NHS

Health InnovationNetwork

Improving cardiovascular health

A summary of the impact of the lipid management and familial hypercholesterolemia national spread programme



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Introduction

The lipid management and familial hypercholesterolaemia national programme ran from October 2020 to March 2023. It was delivered by the <u>Health Innovation Network</u> across England and commissioned by NHS England (NHSE).

The ambitious programme aimed to increase the adoption and adherence to a NICE-endorsed <u>patient pathway</u> for lipid management.

With patient benefit being at the heart of all activities, the programme adopted a whole-system, cross-sector, pan-industry, multi-disciplinary and multi-agency approach to implement population-level strategies for the improved uptake of lipid lowering therapies and increased

diagnosis of the genetic disease familial hypercholesterolemia (FH).

This summary provides an opportunity to showcase the highlights collated from the following:

- An <u>impact report</u> was published in October 2023 capturing the programme's process and its reach, with case studies from the some of the fifteen participating health innovation networks.
- An independent evaluation has been completed by <u>Unity Insights</u>, which provides data on the programme's impact.

A separate evaluation on the use of inclisiran (which forms part of the programme) is to follow.



How did the programme work

The programme was led on behalf of the network by Health Innovation North East and North Cumbria and was launched in October 2020. The aim was to support Clinical Commissioning Groups (CCGs), and later Integrated Care Boards (ICBs) to increase the uptake of lipid lowering therapies, increase the identification and management of people with FH, and enable adoption of the endorsed pathways.

With a focus on primary care (at both GP practice and Primary Care Network levels), it achieved this through engagement and education events, supporting clinicians to identify those at risk, so they could in turn support patients to lower their lipid levels.

It was anticipated that these activities would increase prescribing rates in relevant medicines:

- high intensity statins (HIST);
- ezetimibe; and
- PCSK9 inhibitors (PCSK9i).

These interventions should have an eventual impact on lipid levels, which in turn will lead to a fall in the number of cardiovascular events.

Genetic testing for familial hypercholesterolemia was expected – in the short-term – to show an increase in the prevalence of the condition.

Factors affecting the programme

During the programme, a number of changes occurred, which affected its delivery. These external factors necessitated incremental changes to the aims and scope of the programme and the resource requirements:

- The introduction of lipid management treatments within the Accelerated Access Collaborative's <u>Rapid Uptake</u> <u>Products</u> portfolio. This programme identified and supported products with NICE approval, which support the NHS Long Term Plan's key clinical priorities, but have lower than expected uptake to date.
- Other programmes impacted the lipids and FH programme, including the Health Innovation Network's <u>blood pressure</u> <u>optimisation programme</u> in April 2022 and NHS England's <u>Innovation for</u> <u>Healthcare Inequalities (InHIP)</u> programme in October 2022.
- The introduction of novel therapies by NICE: bempedoic acid in April 2021 and inclisiran in October 2021.
- The COVID-19 pandemic occurred in early 2020.

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What started off as a programme focused upon detection of those with familial hypercholesterolaemia, soon evolved into much more than that, recognising the importance of cholesterol in cardiovascular risk, and the opportunities to improve lipid management even in those without FH.

After a year, we absorbed the ongoing rapid uptake product lipid programme of PCSK9i which had until then run in parallel, allowing us to truly adopt and spread a whole pathway approach to lipid management.

Within that same year the approval of inclisiran and the role of the Health Innovation Network in the implementation of this novel technology really shone a light on our programme and the importance of optimising lipid management if we are to reduce CVD prevalence and the associated health inequalities.

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Professor Julia Newton, Medical Director, Health Innovation NENC (from the impact report)



Lipid management and familial hypercholesterolemia programme

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The potential for patients

The British Heart Foundation estimates that 4 million men and 3.6 million women were living with heart and circulatory diseases in the UK in 2023, and that these diseases cause around 160,000 deaths each year, or one in four deaths in the UK.

Cardiovascular disease (CVD) is also the cause of around 1.18 million hospital admissions and incurs costs of approximately £19bn in the UK each year.

High cholesterol is one of the most significant risk factors for cardiovascular

disease – the single biggest condition where lives can be saved by the NHS over the next 10 years.

CVD is estimated to affect seven million people within the UK, with approximately 28% of CVD deaths due to elevated levels of cholesterol.

Familial hypercholesterolemia is a common inherited disorder associated with elevated LDL cholesterol (sometimes referred to as 'bad cholesterol'), which affects around one in 250 people. Left untreated it can lead to premature coronary heart disease.

The potential for systems

Cardiovascular disease is one of the core clinical areas identified for improvement within the NHS Long Term Plan. It has also been recognised in NHS England's Core20PLUS5, where hypertension and lipid management are one the five adult clinical focus areas where health

inequalities are being addressed.

Treatment with lipid lowering therapies is highly effective at reducing the risk of major adverse cardiovascular events, such as heart attacks and strokes, resulting in direct benefits for the healthcare system.

Evaluation methodology

The independent evaluation carried out by Unity Insights on behalf of the Health Innovation Network used a mixed methods, retrospective approach to explore the implementation of the lipids and FH programme. The aims were to understand impact of programme on the NHS system, its staff, and patients, and to provide recommendations that may support future spread and adoption programmes.

Quantitative analysis of national datasets was undertaken to understand the changes to prescribing volumes both over time and in different geographies. Spread and adoption data was used to establish any links between uptake of the programme and changes to prescribing rates.

Interviews and focus groups were held with stakeholders on the work undertaken, the methods used, and to identify unquantified benefits. The thematic analysis looked for levers for, and barriers to, success. The key questions agreed for the evaluation were:

- How has lipid management prescribing changed since the start of the programme?
- How has knowledge and acceptance of the NICE pathway changed since the start of the programme?
- What are the key enablers and barriers to success?
- What are the wider impacts of the programme?

Figures in this summary report include data from this evaluation and also from other sources, where referenced, such as CVDPREVENT and UCLPartners 'Size of the Prize' infographics.



Programme impact

How has lipid management prescribing changed since the start of the programme?

The evaluation found emerging data to suggest that rates of ezetimibe and PCSK9i prescribing may have changed as a result of the programme, with an additional 9,971 people receiving lipid lowering therapies due to adoption of the programme.

Due to the nature of the patient pathway and complexity of the intervention, it was

not possible to observe changes in high intensity statins during programme delivery. However, it is expected that prescribing practice will change following adoption of the national lipid management pathway and application of NICE guidelines and implementation of the QOF cholesterol management clinical indicators.

Activity between March 2021 and September 2023



High intensity statin

prescribing, as a proportion of all statin prescribing, increased from 62% to 71%, compared with a 3% increase in the year prior to the programme's launch.

Ezetimibe prescriptions increased from 164,970 to 254,654, a net increase of 89,684 during the programme, which represents a 54% increase in uptake.

This indicates that approximately 9,167 additional people started treatment as a result of the programme.

PCSK9i prescriptions increased from 7,496 to 10,674.

This indicates that approximately 804 people started PCSK9i treatment as a result of the programme.



Rates per 100,000 person years for genetically confirmed familial hypercholesterolemia increased from 9.6% to 13.8% (data from CVDPREVENT,

measure CVDP003FH).

The total proportion of people with known CVD treated to NICE-recommended LDL cholesterol thresholds increased from 23.7% to 27.8% (March 2021 – March 2023, data from CVDPREVENT).



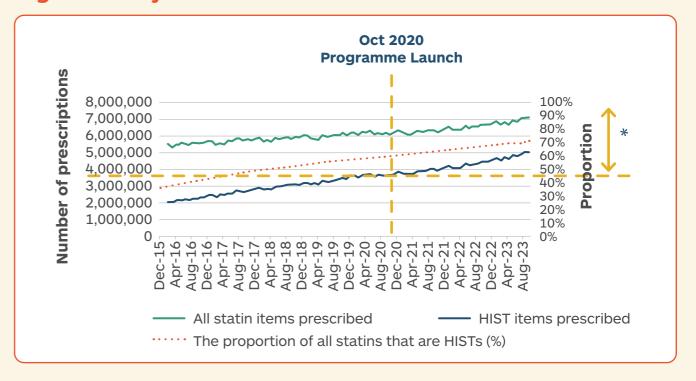
9,422 CVD events, such as heart attacks or strokes, may have

been prevented.*

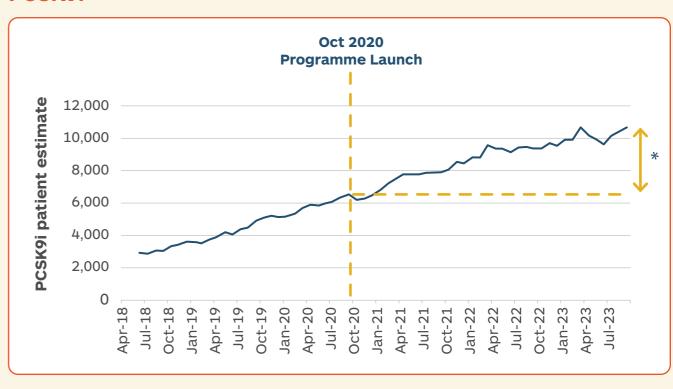


This equates to an estimated cost avoidance to the NHS of between £124m and £150m due to heart attacks and strokes prevented.*

High intensity statins



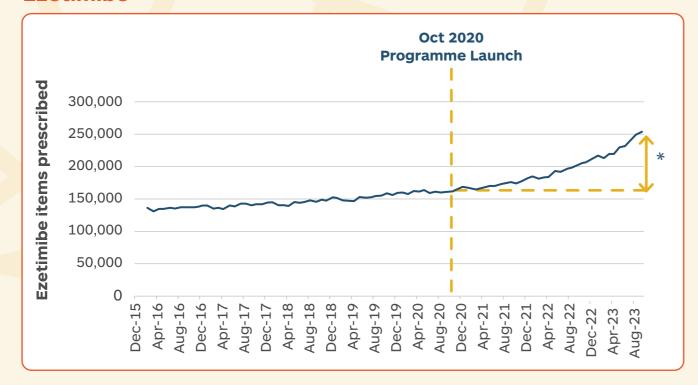
PCSK9i



PCSK9i patient estimate displayed as a 3-month rolling average.

^{*} Demonstrable increase in uptake of lipid-lowering treatments over the duration of programme delivery.

Ezetimibe



Ezetimibe items prescribed as a 3-month rolling average.

How has knowledge and acceptance of the NICE pathway changed since the start of the programme?

The NICE endorsement pathway has been the programme's golden thread connecting all key stakeholders.

Significant numbers of clinicians across primary care benefited from a range of education and training opportunities, as well as access to risk stratification tools to identify and treat patients most at risk.

Local surveys completed at the end of these training sessions demonstrated the value clinicians placed on the training. Their knowledge of the pathway had improved, and health innovation networks supported the sharing of best practice, by highlighting local outcomes and creating case studies demonstrating the work they undertook.



When there's more focus on the drugs rather than the pathway, that has been a massive uphill struggle for us, the way that the system feels like they weren't consulted on a lot of things, and targets having to be met and how realistic they are.



Learning from the programme

The Health Innovation Network has significant experience of spreading innovation in local systems for national impact. The lipid management and FH programme has been a good example of how a targeted national spread programme has resulted in increased adoption, which is evidenced by data on patient outcomes.

The support of individual health innovation data that can help cometworks has been invaluable in making this a and pathway changes.

reality on the ground. Their ability to connect stakeholders and work across different parts of the system – in this case principally with primary care – pays off with improved engagement and tailored approaches that take account of local needs and priorities.

This is turn can positively affect the national landscape, helping to provide data that can help commissioning, funding, and pathway changes.

What are the key enablers and barriers to success?

Enablers

Leadership

Support from the central Health Innovation Network team to regional teams enabled the development of localised implementation plans.

Communication

Central communication plan allowed for timely communications and updates to regional teams on programme updates.

Strategic alignment

The programme aims aligned with system requirements, resources and incentives to support primary care.

Education

Delivery of a national education and training programme in collaboration with Heart UK, 'Tackling Cholesterol Together'.

Funding

Opportunities to bid for national funding enabled the development of innovative projects, such as Pathway Transformation Fund support for system-wide clinical service redesign. There were also incentives to focus resources on case finding and management.

Evidence

NICE lipid management guidance and technology appraisal guidance included all novel therapies, while also recommending an LDL-c target and full lipid profile, before commencing any lipid lowering therapy, in line with national lipid management pathways.

Resources

Development and spread of engagement tool, such as the NICE-endorsed pathway, enabled reduction of national variations in lipid optimisation.

^{*} Demonstrable increase in uptake of lipid-lowering treatments over the duration of programme delivery.

Barriers

There is a finite amount of resource available in primary care, and those resources must align with local and national strategies. The most common barrier involved competing requirements from other CVD-focused initiatives.

Capacity

During the lifetime of the programme, additional focus areas like hypertension and the introduction of novel therapies such as inclisiran risked diluting the capacity of clinicians to focus on lipid management.

Capability

There was a lack of education and awareness of cholesterol management and its importance in the context of reducing CVD events.

Incentives

At the start of the programme, there were no financial incentives to divert staff to case finding. The provision of incentives is key to unlocking otherwise stretched resources.

COVID

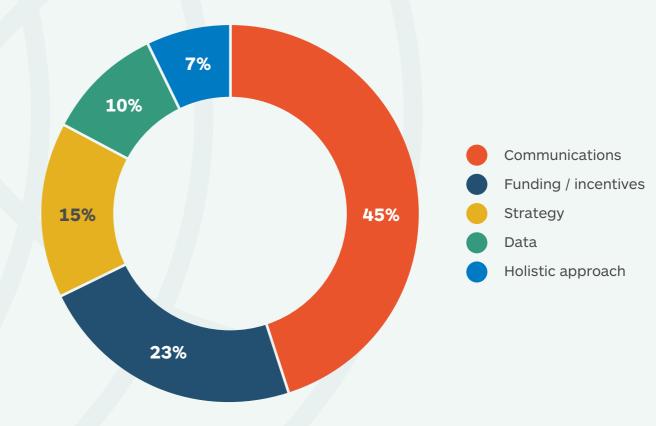
Created a barrier to uptake of the programme as the system pivoted first to managing the pandemic and then to the vaccination programme.

System stability

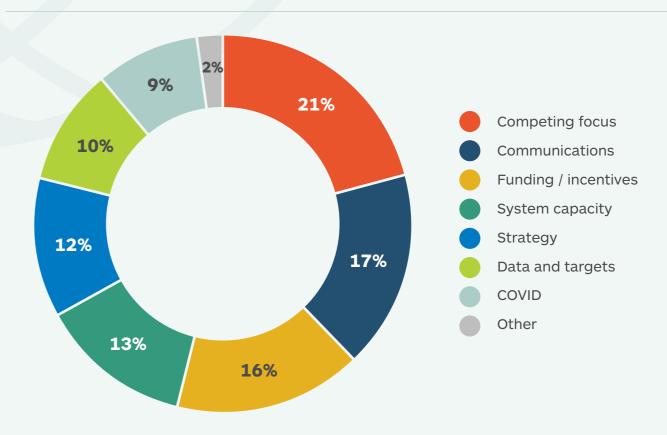
Structural changes with the introduction of Integrated Care Boards created a further barrier, both in terms of differing strategic priorities and changes to key personnel.

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The removal of cholesterol indicators from QOF back in 2014 really shifted the focus away from hypercholesterolemia as being one of those risk factors that you need to manage when it comes to CVD risk factor reduction.



Themes around levers that supported programme implementation.



Themes around barriers to the programme.



Communication and engagement

The most important levers for adoption of the programme centred around the importance of communications at a local level and nationally.

Identifying and utilising advocates who support the programme and who are well regarded locally can act as catalysts to drive progress, while ensuring that all key bodies are consulted early on and understand the programme's aims, can significantly increase engagement and buy-in.

A community of practice approach was greatly valued by health innovation networks and their partners to share programme spread ideas and products, like case-finding tools and regional implementation of national guidance.



Education and training

Educational packages, such as the Health Innovation Network / Heart UK's 'Tackling Cholesterol Together' programme were co-produced and seen as essential to system-wide capacity and capability building.

The focus on clinician training and support to identify and treat patients may have been at the expense of patients in some cases. While some health innovation networks had included patient engagement in their sustainability plans, it has not been possible to evaluate any increase in patient knowledge, adherence, or activation.



Public and patient involvement and engagement

An Equality Health Impact Assessment endorsed by NHSE ensured our programme was not tokenistic and did not widen health inequalities for people most at risk of CVD, with direct involvement from expert patients in key strategic working groups.



Funding

Consideration regarding funding and resource is also very important to ensure that resources can be committed, and that strategic support is in place. At a national level, creation of QOF and PCN DES measures were identified as both a lever when in place, and a barrier when not.

There were issues when local funding bids were unsuccessful, and around remuneration for non-prescribing place-based systems.

What are the wider impacts of the programme?

The main impact discussed in interviews was that the programme had successfully demonstrated proof of concept that an improvement programme which covers an entire clinical pathway and encompasses the whole of England is possible.

The evaluation made the following recommendations to consider for similar programmes in future:

- Perceived barriers and enablers need to be factored in during the programme design phases, through use of logic models or benefit maps to identify wider impact across the system.
- Consider how changes to a programme's scope and management structure can be impacted by national changes to the health and social care delivery and commissioning landscape.
- Link core programme aims and the availability of relevant data sources, where measurable programme impact can be demonstrated from the outset, at the programme design stage.
- Programme evaluation needs to be longitudinal not retrospective at the end of the programme, in order to capture real-time changes in programme deliverables.
- To enable sustainability and continued improvements, there should be a formal mechanism to share learning and communicate handover recommendations to system partners.



We've set up an education forum in [our local area around] hypertension and lipids, and that regularly attracts more than 100 healthcare professionals whenever there's a webinar. We've got a very good relationship with ICB colleagues who promote that and we help coordinate the topics.



The Health Innovation Network has now designed and implemented programmes tackling cardiovascular disease, looking at atrial fibrillation (AF), blood pressure and cholesterol management. In the same way that the lipids and FH national spread programme built on the learnings from a previous AF programme, so other programmes can now benefit from the experiences from this programme. Each provides the 'scaffolding' for the next.

This provides a firm foundation for structured conversations with local systems to address their individual needs and expectations, focusing on specific disease areas as well as enabling holistic discussions around the wider cardiovascular disease agenda.

Next steps

While the national programme has ended, the Health Innovation Network continues to support these innovations as part of its CVD Portfolio Programme which will focus on adoption and spread of innovations in the context of CVD prevention (lipids / FH / blood pressure optimisation, heart failure and chronic kidney disease). It is doing this through a more holistic approach that also recognises the importance of considering multi-morbidities, where patients have two or more long-term health conditions.

Individually, health innovation networks are building on existing relationships with the life sciences sector, in addition to strong local connections, to influence behaviour change within healthcare systems (ICBs and PCNs) and to track sustainability. Many commented in their interviews that they plan to continue their support for lipid management in some way, regardless of funding decisions made. While this will be guided by national and local strategies, care will also be needed to ensure that the gains made over the course of the programme are built upon to demonstrate lasting impact, and not lost as priorities change.



| Conclusion

The national lipid management and FH spread programme proved to be highly ambitious in both its scope and scale. Its delivery coincided with the COVID-19 pandemic and with multiple system-level changes. Despite these challenges, there is evidence of positive impact of the education which has taken place in primary care. There are also lessons around the importance of communications, a clear strategy, and the necessary infrastructure requirements which will benefit future spread programmes across the Health Innovation Network.

Above all, there are good examples of where the programme has become embedded in the system and will continue to be supported by health innovation networks. An independent evaluation describes how the programme has helped to increase the uptake of lipid lowering therapies.

As an example of one of the Health Innovation Network led national spread programmes, the lipids and FH programme was able to demonstrate the concept that a whole pathway improvement programme at a national level can be successfully implemented, and have a positive impact on the management of cardiovascular disease supporting delivery of the ambitions outlined in the NHS Long Term Plan.

For more information visit the Health Innovation Network website and find case studies in <u>The AAC/AHSN Lipid Optimisation & Familial Hypercholesterolaemia National Programme Final Impact Report.</u>

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