



Joint working executive summary

<p><i>Project title</i></p>	<p><i>Improving the identification and management of patients with Familial Hypercholesterolaemia and patients with cardiovascular disease and primary hypercholesterolaemia / mixed dyslipidaemia in Leicester, Leicestershire & Rutland.</i></p>
<p><i>Partner organisation/s</i></p>	<p><i>University Hospital of Leicester NHS Trust & Sanofi.</i></p> <p><i>This Project has been agreed as part of the Accelerated Access Collaborative (AAC).</i></p> <p><i>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.</i></p> <p><i>The AAC supports the rapid uptake of products from 7 high-potential technology areas, selected by leaders in the health and care system, with full evidence-based recommendations from NICE, and have potential to deliver cost-savings in year.</i></p> <p><i>PCSK9 inhibitors for the management of hypercholesterolemia were selected as one of the seven NICE recommended rapid uptake products (RUP) to increase patient access and remove barriers across the health innovation landscape.</i></p> <p><i>Funding announced by government in July 2017 is available through the new Accelerated Access Collaborative Pathway Transformation Fund (PTF) to help NHS organisations integrate the rapid uptake products into everyday practices. Delivered with the support of the Academic Health Science Networks (AHSNs) the PTF seeks to improve equality of access to these products.</i></p> <p><i>The PTF, in relation to PCSK9 inhibitors, combines funding from NHS England, Amgen and Sanofi for selected projects to meet the AAC objectives and increase PCSK9i uptake by addressing barriers such as:</i></p> <ul style="list-style-type: none"> <i>• Lack of patient identification</i> <i>• Inconsistent Pathways</i> <i>• Limited awareness</i> <i>• Restricted prescribing</i> <i>• Sporadic LDL-C measurement</i> <i>• Treatment complexity</i> <p><i>19 applications relating to PCSK9 inhibitors from 12 AHSNs were submitted to the AAC for PFT funding (funding from NHS England, Amgen and Sanofi) and 6 were selected, including University Hospitals of Leicester. Please see resources and costs for more detail.</i></p>

	<p>NHS England have provided equal PTF to the Academic Health and Science Network North East North Cumbria (AHSN-NENC). AHSN-NENC will distribute this accordingly as agreed by the AAC to the 6 successful sites, one of which being Partner for the Project.</p> <p>Details of the parallel funding can be found on Amgen's joint working website.</p>
<i>Project rationale</i>	<p>UHL runs one of the busiest Lipid Service in UK. Annually, around 2,500 patients are seen in the Lipid Clinic and 700 patients in the Virtual Clinic.</p> <p><i>Secondary care pathway</i> Patients with CVD are referred to the Lipid Clinic by rapid access chest pain, cardiology outpatients, cardiac rehabilitation, stroke and vascular clinics. Recently, a novel pathway using MINAP – a cardiac database of all MI patients, has been established. Lipid results of MI patients are reviewed at 3 months post discharge, followed by a letter to the GP to optimise treatment by adding Ezetimibe and/or up titrating statins. A second review is undertaken in a further 3 months and those patients whose lipid results are suboptimal are seen in the Lipid Clinic. A similar pathway is being developed for stroke/LEAD patients.</p> <p><i>Primary care pathway</i> Referral of patients to the Lipid Clinic is recommended as per the local Lipid Guideline. But the quality of referrals is heterogeneous due to information overload in primary care. To improve use of guidelines, pop up boxes on ICE (electronic request system for bloods tests including lipids) and on electronic referrals system will be introduced in the month. These pop boxes will suggest a referral if LDL > 3.5 mmol/L despite optimal treatment and will link to local lipid guidelines.</p> <p>Further, FH cases are referred on an adhoc basis as there is no FH cascade screening service in East Midlands currently. This is being rolled out and this will be in place by May 2020. The above pathways will cover new cases with CVD or suspected FH -both in primary and secondary care, however, a pathway is needed to identify patients with existing CVD or possible FH who are already in primary care databases. The proposed project will aim to identify this important cohort of patients.</p>
<i>Project period</i>	<p>Quarter 2 2020 to Quarter 3 2021</p> <p>The Impact of Covid 19 is likely to lengthen these timelines.</p>
<i>Project objectives</i>	<p>Expected Predicted Benefits for Patients</p> <ul style="list-style-type: none"> • Increased diagnosis rate and improved management of FH, primary hypercholesterolaemia and mixed dyslipidaemia. • These patients can be treated with appropriate doses of cholesterol lowering medicines according to local guidelines which will lower their risk of cardiovascular disease / event (stroke, myocardial infarction or peripheral vascular disease).

	<ul style="list-style-type: none"> • <i>These patients can be educated on FH and cholesterol, diet, exercise and the importance of a healthy lifestyle.</i> • <i>Patient empowerment and engagement in terms of their diagnosis and subsequent clinical management plan (NICE – patient participation is of importance regarding decision making in terms of drug therapy etc)</i> <p><i>Predicted Benefits for NHS Organisations</i></p> <ul style="list-style-type: none"> • <i>Reduce variation in identification and treatment of FH, primary hypercholesterolaemia and mixed dyslipidaemia across Leicestershire.</i> • <i>Assist PCNs in identifying and managing patients with cardiovascular disease in line with the NHS Long Term Plan</i> • <i>Supports implementation of NICE CG71.</i> • <i>Reduction in cardiovascular disease burden amongst Leicestershire patients will reduce associated hospital activity.</i> <p><i>Predicted Benefits for Sanofi</i></p> <ul style="list-style-type: none"> • <i>The project aims to increase the FH, hypercholesterolaemia and mixed dyslipidaemia diagnosis rates. 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 and or local / national guidelines.</i> • <i>Demonstrates collaborative working with the NHS to the benefit of patients and identifies scalable solutions.</i> <p><i>The results of the project will be written up and published to enable the learnings from the project to be shared.</i></p>
<p><i>Contact details</i></p>	<p><i>Sanofi- Fleur Chandler- Head of Market Access 410 Thames Valley Park Drive, Reading, Berkshire. RG6 1PT. GB-MarketAccess@sanofi.com</i></p> <p><i>Dr Pankaj Gupta- Consultant Lipidologist University Hospital of Leicester NHS Trust Department of Metabolic Medicine & Chemical Pathology Sandringham Building. Leicester Royal Infirmary, Leicester, LE1 5WW. Telephone 0300-303-1573</i></p>