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Why do sales of lipid-lowering drugs vary between counties in Norway? Evidence from the OPPHED Health Study 2000–2001.

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Key points

In Norway there have been large and persistent inter-county variations in sales of lipid-lowering drugs (LLDs).

- Inter-county differences in LLD sales are not explained by cardiovascular morbidity, age distribution, socioeconomic structure, or access to health care services.
- Variation in threshold and intensity of LLDs for primary prevention are contributing factors to regional differences in LLD sales.
- Feasible intervention thresholds for primary prevention with concurrent reimbursement rules, should be defined in guidelines to avoid unintentional variation in LLD use in the future.

Abstract

Objective

To study and compare plausible factors that might explain varying sales of lipid-lowering drugs (LLDs) in the two neighbouring counties Hedmark and Oppland in Norway, with a similar age distribution, socioeconomic structure, and access to health care services.

Design, setting, subjects

Cross-sectional population study comprising 10 598 attendants aged 40, 45, 60 and 75 years in the OPPHED Health Study, 2000-2001 (attendance rate 61%).

Main outcome measure

Treatment eligibility (cardiovascular morbidity and risk-score), treatment frequency in treatment-eligible subgroups and treatment intensity in terms of achievement of total cholesterol (TC) goal.

Main results

Proportions eligible for LLD treatment in Hedmark and Oppland were similar. There was no difference in prevalence of LLD use among participants with cardiovascular disease or diabetes (secondary prevention subgroup). However, LLD use among men in the primary prevention subgroup was higher in Hedmark compared with Oppland, 6.3% and 4.1%, respectively ($p<0.05$). The same tendency was seen among women. In both sexes, more LLD users in the primary prevention subgroup achieved the TC goal in Hedmark compared with Oppland ($p<0.05$).

Conclusion and implications

The proportion of the population eligible for LLD treatment in the two counties should imply similar treatment rates in both. Higher LLD treatment frequency and intensity in the primary prevention subgroup in Hedmark are probably both contributing factors that explain the higher sales of LLDs in Hedmark compared with Oppland. Feasible intervention thresholds for primary prevention with concurrent reimbursement rules, should be defined in guidelines to avoid unintentional variation in LLD use in the future.

Keywords

Lipid-lowering drugs, primary prevention, secondary prevention, cardiovascular disease, drug utilization, guidelines, pharmacoepidemiology

Introduction

The 2003 European guidelines on cardiovascular disease (CVD) prevention have provoked a debate regarding their estimated impact on clinical practice relating to risk labelling, medicalisation, as well resource allocation within the health care system [1-4]. However, whereas implementation of the guidelines could imply a larger part of the population on cardiovascular preventive therapy in the future [5, 6], variation in lipid-lowering drug (LLD) sales across Scandinavia and the rest of Europe may reflect uncertainty about how to manage existing guidelines in clinical practice [7]. The variations in LLD use between countries have been little investigated, but may be explained by differences in national treatment guidelines and drug reimbursement systems, as well as variations in cardiovascular morbidity [8, 9].

The sales of LLDs have increased remarkably in Norway since 1994, and are high compared to other European countries [7, 10, 11]. However, within Norway the inter-county variations in LLD sales have been large and persistent (Figure 1) [11]. In 2000–2001 the sales of LLDs were about 40% higher in Hedmark compared to Oppland. The two neighbouring counties have similar age distribution, rural-urban distribution, socioeconomic structures and access to health care services, and these factors may be excluded as major factors contributing to variations in LLD sales [12].

The size of the population eligible for LLD treatment is defined by guidelines, which are subject to changes over time [1, 13-16]. The proportion treated are influenced by reimbursement regulations, which also may vary over time [17-19]. Furthermore, the prevalence of LLD use depends on the extent to which treatment-eligible individuals are treated in clinical practice. There is documented a gap between guidelines for cholesterol management and clinical practice [20, 21]. Variations in treatment intensity, i.e. how closely the patients are titrated with drugs to attain guideline recommended goals, may also influence LLD sales. Previous studies have found low rates of attainment of the total cholesterol (TC) treatment goal among LLD users, but regional variations within a country have barely been explored [20-22].

In this epidemiological study we investigated whether differences in morbidity or in cholesterol management could explain variation in LLD sales between two counties. Hence, the following factors were studied in Hedmark and Oppland:

- *Treatment eligibility*: prevalence of cardiovascular morbidity, including coronary heart disease (CHD) or diabetes; and cardiovascular risk score among participants in the primary prevention subgroup (no CHD or diabetes).
- *Treatment frequency*: LLD use in the primary and secondary prevention subgroups.
- *Treatment intensity*: achievement of TC ≤ 5.0 mmol/l among LLD users.

Methods

Study population

In 2000–2001 the Norwegian Institute of Public Health performed the OPPHED Health Study in the two neighbouring counties Hedmark and Oppland [23]. All individuals aged 40, 45, 60 and 75 years of age were invited, and numbered 8754 from Hedmark and 8592 from Oppland. A total of 10 598 (61%) of these individuals attended the screening, with similar attendance rates within each age- and gender strata.

The screening included self-administered questionnaires [24], blood pressure measurements, and analysis of non-fasting serum total cholesterol (TC). Non-fasting TC was analysed by an enzymatic method at the Department of Clinical Chemistry, Ullevål University Hospital, Oslo (Hitachi 917 auto-analyzer, Roche Diagnostic, Switzerland). The questionnaire included questions on smoking status, family history of CVD and history of diabetes, myocardial infarction (MI), angina pectoris and stroke. Individuals who cited stroke as the only cardiovascular disease (1.3% in Hedmark, 1.8% in Oppland) were excluded from the analyses because of the inability to classify according to stroke subtype [25]. The questionnaire included a question with predefined answering categories (yes/previously/no) on the use of LLDs, phrased as in previous studies [26]. Participants answering ‘yes’ on current use of LLDs were

defined as users in the analyses. The response rate to questions on health status and drug use included in these analyses was almost 100% (92–99 %). In total, 10 205 of the 10 598 attendants were included.

LLD treatment eligibility

The National Cholesterol Guidelines at the time of screening recommended dietary intervention followed by LLD therapy for secondary prevention in those with established CHD and/or diabetes, and for primary prevention in individuals with a high risk of CHD (Framingham 10-year CHD risk ≥ 20%)[14]. The population eligible for LLD use was stratified into two subgroups:

- Secondary prevention subgroup: participants with self-reported CHD (angina pectoris or MI) and/or diabetes.
- Primary prevention subgroup: participants reporting no established CHD or diabetes.

To estimate cardiovascular risk level among participants in the primary prevention subgroup, two different risk models were used. First, the estimated 10-year incidence of CHD was calculated by the Framingham risk model [27]. Second, an MI risk score model, developed in the 1970ies from Norwegian epidemiological data, was used. This model includes (multiplicative) factor values for cigarette consumption, TC concentration, systolic blood pressure, family history of CHD, and gender, totalling the individual's risk score[28, 29]. To exclude the effect of LLD use, the risk scores were calculated for non-users of LLDs only.

LLD treatment frequency

The proportions of LLD use within primary and secondary prevention subgroups in the two counties were compared.

LLD treatment intensity

Treatment intensity was compared in terms of achievement of the TC treatment goal among LLD users. This TC treatment goal was defined according to prevailing national recommendations at the time of screening: TC ≤ 5.0 mmol/l [14].

Statistical methods

SPSS 10.0 for Windows was used. Categorical variables were compared using the χ^2 test. Continuous variables were compared using *t*-tests for variables with a normal distribution or non-parametric Mann–Whitney tests for variables with a skewed distribution. A p value < 0.05 was considered statistically significant.

Ethics

Approval was granted from the National Data Inspectorate and the Regional Committee for Medical Research Ethics.

Results

LLD treatment eligibility

No inter-county differences were found in the prevalence of CHD or diabetes (Table 1). The mean TC concentration among non-users of LLD showed similar patterns in the primary prevention subgroup in both counties (Table 2). In the primary prevention subgroup, the estimated 10-year incidence of CHD (Framingham risk model) and the Norwegian MI score among non-users of LLDs were almost the same in both counties (Table 2). Lack of differences in TC concentrations, MI risk score levels or prevalence of CHD and diabetes should imply similar proportions of the population eligible for LLD treatment.

In the primary prevention subgroup, among men in particular, a large part of those reporting not to be on LLD therapy had a Framingham risk score above the limit set by guidelines (Table 2).

LLD treatment frequency

The prevalence of LLD use among men in the primary prevention subgroup was higher in Hedmark than in Oppland (Table 3). The same tendency was seen among women. By contrast, there were no inter-county differences in LLD use in the secondary prevention subgroup (Table 3).

LLD treatment intensity

In both sexes, a higher proportion of the LLD users in the primary prevention subgroup achieved the TC treatment goal in Hedmark than in Oppland ($p < 0.05$) (Table 4). The same tendency was seen in the secondary prevention subgroup, but the inter-county differences were not significant.

Discussion

Despite equal proportions of population eligible for LLD therapy, more people received LLD therapy for primary prevention in the high-consumption county Hedmark. In addition, the LLD users in the primary prevention subgroup seemed to be treated more intensively, in terms of a higher attainment of TC treatment goals in Hedmark. As the main part of the population belongs to the primary prevention subgroup, even a small percentage inter-county difference in LLD use in this subgroup will make up a large number of LLD users, with a corresponding effect on total LLD sales.

Wholesale statistics may have several limitations. For example, drugs sold from wholesalers are not necessarily dispensed, and dispensed drugs from the pharmacies may not be used. Sales statistics do not distinguish between drugs sold to individual patients and to hospitals, and the patients may have their medication dispensed outside their county of residence. However, LLDs are sold in such a high amount, that pharmacy stocks would only constitute a minor error in the LLD sales. LLDs are reimbursed as chronic drug therapy and mainly dispensed to patients in

primary care. In both counties, only about one per cent of the defined daily doses of LLDs are sold to hospitals or others than patients with prescriptions (Marit Rønning, NorPD, personal communication). Danish drug statistics confirm these figures [30]. The Norwegian Prescription Database (NorPD) shows that only three to four per cent of the C10A prescriptions are dispensed in another county than the patient's home county Hedmark or Oppland (Marit Rønning, NorPD, personal communication). Hence, we can assume that regional differences in LLD sales reflect true differences in LLD consumption.

Some LLD substances may be used in higher doses than the defined daily doses, and the discrepancy between defined daily dose (DDD) and prescribed daily dose (PDD) may vary between the LLD substances. However, the sales of LLDs in both counties are dominated by statins (99%) and the types of statin substances prescribed are similar [11]. Atorvastatin and simvastatin constituted about 90% of total LLD sales in Hedmark and Oppland in 2000-2001 (Atorvastatin 39%, and simvastatin 48%) [11].

A higher percentage of LLD users in Hedmark had TC below treatment target (5 mmol/L). Unfortunately, no information was available of the pre-treatment TC concentration, or the absolute TC reduction for those under treatment. However, mean TC concentrations were similar among the non-users of LLD in the two counties (in this subgroup), which may indicate similar mean pre-treatment TC concentrations in the two primary prevention subgroups on a whole. We therefore conclude that a higher LLD treatment intensity in Hedmark is a plausible contributing factor in explaining differences in LLD sales. The success in achieving the target cholesterol level might reflect the use of higher dosages of LLDs or higher compliance of use. These questions will be studied with data from the Norwegian Prescription Registry.

At the time of screening, the use of LLDs for primary prevention was reimbursed by The Norwegian National Insurance in patients with familiar hypercholesterolaemia and in subjects

with a persistent cholesterol at >8 mmol/L after one year of dietary intervention [17]. Simultaneously, national clinical guidelines recommended a more up-to-date use of LLDs for primary prevention, based on a multiple risk factor evaluation (Framingham 10-year risk scores > 20%) [14]. In this situation, the physicians have graded the cardiovascular risk of their patients, interpreted existing clinical guidelines and reimbursement regulations and made their choices. The regional difference can possibly to some extent be attributed to these ambiguous authoritative instructions. Recently (June 1th 2005), updated reimbursement regulations for LLDs were launched in Norway, concurrent to clinical guidelines for primary prevention [19]. Hopefully, these may reduce unintended regional differences in LLD use for primary prevention in the future.

However, already at 60 year of age a third of men reporting no use of LLDs in the primary prevention subgroup had a Framingham 10-year risk score above the limit set by current national guidelines. Obviously, there was a potential for higher LLD sales in both counties. Hence, the debate regarded the estimated impact of European guidelines on risk labelling, medicalisation and resource allocation in the future, seems to be highly relevant also in discussions of current practice [1-4].

In conclusion, the large and increasing inter-county differences in LLD sales cannot be explained by the size of the population eligible for LLD treatment. A lower threshold for LLD therapy for primary prevention, and a more intensive LLD therapy with higher attainment of the lipid treatment goal, are probable contributing factors to differences in LLD sales between the counties. The gap between observed and guideline-recommended LLD use, may reflect that adherence to Framingham-based thresholds for intervention have been problematic in clinical practice. Norwegian population studies have shown that European SCORE-based guidelines classify most adults at high CVD risk, with an “unfavourable” high cholesterol [2, 5, 6]. Implementation of these guidelines may lead to a marked increase in the pharmacological

treatment, especially in men and among the elderly [5]. Hence, we would expect a continuance in regional differences in LLD sales. If guidelines shall fulfill their intention of being an effective tool in targeting primary prevention intervention, this would obviously presuppose taking into account total resources and follow-up capacity in the primary health care. Hopefully, a revision of Norwegian guidelines will end up in feasible intervention thresholds for primary prevention with concurrent reimbursement rules, thus avoiding regional unintentional variations in LLD use for primary prevention in the future.

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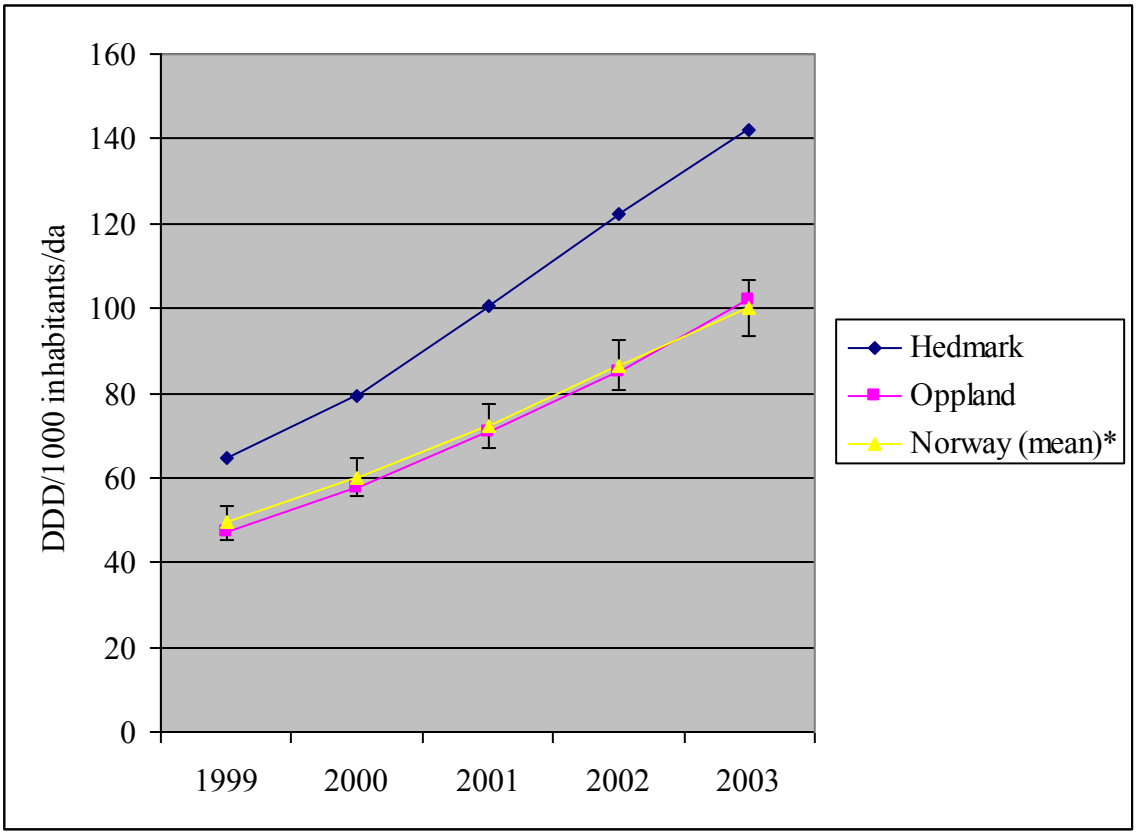
Figures and tables

Figure 1. Sales of lipid-lowering drugs (ATC-group C10) in DDD/1000 inhabitants/day sold in the counties Hedmark and Oppland, and a mean for all counties in Norway in 1999-2003[11]



* Norway (mean) includes a 95% confidence interval.

Table 1. Proportion of participants in secondary and primary prevention subgroup[a] in high (Hedmark) and low (Oppland) lipid-lowering drug (LLD) consumption by county according to age and sex. The OPPHED Health Study 2000-2001.

		Men[b]		Women[b]	
Age (years)	Prevention subgroup[a]	Hedmark (%)	Oppland (%)	Hedmark (%)	Oppland (%)
		N=1350	N=1327	N=1627	N=1583
40+45	Secondary	3.6	2.9	1.7	1.3
	Primary	96.4	97.1	98.3	98.7
		N=641	N=590	N=641	N=694
60	Secondary	17.2	15.8	8.3	8.6
	Primary	82.8	84.2	91.7	91.4
		N=450	N=390	N=480	N=432
75	Secondary	34.7	34.4	27.5	26.6
	Primary	65.3	65.6	72.5	73.4
		N=2441	N=2307	N=2748	N=2709
Total	Secondary	12.9	11.5	7.7	7.2
	Primary	87.1	88.5	97.3	97.8

[a]Secondary prevention subgroup: participants with coronary heart disease(CHD) and/or diabetes, primary prevention subgroup: participants without CHD and diabetes.

[b]All differences are non-significant ($p \geq 0.05$).

Table 2. Mean cardiovascular risk factor level among non-users of lipid-lowering drugs (LLDs) in the primary prevention subgroup[a] in high (Hedmark) and low (Oppland) LLD consumption regions according to age and sex. The OPPHED Health Study 2000–2001.

		Men		Women	
		Hedmark	Oppland	Hedmark	Oppland
Age (years)	Risk factors	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
		N=1226	N=1237	N=1557	N=1509
40+45	Mean TC	5.7 (1.02)	5.7 (1.00)	5.4 (0.91)	5.4 (0.93)
	Framingham score	7.2 (4.21)	6.9 (4.09)	2.6 (2.28)	2.7 (2.44)
	% score > 20	1.0	1.1	0.1	0.1
	MI score[b]	17.5	15.6*	2.6	2.5
		N=446	N=449	N=496	N=545
60	Mean TC	6.0 (0.98)	6.0 (0.92)	6.4 (1.15)	6.4 (0.98)
	Framingham score	17.4 (6.36)	17.6 (6.67)	9.8 (5.24)	9.9 (5.30)
	% score > 20	30.9	33.4	5.2	5.5
	MI score[b]	20.0	19.5	4.3	4.0
		N=252	N=227	N=264	N=269
75	Mean TC	5.9 (1.00)	6.0 (1.00)**	6.7 (1.14)	6.8 (1.24)
	Framingham score	26.9 (8.32)	27.8 (8.22)	12.7 (5.54)	12.8 (5.46)
	% score > 20	80.6	81.9	11.0	11.9
	MI score[b]	25.1	23.8	7.8	7.6
		N=1924	N=1913	N=2317	N=2323
Total	Mean TC	5.8 (1.01)	5.8 (1.00)	5.8 (1.12)	5.8 (1.11)
	Framingham score	12.2 (9.04)	11.9 (9.10)	5.3 (5.32)	5.5 (5.41)
	% score > 20	18.3	18.3	2.4	2.7
	MI score[b]	18.8	17.5	3.2	3.0

[a]Primary prevention subgroup: participants without coronary heart disease (CHD) or diabetes.

[b]Norwegian myocardial infarction (MI) score, median and non- parametric Mann–Whitney test used because of skewed distribution.

TC, total cholesterol.

*$p < 0.01$.

**$p < 0.05$

Table 3. The proportion of lipid-lowering drug (LLD) users in secondary and primary prevention[a] subgroup in high (Hedmark) and low (Oppland) consumption regions. The OPPHED Health Study 2000–2001.

		Men		Women	
Age (years)	Prevention subgroup[a]	Hedmark N (%)	Oppland N (%)	Hedmark N (%)	Oppland N (%)
40+45	Secondary	46 (34.8)	37 (54.1)	25 (24.0)	20 (25.0)
	Primary	1295 (3.9)	1283 (2.7)	1558 (1.6)	1549 (2.1)
	Total	1341 (4.9)	1320 (4.2)	1613 (2.0)	1569 (2.4)
60	Secondary	104 (62.5)	89 (66.3)	52 (57.7)	57 (52.6)
	Primary	504 (10.9)	489 (6.5) *	568 (11.6)	610 (9.8)
	Total	608 (19.7)	578 (15.7)	620 (15.5)	667 (13.5)
75	Secondary	145 (50.3)	122 (47.5)	121 (53.7)	103 (48.5)
	Primary	284 (9.2)	246 (6.5)	319 (14.1)	298 (8.4)
	Total	429 (23.1)	368 (20.1)	440 (25.0)	401 (18.7)
Total	Secondary	295 (52.2)	248 (55.2)	198 (51.0)	180 (47.2)
	Primary	2083 (6.3)	2018 (4.1) *	2475 (5.6)	2457 (4.8)
	Total	2378 (12.0)	2266 (9.7) *	2673 (9.0)	2637 (7.7)

[a]Secondary prevention subgroup: participants with coronary heart disease (CHD) and/or diabetes, primary prevention subgroup: participants without CHD and diabetes.

*$p < 0.05$.

Table 4. Proportion of LLD users achieving serum cholesterol goal of ≤ 5.0 mmol/L . The OPPHED Health Study 2000-2001.

		Men		Women	
Age	Prevention	Hedmark	Oppland	Hedmark	Oppland
(years)	subgroup[a]	N (%)	N (%)	N (%)	N (%)
40+45	Secondary	16 (75.0)	20 (70.0)	6 (83.3)	5 (80.0)
	Primary	50 (40.0)	35 (17.1) **	26 (38.5)	32 (21.9)
60	Secondary	64 (68.8)	59 (62.7)	30 (43.3)	30 (66.7)
	Primary	55 (45.5)	32 (34.4)	66 (36.4)	60 (18.3) **
75	Secondary	73 (68.5)	58 (65.5)	64 (48.4)	50 (40.0)
	Primary	26 (57.7)	16 (31.3)	44 (34.1)	25 (36.0)
Total	Secondary	153 (69.3)	137 (65.0)	100 (49.0)	85 (51.8)
	Primary	131 (45.8)	83 (26.5) *	136 (36.0)	117 (23.1) **
	Total	284 (58.5)	220 (50.5)	236 (41.5)	202 (35.2)

[a] Secondary prevention subgroup: subjects with coronary heart disease(CHD) and/or diabetes, primary prevention subgroup: subjects without CHD and diabetes.

* p-value<0.01

** p-value<0.05