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VALUE IN HEALTH

The Impact of Pharmaceutical Cost Containment Policies on the Range of Medicines Available and Subsidized in Finland and New Zealand

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ABSTRACT

Objective: To identify differences in the range of medicines available and subsidized for ambulatory care in Finland and New Zealand.
Methods: Medical entities listed in national product information sources and their subsidy statuses were compared. The number and overlap of entities available and subsidized were determined. Differences in the age of subsidized medicines were compared using the date of first registration. Differences in licensing delays were compared using a selection of new innovative medicines that provide health gain.
Results: Within the inclusion criteria, 779/763 entities were available and 495/471 subsidized in Finland/New Zealand, of which around 30% (30.9% Finland, 29.5% New Zealand) were not available and approximately 40% (41.4% Finland, 38.4% New Zealand) not subsidized in the other country. The proportion of fully subsidized entities was higher in New Zealand (86.2%/29.1%). The entities only subsidized in New Zealand were significantly older than those only subsidized in Finland and the share of licensed and launched innovative medicines was significantly smaller in New Zealand. The differences were equally distributed across the therapeutic groups but clinically relevant differences were rarely found.
Conclusions: In New Zealand, medicines are heavily subsidized across therapy groups, but those uniquely subsidized were older entities. In Finland, more "newer" medicines are subsidized and available, but the level and coverage of subsidy is lower and thus, the patient cost burden is higher. The cost containment policies adopted seem to affect patients' access to medicines mainly by availability in New Zealand and by affordability in Finland.
Keywords: access to medicines, cost containment policies, cross-national comparison, drug utilization, Finland, New Zealand, pharmaceutical policy, prescription medicines.

Introduction

Finland and New Zealand are relatively small countries within the Organisation for Economic Co-operation and Development (OECD) that have similar public health problems and heath-care systems. Both countries have publicly funded health care with universal coverage (based on the Beveridge model) and low share of health-care funding from private insurance (2% in Finland and 5% in New Zealand in 2005) [1–3].

Total health expenditure per capita (adjusted by purchasing power parities) grew almost identically in the two countries during the past 3 decades, as did pharmaceutical expenditure in the 1980s and early 1990s [3,4]. However from 1995 to 2005, pharmaceutical expenditure grew more slowly in New Zealand (2.5%) than in Finland (5.0%) and substantially less than in OECD countries on average (4.6%). At the end of the period, in 2005, period, the total pharmaceutical expenditure per capita was US$380 (purchasing power parity (PPP)) in Finland and US$290 (PPP) in New Zealand, although total health expenditure per capita was very similar (US$2331 [PPP] in Finland and an estimated US$2343 [PPP] in New Zealand). The public share of pharmaceutical expenditure in 2005 was 10% lower in Finland (56%) than in New Zealand (66%) although the public share of total health expenditure was 78% in both countries [3,4].

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It is likely that the different cost containment policies adopted in Finland and New Zealand have contributed to the different growth rates in pharmaceutical expenditure. Since the establishment of New Zealand's Pharmaceutical Management Agency (PHARMAC) in 1993, growth in pharmaceutical expenditure has decreased [4,5]. Cost containment controls differ from those in Finland. In New Zealand, a range of strategies were used, including reference pricing of therapeutic groups, tendering, generic substitution by pharmacists [6] and in Finland, generic substitution by pharmacists and indirect control of wholesale prices by cost-effectiveness-based subsidy decisions [7,8]. In New Zealand, PHARMAC is not only in charge of reimbursement decisions and pharmaceutical budget, but also directly involved in negotiating purchasing contracts with suppliers. In Finland, reimbursement decisions and reimbursement administration is done separately by the Pharmaceutical Pricing Board (under the Ministry of Social Affairs and Health) and the Social Insurance Institution, respectively. Neither is directly involved in the purchase of medicines.

Pharmaceutical cost containment policies may have a negative impact on patients' access to medicines. The launch of new medicines is likely to be delayed in countries with small potential sales volumes and low expected prices resulting from cost containment policies [9], and higher patient costs may reduce all health-care usage, have negative health outcomes on people with low incomes, but have little or no effect on health on average [10–12]. In cost comparisons, patients' out-of-pocket payments and retail prices were found to be high in Finland when compared with other European countries [13–15], although the wholesale prices were moderate [15].

Table 1 Reimbursements of outpatient pharmaceuticals in Finland and New Zealand in 2007

	Finland	New Zealand
Subsidized items	Positive list, updated monthly. Separate positive lists for 42%/72%/100% subsidized medicines.	Positive list, updated monthly (called the Pharmaceutical Schedule)
General subsidy	Unrestricted 42% of retail price	Unrestricted 100% subsidy with fixed copayment (US$0–11.10 per item, in most cases US$2.22 per item)*
Other subsidies	Restricted 42% subsidy of retail price by prior application for patients meeting specific criteria (very expensive medicines). Seventy-five percent of retail price by prior application for specific list of medicines for patients with severe and chronic conditions (e.g., asthma, hypertension) One hundred percent subsidy with fixed copayment (US$4.03 per item) by prior application for specific list of medicines for patients with severe and life-threatening conditions (e.g., cancer, diabetes)	Part subsidy for specified medicines for which the price exceeds the government subsidy. Patient pays fixed copayment plus manufacturer's surcharge (subsidy decided on a case-by-case basis by the PHARMAC). Special Authority medicines (full or part subsidized). Restricted by prior authorization. Applications can be made for patients meeting specific criteria.
Annual cap	US$843.06 for subsidized medicines per person, after which a fixed copayment applies (US$2.02 per item).§	Twenty prescription charges per family or over 12 visits to a doctor (theoretical maximum copayment US$221.92) after which the level of copayment is reduced (US$ 0–2.22 per item).†‡
Exemptions	None	Children under 6 years are exempt from copayments. Patients on a low income are entitled to a copayment reduction (maximum US$2.22 per item).

*Level of copayment depends on the prescriber, pharmacy, patient's incomes, and health service use.
†Manufacturer's surcharge applies.
‡Medicines outside positive list are not subsidized.
§Medicines outside positive list are not subsidized.
The prices have been converted to US dollars from national currencies (Euro, New Zealand dollar) with the exchange rate at time of analysis (June 1, 2007/European Central Bank [44]).
PHARMAC, Pharmaceutical Management Agency.

In both countries, the medicines are subsidized according a positive list updated monthly [16,17]. Medicines can be fully or partly subsidized (see details in Table 1). Individual patient's medicine costs can vary substantially in both countries when subsidy levels, annual price caps, and prices for nonsubsidized medicines are taken into account, making direct comparisons difficult. Although in general, patient costs are lower in New Zealand, with higher general subsidy and an annual price cap of about a quarter of that of Finland (even if adjusted by 2007 OECD estimated PPPs [18]). In addition, low income people, children, and high health-care users are exempt from or have reduced copayments in New Zealand, whereas no patient group receives a general exemption from payments in Finland. After reaching the annual caps, however, prices in New Zealand can be higher if part-subsidized medicines are used.

As a percentage of annual average income, the patient contribution seems high in Finland. According to Statistics Finland [19], the average income in Finland was €22,621 (2006, average income per income recipient) of which the annual price cap was 2.8%. In New Zealand, the corresponding figure was NZ$31,720 (2006, from average weekly income for all people from all sources) according to Statistics New Zealand [20], and the price cap thus, was only 0.95% of the annual average income. Nevertheless, inequality as measured by the Gini coefficient was 26.1 in Finland (well below the OECD average), whereas New Zealand was clearly above the average with 33.7 [21].

In-patient medicines also affect the range of subsidized medicines available to patients. Medicines used for hospital in-patients are funded from hospital budgets in both countries without cost to the patient. Medicines for treatment of accidents can be paid for by a specific social insurance scheme, the Accident Compensation Commission, in New Zealand, and this is also the case in Finland for road accidents. In very rare cases in New Zealand, medicines not listed in the Pharmaceutical Schedule can be funded on a case-by-case basis under exceptional circumstances-policies [16]. Social welfare can fund some medicines for very low- or no-income patients in both countries.

Each country's pharmaceutical system has been criticized from within. In Finland, there has been concern over the effect of high costs on access to medicines, especially for people with low incomes [7,22]. In New Zealand, the debates concern the lack of new and allegedly more efficient or safe subsidized medicines [23,24]. As both OECD countries are of similar size and have similar public health problems and publicly funded health care, an examination and comparison of access to medicines in these two countries is of interest internationally.

Aims of the Study

The aims of the study are to examine and compare the range of medicines available and subsidized for ambulatory care in Finland and New Zealand in 2007 and to further analyze the differences found by: 1) the age of the medicines subsidized solely in each country (using years since first marketed in reference countries); 2) clinically relevant differences in the three largest anatomical therapeutic chemical (ATC)-groups; and 3) delays in licensing and launch of new innovative medicines that provide health gain.

Methods

Data Sources

The range of medicines for ambulant patients in Finland and New Zealand was compared using published national product information sources by a method modified from that of Chui et al. [25]. For New Zealand, the printed version of MIMS New Ethicals 2007 Issue 6 (January–June) [26] was used as primary source. Additional product information was gathered from Medsafe online Datasheets [27]. Subsidy information was gathered from the published version of the New Zealand Pharmaceutical Schedule June 2007 version [16]. For Finland, the "desk reference" used was the printed version of Pharmaca Fennica 2007 (PF2007) [28]. The subsidy information, as well as additional product information were extracted from an electronic report (Unicode file) received for research purposes from the Association of Finnish Pharmacies, containing ATC codes, price, and subsidy information from June 2007. The original sources of

the data were the National Agency for Medicines for the general information and ATC-codes, the Social Insurance Institution, and the Pharmaceutical Pricing Board for subsidies, and pharmaceutical industry for prices.

For the analysis of the launch delays, a list of new important medicines that provide health gain was gathered as published by Roughead et al. [29] using medicines classified by the United States Food and Drug Administration (US FDA) [30] and the Canadian Patented Medicines Prices Review Board [31], excluding all combination products and products that were not new molecular entities.

Data Management

The medicines were coded with full ATC-code (developed by the WHO Collaborating Centre for Drug Statistics Methodology, ATC index 2007). Where classification was not available in the 2007 version of the index, classes from the 2008 index were added [32]. Where class was available in the ATC-code system but active ingredient was not, the International Nonproprietary Names (INN) from Martindale [33] was used. Where obvious classes were not available, similar classification and naming was done in both countries. Products registered as medicines in New Zealand, but as foods, other medical supplies, or natural remedies in Finland were classified in V03, other therapeutic products, and are therefore excluded (see Inclusion/Exclusion Criteria). Products listed in the Finnish PF2007, but not licensed as medicines were excluded, although medicines listed as being temporarily licensed 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.

Products were classified in six subsidy groups according to subsidy level (part or full) and subsidy 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 subsidized 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 unsubsidized. All products that had more than one active ingredient were classified as combination products.

First registration years were identified from publicly available online databases of regulatory agencies [31,34–40].

The raw data were entered in MS Excel. The collapsing and merging of data sets and statistical analyses were performed in STATA (version 8.0) (StataCorp LP, College Station, TX).

Inclusion/Exclusion Criteria

ATC classes A11 (vitamins), A12 (mineral supplements), B05 (blood substitutes and perfusion solutions), D02 (emollients and protectives), and V (various) were excluded from analyses because of the high percentage of multiple ingredient products that prevented a meaningful comparison.

Medicines used in the treatment of HIV, hepatitis, and tuberculosis in ATC classes J and L were excluded from all analyses. In Finland, these medicines are funded under a specific legislation (Communicable Diseases Act 538/1986, Act on Social and Healthcare Client Charges 734/1992) and are dispensed from hospitals free of charge. Therefore their subsidy status was not available for comparison.

Products only indicated for use as infusions were excluded because information on their outpatient use and thus, funding, was limited and could not be compared. All combination products were excluded from the analyses. To avoid losing entities only subsidized in combination products in one country, all entities only subsidized in one country were checked for subsidized equivalents among the combination products from the other country. A total of 11 such entities were found and these were considered as subsidized in both countries and excluded from analysis of the age of entities.

Data Analysis

Similarity of range of medicines. The number of listed and subsidized medical entities, as well as fully subsidized entities was determined for both countries. The entities included were then classified in the following eight groups:

1. Listed and subsidized in both countries;
2. Listed but not subsidized in both countries;
3. Listed in both countries but only subsidized in Finland;
4. Listed in both countries but only subsidized in New Zealand;
5. Listed and subsidized in Finland, not listed in New Zealand;
6. Listed and subsidized in New Zealand, not listed in Finland;
7. Listed but not subsidized in Finland, not listed in New Zealand; and
8. Listed but not subsidized in New Zealand, not listed in Finland.

The number of entities in each group was determined. Determining the subsidy status for entities in the ATC index class L (antineoplastic and immunomodulating agents) was problematic because policies and cost-sharing between primary and secondary care differed between the two countries. Therefore, two analyses were performed, one with and the other without the ATC class L, to provide a sensitivity analysis.

Differences by therapeutic groups. The number of medical entities listed and subsidized in different therapeutic groups was determined, as was the overlap and difference within the therapeutic groups.

To evaluate the clinical relevance of the differences in numbers (e.g., whether the difference in numbers of entities was only due to subsidizing different therapeutic alternatives), the three largest ATC-therapeutic groups by number of entities available and subsidized were chosen for further analysis. Each fourth level ATC-subgroup (chemical subgroup) containing at least one available entity within inclusion criteria in either country was compared for subsidized entities in the two countries. Subgroups that had subsidized entities only in one of the countries were identified.

Differences in subsidizing old and new medicines. All entities in analysis groups 3 to 6 (i.e., those that were only subsidized in one of the countries) were analyzed to determine their "age" to further evaluate the cause of the difference in numbers found between the two countries. Each medical entity (or formulation of an entity bearing a different ATC-code) was checked for their first year of registration in 1 to 4 reference countries and classified by earliest year found. The number of reference countries used increased for newer medicines as follows:

1. Entities were first searched for their earliest year of registration in Finland or in New Zealand. Those first registered before 1970 in either country were classified by the earliest identified year.
2. Newer entities were searched for their earliest year of registration in another country (Finland or New Zealand depending on the previous search). Entities first registered in

the period 1970 to 1979 according to these two references, were classified by the earliest identified year of registration.

3. Entities registered in Finland and New Zealand on or after 1980 were checked for first year of registration in at least two other reference countries: the United States, the European Union (EU) or France, Canada, and Sweden in that order until at least two additional registration years were found. They were then classified according the earliest identified year in any of the countries. Entities that were not registered in more than one of the countries mentioned were classified according to the earliest year of registration identified.

The sources of registration years were the US FDA Electronic Orange book [34], the Canadian Patented Medicine Prices Review Board Annual Reviews [31] and the online product databases of national regulatory agencies in New Zealand [35], France [36], Finland [37], and Sweden [38]. The European Medicines Agency's database of the European Public Assessment Reports was also used as a secondary source [39], but EU registration dates were primarily collected from the French database due to the technical advantages of their search engine. The FDA Orange book only contained detailed information starting from the year 1982 and for biological products from 2004 and therefore another FDA web database, Drugs@FDA, [40] was used as secondary source. All years preceding 1960 were rounded to 1960.

The first year of registration as previously classified was used to indicate the age of the entity. The mean, median, and percentiles (25% and 75%) were determined for each country and tested for statistically significant difference using STATA. Because the newer medicines were checked in a more comprehensive manner, it is possible that some entities were actually older than their classification, but it is unlikely that they were newer.

Delay in launching new important innovation products that provide health gain. The registration status in New Zealand and Finland was sought from regulatory authority's web pages [35,37] for all 57 identified innovative products described in a previous section (Data Sources). The number of new innovative products registered before June 1, 2007 in the two countries was determined. To compare the launch status, the listing of these entities was searched from national desk references in 2007 (see Data Sources). The proportions of these products registered and listed were determined for each country and tested for statistically significant difference.

Results

Similarity of Range of Medicines

After exclusions of combinations, infusions, and medicines for severe contagious diseases, there were 779 entities in Finland and 763 in New Zealand. From the entities listed in Finland, 241 (30.9%) were not listed in New Zealand and from those listed in New Zealand, 225 (29.5%) were not listed in Finland (Table 2, Fig. 1). Of the 495 entities subsidized in Finland, 205 (41.4%) entities were not subsidized in New Zealand, and of the 471 entities subsidized in New Zealand, 181 (38.4 %) were not subsidized in Finland. In New Zealand, 86.2% of the subsidized entities were fully subsidized whereas only 29.1% were fully subsidized in Finland (Table 2). Furthermore, in Finland, all fully subsidized entities had restrictions on the subsidy although in New Zealand, the majority were subsidized without restrictions. It should be noted, however, that nearly all medicines in Finland that were fully subsidized with restrictions were partly subsidized without restriction for those not meeting the criteria, whereas in New Zealand, those not meeting the criteria had to pay the full cost.

Table 2 Number and overlap of entities by country

	Finland	New Zealand	Extent of overlap (i.e., number of entities in common in the two countries)
Number of listed medical entities or combinations of entities*	1046	1007	647
Number of entities included in the study†	779	763	538
Number of subsidized entities (any level)	495	471	290
Number of fully subsidized entities (fully subsidized without restrictions)	144 (0)	406 (326)	108

*Excluding anatomical therapeutic chemical (ATC) classes A11 (vitamins), A12 (mineral supplements), B05 (blood substitutes and perfusion solutions), D02 (emollients and protectives), and V (various).
†Excluding medicines used in the treatment of HIV, hepatitis, and tuberculosis in ATC classes J (antiinfectives for systemic use) and L (antineoplastic and immunomodulating agents), medicines only indicated for use as infusions and combination products.

The number of entities in different analysis groups including and excluding class L entities were similar with all differences between countries within 1%. Therefore, the results do not appear to be sensitive to including or excluding entities in ATC class L.

Differences in Therapeutic Groups

Differences between the countries in the number of entities available and subsidized in different ATC categories were small (Fig. 2).

There were differences in all therapeutic groups and differences in the number of entities available and subsidized followed similar patterns. The results indicate that differences in the range of medicines are not limited to particular therapeutic groups but occur throughout the groups.

Groups A, C, and N had the most entities, both available and subsidized, and so were selected for further analysis. When possible, the ATC fourth level chemical subgroups were compared and therefore their names are used. In cases, however, where the subgroup only contained one entity, the entity name is used. If all the fourth level subgroups had similar results, the name and code of the level above was used. Unique entities were also compared in chemical subgroups named "others" where entities were not necessarily therapeutic alternatives. More in-detail listings of entities and their availability/subsidy statuses in the two countries are available upon request from the authors.

In ATC group A (alimentary tract and metabolism), many subgroups contained subsidized alternatives in both countries or in neither country. Those subgroups, however, where subsidized entities were only available in New Zealand, contained predominantly older and cheaper entities. These were triamcinolone (A01AC), choline salicylate and benzydamine (A01AD), most antacid subgroups (A02AB/C) as well as bismuth subcitrate and sucralfate (A02BX), drugs for functional bowel disorders (A03A), butylscopolamine (A03BB), scopolamine (A04AD), most laxative subgroups (A06AB/G/X), medicinal charcoal (A07BA), antipropulsives (A07D), intestinal antiallergic agents (A07EB), and acarbose (A10BF). Subgroups where subsidized entities were only available in Finland contained mainly newer and more expensive medicines. These were antiobesity preparations (A08), guar gum, repaglinide and nateglinide in group A10BX, and orphan drugs mercaptamine, nitisinone and miglustat in group A16.

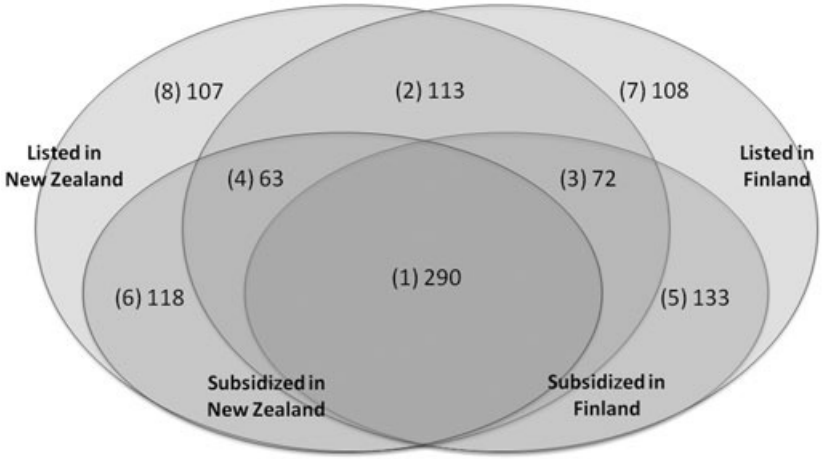

Figure 1 The medical entities available and subsidized in Finland and New Zealand. The larger circles represent the medicines available and the smaller circles the medicines subsidized. The proportions of the sections are not to scale. The numbers of the analysis groups are in brackets followed by the number of entities in each group.

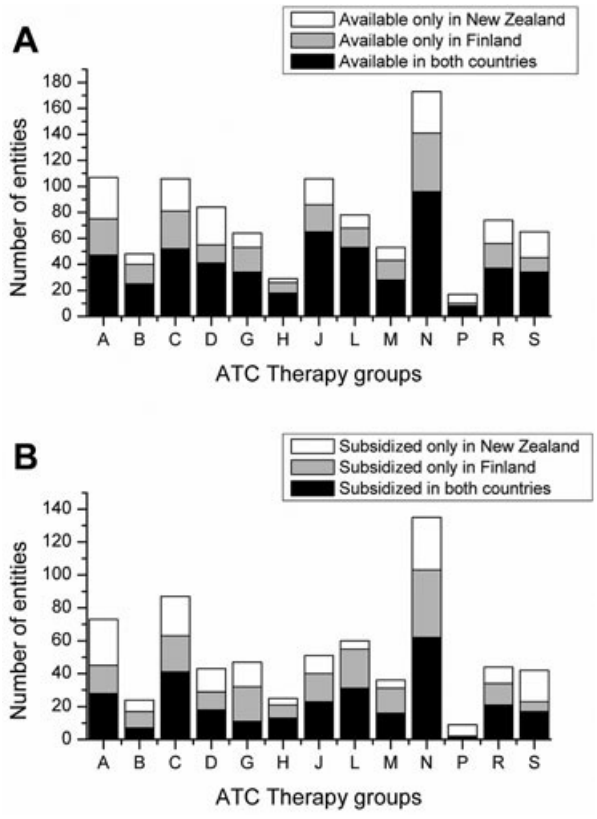

Figure 2 Differences in therapeutic groups. The medical entities in different ATC therapy groups, available (A) and subsidized (B), by country. The lightest part of each column presents the entities available or subsidized in both countries and the darker parts the entities uniquely available or subsidized in one country. The letters on the x-axis represent the ATC-groups according to the WHO ATC-index: A, alimentary tract and metabolism; B, blood and blood forming organs; C, cardiovascular system; D, dermatologicals; G, genitourinary system and sex hormones; H, systemic hormonal preparations, excluding sex hormones and insulins; J, antiinfectives for systemic use; L, antineoplastic and immunomodulating agents; M, musculoskeletal system; N, nervous system; P, antiparasitic products, insecticides and repellents; R, respiratory system; S, sensory organs.

The ATC group C (cardiovascular system) followed a similar pattern. A few subgroups containing older entities only had subsidized options in New Zealand (mexiletine [C01BB], perhexiline [C08E], and nicotinic acid derivates [C10AD]). Within group C02 (other) antihypertensives only New Zealand had subsidized options in few subgroups containing older entities (methyldopa [C02AB], hydralazine [C02DB]), only New Zealand had subsidized options, whereas relatively expensive bosentan (C02KX) was only subsidized in Finland. More subsidized options were available in New Zealand in the groups of peripheral vasodilators (C04) and vasodilators (C05), both containing older entities. In subgroups of cardiac therapies (C01), beta-blocking agents (C07), calcium channel blockers (C08), and agents acting on the renin-angiotensin system (C09), the range of newer entities was wider in Finland (e.g., selective beta-blocking agents [C07AB], selective calcium channel blockers [C08C], angiotensin II antagonists [C09C], HMG CoA reductase inhibitors [C19AA]), but subsidized alternatives were available in New Zealand.

Similar results were found in ATC group N (nervous system). Under N02 (analgesics), few differences were found within older entities (dextropropoxyfene and tramadol were only subsidized in Finland and acetylsalicylic acid, nefopam, and older antimigraine preparations [group N02CX with pizotifen, clonidine] were only subsidized in New Zealand). Within antiepileptics (N03) and anti-Parkinson's agents (N04), few newer entities were only subsidized in Finland (e.g., levetiracetam, pregabalin in group N03AX) and some subgroups containing older entities only had subsidized options in New Zealand (ethosuximide [N03AD], orphenadrine chloride [N04AB], benzatropine [N04AC], amantadine [N04BB]). Within neuroleptics (N05A), indole derivates (N05AE), and sulpride (N05AL), as well as aripriprazole (N05AX), were only subsidized in Finland, and tetrabenazine (N05AK) was only subsidized in New Zealand. Within hypnotics and sedatives (N05C), only New Zealand subsidized aldehydes and derivates (N05CC). Among antidepressants (N06A), nonselective MAO-inhibitors (N06AF) were only subsidized in New Zealand, and in group N06AX (other antidepressants), there were more subsidized options in Finland (trazodone, mirtazapine, milnacipran, reboxetine, duloxetine). Antidementia medicines (N06D) were not subsidized at all in New Zealand but were in Finland. Expensive medicines riluzole and hydroxybutyric acid (sodium oxybate) in group N07XX were only subsidized in Finland.

Although specific entities are used as examples here, trends rather than single missing items can be considered as relevant

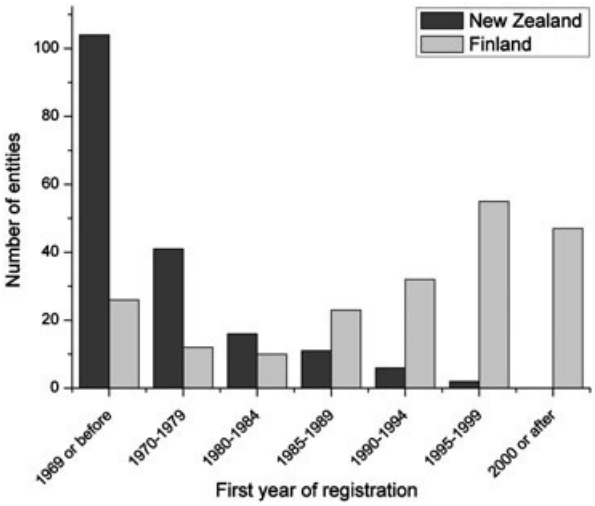

Figure 3 Differences in the age of medical entities only subsidized in either of the countries. Medical entities meeting the inclusion criteria and only subsidized in Finland or New Zealand, classified by their age by oldest identified date of registration. N = 205 (Finland) and 181 (New Zealand). Mean year of registration: 1990 (Finland), 1972 (New Zealand). Percentiles (25%/50%/75%): 1986/1994/1999 (Finland), 1967/1969/1977 (New Zealand). The difference was statistically significant ($P < 0.001$, Mann-Whitney U test).

results from this analysis, because not all available or subsidized entities might be listed in the sources used. Even so, in all analyzed subgroups, three main differences were identified:

1. Subgroups with several commonly used, relatively new, and very similar molecules (some also called "me, too"-drugs) had a wide choice of subsidized options in Finland but at least few subsidized options were also available in New Zealand (e.g., SSRIs, angiotensin II antagonists, 5HT-agonists, statins). In these groups some entities had already generic competition.
2. Subgroups with only expensive, patent protected new entities, very expensive medicines for rare conditions, and orphan drugs often had no subsidized options in New Zealand (e.g., antidementia medicines, anti-obesity medicines, meglitinides, indole derivates, nitisinone, miglustat, bosentan, hydroxybutyric acid, aripiprazole, levetiracetam).
3. Subgroups that had subsidized options only in New Zealand often contained either very old entities (first registered on or before 1960s) no longer used in Finland (e.g., tolbutamide, imipramine, phenelzine, pizotifen) or cheaper entities for treatment of milder conditions, or symptoms (e.g., laxatives, antacids, antipyretics, analgesics).

The higher subsidies in Finland were restricted to severe conditions (e.g., 100% subsidy for diabetes, psychosis, epilepsy, Parkinson's disease and 72% subsidy for colitis ulcerosa, Crohn's disease, several chronic conditions of the cardiovascular system, etc.). Furthermore, additional restrictions were also in place, for example, medicines for depression were only 100% subsidized in severe cases with psychotic symptoms. In New Zealand, there were fully subsidized options across nearly all therapy groups but the newer and more expensive medicines were only subsidized by prior application for patients who fail to tolerate or benefit from other options (e.g., angiotensin II agonists, long-acting insulin analogues).

Differences in Subsidizing Old and New Medicines

The 386 entities in analysis groups 3–6 (i.e., medicines that were subsidized in only one country) were classified by their first year of registration (Fig. 3). The majority (80.7%) of entities only subsidized in New Zealand were older entities first registered before 1980 whereas only 18.5% of the Finnish entities were in this category. Of the medicines only subsidized in Finland, 65.3% were first registered in 1990 or later but only 4.4% of the New Zealand entities were in this category.

Because the results were not normally distributed, a nonparametric test was chosen (Wilcoxon signed-rank or Mann–Whitney U test). The results were highly significant ($P < 0.001$) and exclusion of ATC class L did not change the results. Because other subsidized entities were available in both countries, it appears that the difference in the range of subsidized medicines between the two countries results from New Zealand subsidizing significantly older medicines than Finland.

Delay in Licensing and Launching Important Innovative Products that Provide Health Gain

From the listed 57 new innovative medicinal entities, 47 were registered in Finland and 33 in New Zealand before June 1, 2007. The difference in licensing and launching was consistent between the countries. Thirty-seven entities were listed in Finland and 22 in New Zealand in the national published product information sources in 2007 (Fig. 4). Thus, 29% more were registered and 40% more were launched in Finland according to the sources used. The differences between the two countries were also statistically significant with $P < 0.05$ (Fisher's exact test).

Discussion and Conclusions

In this article, a new method for cross-national comparison is introduced. The comparison of the available and subsidized range of medicines adds one piece to the puzzle of the complex question of patients' access to medicines. The strengths of the method presented were that almost the entire range of medicines was compared and thus, unlike other studies, the results were not

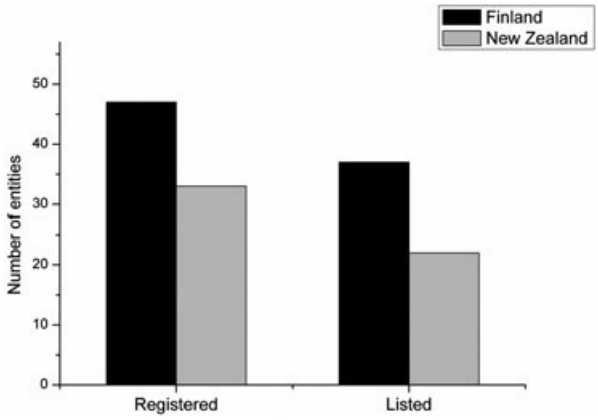

Figure 4 New innovative medicines. Registration and launch status in Finland and New Zealand of 57 new innovative medicines that provide health gain [29]. The columns on the left represent medicines registered before June 1, 2007 and on the right, medicines listed in printed product information sources by 2007. The differences between the countries were statistically significant ($P < 0.05$, Fishers's exact test).

influenced by any selection criteria [41]. Furthermore, three different approaches were used to define the causes of identified differences.

The present study found that the number of medical entities available and subsidized in the two countries was very similar. There was, however, a considerable difference between the entities uniquely available and subsidized in the two countries. In numbers, around 30% (30.9% in Finland and 29.5% in New Zealand) of the medical entities in each country were not available in the other, and approximately 40% (41.4% in Finland and 38.4% in New Zealand) of the entities subsidized in each country were not subsidized in the other. There was also a substantial difference between the numbers of fully subsidized entities. Nearly all subsidized entities (90%) were subsidized in full in New Zealand although less than 30% were fully subsidized in Finland.

The differences between the available and subsidized entities were evenly distributed across the therapy groups but there was a significant difference between the countries in subsidizing old and new medical entities. The entities only subsidized in New Zealand were predominantly older medicines first registered in the 1970s or earlier whereas, those only subsidized in Finland were mostly newer entities registered on or after 1990. The analysis of drugs within therapeutic groups followed the pattern for medicines as a whole and reflects the policies in the two countries. For example, in Finland, over-the-counter medicines are only subsidized in rare cases and higher (72% and 100%) subsidies are restricted to severe and chronic or life-threatening conditions, although in New Zealand, there is a tendency to provide at least one fully subsidized medicine in each therapy group. Accordingly the study found that entities included in over-the-counter products (less expensive products such as laxatives, antacids, analgesics), were rarely subsidized in Finland, but there was a wide range of these fully subsidized in New Zealand. Although usually cheap, these medicines for treatment of milder conditions and symptoms are subject to free pricing in Finland, because they are excluded from subsidy. Furthermore, their costs are not included in the annual price cap.

Among newer and more expensive medicines, the subsidized range was often wider in Finland but therapeutic alternatives were available in New Zealand (e.g., SSRIs, angiotensin antagonists, 5HT1-agonists, statins) indicating that a large part of the difference is due to Finland subsidizing more derivative medicines (and also the so-called "me, too"-drugs). On the other hand, several subgroups with new and expensive medicines had no subsidized alternatives in New Zealand at all (e.g., antidementia medicines, antiobesity medicines, [orphan] medicines used in treatment of rare conditions). Also, the comparison of the launch status of new innovative medicines that provide health gain showed that clinically relevant differences do exist. From the selection of 57 new innovative entities, 29% fewer were registered and 40% fewer were launched in New Zealand when compared to Finland.

These results are consistent with earlier studies. The high patient contribution in Finland was demonstrated by Noyce et al. in a comparison between eight EU countries [14]. Regarding the age of medicines, two earlier studies by Danzon et al. demonstrated that the range of medicines in New Zealand was older than in Germany and in The Netherlands [42], and that New Zealand ranked among those with the least new entities launched, and Finland among those with the most [9] in a comparison of 25 major markets in the 1990s.

Because the purchasing of medicines is done at the national level in New Zealand and the government is sharing the economic risk with the suppliers, substantial discounts can be achieved and patients benefit from very low prices for most prescription medicines. At the same time, the choice of consumers and prescribers is strictly limited by reimbursement restrictions. Interestingly at the same time, New Zealand is one of the only countries in the OECD allowing direct to consumer advertising of prescription medicines (Advertising Requirements of the Medicines Act 1981 [sections 56 to 62], Medicines Regulations 1984 [regulations 7 to 11]). Even so, it seems that the concern over launch delays of new medicines is not entirely unfounded, even among new important innovations. It could not be said, however, whether the delay is caused by suppliers not applying for marketing authorization due to the strict cost containment policies or for some other reason e.g., the isolation of the New Zealand market.

In Finland, consumers or prescribers are given a much wider variety of subsidized options enabling individual tailoring of therapies. Rational prescribing is encouraged with guidelines rather than restrictions, allowing prescribers to make the final decisions about cost-effectiveness in each case. Nevertheless, as the government subsidies are generally low, a large share of the economic risk of introducing new therapies is transferred to the patient. Furthermore, the Finnish system has not been successful enough in slowing down the rise in pharmaceutical expenditure, and therefore new cost-containment policies have been necessary. In 2006, for example, additional restrictions on subsidizing more expensive statins were imposed [43]. Most recently, Finland adopted generic reference pricing in the beginning of 2009 (Amendment 803/2008 on Medicines Act [395/1987]).

A limitation of the design was that the medicines included in this study were from published product information so it is possible that a small proportion of available medicines were not listed and not captured in the analysis. Due to the exclusion of combination products, unique unsubsidized entities only available in combinations might also have gone unnoticed, but these are likely to be few and affect both countries similarly. Furthermore, the possibility of obtaining medicines on a named-patient basis means that almost any single entity could be available for an individual patient, if needed. In ambulatory care, however, under normal conditions, the medicines are usually chosen from those available and listed in published product information, so such a list can be considered the range of generally available medicines for most patients. A limitation concerning the "age" and launch of new medicines analyses is that the results are drawn from a specific selection of entities, which is not intended to be a representative sample. Therefore, the results should not be generalized to represent all subsidized medicines in the two countries and the statistical tests were only used for additional confirmation that there was indeed a difference between the two countries.

High burden of costs in Finland can restrict access for some people and hence, the medicines used by different socioeconomic groups could differ. This might also be the case in New Zealand, if medicines outside the subsidy system are chosen, but with commonly used medicines there seems to be greater equality in access. Further studies of patient out-of-pocket payments as well as of differences in medicines used across socioeconomic groups are needed to better compare the effect of cost-containment policies on access to medicines in these two countries.

In summary, it seems that for most people in New Zealand, commonly used medicines are heavily subsidized, but the range of medicines subsidized is biased toward older entities. In Finland, the subsidy system enables newer medicines to be used at least with a partial level of subsidy but in exchange, patients are expected to bear a high proportion of the cost of everyday medicines for mild to moderate conditions. At national level, New Zealand has been more successful in controlling the rise of

pharmaceutical expenditure, but at the same time, the delays in patients' access to new therapies, also among important new innovations, have not completely been avoided. Finland has been able to enable more choice for individual tailoring of therapies, but it seems that it has lead also to rises in patient out-of-pocket payments.

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