescription Drugs (2005–2006); multiple inferential statistic	Effects of Medicare Part D, other types of insurance and LIS on OOP Rx costs and cost-related non-adherence. Findings: Income, Ethnicity/race (white/African American, Hispanic, Asian, other)	OOP Rx costs / person / month (categorised)
Poisal and Chulis 2000	The US	Medicare beneficiaries (≥ 65 yrs), sample size not given, total Medicare population 37 M people	MCBS (1995–1996); bivariate descriptive statistic	Changes in Rx coverage, Rx use and costs (incl. OOP costs) by Rx coverage. Findings: Income.	OOP Rx costs / person / yr

Table 3 continues.

Table 3 continued.

Study	Country	Population	Design (collection period); methods	Main objective and socio-demographic determinants (income/education/ethnicity or race/ gender) with reported findings in relation to OOP cost	Variables related to OOP costs
Poisal et al. 1999	The US	36,716 community-dwelling Medicare beneficiaries (≥ 65 yrs)	MCBS (1995); bivariate descriptive statistic	Rx coverage, Rx costs (incl. OOP costs) by sociodemographic characteristics. Findings: Income, ethnicity (white/African American/other), gender	OOP Rx costs / person / yr
Safran et al. 2005	The US	17,659 community-dwelling Medicare beneficiaries (65 + yrs)	National Survey of Seniors and Prescription Drugs (2003); multiple inferential statistic	Rx use, OOP spending, cost-related non-adherence by coverage, poverty, disease burden, state. Findings: Income.	OOP Rx costs / person / month (categorised)
Safran et al. 2009	The US	9,573 community-dwelling Medicare beneficiaries (≥ 65 yrs)	National Survey of Seniors and Prescription Drugs (2003, 2006); multiple inferential statistic	Changes in Rx coverage, use and spending, non-adherence and experiences before and after Part D implementation. Findings: Income	OOP Rx costs / person / month (categorised)
Sambamoorthi et al. 2003	The US	8,814 community-dwelling Medicare beneficiaries (≥ 65 yrs)	MCBS (1997); multiple inferential statistic	Total and OOP expenditures for Rx and burden of Rx OOP costs by demographic, socioeconomic, health characteristics, insurance. Findings: Income, education, race/ ethnicity (white/African American/other), gender.	OOP Rx costs /person /yr; OOP Rx costs as a share of income.
Sambamoorthi et al. 2005	The US	7,871–9,116 community-dwelling Medicare beneficiaries annually (≥ 65 yrs)	MCBS (1992–2000); multiple inferential statistic	Trends in OOP Rx costs and burden, by demographic, socioeconomic, health characteristics, insurance. Findings: Income, Ethnicity/race (white/African American/ Hispanic/other), education, gender.	OOP Rx costs / person / yr ; OOP Rx costs as a share of income; OOP Rx costs as a share of total Rx costs.
Sanmartin et al. 2014	Canada	17,077–10,099 households annually	Survey of Household Spending (biennial 1997–2009); multiple inferential statistic	Trends in OOP expenditures for health care services and products (incl. Rx), by income. Findings: Income	OOP Rx costs / person / yr

Table 3 continues.

Table 3 continued.

Study	Country	Population	Design (collection period); methods	Main objective and socio-demographic determinants (income/education/ethnicity or race/gender) with reported findings in relation to OOP cost	Variables related to OOP costs
Sanwald and Theurl 2014	Austria	5,787 private households (noninstitutionalised)	Household Budget Survey (2009/10); multiple inferential statistic	Influence of household characteristics on OOP costs for medicines (Rx and OTC). Findings: Income, education, gender.	OOP Rx/OTC costs/household /month
Searles et al. 2013	Australia	1,502 adults (≥ 18 yrs) from Hunter region, NSW 1,251 with Rx purchases analysed.	Cross-sectional telephone survey (2007); bivariate inferential statistic	Self-reported financial burden of obtaining Rx medicines. Findings: Income, gender.	OOP Rx costs / week (+ annual estimates); Categorised Rx OOP burden
Steinberg et al. 2000	The US	375,480 persons with employer-sponsored Rx coverage (≥ 65 yrs)	Claims register data (1998); descriptive statistic	Total and OOP Rx costs, by age, gender and specific conditions. Findings: Gender.	OOP Rx costs / person / yr
Terraneo et al. 2014	Italy	56,548 households	Household consumption survey and Observatory on the use of medicines data (2001–2010); multiple inferential statistic	The effects of co-payment policies on private expenditure on medicines. Findings: Income.	OOP medicine costs / person /yr
Wei et al. 2006	The US	76,440 person-years representing 30,375 community-dwelling Medicare beneficiaries (≥ 65 yrs)	MCBS (1992–2000); multiple inferential statistic	Gender differences in OOP Rx costs and burden, factors contributing to the gender gap in OOP costs and burden. Findings: Gender..	OOP Rx costs / person / yr ; OOP Rx costs as a share of income
Xu 2003	The US	Community-dwelling adults, representative of the US population, sample size not given	MEPS (1998); multiple inferential statistic	Disparities between working-age and older population in Rx use and costs (incl. OOP). Findings: Income.	OOP Rx costs / person / yr ; OOP Rx costs as a share of family income.
Xu and Borders 2007	The US	4,242 community-dwelling adults (≥ 65 yrs)	MEPS (2002); multiple inferential statistic	Racial/Ethnic disparities in financial burden from Rx OOP costs. Findings: Ethnicity/race (white/African American/Hispanic/Other).	OOP Rx costs / person / yr ; OOP Rx costs as a share of total Rx costs

Abbreviations: OOP = out-of-pocket, Rx = prescription, OTC = over-the-counter, MCBS = Medicare current beneficiary survey, MEPS = Medical expenditure panel survey.

In the USA, decreasing income was associated with increasing absolute out-of-pocket spending on medicines, presumably due to high-income people having a more extensive insurance coverage, together with lower need (Table 4, p. 45). However, at the other end of the spectrum, the poorest people also tended to have had lower absolute out-of-pocket spending despite higher use, due to a high proportion of people being eligible for public programs. (Poisal et al. 1999; Mojtabai and Olfson 2003; Xu 2003; Goulding 2005; Safran et al. 2005.) Wide variation was described between different insurance schemes, with Medicaid providing the most extensive coverage, followed by employer sponsored insurance (Poisal et al. 1999). Insured people were more likely than non-insured to purchase any medicines and they incurred higher costs and paid lower out-of-pocket payments (Poisal et al. 1999; Poisal and Chulis 2000; Safran et al. 2005). In Canada, the highest spending was reported in the second-lowest income quintile and in another analysis, in senior households. Lower spending was reported in the lowest income quintile and among social assistance households. (McLeod et al. 2011; Sanmartin et al. 2014.) In Australia, Germany and Italy lower income was associated with lower out-of-pocket spending on medicines and in Austria income had no independent and significant effect on out-of-pocket costs (Jones et al. 2008; Searles et al. 2013; Bock et al. 2014; Sanwald and Theurl 2014; Terraneo et al. 2014).

Cost-sharing is known to have regressive effects, i.e. individuals with a lower income face a higher burden than individuals with a higher income, even when the absolute payments are lower (Corrieri et al. 2010, Valtorta and Hanratty 2013). The largest regressive effects were described in the US: among the older population,18−26% of the individuals with the lowest and 2−3% of the individuals with the highest income spent over 10% of their income on prescription medicines (Sambamoorthi et al. 2005); and the average spending (as the share of family income) among the individuals with the lowest vs. the highest income individuals was 8% vs. 0.2% within the working-age population and 14% vs. 0.8% within the older population (Xu 2003). In Canada, 0.3% of general households, 1.1% of social assistance households and 2.5% of senior households spent over 10% of their household budget on medicines (McLeod et al. 2011).

Table 4. Results related to the effects of income on out-of-pocket costs.

Study	Key findings (multivariate findings in italics)	Confounders controlled for in multivariate analyses
Bock et al. 2014	Average OOP burden (all health care) 3% of disposable income. Pharmaceuticals accounted for 21% of OOP costs. *Higher income → higher OOP in total and for pharmaceuticals. The wealthiest quintile → smaller OOP cost to income ratio than the poorest for total health care.*	Gender, age, education, health, marital status, insurance, CIRS-G
Goulding 2005	The lowest vs. the highest income → higher N of Rx but lower Rx OOP. No significant difference in total Rx costs. Among the lowest income people, insured individuals had higher N of Rx, higher total Rx costs but lower OOP costs than uninsured.	None
Jones et al. 2008	Low income → lower OOP costs for Rx and OTC, but higher share of total consumption. *Among low-income households, expenditure share on Rx is higher for concession cardholders than non-holders. Lower co-payments seem to be offset by higher utilisation.*	Age, area
McLeod et al. 2011	Social assistance vs. general households → lower median OOP, similar median budget share (0.1% vs. 0.1%), higher OOP costs and OOP share at 95th percentile (5.4% vs. 2.6%), higher frequency of households with high Rx OOP burden i.e. ≥ 10% of household budget (1.1 vs. 0.3). Senior households' median Rx OOP share 1.1% and 2.5% of households with high burden.	None
Mojtabai and Olfson 2003	No significant differences in the likelihood to have any Rx. The lowest income → the lowest OOP costs (descriptive). Low income together with high OOP costs increased the frequency of cost-related poor adherence (descriptive). *Poor adherence associated with adverse health outcomes.*	Age, gender, race/ethnicity, education, income, insurance, OOP costs, access to health services: office visits, preventive services, illness-specific factors (e.g. diet for hypertension outcomes)
Neuman et al. 2007	High-income people → less likely to have Part D and more likely to have employer sponsored Rx coverage. Low-income → more likely to have Part D or no Rx coverage. *No coverage vs. Part D and Part D vs. employer sponsored → higher odds to spend > $100/$300 OOP and to not fill/delay filling Rx.*	Age, gender, urbanity, race/ethnicity, education, poverty level, N of chronic conditions, N of prescriptions.
Poisal and Chulis 2000	People without Rx coverage vs. with coverage → lower use, lower total costs, higher OOP costs across income groups.	None
Poisal et al. 1999	Low-income people with income just above Medicaid limits (second-lowest income groups) → the lowest share with Rx coverage (60% vs. 63% in the lowest income, 72% in the highest income) and the highest OOP costs. Insured people were more likely to incur any costs and incur high total costs.	None

Table 4 continued.

Study	Key findings (multivariate findings in italics)	Confounders controlled for in multivariate analyses
Safran et al. 2005	Low income was associated with higher than average N of Rx but no significant difference in the distribution of OOP costs (8% of all and 9% of low-income beneficiaries spent > $300 / month on Rx). Medicaid covered 33% of poor, 7% of near-poor and 1% of non-poor. Employer sponsored insurance covered 7% of poor, 20% of near-poor and 38% of non-poor. Without Rx coverage: 34% of poor, 33% of near-poor and 23% of non-poor. *Low income, no Rx coverage and high disease burden significantly associated with higher cost-related non-adherence.*	Sociodemographic and health characteristics (not specified in detail).
Safran et al. 2009	*Part D (2006) advantageous to people previously (2003) without coverage/ with individually purchased coverage →decreased OOP costs, increased N of Rx, decreased non-adherence.* They were also likely to have low income (& low education & minority ethnicity/race). *People who transitioned from employer sponsored insurance (2003) to Part D (2006) → Increased OOP costs, increased non-adherence. People who retained employer-sponsored insurance (2003&2006) → Increased OOP costs but the lowest non-adherence before and after Part D.* Those who retained employer-sponsored insurance were disproportionately high income (& high education & white).	Age, race/ethnicity, poverty, number of Rx, change in N of Rx, specific chronic conditions, change in Rx coverage.
Sambamoorthi et al. 2003	Mean Rx OOP burden was 3% of income; 8% of people spent > 10% of income. *Low income → lower odds (OR 0.71) to use any Rx, lower total and OOP costs, higher odds for high (≥ 10% of income) OOP burden (OR 6.3).*	Gender, age, race, education, marital status, poverty (≤ 200% / > 200% FPL), education, insurance, urbanity, area, self-rated health, ADL&IADL, N of chronic conditions.
Sambamoorthi et al. 2005	Low income → lower OOP Rx costs, slower OOP Rx growth 1992–2000 but more frequent high OOP cost burden. Among poorest, 18–26% spent ≥ 10% of income on Rx, among the highest income, 2–3%. *Poorest had significantly lower OOP costs than higher income individuals.*	Gender, race/ethnicity (white/African American/ Hispanic/other), age, marital status, education, urbanity, insurance, self-rated health, year. Poverty included in other analyses except OOP cost burden.
Sanmartin et al. 2014	The highest Rx OOP costs in the second lowest income quintile all years. The lowest Rx OOP costs in the lowest income quintile all years, except in 2009 in the highest quintile. The largest increase in OOP Rx costs between 1997–2006 in the lowest income quintile (64%), the smallest in the highest (21%).	None

Table 4 continues.

Table 4 continued.

Study	Key findings (multivariate findings in italics)	Confounders controlled for in multivariate analyses
Sanwald and Theurl 2014	*Higher income → higher odds for OTC spending. No significant effect of income on OTC/Rx OOP expenditure or odds for Rx spending.*	Household structure, urbanity, age, education, income, insurance, gender (of householder), early retirement status, doctoral visits
Searles et al. 2013	31% with the lowest income vs. 19% with the highest income reported moderate to extreme burden with Rx OOP costs (p = 0.03). No significant difference in reporting moderate to extreme burden between concession card-holders vs. general patients. Patients who reported high financial burden spent more OOP and were more likely to report cost-saving behaviours.	None
Terraneo et al. 2014	*Higher income → higher expenditure on medicines and consumption more elastic in response to changes in cost sharing. For the poorest families, OOP spending remained at fairly constant. Just above the poorest (deciles II–III) cut their spending most in response to increased cost sharing.* Poor families (consumption below 60% of the median equivalised expenditure) vs. higher income families → Lower absolute spending but larger share (approximately 1% more) of overall spending.	Year, region, gender, age, presence of family members aged ≥ 75 years or ≤ 6 years, family size.
Xu 2003	Decreasing income coincided with increasing OOP Rx costs and burden except among the older population, the poorest had the lowest OOP costs but the highest OOP burden.	None

Abbreviations: OOP = out-of-pocket, Rx = prescription, OTC = over-the-counter, FPL = Federal poverty level, LIS = low income support, VA = Veterans Affairs, (I)ADL = (Instrumental) activities of daily living, CIRS-G = Cumulative Illness Rating Scale for Geriatrics.

Smaller scale regressive effects also existed among universally insured populations. The likely explanations were that the exemptions and reduced co-payment policies were not generous enough to entirely compensate for the regressive effects, or comprehensive enough to reach all people in need, or that all necessary medicines were not adequately covered. In Australia, 31% of people with the lowest income vs. 19% of those with the highest income reported a moderate to extreme burden from out-of-pocket costs, while patients with concession cards reported a high burden at a similar rate to the general patients (Searles et al. 2013). Low-income cardholders had higher relative costs than low-income non-cardholders, which was likely to be due to lowered co-payments being off-set by higher utilisation (Jones et al. 2008). In Italy, when compared with other families, low-income families spent approximately 1% more of their total spending on medicines (Terraneo et al. 2014). In Germany, no information was available for medicines but the mean out-of-pocket cost to income ratio was 3% for overall health care in the older population. The lowest income quintile experienced a higher burden than the highest income quintile, despite the presence of an income-dependent annual ceiling (Bock et al. 2014).

Terraneo et al. (2014) found that the spending on medicines of high-income families was more elastic in response to changes in cost-sharing. For the families with the lowest income (the lowest decile), spending remained at a fairly constant level in 2001–2010, apparently due to exemption policies. However, those just above the lowest income level (deciles 2–3) cut their spending most in response to increased cost-sharing. These results suggest that low-income people who are just above the exemption thresholds may end up bearing the highest burden and are, therefore, most vulnerable to the negative effects of cost-sharing. On the other hand, these effects may be due to the higher-income groups limiting the use of discretionary or less necessary medicines. Also in Canada, Sanmartin et al. (2014) suggested that the second-lowest income quintile was at the highest risk, as a result of the highest out-of-pocket costs, and possibly not being eligible for public insurance programs.

Only studies from the US explored ethnic/racial disparities in costs and medicine use (Table 5, p. 49). Several studies reported significant discrepancies in terms of at least one indicator of medicine use or costs, when racial/ethnic/immigrant minorities were compared to their Caucasian/white/US-born counterparts (Poisal et al. 1999; Briesacher et al. 2003; Sambamoorthi et al. 2003; 2005; Xu and Borders 2007; Chen et al. 2010; Chen 2013; Mahmoudi and Jensen 2014). Since ethnic/racial/immigrated population groups also differed from their counterparts and each other by most characteristics (e.g. age, income, education, health status, insurance), several studies, with various methods, assessed the effect of these underlying factors on the observed disparities (Briesacher et al. 2003; Gaskin et al. 2006; Neuman et al. 2007; Xu and Borders 2007; Chen et al. 2010; Chen 2013). Four studies (Gaskin et al. 2006; Chen et al. 2010; Chen 2013; Mahmoudi and Jensen 2014) were based on Andersen's Behavioral Model, according to which health service use is a function of enabling and impeding factors, predisposition to use services and need for care (Andersen 1968; 1995, see also chapter 2.5). Decomposition (Oaxaca-Blinder) techniques were used to determine the extent to which the disparities were attributed to the unobserved factors associated with race/ethnicity/immigration (Gaskin et al. 2006; Chen et al. 2010 Chen 2013). One study assessed underlying differences in health, insurance generosity and utilisation patterns (Xu and Borders 2007).

Observed predisposing, enabling and health related factors did not seem to fully explain the higher use or total costs for medicines among Caucasian/white/US-born individuals (Briesacher et al. 2003; Gaskin et al. 2006; Chen et al. 2010; Chen 2013; Mahmoudi and Jensen 2014) (Table 5). One study suggested that the higher spending observed among white in contrast to African Americans could be even larger if population characteristics were the same (Gaskin et al. 2006). The observed factors seemed, however, to explain the majority of ethnic/racial disparities in out-of-pocket costs and share (Gaskin et al. 2006), and in out-of-pocket cost burden (Sambamoorthi et al. 2003; 2005). Accordingly, further controlling for insurance generosity and prescription medicine use eliminated significant disparities in out-of-pocket costs and share (Xu and Borders 2007).

Table 5. Results related to the effects of ethnicity/race on out-of-pocket costs.

Study	Key findings (multivariate findings in italics)	Confounders controlled for in multivariate analyses
Briesacher et al. 2003	African American/Hispanic vs. white → more often public Rx coverage (e.g. Medicaid) and less often employer sponsored Rx coverage. *African American vs. white with similar types of coverage: No consistent significant differences in OOP costs, except among diabetics with no Rx coverage → lower OOP costs. Lower odds to use antidiabetic medicines with any type of or no Rx coverage. Otherwise few significant differences in overall use or total costs. Hispanic vs. white with similar types of coverage: Mostly lower OOP, especially with Medicaid together with any condition and heart disease together with any type of Rx coverage. Mostly no significant differences in odds to use condition-specific medications, although tendency for lower overall medicine use and total costs.*	Age, gender, income, self-rated health, number of comorbidities. Stratified by Rx insurance coverage type
Chen 2013	*Citizenship: Non-US citizens with ≤ 10 yrs of residence vs. US-born → lower odds to use any Rx. Other immigrants no significant difference vs. US-born in odds to use any Rx. All immigrants vs. US-born → lower total costs. Non-citizens vs. US-born → higher OOP share. Ethnicity: African American/Hispanic/Asian vs. whites → lower odds to use any Rx (the lowest Asians OR 0.6) and lower total costs if any use. No significant difference in OOP share.* *Major significant factors affecting disparities in total costs between US-born and immigrants: Ethnicity and English language, for naturalised citizens and non-US citizens with ≤ 10 yrs of residence also age and health status, for non-US citizens with > 10yrs of residence also education ; in OOP share: US-born vs. naturalised US-citizens → no significant difference; US-born vs. non-citizens → insurance and having usual source of care. Medicaid negatively associated (disparities would be larger without Medicaid).*	Age, gender, marital status, Ethnicity/race, citizenship, self-rated health & mental health, SF-12 PCS&MCS, existence of 7 pre-defined illnesses (e.g. diabetes, hypertension, depression), education, income, having usual source of care (USC), insurance type, employment status, English language, urbanity, region, year.
Chen et al. 2010	*All Latino subgroups vs. whites → less likely to use any Rx and lower total costs (except Cubans no significant difference vs. whites in total costs). Mexicans or other Latinos vs. whites → higher OOP share, Cubans and Central or South American vs. whites → No significant difference in OOP share, Puerto Ricans vs. whites → lower OOP share.* *Major significant factors affecting disparities in medicine use: All subgroups except Puerto Ricans: access to health care, English proficiency, insurance. Puerto Ricans, insurance and having USC; in total costs: All Latino subgroups: Age, citizenship, having USC (except Puerto Ricans); and in OOP share: Puerto Ricans lower predicted share vs. whites, other Latino subgroups higher predicted share vs. whites.* Differences also found in the tendency to use generic medicines (Mexicans the highest share).	Age, gender, marital status, citizenship, education, family income, employment status, self-rated health, IADL&ADL, insurance, having usual source of care (USC), language, area, study year.

Table 5 continued.

Study	Key findings (multivariate findings in italics)	Confounders controlled for in multivariate analyses
Gaskin et al. 2006	*White vs. African American → higher total costs, no difference in OOP, higher N of Rx. White vs. Hispanic → higher total and OOP costs, higher N of Rx. Most of the observed disparities in use not explained by population characteristics, however a substantial proportion of OOP cost disparities was explained.*	Ethnicity, age, gender, marital status, insurance, poverty, education, urbanity, area, self-assessed health, N of ADL&IADL, N of chronic conditions.
Goulding 2005	African Americans vs. white: higher N of Rx, lower OOP Rx costs, no significant difference in total Rx costs.	None
Mahmoudi and Jensen 2014	*Overall: Before and after Part D, in both age groups, African American/Hispanic individuals vs. white were less likely to fill any Rx, filled fewer Rx, had lower total and OOP costs. ≥ 65 + yr-old African American/Hispanic had lower OOP share than white; 55–64 yr-old African American/Hispanic had higher OOP share than white.* *After Part D (2006–2009) vs. before (2002–2005): Use increased, OOP costs and OOP share decreased for all ≥ 65 + year-olds, but effects on disparities were mixed: African American vs. white → net disparity in total costs increased, no significant change in disparity in other measures. Hispanic vs. white → disparities decreased in total and OOP costs (nearly significant in N or Rx). No significant effect on disparities in other utilisation and spending measures.*	Age, gender, marital status, education, income, insurance, area, language, self-rated health and mental health, SF-12 PCS&MCS, existence of 5 pre-specific chronic illnesses (e.g. asthma, arthritis, diabetes), N of functional limitations.
Mojtabai and Olfson 2003	No significant differences in the likelihood of taking Rx medicines. White vs. African American vs. Hispanic → higher OOP Rx spending if any (descriptive).	None
Neuman et al. 2007	African American and Hispanics vs. white → more likely to have Part D but less likely to have employer sponsored Rx coverage.	None
Poisal et al. 1999	African American/other vs. white → more likely to have Rx coverage (59%/75% vs. 64%) due to higher share with Medicaid. White: The highest total Rx costs and OOP Rx costs; African American: The second highest total Rx costs, the lowest Rx OOP costs and OOP share; Other ethnicity: The lowest total Rx costs, the highest OOP share.	None
Sambamoorthi et al. 2003	*African American/other vs. white → no significant difference in odds to use any Rx, lower total and OOP Rx costs, no significant difference in odds for high (≥ 10% of income) OOP burden.*	Gender, age, race, education, marital status, income (≤ 200% / > 200% FPL), education, insurance, urbanity, area, self-rated health, ADL&IADL, N of chronic conditions.

Table 5 continued.

Study	Key findings (multivariate findings in italics)	Confounders controlled for in multivariate analyses
Sambamoorthi et al. 2005	Between 1992 and 2000: White had the highest OOP Rx costs, African Americans the second highest OOP Rx costs and the fastest growth in OOP Rx costs, Hispanic/other had the lowest OOP costs, the slowest growth in OOP Rx costs. High (> 10% of income) OOP burden affected annually 7–11% of white, 7–13% of African American, 6–16% of Hispanic and 4–10% of other individuals. *Hispanic vs. white → significantly lower OOP costs and higher odds of high OOP burden, no significant difference between African American and white.*	Gender, race/ethnicity (white/African American/Hispanic/other), age, marital status, education, urbanity, insurance, self-rated health, year. Poverty included in other analyses except OOP cost burden.
Xu and Borders 2007	Ethnic minorities less likely than white to use Rx but when they did, they had lower OOP share. Hispanics had significantly lower OOP costs than white, between African Americans and white no significant difference. *Need- or utilisation-adjusted models: After controlling for health status, health care utilisation, insurance generosity for other health care and/or prescription medicine utilisation, no significant differences in OOP costs or share were found between African American/ Hispanic vs. white. Variables that had greatest effect in the models were insurance-related.*	Control variables: Ethnicity/race, area, age, gender, education, income, insurance, health care total costs and OOP costs excl. Rx. Need-adjusted model: Control variables and specific chronic conditions, SF-12 PCS&MCS. Utilisation-adjusted model: Control variables and N of medicines, average N of refills / Rx, average quantity / Rx.

Abbreviations: OOP = out-of-pocket, Rx = prescription, OTC = over-the-counter, FPL = Federal poverty level, LIS = low income support, (I)ADL = (Instrumental) activities of daily living, SF-12 = 12-Item Short Form Health Survey, PCS&MCS = Correlated physical health and mental health.

The effects of ethnicity/race and immigration status were interrelated, e.g. the lack of insurance coverage and language barriers affected especially non-US citizens, of whom the majority were Hispanic (Chen 2013) (Table 5, p. 49). In part, associated factors were also offsetting (e.g. lower share of minority populations with (private) insurance but higher share with Medicaid), which diluted overall effects (Poisal et al. 1999; Briesacher et al. 2003; Gaskin et al. 2006; Neuman et al. 2007; Chen et al. 2010). The findings also varied between studied ethnic/racial groups and subgroups (Poisal et al. 1999; Sambamoorthi et al. 2005; Chen et al. 2010; Chen 2013). Increased insurance coverage did not necessarily lead to decreasing disparities between ethnic/racial groups. Implementation of prescription coverage to older population (Medicare Part D) increased spending and use for all, but the increases were larger for whites than for African Americans, which resulted in increasing disparities (Mahmoudi and Jensen 2014) (Table 5). Similar results have been found for health care services (Borrell et al. 2006; Korda et al. 2007).

Table 6. Results related to the effects of gender on out-of-pocket costs.

Study	Key findings (*multivariate findings in italics*)	*Confounders controlled for in multivariate analyses*
Bock et al. 2014	*No independent significant effect between education and OOP costs for medicines or total health care, or between education and OOP costs to income -ratio.*	Gender, age, education, health, marital status, insurance, CIRS-G
Goulding 2005	Females significantly higher use, total costs and OOP costs.	None
Mojtabai and Olfson 2003	Females significantly higher proportion with any Rx. Also higher OOP if any use (descriptive).	None
Poisal et al. 1999	Females vs. males → slightly lower share with Rx coverage (64% vs. 66%), higher total Rx costs, higher OOP costs.	None
Sambamoorthi et al. 2003	*Females vs males → higher odds to use any Rx (OR 1.7), higher total and OOP Rx costs, higher odds for high (≥ 10% of income) OOP burden (OR 1.7).*	Gender, age, race, education, marital status, income (≤ 200% / > 200% FPL), education, insurance, urbanity, area, self-rated health, ADL&IADL, N of chronic conditions.
Sambamoorthi et al. 2005	*Females vs. males → higher OOP Rx costs and higher odds for high (≥ 10% of income) OOP burden.* High burden affected annually 8–12% of women and 6–9% of men.	Gender, race/ethnicity (white/African American/Hispanic/other), age, marital status, education, urbanity, insurance, self-rated health, year. Poverty included in other analyses except OOP cost burden.
Sanwald and Theurl 2014	*Female householder increased the odds of OTC purchases, no effect on odds of Rx purchases or on OOP Rx/ OTC costs.*	Household structure, urbanity, age, education, income, insurance, gender (of householder), early retirement status, doctoral visits
Searles et al. 2013	No significant gender differences in reporting moderate to extreme financial burden with OOP Rx costs.	None
Steinberg et al. 2000	Female vs. male → higher proportion with any Rx/OOP Rx costs, higher Rx and OOP Rx costs. Similar findings across the cost distribution, except among top 1% spenders men had higher total expenditures.	None
Wei et al. 2006	Female vs. male → higher N of prescriptions (22 vs. 18 / yr) → 20% higher OOP Rx costs and higher burden (4.4% vs. 3.2% of income). *Direction and significance of impacts of explanatory variables on OOP Rx costs and burden similar for both genders. According to model 2, the increase in OOP cost per additional Rx was lower for women but the increase in OOP burden was higher. Major factors explaining gender gap in OOP costs were higher Rx use and chronic conditions; and in OOP burden also poverty, whereas Medicaid narrowed the gap.*	Stratified by gender. Adjusted by race/ethnicity, age, marital status, education, urbanity, poverty, insurance, IADL&ADL, self-rated health, N of chronic conditions, year. Model 2 also N of Rx / yr.

Abbreviations: OOP = out-of-pocket, Rx = prescription, OTC = over-the-counter, FPL = Federal poverty level, LIS = low income support, (I)ADL = (Instrumental) activities of daily living, SF-12 = 12-Item Short Form Health Survey, PCS&MCS = Correlated physical health and mental health, CIRS-G = Cumulative Illness Rating Scale for Geriatrics.

Table 7. Results related to the effects of education on out-of-pocket costs.

Study	Key findings (multivariate findings in italics)	Confounders controlled for in multivariate analyses
Bock et al. 2014	*No independent significant effect between gender and OOP costs for medicines or total health care, or between gender and OOP costs to income -ratio.*	Gender, age, education, health, marital status, insurance, CIRS-G
Mojtabai and Olfson 2003	Lower education → lower OOP costs if any (descriptive). No significant differences in the proportion with any Rx use.	None
Sambamoorthi et al. 2003	*More years of education → increased odds to buy any Rx, higher total and OOP Rx costs. No independent effect on odds for high OOP burden after adjusting for income.*	Gender, age, race, education, marital status, income (≤ 200% / > 200% FPL), education, insurance, urbanity, area, self-rated health, ADL&IADL, N of chronic conditions.
Sambamoorthi et al. 2005	*Higher education → higher OOP Rx costs but lower odds for high (≥10% of income) OOP burden.*	Gender, race/ethnicity (white/African American/Hispanic/other), age, marital status, education, urbanity, insurance, self-rated health, year. Poverty included in other analyses except OOP cost burden.
Sanwald and Theurl 2014	*Higher education → higher odds of OTC purchases. No independent effect on OOP OTC/Rx costs or odds of Rx purchases.*	Household structure, urbanity, age, education, income, insurance, gender (of householder), early retirement status, doctoral visits

Abbreviations: OOP = out-of-pocket, Rx = prescription, OTC = over-the-counter, FPL = Federal poverty level, LIS = low income support, (I)ADL = (Instrumental) activities of daily living, SF-12 = 12-Item Short Form Health Survey, PCS&MCS = Correlated physical health and mental health, CIRS-G = Cumulative Illness Rating Scale for Geriatrics.

Female gender was associated with higher medicine use in the US and Austria (Steinberg et al. 2000; Sambamoorthi et al. 2003; 2005; Wei et al. 2006; Sanwald and Theurl 2014) (Table 6, p. 52). This is in line with the known association of female gender and higher use of health-services (e.g. Mustard et al. 1998; Bertakis et al. 2000; Redondo-Sendino et al. 2006). However, higher use seemed to lead to higher out-of-pocket costs and/or cost burden only in the US (Sambamoorthi et al. 2003; 2005; Wei et al. 2006). The major factor contributing to the difference in out-of-pocket cost burden between genders in the US was poverty (Wei et al. 2006). No significant gender difference in out-of-pocket costs for medicines was observed in Germany or Austria (Bock et al. 2014; Sanwald and Theurl 2014) or in burden from out-of-pocket costs in Australia (Searles et al. 2013).

Only five studies included relevant results regarding education and cost-sharing (Table 7). In Austria, higher education had an independent increasing effect on the probability of using OTC-medicines but no independent effect on out-of-pocket

costs or on the probability of using prescription medicines, which was similar to the findings from Germany (Bock et al. 2014; Sanwald and Theurl 2014). In the US, a higher number of years of education was associated with higher odds of using any prescription medicines and higher total costs among older people, even after adjusting for income (Sambamoorthi et al. 2003; 2005). The effect of education on high out-of-pocket cost burden, however, did not seem to be independent from the effects of income (Sambamoorthi et al. 2003).

In summary, most published literature regarding the distribution of out-of-pocket costs derived from the US and was focused on older individuals. Varied methods and outcomes limited the comparability of results across studies. The overall patterns observed in different studies were, however largely consistent. In studies where relative costs were assessed, user charges seemed to have regressive effects even among insured populations, and despite concession mechanisms. More than one of the studies from different systems identified those just above the thresholds for low-income support systems as most vulnerable for the negative effects of cost-sharing. Nevertheless, the income-related differences were much larger in the US and Canada, where only the part of the population are eligible to public programmes, than in countries with universal coverage. Further, gender or education related differences in cost burden were only observed in studies from the USA. Ethnic differences were only studied in the US, where ethnicity-related differences in out-of-pocket costs were associated with insurance generosity and differences in use patterns. However, the differences in use were not fully explained by the observed predisposing, enabling and health related factors.

2.7.2 Access barriers, foregone care and unmet needs

Forgone care and unmet health needs are commonly used measures of health care access in national and cross-national health surveys (de Looper and Lafortune 2009; Moreno-Serra et al. 2012). Depending on the survey, the questions may include unmet needs for any reason, or address reasons for unmet needs by a follow-up question or focus specifically on e.g. cost-related or availability related unmet needs. Cross-national continuously collected surveys with questions related to unmet needs include the Survey on Health, Ageing and Retirement in Europe (SHARE), the EU Survey of Income and Living Conditions (EU-SILC) and the Commonwealth Fund International Health Policy Surveys (CWF IHPS). SHARE includes a question on cost and availability-related access barriers during the past 12 months, and distinguishes the types of care e.g. physician, medicine, dental (Allin and Masseria 2009b; SHARE 2016).

EU-SILC assesses unmet need for medical examination or treatment during the past 12 months due to multiple causes including cost, availability and fear (Hernández-Quevedo and Papanicolas 2012). CWF IHPS focus on experiences with health care systems, especially accessing and affording care (Schoen et al. 2010; Hernández-

Quevedo and Papanicolas 2012). Recently, a module on the social determinants of health was included in the European Social Survey (ESS) Round 7 collected in 2014. This module contained questions on unmet need for medical consultation or treatment for multiple reasons including cost, availability, waiting-list, and inability to take time off work. (Eikemo et al. 2016; ESS 2016.)

EU-SILC aims to collect cross-sectional and longitudinal data on income, poverty, social exclusion and living conditions. The first survey in 2003 included six EU member states and the 2011 survey included all EU27-countries, Croatia, Iceland, Turkey, Norway and Switzerland (Eurostat 2016a). According to EU-SILC 2013, the lowest shares of unmet needs for medical examination due to cost, being too far to travel or waiting list were reported in the Netherlands, Austria and Spain (Eurostat 2016b; Figure 3). Countries with the lowest share of cost-related unmet needs were the UK, the Netherlands, Norway, Denmark and Finland. Finland, the UK and Estonia stood out for relatively low share of cost-related unmet needs in comparison to unmet needs for other causes. The variation between countries was large but unmet needs were consistently more common among low- than high-income respondents (OECD 2015b).

Figure 3. Self-reported unmet need for medical examination due to cost (grey bar) or due to cost, waiting list or travel distance (red bar) based on EU-SILC 2013.[a]
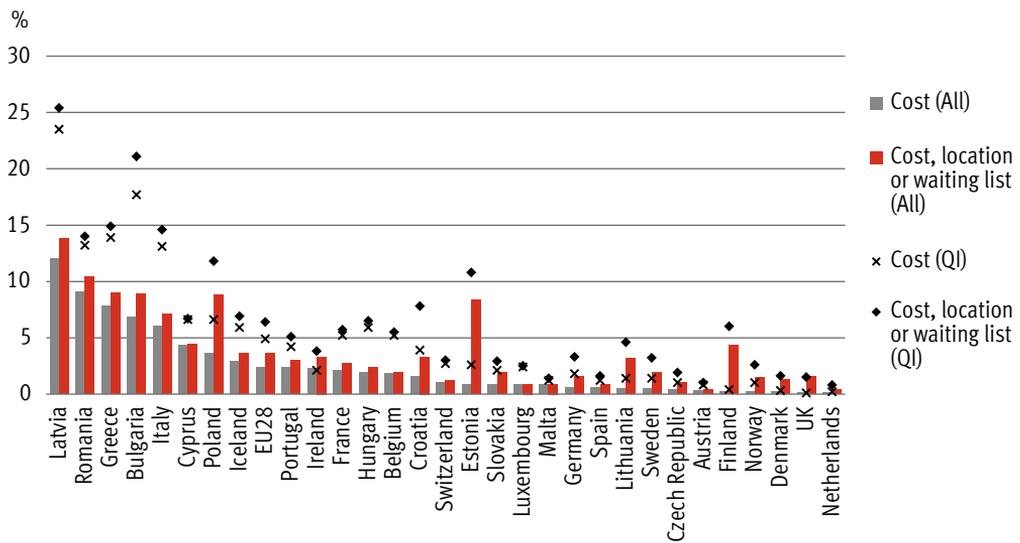
[a] Results for respondents in the first quintile of equivalised income (QI) are included above the respective bars. Countries with complete data for 2013 are included.
Source: Authors representation based on EU-SILC 2013 online data (Eurostat 2016b).

The Commonwealth Fund and its partners have conducted international surveys of health care system performance since 1998, first in five English-speaking countries: Australia, Canada, New Zealand, the UK and the US. Germany was included in 2005, the Netherlands in 2006, France in 2008, Norway, Sweden and Italy (not included in later years) in 2009 and Switzerland in 2010. Surveys included a general sample of adults in 1998, 2001, 2004, 2007, 2010, 2013; a sample of older adults in 1999 and 2014 and a sample of adults with health problems/high health needs in 2002, 2005, 2008 and 2011. Surveys targeted to physicians were conducted in 2000, 2006, 2009, 2012 and 2015, and to hospital executives in 2003. (Commonwealth Fund 2016.)

According to The Commonwealth Fund surveys to the general adult population in 2007, 2010 and 2013, cost-related barriers were consistently more frequent in the US and less frequent in the UK than in the other surveyed countries (Figure 4). Sweden and Norway had low rates of cost-related barriers, together with the Netherlands with the exception of the 2013 survey, presumably due to increases in cost-sharing (Schoen et al. 2013). Australia, Canada and New Zealand tended to fall between the US and European countries. In New Zealand, access barriers seem to decrease over time, especially when compared to earlier studies conducted in 2001 and 2004, which is likely to be due to primary care payment reforms (Schoen et al. 2010).

Figure 4. Self-reported cost-related access problems based on the Commonwealth Fund (CWF) 2007, 2011 and 2013 International Health Policy Surveys of the general adult population and 2011 International Health Policy Survey of Sicker Adults.
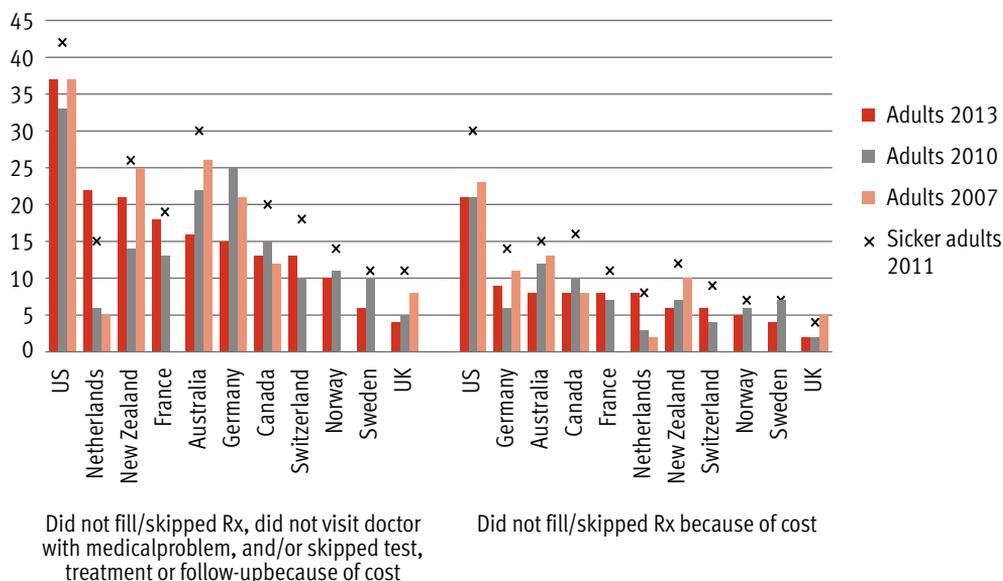
Abbreviation: Rx = Prescription.

Source: Authors representation based on published results of the Commonwealth Fund survey (Schoen and Osborn 2011; Schoen et al. 2007a; 2007b; 2013; Commonwealth Fund 2010b).

Based on the Commonwealth Fund surveys, respondents from countries with low cost-sharing tended to report lower frequencies of cost-related access barriers (Schoen et al. 2007b; 2010; 2011; 2013). Respondents from the US were most likely to report spending over $1,000 during the past year out-of-pocket on medical care, whereas respondents from Sweden, the UK, France, the Netherlands and New Zealand were least likely to report spendings that high (Schoen et al. 2013). Switzerland and Australia had lower rates of cost-related barriers despite high out-of-pocket costs. This is presumably due to ceilings and exemption policies (Schoen et al. 2010; 2013). These findings largely persisted in surveys targeted to older adults and "sicker" adults (Schoen et al. 2009a; 2011; Osborn et al. 2014) and when questions of affordability were targeted to general practitioners (Schoen et al. 2009b; 2012).

The systems in different countries seemed to vary in how they protected patients with high needs and/or low incomes. In France, Germany, the Netherlands, Norway, New Zealand and the UK, respondents with a chronical illness (asthma or chronic lung problems, cancer, diabetes or heart disease) were not significantly more likely to report access problems than people without these conditions, whereas in Australia, Canada, Sweden, Switzerland and the US, access barriers were significantly more common among chronically ill patients than other adults (Schoen et al. 2013). In surveys targeted to "sicker" adults, the lowest out-of-pocket expenditures were reported in the UK, Sweden and France, and the lowest frequency of access barriers in the UK, Sweden and Norway (Schoen et al. 2011). In comparisons adjusted by age and health status, below-average income respondents were more likely to report access barriers than above-average income respondents in all countries except the UK (Schoen et al. 2010).

Generally, people who report unmet need or forgone care tend to have worse health and a lower income or socioeconomic position. Other factors that have been associated with unmet needs are female gender, lack of insurance coverage and belonging to an ethnic/racial minority or immigrant group. (Mielck et al. 2007; 2009; Allin and Masseria 2009a; 2009b; Allin et al. 2010; Bryant et al. 2009; de Looper and Lafortune 2009; Litwin and Sapir 2009; Israel 2016.) However, unmet needs derive from a variety of reasons with different impacts on equity and utilisation. Overall, in Europe, individuals with unmet needs due to any cause have been found to use more services and spend more out-of-pocket than expected based on observed need-related factors (Allin and Masseria 2009a; 2009b). More specifically, based on a Canadian study, unmet needs related to waiting times have been associated with higher health care service use, and higher education, whereas unmet needs due to barriers (e.g. costs) have been associated with lower service use and lower income. Also unmet needs for personal reasons (e.g. dislike, personal choice, too busy) seem to coincide with low service use. (Allin et al. 2010.)

Factors that increase the tendency to seek care, specifically education and labour force participation, can also influence the extent to which unmet needs are perceived and unperceived (Allin et al. 2010; van Doorslaer et al. 2004). These variables are especially of interest in explaining unmet needs with a structural-critical approach, where the focus is on the distribution of economic and social resources and how they shape the opportunities provided by society. Other approaches include social capital and social support approaches, with focus on coping and opportunities shaped by community and individual factors, and a more narrow lifestyle approach, with focus on personal factors and choices (Bryant et al. 2009). Social and cultural differences may also exist across countries in reporting unmet needs, e.g. due to differences in expectations and experiences (Allin and Masseria 2009b). Across-country differences in the level of unmet needs may be influenced by differences in income level and inequalities (Mielck et al. 2007).

Suggested factors that influence cost-related underuse of *medicines* include system-related factors (e.g. barriers to refilling prescriptions or applying for benefits, prescriber incentives), financial pressures (e.g. income, insurance), patient characteristics (e.g. sociocultural, health, perceived treatment benefits, health literacy), clinician-related factors (e.g. knowledge of costs, understanding and discussion about prescription costs and adherence), treatment related factors (e.g. regimen complexity, adverse effects, perceived need) and diagnosis-related factors (e.g.quality of life and life expectancy). (Piette et al. 2006.) Robust risk factors for cost-related non-adherence identified in the literature mainly deriving from the US include low income, lack of or inadequate insurance coverage, high cost-sharing, disease burden and poor health (mental or physical or poor health habits) and younger age. Mixed results have been found for gender, education and race/ethnicity, after controlling for income and insurance. Some evidence was found to support the association of perceived risks or benefits of treatment and good physician-patient relationship on protecting from cost-related non-adherence. No evidence was found on the association of polypharmacy and no clear patterns were observed in regards essential and non-essential medicines. (Briesacher et al. 2007.)

Patients vary in their response to cost-sharing for medicines. Besides restricting use (stop taking, split pills, delay refills, skip doses, avoid prescription), patients may use other coping strategies to manage costs, e.g. seek the best price or free samples, request generics, increase debt, import or cut back on basic needs. (Piette et al. 2006; Briesacher et al. 2007.) In the US, female gender, older age and minority race/ethnicity were associated with the likelihood to cut back necessities as a coping strategy, minority race/ethnicity also with the likelihood of increasing debt. Low income, oldest age and high out-of-pocket costs were associated with all assessed coping strategies: cutting necessities, increasing debt and restricting use. No independent associations were found for education and number of medicines used. (Heisler et al. 2005.) Of note, socioeconomic disadvantage has also been associated with poor adherence

and primary non-adherence (due to any cause) to medicines (e.g. DiMatteo 2004; Wamala et al. 2007; Kardas et al. 2013).

In a comparative analysis of the US, Canada, Germany, the UK, the Netherlands, Australia and New Zealand, medicine underuse due to cost was most frequent in the countries with higher out-of-pocket costs and least frequent in countries with low out-of-pocket costs. The US (median out-of-pocket costs $300) and Australia ($140) had the highest proportion of non-adherence while the Netherlands ($0) and the UK ($0) had the lowest. High out-of-pocket costs and low income were significantly associated with non-adherence in all countries except Germany. Also in the Netherlands the association was not consistent. The results from Germany may be influenced by the income-based annual ceiling. Higher education increased the odds for non-adherence in Germany but the effect of education was not significant in other countries. Insurance was only assessed in the US and Canada, where public insurance only or no insurance increased odds for non-adherence. Female gender was associated with higher odds for non-adherence only in the US. Ethnic minorities had higher odds for non-adherence in Australia, Canada, the Netherlands and New Zealand but not in the US (not assessed in Germany and the UK). Younger age (18−64 vs. 65 +) was associated with higher odds in all countries except Germany and the Netherlands. Diagnosed depression increased the odds significantly in all countries except Australia and the UK, other diagnosed chronic conditions only in the Netherlands. Poor health status increased the odds in Australia, Canada and the US. Involvement with treatment decisions decreased odds in all countries except the Netherlands and New Zealand. (Kemp et al. 2010.)

In summary, cost-related barriers to care and medicines were reported in all countries, and they were nearly always more frequent among individuals with lower incomes. Countries differed in how the experiences of patients with high health needs differed from the experiences of the general population. Worse health and lower income were robust risk factors for cost-related access-barriers. Depending on the system, other important associated factors were insurance coverage and high out-of-pocket costs. Mixed results were found for age, female gender and ethnicity/race, as well as factors related to prescriber and attitudes towards the treatment.

3 Aims of the study

The overall purpose of this study was to examine and compare the features of pharmaceutical systems in Finland and New Zealand and assess how they translate into affordability-related outcomes: distribution of out-of-pocket costs and cost-related access-barriers. The system features of interest in this study are those related to access, operationalised by using adapted indicators of de-commodification: conditions, disincentives, benefit level and universality. The comparative analysis is based on literature, international statistics and four sub-studies presented in this thesis. The aims of the sub-studies were to shed light on specific dimensions of affordability of which limited information was available in the published literature.

The comparative method, especially when a case-oriented approach is taken, aims to investigate situations as wholes, by determining a combination of conditions associated with specific outcomes or processes, and by examining similarities and differences (Ragin 1987, 14–16; Kangas 1994). In the case-oriented approach, the focus is on understanding the dynamics of a few cases, which are selected because of their significance to the research question. Case-oriented studies benefit from using methodological triangulation and typically the data is derived from various sources. (Cacace et al. 2013.) When directly comparable data is not available from different countries, country-level associations can be compared to identify similarities and differences in the patterns observed in countries with different systems (Kangas and Hussain 2014).

Methodologically, the purpose was to examine the usability of different data sources in measuring dimensions of availability and affordability of medicines.

The more specific aims of the sub-studies were as follows:

a) Examine the distribution of out-of-pocket costs by income in Finland (Study I)
b) Examine the distribution of out-of-pocket costs by socioeconomic deprivation and ethnicity in New Zealand (Study II).
c) Assess cost-related access barriers to prescription medicines and health care in Finland (Study III).
d) Compare the range of medicines available and reimbursed in Finland and New Zealand (Study IV).

4 Materials and methods

The present thesis comprises four sub-studies summarised in Table 8.

Table 8. Design and methods of publications (studies I–IV refers to original publications) presented in this doctoral thesis.

Study	Countries	Aims	Design	Data	Time	Population
I	Finland	To examine out-of-pocket costs for medicines in Finland	Cross-sectional time series	Household Budget Survey	1985, 1990, 1995, 2001, 2006	Finnish household population
II	New Zealand	To explore out-of-pocket costs for medicines among older people in New Zealand	Cross-sectional register	Community pharmacy dispensing data	2005–2006	65 years and older population with prescription purchases in Te Tairāwhiti region
III	Finland	To examine cost-related barriers to using health services and prescription medicines in Finland	Cross-sectional postal survey	Population based postal survey	2010	Community dwelling Finnish citizens aged 18–74
IV	Finland and New Zealand	To compare the range of available and reimbursed medicines in Finland and New Zealand	Cross-sectional observational	Product information sources	2007	Product level examination

4.1 Settings

4.1.1 Finland and New Zealand – population and population health

Finland and New Zealand are high-income OECD countries (Appendix). They are similar in geographical and population size and in population density. The population of New Zealand is slightly younger and ethnically more diverse than Finnish population. Between 2002–2009 the GDP per capita in Finland was higher, and in New Zealand lower, than the average of the European Union or high-income OECD countries. Between 2010–2014, the GDP per capita in New Zealand exceeded the average of EU or OECD high-income countries, due to more rapid growth (The World Bank 2016). Income inequality and poverty rates are slightly higher in New Zealand than in Finland.

In Finland and New Zealand, life expectancy at birth was approximately 81 years in 2013, and both countries rate above the OECD average (80.5 years) (OECD 2015b). Finland has one of the lowest infant and maternal mortality rates in the OECD, together with other Nordic countries and Japan. New Zealand, ranks at the higher end, together with Eastern European countries and the United States. By potential life

years lost (PYLL) due to any cause of death, both Finland and New Zealand are close to the OECD average (Appendix). New Zealanders have more potential years of life lost due to neoplasms, endocrine, nutritional and metabolic diseases and diseases of respiratory system, whereas Finns have more potential years of life lost due to mental and behavioural diseases and diseases of the circulatory system. Smoking rates have decreased below the OECD average between 2000 and 2012 in both countries (17% in both countries vs. 21% OECD average) while obesity rates have increased. Among the 16 OECD countries with measured data, the mean obesity rate was 22.7%. Finland ranked the 13th highest with 20.2% obesity rate and New Zealand the 4th highest with 28.4% obesity rate (OECD 2014a; 2014b).

Both countries are characterised by relatively high health inequalities. In New Zealand, indigenous Māori (15% of the population) have a lower life expectancy, higher mortality and poorer health outcomes than New Zealanders of European descent (Bramley et al. 2005; Elley et al. 2008; Kenealy et al. 2008; Robinson et al. 2016). In Finland, studies have shown an increasing trend in relative excess mortality among the lowest income groups (Tarkiainen et al. 2013).

By self-reported health status, Finland and New Zealand have notable response pattern differences. In New Zealand, 94% of the highest income adults and 87% of the lowest income adults reported being in good or very good health in 2013. In Finland, the respective shares were 77% and 49%. (OECD 2015b.)

4.1.2 Health care systems in Finland and New Zealand

The institutional setting of the health care systems in Finland and New Zealand bring them closest to the National Health Service (Beveridge) model, although both systems have traces of other models (Häkkinen and Lehto 2005; Blank and Bureau 2014, 97). Finland and New Zealand also have similarities in their health political culture, both are traditionally characterised by egalitarianism rather than communitarianism or individualism (Blank and Burau 2014, 50–54). Both countries are characterised by universal coverage and the main source of health care funding is general taxation (Häkkinen and Lehto 2005; Blank and Bureau 2014, 97). The majority of services are also publicly provided, although in New Zealand, the primary care services have traditionally been provided by private practitioners and, until recently, these services been subject to particularly high patient payments (Hefford et al. 2005; Häkkinen and Lehto 2005; Cumming et al. 2014, 117). The Finnish system has a Bismarckian element: a small part of services, including reimbursement for medicines, are funded via National Health Insurance (Häkkinen and Lehto 2005). The development of the Finnish system has been gradual and characterised by layering and institutional path dependency whereas the system in New Zealand has gone through several larger structural reforms (French et al. 2001, 105; Häkkinen and Lehto 2005; Mattila 2011, 342).

Development

A national department of health was set up in New Zealand in 1900, and in 1938, New Zealand became the first country to introduce tax-funded National Health Service (NHS) with universal coverage (WHO 2000, 12; French et al. 2001, 23). By the end of 1940s, most services were provided free of charge, including hospital services and medicines. Practitioners remained independent, and were remunerated on fee-for-service basis, although they also had the right to charge fees from patients. (French et al. 2001, 23.) The centrally funded and managed system was gradually decentralised during the 1970s and 1980s, first by increasing the autonomy of Hospital Boards and later by introduction of regional authorities (14 Area Health Boards). The changes resulted from attempts to strengthen the integration of health services and improve equitable access, compromised by the increasing patient charges that remunerations were not able to compensate. (French et al. 2001, 25; Cumming et al. 2014, 21, 153.)

In Finland, the legislative basis for primary and secondary health care was set in the 1940s, including municipal GPs, mainly financed by patient payments with small state subsidies, and universal rights to maternal and child health care services (Vuorenkoski et al. 2008, 21–22; Mattila 2011, 67; Niemelä and Saarinen 2015, 14). The time period from 1960s to 1980s was characterised by the expansion of the welfare state, which in health care meant fast development and improvements in access to and quality of health care services (Niemelä and Saarinen 2015, 16). The National Health Insurance was introduced in 1960s, to shift focus from inpatient to outpatient care and to improve affordability of care. (Järvelin 2002, 13; Vuorenkoski et al. 2008, 22; Mattila 2011, 83). The NHI covered part of the costs for medicines and outpatient health services (Häkkinen and Lehto 2005; Vuorenkoski et al. 2008, 21–22). The initial level of reimbursement for medicines was 50%, after a fixed deductible, but medicines for certain serious and long-term illnesses were reimbursed in full (Niemelä 2014, 111). In the beginning of the 1970s, publicly provided local health centers were positioned as the main providers of primary care services in Finland (Häkkinen and Lehto, 2005; Vuorenkoski et al. 2008, 22; Niemelä and Saarinen 2015, 17). In 1979, employers were obliged to arrange occupational preventive health care services, which were later extended to curative services through labour market agreements (Vuorenkoski et al. 2008, 22; Niemelä and Saarinen 2015, 18).

In the 1980s and 1990s, health care systems worldwide were faced with sustainability issues, influenced by the global economic circumstances together with technological development, rising expectations and population ageing. At the same time, an ideological shift towards neo-liberalism shaped the political atmosphere and changed political foci from access and quality to productivity, cost containment and consumerism. Reforms influenced by the New Public Management (NPM) -approach aimed to increase efficiency by applying private sector management models to public sector. (Häkkinen and Lehto, 2005; Vuorenkoski et al. 2008, 123; Blank and Burau 2014, 117; Lehto et al. 2015; Niemelä and Saarinen 2015, 21.) The development of health tech-

nologies and pharmaceutical treatments facilitated deinstitutionalisation, i.e. shifting focus from inpatient and institutional care to outpatient services (Vuorenkoski et al. 2008, 123; Lehto et al. 2015).

In Finland, the deregulation and decentralisation reforms were implemented in the 1990s, at the same time when Finland was impacted by a deep economic recession (Häkkinen and Lehto 2005; Vuorenkoski et al. 2008, 25; Niemelä and Saarinen 2015, 19). The state subsidy reform (1993), which strengthened the responsibility and autonomy of the municipalities in organising and funding health care, coincided with deinstitutionalisation and several cuts and cost-shifting measures: re-introduction of user charges to municipal health care services, abolishing health-related tax refunds and raising patient co-payments for medicines, dental care and long-term care. The state subsidies were previously paid to providers based on delivered care but after 1993, the subsidies were calculated based on population need and paid directly to municipalities. Municipalities were also permitted to purchase services from private providers. (Martikainen et al. 1999; Järvelin 2002, 14; Lehto et al. 2015; Niemelä and Saarinen 2015, 19; Ruskoaho 2016, 27.) The Act on Specialised Medical Care in 1991 led to the introduction of current hospital districts, owned by municipalities or federations of municipalities (Vuorenkoski et al. 2008, 25). In 1994, Finland joined the European Union (EU) and signed the Agreement on European Economic Area (EEA).

The reforms in New Zealand in the 1990s aimed to further improve access to health care, and to improve system efficiency (French et al. 2001, 26). The 1993 reform introduced a quasi-market model (referred to as purchase/provider split), where ownership, purchasing and provision were separated (French et al. 2001, 26). The Crown remained the owner, but financing was decentralised to four regional authorities. These authorities were given a budget to purchase services for their residents from public and private providers. (French et al. 2001, 27; Cumming et al. 2014, 23.) The 14 Area Health Boards were transformed into 23 Crown Health Enterprises, which were expected to run hospital and health care services as commercial units, and to make a surplus (Cumming et al. 2014, 23). The experiment was highly unpopular among health professionals and the public, and the dissatisfaction, together with failure to reach the original objectives of the reform soon led to a series of readjustments. (Blank and Burau 2014, 54; Cumming et al. 2014, 160–164.) Between 1996 and 1999 the four regional authorities were replaced by one purchasing agency, the Health Funding Authority, and the Crown Health Enterprises became Hospital and Health Services, which continued to operate hospitals and other services but were no longer expected to make profit (Cumming et al. 2014, 165). A shift back towards a non-commercial model of health care begun in 1999, which led to another structural reform of the health care sector implemented in the 2000s (Cumming et al. 2014, 166).

The establishment of the Pharmaceutical Management Agency (PHARMAC) has been seen as one of the advantages of the 1990s reforms (Cumming et al. 2014, 23).

PHARMAC was first established in 1993 to develop new strategies to control pharmaceutical expenditure. In the following reforms, PHARMAC first became a non-profit company and later in 2000, a separate Crown agency (French et al. 2001, 98). PHARMACs strategies are reviewed in more detail in Chapter 4.1.3.

In the 2000s, emphasis has been placed on health care performance through integration, increasing the role of primary care, system responsiveness and inequalities in health. In Finland, responsiveness has been addressed mainly by increasing freedom of choice and in New Zealand, by the more active involvement of communities and consumers. Both countries have also attempted to shorten waiting times. (Cumming et al. 2014, 166, 167, 187, 179; Niemelä and Saarinen 2015, 22–25.) Nevertheless, efficiency and cost containment continue to be on the agenda in both countries, especially since the beginning of the global financial crisis in 2008 (Ministry of Social Affairs and Health 2012; Cumming et al. 2014, 7, 176). Both countries have also increased national coordination and steering and addressed inefficiencies related to decentralisation by attempts to reduce the number of local administrations (Blank and Burau 2014, 97; Cumming et al. 2014, 24, 166, 177; Lehto et al. 2015; Niemelä and Saarinen 2015, 14).

In the beginning on 2000s, New Zealand ended the purchaser/provider spilt and returned to regional governance by establishing 21 District Health Boards (DHBs) (20 since 2010) that became responsible for purchasing and providing primary, secondary and tertiary health services, as well as aged care services, with population-based funding (French et al. 2001, 31; Cumming et al. 2014, 153, 167). In 2001, a new strategy for primary care was released based on rising concerns over access to primary health care, inequalities in health and pressures on inpatient care (Cumming et al. 2014, 183). At the time, primary care services were mainly funded by co-payments (60%), which, together with strong gatekeeping, were thought to increase inequalities in access and health. Government subsidies for primary care, which in most cases covered less than half of the costs, were limited to children, certain beneficiaries, individuals with low-income and high users of health care. (Hefford et al. 2005.) Since 2002, local non-profit structures, Primary Health Organisations (PHO), have been funded by DHBs to coordinate health care services (Cumming et al. 2014, 36). Membership of a Primary Health Organisation (PHO) was voluntary for both practitioners and patients but it meant switching to more generous capitation-based government funding (Hefford et al. 2005). In 2004, PHOs covered approximately three quarters of the population and in 2009, 95% (Commonwealth Fund 2010a; Cumming et al. 2014, 36). However, GPs continued to have the right to set co-payments for patients, although the fees are reviewed by DHBs. PHO enrolees also had reduced co-payments for reimbursed prescription medicines (from NZ$15 to NZ$3) since 2004. In 2008 lowered co-payment (NZ$3) were extended to most prescriptions, and in 2013, this standard co-payment was raised to NZ$5. (Hefford et al. 2005; Cumming et al. 2014, 66, 70, 170.)

In 2008, attempts to increase coordination and integration led to the establishment of the National Health Board (NHB), with responsibility for funding and planning national health services, and the Shared Service Agency, to reduce duplication and the administrative work of the DHBs by offering support services. Merges of PHOs and DHBs are encouraged, to improve system efficiency (Blank and Burau 2014, 97; Cumming et al. 2014, 153).

In Finland, no major health care reforms have been implemented in the 2000s, although the planning of a major structural reform of health care and social services has been ongoing for most of the time period (Vuorenkoski et al. 2008, 123; Lehto et al. 2015; Niemelä and Saarinen 2015, 22–26). Since 2005, the municipalities have been encouraged to merge and form larger units, to increase productivity, coordination and freedom of choice (Mattila 2011, 241; Niemelä and Saarinen 2015, 22). Smaller legislative changes included a statutory care guarantee, implemented in 2005, to shorten waiting times and increase equity. Since 2009, municipalities have had the possibility to offer vouchers for patients, to purchase services from private provides, and in 2011, patients' rights to choose between public service providers were extended. (Mattila 2011, 230–241, 245; Niemelä and Saarinen 2015, 22–23). Reimbursements for medicines, as well as other benefits under the National Health Insurance have been subject to continuous savings measures (Ministry of Social Affairs and Health 2011; Ruskoaho 2016, 27–29). Cost containment measures in the pharmaceutical sector were focused on both the supply and demand side, and included implementations of mandatory generic substitution by pharmacists in 2003 and an internal generic reference price system in 2009. Savings were sought in 2006 and 2013 by statutory price cuts for reimbursable products and by adjustments and increases to patients' share of costs in 2003, 2006 and 2013. (Ruskoaho 2016, 27–29).

Organisation

In Finland, the main responsibility for ensuring basic health services lies with the municipalities. Municipalities have elected councils and a right to collect taxes (Vuorenkoski et al. 2008). Municipalities also receive state subsidies based on the characteristics of the residing population. The government steers the health care system at a general level, by legislation and financing. Health care policy is mainly the field of the Ministry of Social Affairs and Health. Primary health care services are delivered from health centres provided by individual municipalities or joint municipal boards. Municipalities may also purchase health care services from other municipalities, non-governmental organisations or the private sector. Municipalities fund and manage secondary care services, through federations of municipalities, i.e. hospital districts. All hospital districts have a central hospital, some of which are university-level teaching hospitals. (Vuorenkoski et al. 2008; Peura et al. 2011.)

Part of the health care services, e.g. reimbursements for outpatient medicines, sickness allowances and reimbursements for rehabilitation services, are financed through the statutory National Health Insurance (NHI). The NHI is administered by the Social Insurance Institution (Kela), operating directly under the Parliament. The NHI is financed by statutory contributions from the insured, employers, and with funding from the state (Kela 2015). The NHI also reimburses part of the cost of private health care services, including specialist visits, to patients. Alongside municipal health care, the occupational health service system covers the majority of the working population. Occupational health care is financed by employers, employees and the state. (Vuorenkoski et al. 2008; Peura et al. 2011.)

In New Zealand, the Ministry of Health (MOH) has the overall responsibility for the health care system. Public health care is mainly financed by general taxation with the Accident Compensation Corporation (ACC) as the second largest source of government funding. The ACC is an insurance scheme arranged by the state and funded through employer, employee and car-licensing levies. District Health Boards (DHB) are responsible for planning and funding health care services in their geographical area. DHBs are crown agents governed by DHB boards with both elected and MOH appointed members. DHBs are funded by the MOH based on a population-based formula. Primary health care is coordinated through Primary Health Organisations (PHO) with capitation (population needs) based funding from the DHBs. PHOs are non-profit-organisations that contract general practitioners (GP) and other for-profit or non-profit providers. Patients are free to choose their GPs. Specialist care is provided in public or private clinics and hospital outpatient departments. Public inpatient and outpatient hospital services are provided by public hospitals that can be owned or funded by the DHBs. Primary health care and health promotion services are also offered by Māori and Pacific health providers. (Cumming et al. 2014.)

Health expenditure and health care utilisation

The total per capita health expenditure in New Zealand was almost the same as that in Finland in 2013, and both countries ranked just below the OECD average (USD PPP 3,453) (Appendix). In the previous years, growth was faster in New Zealand during 2005–2009 and in Finland during 2009–2013. The public per capita spending on health was higher in New Zealand than in Finland, and in both countries, it was higher than on average among OECD countries. The public share of health care financing is higher and the private out-of-pocket share lower in New Zealand than in Finland. In New Zealand, health expenditure made up 22% of the total government expenditure in 2013, which was the highest share among OECD countries. In Finland, the respective share was 11%. (OECD 2015b.) Private insurance accounted for 2% of total health care financing in Finland and 5% in New Zealand.

On average, New Zealanders consult doctors more often than Finns, but both countries rank in the lower end in the number of doctor consultations among OECD countries (OECD 2015b) (Appendix). According to international comparisons, Finland has slightly larger income-related inequities in visits to doctor (OECD 2011a, 138–139). By hospital discharge rate, New Zealand ranks below average and Finland above average. By the average length of stay (ALOS) and waiting times for elective surgery, New Zealand performs slightly better. However, waiting times for revascularisation procedures were shorter in Finland. (Appendix.)

Pharmaceutical expenditure

No recent directly comparable data of total pharmaceutical expenditure is publicly available for New Zealand. The latest OECD data of spending on medical goods is from 2007 (Appendix). At that time, the per capita total and out-of-pocket spending for prescription medicines and OTC medicines were lower in New Zealand than in Finland. More recent figures are only available for pharmaceutical sales, however the Finnish and New Zealand data are not comparable (OECD 2015c). The data from New Zealand (ex-manufacturer prices) exclude the share of costs paid by the patients as well as hospital medicines and non-reimbursed prescription medicines. The Finnish data (wholesale prices) include all pharmaceuticals used in hospitals as well as reimbursed and non-reimbursed prescription medicines and OTC-medicines. Nevertheless, growth seems slower in New Zealand, as between 2000 and 2013 the per capita total pharmaceutical sales increased 1.8-fold in Finland and 1.5-fold in New Zealand. The generic share of the pharmaceutical market, both in value and volume, seems notably larger in New Zealand.

Household spending on health

Although national Household Economic/Budget Survey results are not directly comparable, they support the assumption of lower out-of-pocket contributions in New Zealand, for both health care and pharmaceuticals (Table 9, p. 69). Calculated from weekly expenditures, New Zealand households used 0.6% of their household total spending on pharmaceutical products and 2.4–2.5% on health in 2007–2013 (Statistics New Zealand 2016). In Finland, calculated from annual expenditures in 2006–2012, households used on average 1.4–1.2% of their total spending on pharmaceutical products and 3.5–3.2% on health (Statistics Finland 2016c). Pharmaceutical products accounted for 25% of total household health spending in New Zealand and 39–40% in Finland. According to OECD Health data 2015, the out-of-pocket medical spending as a share of final household consumption in 2013 (or nearest year) was 2.9% in Finland, 2.2% in New Zealand and 2.8% on average in the OECD countries (OECD 2015b).

Table 9. Household expenditures for health and pharmaceuticals according to national Household Budget/Economic Survey results in Finland and New Zealand.

Country	Household expenditure (annual/weekly)	FI 2006/ NZ 2007	2010	FI 2012/ NZ 2013	Source
Finland Euros per year	Total, euros	30,275		35,770	HBS[a]
	Health, euros	1,053		1,130	HBS
	Health, % of total	3.5%		3.2%	*
	Pharmaceutical products, euros	418		442	HBS
	Pharmaceutical products, % of total	1.4%		1.2 %	*
	Pharmaceutical products, % of health	39.7%		39.1 %	*
New Zealand NZD per week	Total, NZD	966.1	1,021.3	1,110.1	HES[b]
	Health, NZD	23.9	24.4	27.2	HES
	Health, % of total	2.5%	2.4%	2.5%	*
	Pharmaceutical products, NZD	5.9	6.1	6.9	HES
	Pharmaceutical products, % of total	0.6%	0.6%	0.6%	*
	Pharmaceutical products, % of health	24.7%	25.0%	25.4%	*

[a] HBS: Household Budget Survey (Statistics Finland 2016c); [b] HES: Household Economic Survey (Statistics New Zealand 2016).
* Calculated by the author.

4.1.3 Pharmaceutical systems in Finland and New Zealand

Both Finland and New Zealand have centralised pharmaceutical systems, with Ministry of Social Affairs and Health (MSAH, in Finland) and Ministry of Health (MOH, in New Zealand) holding the overall responsibility. Both countries have separate institutions in charge of regulation, marketing authorisations and vigilance: the Finnish Medical Agency (Fimea, formerly: National Agency for Medicines) and the New Zealand Medicines and Medical Devices Safety Authority (Medsafe). (Peura et al. 2011; Cumming et al. 2014.) In Finland, pharmaceuticals brought to the market can be authorised by Fimea, though national, mutual recognition or decentralised procedures, or by the European Medicinal Agency (EMA), through centralised procedure (Directive 2001/83/EC; Peura et al. 2011). In New Zealand, a national pre-marketing approval from Medsafe is required for all pharmaceuticals (Cumming et al. 2014). In 2006, the number of pharmaceutical companies operating in Finland was 64 and pharmaceutical industry employed approximately 6,700 persons. (Peura et al. 2011). Most pharmaceutical products are imported into New Zealand, with a small amount of local production (Cumming et al. 2014).

Product reimbursement status and price are assessed and decided on the national level in both countries: In Finland, by the Pharmaceutical Pricing Board (PPB), operating under the MSAH, and in New Zealand, by the Pharmaceutical Management

Agency (PHARMAC), a separate Crown Agency (Grocott 2009; Peura et al. 2011; Babar 2015). In Finland, reimbursements for medicines are benefits administered under the National Health Insurance. The NHI medical care insurance component is funded by contributions from employees and the state. (Health Insurance Act 1224/2004.) In New Zealand, PHARMAC manages the capped national pharmaceutical budget on behalf of the DHBs and acts as a monopsony purchaser of reimbursed medicines (Cumming et al. 2014, 28; Babar 2015). PHARMAC also negotiates the purchase of medicines directly with the companies (Grocott 2009; Cumming et al. 2014, 28; Babar 2015). The reimbursement process is generally initiated by an application from the holder of the marketing authorisation in both countries, but in New Zealand also e.g. doctors, patients or interest groups can make applications (Health Insurance Act 1224/2004; PHARMAC 2015, 10).

In Finland, the diseases attached to higher reimbursements are regulated by government decree. The PPB makes product-level decisions on the level and conditions of reimbursements and Kela makes patient-level decisions on eligibilities to disease-based and restricted reimbursements. *Restricted reimbursement* by prior authorisation (needs-test) applies to particularly expensive treatments. (Health Insurance Act 1224/2004.) In New Zealand, the PHARMAC Board makes decisions on the listing of products on the positive list called the Pharmaceutical Schedule, the reimbursement levels, prescribing guidelines and conditions (Cumming et al. 2014, 28; PHARMAC 2015, 16). PHARMAC also makes patient-level decisions on eligibility to restricted reimbursements and based on exceptional circumstances. Restricted reimbursement, under Special Authority scheme, by prior authorisation (needs-test) applies to many second- or third-line treatments, especially newer and more expensive treatment alternatives. (PHARMAC 2004–2010.)

The criteria for price and reimbursement assessment derive in Finland from the Health Insurance Act (1224/2004), based on which products that are indicated for treatment or relieving of an illness or its symptoms are reimbursable. Price evaluation criteria include therapeutic value, comparison to other treatments, sales estimate, cost-effectiveness and prices in other EEA-countries. PHARMAC decision criteria include the health needs of all eligible people within New Zealand and the particular needs of Māori and Pacific people, other available therapeutic options, clinical benefits and risks, cost-effectiveness, budgetary impact, costs to users and the Government's priorities. (PHARMAC 2004–2010; PHARMAC 2015, 15). Proposals undergo a cost-utility analysis, usually conducted by PHARMAC, and the focus is strongly on relative cost-effectiveness. Any funding decision is weighted against other possible reimbursable medicines or extending reimbursements to new patient groups. Programme Budgeting Marginal Analysis is used to maximise health gains with consideration of the opportunity costs. (Braae et al. 1999; Grocott 2009; Babar 2015.)

In both countries, price regulation applies to reimbursed products only, and non-reimbursed products are under free pricing. Finnish pharmacies are remunerated via a statutory regressive mark-up scheme based on the approved wholesale price or pharmacy purchase price. Pharmaceutical cost-containment policies include mandatory *generic substitution* by pharmacists and generic *reference pricing*. (Peura et al. 2011.) In New Zealand, the manufacturers are able to set their own prices to pharmacies. When this price exceeds PHARMAC reimbursement, the difference – called Manufacturer's surcharge – is paid in full by the patient. The reimbursement is paid to pharmacies, supplemented with a dispensing and distribution service fee. PHARMAC aims to fully reimburse at least one pharmaceutical in each therapeutic group (PHARMAC 2004–2010). PHARMAC uses several strategies to influence prices, including generic and therapeutic reference pricing, tendering (with sole supplier agreements), risk-sharing agreements (e.g. rebates) and multiproduct agreements (PHARMAC 2006; Grocott 2009; Ragupathy et al. 2012). Due to the complex arrangements between PHARMAC and pharmaceutical companies, as well as rebates, the actual prices paid for pharmaceutical products are not publicly available. (PHARMAC 2004–2010; OECD 2015c.)

In both Finland and New Zealand, all residents are eligible for reimbursed medicines (Health Insurance Act 1224/2004; Ragupathy et al. 2012). In Finland, reimbursement eligibility is *disease-specific*, i.e. the reimbursements for medicines are differentiated by disease severity and one pharmaceutical may be reimbursed at different rates for different medical conditions (Peura et al. 2011). No *population group-specific* eligibilities were applied to medicines, e.g. based on age or income, before 2016. Municipal social assistance acts as a means-tested last resort minimum income assistance resource (Vuorenkoski et al. 2008). In New Zealand, reimbursement eligibility is *product-specific,* i.e. eligibility is considered based on an evaluation of different aspects of the pharmaceutical product and is *population group-specific,* i.e. children are eligible to exemptions and reductions in payments. (PHARMAC 2004–2010.) In Finland, cost-sharing for medicines is a mix of deductibles, fixed co-payments and co-insurances, the level of which are regulated by the Health Insurance Act (1224/2004). In New Zealand cost-sharing applies to most purchased medicines and prescription charges are regulated by the government (Norris et al. 2011a; PHARMAC 2017).

4.1.4 Reimbursement schemes for pharmaceuticals at the time of Studies I–IV (2005–2010) in Finland and New Zealand

In Finland, prior 2006, three reimbursement rates applied: 100% for vital medicines, 75% for chronic and severe conditions and 50% for other medicines on the positive list. A *deductible* applied to each purchase (€5–10 in total for all items) but no co-payments applied after exceeding the annual ceiling. In 2006, deductibles were abolished, and instead, fixed co-payments were implemented to 100% reimbursed medicines (€3/item/purchase, max 3 months) and to medicines purchased after exceeding the annual ceiling (€1.50/item/purchase, max 3 months). At the same time,

reimbursement rates were decreased from 75% to 72% and from 50% to 42%. (Kela 2014.) The *annual ceiling* was based on individual patient's cumulative co-payment expenditure for reimbursed medicines. The level of the annual ceiling is index-linked (€616.72 in 2006).

In New Zealand, the level of prescription charge depended on the prescriber, pharmacy, patient's age and concession mechanisms. For *fully reimbursed products*, patients paid a *fixed prescription charge*. For *partly reimbursed products,* patients paid the applicable prescription charge plus the manufacturer's surcharge. The *annual ceiling* is based on the number of prescription items for the family, and after 20 prescription items per year, the prescription charge is lowered (to $2) or waived. In 2005, the maximum prescription charge for adults not enrolled to a low-cost PHO and without concession cards was $15 per three month's course, $10 to children aged 6–17 and $0 to children under the age of 6. However, a $3 prescription charge applied to low-cost PHO enrolees, high-need *Care-plus* -patients, and people with certain types of concession cards (Community Services Card, High Use Health Card). (PHARMAC 2004–2010.) In September 2008, the $3 co-payment was extended to all people eligible to publicly funded health care and to most prescriptions, e.g. all prescriptions from prescribers (incl. specialists, dentists, midwives) employed by a public hospital or with a District Health Board (DHB) or a PHO contract (PHARMAC 2004–2010).

4.2 Studies I–IV

4.2.1 Trends and income related differences in out-of-pocket costs for medicines in Finland (I)

Out-of-pocket costs for medicines in Finland were assessed by using Household Budget Survey (HBS) data. HBS is an EU-harmonised survey, conducted in all EU member states with the primary aim to calculate weights for the Consumer Price Index. HBS is also used in determining the consumption of the household sector in the National Accounts and the official statistics on Household's Consumption are composed based on HBS data (Statistics Finland 2014b; 2016a). In Finland, Statistics Finland has conducted HBSs periodically since 1966. Eurostat, the Statistical Office of the European Communities, provides guidelines to achieve better international comparability. The concepts, definitions and classifications are harmonised but the methodologies for e.g. data collection may vary by country. (Statistics Finland 2009; 2014a; 2016a; Eurostat 2016c.)

Sampling unit: The target population of Statistic Finland's HBS was the Finnish household population, which comprised private households permanently resident in Finland, excluding institutionalised persons (e.g. in care institutions, prisons and hospitals). The basic sampling frame for HBS was the population database. Stratified (by area of residence) probability sampling was used with community dwelling Finnish residents aged 15 years or older as the sampling unit. Dwelling-unit members were

linked to the selected persons based on registers. The household was further defined at the beginning of the interview as consisting of persons who shared meals, lived together and used their income together. (Statistics Finland 2009; 2014a; 2016b.) In this study, cross-sectional, comparable HBS data from 1985, 1990, 1995 (combined from 1994, 1995, 1996), 2001 and 2006 were used (Table 10).

Table 10. Sampling in Statistics Finland's Household Budget Surveys used in Study I.

	1985	1990	1995[a]	2001	2006
Gross sample, N	12,174	12,053	10,608	8,960	7,852
Ineligible[b], N	398	297	237	167	194
Net sample, N (%)	11,776 (100%)	11,756 (100%)	10,371 (100%)	8,793 (100%)	7,658 (100%)
Total non-response, N (%)	3,756 (30.4%)	3,498 (29.8%)	3,628 (35.0%)	3,298 (37.5%)	3,651 (47.7%)
Final sample, N (%, response rate)	8,200 (69.6%)	8,258 (70.2%)	6,743 (65.0%)	5,495 (62.5%)	4,007 (52.3%)

[a] Combined from data collected in 1994, 1995 and 1996, [b] Due to e.g. death, becoming institutionalised or emigration.
Source: Statistics Finland 2009.

Measurements: The household's background data, e.g. on ownership and purchasing of durable goods, and residential costs, were collected with interviews (face-to-face or telephone). After the interview, the households kept a diary about their consumption expenditure and retained receipts on their purchases for two weeks. Annual consumption expenditures were based on aggregated consumption data from the two-week collection periods, distributed throughout the year. Consumption was divided in approximately 900 categories based on the Classification of Individual Consumption According to Purpose (COICOP-HBS) nomenclature. Further background data were retrieved from administrative registers, e.g. the population register, tax register, social security registers. (Statistics Finland 2009; 2014a; 2016a.)

The main explanatory variable in the analyses was annual out-of-pocket costs for medicines. The classification of medicine expenditure in the Finnish HBSs was more detailed than in the original COICOP-HBS by Eurostat. In this study, two expenditure variables were used to calculate total out-of-pocket costs: prescription medicines (Statistic Finland code A0611101, COICOP-HBS code 06.1.1.) and OTC medicines (Statistic Finland code A0611102, COICOP-HBS code 06.1.1.). Excluded were costs for preparations with vitamins and trace elements (Statistic Finland code A0611103), as well as natural and herbal products (Statistic Finland code A0611104). All prices were adjusted for inflation to 2006 currency value using the Cost of Living Index (Statistics Finland 2006).

Independent variables in the analyses were total annual disposable household income and household actual total consumption. the age of the reference person was used as a covariate. The reference person was the person with the highest personal income.

The total annual disposable household income consisted of total income (employee or self-employment income + capital income + current transfers received) after deduction of current transfers paid, as defined by the Expert group on Household Income Statistics (2011). In the Finnish context, current transfers paid consisted of, e.g. direct taxes, social security contributions, compulsory pension, and unemployment insurance premiums. Current transfers received consisted of, e.g. pensions, social security benefits and social allowance (Statistics Finland 2012). To standardise the size and age differences of households, incomes were divided by the number of consumption units – i.e. household equivalents – in the household. The equivalence scale used was the modified OECD scale:

$$m = 1 + a\ (A-1) + b\ C$$

in which A is the number of adults and C the number of children in the household. The parameter a has a weight of 0.5 and the parameter b a weight of 0.3 (OECD 2011b). For the current study, the households were divided into five income quintiles based on household total annual disposable income. Each income quintile contained an equal number of household equivalents.

Household actual total consumption, according to European System of Accounts 1995 framework definition *ESA 95, 3.82*, consists of "Goods and services for individual consumption ('individual goods and services') that are acquired by a household and used to satisfy the needs and wants of members of that household. Individual goods and services have the following characteristics: a) It must be possible to observe and record the acquisition of the good or services by an individual household or member thereof and also the time at which it took place; b) the household must have agreed to the provision of the good or service and take whatever action is necessary to make it possible, for example by attending a school or clinic; c) the goods or service must be such that its acquisition by one household or person, or possibly by a small, restricted group of persons, precludes its acquisition by other households or persons." Thus, services for collective consumption (such as national defence, the usage of public infrastructures or public broadcasting) are excluded. (Eurostat 2003.)

Statistical analyses: Mean out-of-pocket costs for medicines and their share of total consumption were calculated for each study year. Separate analysis of covariance (ANCOVA) with general linear model (GLM) procedure was conducted for each year and for different types of medicines, in order to examine the variation of out-of-pocket costs and their share of total consumption between income quintiles with the age of the reference person as a covariate. Age-adjusted marginal means estimates

for household out-of-pocket costs by income quintile for medicines were derived in total, for prescription medicines and for over-the-counter medicines. Test of main effect of income quintile was used, and differences at p < 0.05 level were considered as statistically significant. The interaction effect between age and income group was significant only for prescription medicines and all medicines in 1990 and therefore it was excluded from the main analyses. All statistical analyses were performed using Predictive Analytics Software (PASW) version 18.

Aggregating the consumption data to annual level, as well as weighting and calibration as means to correct for non-response and sampling errors were conducted previously by Statistics Finland (2009).

4.2.2 Distribution of out-of-pocket costs for medicines among community dwelling older people in New Zealand (II)

The distribution of out-of-pocket costs for medicines among community dwelling older people was assessed by using data from a previously collected dataset for a larger study project – The Equity in Prescription Medicine Use Study (EIPMU) (Horsburgh et al. 2010; Norris et al. 2011a; 2011b; 2014). For the EIPMU-study, pharmacy dispensing data were collected in the Te Tairāwhiti region of New Zealand (1% of the New Zealand population).

The EIPMU-study was granted an ethical approval by a New Zealand Ministry of Health accredited ethics committee (Ethics approval NTX/06/09/111).

EIPMU-dataset: In the EIPMU-study, electronic records were collected from all eight community pharmacies in Gisborne for the period from 1 October 2005 to 30 September 2006 (Horsburgh et al. 2010). Records of outpatient dispensings were also obtained from the hospital pharmacy. The pharmacy records included information on patient demographics (name, date of birth, gender, address and health system identifier), the dispensed medicine (brand and generic name, quantity, strength, product specific pharmacode) and costs (patient payment, reimbursement, fees associated with the dispensing, concessions applied). For each purchase with sufficient information, Anatomical Therapeutic Chemical (ATC, WHO CC for Drug Statistics Methodology 2008) codes were linked and the dispensed quantity was calculated in Defined Daily Doses (DDDs). Probabilistic matching methods, using an individual's full name, date of birth, gender and health identifier (if recorded), were used to link records belonging to the same individual across pharmacies. Information of individual's age and gender were primarily obtained from the pharmacy records and if they were not present, from the central repository. Information on ethnicity derived solely from the central repository. Socioeconomic deprivation was derived from patient address in the database, which had been matched with an area measure of relative socio-economic deprivation, NZDep2006. (Horsburgh et al. 2010.) NZDep2006 is a widely used, previously validated small area measure of material socioeconomic

deprivation, which combines variables from the New Zealand Census into a single measure of deprivation. (Salmond et al. 2002; 2007).

Population: For the present study, records for individuals aged 65 years or older (N = 5,217) were extracted from the previously created EIPMU-dataset described above. The dataset encompassed nearly all residents of the area, since in Census 2006, the total ≥ 65 year-old population count (end of year) in the Te Tairāwhiti region was 5,346 (Statistics New Zealand 2006). In the study population, 23% (N = 1,155) were Māori and 77% (N = 3,864) were non-Māori. Māori were on average younger than non-Māori (mean age 73 vs. 76 years) and they were more likely to be living in non-urban (36% vs. 11%) and the most deprived (77% vs. 42%) areas.

Variables: The main explanatory variable was out-of-pocket costs. These were defined as the total amount paid by the patients for all their prescription items, including fees (e.g. for safety cap [pharmacists are required to use safety caps with specific medicines, and these are also reimbursed], after hours, phone and fax, dose packs) and adjustments. High out-of-pocket costs were defined as costs exceeding the 90th percentile of the annual out-of-pocket costs in the study population (NZ$217.50). Other explanatory variables were reimbursements and medicine use. Reimbursements were calculated from the pharmacy dispensing database excluding purchases extracted from pharmacy software Galen, which did not contain reimbursement information (0.3% of all purchases). Medicine use was defined as the number of distinct medicines, i.e. distinct ATCs at level 5, used per person per year and as the quantity of purchased medicines, i.e. the number of dispensed DDDs per person per year.

The main independent variable was ethnicity (indigenous Māori/non-Māori). Other independent variables used were age, gender, area of residence and socioeconomic deprivation by NZDep2006. Area of residence was classified as urban or non-urban (including rural or mixed area).

Statistical analyses: Distribution of costs, reimbursements and medicine use were assessed using descriptive statistics and by comparing the top 1%, 5%, 10%, 25%, 50% and bottom 50% spenders ranked by their total annual out-of-pocket costs. Further examination was conducted by ethnicity, while adjusting for differences in age structures by direct standardisation.

Multivariate logistic regression was used to compute odds ratios (ORs) and 95% confidence intervals (CIs) for characteristics associated with high out-of-pocket costs. Logistic regression was used, since out-of-pocket costs have a strongly right-skewed distribution, with a multitude of observations for a specific value. The first model included sociodemographic covariates (age, gender, deprivation index and area of residence), and in the second model the number of used medicines (distinct ATCs) was added. The chi-squared test was used for the bivariate associations. Differences at

p < 0.05 level were considered as statistically significant. All statistical analyses were performed using SAS software version 9.2 (SAS Institute Inc., Cary, North Carolina). All prices are in New Zealand dollars (NZ$), 2006 currency value. In relation to $US, the $NZ exchange rate in 2006 was 0.6132 (Mid-rate 31 March 2006, Reserve Bank of New Zealand).

4.2.3 Cost-related barriers to prescription medicines and health care in Finland (III)

Cost-related access barriers to medicines and health care were assessed by using national cross-sectional postal survey data, previously conducted in 2010 by the Social Insurance Institution of Finland. The original purpose of the survey was to assess adults' experiences of and opinions about the social security system. People's economic problems and the solutions they found, their health, social relations and welfare deficiencies were among the topics investigated in the study. (Airio 2013.)

Data: A total of 5,000 community dwelling Finnish- or Swedish-speaking Finnish citizens aged 18–74 years were randomly selected from the national population register. The sampling frame included 3,633,643 individuals. The questionnaire was administered in Finnish and in Swedish. The final response rate was 35% (n = 1,770) after three reminders. All information was derived from the survey and was based on self-report.

Participants were asked whether they encountered cost-related access barriers by the following questions, each with five response options (i) No, ii) Once, iii) A few times, iv) Often, v) Repeatedly): "In the past year, have you or a member of your household experienced any of the following situations? a) You did not go to a hospital visit because you didn't have the money; b) You did not fill a prescription due to cost; c) You also went without a treatment that was recommended by a doctor because you didn't have the money."

Receipt of social assistance and other social benefits was measured by a multiple response question: "In the past year, have you or a member of your household received any of the following benefits? (Select all appropriate options)". Social assistance was listed among 19 other options. Applying for social assistance was investigated using the follow-up question: "How have you tried to solve the financial problems you indicated in the previous question? (If you did not indicate any financial problems, please move to the next question)". Applying for social assistance was listed among 12 other pre-defined coping strategies with four options (i) No, ii) Once, iii) A few times, iv) Repeatedly).

Variables: The main explanatory variables were cost-related barriers to access to hospital, medicines or other treatments. For the bivariate and multivariate analyses, the responses were dichotomised into once or more vs. not at all. A dichotomous composite variable of having encountered at least one of the aforementioned access

barriers vs. none was also formed. Applying for and receiving social assistance were used as secondary outcome variables, to explore financial coping strategies among respondents who reported encountering access barriers.

The main independent variable was household members' total monthly net income categorised into tertiles (low/mid/high) according to the sample distribution. Other independent variables were family structure, area of residence (urban/rural), respondent's state of health, age, gender and education. Family structure was categorised into four categories (i) couple with children (0–17 years), (ii) couple only, (iii) single parent with children (0–17 years) and (iv) others (including adults living with parents). State of health was based on self-assessment (How would you rate your current health status? (i) very good, (ii) good, (iii) average, (iv) fair and (v) poor) and by presence of a diagnosed disabling illness or impairment (Have you been diagnosed with a permanent or long-term illness or impairment that decreases your ability to work or function?). The primary unit of analysis in the survey was household. However, certain background information – age, gender, education, state of health – used in the analyses related to the respondent (reference person). the adults in a family were assumed to belong to the same wide age group and to have a similar level of education and thus these variables were used as proxies for the entire household. The explanatory role of gender, however, is of limited importance for couples and families. Therefore, gender was mainly used as a covariate.

Statistical analyses: The frequency of and the characteristics associated with cost-related access barriers to prescription medicines and health services by population group were assessed by bivariate analyses and multivariate logistic regression. The bivariate associations were tested for statistically significant differences by a Chi-squared-test.

Based on bivariate associations (significant at a $p < 0.05$ level), education, income and health status were included in the multivariate models. Both health predictors gave similar results, but only one was included in the model since these variables were highly correlated. Self-assessed health was selected for the model over permanent or long-term illness or impairment, since it covered a wider range of health problems, and is commonly used in other studies (Mackenbach et al. 2008; Jatrana et al. 2011). Relevant covariates (age, gender and family structure) were also included in the multivariate model. The interaction effect between education and income was excluded from the main analysis, since it did not reach statistical significance.

The extent to which the experiences of encountering access barriers differed by income were examined by comparing the results of above average income and below average income respondents, after adjusting for age and health by weighting (*w2, see below*). Applying for and receipt of social assistance were assessed among people who experienced barriers and compared with the results from all respondents.

To account for non-respondents, the results were weighted (*w*) using post-stratification by respondent age, gender, education (primary/secondary/tertiary) and working status (employed/unemployed/pensioner) to represent the studied population. For multiple variables (age group, gender, education and working status), the post-stratification was conducted using an SAS raking algorithm. The weighting process has been described in more detail elsewhere (Miettinen 2013). Weights (*w*) were used in all analyses, except for the comparison between above and below average income. For this comparison, adjusting was conducted by creating two subsets (above average = above median/ below average = median or below) and applying a post-stratification weighting procedure to stratify the differences in age and health status between the two subsets (*w2*). The post-stratification for multiple variables was conducted using a SAS raking algorithm (Izrael et al. 2000).

The population used in the age- and health adjusted comparison by income consisted of 1,609 people and in the regression analysis of 1,412 people, of whom complete information on all of the variables under analysis was available. Differences at $p < 0.05$ level were considered as statistically significant. All statistical analyses were performed using SAS software version 9.2 (SAS Institute Inc., Cary, North Carolina).

4.2.4 Range of available and reimbursed medicines in Finland and in New Zealand (IV)

A four-dimensional approach was used to compare the available and reimbursed medicines in Finland and New Zealand in terms of the following: (i) the total numbers and overlap of medicines (unique ATC-codes); (ii) differences by therapeutic group; (iii) differences in reimbursing old and new medicines; and (iv) numbers of innovative medicines licensed and brought to market. The time point of comparison was June 1st 2007. The unit of examination was medicine, defined as a unique ATC-level 5 code, i.e. products within the same ATC level 5 class (active ingredient) were treated as one medicine.

Data: To form an equally representative, comparable dataset of available products on the market, a method published earlier by Chui et al. (2004; 2005) was used. In this method, available medicines are determined based on being listed in the published national physician's desk reference.

The products from New Zealand were manually entered from the published desk reference, *MIMS – Monthly Index of Medical Specialities – New Ethicals* 2007 Issue 6 (January–June), with information on product name, active ingredients, formulation (Donohoo 2007). The reimbursement status for each product was sought from the published version of the New Zealand Pharmaceutical Schedule June 2007 version (PHARMAC 2007). An ATC-code was assigned to each product primarily based ATC Index 2007, or secondarily based on the 2008 index (WHO CC for Drug Statistics Methodology 2008). If the ATC-group was available in the ATC-code system but the active ingredient was not, the International Non-proprietary Name (INN) was

used (Sweetman 2008). Where several classes were suitable, classification and naming was conducted similarly to the Finnish listing.

The Finnish products were imported from an electronic file received for research purposes from the Association of Finnish Pharmacies, where such price and product lists were composed regularly, to update pharmacy dispensing software systems. From the original list, products listed on the published version of *Pharmaca Fennica* 2007 (Lääketietokeskus 2007), were included. The original file contained detailed product information, e.g. name, active ingredients, formulation, package size, strength, ATC code, prices, reimbursement status and reimbursement restrictions.

Each product, from both countries, was classified by their reimbursement status according to the level of reimbursement (part or full) and restrictions (restricted or unrestricted) and any combinations of these (e.g. full subsidy with restrictions but part subsidy for all). For consistency, products that were reimbursed in New Zealand only in extemporaneous products or only when distributed by primary or secondary health-care providers (e.g. influenza vaccines) were classified as not reimbursed.

Further information to determine the "global age" of medicines was retrieved from publicly available databases with historical registration years: the US FDA Electronic Orange book (FDA 2008a) and Drugs@FDA (FDA 2008b), the Canadian Patented Medicine Prices Review Board Annual Reviews (Patented Medicine Prices Review Board 2000–2007), The European Medicines Agency (EMA 2008) and the online product databases of national regulatory agencies in New Zealand (Medsafe 2008), France (AFSSPS 2008), Finland (National Agency for Medicines 2008), and Sweden (Medical Products Agency 2008). FDA Fast Track -listings (FDA 2008c) and abovementioned (Canadian) Patented Medicines Prices Review Board Annual Reviews were also used in forming the list of new important medicines that provide health gain.

The final dataset of medicines was formed by collapsing the product-level listings described above based on distinct ATC level 5 code and the highest observed reimbursement status, after removing excluded ATC-classes (see below). Full reimbursement (100%) was the highest and no reimbursement was the lowest reimbursement status. The dataset contained 1,046 distinct ATCs for Finland and 1,007 for New Zealand. After excluding combination ATCs, the final dataset contained 779 medicines (distinct ATC-codes) for Finland and 763 for New Zealand.

Exclusion criteria included ATC classes A11 (vitamins), A12 (mineral supplements), B05 (blood substitutes and perfusion solutions), D02 (emollients and protectives), and V (various) because of the high percentage of combination products that prevented a meaningful comparison. All combination products from other therapeutic groups were excluded from the analyses, although combination products were

searched for reimbursed equivalents for those active ingredients only reimbursed in one of the countries (11 more common reimbursed active ingredients were found). Products registered as medicines in New Zealand, but as foods, other medical supplies, or natural remedies in Finland were classified in V03, and were therefore excluded. Products listed in the Finnish *Pharmaca Fennica*, but not licensed as medicines were excluded, although medicines with a temporary license (batch-specific exemption from the conditions of a marketing authorisation or registration) were included. From New Zealand, products listed as being available under section 29 of the Medicines Act 1981 (unregistered medicines approved for use by medical practitioners) were included. Differing funding mechanisms and distribution channels led to the exclusion of medicines used in the treatment of HIV, hepatitis, and tuberculosis, as well as infusions.

Data analyses

Similarity of range of medicines: The medicines in the final dataset were categorised into the following eight classes and the number of medicines in each group was determined.

i.   Available and reimbursed in both countries;
ii.   Available but not reimbursed in both countries;
iii. Available in both countries but only reimbursed in Finland;
iv.   Available in both countries but only reimbursed in New Zealand;
v.   Available and reimbursed in Finland, not available in New Zealand;
vi.   Available and reimbursed in New Zealand, not available in Finland;
vii. Available but not reimbursed in Finland, not available in New Zealand; and
viii. Available but not reimbursed in New Zealand, not available in Finland.

Differences by therapeutic groups: The numbers and overlap of medicines available and reimbursed were determined by ATC-level 1 group (anatomical main group). A further qualitative within-class assessment was conducted at ATC level 4 (Chemical subgroup) for medicines in three largest ATC main groups. The largest ATC main groups were determined by the total number of medicines.

Differences in reimbursing old and new medicines: All medicines only reimbursed in one of the countries were ranked by their "global age", i.e. first year of registration. For each medicine, the "global age" was determined by a three-stage procedure based on first registration years in 1–4 reference countries or areas. The first reference country was Finland or New Zealand and when the registration date was prior 1970, no further references were sought (prior 1960 registration years were rounded to 1960). The second reference country was New Zealand or Finland, depending which had not been referenced at the first stage, and for medicines with registration dates in both countries between 1970–1979, the earliest of the identified years was selected. The third round applied to medicines with post-1980 (inclusive) registration years in

both Finland and New Zealand. For these medicines, further registration dates were searched from all of the following countries or areas, or until two years of registration were identified: United States, the European Union (EU) or France, Canada, and Sweden. After assigning a year of first registration to each medicine, the mean, median, and percentiles (25% and 75%) were determined.

Delay in licensing and launching innovative products: A list of 57 innovative products was constructed, as previously published by Roughead et al. (2007), by using the listing of products selected for "fast-track" approval (FDA 2008c) and the products classified as a "breakthrough or substantial improvement" by the Canadian Patented Medicines Price Review Board (Patented Medicine Prices Review Board 2000–2007). In the present analysis, products with new chemical entities that had one active ingredient only were included. The proportion of innovative products registered and launched in Finland and New Zealand was determined. Registration status in Finland and New Zealand in June 1st, 2007 was sought from national regulatory authorities' web pages (see data collection). To compare the launch status, the listing of these entities was searched from national desk references in 2007 (see data collection).

The raw data were entered into MS Excel. The collapsing and merging of data sets and statistical analyses were performed in STATA (version 8.0) (StataCorp LP, College Station, TX). The between-country differences were tested for statistical significance by using bivariate methods. Differences at $p < 0.05$ level were considered as statistically significant.

5 Results

5.1 Trends and income related differences in out-of-pocket costs for medicines in Finland (I)

In Finland, between 1985 and 2006, the mean out-of-pocket costs for medicines increased from €138 to €373 (2.7-fold, in 2006 currency value) and the share of total actual consumption spent on medicines from 0.8% to 1.6% (Figure 5). Household spending on medicines increased over time in all income quintiles for both prescription and OTC-medicines. Lower income was associated with lower sums spent on medicines and less rapid growth of out-of-pocket costs. This difference was most distinct between the lowest income quintile when compared to the others. Between

Figure 5. The age-adjusted marginal means estimates for out-of-pocket costs for medicines by income quintile (I–V) in total (A), for prescription medicines (B) and for over-the-counter medicines (C) during 1985–2006 (Euros, 2006 currency value).[a]
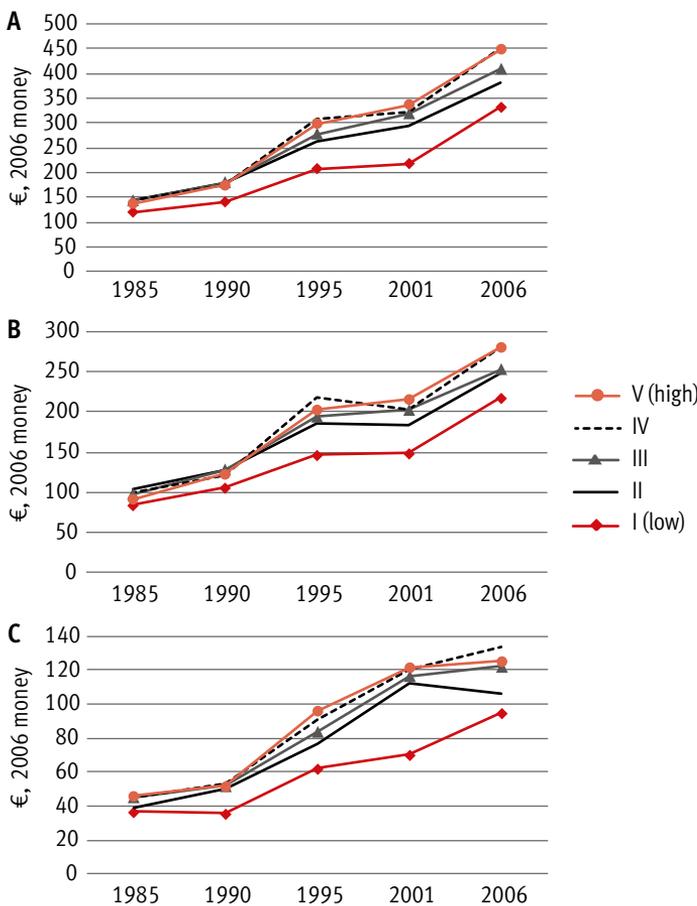
[a] Reproduced with the kind permission of Elsevier.

1985 and 2006, the increase was 2.7-fold for the lowest income quintile and 3.3-fold for the highest quintile.

Medicines accounted for a larger share of total actual household consumption for lower income than for higher income households (Figure 6). Although the share of consumption spent on medicines increased over time in all income quintiles, the increase was largest in the lowest income quintile, from 1.1% to 2.2%, and smallest in the highest income quintile, from 0.5% to 1.1%, which resulted in a widening gap between the lowest and the highest income quintiles.

Figure 6. The age-adjusted marginal means estimates for out-of-pocket costs for medicines as a share of household total consumption, by income quintile (I–V) during 1985–2006 (%).[a]
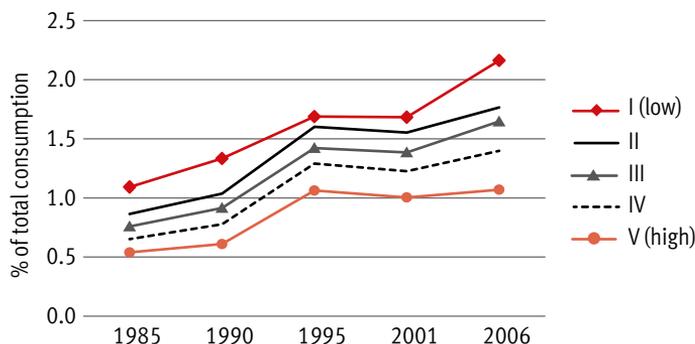
[a] Reproduced with the kind permission of Elsevier.

5.2 Distribution of out-of-pocket costs for medicines among community dwelling older people in New Zealand (II)

In Gisborne, New Zealand, the top 50% spenders of older people, ranked by their out-of-pocket costs, accounted for 86% of the total out-of-pocket expenditure (Table 11, p. 85). The mean annual out-of-pocket expenditure for those in the top half was NZ$201 and the average reimbursement rate was 86% of total costs. The bottom 50% accounted for 14% of the total out-of-pocket expenditure (mean out-of-pocket costs NZ$33/year) with 93% average reimbursement rate. The top 1% accounted for 16% of the total out-of-pocket costs (mean out-of-pocket costs NZ$1,863/year) and their average reimbursement rate was 45%. The average out-of-pocket costs in the top 1% were 5.9 times higher than in the top 25%. However, the higher out-of-pocket costs in the top 1% did not coincide with higher reimbursements or medicine use: the difference in reimbursements was 1.0-fold, the numbers of ATCs used were 14 vs. 14, and the difference in the number of DDDs was 1.4-fold when top 1% spenders were compared to top 25% spenders. Māori and females were underrepresented among people with high out-of-pocket costs.

Table 11. Distribution of the annual out-of-pocket (OOP) costs and government reimbursements ($NZ), and medicine use, among older people in Gisborne, New Zealand.

Percentile of OOP costs	Characteristics				Annual costs for medicines						Medicine use	
	N	Mean age (years)	Maori (%)	Male (%)	Total OOP costs ($NZ)	% of the OOP costs	Average OOP cost per patient ($NZ)	Average reim-burse-ment per patient ($NZ)[a]	Average reim-burse-ment rate (%)[a]		Mean num-ber of medi-cines	Mean num-ber of DDDs
Top 1%	53	76	15	53	98,740	16	1,863	1,388	45		14	3,816
Top 5%	261	77	13	45	216,264	36	829	1,324	64		15	3,176
Top 10%	522	77	12	44	287,285	47	550	1,443	74		15	2,955
Top 25%	1,305	77	17	43	408,933	67	313	1,326	82		14	2,712
Top 50%	2,610	76	20	41	524,165	86	201	1,133	86		13	2,472
Bottom 50%	2,607	74	24	44	85,594	14	33	424	93		6	1,056
All	5,217	75	22	43	609,759	100	117	779	88		9	1,771

[a] Excluding purchases from pharmacy using Galen-software (0.3%).
Abbreviation: DDD = Defined Daily Doses.

In the study population, mean out-of-pocket costs were NZ$117 and the median number of medicines (distinct ATCs) was 9. Out-of-pocket costs and number of medicines increased with increasing age. Reimbursements and the number of DDDs were the highest in the middle age group (75–84 years). Māori had lower mean and median out-of-pocket costs and reimbursements, as well as a lower number of DDDs than non-Māori. The average number of distinct ATCs was similar for Māori and non-Māori. People living in the urban or mid deprived areas had higher mean and median out-of-pocket costs and reimbursements than their counterparts.

After adjusting for age, out-of-pocket costs, reimbursements and medicine use were lower for Māori than for non-Māori. For all variables, the difference between Māori and non-Māori became larger in the top quantiles.

In the multivariate analyses, non-Māori ethnicity (Reference: Māori OR 1.9; 95% Confidence intervals (CI) 1.4; 2.7), older age (85 + years vs. 65–74 years OR 1.6; 95% CI 1.2; 2.2) and male gender (females vs. males OR 0.7; 95% CI 0.6; 0.9) were signifi-cantly associated with high out-of-pocket costs (Table 12, p. 86). Although significant in the bivariate comparisons, socioeconomic deprivation or area of residence were not significantly associated with high costs after adjusting for ethnicity, gender and age. A higher number of medicines was also significantly associated with high costs.

Table 12. Bivariate (%, chi-squared test) and multivariate [odds ratios (OR) with 95% confidence intervals (CI), logistic regression] associations between high out-of-pocket costs (NZ\$217.50/year or more) and independent variables (N = 4,497) among older people in Gisborne, New Zealand.

		% of people		Model 1 with sociodemographic variables only		Model 2 with sociodemographic variables and number of medicines	
		%	p	OR with 95% CI	p	OR with 95% CI	p
Age group	65–74	8	< 0.001	1		1	
	75–84	11		1.4 (1.1;1.7)	0.004	1.1 (0.9;1.4)	0.458
	85 +	16		2.1 (1.5;2.7)	< 0.001	1.6 (1.2;2.2)	0.002
Gender	Male	11	0.207	1		1	
	Female	10		0.8 (0.7;1.0)	0.082	0.7 (0.6;0.9)	0.004
Ethnicity	Māori	6	< 0.001	1		1	
	Non-Māori	11		1.8 (1.3;2.5)	< 0.001	1.9 (1.4;2.7)	< 0.001
Socio-economic deprivation	Least	10	0.002	1		1	
	Mid	12		1.2 (0.9;1.6)	0.213	1.0 (0.7;1.3)	0.828
	Most	9		0.9 (0.7;1.2)	0.663	0.8 (0.6;1.1)	0.205
Area of residence	Rural/mixed	8	0.023	1		1	
	Urban	10		1.1 (0.8;1.5)	0.527	0.9 (0.7;1.3)	0.58
N of distinct ATCs						1.2 (1.1;1.2)	< 0.001

Abbreviation: ATC = Anatomical Therapeutic Chemical system.

5.3 Cost-related barriers to prescription medicines and health care in Finland (III)

In Finland, in a survey targeted to general population households with a reference person aged between 18–74 years, 18% of the respondents reported at least one problem with access to health care due to cost within the past year (Table 13, p. 87). In total, 11% reported not filling a prescription, 8% not going to hospital and 13% going without some other form of treatment prescribed by a doctor due to cost during the previous 12 months. Of respondents who assessed their health as fair or poor, 53% had encountered at least one access problem, and of respondents with a diagnosed disabling illness or impairment, 32%. Those living alone, those with lower education or income and those reporting worse health or disabling illness or impairment were all significantly more likely to encounter access problems than their counterparts. The bivariate associations were mostly not significant for age, gender and area of residence. After adjusting for age and health status, 25% of below-average income households and 12% of above-average income households experienced access problems (P < 0.001).

Table 13. Characteristics of the study population (n = 1,770) and bivariate associations with statistical significance (p, by Chi-squared test) between the studied cost barriers and included background variables.[a]

			Respondents who reported problems with access because of cost (row %)			
		N (%)	Did not fill prescription	Did not go to a hospital visit	Went without other form of care	Had at least one access problem
Total		1,770 (100%)	11%	8%	13%	18%
Missing (n)		0	184	185	188	162
Gender	Male	877 (50%)	9%	8%	11%	16%
	Female	884 (50%)	12%	8%	14%	20%
	Missing (n)	9	189	192	193	169
			p = NS	p = NS	p = NS	p = 0.038*
Age, years	18–34	508 (29%)	14%	11%	13%	21%
	35–49	464 (26%)	9%	8%	12%	17%
	50–64	538 (31%)	11%	6%	13%	18%
	65–74	254 (14%)	7%	4%	11%	15%
	Missing (n)	5	185	187	189	164
			p = NS	p = 0.003*	p = NS	p = NS
Family structure	Couple with children	547 (31%)	8%	6%	9%	14%
	Couple only	657 (37%)	11%	7%	11%	17%
	Single parent	61 (3%)	13%	7%	13%	22%
	Others	498 (28%)	15%	12%	18%	25%
	Missing (n)	6	185	186	189	163
			p = 0.003*	p = 0.001*	p < 0.001*	p < 0.001*
Education	Primary	419 (24%)	17%	11%	18%	24%
	Secondary	773 (44%)	13%	10%	15%	21%
	Tertiary	551 (32%)	5%	4%	6%	11%
	Missing (n)	28	200	201	204	178
			p < 0.001*	p < 0.001*	p < 0.001*	p < 0.001*
Income	Low	582 (36%)	20%	16%	21%	31%
	Mid	509 (32%)	11%	5%	12%	17%
	High	523 (32%)	3%	3%	4%	7%
	Missing (n)	156	295	295	296	275
			p < 0.001*	p < 0.001*	p < 0.001*	p < 0.001*

Table 13 continues.

Table 13 continued.

		N (%)	Respondents who reported problems with access because of cost (row %)			
			Did not fill prescription	Did not go to a hospital visit	Went with-out other form of care	Had at least one access problem
Area of residence	Urban	1,298 (74%)	12%	9%	13%	19%
	Rural	458 (26%)	9%	7%	12%	17%
	Missing (n)	14	191	192	194	169
			p = NS	p = NS	p = NS	p = NS
Self-assessed health	Very good/good	1,277 (73%)	7%	6%	8%	13%
	Average	315 (18%)	15%	11%	19%	26%
	Fair/Poor	153 (9%)	37%	25%	43%	53%
	Missing (n)	25	201	202	204	179
			p < 0.001*	p < 0.001*	p < 0.001*	p < 0.001*
Diag-nosed disabling illness or impair-ment	No	1,198 (70%)	7%	6%	8%	13%
	Yes	516 (30%)	21%	13%	25%	32%
	Missing (n)	56	222	223	223	200
			p < 0.001*	p < 0.001*	p < 0.001*	p < 0.001*

*Statistically significant at p < 0.05 level.
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According to multivariate analysis, low income (the lowest vs. the highest income tertile odds ratio (OR) 4.95 (95% confidence intervals (CI) 3.02; 8.12)) and poor health (Fair/poor vs. very good/good health OR 7.07 (95% CI 4.45; 11.22)) had independent and strong associations with going without care due to cost, after adjusting for gender, age, education and family structure (Table 14, p. 89). Lower education was associated with a small (primary vs. tertiary education OR 1.63 (95% CI 1.02; 2.61)) but significant increased likelihood of encountering cost-related access problems. Among the covariates in the model, which were mostly not significant in the bivariate associations, younger age had a moderately strong and increasing association with access problems (18–34 vs. 65–74 years OR 3.8 (95 % CI 2.06; 7.01)). According to the model, female gender was also associated with slightly more frequent access problems (OR 1.39 (95% CI 1.04; 1.87)).

Table 14. Odds Ratios (ORs), with 95% confidence intervals (CIs) of reporting at least one health related access problem, with adjusting for effects of socioeconomic and health predictors.[a]

		OR	95 % CI	p
Gender	Male	1		
	Female	1.39	(1.04–1.87)	0.028
Age, years	18–34	3.80	(2.06–7.01)	< 0.0001
	35–49	3.19	(1.69–6.02)	0.0003
	50–64	1.9	(1.06–3.40)	0.0306
	65–74	1		
Family structure	Couple with children	1		
	Couple only	1.02	(0.69–1.53)	0.911
	Single parent	0.77	(0.35–1.68)	0.506
	Others	0.76	(0.49–1.18)	0.228
Education	Primary	1.63	(1.02–2.61)	0.043
	Secondary	1.64	(1.13–2.38)	0.009
	Tertiary	1		
Household net income	Low	4.95	(3.02–8.12)	< 0.0001
	Mid	2.24	(1.40–3.57)	0.001
	High	1		
Self-assessed health	Very good/Good	1		
	Average	2.34	(1.61–3.40)	< 0.0001
	Fair/Poor	7.07	(4.45–11.22)	< 0.0001

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Among households that had encountered access problems in health care, 34% had applied for social assistance and 17% had received this benefit. Among all respondent households, 5% had received social assistance. Social assistance is the last resort financial aid in the Finnish social security system, received by 7% of all households, according to the National Statistics in 2010 (National Institute for Health and Welfare 2011).

5.4   Range of available and reimbursed medicines in Finland and in New Zealand (IV)

In Finland, 779 distinct medicines were available and 495 were reimbursed. In New Zealand 763 medicines were available and 471 were reimbursed. The overlap, i.e. the number of medicines that were the same in both countries, was 538 for available and 290 for reimbursed medicines (Figure 7, p. 90). Hence, 69–71% of the available medicines and 59%–62% of the reimbursed medicines were the same in Finland and New Zealand. In New Zealand, 86% of all reimbursed medicines were reimbursed

in full and in Finland, 29%. Restrictions (means-test) applied to all fully reimbursed medicines in Finland, however, fully reimbursed medicines were typically also partly reimbursed without restrictions. In New Zealand, the majority of medicines were fully reimbursed to all, with no restrictions. Restrictedly reimbursed medicines were generally not reimbursed at all for those not meeting the criteria.

Figure 7. The number and overlap of active ingredients available (listed) and reimbursed (subsidised) in Finland and in New Zealand.[a, b]
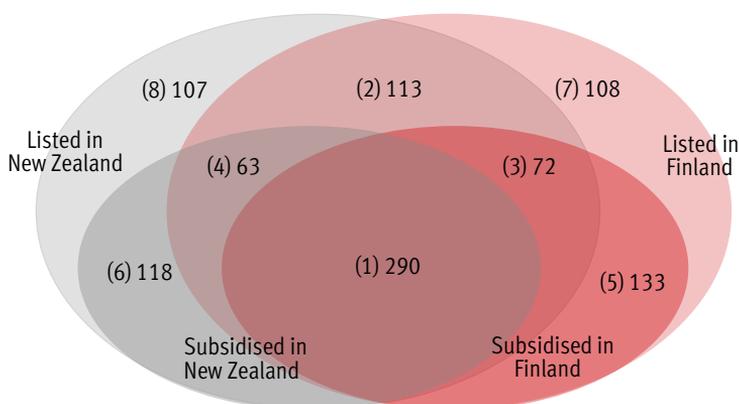
[a] The larger circles represent the medicines available and the smaller circles the medicines reimbursed. The proportions of the sections are not to scale. The numbers of the analysis groups are in brackets followed by the number of entities in each group.
[b] Reproduced with the kind permission of Elsevier.

The numbers of medicines available and reimbursed were similar across the main ATC-groups. In further examination of the ATC-level 4 chemical subgroups within the three largest ATC main groups – Alimentary tract and metabolism (A), Cardiovascular system (C) and Nervous system (N) – the following general differences were observed: i) Within chemical groups which included several new and relatively commonly used similar molecules (me-too products), some of which were on-patent and some generic competition (e.g., SSRIs, angiotensin II antagonists, 5HT-agonists, statins), a larger variety was reimbursed in Finland, but at least one reimbursed option was also available in New Zealand; ii) Within chemical groups that only included one or a few expensive, mostly on-patent new medicines or very expensive medicines for rare conditions (orphan medicines), often only Finland had reimbursed options (e.g., antidementia medicines, anti-obesity medicines, meglitinides, indole derivates, nitisinone, miglustat, bosentan, hydroxybutyric acid, aripiprazole, levetiracetam); iii) Chemical groups that only had reimbursed options in New Zealand usually contained old medicines no longer marketed in Finland (e.g. tolbutamide, imipramine, phenelzine, pizotifen), or medicines used for treatment of milder conditions, or symptoms (e.g., laxatives, antacids, antipyretics, analgesics), commonly sold over the counter.

Figure 8. Medicines (entities) only reimbursed in Finland or New Zealand, by their first year of registration. N = 205 (Finland) and 181 (New Zealand).[a]

First year of registration
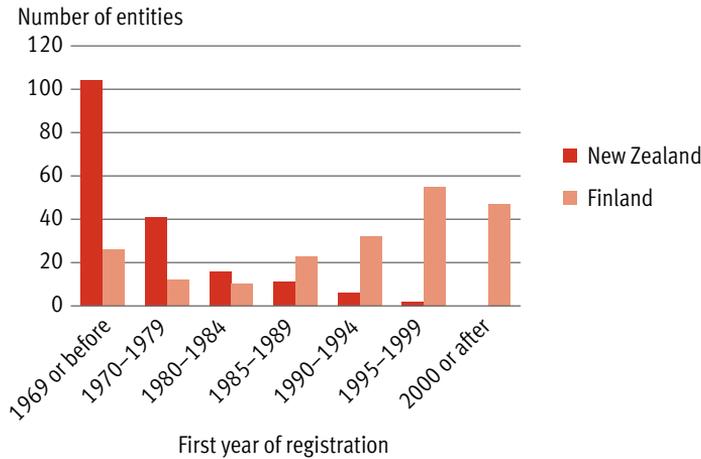
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The mean registration year for medicines only reimbursed in Finland (n = 205) was 1990 and for medicines only reimbursed in New Zealand, 1972 (Figure 8). Fewer new innovative medicines that provide health gain were registered and launched in New Zealand than in Finland. From the list of the examined 57 innovative medicines, 47 were registered in Finland and 33 in New Zealand, and 37 and 22, respectively, were launched based on being listed in the national desk references.

5.5   Summary of the main results

In Finland, higher income households tended to spend higher sums on both prescription and OTC medicines than lower income households, although the largest differences were observed between the lowest income quintile and quintiles II–V. Despite lower absolute sums, medicines accounted for a larger share of the total consumption for low-income households. Almost every fifth Finnish household had encountered cost-related access barriers to prescription medicines, other recommended treatments or hospital visits at least once during the previous year. Low income, worse self-assessed health, younger age, lower level of education and female gender were associated with access problems.

In Gisborne, New Zealand, a large majority of older people paid relatively little for their medicines while few individuals paid a lot. Medicines not reimbursed in full or at all contributed to the high out-of-pocket payments. High costs were not associated with socioeconomic deprivation, however, Māori spent less on medicines and used fewer medicines than non-Māori.

In comparison, a larger variety of older active ingredients and active ingredients commonly sold over the counter were reimbursed in New Zealand. In addition, a larger share of reimbursed medicines was reimbursed in full. In Finland, a wider range of newer active ingredients, as well as more options within therapeutic groups (including me-too -products) were reimbursed and a higher share of innovative medicines were available.

6 Discussion

6.1 Methodological considerations

The methodological purpose of this study was to assess the usability of used data sources in examining dimensions of affordability. Below, the methodological aspects of each phenomenon examined in the sub-studies are discussed in this context.

6.1.1 Distribution of out-of-pocket costs

Studies I and II assessed the distribution of out-of-pocket costs for medicines in Finland and New Zealand. In Finland, the focus was on income differences, and in New Zealand, in ethnic differences, due to previously reported country-specific inequalities in health (e.g. Bramley et al. 2005; Tarkiainen et al. 2013). The used sources of data were chosen because they contained information on out-of-pocket costs for non-reimbursed medicines, which is generally lacking from comprehensive claims-based registers and of which limited information was thus available in the earlier literature.

The data used in Study I derived from national Household Budget Surveys (HBS) conducted in Finland. Previous studies have also used household expenditure survey data to assess the distribution of costs for medicines and health care in e.g. Australia, Canada, Italy and Austria (Jones et al. 2008; McLeod et al. 2011; Sanmartin et al. 2014; Sanwald and Theurl 2014; Terraneo et al. 2014). HBSs or other household surveys are conducted in most developed countries and many developing countries (Xu et al. 2009; Seiter 2010). The strengths of HBS data include national representativeness and comparable measuring points over time. The limitations derive from the short collection periods and the aggregated nature of information due to which individual level information cannot be used (Statistics Finland 2009). Further, differences between any two surveys are expected because of differences in e.g. the survey years, survey designs and recall periods (Eurostat 2003; Xu et al. 2009). A further limitation of the data is that no information is available on the medicines used, or the illnesses of included household members, and therefore examinations of specific conditions or therapeutic groups are out of scope.

In the sensitivity analyses in Study I, removing age from the model decreased the differences between income groups, since lower income groups composed a larger share of older households with higher costs. Using costs in relation to disposable income instead of total consumption resulted broadly in similar findings as the main analyses. However, the results were more inconsistent when income was used as a denominator, because of the aggregated nature of the cost and consumption data. Excluding households without recorded purchases decreased differences between income groups to negligible levels. This finding suggests that the observed differences were more likely to be due to fewer low-income households reporting purchases than e.g. differences in the prices paid. However, this approach is also limited by the applicability of aggregated data. It was also noted that the overall proportion of households

with purchases was also markedly higher in the two earlier time points than in the latter three (91−92% vs. 39−45%), possibly due to unreported differences between studies conducted at different time points.

In Study II, pharmacy register data from one area of New Zealand were used. The strength of the data was the inclusion of out-of-pocket costs for medicines outside the reimbursed range as well as all patient fees related to purchasing medicines. However, since pharmacy dispensing data are not routinely pooled or collected, these had to be obtained separately from each pharmacy. The limitations of the current study included the lack of information regarding health needs apart from age and ethnicity, and regarding income, which meant that costs relative to income could not be calculated. The study was also limited to older people and one area, and they may not be generalisable to other age groups and parts of the country. An alternative source of data could have been the Pharmaceuticals Collection database (Pharms), maintained by the Ministry of Health and the PHARMAC (Ministry of Health 2015, PHARMAC 2016b). However, the national database only contains reimbursed purchases of medicines (Horsburgh et al. 2010). Therefore, the share of costs deriving from using medicines outside the reimbursed range could not have been assessed with the national data.

Overall, there is limited published information of the out-of-pocket costs and medicines used in New Zealand. The Ministry of Health provides no routine reports or publications based on register data on medicine use and PHARMAC only publishes limited information in Annual Reports and Annual Reviews. The latest OECD data of health spending on medical goods for New Zealand is from 2007 and data on pharmaceutical sales is largely incomparable (OECD 2015c). Data on out-of-pocket health expenditure derive from Household Economic Surveys (HES) instead of registers (Ministry of Health 2012).

Several limitations also need to be noted in regards to measuring medicine use by using defined daily doses (DDD). DDDs are average daily doses, estimated based on the main indication of the active ingredient. They allow standardising between different formulations and doses but only give a rough estimate of actual use. The doses prescribed and used by patients may differ e.g. because of patient characteristics (age, weight, tolerance, pharmacokinetics), when used for different indications, because of treatment guidelines and traditions in different countries (WHO 2003; WHO CC 2017). It is therefore possible, that the observed differences are caused by underlying differences of the population subgroups.

In summary, in assessing out-of-pocket costs, both HBS and pharmacy register data had the advances of including the out-of-pocket costs of non-reimbursed medicines. However, neither source of data alone provided sufficient information to comprehensibly assess the equity of the distribution of out-of-pocket costs in relation to need.

The HBS data lacked the information on the share of costs that were covered, and the treatments that the payments represented, and thus offered limited information on whether differences persisted in medicine use. The pharmacy register data lacked information on need and on the socioeconomic characteristics, which prevented e.g. the assessment of out-of-pocket costs in relation to income. Nevertheless, the results of the studies presented here are of importance in assessing to what extent the results from claims-based studies are biased due to the lack of non-reimbursed purchases.

HBS data is available for long periods of time and from a large number of countries and thus could best serve as a crude indicator of the level and distribution of out-of-pocket spending in relation to income across countries and over time. It could also be used to assess the validity of the patterns observed in analyses based on claims-based registers. Pharmacy data includes purchase-level information and therefore further examinations of specific conditions or therapeutic groups are feasible. Several examples of studies focusing on specific therapeutic groups have already been published (Norris et al. 2011a; 2011b; 2014).

6.1.2 Cost-related access barriers

Access barriers and unmet needs are commonly used features of national and international health or health insurance related surveys (de Looper and Lafortune 2009; Schoen et al. 2010; Moreno-Serra et al. 2012). This self-assessment-based method is relatively straightforward when compared to e.g. examining access based on utilisation (e.g. van Doorslaer et al. 2004; Bago d'Uva et al. 2009; Mayer and Österle 2014), although each method has its limitations. The pros of using self-report include being able to separate between different reasons for forgone care and therefore being able to distinguish cost-related barriers from other reasons, e.g. waiting times or personal reasons. The cons include common limitations of surveys, e.g. recall bias, non-response, selective attrition and the comparability of results from surveys from different countries and at different points of time. Further, it is usually not possible to assess the necessity of forgone care. Individual cross-sectional surveys also provide no information on causalities.

In Study III, national survey data from Finland were used. The largest limitation was that the survey was not designed to specifically address access barriers to medicines and therefore the range of independent variables was very limited, e.g. the Finnish data did not include variables related to psychological distress or health behaviour. Other factors associated with use (Piette et al. 2006), that could not be assessed, included physician-related factors (e.g. physician knowledge, therapeutic choices), factors related to patient attitudes or experiences (e.g. physician-patient relationship, past experiences), treatment-related factors (essentiality, side effects, polypharmacy) or diagnosis-related factors (e.g. quality of life). Further, barriers to accessing doctors were not assessed. There was also no distinction between people who did not encounter access barriers and who did not use medicines.

The questions used in the Finnish survey were constructed based on a previous Finnish study, conducted in 2000, to produce comparative results. However, the results were not directly comparable to international surveys, e.g. Commonwealth Fund International Health Policy Surveys, due to differences in questions and survey methods (postal vs. telephone). Overall, nevertheless, comparisons of results from surveys conducted in different countries need to be interpreted with caution. Especially attitudes towards unmet needs can be affected by e.g. cultural factors, public expectations and policy debates (OECD 2013). Further, there are limitations of generalisability of the results. The response rate was low, 35%, and the weighting might not fully account for non-response, e.g. due to selective attrition. Also, people aged over 75 years were not included in the survey.

Inequities in access to health care have previously commonly been examined by using doctor visits as an indicator of access to care (e.g. van Doorslaer et al. 2004; 2006; Allin and Masseria 2009a; 2009b). However, the results related to doctor visits may not act as a reliable proxy of overall access. Based on EU-SILC-surveys, Finland was among the countries with the least cost-related access barriers to medical examination (instead, barriers related to waiting times were common) (Eurostat 2016b). The results from Study III indicate that although costs may not limit access to medical examination, they are an important factor in limiting access to treatments recommended or prescribed during those visits.

Overall, to aid policymaking, more in-detail research is needed on the necessity of forgone treatments and of the specific reasons behind cost-barriers, i.e. whether the barriers are related to the level of cost-sharing or reliance on medicines not covered within the basic range. In comparative analyses, more information is needed on the comparability of results related to cost-related access barriers across countries. Comparing differences between population subgroups observed within countries instead of directly comparing observed percentages could partly resolve the uncertainty related to country-specific response patterns.

6.1.3 Range of available and reimbursed medicines

In Study IV, the range of compared medicines was defined as published by Chui et al. (2004; 2005). In this method, available (licensed) medicines are determined based on being listed in the published national physician's desk reference. Such a list represents the range of generally available medicines, for most patients, under normal ambulatory care conditions. No 100% comprehensive list of products was available from either country, and almost any single entity could be available for an individual patient in hospital settings or under named-patient or Exceptional Circumstances policies.

One limitation of this study (IV) was the lack of electronic records from New Zealand. The Finnish data was composed of electronic records, which have obvious advances in terms of accuracy and consistency. However, electronic records from dif-

ferent countries may vary in completeness or they may not be available (Folino-Gallo et al. 2001). The standardised assignment of ATC-codes to New Zealand data was also challenging, especially for combination products and products with the same active ingredient but different administration routes and indications. Further challenges in standardisation included differences in licensing (e.g., medicines vs. foods vs. medical supplies vs. complementary and alternative products), funding (communicable diseases, vaccines, infusions) and distribution (hospital only, general sales, OTC). It was also noted that the disproportionate use of combination products in the compared countries might bias comparisons in several ways: including combination products in the comparison may result in the multiple counting of active ingredients (each under separate ATC-codes) and excluding combination products may result in losing active ingredients only available in combinations. In this study, combination products were excluded from the analyses but active ingredients only available in combination products were included. Differences in reimbursement were only assessed on a general level, however, the criteria for reimbursement, reimbursed indications and covered population subgroups may vary (Ballem and Krause 2011; Blankart et al. 2011).

The comparison of availability of innovative products in Study IV may have been influenced by how the compared products were chosen. In this study, a method published by Roughead et al. (2007) was used. Alternative assessments of therapeutic innovation have been published by e.g. Motola et al. (2005; 2006) and the French medicine bulletin La Revue Prescrire / Prescrire International (e.g. Prescrire editorial 2012). Ahlqvist-Rastad et al. (2004) found broadly similar ratings by Prescrire and by the Swedish national regulatory agency. Conversely, Lexchin (2015) only found fair agreement between Health Canada's priority approval and ratings by PMPRB or Prescrire. Of note, disconcordance was also found in the ratings by PMPRB and Prescrire. Lexchin (2012) also found differences in the assessments of Prescrire, the US FDA, Health Canada and PMPRB. According to Vitry et al. (2013), who used Motola et al. and Ahlqvist-Rastad et al. (based on Prescrire) classifications to examine the therapeutic value of medicines available in Australia, both classification systems were broadly consistent. It seems thus that using different classifications is likely to alter the compared selection, but it is unlikely that the overall results would be different. However, unobserved differences may persist in the approved indications (Blankart et al. 2011; Cheema et al. 2012).

Nevertheless, the differences in the reimbursed and available range of medicines between Finland and New Zealand observed in Study IV were in line with other published comparative results. In comparisons where both Finland and New Zealand were included, New Zealand was among the countries with least launches of innovative medicines in a comparison of 25 countries (Danzon et al. 2005); and New Zealand had the lowest share of reimbursed indications for new oncology medicines in a comparison of 13 countries (Cheema et al. 2012). Finland, on the other hand,

ranked relatively high in these comparisons. In comparisons where New Zealand was included but Finland was not, New Zealand had a more narrow range of newer medicines than Germany and the Netherlands (Danzon and Kelcham 2004); fewer available and reimbursed medicines and a narrower range of reimbursed and available innovative and/or new medicines than the US VANF, Australia and the UK (Ragupathy et al. 2012); and fewer available and reimbursed medicines and formulations suitable for paediatric use than Australia and the UK (Ragupathy et al. 2010). In European comparisons, Finland and other Nordic countries tended to have a low number of medicines in comparison to Central-European countries (Folino-Gallo et al. 2001); and a higher share of reimbursable products (Vogler 2008).

An overall challenge in designing meaningful comparisons of product ranges is the lack of standardised methodology in identifying when the observed differences are clinically relevant. Especially when the comparison is not limited to one or a few conditions, assessment of available treatment alternatives, possibly across therapeutic groups, becomes challenging. Differences due to reimbursement restrictions may also go unnoticed. If comparable sales or claims statistics were available, an alternative method would be to assess differences in actual patterns of use. Using therapeutic innovations as a proxy of availability is less cumbersome, although not without limitations. Products ranked as innovations at the time of market entry may turn out to be less effective, or even harmful, in real-life settings. Fast reimbursement of new medicines also needs to be assessed in relation to opportunity costs.

6.2 Discussion with comparative perspective

6.2.1 Pharmaceutical systems in shaping affordability

In terms of protective strength, the reimbursement systems in both countries have strengths and weaknesses. By using modified indicators of de-commodification (adapted from Reibling 2010) to compare the dimensions of access in each system, the Finnish pharmaceutical system seemed to provide a better *benefit level*, in particular a faster access to new and innovative medicines, as well as a wider choice between therapeutic options. New Zealand´s system provides reimbursed options across most therapeutic groups, although the options within the groups are few. Cost-sharing, the main *disincentive*, is softer in New Zealand. The two countries both had universal coverage for prescription medicines and they also had similarities in determining the *conditions* for lower cost-sharing or exemptions. Both systems used ceiling mechanisms and targeted specific groups, although on different grounds. The Finnish system is disease-specific (needs-test) whereas the New Zealand system is population group-specific (means-test: low-income, age-based: children). Both countries also use restricted reimbursements to influence prescribing, although in Finland these restrictions are limited to new and the most expensive medicines. In New Zealand, restrictions apply to many second and third-line options.

Within published health system typologies, the health care system in New Zealand best fits the criteria of the Beveridge model (OECD 1987), the "entrenched command-and-control state" (Moran 1999; 2000; Burau and Blank 2006) or, based on the similarity to the UK system, the "universal coverage – controlled access" and "strong gatekeeping and low supply" models (Wendt 2009; Reibling 2010). Characteristics of these systems include a strong public role, gatekeeping and regulation, a low level of cost-sharing, low number of providers and high equity in access. The Finnish health care system has also been classified as best fitting the criteria of the Beveridge model (Häkkinen and Lehto 2005; Klavus et al. 2012; Lehto 2014). Moran (1999; 2000) classified all Nordic countries as "entrenched command-and-control states". However, based on the cluster analyses by Wendt (2009) and Reibling (2010), Finland represented the "mixed regulation model" or "low budget – restricted access model", together with Portugal, Italy and Spain. These systems were characterised by high gatekeeping, high cost-sharing and technology, and by very low prescriber autonomy.

The institutional differences identified by the more recent cluster analyses reflect some of the differences in the pharmaceutical systems in Finland and New Zealand. The main routes of regulation differ between the two countries. Conventional regulation, i.e. command-and-control activities, designed to override market forces (Saltman 2002; Blank and Burau 2014, 129), is the predominant route applied in New Zealand. PHARMAC has an active role in shaping the streamlined list of reimbursed products as an entity, with multiple supply side strategies to maximising value for money. On the demand side, prescriber autonomy is limited by the narrow choice of reimbursed medicines and detailed restrictions on the use of therapeutic options, which also lessens the risk of moral hazard. Prescribers and patients have limited choice between reimbursed options, but they may participate by initiating the reimbursement evaluation process (PHARMAC 2015), which is in line with the overall health policy goals to involve consumers and communities in decision-making. Individual decisions are also allowed under the Exceptional Circumstances framework, although for clinical reasons only, not because of patient preference.

When compared to New Zealand, the Finnish pharmaceutical system has more characteristics of pro-market regulation, in which the public role is to provide balance among stakeholders but maximise the autonomy of providers and consumers through marketplace principles (Saltman 2002; Blank and Burau 2014, 129). On the supply side, the reimbursement process can only be initiated by pharmaceutical companies and the public focus is on price regulation. However, active control is used for new and expensive medicines, which are often reimbursed with restrictions. Besides broad determination of reimbursable products in the legislation, there is no active public control in determining the "benefit package" of reimbursed medicines. Instead, it is a selection guided by the principles of demand and supply, together with company marketing strategies. On the demand side, Finland relies more heavily on influencing patients than prescribers.

The reimbursement systems also have institutional differences related to funding. Public control is expected to be the highest in systems where the majority of funding derives from general taxation, which is the case for New Zealand (Blank and Burau 2014, 87). Accordingly, in New Zealand, PHARMAC has had considerable autonomy in the policies and procedures it uses to control prices and reimbursements, and the public control over the overall budget is high. In Finland, the reimbursements for medicines are paid through National Health Insurance, which is funded by employee contributions and state funding. The reimbursement system therefore shares characteristics of the social insurance model (Moran 1999; 2000). The public budget control is weaker and reform processes more rigid since changes in the health insurance benefits, including implementation of cost containment policies, are subject to legislative process. The stakeholders, including labour market parties and lobbyists of interest groups thus also have higher possibilities in influencing decision making. (Immergut 1992; Niemelä 2014, 239–248; Saarinen 2011.)

Furthermore, the low prescriber autonomy associated with national health service systems does not seem to apply to the Finnish pharmaceutical system. Due to the dual funding mechanisms, doctors are not subject to financial incentives as regards the prescribed medicines and the expenditure on medicines has no direct budgetary effects (Vuorenkoski et al. 2008). Further, there are no national formularies or prescription guidelines based on cost-effectiveness. In New Zealand, although the pharmaceutical budget is de facto centralised to PHARMAC, exceeding the budgetary cap would lead to the DHBs having to reduce their spending in other areas (PHARMAC 2016a). Cost-effectiveness and opportunity costs are used as criteria by PHARMAC in determining the Pharmaceutical Schedule, which is in fact a national formulary. Nevertheless, restricted reimbursements are used in both countries rather widely, as a form of a cost-containment measure.

Differences have also been shaped by supranational institutions and pharmaceutical industry business strategies. The Finnish available range of medicines is shaped by the centralised and mutual recognition marketing authorisation processes of the EU, with specific favourable regulation concerning orphan medicines and paediatric medicines (Greer et al. 2013). The EU also imposes requirements for the national pricing and reimbursement process, in terms of timeframe, transparency of decision criteria, and appealability (Directive 2013/50/EU). Similar requirements of increased transparency and appealability concerning pricing and reimbursement processes, together with extended intellectual property rights, have been proposed in trade and investment agreement negotiations between the US and Pacific countries, including New Zealand and Australia. The proposed measures were estimated to lead to increased secondary patenting and evergreening, delay access to generic medicines, and increase prices for pharmaceuticals in New Zealand and Australia and thus increase either public or private expenditure, or lead to restricting the reimbursed range. (Gleeson et al. 2013; 2015.) On the other hand, lower expected profits from extensive

cost-containment policies in New Zealand, together with small market size, are likely to affect availability via market mechanisms (Kyle 2007; Kanavos et al. 2011). Accordingly, New Zealand has had comparatively few submissions to reimbursement from pharmaceutical companies (Cheema et al. 2012).

6.2.2 Distribution of out-of-pocket costs

Based on publicly available national statistics, the average level of out-of-pocket costs is lower in New Zealand than in Finland, even when adjusted to differences in price and income levels. However, to assess fairness, also distribution matters (WHO 2000, 26), especially since the distribution of health care utilisation and needs is strongly skewed (Steinberg et al. 2000; Berk and Monheit 2001; Goulding 2005; Zuvekas and Cohen 2007; Saastamoinen and Verho 2013).

In Finland, after adjusting for age, lower income households paid lower sums than high income households, but spent a higher share of their overall consumption on medicines (Study I). Out-of-pocket costs for medicines thus had some regressive effects in Finland. Similar findings, regarding costs for medicines, have been described in studies from Germany, Australia and Italy (Jones et al. 2008; Bock et al. 2014; Terraneo et al. 2014). Also in Canada, social assistance households spent a similar share on medicines compared to households in general, but were more likely to spend over 10% of consumption on medicines (McLeod et al. 2011). In Austria, higher income was associated with higher likelihood of buying OTC-medicines (Sanwald and Theurl 2014), which was in line with the higher expenditures found in Finland.

Previous descriptions of the distribution of out-of-pocket costs from Finland are scarce. In an unadjusted analysis, which only encompassed people with reimbursed purchases, co-payments were found to be highest in the second lowest income decile, which also contained a high share of older people (Martikainen et al. 2008). Similar unadjusted findings were reported from Canada (Sanmartin et al. 2014). Accordingly, in Study I, without adjusting for age, the differences between income quintiles decreased. Differences also decreased when only households with purchases were included, since the lowest income quintile also had lowest share of households with purchases.

The magnitude of the difference in the share of total consumption spent on medicines between the lowest and the highest income households in Finland increased over time and was 1.1 percentage points in 2006. Similarly, Terraneo et al. (2014) found a one percentage point difference between the poorest and other families in Italy. However, it is likely that the regressive effects in Finland would be even larger without the progressive effects of the disease-based eligibilities to higher reimbursement, since eligibilities to the highest reimbursements are most common among low-income population groups (Aaltonen 2015). Studies from the US, where cost-sharing and in-

surance coverage varies widely, have described much larger income differences, and high burden resulting from out-of-pocket costs (Sambamoorthi et al. 2003; 2005).

In New Zealand, according to Study II, high out-of-pocket costs from using medicines outside the reimbursed or fully reimbursed range were rare. This may indicate that, at least among older people, the fully reimbursed range addresses relatively adequately the health needs for most. On the other hand, it may also indicate that the majority of older people are either unwilling or unable to pay higher costs for medicines outside the fully reimbursed range. High out-of-pocket costs for medicines were not significantly more or less frequent among people with higher socioeconomic position.

Nevertheless, high costs were less frequent among Māori and they coincided with a lower level of medicine use. Similarly, previous research from New Zealand has shown that Māori tend to be less likely to purchase prescription medicines and also to have fewer subsequent dispensings than non-Māori, after adjusting for need (Metcalfe et al. 2013); that Māori, also children living in rural areas, had few dispensings and low quantities of antibiotics, despite their higher prevalence of rheumatic fever (Norris et al. 2011a); and that older Māori are less likely than older non-Māori to be dispensed psychotropic medicines (Norris et al. 2011b).

The lower level of utilisation is of concern, since Māori tend to have a lower life expectancy, higher mortality and poorer health outcomes, together with higher prevalence of risk factors (e.g. obesity) than New Zealanders of European descent (Bramley et al. 2005; Elley et al. 2008; Kenealy et al. 2008; Robinson et al. 2016). Ethnic/racial differences in health have also been identified in other populations (Bramley et al. 2004; 2005). Nevertheless, the manifold causes behind these differences are out of scope of this research and they are likely to vary depending on the group of population and the health system in question, as well as the cultural, historical and political context (Dahlgren and Whitehead 1991, 39–40; Smedley et al. 2003; Kawachi et al. 2005; Kenealy et al. 2008; Chen et al. 2010).

Measurements of disparities based on overall costs and utilisation have their limitations. Medicines differ in their therapeutic value, and thus higher utilisation or costs may also represent irrational use. This is most evident with discretionary medicines and to some extent, with OTC medicines. Also the tendency to use expensive treatment alternatives without therapeutic reasons, e.g. "me too" products, or branded medicines instead of generics, could create clinically less relevant disparities. Even so, from the perspective of public spending, the financial consequences of irrational use may have consequences in terms of efficiency. It has been suggested that new medicines can behave, in terms of demand and price elasticity, as luxury goods, as they cover a more "marginal" demand with higher price to patients and consumers (Clemente et al. 2008). The price elasticity has also been show to differ between income groups (Terraneo et al. 2014). Further, increasing the overall insurance coverage may

not always decrease disparities, since those with previously the highest consumption patterns may increase their consumption the most (Borrell et al. 2006; Korda et al. 2007; Mahmoudi and Jensen 2014).

The public willingness to pay and the general attitudes towards cost-sharing also need to be viewed in a historical context. New Zealand has a long tradition of no or very low cost-sharing, dating back to the New Zealand Social Security Act of 1938, when all New Zealanders became eligible to free medicines and hospital services (Cumming et al. 2014). In comparison, Finns are used to a much higher level of cost-sharing since the relatively late establishment of National Health Insurance in 1963, when the standard reimbursement rate for medicines was set to 50% (Health insurance Act 364/1963). Even though both countries have increased cost-sharing for medicines over time, New Zealand has a notably lower level of cost-sharing than Finland, in absolute and relative terms.

The results from Study I thus offered support for the prior concern of the inequitable distribution of out-of-pocket costs in Finland. Study II showed that whether or not the fully reimbursed range in New Zealand was adequate, most older people relied on it, regardless of their incomes. The use of expensive medicines outside the reimbursed range did therefore not seem to have a socioeconomic gradient. However, the lower costs and use among Māori, who also have higher health needs, is of concern. Since need could not be assessed in this study, further research is needed to understand whether the different use patterns derive from over or underuse, and whether they are caused by economic, cultural or other factors.

Out-of-pocket costs in health care generally tend to have regressive effects, since they are difficult to allocate otherwise (WHO 2000, 35). However, it must be noted, that in both Finland and New Zealand out-of-pocket payments only represent a small part of the total pharmaceutical expenditure, while the public funding derives from progressive forms of prepayments (taxes and social insurance contributions).

6.2.3 Cost-related access barriers

Besides out-of-pocket costs in relation to income, unmet needs are a commonly used indicator of inequities in access (de Looper and Lafortune 2009). The Commonwealth Fund has conducted health policy surveys in several countries, including New Zealand since 1998, to assess people's experiences related to their health care and health insurance systems (Schoen et al. 2010; OECD 2015b; Commonwealth Fund 2016). Finland has not been included in these surveys, and no published direct comparisons of access barriers between Finland and New Zealand were found in the literature. Therefore, although results from different surveys and from different countries are not directly comparable due to multiple reasons, the results from Study III represented the best available information from Finland. The findings of Study

III are compared with findings and patterns observed in previous studies from New Zealand.

Based on indirect comparison between the results from Study III and Commonwealth Fund survey results (Schoen et al. 2010; Commonwealth Fund 2010b), Finland would rank the third highest by the frequency of reported access barriers both to prescription medicines and to other forms of treatment, after the US and Australia. Cost-related barriers seem thus more frequent in Finland than in New Zealand or the European countries surveyed by the Commonwealth Fund: Sweden, Norway, Germany, the Netherlands, Switzerland, France and the UK. Examination of reporting any cost-related barriers by income (Study III and Schoen et al. 2010) would place Finland close to Australia and Germany, and above New Zealand, in the frequency of barriers for both above and below average income groups. Earlier (year 2000) results from Finland (Lindholm 2001), in comparison to the Commonwealth Fund 2001 study results (Commonwealth Fund 2001; Schoen et al. 2002), would place Finland the third highest in frequency of access barriers to prescription medicines, after the US and Australia, and the highest in barriers to other treatments.

Based on indirect evidence, cost barriers seem thus to be slightly more common in Finland than in New Zealand. Due to the lower level of cost-sharing in New Zealand, this finding is expected. However, in direct comparisons, New Zealand has ranked high in relation to other countries with low level of cost-sharing (UK, Netherlands and Sweden). New Zealand does, therefore, not seem to reach the same level of equity than its benchmark countries. This difference is likely to be influenced by the narrow choice of reimbursed products, together with, at least in comparison to the UK, a slightly higher level of cost-sharing (Ragupathy et al. 2012). Also, a previous study from New Zealand has shown that for people with no or very low income, even low fees may have catastrophic financial effects (Norris et al. 2015).

In Commonwealth Fund surveys to the general population conducted between 1998–2013, New Zealand ranked higher for cost-related access barriers to care than to prescription medicines. Accordingly, New Zealand has traditionally had relatively high patient fees in primary care. New Zealanders tended to report access barriers to care less frequently than respondents from the US but more often than respondents in the UK, Netherlands (except 2013), Norway, Switzerland, Canada and Sweden. Ranking with Australia, France and Germany varied. In the later years, the frequency of reported barriers to medicines seemed to decrease in New Zealand, possibly due to the reforms in primary care that decreased co-payments for doctor services and medicines. (Commonwealth Fund 1998; 2001; 2010b; Schoen et al. 2002; 2007a; 2007b; 2010; 2013.)

The Finnish survey (Study III) did not assess cost-related access barriers to prescribers. The pro-rich inequity in doctor use, especially access to specialists, has previously

been found to be particularly large in Finland in relation to other developed countries (van Doorslaer et al. 2006). However, access barriers to medical examination in Finland derived mainly from other reasons (e.g. waiting time) than cost, according to EU-SILC surveys (Eurostat 2016b). Patients thus seem to experience barriers to prescribers in both countries, although for different reasons. However, socioeconomic factors are likely to play a key role in shaping inequalities in access and use in both countries, regardless of the specific barriers (van Doorslaer et al. 2006; Allin and Masseria 2009a; de Looper and Lafortune 2009). According to Commonwealth Health policy survey 2010, the UK was the only country where no significant differences in the frequency of cost-related access barriers to care were observed between above and below-average respondents (4% for both groups, after adjusting for health and age). In the UK, also a significant proportion of people are completely exempt from user charges. (Schoen et al. 2010.)

Besides low income, other risk factors for cost-related access barriers observed in Finland included poor health status, lower education, younger age and female gender. A parallel analysis, limited to cost-related barriers to prescription medicines, gave broadly similar results in terms of income, education and health. However, gender was not significantly associated with cost-related access barriers to medicines, but a more rural area of residence was significantly associated. (Aaltonen et al. 2013.) In studies from other countries, lower income or socioeconomic status and poor health have been robust risk factors for cost-related non-adherence and unmet needs (Briesacher et al. 2007; Mielck et al. 2007; 2009; Allin and Masseria 2009a; 2009b; Bryant et al. 2009; de Looper and Lafortune 2009; Allin et al. 2010; Israel 2016). Mixed results have been found for gender in regards to medicines (Briesacher et al. 2007).

In New Zealand, Jatrana et al. (2009; 2011) assessed determinants of cost related access barriers to prescription medicines and primary care based on national Survey of Family, Income and Employment (SoFIE) Health add-on module results in 2004–2005. In multivariate analyses, factors associated with deferring both doctor visits and prescription medicines were socioeconomic deprivation, higher co-morbidity, psychological distress, younger age, female gender and current smoking. Māori were less likely than European to defer doctor visits but more likely to defer prescriptions, after adjusting for other factors. Those living alone, with the highest level of education or with a lower level of income were more likely to defer doctor visits than their counterparts, but the results for prescription medicines were mixed or not significant. Self-assessed health was not significantly associated, after adjusting for co-morbidities, psychological stress, smoking and other factors. Socioeconomic deprivation and the presence of one or more co-morbid diseases were significant determinants of deferring prescriptions for all examined ethnic groups: European, Asian, Māori and Pacific (Jatrana et al. 2011). According to a subsequent study, people who reported deferring buying medicines because of cost also had an increased risk of a decline in health (Jatrana et al. 2015).

Despite the differences in the level of out-of-pocket costs, cost-related access barriers are reported in both Finland and New Zealand, and similar patterns have been observed across studies regarding the determinants of access barriers. Although the reimbursement systems in both countries are likely to promote equitable access, the used mechanisms seem not generous and extensive enough to entirely counterbalance the negative effects of cost-sharing, as has been previously found in several studies from other countries (Jones et al. 2008; McLeod et al. 2011; Terraneo et al. 2014).

The overall level of social security influences the ability to pay, especially for individuals most dependent on income transfers. Countries vary in the emphasis they place on different types of social provision: services and cash transfers (e.g. pensions, sickness benefits, unemployment benefits). Nordic countries, including Finland, have rated high for both types of provision. New Zealand, conversely, has rated relatively high in services but low in cash transfers. (Bambra 2005.) The differences in the level of cash transfers is out of the scope of this study but may provide one explanation for why the two countries rate relatively similarly in financial access barriers despite the differences in the level of cost-sharing.

7 Conclusions

Based on the present study, the following conclusions can be drawn:

- The reimbursement systems in Finland and New Zealand both had strengths and weaknesses related to different dimensions of affordability. In New Zealand, the high control over the range of medicines limits the risk of moral hazard and prescriber autonomy and thus low user charges apply to medicines across therapeutic groups. In Finland, supply side regulation is targeted to patients, who pay relatively high out-of-pocket costs for most treatments. Prescribers, on the other hand, have a wide choice over reimbursed therapeutic alternatives, although restrictions apply to new and expensive treatments.

- Fewer new innovative medicines that provide health gain are registered and brought to market in New Zealand than in Finland. Since the countries are similar in market size, the differences are likely to be influenced by the lower potential profits made in New Zealand, due to cost-containment policies, and by the effects of the European Union on Finnish pharmaceutical policies, which are beneficial to pharmaceutical companies.

- The level of out-of-pocket costs was higher in Finland than in New Zealand. In Finland, out-of-pocket costs had regressive effects. In New Zealand, most older people relied on the fully reimbursed range of medicines regardless of their incomes and the use of expensive medicines outside the reimbursed range did not seem to have a socioeconomic gradient. However, high costs were less frequent among Māori and they seemed to coincide with lower level of medicine use.

- Cost-related access barriers to medicines seem relatively high in Finland, when compared to results from previous studies from other European countries and New Zealand. Access barriers were associated with higher health needs and lower socioeconomic position in Finland. Similar patterns have been previously described for New Zealand. It seems therefore that, although both countries use mechanisms to protect patients from high burden of costs, these are not sufficient to counterbalance the negative effects of user charges entirely.

8   Implications for research and practice

In the recent years, fiscal sustainability issues have led to increasing patients' share of costs in both Finland and New Zealand, and thus increasing individuals' financial responsibility. At the same time, new high cost therapies for small patient groups take up a growing share of the public pharmaceutical budget. There is often limited information on the therapeutic value of new products, and the line between necessities and luxury products is not always easy to draw. These trends make decisions on the level and allocation of resources increasingly difficult. Public pressure, industry influence and political forces challenge the systems in their ability to justify public control over costs and utilisation. Social and political solutions are essential in promoting the rational use of medicines. In finding the solutions, policymakers should be aware of the trade-offs between individual choice and equitable access. Future research can contribute by making these trade-offs more visible.

Addressing the financial barriers to prescription medicines is important in both Finland and New Zealand, although similar measures may not be effective in both countries and for all population groups. Clinicians and pharmacists could mitigate the negative effects of increased cost-sharing to patients by rational prescribing and promoting the rational use of medicines.

In Finland, shifting the focus of cost containment policies from influencing patients to influencing prescribers could better serve the aims of increasing equity in access and promoting the rational use of medicines. By definition, rational use of medicines requires that appropriate medication is received at the lowest cost to patients, not only to their community. In New Zealand, patients and society are both likely to have financially benefitted from the complex arrangements between PHARMAC and pharmaceutical companies. However, the confidential nature of these arrangements have an impact on transparency. Comparable data, even on system level, on medicine use and costs is scarce and largely outdated.

A number of questions remain unanswered and should be addressed in further studies. First, the processes, causes and consequences of socioeconomic and ethnic differences in medicine use require further assessment. The multiple factors that influence the different steps of the process of care – seeking care, accessing care, care received, adherence to care, and the relative impact that the different barriers in the course of the process have on health outcomes, need to be better understood. Second, further studies should focus on understanding the necessity of care to distinguish patterns related to underuse of necessary treatments, and on the other hand, patterns related to using discretionary or unnecessarily expensive treatments.

Third, to be able to better understand and compare pharmaceutical systems across countries, standardised methods and outcomes are needed. Instead of focusing on differences in system characteristics, relative performance should be assessed. In re-

gards fairness in financing, the distribution of out-of-pocket spending is of interest. Assessing policies and utilisation patterns together, within specific therapeutic groups, could serve in estimating the joint effects of conditions and disincentives on use in different countries. Further, little is known of how well the different reimbursement systems respond to patient and prescriber expectations.

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Appendix

Key facts and statistical indicators of society, health care and pharmaceutical sector in Finland and New Zealand

		Year	Finland	New Zealand	Source of data
General	Surface area, km2	2014	338,420	267,710	World Bank, WDI
	Population, total	2014	5.5 Million	4.5 Million	World Bank, WDI
	Population growth, annual %	2000–2014	0.2–0.5%	0.5–1.5%	World Bank, WDI
	Population density, people per km2	2014	18	17	World Bank, WDI
	Urban population, % of total	2014	84%	86%	World Bank, WDI
People	Population, female (% of total)	2000 / 2014	51% / 51%	51% / 51%	World Bank, WDI
	Population, ages 0–14 (% of total)	2000 / 2014	18% / 16%	23% / 20%	World Bank, WDI
	Population, ages 15–64 (% of total)	2000 / 2014	67% / 64%	65 % / 65%	World Bank, WDI
	Population, ages 65 and above (% of total)	2000 / 2014	15% / 20%	12% / 14%	World Bank, WDI
	Ethnic groups	FI: 2006 NZ: 2013	Finn 93%, Swede 6%, Russian 0.5%, Estonian 0.3%, Roma 0.1%, Sami 0.1%	European 71%, Maori 14%, Asian 11%, Pacific peoples 8%, Middle Eastern, Latin American, African 1%, other 2%, not stated/unidentified 5% (people may belong to more than one ethnic group)	CIA World Factbook
Income	GDP per capita, USD PPP	2000 / 2014	26,470 / 40,200	21,570 / 37,510	OECD Health Statistics
	Annual median equivalised disposable household income, USD PPP (current prices, current PPP)	2010	23,700 (rank 13. among OECD countries)	21,900 (rank 18. among OECD countries)	OECD Society at a glance 2014
	Gini coefficient of household disposable income	2010	0.26 (rank 6. among OECD countries)	0.32 (rank 20. among OECD countries)	OECD Society at a glance 2014
	People living with less than 50% of median equivalised household income (%)	2010	7.3 (rank 6. among OECD countries)	10.3 (rank 19. among OECD countries)	OECD Society at a glance 2014

		Year	Finland	New Zealand	Source of data
Health	Life expectancy at birth, years, total (male; female)	2000 / 2013	78 (M 74; F 81) / 81 (M 78; F 84)	78 (M 76; F 81) / 81 (M 80, F 83)	OECD Health Statistics
	Infant mortality, deaths per 1,000 live births	2000 / 2011	3.8 / 2.4 (rank 4. among OECD in 2011)	6.3 / 5.2 (Rank 30. among OECD in 2011)	OECD Health Statistics
	Maternal mortality, deaths per 100,000 live births	2000 / 2011	5.3 / 0 (rank 1. among OECD in 2011)	8.8 / 11.3 (rank 27. among OECD in 2011)	OECD Health Statistics
	Potential years of life lost / 100,000 population aged 0–69 years old: - all causes of death	2005 / 2011	4,028 / 3,395	3,675 / 3,378	OECD Health Statistics
	- neoplasms	2005 / 2011	849 / 728	1,030 / 916	OECD Health Statistics
	- endocrine, nutritional and metabolic diseases	2005 / 2011	87 / 70	135 / 115	OECD Health Statistics
	- mental and behavioural diseases	2005 / 2011	67 / 50	18 / 11	OECD Health Statistics
	- diseases of circulatory system	2005 / 2011	719 / 599	601 / 492	OECD Health Statistics
	- diseases of respiratory system	2005 / 2011	83 / 81	112 / 109	OECD Health Statistics
Health care utilisation	Number of doctor consultations per person	2012	2.7 (rank 33. among the OECD)	3.7 (rank 39. among the OECD)	OECD Health at a glance 2015
	Inpatient care discharges per 100,000 population	2005 / 2013	19,680 / 16,950	13,270 / 13,960	OECD Health Statistics
	Inpatient care average length of stay, days (all hospitals)	2005 / 2013	12.7 / 10.8	9.0 / 7.9	OECD Health Statistics
	Waiting times, median days - cataract surgery	2005 / 2013	174 / 87	57 / 75	OECD Health Statistics
	- hip replacement	2005 / 2013	145 / 103	42 / 98	OECD Health Statistics
	- coronary bypass	2005 / 2013	50 / 21	34 / 27	OECD Health Statistics
	- Percutaneous transluminal coronary angioplasty (PTCA)	2005 / 2013	22 / 17	53 / 41	OECD Health Statistics

		Year	Finland	New Zealand	Source of data
Financing	Health expenditure per capita, USD PPP	2013	3,442 (rank 17. among OECD countries)	3,328 (rank 18. among OECD countries)	OECD Health Statistics
	Annual average growth in expenditure on health, in real terms, %	2005–2009 / 2009–2013	1.7% / 1.3%	4.1% / 0.6%	OECD Health Statistics
	Public share of total health expenditure, % of total	2013	75%	80%	OECD Health Statistics 2015
	Health expenditure by type of financing, % of total (General government / social security / private OOP / Private insurance / other)	2013	61% / 14% / 19% / 2% / 4%	72% / 8% / 13% / 5% / 3%	OECD Health at a glance 2015
Pharmaceutical market	Health expenditure per capita on medical goods, USD PPP (total expenditure/private OOP) - prescribed medicines	2007	365 / 133	217 / 51	OECD Health Statistics
	- OTC-medicines	2007	55 / 55	28 / 28	OECD Health Statistics
	Pharmaceutical sales (NZ: paid reimbursements only, FI: all pharmaceutical sales) - total, Million USD PPP	2000 / 2013	1.122 / 2.183	366 / 629	OECD Health Statistics
	-per capita, USD PPP (current prices, current PPPs)	2000 / 2013	217 / 401	95 / 141	OECD Health Statistics
	Generic share of total pharmaceutical market, % (FI: community pharmacy market; NZ: reimbursed pharmaceuticals)	2008 / 2013	12% / 18% (value) 36% / 40% (volume).	27% / 34% (value) 64% / 77% (volume)	OECD Health Statistics

References: World Bank 2016; CIA 2016; OECD 2014c; 2015a; 2015b.

Medicines are among the most common and important health care interventions. Most high income countries have implemented reimbursement systems, to ensure economic access to necessary medicines. This study aimed to examine the features of pharmaceutical systems in Finland and New Zealand, and how they translate into affordability-related outcomes.

The study found that the Finnish system provides a wider choice between reimbursed therapeutic options, and faster availability of new innovative medicines. However, medicines were subject to higher patient payments, which had inequitable effects.

Within the New Zealand system, patient payments are generally low for most health needs, but the choice between therapeutic options is narrower and the availability of new innovative medicines lower. Despite the narrow range, the utilisation of non-reimbursed medicines was rare among older people and did not seem to have a socioeconomic gradient.