Improving the identification and management of patients with Familial Hypercholesterolaemia (FH) and patients with cardiovascular disease and primary hypercholesterolaemia/mixed dyslipidaemia in Leicester, Leicestershire & Rutland.

This Project was agreed as part of the Accelerated Access Collaborative (AAC). The AAC was formed in response to the independently chaired Accelerated Access Review published in October 2016. The AAC brings industry, government and the NHS together to remove barriers to uptake of innovations, so that NHS patients have faster access to innovations that can transform care.

The joint working project was completed at the end of 2021 following a number of delays due to the Covid-19 pandemic.

Below outlines the outcomes against the original objectives for the project.

Please briefly outline the key objectives and outcomes the project set out to achieve as stated in your application. How has the project performed against these?		
Proposed objective/outcome	Status *Achieved, Partially Achieved, Not achieved*	Narrative
To identify and optimise lipids in two cohorts in primary care across Leicestershire: 1) Patients with Cardiovascular disease (CVD) and Low Density Lipoprotein (LDL) >3.5 mmol/L 2) Identify patients with possible Familial Hypercholesterolaemia (FH)	Achieved at a pilot level	The project aimed to identify and optimise lipids in two cohorts of patients, in primary care, across Leicestershire. These were patients with either CVD and LDL >3.5 mmol/L or patients with possible FH. Once identified, the patients were reviewed and managed by the Lipid Team through virtual and face to face clinics. The project enabled University Hospitals of Leicester (UHL) NHS Trust to employ a clinical fellow and a nurse to manage the workload associated with the project. 2052 patients from 7 GP practices in Leicester were identified and given information regarding the project. Out of these 511 patients showed interest to take part in the project. These patients were sent blood forms and a detailed questionnaire. The response rate was 81% (413) patients responded with questionnaires and having undertaken blood tests. 64 patients were discharged right at the beginning of the project as they were misidentified by searches and did not meet the criteria for FH or have a history of

		CVD. Their GPs were advised to optimise lipids as per local guidelines and they were discharged back to primary care.1 patient unfortunately passed away after their first review. Of the remaining 348 patients reviewed, 68 patients are awaiting their subsequent review and/or blood test. 280 patients showed an average LDL reduction of 30.06%. 120 patients achieved ≥ 40% reduction in LDL. 116 patients achieved <40% reduction in LDL. 23 patients no reduction in LDL. 21 patients had a recorded rise in LDL primarily due to non-adherence, medication intolerance and reluctance to start on medications. 62.95% patients have been prescribed a high intensity statin and 103 patients had addition of ezetimibe. 17.92% of patients had their cholesterol levels optimised and were then discharged. 137 patients were to be seen in the lipid clinic, either for physical assessment to identify FH, to determine eligibility for PCSK9 inhibitors, in accordance with local / national guidelines, medication optimization or to devise a treatment plan for patients with multiple drug intolerances. 10 patients were assessed for PCSK9i eligibility and 3 patients were commenced on PCSK9 inhibitors. All of the above patients were assessed and managed in a holistic way including making referrals to other disciplines, such as, chest pain rapid access clinic, stroke clinic, sleep clinic. We have also requested the GP to refer patients to

		weight loss management programmes. Also where needed, further investigations including special blood investigations (liver, renal screen) and radiological investigations were performed. All patients were given advice regarding lifestyle modification.

What have been the key achievements and highlights of the project?

The key achievements of this project which were:

- 2052 patients identified with 413 patients responding. 17.92% of patients had their cholesterol levels optimised and have been discharged.
- We achieved an average percentage LDL reduction of 30.06% in 280 patients with ≥ 40% reduction in LDL in 120 patients.
- Approximately 70% of case management was undertaken remotely, demonstrating that it is effective and accepted by patients.
- The majority of patients did not require PCSK9i, instead required up titration of their statins with 30% requiring ezetimibe
- Approximately 15% of patients had no reduction in lipids or a paradoxical rise, showing possible non-adherence which needs to be addressed by discussion and better information.
- Improved health awareness among our cohort of patients by providing advice on lifestyle modification.
- Genetic testing for 36 patients with probable and definite FH, 18 were identified by Dutch criteria and 18 by Simon Broome.
- Improved awareness among patients about the pattern of inheritance and possibility of passing FH down to generations thereafter. We also identified associated co-morbidities and ensured appropriate referral and multidisciplinary care

What challenges and issues were encountered and how did these impact on the project performance?
• COVID-19 delayed the project for approximately a year and impacted patient participation in the project. The response rate and engagement with primary care was very limited, only seven practices responding, despite a number of attempts through CCGS leads, raising awareness through presentations at protected learning events and contacting some GPs personally. • 2052 patients were made aware of the project however only ~25% initially responded, with 20.13% of patients completing the questionnaire and having bloods taken. Patients voiced their reluctance to travel to a healthcare centre for investigation due to the fear of exposure to COVID-19 infection. • An important impediment was the inability of secondary care to directly conduct searches on GP database due to GDPR issues.
What are the key lessons learned that you think would be valuable for other adopting sites to know if they attempted a similar pathway transformation?
The key lessons learnt are: • Virtual management of patients is possible and could be effective. • Initiatives such as this project need to be linked with raising awareness through social and regular media: for example, Patient education campaigns, pamphlets “Know your number” so patients can take ownership. This will help improve response rates.

- While local initiatives can work, unless there is a strong national directive by bodies such as NHSI uptake in primary care will be variable. The CVD audit which has reported its findings needs to be linked with incentives such as QOF for optimisation of Lipids
- Future projects have to be COVID-19 proof
- Optimisation within the project was achieved without PCSK9i in the vast majority of patients. The project demonstrates the need for increased education in primary care about the use of Ezetimibe.
- Optimisation of care of patients with CVD while they are inpatients, in rehabilitation or when discharged with a clear plan in discharge letters focusing on the need to add Ezetimibe within 4 -6 weeks if LDL is not at target may be a useful measure
- Further, it is important to lower barriers of access to primary care data in secondary care and development integrated care services will be of help.

What are the next steps now the project has concluded? How will the change be embedded and made sustainable? Are you planning further developments to build on the work of the project

The Trust plans to:

1) Link advice to a simplified one-page pathway (adopted from the ACC pathway – approved by NICE) to the electronic PRISM patient referral pathway- so that more patients will be prescribed Ezetimibe.
2) Initiate involvement of community Pharmacists and set up MDTs to help optimise lipids.
3) Education of GPs and Allied Health Professionals (AHPs) through protected learning time events.
4) Consolidate and embed our identification of patients with CVD through Myocardial Ischaemia National Audit Project (MINAP - a national database of pts with CVD that each cardiology department across UK must maintain). Since the last 2 years, we have an agreement with Cardiology and regularly access these records to review patient results, if required send them blood forms and letters to GP to optimise the lipids and call them to clinic.

5) We will be unable to add a standard comment to the discharge letter about the need to start Ezetimibe (due to current limitations of our IT system) but this will be kept under review.
6) This project, as conducted, has been identified by our secondary care team for pathway transformation but whether it will be accepted by the new Integrated Care Board (ICB) is uncertain.

In what demonstrable way has the project tackled health inequalities?

Leicester has a higher CVD risk than the national average. This disparity is higher in the Leicester city population vs. the rest of Leicestershire. Amongst the seven surgeries that participated in the project six were from Leicester city.
10 patients who did not have access to get online resources such as heart UK were posted information leaflets for lifestyle modification.
1 patient who struggled as a result of a language barrier had an interpreter arranged and 1 patient with mobility issues had phlebotomy arranged at home.

Quantitative feedback

Metric / measure	Number	Comments
Number of secondary prevention patients who have had an adverse reaction to statins	7	Adverse effects most commonly experienced were muscle aches, generalised weakness and rarely deranged LFT.
Number of secondary prevention patients who have accessed ezetimibe	13	Out of the 27 secondary prevention patients only one patient was already on ezetimibe prior to being part of the project, 13 others were started on ezetimibe.
Number of secondary prevention patients who have accessed PCSK9i Alirocumab 75 mg Q2W	0	
Number of secondary prevention patients who have accessed PCSK9i Alirocumab 150 mg Q2W	0	
Number of secondary prevention patients who have accessed PCSK9i Evolocumab 140 mg Q2W	1	A total of 3 patients were started on PCSK9i, only one of them was a secondary prevention patient.

Number of secondary prevention patients who have accessed other drug/dose/frequency combinations	13	13 patients were initiated on ezetimibe.
Number of secondary prevention patients who had an adverse reaction to PCSK9i drugs	0	
Percentage of secondary prevention patients who had their annual medicine review with a blood lipid profile	n/a	
Percentage of secondary prevention patients who had their annual medicine review without a blood lipid profile	n/a	
Number of secondary prevention patients not eligible for PCSK9i therapy	4	Out of 10 patients referred for PCSK9i eligibility 3 have been started on PCSK9i, 4 are not eligible while 3 others are awaiting risk stratification.

The outcome measures listed in the bid are as follows:

o Total number of patients reviewed: 413

o Patients with suboptimal lipid control reviewed: 348 (as 64 were discharged immediately after the first review and 1 passed away)

o Patients with changes to statin therapy and % patients who have been put on a high intensity statin: 311 and 62.95% respectively.

o Patients with addition of ezetimibe: 103

o Patients referred for PCSK9i eligibility: 10 (3 were initiated on PCSK9i)

o % patients whose cholesterol has been optimised: 17.92%