

PREVENTION AND MANAGEMENT OF DYSLIPIDAEMIA AND FAMILIAL HYPERCHOLESTEROLAEMIA: AN EVALUATION OF CLINICAL MANAGEMENT

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EXECUTIVE SUMMARY

A primary care data service evaluation was completed across the Cheshire and Merseyside geography (1) to assess current lipid management in patients with either established athero-thrombotic vascular disease or at high-risk of developing it. The acquisition fields reviewed were: -

- Atherothrombotic Cardiovascular Disease (A-T CVD)
- Ischaemic Heart Disease (IHD)
- Myocardial Infarction (MI)
- Diabetes Mellitus type II (DM)
- Chronic Kidney Disease stage 3 or more (CKD)
- Stroke / Transient Ischaemic Attack (TIA)
- Peripheral Artery Disease (PAD)
- QRISK 2- risk % ≥ 10% (excluding patients with existing A-T CVD)
- Total Cholesterol ≥ 7.5 mmol/L
- Familial Hypercholesterolaemia (FH)

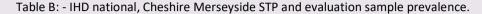
There were 10 GP practices in the evaluation sample from 5 different Clinical Commissioning Groups. Each of the practices were classified using their practice postcode categorisation and given an index of multiple deprivation score (IMD). Therefore, these practices provide a representative sample from across the Sustainable Transformation Partnership (STP) footprint. The total registered population of the sample reviewed totalled 95,732 with a total number of 24,076 patients who met the inclusion criteria.

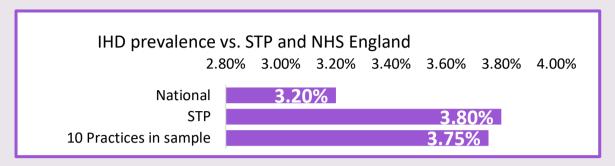
Table a: - Summary detail of 10 practices included within the database including population, patients identified, IHD prevalence and statin treatment/exception rates within IHD and index of multiple deprivation 2015 IMD score¹

Practice Name	List Size	Practice postcode categorisation	Number of patients identified	IHD Prevalence (%)	Patients with IHD taking a statin (%)	Exception rate for patients with IHD (%)	Patients with QRISK recorded (%)†	IMD Score*
Practice 1	9,900	Urban City and Town Area	2,126	3.30%	76%	18%	38%	11
Practice 2	13,400	Urban City And Town area	3,784	4.00%	78%	13%	74%	14
Practice 3	4,300	Urban Major Conurbation area	1,082	4.04%	87%	4%	96%	50
Practice 4	9,200	Urban Major Conurbation area	2,445	3.87%	88%	1%	96%	58
Practice 5	2,500	Urban Major Conurbation area	609	2.96%	85%	0%	95%	37
Practice 6	10,700	Urban Major Conurbation area	2,463	3.62%	86%	3%	97%	41
Practice 7	9,600	Urban City and Town Area	2,754	4.66%	74%	13%	64%	11
Practice 8	12,200	Urban City and Town Area	2,706	3.53%	90%	4%	75%	20
Practice 9	16,600	Urban Major Conurbation area	4,522	4.05%	79%	11%	69%	11
Practice 10	7,800	Urban Major Conurbation area	1,585	3.49%	80%	4%	37%	42



† determined as % of patients without IHD/Stroke with a record of QRISK *IMD score rounded to nearest whole number The Cheshire Merseyside STP population has an increased average prevalence of IHD (3.80%) vs the national average (3.2%). The average IHD prevalence across the sample was 3.75%.





Across the sample population, the percentage of patients with A-T CVD who are prescribed statin treatment ranges from 71% -86%, with an identified level of exception reporting (contraindication; intolerance to any or a higher intensity statin; patient refusal) ranging from 8% - 65%. Statin treatment for primary prevention ranges from 42% - 57%, with an identified level of exception reporting (contraindication; intolerance; patient refusal) of 5% - 35%.

Key findings of a total population of 24,076 with established A-T CVD or at high risk of developing it:

- 11,325 patients (47%) were prescribed statin therapy and, of these, 77% were receiving high-intensity therapy
- 12,751 patients (53%) were not prescribed statin therapy and, of these, 9315 (73%) have no read code to suggest contraindications, intolerance or refusal
- 4510 patients (78%) with established A-T CVD were currently prescribed statin therapy and, of these, 762 (17%) were receiving guideline recommended Atorvastatin 80mg.
- 3,660 patients had confirmed IHD and 82% were prescribed statin medication. However, less than 20% were receiving the guideline recommended therapy of Atorvastatin 80mg with 36% of IHD patients prescribed only a low or medium-intensity statin
- 2,907 patients had PAD and/or a history of ischaemic stroke/TIA with almost 3 out of 4 patients identified as receiving statin therapy. However, only half of this group were prescribed a high-intensity statin and only a very small minority were prescribed the guideline recommendation of Atorvastatin 80mg.
- 5,245 patients had a diagnosis of Type II DM of which 3,602 were prescribed a statin. However, only 1 in 3 diabetic patients were prescribed statin therapy in accordance with guideline recommendations
- Of the 4,461 patients with established CKD stages 3 to 5, less than half were prescribed high-intensity statin treatment as per guideline recommendations. 42% of patients with CKD were not prescribed any statin therapy, and the majority 71% had no read code for any documented exception report.
- Within NICE Clinical Guideline CG181 (2), a QRISK2 score of ≥10% defines an individual as being at high-risk for myocardial infarction or stroke therefore a high-intensity statin (Atorvastatin 20mg) should be considered. Of the 11,429 adults who were identified as high-risk according to this criterion, less than half were prescribed statin therapy as per guideline recommendation.
- The number of patients in an average sized practice (i.e. list size of 9,573 represents an average size across the reviewed population) with IHD who are not prescribed a statin, who could/should be, is 49.

The projected total number of patients across the STP with IHD not prescribed statin therapy is 18,275

INTRODUCTION

This evaluation report has been developed to support providers, public health commissioners and NHS commissioners to develop services and improve clinical practice for people with established A-T CVD or those at high-risk of developing it. High-risk populations include: individuals with an estimated 10-year risk of heart attack or stroke of ≥10%; individuals with CKD stage 3, 4, or 5; individuals with type 2 DM who are either over the age of 40 and/or have evidence of diabetic renal/microvascular disease; individuals with inherited forms of dyslipidaemia and FH.

It is hoped that the information presented within this document will highlight areas of both A-T CVD clinical and prevention management which can be improved upon through the effective use of the Cheshire Merseyside Clinical Commissioning Pathway for Prevention and Management of Dyslipidaemia and Familial Hypercholesterolaemia (3). This in turn will help to encourage discussion and collaboration between different stakeholders and facilitate the process of delivering high quality clinically effective and coordinated holistic services aimed at preventing de novo or recurrent A-T CVD across the full pathway of care.

The overall Cheshire and Merseyside STP population currently stands at 2.6 million (average STP practice size 7,060). This study included a review of 95,732 patients across the 10 GP practices, with an average practice size of 9,573.

AIMS

Following the development of the Cheshire Merseyside Clinical Commissioning Pathway for Prevention and Management of Dyslipidaemia and Familial Hypercholesterolaemia a primary care data service evaluation was undertaken across the Cheshire and Merseyside geography in order to:

- 1. Assess current lipid management in patients with either established A-T CVD or at high-risk of developing it.
- 2. Identify areas for improvement between current lipid management and best practice from guidelines and the newly developed pathway.
- 3. Provide evidence to support the implementation of the Cheshire and Merseyside lipid management pathway.

METHODOLOGY

The method for collection of data was completed with authorisation being gained from individual GP practices to run a set of queries on the GP clinical system designed to interrogate and extract data relevant to lipid management for a defined group of patients meeting agreed inclusion criteria. Date period for collecting data was June – July 2018.

The definition of clinical inclusion criteria was described as patients being included within the data set if they matched any of the following criteria:

- 1. A recorded diagnosis of any of the following conditions: IHD, MI, type II DM, stroke or TIA, CKD stages 3,4 &5, PAD, FH
- 2. A recorded QRISK score ≥10%
- 3. Currently receiving statin/lipid lowering therapies
- 4. Possible FH due to total cholesterol of ≥7.5 mmol/L

Assumptions and limitations

Using the dataset calculations to determine % reduction in non-HDL cholesterol (non-HDL-C) levels was performed using the following assumptions:

- The highest recorded total cholesterol (TC) and/or low-density lipoprotein cholesterol (LDL-C) reading recorded in an individual's clinical record was assumed to be the baseline value i.e. untreated level
- The most recent TC/LDL-C/HDL-C value recorded in an individual's clinical record was taken as the latest value, reflecting any reduction resulting from lipid modification therapy
- Where a patient is prescribed a statin, the difference in baseline to latest value was assumed to be an effect of that statin therapy rather than any other statin therapy taken between baseline and latest values

Limitations exist when using the above method to calculate treatment effect including:

- The baseline may not be a true baseline figure as the patient may have been receiving a statin or other lipid modulating therapy when the measurement was taken
- The non-HDL-C calculation uses the same HDL-C value for calculating both baseline and the most recent non-HDL-C value since for most patients only one HDL-C value was available

Table C: - Definition of statin intensities used in dashboard report (NICE CG181 Appendix A: Grouping of statins)

	Reduction in low-density lipoprotein cholesterol					
Dose (mg/day)	5	10	20	40	80	
Fluvastatin	-	-	21% ¹	27% ¹	33%2	
Pravastatin	-	20%1	24% ¹	29%1	-	
Simvastatin	-	27% ¹	32%²	37%²	42% ^{3,4}	
Atorvastatin	-	37%²	43% ³	49% ³	55% ³	
Rosuvastatin	38%²	43% ³	48% ³	53% ³	-	

¹ 20%-30%: low intensity.

RESULTS

The acquisition fields reviewed were: -

- Atherothrombotic Cardiovascular Disease (A-T CVD)
- Ischaemic Heart Disease (IHD)
- Myocardial Infarction (MI)
- Diabetes Mellitus Type II (DM)
- Chronic Kidney Disease stage 3,4 or 5 (CKD)
- Stroke / Transient Ischaemic Attack (TIA)
- Peripheral Artery Disease (PAD)
- QRISK 2- risk % ≥ 10% (excluding patients with existing A-T CVD)
- Total Cholesterol ≥ 7.5 mmol
- Familial Hypercholesterolaemia (FH)

The data sample audit results have given an in-depth analysis of statin therapy across all the acquisition fields which has been presented in each disease area for ease of read. Table 1 demonstrates the latest average lipid levels across all patients identified within the sampled dataset, displayed according to statin therapy prescription.

Table 1: - Averaged Current Total Cholesterol Values

Average last TC readings	Atorvastatin 80mg	High intensity	Medium intensity	Low intensity	No Statin
A-T CVD	4.0	4.2	4.1	4.5	5.1
MI	3.9	4.0	4.0	4.3	5.0
Primary prevention	5.0	4.8	4.5	4.8	5.6
Coded FH	5.8	6.0	5.4	5.3	7.0

Table 2: - Average Current Low – density Lipoprotein Cholesterol

Average last LDL-C reading	Atorvastatin 80mg	High intensity	Medium intensity	Low intensity	No Statin
A-T CVD	2.3	2.3	2.1	2.4	2.9
MI	2.3	2.2	2.0	2.3	2.9
Primary prevention	2.8	2.8	2.4	2.7	3.4

² 31%-40%: medium intensity.

³ Above 40%: high intensity.

 $^{^4}$ Advice from the MHRA: there is an increased risk of myopathy associated with high-dose (80 mg) simvastatin. The 80 mg dose should be considered only in patients with severe hypercholesterolaemia and high risk of cardiovascular complications who have not achieved their treatment goals on lower doses, when the benefits are expected to outweigh the potential risks.

Coded FH	4.1	3.8	3.6	2.8	4.8

Table 3: - Average Current non-High-density Lipoprotein Cholesterol

Average last non-HDL-C reading	Atorvastatin 80mg	High intensity	Medium intensity	Low intensity	No Statin
A-T CVD	2.8	2.9	2.7	3.1	3.7
MI	2.7	2.8	2.7	3.0	3.7
Primary prevention	3.7	3.4	3.1	3.4	4.1
Coded FH	4.4	4.5	3.9	3.9	5.6

Each condition area contains key findings, a report definition, data on statin status, analysis of potency across statin therapy and the reasons for exception reporting.

ATEROTHROMBOTIC CARDIOVASCULAR DISEASE (A-T CVD): TOTAL PATIENTS = 5794

Key findings: - Of 5,794 patients with a recorded diagnosis of A-T CVD, 4,510 (78%) were receiving statin therapy. Of 4,510 patients with A-T CVD taking a statin, 762 (17%) were taking atorvastatin 80mg as recommended in NICE CG181. Of 762 patients with A-T CVD taking atorvastatin 80mg, 452 (59%) had achieved a non-HDLC reduction of >40%

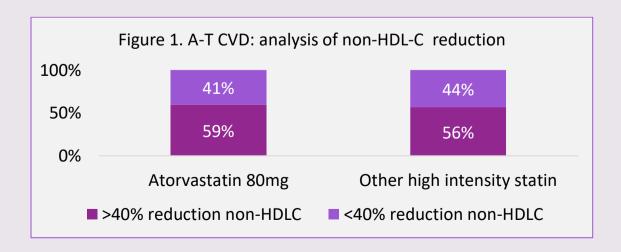
Reporting definition: - All patients with a read coded history of either ischemic heart disease (IHD), myocardial infarction (MI), stroke (CVA) or transient ischaemic attack (TIA) or peripheral arterial disease (PAD)

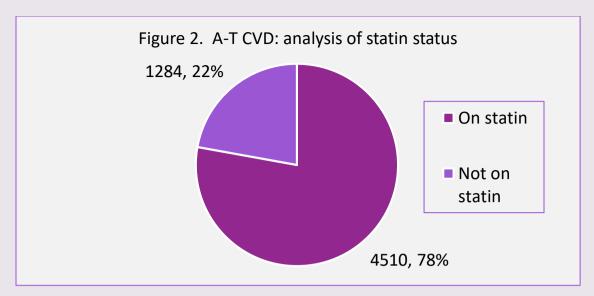
Patients with A-T CVD (IHD/MI/CVA/TIA/PAD): On Atorvastatin 80mg

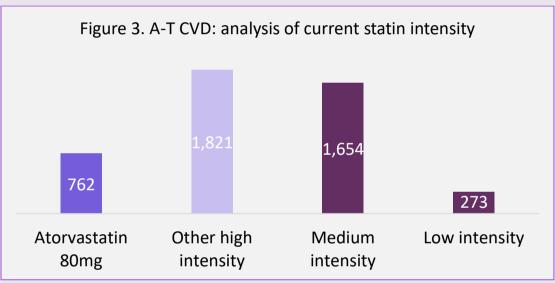
- 1. 5.5% (n=42) had a latest LDL-C measurement >4mmol/L
- 2. 5.0% (n=38) had a latest TC measurement > 6 mmol/L

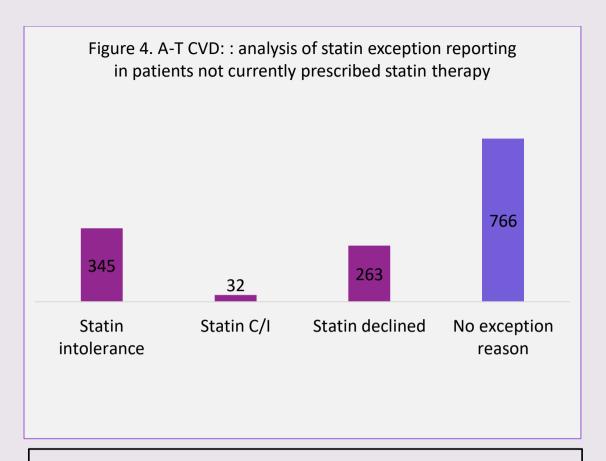
Patients with A-T CVD (IHD/MI/CVA/TIA/PAD): On other high intensity statin

- 1. 5.7% (n=103) has a latest LDL-C measurement > 4mmol/L
- 2. 5.7% (n=104) had a latest TC measurement > 6mmol/L







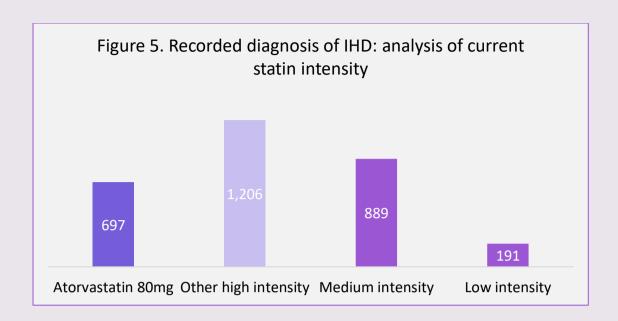


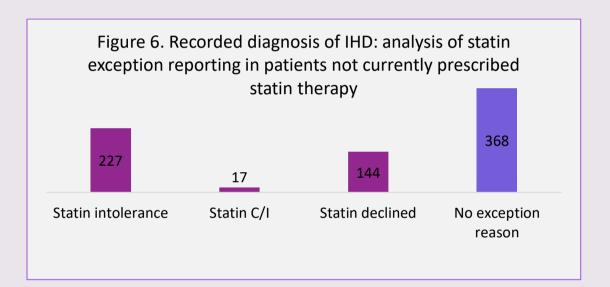
Of 1,284 people with A-T CVD not prescribed statin therapy, 766 had no documented reason. In 518 people with a recorded reason, 122 had \geq 2 documented reasons for not receiving statin therapy.

ISCHAEMIC HEART DISEASE (IHD): TOTAL PATIENTS = 3,660

Key findings: - Of 3,660 patients with a recorded diagnosis of IHD, 2983 (82%) were prescribed statin therapy. Of the 2983 patients with IHD prescribed a statin, only 697 (23%) were prescribed Atorvastatin 80mg as recommended within NICE guidelines CG 181.

Reporting definition: - Report on all patients with a read code diagnosis of ischaemic heart disease defined in line with QOF register inclusion criteria.



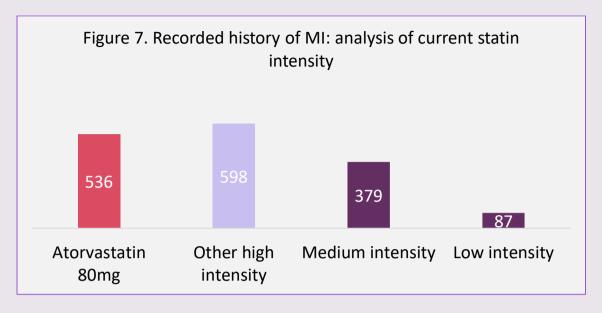


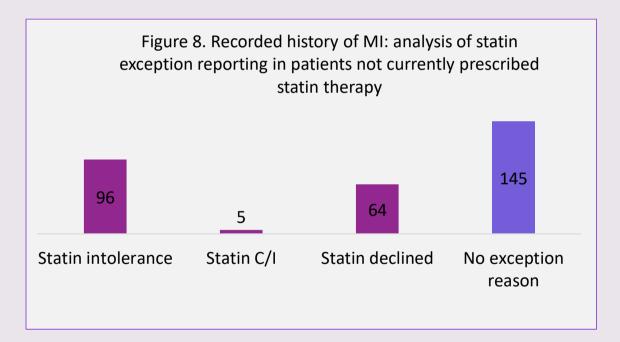
Of 677 people with IHD not prescribed statin therapy, 368 had no documented reason. In 309 people with a recorded reason, 79 had \geq 2 documented reasons for not receiving statin therapy.

MYOCARDIAL INFARCTION (MI): TOTAL PATIENTS = 1,877

Key findings: - Of 1,877 patients with a recorded history of MI, 1,600 (85%) were receiving statin therapy. Of 1,600 patients with MI prescribed a statin, 536 (34%) were prescribed Atorvastatin 80mg as recommended in NICE CG181. Of 536 patients with A-T CVD prescribed Atorvastatin 80mg, 311 (58%) had achieved a non-HDL-C reduction of >40%.

Reporting definition: - Report on all patients with a recorded history of myocardial infarction (MI) defined using Read code terms relevant to MI* (* 2 patients were recorded with h/o MI, but without a recorded diagnosis of IHD)



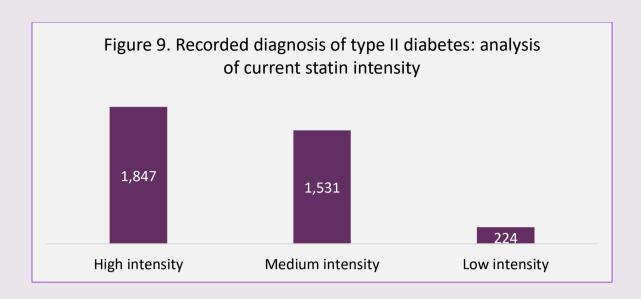


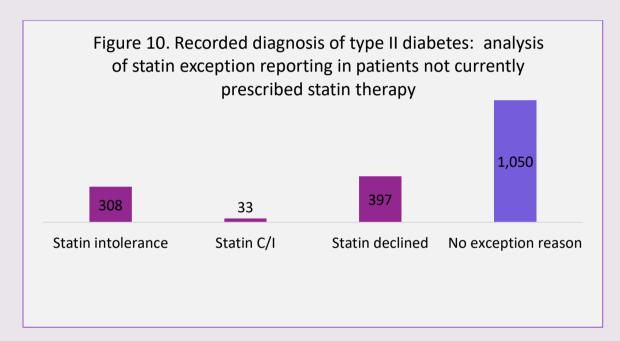
Of 277 people with MI not prescribed statin therapy, 145 had no documented reason. In 132 people with a recorded reason, 33 had \geq 2 documented reasons for not receiving statin therapy.

DIABETES MELLITUS TYPE II (DM): TOTAL PATIENTS = 5,245

Key findings: - Of 5245 patients with a recorded diagnosis of Type II DM 3602 (69%) were prescribed statin therapy. Of 1,457 patients with a recorded diagnosis of type II DM & A-T CVD, 1,210 (83%) were prescribed statin therapy.

Reporting definition: - Report on all patients with a recorded diagnosis of Type II DM defined in line with QOF register inclusion criteria.



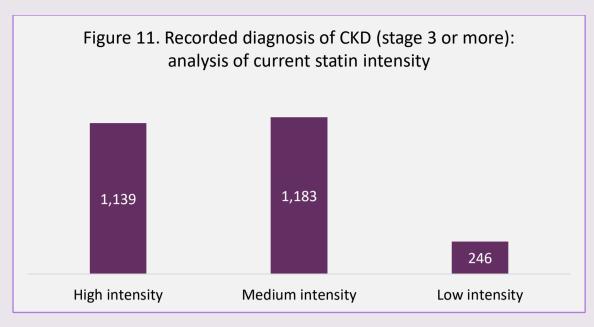


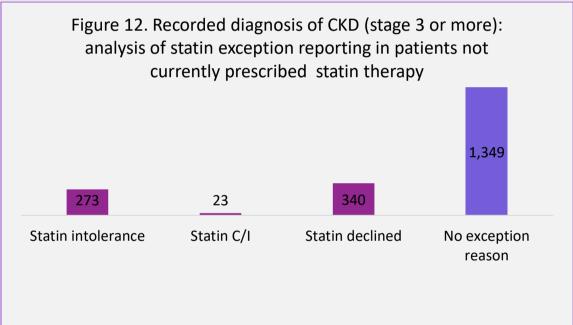
Of 1,643 people with Diabetes not currently prescribed a statin, 1,050 had no documented reason. In 593 people with a recorded reason, 145 had \geq 2 documented reasons for not receiving statin therapy.

CHRONIC KIDNEY DISEASE (CKD) STAGE 3 OR MORE: TOTAL PATIENTS = 4,461

Key findings: - Of 4461 patients with a recorded diagnosis of CKD stage 3, 4 and 5, 2568 (58%) were prescribed statin therapy. Of 1,513 patients with a recorded diagnosis of CKD & A-T CVD, 1,147 (76%) were prescribed statin therapy.

Reporting definition: - Report on all patients with a recorded diagnosis of CKD stage 3,4 and 5, defined in line with QOF register inclusion criteria.



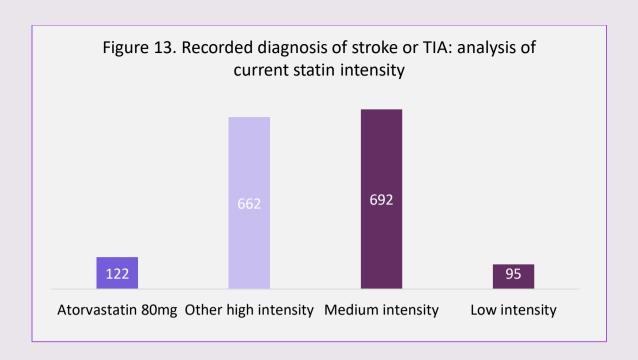


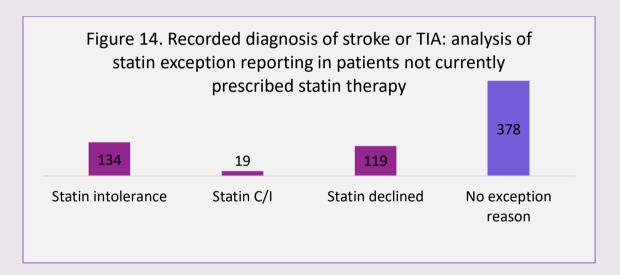
Of 1,893 people with CKD not taking a statin, 1,349 had no documented reason. In 544 people with a recorded reason, 92 had \geq 2 documented reasons for not receiving statin therapy.

STROKE / TRANSIENT ISCHEMIC ATTACK (TIA): TOTAL PATIENTS = 2,169

Key findings: - Of 2169 patients with a recorded diagnosis of stroke and/or TIA 1571 (72%) were prescribed statin therapy. Of 1,571 patients with CVA / TIA prescribed a statin, 122 (8%) were prescribed Atorvastatin 80mg as recommended in NICE guidelines CG181.

Reporting definition: - Report on all patients with a recorded diagnosis of stroke or TIA defined in line with QOF register inclusion criteria.



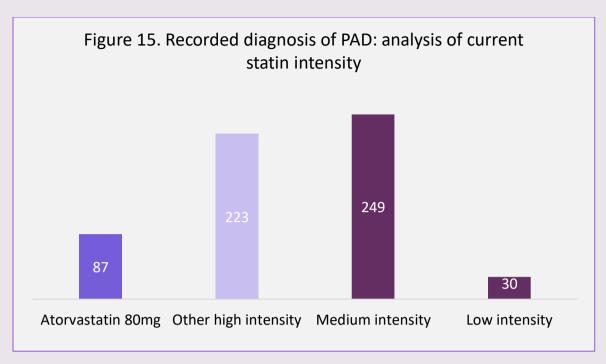


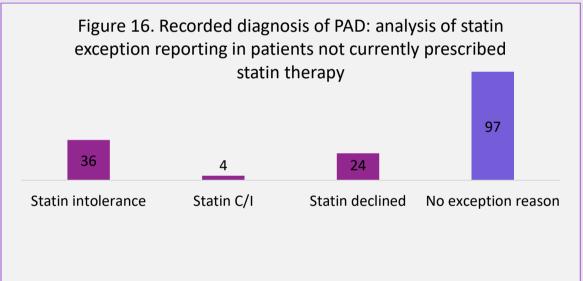
Of 598 people with stroke / TIA not prescribed a statin, 378 had no documented reason. In 220 people with a recorded reason, 52 had \geq 2 documented reasons for not receiving statin therapy.

PERIPHERAL ARTERY DISEASE (PAD): TOTAL PATIENTS = 738

Key findings: - Of 738 patients with a recorded diagnosis of PAD 589 (80%) were prescribed statin therapy. Of 589 patients with PAD prescribed a statin, 87 (15%) were prescribed Atorvastatin 80mg as recommended in NICE guidelines CG181.

Reporting definition: - Report on all patients with a recorded diagnosis of peripheral arterial disease (PAD) defined in line with QOF register inclusion criteria.



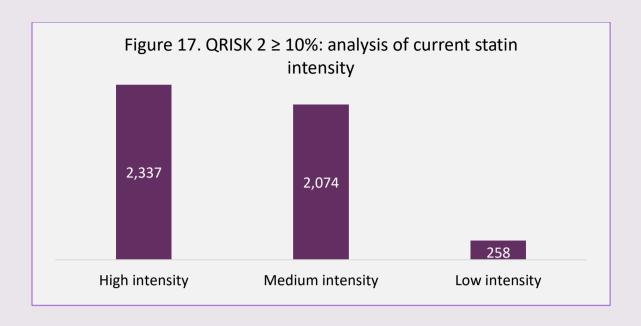


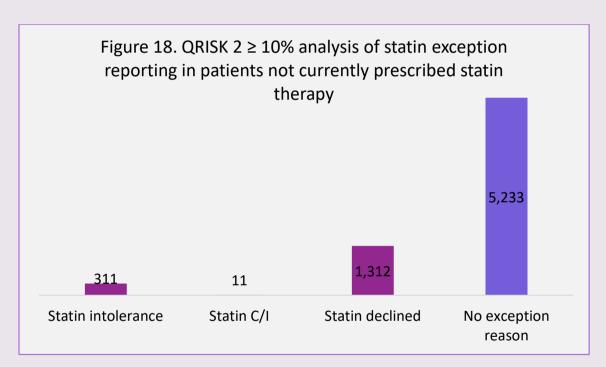
Of 149 people with PAD not prescribed a statin, 97 had no documented reason. In 52 people with a recorded reason, 12 had \geq 2 documented reasons for not receiving statin therapy.

QRISK 2 - RISK % EQUAL TO OR GREATER THAN 10% (EXC. PATIENTS WITH EXISTING IHD): TOTAL PATIENTS = 11,422

Key findings: - Of 14,165 patients with a documented QRISK2 score in their medical notes, 11,429 (81%) had a QRISK2 score \geq 10%. Of 11,429 patients with a recorded QRISK2 score \geq 10%, 4,669 (41%) were prescribed statin therapy.

Reporting definition: - Report on patients with a documented QRISK $2 \ge 10\%$ (excluding patients with existing cardiovascular disease).



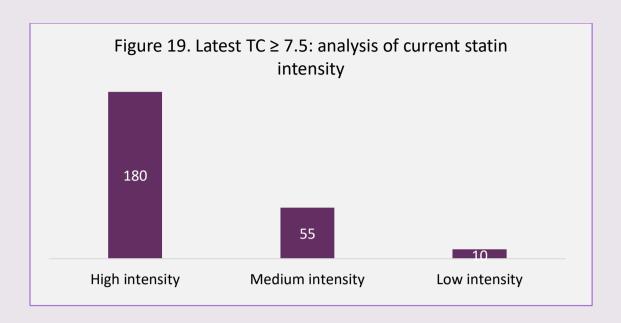


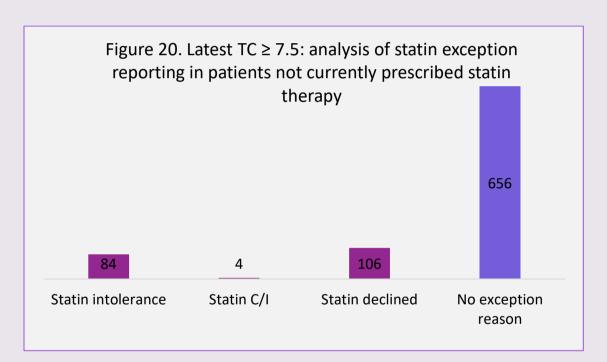
Of 6,760 people with QRISK2 not taking a statin, 5,233 had no documented reason. In 1,527 people with a recorded reason, 107 had \geq 2 documented reasons for not receiving statin therapy.

TOTAL CHOLESTEROL GREATER THAN OR EQUAL TO 7.5MMOL: TOTAL PATIENTS = 1066

Key findings: - Of 1066 patients with a latest total cholesterol \geq 7.5 mmol/L, 245 (23%) were prescribed statin therapy. Of 71 patients with a latest total cholesterol \geq 7.5 mmol/L & A-T CVD, only 32 (45%) were prescribed statin therapy.

Reporting definition: - Report on patients with a documented latest total cholesterol level ≥ 7.5 mmol/L.



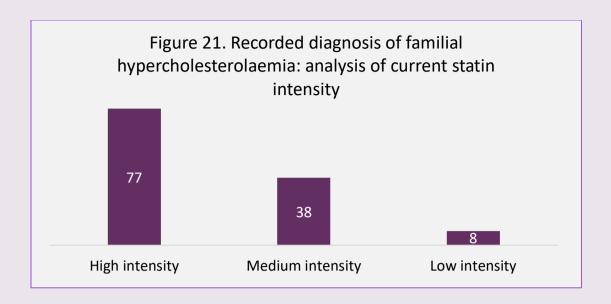


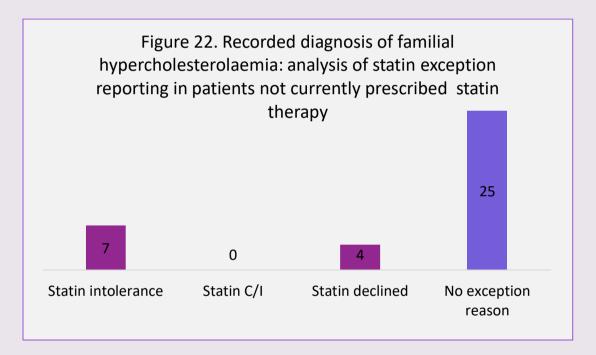
Of 821 people with cholesterol \geq 7.5 mmol/L not taking a statin, 656 had no documented reason. In 165 people with a recorded reason, 29 had \geq 2 documented reasons for not receiving statin therapy.

FAMILIAL HYPERCHOLESTEROLAEMIA: TOTAL PATIENTS = 159

Key findings: - Of 158 patients with a recorded diagnosis of FH, 123 (78%) were prescribed statin therapy. Of 19 patients with a recorded diagnosis of FH & A-T CVD, 17 (89%) were prescribed statin therapy.

Reporting definition: - Report on all patients with a recorded diagnosis of FH (please note a read code for FH does not confirm the presence of a diagnosis validated through genetic testing).





Of 35 people with FH not taking a statin, 25 had no documented reason. In 10 people with a recorded reason, 1 had \geq 2 documented reasons for not receiving statin therapy.

CONCLUSION

In 2014, both the National Institute for Health & Care Excellence and the Joint British Societies for The Prevention of Cardiovascular Disease (4), published pivotal documents with key recommendations regarding the assessment and treatment of patients with established athero-thrombotic CVD (A-T CVD) and those at high-risk of developing it. Both sets of guidelines devoted significant attention to the importance of lipid modulation and both placed a greater emphasis on the wider use of HMG-CoA reductase inhibitors (statins). Key aspects of NICE

guidelines CG181 were the default use of both high dose Atorvastatin 80mg for "secondary prevention" purposes and moderate dose (although still high-intensity) Atorvastatin 20mg for "primary prevention" along with a broadening of the in-scope high-risk population to include most patients with DM, CKD and QRISK2 scores of ≥ 10%.

The subsequent response to these recommendations, particularly within the reporting media, were sceptical at best and scare-mongering at worst. Yet, the medical scientific community and clinicians within the field of CVD were almost unanimously supportive of these evidence-based guidelines and, coupled with a marked reduction in the acquisition cost of high-intensity statin therapies, the expectation was that these guidelines would be fully implemented.

The result of our large-scale audit across an entirely representative sample of patients from the Cheshire and Merseyside region would suggest something quite different. The gap between the guideline recommendations and the actual reality of current clinical prescribing is quite astonishing. Of the 24,076 individuals who could/should be on statin therapy less than half actually were, with people living with diabetes (33%), patients with CKD (42%) and those with a QRISK2 score ≥ 10% (59%) forming the majority of those inadequately treated. Even when examining the highest of the high-risk groups, i.e. those with established vascular disease, only 57% of these 4510 patients were prescribed high intensity statin therapy with just 17% actually receiving the recommended therapy of Atorvastatin 80mg. A total of 1,284 patients with confirmed A-T CVD were receiving no statin therapy whatsoever.

Clearly, an audit evaluation such as this has limitations and the data presented almost certainly represents a "worst case scenario". Clinician to patient discussions involving decisions to improve risk status through behaviour/life-style interventions (and thus delaying / deferring the initiation of medication) will not have been captured. Equally, patients struggling with side-effects from high-intensity statin therapy may quite reasonably have had their statin dose and/or type adjusted in order to improve tolerance. In addition, a proportion of patients with genuine contra-indications, intolerances and/or personal objections to statin therapy will not have been appropriately coded and thereby misrepresented within this audit. Nevertheless, the gap that has been highlighted between what should be done and what is actually happening is too vast to be dismissed by the methodological shortcomings of this analysis.

Lipid modulation is but one aspect of an entire primary/secondary/tertiary CVD prevention strategy but is without doubt an element which is easy to target and for which we already have highly effective and low-cost interventions. More advanced agents are already either formally approved (PCSK9-inhibitors) or reaching the later stages of development, and these therapies will provide even greater non-HDL cholesterol lowering potency for patients either sub-optimally treated with statins or completely intolerant to them.

The results of this audit evaluation within the Cheshire & Mersey region highlights the inadequacy of current lipid management and the need for the full adoption and subsequent implementation of a comprehensive pathway of lipid interventions across the entire stakeholder group – patients, clinicians and commissioners alike.

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