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Gender inequality in lipid control: use of primary care data to evaluate equity of management of lipid control for secondary prevention of heart disease and stroke using a cross sectional design.

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Abstract

Background: Lipid control is important for the secondary prevention of cardiovascular disease (CVD). There is robust evidence that the use of statins reduces risk of major vascular events regardless of gender.

Design: Cross sectional design of 7869 patients on heart disease and/or stroke registers

Setting: Inner city London borough, with a registered population of 378,000 (2013).

Methods: We assessed quality and equity of care against pre-defined standards. A descriptive analysis was used to assess against these standards . We then assessed group differences using multilevel regression models.

Findings:

Patients with a current cholesterol measurement >5 mmol/l were less likely to have a current statin prescription (adjusted OR = 3.16; 95% CI: 2.74 to 3.65). They were also more likely to be current smokers and have raised blood pressure. Women were significantly more likely to have raised cholesterol after adjustment for other risk factors (adjusted OR = 1.78; 95% CI: 1.55 to 2.03).

Conclusion

In this study the key factor that explained poor lipid control in people with CVD was having no current prescription record of a statin. Women are more likely than men to have poorly controlled cholesterol (independent of smoking status, blood pressure, statin prescription and type 2 diabetes status and after adjusting for age, ethnicity, deprivation index and practice level variation. Women with CVD should be offered statin prescription and may require higher statin dosage for improved control.

Key word: Equity profile, cholesterol, cardiovascular disease, secondary prevention, gender inequality.

Strengths include:

- large study using epidemiological design and multi-level modelling regression methods to identify inequity in management of lipid control using routine data.
- systematic approach that can be used by Clinical Commissioning Groups to meet their duty to reduce inequality in access and outcomes to healthcare

Limitations include:

- potential measurement errors /biases
- data did not include date of any original CVD event
- findings may not be generalisable

Introduction

Hyperlipidaemia contributes a significant proportion of modifiable cardiovascular disease (CVD) risk. (1) Most of the CVD risk attributable to lipids is due to lipoprotein particles associated with cholesterol deposition in the vascular wall including total cholesterol, non-HDL-cholesterol and low density lipoprotein cholesterol (LDL-C). (2) Interventions that reduce LDL-C reduce CVD risk with a relationship from clinical trials that shows that a 21% relative risk reduction in major vascular events per 1mmol/L reduction in LDL-C in all groups. (3).

The National Institute for Health and Clinical Excellence (NICE) lipid modification guidelines (CG67; 2008) advise clinicians to offer statins to all individuals with increased risk of CVD as determined by a QRISK2 or Framingham (1991) -based CVD risk score of 20% over the next decade.(4-6) These risk calculation tools give similar results but Framingham overpredicts CVD in UK populations. (7) Statin treatment is to be prescribed to all patients with established CVD using simvastatin 40mg in most patients and atorvastatin 80mg in acute coronary syndromes. NICE CG67 advises that cholesterol is checked within 3 months of starting a statin with the aim that patients with established CVD should ideally reach total cholesterol <4 mmol/L; LDL-C <2 mmol/L with an audit standards of total cholesterol < 5mmol/L and LDL-C <3mmol/L. (4) In primary prevention no target is specified but all should be treated with simvastatin 40mg or another off-patent agent of similar efficacy. If this target has not been met, then patients are to be given advice around compliance and lifestyle and consideration was originally given to increasing the dose of simvastatin to 80mg. However, later safety concerns about simvastatin 80mg and its drug interactions mean this suggestion was not implemented in many areas (including South East London). Patients are to be monitored annually once they are meeting targets. (8)

GPs are currently incentivised to manage CVD by the Quality and Outcomes Framework (QOF). The QOF control target in 2012-13 was total cholesterol of <5mmol/l. (9)

Our aim was to evaluate the management of cholesterol for the secondary prevention of CVD in Lambeth patients on the Coronary Heart Disease (CHD) and / or stroke registers. We compared lipid measurement and control to pre-defined standards based on QoF and NICE guidelines. (4;9) We also evaluated the equity of lipid control and hypothesized that there should be no group differences in the management of cholesterol in Lambeth patients on the above registers, according to these pre-defined standards.

Methods

This evaluation was carried out in an inner city London borough, with a registered population of 378,000 (2013). We used a cross-sectional study design and identified those patients who were on the CHD and/or stroke registers as of 31/3/2013 and the period 15 months prior to this date.

We used patient level data from the Lambeth DataNet. This is a pseudo -anonymised database of patients registered with practices in primary care that supports local commissioning, health care/service evaluation and equity profiling. We identified people registered on the CHD and / or stroke registers from 48 of 49 practices that contribute data to the Lambeth DataNet.

Pre-defined standards:

The standards that were used to assess the quality of care were a combination of the upper range of the QOF 12-13 and NICE CG67 guidelines. (4;9)

CHD:

- Cholesterol level is measured in last 15 months (at or prior to 31/03/13) in 90% (range 50-90%)of all patients on the CHD register;
- Cholesterol control </=5 mmol/l in 70% (range 45 to 70%) of all patients on CHD register

Stroke:

- Cholesterol level measured in last 15 months (at or prior to 31/03/13) in 90% (range 50-90%) of all patients on the stroke register;
- Cholesterol </= 5 mmol/l in 65% (range 40 to 65%) of all patients on stroke register

We also collated data on the current prescription of statins for this cohort of patients within the last 3 months from their last review date. NICE guidelines recommend that all patients with heart disease or stroke s should be prescribed a statin or have reasons recorded if not prescribed.

Hypothesis tested:

The hypotheses we were testing were as follows:

1/ Patients in Lambeth with one or more diagnoses of CHD and stroke are managed according to the pre-defined standards for cholesterol for people on these two registers as of 2012/13.

2/ In Lambeth patients with one or more diagnoses of CHD and stroke - there are no significant group differences as assessed by age, sex, ethnicity, deprivation, presence of other risks or comorbidity in meeting these pre-defined standards.

Analysis

We used STATA 13.1 to test the hypotheses.(10) Descriptive analyses were done to test the first hypothesis. A number of univariate multilevel logistic regression models taking into account the variation among different general practices were fitted to explore the associations between the predefined standards and different potential predictor variables tested in the second hypothesis. Then a series of multivariate multilevel logistic regression models were fitted to investigate the associations between the pre-defined standards and all potential predictor variables. Best and final models chosen by series of Wald goodness of fit tests were reported in the result section. (11)

The presence of group differences in these were reviewed by: age group (16-44, 45-54, 55-64, 65-74 & >/=75) , sex (male, female) , ethnic groups (White group, Black/Black British group,

Missing/unknown, Asian/Asian-British group, Mixed group, Other ethnic group), index of multiple deprivation quintiles (grouped as follows: least deprived two quintiles 0-40%, 40-60%, 60-80%, Most deprived 80-100%) , as well as risk factors for smoking (current somkers, ex-smokers, non-smokers and unknown) and blood pressure or BP (controlled defined as BP</=150/90; uncontrolled defined as BP>150/90), type 2 diabetes status (yes or no) & statin prescription status within time frame described above (yes or no) and total cholesterol (controlled defined as </= 5 mmol/L, uincontrolled defined as >5 mmol/L).

Results

The total number of primary care practices that participated was 48/49 (98%). The number of people on the CHD & Stroke registers was 7869 (CHD only: 4464; Stroke only: 2738; combined CHD/stroke = 667). The diagnosed prevalence of CHD and stroke were 1.3% and 0,9% respectively in Lambeth in 2012-13. (12) The mean age was 69.8 years (95% confidence limits: 69.5 to 70.1). There were significantly more males on the registers: male 57.8% (56.7 to 58.9) compared to female 42.2% (41.1 to 43.3). Other demographic characteristics are shown in table 1.

Table 1 here

Table 2 shows the risk factor characteristics**.**

Table 2 here

Hypothesis 1: Patients with one or more of CHD and stroke are managed according to pre-defined standards for cholesterol measurement and control for people on these two registers as of 2012/13 and 13/14

Table 3 shows the evaluation of patients having a current record for cholesterol measurement, degree of cholesterol control achieved and a record of a statin prescription. Overall pre-defined auditable standards were not met for current records for both cholesterol measurement and statin

prescription. However pre-defined auditable standards for those patients with a current record the proportion of patients whose cholesterol was below 5mmol/l were met. When comparing subgroups within the study, patients with a history of stroke were consistently the least likely to meet all three QOF standards.

Primary care records showed that 80.1% of patients had been prescribed a statin in the last 6 months. This rate was significantly lower in stroke patients.

Table 3 here

Hypothesis 2: In patients with one or more of CHD and stroke - there are no significant group differences as assessed by age, sex, ethnicity and deprivations in meeting the predefined standards.

We found significant group differences in meeting the lipid measurement standards. Table 4 shows the findings for patients who did not have a current record of cholesterol measurement in the last 15 months. The random effect at the general practice level is reported at the bottom of the table. The variance component was estimated to be 0.12. Patients categorised as black/black British group (compared to the white group) were significantly more likely to have a current record, as were patients with type 2 diabetes (compared to people without type 2 diabetes). Patients with no current records were significantly more likely to be between 16-64 years or over 75 years. Patients aged 16-44 were 68% more likely to not have a current record compared to those aged 65-74. After taking into account other factors deprivation did not appear to have an effect of current cholesterol recording. Patients who did not have a current record of cholesterol measurement were more likely to a record for being current smokers, and a previously raised cholesterol level.

Patients with no current record for cholesterol in the past 15 months were nearly three times less likely (adjusted odds = 2.95; 95% CI: 2.49 to 3.50) to have a record of a current statin prescription.

Table 4 here

Table 5 shows the finding for the subgroup of patients who were not achieving a lipid control standards (cholesterol level <5mmol/L) within the last 15 months of the study date. The random effect at the general practice level is reported at the bottom of the table. The variance component was estimated to be 0.021. These patients were significantly more (OR 3.16 95% CI 2.74 to 3.65) likely not to have a current record for a statin prescription. After adjustment for other factors they were also more likely to be current smokers and to have raised blood pressure. Women were also significantly more likely than men to have raised cholesterol after adjustment for other factors. Women were also significantly less likely to have a current record for a statin prescription (75.4%; 73.8% to 77.0%) compared to men (82.7%; 81.5% to 83.9%). Patients with additional comorbidity with type 2 diabetes were significantly more likely to achieve cholesterol control <5mmol/L.

Table 5 here

Discussion

Key findings

In this study of patients attending primary care practices in an inner London borough in South London the key factor that explained poor lipid control in people on the CHD and Stroke registers was having no record of having been prescribed a statin in the last three months from their last review date. Women were less likely to be prescribed a statin compared to men. Amongst individuals with previous history of CHD or Stroke, women are more likely than men to have poorly controlled cholesterol. This finding was independent of smoking status, blood pressure, statin prescription and type 2 diabetes status and also remained unchanged after adjusting for age, ethnicity, deprivation index and practice level variation.

Patients with a history of both CHD and stroke were those most likely to be managed according to current guidelines. Patients who had only had a stroke were less likely to have had their cholesterol measured, controlled or to be prescribed a statin than patients with CHD.

Patients who had poor control were also more likely to be current smokers, have raised blood pressure and were less likely to have been prescribed a statin.

What is already known

Studies looking at the efficacy of lipid lowering treatments in patients with established CVD have found no significant differences between sexes but found that women were more likely than men to have higher LDL-C levels both before and after treatment suggesting that women may need more aggressive lipid lowering treatment than men to achieve targets. (13-18)

Women are less likely to be prescribed medication including statins as secondary prevention following stroke (19;20) and Acute Coronary Syndrome. (21) These findings are true internationally with similar results being found in Ireland (22), Italy (23), and Sweden. (24) Large studies suggest that the effect is mainly seen in younger women (25;26;26) Similar results have previously been found in East London. (27) Women were also less likely to be prescribed aggressive lipid lowering treatment or any treatment at all. A Canadian study also found discrepancies between the three groups; stroke, CHD and both, as well as gender discrepancies similar to the results found in Lambeth.(28) Some studies have failed to find a significant difference in lipid treatment between genders. (29;30). Others suggest that gender differences disappear once the data has been adjusted for age and severity of disease. (31;32)

What this paper adds

The Health and Social Care Act 2012, places a duty on Clinical Commissioning Groups, to reduce inequalities in access and outcomes of care. (33) This paper shows that routine pseudo-anonymised patient level data can be used to monitor quality and equity of care in a systematic way. We found important age differences in the processes of care – people aged 16-64 were less likely to meet lipid measurement standards. Patients from black ethnic groups and with co-morbidity with diabetes were more likely to meet the lipid measurement standard. Practice variation had a significant effect

on these processes of care. For the lipid control standards the findings of this study in South London are similar to those observed worldwide. In patients with established CVD population women are more likely than men to have raised cholesterol, and yet they are less likely to be prescribed a statin. Critically patients with poor lipid control were also significantly less likely to have a current statin prescription record. However, patients with diabetes (as an additional comorbidity) were more likely to be meet lipid control standards.

Limitations

There was a small proportion of data that was missing in the age, ethnicity, deprivation and some of the risk factors in the disease registers. However as this was a large study we do not think this will have introduced substantial non-response biases. This study used data collected from routine practice consultations so there could be potential measurement errors or biases introduced as part of this. The data gathered did not include the date of any original CVD event and this factor was not considered in the regression analysis. Registry studies show a decline in adherence with cardiovascular preventive therapies including statins with time post-event (34)[9]. The data gathered in this study does not allow differentiation of haemorrhagic from ischaemic strokes which may explain some of the differences in prescriptions. However it is likely that most strokes were ischaemic in aetiology in this population. We also did not assess whether there was a record of prescriptions for other lipid lowering strategies in this cohort, though statins are the most commonly prescribed lipid-lowering drugs there is substantial usage of ezetimibe in some areas in the UK. (35) The data obtained did not include reasons for why women are not being prescribed statins for example whether they were declining them when offered, or whether they were experiencing more side effects and asking to stop taking statins or whether they were not being offered statins in the first place. We also were not able to explore whether healthcare professionals have a perception that women are lower risk of further CVD and not treated as aggressively as men. The study findings may not be more widely generalisable to the UK population but some of these

results on lipid control outcomes are consistent with findings from other studies. These factors need further exploration to inform future strategies.

Conclusions

This evaluation has identified important health inequities in the secondary prevention of heart disease and stroke using routine primary care data available at a patient level. The findings suggests that primary care has an important role in identifying & optimising management in those patients with CVD who don't have current record of cholesterol reading. GPs should also identify people with established CVD who have no current record of statin prescription as these patents had a greater probability of poor lipid control. This evaluation identified these patients were also more likely to have other CVD risks (raised blood pressure and current smokers). Finally this study suggests that primary care professionals need to identify and optimise lipid management in patients with CVD who have no current statin prescription and also that woman with CVD may require higher statin dosage for better lipid control for secondary prevention.

Word count 2642

Foot note

- Contributors: HD and JC designed the study. JC extracted and cleaned the data from Lambeth DataNet and HD and JC performed the primary analyses. KL and HD performed the logistic regression analyses & KL performed the multi-level logistic regression analyses. HLE reviewed the literature. HD and HLE drafted the manuscript and AW, HW, AH and JB critically edited the manuscript and provided final approval. . HD is guarantor of this work and had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
- Competing interests: All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and have nothing to declare. The views expressed are those of the authors and not necessarily those of the NHS, the National Institute for Health Research, or the Department of Health. No other relationships or activities could appear to have influenced the submitted work.
- Transparency: HD affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained.
- Ethical approval: this was not required as this was a service evaluation of current practice against auditable standards

- Data sharing: This data cannot be shared without agreement with participating General Practices in Lambeth CCG area.

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Table 1 – Demographic baseline characteristics

Demographic Characteristics	Sub-level	Number (n = 7,869)	Percent
Age	16-44	333	4.2
	45-54	840	10.7
	55-64	1,340	17.0
	65-74	2035	25.9
	>/=75	3,293	41.9
	Unknown	28	0.4
Sex	Male	4,547	57.8
	Female	3,322	42.2
Ethnicity	White group	4,361	55.4
	Black/Black British group	1,616	20.5
	Asian/Asian-British group	694	8.8
	Mixed group	212	2.7
	Other ethnic group	193	2.5
	Missing/unknown	793	10.1
Index of deprivation	Least deprived	195	2.5
	40-60%	976	12.4
	60-80%	3,816	48.5
	Most deprived80-100%	2,837	36.1
	Missing	45	0.6

Table 2: Risk factor characteristics

Risk factor	**Sub-level**	**Number**	**Per cent**
Smoking *	Non-smoker	4,146	52.7
	Current smoker	1,456	18.5
	Ex-smoker	2,191	27.8
	Unknown	76	1.0
Blood pressure *	BP</=150/90	5,604	71.2
	BP>150/90	2,182	27.7
	Missing	83	1.1
Body Mass index **	<18.5	138	1.9
	18.5 to 24.9	1,999	27.8
	25 to 29.9	2,613	36.4
	30 to 39.9	2,164	30.1
	>/=40	267	3.7
Type 2 diabetes*	Yes	2,104	26.3
	No	5,765	73.3
Note: * n = 7,869 ** n = 7181			

Table 3: Evaluation against standards

Register	Number	Per cent	95% Confidence Limits		Standard
			Lower limit	Upper limit	
Current record last 15 months					
Stroke only	2,284	83.4	82.0	84.8	90
CHD only	3,831	85.8	84.8	86.8	90
CHD & Stroke	597	89.5	86.9	91.7	90
Cholesterol </=5 mmol/L with current record in last 15 months					
Stroke only	1,716	75.1	73.3	76.9	65
CHD only	3,114	81.3	80.0	82.5	70
Stroke & CHD	505	84.6	81.4	87.4	70
Statin prescription recorded in last 6 months & current record in last 15 months					
Stroke only	1,630	71.4	69.5	73.2	100
CHD only	3,203	83.6	82.4	84.8	100
Stroke & CHD	511	85.6	82.5	88.3	100

Table 4 Multi-level logistic regression model – current record for measurement of cholesterol in the last 15 months and demographic, risk factor and treatment with statin characteristics

Variable	Category	N	Adjusted odds ratio (95% confidence limits)	p-value
Age (years) (n = 7,841)	16-44 45-54 55-64 65-74 75+	333 840 1,340 2,035 3,293	**1.68 (1.14 to 2.47)** **1.51 (1.14 to 1.99)** **1.46 (1.13 to1.88)** Ref **1.39 (1.12 to 1.73)**	0.008 0.004 0.003 0.003
Ethnicity (n = 7,869)	White Group Black/Black British Asian/Asian British Mixed groups Other ethnic groups Not known/missing	4361 1616 694 212 193 793	Ref **0.78 (0.62 to 0.97)** 1.08 (0.79 to 1.48) 1.07 (0.67 to 1.72) 1.18 (0.90 to 1.55) 1.18 (0.90 to 1.55)	 0.026 0.626 0.772 0.509 0.224
Deprivation – Index of Multiple Deprivation national ranking (n = 7,824)	Least deprived 40-60% 60-80% Most deprived	195 976 3816 2837	Ref 1.46 (0.77 to 2.81) 1.49 (0.80 to 2.78) 1.60 (0.85 to 2.99)	 0.2459 0.207 0.144
Smoking (7,869)	Non-smoker Ex-smoker Current Smoker Unknown	4146 2191 1456 76	Ref 1.09 (0.90 to 1.32) **1.43 (1.16 to 1.77)** 1.58 (0.53 to 4.74)	 0.352 0.001 0.416
Blood pressure (n = 7786)	</=150/90 mmHg >150/90 mmHg	5604 2182	Ref 1.15 (0.97 to 1.37)	 0.117
Total Cholesterol (n = 7562)	</= 5 mmol/L >5 mmol/L	5897 1665	Ref **1.32 (1.11 to 1.57)**	 0.002
Statin prescription (n = 7869)	Yes No	5891 1978	Ref **2.95 (2.49 to 3.50)**	 <0.0001
BMI (kg/m^2) (n = 7181)	<18.5 18.5 to 24.9 25 to 29.9 30 to 39.9 >/=40	138 1999 2613 2164 267	1.21 (0.74 to 2.00) Ref 0.97 (0.80 to 1.18) 0.93 (0.75 to 1.15) 0.92 (0.58 to 1.46)	0.45 0.796 0.527 0.718
Type 2 diabetes (n = 7869)	Yes No	2,104 5,765	**0.37 (0.29 to 0.47)** Ref	<0.0001
Practice level variance			0.12 (0.06 to 0.25)	

Note: logistic model for current record for Cholesterol in the last 15 months, goodness-of-fit test; number of observations = 7135 ; number of groups = 10 ; Hosmer-Lemeshow chi^2(8) = 5.74; Prob > chi^2 = 0.676; Likelihood Ratio test for testing multilevel logistic regression model compared to conventional logistic regression model p-value < 0.0001.

Table 5: Multi-level logistic regression model – cholesterol control standard > 5mmol/L in last 15 months

Variable	Category	N	Adjusted odds ratio (95% confidence limits)	p-value
Age (n= 6711)	16-44	186	0.79 (0.54 to 1.14)	0.208
	45-54	670	1.20 (0.96 to 1.50)	0.102
	55-64	1149	1.10 (0.91 to 1.33)	0.330
	65-74	1846	Ref	
	75+	2860	**0.74 (0.63 to 0.887)**	<0.0001
Sex (n = 6711)	Male	3883	Ref	
	Female	2828	**1.74 (1.53 to 1.98)**	<0.0001
Ethnicity (n = 6711)	White Group	3717	Ref	
	Black/Black British	1419	0.99 (0.84 to 1.16)	0.892
	Asian/Asian British	612	0.85 (0.66 to 1.09)	0.198
	Mixed groups	174	1.04 (0.71 to 1.54)	0.830
	Other ethnic groups	165	0.85 (0.56 to 1.31)	0.470
	Not known/missing	624	1.13 (0.91 to 1.40)	0.264
Deprivation (Index of Multiple Deprivation national ranking) (n = 6672)	Least deprived	173	Ref	
	40-60%	822	0.79 (0.52 to 1.21)	0.276
	60-80%	3278	0.91 (0.61 to 1.35)	0.634
	Most deprived	2399	0.91 (0.61 to 1.37)	0.664
Smoking (n = 6711)	Non-smoker	3566	Ref	
	Ex-smoker	1925	1.00 (0.86 to 1.18)	0.939
	Current Smoker	1185	**1.28 (1.07 to 1.52)**	0.006
	Unknown	35	1.33 (0.57 to 3.11)	0.506
Blood pressure (n = 6700)	</=150/90 mmHg	4861	Ref	
	>150/90 mmHg	1839	**1.35 (1.17 to 1.54)**	<0.0001
Statin prescription (n = 6711)	Yes	5344	Ref	
	No	1367	**3.10 (2.70 to 3.56)**	<0.0001
Type 2 diabetes (n = 6711)	Yes	1993	**0.62 (0.53 to 0.72)**	<0.0001
	No	4718	Ref	
Practice level variance			0.022 (0.005 to 0.095)	

Note: Logistic model for lipid control < 5 mmol in last 15 months, goodness-of-fit test number of observations = 6370; number of groups = 10; Hosmer-Lemeshow chi^2(8) = 16.26; Prob > chi^2 = 0.039; Likelihood Ratio test for testing multilevel logistic regression model compared to conventional logistic regression model p-value = 0.045.

STROBE Statement—Checklist of items that should be included in reports of ***cross-sectional studies***

	Item No	Recommendation	Comment re article submitted to JECH
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	This is done
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	This is done
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	This is provided
Objectives	3	State specific objectives, including any prespecified hypotheses	This is provided
Methods			
Study design	4	Present key elements of study design early in the paper	This is provided
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	This is provided
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	This is provided
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	This is provided
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	We used routine data collected in primary care for this evaluation (no additional measurements)
Bias	9	Describe any efforts to address potential sources of bias	We used logistic regression models to control for bias
Study size	10	Explain how the study size was arrived at	Not applicable – we evaluated all patients on the two disease registers
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	This is described
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	This is described
		(*b*) Describe any methods used to examine subgroups and interactions	This is described
		(*c*) Explain how missing data were addressed	

		(*d*) If applicable, describe analytical methods taking account of sampling strategy	Not applicable
		(*e*) Describe any sensitivity analyses	Not applicable
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Not applicable
		(b) Give reasons for non-participation at each stage	Not applicable
		(c) Consider use of a flow diagram	Not applicable
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	This is described
		(b) Indicate number of participants with missing data for each variable of interest	This is described
Outcome data	15*	Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Unadjusted estimates can be provided as supplementary tables – we have only provided adjusted estimates with 95% confidence limits
		(*b*) Report category boundaries when continuous variables were categorized	This is described
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Not applicable
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Not applicable
Discussion			
Key results	18	Summarise key results with reference to study objectives	This is done
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	This is done
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	This is done
Generalisability	21	Discuss the generalisability (external validity) of the study results	This is done
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Not funded

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Inequality in lipid control: use of primary care data to evaluate inequality in the management of lipid control for secondary prevention of heart disease and stroke using a cross sectional design in an inner London Borough.

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Title: Inequality in lipid control: use of primary care data to evaluate inequality in the management of lipid control for secondary prevention of heart disease and stroke using a cross sectional design in an inner London Borough.

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Abstract

Objectives: To assess quality of management and inequality in lipid control for secondary prevention of cardiovascular disease using multilevel regression models.

Design: Cross-sectional study

Setting: Inner London borough, with a primary care registered population of 378,000 (2013)

Participants: 48/49 participating general practices with 7869 patients on heart disease /stroke registers were included.

Outcome measures: 1/Recording of current total cholesterol levels and lipid control according to national evidence based standards. 2/ Assessment of health inequalities by age, sex, ethnicity, deprivation, presence of other risks or comorbidity in meeting in both lipid measurement and control standards.

Results: Some process standards were not met. Patients with a current cholesterol measurement >5 mmol/l, were less likely to have a current statin prescription (adjusted OR = 3.10; 95% CI: 2.70 to 3.56). They were more likely to have clustering of other CVD risk factors. Women were significantly more likely to have raised cholesterol after adjustment for other factors (adjusted OR = 1.74; 95% CI: 1.53 to 1.98).

Conclusions: In this study the key factor that explained poor lipid control in people with CVD was having no current prescription record of a statin. Women were more likely to have poorly controlled cholesterol (independent of co-morbid risk factors and after adjusting for age, ethnicity, deprivation index and practice level variation). Women with CVD should be offered statin prescription and may require higher statin dosage for improved control.

Strengths include:

Large study using epidemiological design and multi-level regression modelling to identify inequality in management of lipid control using routine data.

systematic approach that can be used by Clinical Commissioning Groups to meet their duty to reduce inequality in access and outcomes to healthcare

Limitations include:

potential measurement errors /biases

data did not include date of any original CVD event

findings may not be generalisable to rest of UK

Key word: Equity profile, cholesterol, cardiovascular disease, secondary prevention, gender inequality.

Introduction

Hyperlipidaemia contributes a significant proportion of modifiable cardiovascular disease (CVD) risk. (1) Most of the CVD risk attributable to lipids is due to lipoprotein particles associated with cholesterol deposition in the vascular wall including total cholesterol, non-HDL-cholesterol and low density lipoprotein cholesterol (LDL-C). (2) Interventions that reduce LDL-C reduce CVD risk with a relationship from clinical trials that shows that a 21% relative risk reduction in major vascular events per 1mmol/L reduction in LDL-C in all groups. (3).

The National Institute for Health and Clinical Excellence (NICE) lipid modification guidelines (CG67; 2008) advise clinicians to offer statins to all individuals with increased risk of CVD as determined by a QRISK2 or Framingham (1991) -based CVD risk score of 20% over the next decade.(4-6) These risk calculation tools give similar results but Framingham overpredicts CVD in UK populations. (7) Statin treatment is to be prescribed to all patients with established CVD using simvastatin 40mg in most patients and atorvastatin 80mg in acute coronary syndromes. NICE CG67 advises that cholesterol is checked within 3 months of starting a statin with the aim that patients with established CVD should ideally reach total cholesterol <4 mmol/L; LDL-C <2 mmol/L with an audit standards of total cholesterol < 5mmol/L and LDL-C <3mmol/L. (4) In primary prevention no target is specified but all should be treated with simvastatin 40mg or another off-patent agent of similar efficacy. If this target has not been met, then patients are to be given advice around compliance and lifestyle and consideration was originally given to increasing the dose of simvastatin to 80mg. However, later safety concerns about simvastatin 80mg and its drug interactions mean this suggestion was not implemented in many areas (including South East London). Patients are to be monitored annually once they are meeting targets. (8)

GPs are currently incentivised to manage CVD by the Quality and Outcomes Framework (QOF) which is a "Pay for Performance" (P4P) system. The QOF control target in 2012-13 was total cholesterol of <5mmol/l. (9) There is some evidence that P4P can improve quality of care but this evidence is not strong and other factors are also likely to play a role. (10;11) In addition the EUROASPIRE III survey has shown that evidence based guideline targets for lifestyle, risk factors and drug treatments are not being achieved and there remains considerable potentential to raise standards to prevent further events and that statins are suboptimally used . (12;13) Inequalities in the management of cardiovascular disease in primary care have been reported previously with key sex inequalities between men and women and ethnic inequalities. (14;15)

The Health and Social Care Act 2012 in the UK, places a duty on Clinical Commissioning Groups to improve quality and reduce inequalities in access and outcomes of care.(16;17) Our aim was to evaluate the quality in the management of cholesterol for the secondary prevention of CVD in Lambeth patients on the Coronary Heart Disease (CHD) and / or stroke registers. We compared lipid measurement and control to pre-defined standards based on QoF and NICE guidelines (4;18) We also evaluated the inequality in the management of lipid control and hypothesized that there should be no group differences in the management of cholesterol in Lambeth patients on the above registers, according to these pre-defined standards.

Methods

This evaluation was carried out in an inner city London borough, with a registered population of 378,000 (2013). We used a cross-sectional study design and identified those patients who were on the CHD and/or stroke registers as of 31/3/2013 and the period 15 months prior to this date.

We used patient level data from the Lambeth DataNet. This is a pseudo -anonymised database of patients registered with practices in primary care that supports local commissioning, health care/service evaluation and monitoring health inequalities. We identified people registered on the

CHD and / or stroke registers from 48 of 49 practices that contribute data to the Lambeth DataNet. A key purpose of this database is also to collect and analyse markers of health inequalities such as ethnicity, index of multiple deprivation (IMD), as well as age and sex. The IMD includes income deprivation; employment deprivation; health deprivation and disability; education deprivation; and other markers of deprivations such as crime, barriers to housing and services and the living environment.

Pre-defined standards:

The standards that were used to assess the quality of care were a combination of the upper range of the QOF 12-13 and NICE CG67 guidelines. (4;9)

CHD:

- Cholesterol level is measured in last 15 months (at or prior to 31/03/13) in 90% (range 50-90%)of all patients on the CHD register;
- Cholesterol control </=5 mmol/l in 70% (range 45 to 70%) of all patients on CHD register

Stroke:

- Cholesterol level measured in last 15 months (at or prior to 31/03/13) in 90% (range 50-90%) of all patients on the stroke register;
- Cholesterol </= 5 mmol/l in 65% (range 40 to 65%) of all patients on stroke register

We also collated data on the current prescription of statins for this cohort of patients within the last 3 months from their last review date. NICE guidelines recommend that all patients with heart disease or stroke s should be prescribed a statin or have reasons recorded if not prescribed.

Hypothesis tested:

The hypotheses we were testing were as follows:

1/ Patients in Lambeth with one or more diagnoses of CHD and stroke are managed according to the pre-defined standards for cholesterol for people on these two registers as of 2012/13.

2/ In Lambeth patients with one or more diagnoses of CHD and stroke - there are no significant group differences as assessed by age, sex, ethnicity, deprivation, presence of other risks or comorbidity in meeting these pre-defined standards.

Analysis

We used STATA 13.1 to test the hypotheses.(19) Descriptive analyses were done to test the first hypothesis. The outcome (dependent) variables for the regression models were: 1/ measurement of cholesterol (DO1) and 2/ total cholesterol </= 5 mmols/l (DO2) as defined above in the "pre-defined standards" section.

The presence of group differences (independent variables) in these were reviewed by: age group (16-44, 45-54, 55-64, 65-74 & >/=75) , sex (male, female) , ethnic groups (White group, Black/Black British group, Missing/unknown, Asian/Asian-British group, Mixed group, Other ethnic group), index of multiple deprivation quintiles (grouped as follows: least deprived two quintiles 0-40%, 40-60%, 60-80%, Most deprived 80-100%) , as well as risk factors for smoking (current smokers, ex-smokers, non-smokers and unknown) and blood pressure or BP (controlled defined as BP</=150/90; uncontrolled defined as BP>150/90), type 2 diabetes status (yes or no) & statin prescription status within time frame described above (yes or no).

A number of univariate multilevel logistic regression models taking into account the variation among different general practices were fitted to explore the associations between the outcome variable and different independent variables tested in the second hypothesis. Then a series of multivariate multilevel logistic regression models were fitted to investigate the associations between the pre-defined standards and all potential independent variables. Best and final models chosen by series of Wald goodness of fit tests were reported in the result section. (20)

Results

The total number of primary care practices that participated was 48/49 (98%). The number of people on the CHD & Stroke registers was 7869 (CHD only: 4464; Stroke only: 2738; combined CHD/stroke = 667). The diagnosed crude prevalence of CHD and stroke were 1.3% and 0.9% respectively in Lambeth in 2012-13. (18) The mean age was 69.8 years (95% confidence limits: 69.5 to 70.1). There were significantly more males on the registers: male 57.8% (56.7 to 58.9) compared to female 42.2% (41.1 to 43.3). Other demographic characteristics are shown in table 1.

Table 1 here

Table 2 shows the risk factor characteristics**.** In this population about 19% of people with coronary heart disease or stroke remained current smokers, just over 1 in 4 were not controlled for their blood pressure to a level of 150/90 mmHg and 70% were overweight or obese. Just over 1 in 4 had type 2 diabetes.

Table 2 here

Hypothesis 1: Patients with one or more of CHD and stroke are managed according to pre-defined standards for cholesterol measurement and control for people on these two registers as of 2012/13 and 13/14

Table 3 shows the evaluation of patients having a current record for cholesterol measurement, degree of cholesterol control achieved and a record of a statin prescription. Overall pre-defined auditable standards were not met for current records for both cholesterol measurement and statin prescription. However pre-defined auditable standards for those patients with a current record the proportion of patients whose cholesterol was below 5mmol/l were met. When comparing subgroups within the study, patients with a history of stroke were consistently the least likely to meet all three QOF standards.

Primary care records showed that overall 80.1% of patients had been prescribed a statin in the last 6 months. This rate was significantly lower in stroke patients.

Table 3 here

Hypothesis 2: In patients with one or more of CHD and stroke - there are no significant group differences in the outcome (dependent) variables DO1 and DO2 as assessed by age, sex, ethnicity and deprivation in meeting the predefined standards.

We found significant group differences in meeting the lipid measurement standards. Table 4 shows the findings for patients who did not have a current record of cholesterol measurement in the last 15 months. The random effect at the general practice level is reported at the bottom of the table. The variance component was estimated to be 0.12. Patients categorised as black/black British group (compared to the white group) were significantly more likely to have a current record, as were patients with type 2 diabetes (compared to people without type 2 diabetes). Patients aged between 16-64 years or over 75 years were significantly less likely to have a current record for cholesterol levels. Patients aged 16-44 were 68% more likely to not have a current record compared to those aged 65-74. After taking into account other factors deprivation did not appear to have an effect on current cholesterol recording. Those who were current smokers and had previously raised cholesterol level were also less likely to have a current record of cholesterol level.

Patients with no current record for cholesterol in the past 15 months were nearly three times less likely (adjusted odds = 2.97; 95% CI: 2.51 to 3.52) to have a record of a current statin prescription.

Table 4 here

Table 5 shows the finding for the subgroup of patients who had a current record of cholesterol but were not achieving a lipid control standards (cholesterol level <5mmol/L) within the last 15 months of the study date. The random effect at the general practice level is reported at the bottom of the table. The variance component was estimated to be 0.022. These patients were significantly more

(OR 3.10 95% CI 2.70 to 3.56) likely not to have a current record for a statin prescription. After adjustment for other factors they were also more likely to be current smokers and to have raised blood pressure. Women were also significantly more likely than men to have raised cholesterol after adjustment for other factors. Women were significantly less likely to have a current record for a statin prescription (75%; 74% to 77%) compared to men (83%; 82% to 84%). There were significant differences in current recorded prescribing with age (those aged 16-44 and 45-54 were less likely to have a current record of statins prescribed: 44% and 71% respectively) and ethnicity (black /black British groups were less likely to have statins prescribed and Asian groups more likely: 74% and 88% respectively). However there was no significant difference in the adjusted odds ratio with age (apart from the 75+ age group who were significantly better controlled) and ethnicity for poor lipid control. Patients with additional comorbidity with type 2 diabetes were significantly more likely to achieve cholesterol control <5mmol/L.

Table 5 here

Discussion

Key findings

In this study of patients attending primary care practices in an inner London borough in South London the key factor that explained poor lipid control in people on the CHD and Stroke registers was having no record of having been prescribed a statin in the last three months from their last review date. Women were less likely to be prescribed a statin compared to men. Amongst individuals with previous history of CHD or Stroke, women are more likely than men to have poorly controlled cholesterol. This finding was independent of smoking status, blood pressure, statin prescription and type 2 diabetes status and also remained unchanged after adjusting for age, ethnicity, deprivation index and practice level variation. We found no ethnic difference in lipid

control after adjustment for other factors. The very elderly (75+) were significantly better controlled.

Patients with a history of both CHD and stroke were those most likely to be managed according to current guidelines. Patients who had only had a stroke were less likely to have had their cholesterol measured, controlled or to be prescribed a statin than patients with CHD.

There was a clustering of risk factors in that patients who had poor lipid control were also more likely to be current smokers, have raised blood pressure and were less likely to have a current statin prescription recorded.

What is already known

Studies looking at the efficacy of lipid lowering treatments in patients with established CVD have found no significant differences between sexes but found that women were more likely than men to have higher LDL-C levels both before and after treatment suggesting that women may need more aggressive lipid lowering treatment than men to achieve targets. (14;21-25)

Women are less likely to be prescribed medication including statins as secondary prevention following stroke (26;27) and Acute Coronary Syndrome. (28) These findings are true internationally with similar results being found in Ireland (29), Italy (30), and Sweden. (31) Large studies suggest that the effect is mainly seen in younger women. (32;33) Similar results have previously been found in East London. (34) Women were also less likely to be prescribed aggressive lipid lowering treatment or any treatment at all. A Canadian study also found discrepancies between the three groups; stroke, CHD and both, as well as gender discrepancies similar to the results found in Lambeth.(35) Some studies have failed to find a significant difference in lipid treatment between genders. (36;37). Others suggest that gender differences disappear once the data has been adjusted for age and severity of disease. (38;39) Millet et al in their study identified improvements in lipid control and blood pressure targets in ethnic groups although black groups were less likely to

be prescribed statins. They suggested that the introduction of QoF led to marked improvements in both the process and management of CHD. They did not report on sex or age differences in lipid control. (15)

What this paper adds

The Health and Social Care Act 2012, places a duty on Clinical Commissioning Groups, to reduce inequalities in access and outcomes of care. (16) This paper shows that routine pseudo-anonymised patient level data can be used to monitor quality and equity of care in a systematic way. We found important age differences in the processes of care – people aged 16-64 were less likely to meet lipid measurement standards. Patients from black ethnic groups and with co-morbidity with diabetes were more likely to meet the lipid measurement standard. Practice variation had a significant effect on these processes of care. For the lipid control standards the findings of this study in South London are similar to those observed worldwide. In patients with established CVD population women are more likely than men to have raised cholesterol, and yet they are less likely to be prescribed a statin. Critically patients with poor lipid control were also significantly less likely to have a current statin prescription record. However patients with diabetes (as an additional comorbidity) were more likely to be meet lipid control standards. We have provided supplementary data tables that show improvements overall in recording of total cholesterol, current statin prescription and change in mean total cholesterol by age, sex, ethnicity and deprivation for the cohort of patients that had records in 2013 and 2011. These supplementary data suggest that P4P is continuing to have a positive impact locally but also shows differential changes in total cholesterol control with some worsening in inequalities.

Limitations

In the UK all diagnosed cases of CHD and stroke are registered by GPs as part of QoF disease registers as this is part of the GP contract. We know from modelled estimates that the registers may under estimate actual number of cases by as much as 50% - however these estimates are based on a

number of assumptions and there is uncertainty in modelled prevalence estimates. (40) This study used data from all cases that were diagnosed and on the QoF registers from all but one practice. There was a small proportion of data that was missing in the age, deprivation and some of the risk factors in the disease register. This varied for different indicators – (e.g. for the first outcome of recorded cholesterol: missing age was 28 records or 0.4% of all records; IMD 45 records or 0.6% of all records; cholesterol level recorded – this was 307 records or 4% of all records; BMI was 688 records or 9% of all records; for the second outcome cholesterol level >5 mmol missing data was: IMD 39 records or 0.6% and 1 record for cholesterol level. However as this was a large study we do not think this will have introduced substantial non-response biases. This study used data collected from routine practice consultations so there could be potential measurement errors or biases introduced as part of this. The data gathered did not include the date of any original CVD event and this factor was not considered in the regression analysis. Registry studies show a decline in adherence with cardiovascular preventive therapies including statins with time post-event (12)[9]. The data gathered in this study does not allow differentiation of haemorrhagic from ischaemic strokes which may explain some of the differences in prescriptions. However it is likely that most strokes were ischaemic in aetiology in this population. We also did not assess whether there was a record of prescriptions for other lipid lowering strategies in this cohort, though statins are the most commonly prescribed lipid-lowering drugs there is substantial usage of ezetimibe in some areas in the UK. (41) The data obtained did not include reasons for why women are not being prescribed statins for example whether they were declining them when offered, or whether they were experiencing more side effects and asking to stop taking statins or whether they were not being offered statins in the first place. We also were not able to explore whether healthcare professionals have a perception that women are lower risk of further CVD and not treated as aggressively as men. This study was conducted in a single setting and the findings may not be more widely generalisable to the UK population as implementation of NICE guidelines may vary in different areas. However

some of these results on lipid control outcomes are consistent with findings from other studies. These factors need further exploration to inform future strategies.

Conclusions

This evaluation has identified important health inequities in the secondary prevention of heart disease and stroke using routine primary care data available at a patient level. The findings suggests that primary care has an important role in identifying & optimising management in those patients with CVD who don't have current record of cholesterol reading. GPs should also identify people with established CVD who have no current record of statin prescription as these patents had a greater probability of poor lipid control. This evaluation identified these patients were also more likely to have other CVD risks (raised blood pressure and current smokers). Finally this study suggests that primary care professionals need to identify and optimise lipid management in patients with CVD who have no current statin prescription and also that woman with CVD may require higher statin dosage for better lipid control for secondary prevention.

Word count 3349

Foot note

- Contributors: HD and JC designed the study. JC extracted and cleaned the data from Lambeth DataNet and HD and JC performed the primary analyses. KL and HD performed the logistic regression analyses & KL performed the multi-level logistic regression analyses. HLE reviewed the literature. HD and HLE drafted the manuscript and AW, HW, AH and JB critically edited the manuscript and provided final approval. . HD is guarantor of this work and had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
- Competing interests: All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and have nothing to declare. The views expressed are those of the authors and not necessarily those of the NHS, the National Institute for Health Research, or the Department of Health. No other relationships or activities could appear to have influenced the submitted work.
- Transparency: HD affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained.
- Ethical approval: this was not required as this was a service evaluation of current practice against auditable standards

- Data sharing: This data cannot be shared without agreement with participating General Practices in Lambeth CCG area.

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Table 1 – Demographic baseline characteristics

Demographic Characteristics	Sub-level	Number (n = 7,869)	Percent
Age	16-44	333	4.2
	45-54	840	10.7
	55-64	1,340	17.0
	65-74	2035	25.9
	>/=75	3,293	41.9
	Unknown	28	0.4
Sex	Male	4,547	57.8
	Female	3,322	42.2
Ethnicity	White group	4,361	55.4
	Black/Black British group	1,616	20.5
	Asian/Asian-British group	694	8.8
	Mixed group	212	2.7
	Other ethnic group	193	2.5
	Missing/unknown	793	10.1
Index of deprivation	Least deprived	195	2.5
	40-60%	976	12.4
	60-80%	3,816	48.5
	Most deprived80-100%	2,837	36.1
	Missing	45	0.6

Table 2: Risk factor characteristics

Risk factor	**Sub-level**	**Number**	**Per cent**
Smoking *	Non-smoker	4,146	52.7
	Current smoker	1,456	18.5
	Ex-smoker	2,191	27.8
	Unknown	76	1.0
Blood pressure *	BP</=150/90	5,604	71.2
	BP>150/90	2,182	27.7
	Missing	83	1.1
Body Mass index **	<18.5	138	1.9
	18.5 to 24.9	1,999	27.8
	25 to 29.9	2,613	36.4
	30 to 39.9	2,164	30.1
	>/=40	267	3.7
Type 2 diabetes*	Yes	2,104	26.3
	No	5,765	73.3
Note: * n = 7,869 ** n = 7181			

Table 3: Evaluation against standards

Register	Number	Per cent	95% Confidence Limits		Standard (%)
			Lower limit	Upper limit	
Current record last 15 months					
Stroke only	2,284	83.4	82.0	84.8	90
CHD only	3,831	85.8	84.8	86.8	90
CHD & Stroke	597	89.5	86.9	91.7	90
Cholesterol </=5 mmol/L with current record in last 15 months					
Stroke only	1,716	75.1	73.3	76.9	65
CHD only	3,114	81.3	80.0	82.5	70
Stroke & CHD	505	84.6	81.4	87.4	70
Statin prescription recorded in last 6 months & current record in last 15 months					
Stroke only	1,630	71.4	69.5	73.2	100
CHD only	3,203	83.6	82.4	84.8	100
Stroke & CHD	511	85.6	82.5	88.3	100

Table 4 Multi-level logistic regression model – current record for measurement of cholesterol (DO1) in the last 15 months and demographic, risk factor and treatment with statin characteristics

Variable	Category	Total N	DO1: N (%)	Adjusted odds ratio (95% confidence limits)	p-value
Age (years) (n = 7,841)	16-44 45-54 55-64 65-74 75+	333 840 1,340 2,035 3,293	147 (44) 170 (20) 190 (14) 189 (9) 433 (13)	**1.68 (1.14 to 2.47)** **1.50 (1.13 to 1.98)** **1.45 (1.13 to1.87)** Ref **1.41 (1.13 to 1.75)**	0.008 0.005 0.004 0.002
Sex (n = 7,869)	Male Female	4,547 3,322	663 (15) 494 (15)	Ref 0.90 (0.76 to 1.06)	 0.220
Ethnicity (n = 7,869)	White Group Black/Black British Asian/Asian British Mixed groups Other ethnic groups Not known/missing	4361 1616 694 212 193 793	643 (15) 197 (12) 82 (12) 38 (18) 28 (15) 169 (21)	Ref **0.78 (0.62 to 0.97)** 1.07 (0.78 to 1.47) 1.07 (0.67 to 1.72) 1.18 (0.72 to 1.93) 1.18 (0.90 to 1.54)	 0.029 0.6736 0.769 0.5010 0.231
Deprivation – Index of Multiple Deprivation national ranking (n = 7,824)	Least deprived 40-60% 60-80% Most deprived	195 976 3816 2837	22 (11) 153 (16) 538 (14) 438 (15)	Ref 1.46 (0.76 to 2.79) 1.49 (0.80 to 2.78) 1.59 (0.85 to 2.99)	 0.254 0.210 0.147
Smoking (7,869)	Non-smoker Ex-smoker Current Smoker Unknown	4146 2191 1456 76	579 (14) 266 (12) 271 (19) 41 (54)	Ref 1.07 (0.88 to 1.30) **1.40 (1.13 to 1.74)** 1.54 (0.51 to 4.63)	 0.514 0.002 0.440
Blood pressure (n = 7786)	</=150/90 mmHg >150/90 mmHg	5604 2182	742 (13) 343 (16)	Ref 1.15 (0.96 to 1.36)	 0.123
Total Cholesterol (n = 7562)	</= 5 mmol/L >5 mmol/L	5897 1665	562 (10) 289 (17)	Ref **1.33 (1.12 to 1.59)**	 0.001
Statin prescription (n = 7869)	Yes No	5891 1978	547 (9) 610 (31)	Ref **2.97 (2.51 to 3.52)**	 <0.0001
BMI (kg/m^2) (n = 7181)	<18.5 18.5 to 24.9 25 to 29.9 30 to 39.9 >/=40	138 1999 2613 2164 267	23 (17) 255 (13) 267 (10) 201 (9) 24 (9)	1.24 (0.75 to 2.04) Ref 0.97 (0.80 to 1.18) 0.94 (0.76 to 1.16) 0.94 (0.59 to 1.50)	0.403 0.742 0.576 0.801
Type 2 diabetes (n = 7869)	Yes No	2,104 5,765	111 (5) 1,046 (18)	**0.37 (0.29 to 0.47)** Ref	<0.0001
Practice level variance				0.12 (0.06 to 0.25)	

Note: logistic model for current record for Cholesterol in the last 15 months, goodness-of-fit test; number of observations = 7135 ; number of groups = 10 ; Hosmer-Lemeshow chi^2(8) = 5.74; Prob > chi^2 = 0.676; Likelihood Ratio

test for testing multilevel logistic regression model compared to conventional logistic regression model p-value < 0.0001.

Table 5: Multi-level logistic regression model – cholesterol control standard > 5mmol/L (DO2) in last 15 months

Variable	Category	Total N	DO2: N (%)	Adjusted odds ratio (95% confidence limits)	p-value
Age (n= 6711)	16-44	186	49 (26)	0.79 (0.54 to 1.14)	0.208
	45-54	670	186 (28)	1.20 (0.96 to 1.50)	0.102
	55-64	1149	261 (23)	1.10 (0.91 to 1.33)	0.330
	65-74	1846	380 (21)	Ref	
	75+	2860	500 (17)	**0.74 (0.63 to 0.88)**	<0.0001
Sex (n = 6711)	Male	3883	649 (17)	Ref	
	Female	2828	727 (26)	**1.74 (1.53 to 1.98)**	<0.0001
Ethnicity (n = 6711)	White Group	3717	762 (21)	Ref	
	Black/Black British	1419	310 (22)	0.99 (0.84 to 1.16)	0.892
	Asian/Asian British	612	90 (15)	0.85 (0.66 to 1.09)	0.198
	Mixed groups	174	41 (24)	1.04 (0.71 to 1.54)	0.830
	Other ethnic groups	165	29 (18)	0.85 (0.56 to 1.31)	0.470
	Not known/missing	624	144 (23)	1.13 (0.91 to 1.40)	0.264
Deprivation (Index of Multiple Deprivation national ranking) (n = 6672)	Least deprived	173	37 (21)	Ref	
	40-60%	822	148 (18)	0.79 (0.52 to 1.21)	0.276
	60-80%	3278	677 (21)	0.91 (0.61 to 1.35)	0.634
	Most deprived	2399	508 (21)	0.91 (0.61 to 1.37)	0.664
Smoking (n = 6711)	Non-smoker	3566	736 (21)	Ref	
	Ex-smoker	1925	346 (18)	1.00 (0.86 to 1.18)	0.939
	Current Smoker	1185	286 (24)	**1.28 (1.07 to 1.52)**	0.006
	Unknown	35	8 (23)	1.33 (0.57 to 3.11)	0.506
Blood pressure (n = 6700)	</=150/90 mmHg	4861	898 (18)	Ref	
	>150/90 mmHg	1839	477 (26)	**1.35 (1.17 to 1.54)**	<0.0001
Statin prescription (n = 6711)	Yes	5344	845 (16)	Ref	
	No	1367	531 (39)	**3.10 (2.70 to 3.56)**	<0.0001
Type 2 diabetes (n = 6711)	Yes	1993	1098 (23)	**0.62 (0.53 to 0.72)**	<0.0001
	No	4718	278 (14)	Ref	
Practice level variance				0.022 (0.005 to 0.095)	

Note: Logistic model for lipid control < 5 mmol in last 15 months, goodness-of-fit test number of observations = 6370; number of groups = 10; Hosmer-Lemeshow chi^2(8) = 16.26; Prob > chi^2 = 0.039; Likelihood Ratio test for testing multilevel logistic regression model compared to conventional logistic regression model p-value = 0.045.

Title: Inequality in lipid control: use of primary care data to evaluate inequality in the management of lipid control for secondary prevention of heart disease and stroke using a cross sectional design in an inner London Borough(supplementary data tables).

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Supplementary data:

The following tables provide supplementary data referred to in the response to the peer reviewers comments.

Supplementary table 1: Variation in statin prescribing by age, sex, ethnicity and deprivation index.

Factor	Detail	Current prescription record (%)	95% confidence interval
Age (n = 6711)	16-44	44	37 to 51
	45-54	71	68 to 75
	55-64	83	81 to 85
	65-74	84	82 to 85
	75+	80	78 to 81
Sex (n = 6711)	Male	83	82 to 84
	Female	75	74 to 77
Ethnicity (n = 6711)	White Group	81	79 to 82
	Black/Black British	74	72 to 76
	Asian/Asian British	88	86 to 91
	Mixed groups	78	72 to 84
	Other ethnic groups	83	77 to 89
	Not known/missing	78	75 to 81
IMD (6672)	Least deprived 0-40%	78	72 to 84
	40-60%	80	78 to 83
	60-80%	80	79 to 82
	Most deprived 80-100%	79	77 to 80

Supplementary table 2: Comparison of recording of current (within 15 months) recording of cholesterol status between 2011 & 2013 in cohort of patients with two readings

Cholesterol record in 2013

Cholesterol record in 2011	Yes	No	Total
Yes	5,557	645	6,202
Row %	*90*	*10*	*100*
Column %	*83*	*56*	***79***
No	1,155	512	1,667
Row %	*69*	*31*	*100*
Column %	*17*	*44*	*21*
Total	6,712	1,157	7,869
Row %	***85***	*15*	*100*
Column %	*100*	*100*	*100*

Pearson chi square < 0.0001

Recording of cholesterol improved from 79% to 85% in the cohort of patients who had records in both time periods.

Supplementary table 3: Comparison of current statin prescribing between 2011 & 2013 in cohort of patients with two readings

Current statin prescription record in 2013

Current statin prescription record in 2011	Yes	No	Total
Yes	4,120	313	4,433
Row %	*93*	*7*	*100*
Column %	*77*	*23*	***66***
No	1,224	1,055	2,279
Row %	*53.71*	*46.29*	*100*
Column %	*23*	*77*	*34*
Total	5,344	1,368	6,712
Row %	***80***	*20*	*100*
Column %	*100*	*100*	*100*

Pearson chi square < 0.0001

Recording of current statin prescribing improved from 66% to 80% in the cohort of patients who had records in both time periods.

Supplementary table 4: Comparison of mean total cholesterol by age, sex, ethnicity and deprivation index between 2011 & 2013 in cohort of patients with two readings

Profile characteristics	Number	Mean 2011	Mean 2013	Difference in mean	95% confidence limits	p-value (paired t-test)
Overall	6931	4.50	4.33	**0.17**	0.14 to 0.19	<0.0001
Age group						
16-44	144	4.77	4.55	0.22	0.02 to 0.41	0.03
45-54	665	4.73	4.55	0.18	0.09 to 0.27	0.0001
55-64	1184	4.64	4.41	0.22	0.16 to 0.29	<0.0001
65-74	1865	4.46	4.31	0.15	0.10 to 0.19	<0.0001
75+	3072	4.40	4.24	0.16	0.13 to 0.19	<0.0001
Sex						
Male	3955	4.35	4.17	**0.18**	0.15 to 0.21	<0.0001
Female	2976	4.69	4.54	**0.15**	0.11 to 0.18	<0.0001
Ethnic category						
White Group	3860	4.51	4.35	0.16	0.14 to 0.20	<0.0001
Black/Black British group	1442	4.50	4.36	0.14	0.10 to 0.20	<0.0001
Asian/Asian British	607	4.28	4.10	0.18	0.10 to 0.26	<0.0001
Mixed groups	183	4.41	4.29	0.12	- 0.02 to 0.27	0.08
Other ethnic groups	166	4.35	4.23	0.12	-0.02 to 0.26	0.09
Not known/missing	673	4.65	4.43	0.22	0.15 to 0.30	<0.0001
IMD						
Least deprived (0-40%)	178	4.54	4.27	0.27	0.14 to 0.41	0.0001
40-60%	836	4.49	4.25	0.24	0.18 to 0.30	<0.0001
60-80%	3376	4.51	4.34	0.17	0.14 to 0.20	<0.0001
Most deprived	2500	4.48	4.35	0.13	0.10 to 0.17	<0.0001

Note greater improvements in mean total cholesterol seen in younger age groups, men (compared to women), Asian/Asian British and least deprived categories compared to most deprived groups. However none of these differential impacts are significantly different within each category analysed.

STROBE Statement—Checklist of items that should be included in reports of ***cross-sectional studies***

	Item No	Recommendation	Comment re article submitted to JECH
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	This is done
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	This is done
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	This is provided
Objectives	3	State specific objectives, including any prespecified hypotheses	This is provided
Methods			
Study design	4	Present key elements of study design early in the paper	This is provided
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	This is provided
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	This is provided
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	This is provided
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	We used routine data collected in primary care for this evaluation (no additional measurements)
Bias	9	Describe any efforts to address potential sources of bias	We used logistic regression models to control for bias
Study size	10	Explain how the study size was arrived at	Not applicable – we evaluated all patients on the two disease registers
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	This is described
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	This is described
		(*b*) Describe any methods used to examine subgroups and interactions	This is described
		(*c*) Explain how missing data were addressed	

		(*d*) If applicable, describe analytical methods taking account of sampling strategy	Not applicable
		(*e*) Describe any sensitivity analyses	Not applicable
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Not applicable
		(b) Give reasons for non-participation at each stage	Not applicable
		(c) Consider use of a flow diagram	Not applicable
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	This is described
		(b) Indicate number of participants with missing data for each variable of interest	This is described
Outcome data	15*	Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Unadjusted estimates can be provided as supplementary tables – we have only provided adjusted estimates with 95% confidence limits
		(*b*) Report category boundaries when continuous variables were categorized	This is described
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Not applicable
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Not applicable
Discussion			
Key results	18	Summarise key results with reference to study objectives	This is done
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	This is done
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	This is done
Generalisability	21	Discuss the generalisability (external validity) of the study results	This is done
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Not funded

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Evaluating quality and its determinants in lipid control for secondary prevention of heart disease and stroke in primary care – a study in an inner London Borough.

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Title: Evaluating quality and its determinants quality in lipid control for secondary prevention of heart disease and stroke in primary care – a study in an inner London Borough.

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Abstract

Objectives: To assess quality of management and determinants in lipid control for secondary prevention of cardiovascular disease using multilevel regression models.

Design: Cross-sectional study

Setting: Inner London borough, with a primary care registered population of 378,000 (2013)

Participants: 48/49 participating general practices with 7869 patients on heart disease /stroke registers were included.

Outcome measures: 1/Recording of current total cholesterol levels and lipid control according to national evidence based standards. 2/ Assessment of quality by age, sex, ethnicity, deprivation, presence of other risks or comorbidity in meeting both lipid measurement and control standards.

Results: Some process standards were not met. Patients with a current cholesterol measurement >5 mmol/l, were less likely to have a current statin prescription (adjusted OR = 3.10; 95% CI: 2.70 to 3.56). They were more likely to have clustering of other CVD risk factors. Women were significantly more likely to have raised cholesterol after adjustment for other factors (adjusted OR = 1.74; 95% CI: 1.53 to 1.98).

Conclusions: In this study the key factor that explained poor lipid control in people with CVD was having no current prescription record of a statin. Women were more likely to have poorly controlled cholesterol (independent of co-morbid risk factors and after adjusting for age, ethnicity, deprivation index and practice level variation). Women with CVD should be offered statin prescription and may require higher statin dosage for improved control.

Strengths include:

Large study using epidemiological design and multi-level regression modelling to identify determinants in management of lipid control using routine data.

systematic approach that can be used by Clinical Commissioning Groups to meet their duty to understand & reduce variation in access and outcomes to healthcare

Limitations include:

potential measurement errors /biases

data did not include date of any original CVD event

findings may not be generalisable to rest of UK

Key word: quality, determinants in quality of cholesterol control, cardiovascular disease, secondary prevention,

Introduction

Hyperlipidaemia contributes a significant proportion of modifiable cardiovascular disease (CVD) risk. (1) Most of the CVD risk attributable to lipids is due to lipoprotein particles associated with cholesterol deposition in the vascular wall including total cholesterol, non-HDL-cholesterol and low density lipoprotein cholesterol (LDL-C). (2) Interventions that reduce LDL-C reduce CVD risk with a relationship from clinical trials that shows that a 21% relative risk reduction in major vascular events per 1mmol/L reduction in LDL-C in all groups. (3) .

The National Institute for Health and Clinical Excellence (NICE) lipid modification guidelines (CG67 2008 and updated CG181, 2014) advise clinicians to offer statins to all individuals with increased risk of CVD as determined by a QRISK2 or Framingham (1991) -based CVD risk score of 20% over the next decade.(4-6) These risk calculation tools give similar results but Framingham overpredicts CVD in UK populations. (7) Statin treatment is to be prescribed to all patients with established CVD using simvastatin 40mg in most patients and atorvastatin 80mg in acute coronary syndromes. NICE guideline advises that cholesterol is checked within 3 months of starting a statin with the aim that patients with established CVD should ideally reach total cholesterol <4 mmol/L; LDL-C <2 mmol/L with an audit standards of total cholesterol < 5mmol/L and LDL-C <3mmol/L. (6) In primary prevention no target is specified but all should be treated with simvastatin 40mg or another off-patent agent of similar efficacy. (8)

GPs are currently incentivised to manage CVD by the Quality and Outcomes Framework (QOF) which is a “Pay for Performance” (P4P) system. The QOF control target in 2012-13 was total cholesterol of <5mmol/l. (9) There is some evidence that P4P can improve quality of care but this evidence is not strong and other factors are also likely to play a role. (10;11) In addition the EUROASPIRE III survey has shown that evidence based guideline targets for lifestyle, risk factors and drug treatments are not being achieved and there remains considerable potentential to raise standards to prevent further events and that statins are suboptimally used . (12;13) Inequalities in the management of

cardiovascular disease in primary care have been reported previously with key sex inequalities between men and women and ethnic inequalities. (14;15)

The Health and Social Care Act 2012 in the UK, places a duty on Clinical Commissioning Groups to improve quality and reduce inequalities in access and outcomes of care.(16;17) Our aim was to evaluate the quality in the management of cholesterol for the secondary prevention of CVD in Lambeth patients on the Coronary Heart Disease (CHD) and / or stroke registers. We compared lipid measurement and control to pre-defined standards based on QoF and NICE guidelines (6;18) We also evaluated the determinants in the management of lipid control and hypothesized that there should be no group differences in the management and control of cholesterol in this cohort of patients on the above registers, according to the pre-defined standards.

Methods

This evaluation was carried out in an inner city London borough, with a registered population of 378,000 (2013). We used a cross-sectional study design and identified those patients who were on the CHD and/or stroke registers as of 31/3/2013 and the period 15 months prior to this date.

We used patient level data from the Lambeth DataNet. This is a pseudo -anonymised database of patients registered with practices in primary care that supports local commissioning, health care/service evaluation and monitoring health inequalities. We identified people registered on the CHD and / or stroke registers from 48 of 49 practices that contribute data to the Lambeth DataNet. A key purpose of this database is also to collect and analyse markers of health inequalities such as ethnicity, index of multiple deprivation (IMD), as well as age and sex. The IMD includes income deprivation; employment deprivation; health deprivation and disability; education deprivation; and other markers of deprivations such as crime, barriers to housing and services and the living environment.

Pre-defined standards:

The standards that were used to assess the quality of care were a combination of the upper range of the QOF 12-13 and NICE guidelines. (6;9)

CHD:

- Cholesterol level is measured in last 15 months (at or prior to 31/03/13) in 90% (range 50-90%)of all patients on the CHD register;
- Cholesterol control </=5 mmol/l in 70% (range 45 to 70%) of all patients on CHD register

Stroke:

- Cholesterol level measured in last 15 months (at or prior to 31/03/13) in 90% (range 50-90%) of all patients on the stroke register;
- Cholesterol </= 5 mmol/l in 65% (range 40 to 65%) of all patients on stroke register

We also analysed data on the current prescription of statins for this cohort of patients within the last 3 months from their last review date. NICE guidelines recommend that all patients with heart disease or stroke s should be prescribed a statin or have reasons recorded if not prescribed.

Hypothesis tested:

The hypotheses we were testing were as follows:

1/ Patients in Lambeth with one or more diagnoses of CHD and stroke are managed according to the pre-defined quality standards for cholesterol for people on these two registers as of 2012/13.

2/ In Lambeth patients with one or more diagnoses of CHD and stroke - there are no significant group differences as assessed by age, sex, ethnicity, deprivation, presence of other risks or comorbidity in meeting these pre-defined quality standards.

Analysis

We used STATA 13.1 to test the hypotheses. (19) Descriptive analyses were done to test the first hypothesis. The outcome (dependent) variables for the regression models were dichotomous and were defined above in the "pre-defined standards" section. They include: 1/ measurement of cholesterol (DO1 – yes/no) and 2/ total cholesterol </= 5 mmols/l (DO2 – as controlled and > 5 mmols/l as uncontrolled)

The presence of group differences (independent variables) in these were reviewed by: age group (16-44, 45-54, 55-64, 65-74 & >/=75) , sex (male, female) , ethnic groups (White group, Black/Black British group, Missing/unknown, Asian/Asian-British group, Mixed group, Other ethnic group), index of multiple deprivation quintiles (grouped as follows: least deprived two quintiles 0-40%, 40-60%, 60-80%, Most deprived 80-100%) , as well as risk factors for smoking (current smokers, ex-smokers, non-smokers and unknown) and blood pressure or BP (controlled defined as BP</=150/90; uncontrolled defined as BP>150/90), type 2 diabetes status (yes or no) & statin prescription status within time frame described above (yes or no).

A number of univariate multilevel logistic regression models taking into account the variation among different general practices were fitted to explore the associations between the outcome variable and different independent variables tested in the second hypothesis. Then a series of multivariate multilevel logistic regression models were fitted to investigate the associations between the pre-defined standards and all potential independent variables, using random effect equation for the practice level variation. Best and final models chosen by series of Wald goodness of fit tests were reported in the result section. (20)

Results

The total number of primary care practices that participated was 48/49 (98%). The number of people on the CHD & Stroke registers was 7869 (CHD only: 4464; Stroke only: 2738; combined CHD/stroke = 667). The diagnosed crude prevalence of CHD and stroke were 1.3% and 0.9%

respectively in Lambeth in 2012-13. (18) The mean age was 69.8 years (95% confidence limits: 69.5 to 70.1). There were significantly more males on the registers: male 57.8% (56.7 to 58.9) compared to female 42.2% (41.1 to 43.3). Other demographic characteristics are shown in table 1.

Table 1 here

Table 2 shows the risk factor characteristics. In this population about 19% of people with coronary heart disease or stroke remained current smokers, just over 1 in 4 were not controlled for their blood pressure to a level of 150/90 mmHg and 70% were overweight or obese. Just over 1 in 4 had type 2 diabetes.

Table 2 here

Hypothesis 1: Patients with one or more of CHD and stroke are managed according to pre-defined standards for cholesterol measurement and control for people on these two registers as of 2012/13 and 13/14

Table 3 shows the evaluation of patients having a current record for cholesterol measurement, degree of cholesterol control achieved and a record of a statin prescription. Overall pre-defined auditable standards were not met for current records for both cholesterol measurement and statin prescription. However pre-defined auditable standards for those patients with a current record the proportion of patients whose cholesterol was below 5mmol/l were met. When comparing subgroups within the study, patients with a history of stroke were consistently the least likely to meet all three QOF standards.

Primary care records showed that overall 80.1% of patients had been prescribed a statin in the last 6 months. This rate was significantly lower in stroke patients.

Table 3 here

Hypothesis 2: In patients with one or more of CHD and stroke - there are no significant group differences in the outcome (dependent) variables DO1 and DO2 as assessed by age, sex, ethnicity and deprivation in meeting the predefined standards.

We found significant group differences in meeting the lipid measurement standards. Table 4 shows the findings for patients who did not have a current record of cholesterol measurement in the last 15 months. The random effect at the general practice level is reported at the bottom of the table. The variance component was estimated to be 0.12. Patients categorised as black/black British group (compared to the white group) were significantly more likely to have a current record, as were patients with type 2 diabetes (compared to people without type 2 diabetes). Patients aged between 16-64 years or over 75 years were significantly less likely to have a current record for cholesterol levels. Patients aged 16-44 were 68% more likely to not have a current record compared to those aged 65-74. After taking into account other factors deprivation did not appear to have an effect on current cholesterol recording. Those who were current smokers and had previously raised cholesterol level were also less likely to have a current record of cholesterol level.

Patients with no current record for cholesterol in the past 15 months were nearly three times less likely (adjusted odds = 2.97; 95% CI: 2.51 to 3.52) to have a record of a current statin prescription.

Table 4 here

Table 5 shows the finding for the subgroup of patients who had a current record of cholesterol but were not achieving a lipid control standards (cholesterol level <5mmol/L) within the last 15 months of the study date. The random effect at the general practice level is reported at the bottom of the table. The variance component was estimated to be 0.022. These patients were significantly more (OR 3.10 95% CI 2.70 to 3.56) likely not to have a current record for a statin prescription. After adjustment for other factors they were also more likely to be current smokers and to have raised blood pressure. Women were also significantly more likely than men to have raised cholesterol

after adjustment for other factors. Women were significantly less likely to have a current record for a statin prescription (75%; 74% to 77%) compared to men (83%; 82% to 84%). There were significant differences in current recorded prescribing with age (those aged 16-44 and 45-54 were less likely to have a current record of statins prescribed: 44% and 71% respectively) and ethnicity (black /black British groups were less likely to have statins prescribed and Asian groups more likely: 74% and 88% respectively). However there was no significant difference in the adjusted odds ratio with age (apart from the 75+ age group who were significantly better controlled) and ethnicity for poor lipid control. Patients with additional comorbidity with type 2 diabetes were significantly more likely to achieve cholesterol control <5mmol/L.

Table 5 here

Discussion

Key findings

In this study of patients attending primary care practices in an inner London borough in South London the key factor that explained poor lipid control in people on the CHD and Stroke registers was having no record of having been prescribed a statin in the last three months from their last review date. Women were less likely to be prescribed a statin compared to men. Amongst individuals with previous history of CHD or Stroke, women are more likely than men to have poorly controlled cholesterol. This finding was independent of smoking status, blood pressure, statin prescription and type 2 diabetes status and also remained unchanged after adjusting for age, ethnicity, deprivation index and practice level variation. We found no ethnic difference in lipid control after adjustment for other factors. The very elderly (75+) were significantly better controlled.

Patients with a history of both CHD and stroke were those most likely to be managed according to current guidelines. Patients who had only had a stroke were less likely to have had their cholesterol measured, controlled or to be prescribed a statin than patients with CHD.

There was a clustering of risk factors in that patients who had poor lipid control were also more likely to be current smokers, have raised blood pressure and were less likely to have a current statin prescription recorded.

What is already known

Studies looking at the efficacy of lipid lowering treatments in patients with established CVD have found no significant differences between sexes but found that women were more likely than men to have higher LDL-C levels both before and after treatment suggesting that women may need more aggressive lipid lowering treatment than men to achieve targets. (14;21-25)

Women are less likely to be prescribed medication including statins as secondary prevention following stroke (26;27) and Acute Coronary Syndrome. (28) These findings are true internationally with similar results being found in Ireland (29), Italy (30), and Sweden. (31) Large studies suggest that the effect is mainly seen in younger women. (32;33) Similar results have previously been found in East London. (34) Women were also less likely to be prescribed aggressive lipid lowering treatment or any treatment at all. A Canadian study also found discrepancies between the three groups; stroke, CHD and both, as well as sex discrepancies similar to the results found in Lambeth.(35) Some studies have failed to find a significant difference in lipid treatment between the sexes. (36;37). Others suggest that sex differences disappear once the data has been adjusted for age and severity of disease. (38;39) Millet et al in their study identified improvements in lipid control and blood pressure targets in ethnic groups although black groups were less likely to be prescribed statins. They suggested that the introduction of QoF led to marked improvements in both the process and management of CHD. They did not report on sex or age differences in lipid

control. (15) A systematic review of 27 studies looking at equity dimensions in the evaluation of QOF, across a range of conditions, did not suggest worsening inequity in treatment or treatment outcomes. (40)

What this paper adds

The Health and Social Care Act 2012, places a duty on Clinical Commissioning Groups, to reduce inequalities in access and outcomes of care. (16) This paper shows that routine pseudo-anonymised patient level data can be used to monitor quality and its determinants in a systematic way. We found important age differences in the processes of care – people aged 16-64 were less likely to meet lipid measurement standards. Lack of cholesterol measurement may be a proxy to access to care. Possible explanations for these age differences need further exploration but could be related to higher risk taking behaviour in younger age groups, more reluctance to take time off work and attend routine health care leading to lower access to care in this age group. Patients from black ethnic groups and with co-morbidity with diabetes were more likely to meet the lipid measurement standard. Possible explanations for this may be better systems in place for people with co-morbidities or that they are more likely to attend or be followed up for care processes. For the lipid control standards the findings of this study in South London are similar to those observed worldwide. In patients with established CVD population women are more likely than men to have raised cholesterol, and yet they are less likely to be prescribed a statin. Critically patients with poor lipid control were also significantly less likely to have a current statin prescription record. Possible explanation for these findings need further exploration but could include: 1/ the majority of women live in this area live in more deprived circumstances which may lead to lower health literacy and lower level of clinical engagement; 2/ women may see themselves as lower risk of CVD and can be mistakenly perceived as being at lower risk by clinicians. However patients with diabetes (as an additional comorbidity) were more likely to be meet lipid control standards. Possible explanations for this are that additional co-morbidity may lead to better systems of care provided by primary

care. We believe that the methodology used in this paper provides an approach for evaluating determinants of quality of care that partly fit into the theory based framework for conceptualising equity of care developed by Pauline Boeckxstaens et al. (40) We have outlined some of the limitations to our approach below. We have also provided supplementary data tables that show improvements overall in recording of total cholesterol, current statin prescription and change in mean total cholesterol by age, sex, ethnicity and deprivation for the cohort of patients that had records in 2013 and 2011. These supplementary data suggest that P4P is continuing to have a positive impact locally but also shows differential changes in total cholesterol control by some of the characteristics we have reported.

Limitations

In the UK all diagnosed cases of CHD and stroke are registered by GPs as part of QoF disease registers as this is part of the GP contract. We know from modelled estimates that the registers may under estimate actual number of cases by as much as 50% - however these estimates are based on a number of assumptions and there is uncertainty in modelled prevalence estimates. (41) It would be important to understand the characteristics of people who may not be registered on the CHD/Stroke registers to understand equity of access to care more completely. This study used data from all cases that were diagnosed and on the QoF registers from all but one practice. There was a small proportion of data that was missing in the age, deprivation and some of the risk factors in the disease register. This varied for different indicators – (e.g. for the first outcome of recorded cholesterol: missing age was 28 records or 0.4% of all records; IMD 45 records or 0.6% of all records; cholesterol level recorded – this was 307 records or 4% of all records; BMI was 688 records or 9% of all records; for the second outcome cholesterol level >5 mmol missing data was: IMD 39 records or 0.6% and 1 record for cholesterol level. However as this was a large study we do not think this will have introduced substantial non-response biases. This study used data collected from routine practice consultations so there could be potential measurement errors or biases introduced as part of this. The data gathered did not include the date of any original CVD event and this factor was not

considered in the regression analysis. Registry studies show a decline in adherence with cardiovascular preventive therapies including statins with time post-event (12)[9]. The data gathered in this study does not allow differentiation of haemorrhagic from ischaemic strokes which may explain some of the differences in prescriptions. However it is likely that most strokes were ischaemic in aetiology in this population. We also did not assess whether there was a record of prescriptions for other lipid lowering strategies in this cohort, though statins are the most commonly prescribed lipid-lowering drugs there is substantial usage of ezetimibe in some areas in the UK. (42) The data obtained did not include reasons for why women are not being prescribed statins for example whether they were declining them when offered, or whether they were experiencing more side effects and asking to stop taking statins or whether they were not being offered statins in the first place. We also were not able to explore whether healthcare professionals have a perception that women are lower risk of further CVD and not treated as aggressively as men. This study was conducted in a single setting and the findings may not be more widely generalisable to the UK population as implementation of NICE guidelines may vary in different areas. However some of these results on lipid control outcomes are consistent with findings from other studies. These factors need further exploration to inform future strategies.

Conclusions

This evaluation has identified important quality issues and their determinants. Some of these variations in quality suggest possible health inequities in the secondary prevention of heart disease and stroke. The findings suggests that primary care has an important role in identifying & optimising management in those patients with CVD who don't have current record of cholesterol reading. GPs should also identify people with established CVD who have no current record of statin prescription as these patents had a greater probability of poor lipid control. This evaluation identified these patients were also more likely to have other CVD risks (raised blood pressure and current smokers). Finally this study suggests that primary care professionals need to identify and

optimise lipid management in patients with CVD who have no current statin prescription and also that woman with CVD may require higher statin dosage for better lipid control for secondary prevention. Potential policy implications for P4P systems such as QOF are that these need to consider the determinants of quality and the variation in implementation by social characteristics within a broader framework of equity of access, treatment and treatment outcomes based on an assessment of needs. (40)

Word count 3629

Foot note

- Contributors: HD and JC designed the study. JC extracted and cleaned the data from Lambeth DataNet and HD and JC performed the primary analyses. KL and HD performed the logistic regression analyses & KL performed the multi-level logistic regression analyses. HLE reviewed the literature. HD and HLE drafted the manuscript and AW, HW, AH and JB critically edited the manuscript and provided final approval. . HD is guarantor of this work and had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
- Competing interests: All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and have nothing to declare. The views expressed are those of the authors and not necessarily those of the NHS, the National Institute for Health Research, or the Department of Health. No other relationships or activities could appear to have influenced the submitted work.
- Transparency: HD affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained.
- Ethical approval: this was not required as this was a service evaluation of current practice against auditable standards
- Data sharing: No additional data available.

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Table 1 – Demographic baseline characteristics

Demographic Characteristics	Sub-level	Number (n = 7,869)	Percent
Age	16-44	333	4.2
	45-54	840	10.7
	55-64	1,340	17.0
	65-74	2035	25.9
	>/=75	3,293	41.9
	Unknown	28	0.4
Sex	Male	4,547	57.8
	Female	3,322	42.2
Ethnicity	White group	4,361	55.4
	Black/Black British group	1,616	20.5
	Asian/Asian-British group	694	8.8
	Mixed group	212	2.7
	Other ethnic group	193	2.5
	Missing/unknown	793	10.1
Index of deprivation	Least deprived	195	2.5
	40-60%	976	12.4
	60-80%	3,816	48.5
	Most deprived80-100%	2,837	36.1
	Missing	45	0.6

Table 2: Risk factor characteristics

Risk factor	**Sub-level**	**Number**	**Per cent**
Smoking *	Non-smoker	4,146	52.7
	Current smoker	1,456	18.5
	Ex-smoker	2,191	27.8
	Unknown	76	1.0
Blood pressure *	BP</=150/90	5,604	71.2
	BP>150/90	2,182	27.7
	Missing	83	1.1
Body Mass index **	<18.5	138	1.9
	18.5 to 24.9	1,999	27.8
	25 to 29.9	2,613	36.4
	30 to 39.9	2,164	30.1
	>/=40	267	3.7
Type 2 diabetes*	Yes	2,104	26.3
	No	5,765	73.3
Note: * n = 7,869 ** n = 7181			

Table 3: Evaluation against standards

Register	Number	Per cent	95% Confidence Limits		Standard (%)
			Lower limit	Upper limit	
Current record last 15 months					
Stroke only	2,284	83.4	82.0	84.8	90
CHD only	3,831	85.8	84.8	86.8	90
CHD & Stroke	597	89.5	86.9	91.7	90
Cholesterol </=5 mmol/L with current record in last 15 months					
Stroke only	1,716	75.1	73.3	76.9	65
CHD only	3,114	81.3	80.0	82.5	70
Stroke & CHD	505	84.6	81.4	87.4	70
Statin prescription recorded in last 6 months & current record in last 15 months					
Stroke only	1,630	71.4	69.5	73.2	100
CHD only	3,203	83.6	82.4	84.8	100
Stroke & CHD	511	85.6	82.5	88.3	100

Table 4 Multi-level logistic regression model – current record for measurement of cholesterol (DO1) in the last 15 months and demographic, risk factor and treatment with statin characteristics

Variable	Category	Total N	DO1: N (%)	Adjusted odds ratio (95% confidence limits)	p-value
Age (years) (n = 7,841)	16-44 45-54 55-64 65-74 75+	333 840 1,340 2,035 3,293	147 (44) 170 (20) 190 (14) 189 (9) 433 (13)	**1.68 (1.14 to 2.47)** **1.50 (1.13 to 1.98)** **1.45 (1.13 to1.87)** Ref **1.41 (1.13 to 1.75)**	0.008 0.005 0.004 0.002
Sex (n = 7,869)	Male Female	4,547 3,322	663 (15) 494 (15)	Ref 0.90 (0.76 to 1.06)	 0.220
Ethnicity (n = 7,869)	White Group Black/Black British Asian/Asian British Mixed groups Other ethnic groups Not known/missing	4361 1616 694 212 193 793	643 (15) 197 (12) 82 (12) 38 (18) 28 (15) 169 (21)	Ref **0.78 (0.62 to 0.97)** 1.07 (0.78 to 1.47) 1.07 (0.67 to 1.72) 1.18 (0.72 to 1.93) 1.18 (0.90 to 1.54)	 0.029 0.6736 0.769 0.5010 0.231
Deprivation – Index of Multiple Deprivation national ranking (n = 7,824)	Least deprived 40-60% 60-80% Most deprived	195 976 3816 2837	22 (11) 153 (16) 538 (14) 438 (15)	Ref 1.46 (0.76 to 2.79) 1.49 (0.80 to 2.78) 1.59 (0.85 to 2.99)	 0.254 0.210 0.147
Smoking (7,869)	Non-smoker Ex-smoker Current Smoker Unknown	4146 2191 1456 76	579 (14) 266 (12) 271 (19) 41 (54)	Ref 1.07 (0.88 to 1.30) **1.40 (1.13 to 1.74)** 1.54 (0.51 to 4.63)	 0.514 0.002 0.440
Blood pressure (n = 7786)	</=150/90 mmHg >150/90 mmHg	5604 2182	742 (13) 343 (16)	Ref 1.15 (0.96 to 1.36)	 0.123
Total Cholesterol (n = 7562)	</= 5 mmol/L >5 mmol/L	5897 1665	562 (10) 289 (17)	Ref **1.33 (1.12 to 1.59)**	 0.001
Statin prescription (n = 7869)	Yes No	5891 1978	547 (9) 610 (31)	Ref **2.97 (2.51 to 3.52)**	 <0.0001
BMI (kg/m^2) (n = 7181)	<18.5 18.5 to 24.9 25 to 29.9 30 to 39.9 >/=40	138 1999 2613 2164 267	23 (17) 255 (13) 267 (10) 201 (9) 24 (9)	1.24 (0.75 to 2.04) Ref 0.97 (0.80 to 1.18) 0.94 (0.76 to 1.16) 0.94 (0.59 to 1.50)	0.403 0.742 0.576 0.801
Type 2 diabetes (n = 7869)	Yes No	2,104 5,765	111 (5) 1,046 (18)	**0.37 (0.29 to 0.47)** Ref	<0.0001
Practice level variance				0.12 (0.06 to 0.25)	

Note: logistic model for current record for Cholesterol in the last 15 months, goodness-of-fit test; number of observations = 7135 ; number of groups = 10 ; Hosmer-Lemeshow chi^2(8) = 5.74; Prob > chi^2 = 0.676; Likelihood Ratio

test for testing multilevel logistic regression model compared to conventional logistic regression model p-value < 0.0001.

Table 5: Multi-level logistic regression model – cholesterol control standard > 5mmol/L (DO2) in last 15 months

Variable	Category	Total N	DO2: N (%)	Adjusted odds ratio (95% confidence limits)	p-value
Age (n= 6711)	16-44	186	49 (26)	0.79 (0.54 to 1.14)	0.208
	45-54	670	186 (28)	1.20 (0.96 to 1.50)	0.102
	55-64	1149	261 (23)	1.10 (0.91 to 1.33)	0.330
	65-74	1846	380 (21)	Ref	
	75+	2860	500 (17)	**0.74 (0.63 to 0.88)**	<0.0001
Sex (n = 6711)	Male	3883	649 (17)	Ref	
	Female	2828	727 (26)	**1.74 (1.53 to 1.98)**	<0.0001
Ethnicity (n = 6711)	White Group	3717	762 (21)	Ref	
	Black/Black British	1419	310 (22)	0.99 (0.84 to 1.16)	0.892
	Asian/Asian British	612	90 (15)	0.85 (0.66 to 1.09)	0.198
	Mixed groups	174	41 (24)	1.04 (0.71 to 1.54)	0.830
	Other ethnic groups	165	29 (18)	0.85 (0.56 to 1.31)	0.470
	Not known/missing	624	144 (23)	1.13 (0.91 to 1.40)	0.264
Deprivation (Index of Multiple Deprivation national ranking) (n = 6672)	Least deprived	173	37 (21)	Ref	
	40-60%	822	148 (18)	0.79 (0.52 to 1.21)	0.276
	60-80%	3278	677 (21)	0.91 (0.61 to 1.35)	0.634
	Most deprived	2399	508 (21)	0.91 (0.61 to 1.37)	0.664
Smoking (n = 6711)	Non-smoker	3566	736 (21)	Ref	
	Ex-smoker	1925	346 (18)	1.00 (0.86 to 1.18)	0.939
	Current Smoker	1185	286 (24)	**1.28 (1.07 to 1.52)**	0.006
	Unknown	35	8 (23)	1.33 (0.57 to 3.11)	0.506
Blood pressure (n = 6700)	</=150/90 mmHg	4861	898 (18)	Ref	
	>150/90 mmHg	1839	477 (26)	**1.35 (1.17 to 1.54)**	<0.0001
Statin prescription (n = 6711)	Yes	5344	845 (16)	Ref	
	No	1367	531 (39)	**3.10 (2.70 to 3.56)**	<0.0001
Type 2 diabetes (n = 6711)	Yes	1993	1098 (23)	**0.62 (0.53 to 0.72)**	<0.0001
	No	4718	278 (14)	Ref	
Practice level variance				0.022 (0.005 to 0.095)	

Note: Logistic model for lipid control < 5 mmol in last 15 months, goodness-of-fit test number of observations = 6370; number of groups = 10; Hosmer-Lemeshow chi^2(8) = 16.26; Prob > chi^2 = 0.039; Likelihood Ratio test for testing multilevel logistic regression model compared to conventional logistic regression model p-value = 0.045.

Title: Inequality in lipid control: use of primary care data to evaluate inequality in the management of lipid control for secondary prevention of heart disease and stroke using a cross sectional design in an inner London Borough(supplementary data tables).

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Supplementary data:

The following tables provide supplementary data referred to in the response to the peer reviewers comments.

Supplementary table 1: Variation in statin prescribing by age, sex, ethnicity and deprivation index.

Factor	Detail	Current prescription record (%)	95% confidence interval
Age (n = 6711)	16-44	44	37 to 51
	45-54	71	68 to 75
	55-64	83	81 to 85
	65-74	84	82 to 85
	75+	80	78 to 81
Sex (n = 6711)	Male	83	82 to 84
	Female	75	74 to 77
Ethnicity (n = 6711)	White Group	81	79 to 82
	Black/Black British	74	72 to 76
	Asian/Asian British	88	86 to 91
	Mixed groups	78	72 to 84
	Other ethnic groups	83	77 to 89
	Not known/missing	78	75 to 81
IMD (6672)	Least deprived 0-40%	78	72 to 84
	40-60%	80	78 to 83
	60-80%	80	79 to 82
	Most deprived 80-100%	79	77 to 80

Supplementary table 2: Comparison of recording of current (within 15 months) recording of cholesterol status between 2011 & 2013 in cohort of patients with two readings

Cholesterol record in 2013

Cholesterol record in 2011	Yes	No	Total
Yes	5,557	645	6,202
Row %	*90*	*10*	*100*
Column %	*83*	*56*	***79***
No	1,155	512	1,667
Row %	*69*	*31*	*100*
Column %	*17*	*44*	*21*
Total	6,712	1,157	7,869
Row %	***85***	*15*	*100*
Column %	*100*	*100*	*100*

Pearson chi square < 0.0001

Recording of cholesterol improved from 79% to 85% in the cohort of patients who had records in both time periods.

Supplementary table 3: Comparison of current statin prescribing between 2011 & 2013 in cohort of patients with two readings

Current statin prescription record in 2013

Current statin prescription record in 2011	Yes	No	Total
Yes	4,120	313	4,433
Row %	*93*	*7*	*100*
Column %	*77*	*23*	***66***
No	1,224	1,055	2,279
Row %	*53.71*	*46.29*	*100*
Column %	*23*	*77*	*34*
Total	5,344	1,368	6,712
Row %	***80***	*20*	*100*
Column %	*100*	*100*	*100*

Pearson chi square < 0.0001

Recording of current statin prescribing improved from 66% to 80% in the cohort of patients who had records in both time periods.

Supplementary table 4: Comparison of mean total cholesterol by age, sex, ethnicity and deprivation index between 2011 & 2013 in cohort of patients with two readings

Profile characteristics	Number	Mean 2011	Mean 2013	Difference in mean	95% confidence limits	p-value (paired t-test)
Overall	6931	4.50	4.33	**0.17**	0.14 to 0.19	<0.0001
Age group						
16-44	144	4.77	4.55	0.22	0.02 to 0.41	0.03
45-54	665	4.73	4.55	0.18	0.09 to 0.27	0.0001
55-64	1184	4.64	4.41	0.22	0.16 to 0.29	<0.0001
65-74	1865	4.46	4.31	0.15	0.10 to 0.19	<0.0001
75+	3072	4.40	4.24	0.16	0.13 to 0.19	<0.0001
Sex						
Male	3955	4.35	4.17	**0.18**	0.15 to 0.21	<0.0001
Female	2976	4.69	4.54	**0.15**	0.11 to 0.18	<0.0001
Ethnic category						
White Group	3860	4.51	4.35	0.16	0.14 to 0.20	<0.0001
Black/Black British group	1442	4.50	4.36	0.14	0.10 to 0.20	<0.0001
Asian/Asian British	607	4.28	4.10	0.18	0.10 to 0.26	<0.0001
Mixed groups	183	4.41	4.29	0.12	- 0.02 to 0.27	0.08
Other ethnic groups	166	4.35	4.23	0.12	-0.02 to 0.26	0.09
Not known/missing	673	4.65	4.43	0.22	0.15 to 0.30	<0.0001
IMD						
Least deprived (0-40%)	178	4.54	4.27	0.27	0.14 to 0.41	0.0001
40-60%	836	4.49	4.25	0.24	0.18 to 0.30	<0.0001
60-80%	3376	4.51	4.34	0.17	0.14 to 0.20	<0.0001
Most deprived	2500	4.48	4.35	0.13	0.10 to 0.17	<0.0001

Note greater improvements in mean total cholesterol seen in younger age groups, men (compared to women), Asian/Asian British and least deprived categories compared to most deprived groups. However none of these differential impacts are significantly different within each category analysed.

STROBE Statement—Checklist of items that should be included in reports of ***cross-sectional studies***

	Item No	Recommendation	Comment re article submitted to JECH
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	This is done
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	This is done
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	This is provided
Objectives	3	State specific objectives, including any prespecified hypotheses	This is provided
Methods			
Study design	4	Present key elements of study design early in the paper	This is provided
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	This is provided
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	This is provided
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	This is provided
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	We used routine data collected in primary care for this evaluation (no additional measurements)
Bias	9	Describe any efforts to address potential sources of bias	We used logistic regression models to control for bias
Study size	10	Explain how the study size was arrived at	Not applicable – we evaluated all patients on the two disease registers
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	This is described
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	This is described
		(*b*) Describe any methods used to examine subgroups and interactions	This is described
		(*c*) Explain how missing data were addressed	

		(*d*) If applicable, describe analytical methods taking account of sampling strategy	Not applicable
		(*e*) Describe any sensitivity analyses	Not applicable
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Not applicable
		(b) Give reasons for non-participation at each stage	Not applicable
		(c) Consider use of a flow diagram	Not applicable
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	This is described
		(b) Indicate number of participants with missing data for each variable of interest	This is described
Outcome data	15*	Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Unadjusted estimates can be provided as supplementary tables – we have only provided adjusted estimates with 95% confidence limits
		(*b*) Report category boundaries when continuous variables were categorized	This is described
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Not applicable
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Not applicable
Discussion			
Key results	18	Summarise key results with reference to study objectives	This is done
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	This is done
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	This is done
Generalisability	21	Discuss the generalisability (external validity) of the study results	This is done
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Not funded

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.