

A Collaborative Working Project between East Lancashire NHS Trust (ELHT), Oakenhurst Medical practice in Blackburn, Innovation Agency North West Coast AHSN and Sanofi to pilot a structured lipid service.

End of Project Evaluation Report

1.0 Project Aim

It is acknowledged that there is substantial unmet need in lipid management, with delay in identification of patients who may benefit from lipid therapy optimisation and of those patients who may have familial hypercholesterolaemia.

- The project aimed to pilot a specialist nurse-led clinic in primary care supported by the GP and by specialist endocrinologist in secondary care, to proactively identify and optimise therapy for familial hypercholesterolaemia (FH) patients and those requiring secondary prevention following cardiovascular events, and with a view to commissioning and implementation of the model and pathway across other Primary Care Networks/elsewhere and develop an Endocrinologist Led MDT lipid service.

2.0 Project Objectives

The initial objectives of the Collaborative Working Project were:

- Identification of patients who may benefit from lipid optimisation services using UCLP Lipid Search Stratification Tool.
- Specialist nurse-led follow up of patients, including monitoring of treatment, side effects and appropriate referrals to relevant services
- Develop links between primary and secondary care clinicians (nursing, GP, pharmacist) to develop a lipid treatment pathway across the health economy
- Implement lipid treatment pathway, including education events and training of relevant primary and secondary care professionals
- Use of prescribing pharmacists to achieve the standards set out in NICE TA393 and TA394 to work alongside existing medical teams to optimise therapies, including referral to consultant endocrinologist or consultant cardiologist if appropriate.
- Optimisation of oral lipid lowering therapies for patients with FH and patients requiring secondary prevention following cardiovascular events.
- Support access to relevant diagnostic and screening services for FH.

3.0 Project Outcomes and Benefits

The expected outcomes and benefits of the project were:

Patients

- Increased diagnosis rate and improved management of high-risk cardiovascular patients with elevated LDL-C.
- Optimisation of treatment and lipid management with access to new Endocrinology led MDT lipid service and access to genetic cascade screening.
- Care closer to home
- Patient empowerment and engagement in terms of their diagnosis and subsequent clinical management plan.
- Support implementation of NICE CG181

The NHS:

- Development of an Endocrinologist Led MDT specialist lipid service.
- Increased capacity of lipid service
- Reduction in waiting time.
- Alignment with NHS Long term plan and CVD Prevent Audit in Primary Care.
- Support implementation of NICE CG181
- Pilot of a practice-based Nurse led service that could be implemented and commissioned across other Primary Care Networks/elsewhere.

Sanofi:

The project aims:

- a) to increase the diagnosis rate and improved management of high-risk cardiovascular patients with elevated LDL-C. Patients diagnosed with these conditions will be treated with cholesterol lowering medicines which may include Sanofi medicines for suitable patients in line with NICE TA393 / TA394 and or local / national guidelines.
- b) to demonstrate collaborative working and enhanced reputation with the NHS to the benefit of patients that identifies scalable solutions.

4.0 Project Implementation

The project focused on Oakenhurst Medical Practice which has a list of 10,068 patients. The Collaborative Working Project commenced in April 2022.

A Project Steering Group was established to agree on a project plan to oversee delivery of the project, consisting of members of the Innovation Agency North West Coast AHSN team, members of the Sanofi team, the GP Principal at Oakenhurst Medical Practice, and the lipid lead consultant endocrinologist at East Lancashire Hospitals NHS Trust. Monthly meetings of the Project Steering Group were organised to review project delivery.

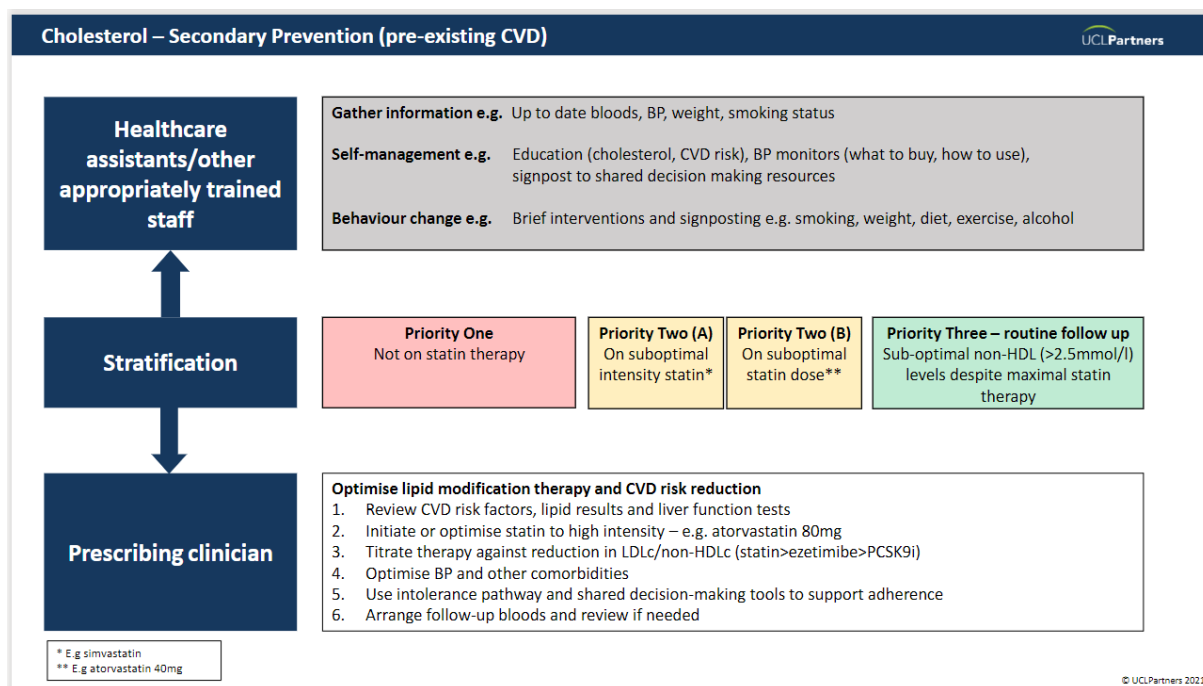
A nurse already working as diabetes specialist nurse at ELHT and as research nurse at Oakenhurst Medical Practice was identified and funded for 2 days a week over a 6-month period (the timeline was subsequently extended due to external demands reducing weekly time availability). Her role was to run the patient searches, and contact and optimise treatment of eligible patients, identifying those potentially suitable for injectable therapy to be referred to the endocrinologist in secondary care. The specialist nurse joined the steering group meetings as and when possible and needed.

The clinical team was supported by the Innovation Agency North West Coast AHSN team, prior to the clinical start of the project, to attend the University of Northumbria FH module. The specialist nurse received additional support for lipid optimisation therapy from the GP and secondary care consultant. The specialist nurse worked with the Innovation Agency NWC AHSN project manager to establish a data-collection system.

An initial practice database search prior to clinical start of project showed that the FH potential of the practice was 28 patients. The total number of secondary prevention patients who were not optimised was 538, classified as described by UCL Partners Lipids and FH Framework (shown below) as follows:

- Those not on statin 127 - Priority One
- Those on suboptimal statin 145 – Priority Two (A)

- Those on suboptimal statin dose 226 – Priority Two (B)
- Those with sub-optimal non-HDL (>2.5mmol/l) levels despite maximal statin therapy: 40 – Priority Three



Following initial assessment of numbers of patients in different groups and available resource within a funded project timeline of 6 months, it was decided to focus on patients in Priority Two (B) and Priority Three of the UCL Partners Secondary Prevention Framework in order to maximise the number of patients who could benefit from the project within the relatively short project time span. This therefore excluded Priority One and Priority Two (A), and the 28 potential FH patients from the project.

The clinical members of the project steering group decided that the following patients were not suitable for intensive lipid-lowering intervention.

- Patients aged 90 years old or above
- Patients with severe frailty or housebound,
- Care home/nursing home residents
- Anyone not suitable due to other health issues, ie patients undergoing chemotherapy, acutely unwell or prolonged hospitalisation.

The key milestones delivered in implementation of the Project are as follows:

- **April 2022**
- Developed Project Plan to set out and monitor delivery of the aims and objectives of the Project.
- **May 2022**
 - Specialist Nurse downloads search tool and began to work through first cohort.
 - Steering Group have access to Teams site where project plan and other relevant documents are stored.
 - Project metrics agreed
- **July 2022**
 - Clinical Staff report progress made with patients in 2 focus cohort groups.
 - Data collection process agreed.
- **Aug 2022**
 - Specialist Nurse links in with colleague in neighbouring locality for conversation on best practice from a similar project.

- Steering Group agree to do patient re-test at 6 weeks instead of 3 months to expedite progress.
- Project to be extended in view of inability of clinical team to devote 2 days/ week every week.
- **Oct 2022**
 - Reported that 4 patients have been referred to secondary care endocrinologist. One of these was prescribed PCSK9i.
 - A key learning is identified: Future projects should factor in admin time/ support.
- **Jan 2023**
 - Confirmed that pathway into endocrinologist-led lipid management service will remain open after project close though the setting up of dedicated consultant-led lipid clinics.
 - Discussion around publicising results
- **Feb 2023**
 - Available data to-date presented to steering group. Learnings shared.
- **Mar 2023**
 - End of clinical project timeline. Last consultations and blood tests. A total of 151 appointments had been given during the course of the project, of which 6 appointments had not been attended by the patients. This was an excellent attendance rate in those patients who agreed to participate.
 - Completion of data input and analysis.
- **Apr 2023**
 - First draft of evaluation report produced.
- **May-June 2023**
 - Project team review and discuss evaluation report (delay due to annual leave).
- **July 2023**
 - Project report finalised.

5.0 Outcomes and Benefits Achieved

The table below outlines the key project outcomes against the objectives of the project.

Objective	Outcomes and benefits achieved
Identification of patients who may benefit from lipid optimisation services	<ul style="list-style-type: none"> • FH Cascade Screening education delivered to 4 primary and secondary care HCPs prior to clinical project start. • Secondary prevention cohorts identified through specialist nurse primary care data searches.
Develop links between primary and secondary care clinicians (nursing, GP, pharmacist) to develop a lipid treatment pathway across the health economy	<ul style="list-style-type: none"> • Lipid pathway established between primary care and secondary care. The primary care team noted the timely review of these patients by Consultant once referred. • 4 patients referred to endocrinologist for specialist intervention. One of these was prescribed PCSK-9 inhibitor. • Endocrinologist-led lipid clinics in process of being set-up at East Lancashire Hospitals NHS trust, Go Live date 1st August 2023. This project was the catalyst for this development. • Endocrinology specialist nurse has been appointed in the service at East Lancashire Hospitals NHS Trust, currently in induction phase, whose role is expected to include supporting the lipid clinics
Implement lipid treatment pathway, including education events and training of relevant primary and secondary care professionals	<ul style="list-style-type: none"> • Adopted AAC/ NICE Guidelines for lipid treatment. • Internal secondary prevention education session at East Lancs NHS Trust delivered on 01/03/23. A direct result of awareness raising within the team from participation in this project, resulted in a request for the teaching. Findings from the project were shared with team.



	<ul style="list-style-type: none"> • Education delivered to wider primary care workforce. Meetings held on 02/02/23 and 23/03/23- all for practice nurses. • Education of practice pharmacists.
Specialist nurse-led follow up of patients, including monitoring of treatment, side effects and appropriate referrals to relevant services	<ul style="list-style-type: none"> • Specialist nurse was the main clinical team member delivering the patient contacts and interventions with the support of the GP Principal and secondary care consultant.
Use of prescribing pharmacists to achieve the standards set out in NICE TA393 and TA394 to work alongside existing medical teams to optimise therapies, including referral to consultant endocrinologist or consultant cardiologist if appropriate.	<ul style="list-style-type: none"> • Practice pharmacist provided some support to follow up and optimise patients' care in collaboration with Specialist Nurse.
Optimisation of oral lipid lowering therapies for patients with FH and patients requiring secondary prevention following cardiovascular event	<ul style="list-style-type: none"> • Two secondary prevention patient cohorts as described above were targeted for intervention with a total of 266 patients. • 95 patients were contacted for lipid optimisation. 55 patients accepted and received lipid lowering interventions • At the end of the project 20 of 55 patients (36% of patients receiving interventions) achieved target lipid levels. 19 patients (35%) had not had a repeat blood test following their last intervention. • Following end of project timeline all patients are expected to continue to be followed up within the standard primary care service, with those identified as needing injectables to be referred to secondary care.

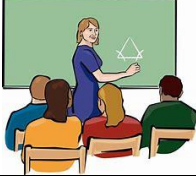

Detailed Processes and Outcomes:

Priority Three: Patients with sub optimal non-HDL (>2.5mmol/l) levels despite maximal statin therapy	
Total population at initial data search	40
Not clinically suitable for project as per agreed criteria	9
Did not want to participate	5
Already to target on project start	14
Patients targeted for intervention	12
Ezetimibe Added	9
Number of patients on max dose of statin + Ezetimibe at end of study	9
Number of patients declined additional treatment	3
Summary outcomes	
Total Patients optimised (following ezetimibe intervention)	4

Lipid levels improving at last blood tests during project	4
Average Non-HDL Reduction	1.1
Potential Patients eligible for injectables	0
Priority TWO (B): Patients on a suboptimal intensity statin	
Total population at initial data search	226
Not clinically suitable for project as per agreed criteria	35
Did not want to participate	4
Already to target on project start	79
Patients already to target at first appointment	25
Patients targeted for intervention	83
Did not manage to see within project timeline	25
Number of patients declined additional treatment/ no intervention given	12
Total number of patients who received lipid lowering intervention	46
Ezetimibe Added	2
Statin intervention (dose/preparation change)	32
Number of patients receiving both statin intervention and Ezetimibe	6
Number of patients receiving other LLT (ezetimibe/bempedoic acid & Icosapent ethyl)	6
Number of patients on maximum dose of statin + Ezetimibe at end of study	6
Summary outcomes	
Total patients optimised	16
Total patients improving (of whom 19 have not had a repeat blood test within project timeline following their last intervention)	30
Average Non-HDL Reduction*	0.6
Potential patients eligible for injectables	4
*out of 46 patients who were not at target on first consultation and accepted amendments to LLT	

Over a period of 12 months of the project timeline

	<ul style="list-style-type: none"> • Specialist nurse-led service established in Oakenhurst Medical Centre for duration of project. • Practice pharmacist received in-house training and supported the project. • Close collaboration with endocrinologist for lipid optimisation established • Specialist endocrinologist-led lipid service in process of being set up at ELHT, Go Live date 1st August 2023- increasing capacity to see high risk patients.
	<ul style="list-style-type: none"> • During nurse-delivered education, patients received information on self-management of their cholesterol.

	<ul style="list-style-type: none"> • Several key educational sessions delivered across area, sharing findings of project.
	<ul style="list-style-type: none"> • 95 patients were contacted for lipid optimisation. • 20 patients (36% of patients receiving lipid lowering interventions) achieved target lipid levels by the end of the project. • PRIORITY THREE: Average LDL Reduction: 0.9 mmol/l Average Non-HDL Reduction: 1.1 mmol/l • PRIORITY TWO (B): Average Non-HDL Reduction: 0.6 mmol/l (* out of 46 patients who were not at target on first consultation and accepted amendments to LLT).

7.0 Challenges and Issues

- Administrative staff at surgery were unable to help with texting appointments or sending appointment letters as this was not included within the Practice budget.
- In view of the lack of administrative support at the practice, it was time-consuming for the specialist nurse to follow the process of:
 - Contacting all patients
 - Arranging all appointments to follow up blood results
 - Contacting all the patients again to discuss results and offer follow up as appropriate.
 - Repeating process if patients were not to target. Some patients needing up to 4 consultations.
- If a patient had raised blood pressure or other concerns, Specialist Nurse was not familiar with Primary Care procedures and had to seek advice from surgery staff to help signpost patient to correct HCP.
- Reference Range on Laboratory reporting system does not indicate specific secondary prevention targets. This led to some patients not willing to engage due them believing that their markers were in range.
- If Total Cholesterol was to Reference Range target, other parameters were not addressed.
- Blister packs for medication were problematic as some patients did not like to waste medications and were reluctant to double the doses as it would impact on other medications within the packs.
- Availability of Point Of Care Testing (POCT) throughout the project timeline would have sped up process significantly. There were technical challenges around getting this installed. It takes at least 2 weeks for patients to get an appointment for blood tests in the usual practice setup.
- Completing the data base was extremely time-consuming.

8.0 Observations and Lessons Learned

A number of key observations were made and lessons were learned that would be valuable for other project groups to know if they were to explore a similar pathway transformation:

- The importance of having dedicated Project Management time devoted to co-ordinating the implementation of the project.

- The benefit of having a Project Steering Group to oversee and monitor implementation of the project as this has helped to keep the project on track and has supported the management of issues and risks in a timely manner. Monthly meetings worked well in co-ordinating the project.
- The importance of setting out clearly at the start of the project the expectations from all partners. Involvement of the administrative staff of the practice would have freed up clinical time for the specialist nurse to focus on patient care and improving patient clinical outcomes. Contracts should include all parties in order to ensure this. Also, time spent prior to project start in educating the staff around the value of the project to the patients, could have achieved improved engagement.
- The importance of setting out at the start of the project the outcomes to be achieved and the outcome measures to be used to evaluate the benefits of the project. Data sets should be streamlined to the minimum dataset required for key process and outcome measures (interventions received, end of project blood test results).
- Installing and ensuring working equipment (POCT) and completing staff training prior to project start.
- Counselling of patients in the context of previous adverse publicity on statins and previous lack of patient engagement and knowledge about lipid targets was very time consuming.
- It should be possible with sufficient dedicated resource and a healthcare set-up that is smoothly functioning in all supportive functions to optimise to target a good proportion of secondary patients within primary care. This project suggests that of the 268 patients in the two groups initially identified for optimisation, 118 (44%) were already at target by the time of clinical project start and first attempted contacts. 36% of patients receiving lipid lowering interventions during the study timeline were at target when re-tested within study timeline.
- By up-titrating statins directly to maximum dose of at least moderate intensity statin (Atorvastatin 80 mg daily equivalent) rather than step wise, patients may have reached target faster and with less HCP intervention requirement, so that more patients could have received interventions, instead of a smaller proportion of patients receiving multiple appointments and interventions.
- The data suggests that between 5-10% of patients (7% in our dataset identified so far) in PRIORITY TWO (B) may need injectable therapy.
- Significant additional resource would be required to address patients in PRIORITY ONE, not on any statin, as this is likely to require more discussion time with patient, and to address identification of FH patients.

8.1 Recommendations

- Comments included in lab results, highlighting clear targets for high-risk patients, could improve patient understanding and need for consultation and optimisation of lipid profile. A new domain for secondary prevention has now established in QoF, and the clear non-HDL target of ≤ 2.5 mmol/L will be helpful going forward. This needs to be clearly stated in laboratory reports.
- Emphasis should be put on installation of POCT equipment in primary care and training practice staff on their use in order to speed up lipid management and management of other conditions amenable to POCT. This would reduce demand on the venesection and laboratory services and improve access to venesection for other patients and other investigations not amenable to POCT.
- Having demonstrated that it is possible with dedicated resource to optimise to target a large proportion of secondary prevention patients in Primary Care, there should be dedicated resource for PCNs to provide support to practices on the model demonstrated, to maximise lipid optimisation therapy for such patients in primary care, improving patient outcomes, while releasing capacity both within primary care for GPs and in secondary care.
- Lipid treatment optimisation for CV prevention is not currently part of the PCN Pharmacist remit within the routine pharmacist led structured medicines review service. PCNs should review the remit of these services

and consider whether including optimising lipid treatment could form part of their structured medication reviews. Many of these patients are eligible for the structured medication review process.

9.0 Next Steps

- Share recommendations with regional lipid steering group and ICB CV Prevention Group.
- Continuation and expansion of endocrinologist led specialist lipid clinic to address the substantial unmet need, especially in identification of FH patients.
- The participating GP Principal will be doing pharmacist education for the whole PCN in September 2023, so will cascade the learning and recommendations and look to incorporate lipid targets for the pharmacist-delivered structured medication reviews. He is working on rolling this out in one locality in PCN initially.

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