Health & Care Partnership for Cheshire & Merseyside

PROGRAMME END REPORT

PROGRAMME	CHESHIRE MERSEYSIDE LIPID COMMISSIONING FOR VALUE PROGRAMME
PROGRAMME STAKEHOLDERS	HEALTH & CARE PARTNERSHIP FOR CHESHIRE & MERSEYSIDE NORTH WEST COAST STRATEGIC CLINICAL NETWORK NORTH WEST COAST ACADEMIC HEALTH CARE NETWORK INNOVATION AGENCY AMGEN LIMITED SALVERA SERVICES
PROGRAMME LEAD	WENDY O'CONNOR – PRINCIPAL CONSULTANT SALVERA SERVICES
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EXECUTIVE SUMMARY

Cardiovascular disease (CVD) affects the lives of millions of people and is one of the largest causes of death and disability in England (1). CVD shows strong age dependence and predominantly affects people older than 50 years. Risk factors for CVD include non-modifiable factors such as age, sex, family history of CVD, ethnic background and modifiable risk factors such as smoking, raised blood pressure and cholesterol. CVD is strongly associated with low income and social deprivation and shows a North–South divide, with higher rates in the north of England.
In response to improving outcomes for people with cardiovascular disease the CVD outcomes strategy 2013 encourages the use of pathways for both providers and commissioners and in addition, the strategy demonstrates where pathways can benefit patients and the wider healthcare system. The broad cardiovascular disease benefits of clinical pathways [taken from the strategy] are highlighted below:

- Pathways are cost-effective
- Improves outcomes
- Improves quality of services
- Reduces duplication of care and processes

The burden of disease on population health across Cheshire and Merseyside reflects the national current state. The CVD outcomes strategy 2013 has identified four key areas relating to problems in treatment and care for patients with CVD caused by atherosclerosis:

1. Case finding in primary care – all CVD patients should have access to what is recognized as the right treatment.
2. Identification of very high-risk families and individuals with inherited cardiac conditions, such as familial hypercholesterolemia (FH).
3. Early identification could improve quality of life.
4. Variation in care – early management and secondary prevention in the community.

In September 2017 a Joint Partnership Agreement contract was agreed between Cheshire Merseyside Health Care Partnership, North West Coast Strategic Clinical Network, North West Coast Academic Health Science Network -Innovation Agency, Amgen Limited and Salvera Services Limited to develop a programme - Cheshire Merseyside Lipids Commissioning for Value Programme with aims and objectives that would develop tools, produce data evidence, and support service transformation for patients with dyslipidaemia and familial hypercholesterolaemia (FH)

The major aims and objectives of the Cheshire Merseyside Lipids Commissioning for Value Programme were: -
Aims

1. Promote high quality clinical management across the pathway of care for people with CVD caused by atherosclerosis.
2. Improve diagnosis and outcomes for people with FH and CVD caused by atherosclerosis.
3. Enhance effectiveness and efficiency in the NHS.
4. Strengthen clinical service delivery through robust evaluation of a pilot project.

Objectives

1. Develop a Clinical and Commissioning Pathway locally with experts from across multi professional backgrounds and services - Clinical & Commissioning Pathway for the Prevention and Management of Dyslipidaemia and Familial Hypercholesterolaemia (2)
2. Complete a primary care service review across an estimated 100K population sample in 10 GP practices – Interface Clinical Services Attend2 Lipid Dashboard (3)

3. Develop an evaluation on the data sample produced to inform on the current state - Prevention and Management of Dyslipidaemia and Familial Hypercholesterolaemia: An Evaluation of Clinical Management (4)

The Cheshire Merseyside Clinical & Commissioning Pathway for the Prevention and Management of Dyslipidaemia and FH outlines specific areas for gold standard clinical and lifestyle management:

- Population health – to improve CVD prevention, education and lifestyle advice needs to be embedded across all clinical services and delivered by multi professionals.
- Primary prevention identification, assessment and management – to improve the clinical and educational management of patients through clinical flow charts and lifestyle education signposting
- Secondary prevention assessment and management – to improve the clinical and educational management of patients through clinical flow charts and lifestyle education signposting
- Specialist Lipid services& FH pathway – to improve clinical care and support commissioning for specialist FH services

It is important to remember that whilst large numbers of patients are treated appropriately there are a considerable number of patients who need further review, not only through clinical management but need education on lifestyle change. The evaluation report highlighted areas for review, specifically:

- Review high-risk patients with Atherothrombotic Cardiovascular Disease (A-T CVD) to ensure appropriate statin therapy is prescribed in line with NICE guidelines CG 181 (5)
- Review patients with A-T CVD to check % reduction in lipid levels is achieved in line with NICE guidance CG 181
- Review patients with Type II DM and QRISK 2 ≥ 10% for appropriate initiation and/or optimisation
- Review large % of patients reported with 'No exempt reason'
- Validate FH coded patients and review patients with total cholesterol ≥ 7.5 mmol/L for FH

REVIEW OF TEAM PERFORMANCE

The Cheshire Merseyside Clinical & Commissioning for Value Programme was developed by disease experts and commissioners, listed below, from across Cheshire and Merseyside area.

The programme was supported by Clinical Lead, Dr Joe Mills, Cardiac Clinical Lead – North West Coast Strategic Clinical Network, Programme & Pathway Lead, Wendy O'Connor – Principal Consultant - Salvera Services Limited, Pathway Facilitator, Steve Callaghan – EQE Health and Service Review facilitation - Interface Clinical Services Limited.

The development of the pathway would not have been possible without the expertise and commitment of local and national experts from multi professional backgrounds in NHS clinical services, Public Health, CCG, Charity & Third sector and Independent services: -

Dr Abraham Abraham, Dr Aftab Ahmad, Hassan Argomandkhah, Joanne Bateman, Dr Shirley Bowles, Amanda Brookes, Jennie Barr, Jack Birchall, John Booth, Julie Brake, Steve Callaghan, Helen Cartwright, Dr Rob Cooper, Dr Alison Davis, Lisa Devitt, Dr Mike Fisher, Danny Forrest, Dr Phil Jennings, Dr Matt Kearney, Dr Sue Kemsley, Dr Ranganath Lakshminarayan, Dr Deborah Lowe, Susanne Lynch, Dr Paul Mackenzie, Jim McArdle, Sophie McIntosh, Zoe McIntosh, Dr Victoria McKay, Dr Sarah McNulty, Dr Mike Merryman, Jason Miller, Dr Joseph Mills, Dr Vinita Mishra, Dr Scott Murray, Wendy O'Connor, Dr David Oleesky, Dr Ifeoma Onyia, Penny Owen, Paula Peacock, Dr Marga Perez-Casal, Dr Tejpal Purewal, Julia Reynolds, Dr Nigel Taylor, Jan Vaughan, Louise Vernon, Joanne Whitmore, Simon Williams and Dr Rahul Yadav.

A special thanks must be given to every member of the panel for their involvement with the development of the pathway giving their specific expert knowledge into each section and continuous support throughout the task to completion.

REVIEW OF PROGRAMME OBJECTIVES

The objectives of the Cheshire Merseyside Lipid Commissioning for Value Programme were: -

- Clinical & Commissioning Lipid Pathway – 'Cheshire Merseyside Clinical & Commissioning Pathway for the Prevention and Management of Dyslipidaemia and Familial Hypercholesterolaemia'
- Primary Care Service Review – Attend 2 Lipid Dashboard
- Programme Evaluation Report – Prevention and Management of Dyslipidaemia & FH: An Evaluation of Clinical Management

CLINICAL & COMMISSIONING LIPID PATHWAY

The pathway was completed over a 15-month period, September 2017 – December 2018. It was developed with the support of the programme stakeholders and an expert panel of professionals and commissioners across multi professional backgrounds and services.

The pathway is a guide to identify patients who need to be screened for lipid disorders and the approach to be adopted in prevention and management of lipid disorders once identified. This supports comprehensive clinical and commissioning support, by introducing and implementing a pathway for dyslipidaemia and FH across different care settings based on four core principles:

- Population Health Lifestyle Intervention
- Primary Prevention of CVD
- Secondary Prevention of CVD
- Specialist Lipid Services and Familial Hypercholesterolaemia Pathway

POPULATION HEALTH LIFESTYLE INTERVENTION

The Population Health Section focuses on lifestyle intervention and population health education.

(Text taken from the Cheshire Merseyside Clinical & Commissioning Pathway for the Prevention and Management of Dyslipidaemia and Familial Hypercholesterolaemia)

Purpose of this stage

Population health can be supported by a wide variety of lifestyle advice, services and interventions. Lifestyle advice should be embedded into all advice / education given to patients who have or are at risk of CVD.

A wide range of services are available across all sectors of NHS services, including community services. All opportunities for interventions, sign posting and referral to services should be taken to support clinical management, self-management and education.

PRIMARY PREVENTION OF CVD

Primary Prevention section focused on the identification, assessment of management of cardiovascular risk in people without clinical evidence of cardiovascular disease and highlights the importance of identifying patients with possible FH.

(Text taken from the Cheshire Merseyside Clinical & Commissioning Pathway for the Prevention and Management of Dyslipidaemia and Familial Hypercholesterolaemia)

Purpose and Importance of this stage

To identify patients at increased CVD risk or FH at an early stage, in order to reduce morbidity and mortality. Patients with FH are at high CVD risk and should be managed accordingly to the FH Pathway.

In patients on statins or other lipid lowering therapy, a total cholesterol TC level of < 7.5mmol/L cannot be used to exclude the possibility of FH.

Tools within the primary prevention section included flow charts for clinical referral and management support, risk calculators to determine risk, commissioning standards, indicators and guidelines, and notes to supplement knowledge on areas within the section.

SECONDARY PREVENTION OF CVD

Secondary Prevention section focused on the process of detection and management of patients with dyslipidaemia and or FH after a CVD event.

(Text taken from the Cheshire Merseyside Clinical & Commissioning Pathway for the Prevention and Management of Dyslipidaemia and Familial Hypercholesterolaemia)

Purpose and Importance of this stage

To promote clinical management of all post CVD event patients with national recognised standards of care for the management of dyslipidaemia, to minimise CVD risk and offer lifestyle intervention and opportunity to modify the lifestyle.

The clinical management and lifestyle modification of patients, who have been diagnosed with CVD, and directs to services that will support identification of FH at an early stage to reduce morbidity and mortality.

Tools within the secondary prevention section included flow charts for clinical referral and management support, commissioning standards, indicators and guidelines, and notes to supplement knowledge on areas within the section.

SPECIALIST LIPID SERVICES AND FAMILIAL HYPERCHOLESTEROLAEMIA (FH) PATHWAY

The last section Specialist Lipid Services and FH Pathway focuses on the treatment of Dyslipidaemia and FH across primary, secondary and tertiary sectors.

(Text taken from the Cheshire Merseyside Clinical & Commissioning Pathway for the Prevention and Management of Dyslipidaemia and Familial Hypercholesterolaemia)

Purpose and importance of this section

To provide education and support across NHS structures, to ensure the identification, diagnosis and optimal management of patients with dyslipidaemia and, in particular, FH.

Many forms of dyslipidaemia are associated with an increased risk of cardiovascular disease but there is incontrovertible evidence that this risk can be ameliorated by effective treatment.

Tools within this section included flow charts for clinical referral and management support, commissioning standards, indicators and guidelines, and notes to supplement knowledge on areas within the section.

PRIMARY CARE SERVICE REVIEW & PROGRAMME EVALUATION REPORT

A primary care data service evaluation was completed across the Cheshire and Merseyside geography 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: -

- 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 % greater than 10% (excluding patients with existing A-T CVD)
- Total Cholesterol > 7.5 mmol
- Familial Hypercholesterolaemia (FH)

There were 10 GP practices in the evaluation sample from 5 different Clinical Commissioning Groups. The total registered population of the sample reviewed totalled 95,732 with a total number of 24,076 patients who were met the inclusion criteria.

Key findings, shown in the Programme Evaluation Report, of a total population of 24,076 with established disease or at high risk of developing it:

- 11,325 patients (47%) were currently prescribed statin therapy and, of these, 77% were prescribed high-intensity therapy.
- 12,751 patients (53%) were currently not prescribed statin therapy and, of these, 9315 (73%) have no read code to suggest contraindications, intolerance or refusal.

- 3,660 patients had confirmed IHD and 82% were currently prescribed statin medication. However, less than 20% were prescribed 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 chronic kidney disease 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 statin therapy and the majority (71%) had no read code for any documented exception report.
- Within NICE Clinical Guideline 181, 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 currently prescribed statin therapy as per guideline recommendation.
- Number of patients in an average sized practice (ie. List size of 9,573 represents an average size across the reviewed population) with IHD who are not receiving a statin, who could/should be, is 49.
- Projected total number of patients across the STP with IHD not prescribed statin therapy is 18,275.

RECOMMENDED GOOD PRACTICE

The programme has intended to define the service a patient should receive when identified with raised cholesterol, and what a new FH service should look like with full implementation of NICE clinical guideline for FH CG71 (6)

Good practice guidance: -

- The national CVD prevention agenda has been widely recognised and multi structures across NHS and Public Health are now developing tools to support the agenda outcomes. The Cheshire Merseyside Clinical & Commissioning Pathway for the Prevention & Management of Dyslipidaemia and FH can be used as a tool for prevention and is easily adaptable across other localities.
- The pathway is intended to help inform and standardise the approach for identification and management of patients who require some intervention to manage their lipids as part of CVD prevention. It addresses four important areas which are public health interventions, primary prevention, secondary prevention and FH.
- Whilst large numbers will be successfully managed through diet and exercise, notably public health and some primary prevention patients, it is important that patients who require medical intervention are routinely followed up to ensure optimisation of their treatment.
- Key tools are identified throughout the pathway sections to enable and support the identification of patients at risk of CVD and also highlight the possible FH patients.
- Key to helping implement recommendations within the pathway will be, not only, its application to new patients, but also reviewing existing patients to ensure they are appropriately managed; for example, by re-checking cholesterol levels in selected groups and ensuring they are on the appropriate dose of statin or require referral to a specialist.
- Endorsement and embedding the pathway in services locally will also help to raise the importance of cholesterol as a manageable and modifiable risk factor.
- CCGs and practices may want to put in place processes and programmes of work to review both new and existing patients in line with this pathway. This would also help identify those patients who achieve NICE recommended targets, but still have high cholesterol so still be at increased CVD risk and requiring further intervention.
- It is important to consider recommendations in the pathway alongside management of other CV risk factors such as raised blood pressure and the presence of AF.
- Commissioning of a structured FH service across Cheshire and Merseyside, adopting the referral and service model pathway, will promote the identification of patients with suspected or definite FH, and ensure optimal clinical management is offered to patients from specialist practitioners.

SUMMARY OF FOLLOW ON RECOMMENDDATIONS

Recommendations have been derived from the development of the Cheshire Merseyside Lipid Commissioning for Value Programme. The areas that have been highlighted with recommendations are: -

1. Identification, Assessment and Management for CVD Prevention – Cheshire Merseyside Clinical & Commissioning Pathway for the Prevention and Management of Dyslipidaemia and FH
2. Evidence for improved clinical management – Primary Care Service Review and Evaluation Report
3. Service commissioning / case for change
4. Workforce review to support service change
5. Challenges
6. Benefits

1. CHESHIRE MERSEYSIDE CLINICAL & COMMISSIONING PATHWAY FOR THE PREVENTION AND MANAGEMENT OF DYSLIPIDAEMIA AND FAMILIAL HYPERCHOLESTEROLAEMIA

- The pathway is intended to help inform and standardise the approach for identification and management of patients who require some intervention to manage their lipids as part of CVD prevention. It addresses four important areas which are public health interventions, primary prevention, secondary prevention and familial hypercholesterolaemia.

- Whilst large numbers will be successfully managed through diet and exercise, notably public health and some primary prevention patients, it is important that patients who require medical intervention are routinely followed up to ensure optimisation of their treatment.

- Key to helping implement recommendations within the pathway will be, not only, its application to new patients, but also reviewing existing patients to ensure they are appropriately managed; for example, by re-checking cholesterol levels in selected groups and ensuring they are on the appropriate dose of statin or require referral to a specialist.

- Endorsement and embedding the pathway in services locally will also help to raise the importance of cholesterol as a manageable and modifiable risk factor.

- It is important to consider recommendations in the pathway alongside management of other CV risk factors such as raised blood pressure and the presence of AF.

- An implementation plan to embed the pathway in clinical services is needed to ensure awareness and action on CVD prevention is achieved.

2. PRIMARY CARE SERVICE REVIEW AND EVALUATION REPORT FOLLOW ON RECOMMENDATIONS

The results of the Primary Care Service review, documented in the Cheshire Merseyside Lipid Programme Evaluation Report, 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.

Evidence from the Primary Care Service review and Evaluation Report also demonstrate that there are some areas that merit looking at further where care could be improved. Highlighted areas are: -

IHD and MI:

Use of statins, and indeed the proportion of patients on a high intensity statin, is relatively high in these two high risk populations.

Of the 1,877patients with MI, 225 out of 536 on Atorvastatin 80mg and 273 out of 598 on another high intensity statin did not get a >40% reduction in non-HDL cholesterol.

Broadening this out to the 5,794 patients with established CVD (IHD, MI, CVA, TIA or PAD), 309 out of 761 on Atorvastatin 80mg and 796 out of 1,822 on another high intensity statin did not get a >40% reduction in non-HDL cholesterol.

Type II DM**:**

31%of patients are not on a statin and of these 64% (1,050) are exempt reported without reason. This represents an opportunity to improve lipid levels in line with pathway recommendations.

CKD:

4,461 patients with established CKD stages 3,4 and 5 represents almost 5% of the population and 42 % are not receiving statin therapy of any strength. Only 44% are prescribed a high-intensity statin and 71% are exempt reported without reason.

PAD and Stroke / TIA:

2,907 patients have PAD and/or a history of ischaemic stroke/TIA with almost 3 out of 4 patients currently on statin therapy. However, only half of this group are receiving high intensity statin and only a very small minority are receiving the guideline recommendation of Atorvastatin 80mg

QRISK 2:

Only 41% of patients are prescribed a statin and of the 59% not on a statin 77% are exempt reported without a reason. In addition, a high potency statin is the one most commonly prescribed, which may not be appropriate for a primary prevention cohort.

TC ≥ 7.5mmol/l:

77% of patients are not prescribed a statin, with a large number 'no exemption reason' reported. In line with NICE's clinical guideline, CG71, this group of patients should be reviewed to assess for FH using the Simon Broome or DLCN criteria and refer the person to an FH specialist service for DNA testing if they meet the criteria for possible or definite FH. Of those not on a statin, their cholesterol could drop significantly with appropriate statin treatment.

FH:

Estimates suggest that the prevalence of FH is about 1 in 250 (0.4%) whereas the 159 patients coded as FH here would represent 0.17%, just under half (42.5%) of this prevalence. If it is assumed that only around 10% of patients with FH are known, these data suggest Cheshire and Merseyside is doing extremely well in

identifying patients with FH by around 4 times the average (42.5% Vs 10%), but a read code for FH does not confirm the presence of a diagnosis validated through genetic testing, so it would be worth validating those coded for FH to ensure an accurate diagnosis.

3. SERVICE COMMISSIONING / CASE FOR CHANGE

It is evident from both national and local data that significant % of patients with raised cholesterol are not adequately clinically treated, either for primary or secondary prevention. Primary care is highlighted as overburdened, and with growing pressure on the system, other services and systems need to be explored to support change. Other services and professions that could aid this process are:

Allied HCPs:

A large number of improvements in care highlighted in the evaluation report could be achieved in primary care and by other allied professionals such as nurses and pharmacists. The investment in practice-based pharmacists by NHSE, along with practice nurses where suitably resourced, are ideally placed to undertake much of this work such as statin/cholesterol optimisation, medicines reviews and re-challenging of some patient's exemption coding.

Cardiac Rehabilitation services:

Cardiac rehabilitation services offer an excellent opportunity to follow up patients post MI to assess patient engagement with their care, including compliance with all their medication. This also offers opportunity to re-check LDL-C levels, alongside compliance with their statin, to assess whether the patient needs referral to a lipid specialist.

A&E:

To inform treatment decisions, it would also be helpful, if lipids are measured on arrival in A&E when bloods are taken for other measures. Being able to ascertain whether a patient has achieved the 40% reduction in cholesterol requires a baseline measurement, which is often not recorded thus delaying statin optimisation and other treatment decisions.

Independent Services:

Interface Clinical Services have developed a quality improvement platform, Attend2 Lipid Management, to support GP practices in the proactive risk management of patients currently receiving lipid modifying drugs, or who may require lipid modifying drugs. This is an interactive platform utilising data extracted from the GP clinical systems, and compatible with all GP clinical systems. This will enable practices to benchmark current practice, isolate key cohorts of interest in line with NICE guideline recommendations and create manageable work streams to improve gaps in care in lipid management.

4. WORKFORCE REVIEW TO SUPPORT SERVICE CHANGE

Current lipid specialist services across Cheshire and Merseyside appear at maximum capacity, if not overstretched. To ensure an appropriate level of delivery of, and future proofing of, specialist care, there needs to be an increase in resource to meet future challenges including those highlighted in the audit.

A ground roots approach to education and lifestyle change is needed across all structures of the NHS. Promoting lifestyle change and ensuring patients understand prevention strategies they can adopt themselves is a challenge which both local and national systems are approaching and should be supported.

Cardiology initiation of PCSK9 inhibitors is one way to support lipidologists, and reduce patient waiting times, as suggested in the pathway. How this is practically implemented at trust level could be decided by an appropriate MDT to agree who does what locally.

5. CHALLENGES

- Education of primary, secondary and tertiary care staff to think CVD prevention.
- Education and public awareness on the importance of lifestyle modifications for CVD prevention
- Education of primary, secondary and tertiary care staff to think FH.
- Public awareness of FH and its risks.
- Coordination of a FH service across different parts of the system, and financial costs to the system upfront.
- Financial constraints to commission new services.

6. BENEFITS

- Identification, assessment and management of patients with dyslipidaemia is optimised.
- Lifestyle education & modifications promote CVD prevention with the wider clinical and public communities.
- Patients with suspected FH will follow a clear pathway of care.
- Relatives of suspected FH will be identified and contacted through cascade testing programme.
- The service can also include children under 16 who will be under the care of a paediatric lipid specialist.
- The early identification of FH patients will be expected to reduce the number of CVD events in this population. It is calculated that there should be a reduction in the number of heart attacks by approximately 12 per year (and this would start from year 1)
- Estimated reduction in CVD linked mortality in patients with FH identified early and managed through the pathway.
- Expected cost savings for the system based on a reduction in the number of CABG and PPCI required because of appropriate management of FH patients.

References

1. CVD Outcomes Strategy 2013
2. Clinical & Commissioning Pathway for the Prevention and Management of Dyslipidaemia and Familial Hypercholesterolaemia 2018
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4. Prevention and Management of Dyslipidaemia and Familial Hypercholesterolaemia: An Evaluation of Clinical Management Nov 2018
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