

Evaluation & Learning Health Innovation South West

Collaborative Lipids Fund Early Insights: Somerset Lipids Project Evaluation Report

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Nic Ferreira, Evaluation Lead
Health Innovation South West



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Executive Summary

Context

Cardiovascular disease (CVD) causes a quarter of all deaths in England and is the leading cause of premature mortality in deprived areas (Raleigh, *et al.*, 2022). Heart attacks and strokes can be prevented, and the NHS has made CVD prevention a priority, committing to preventing 150,000 heart attacks and strokes by 2029 (Ahmad, *et al.*, 2022).

It is estimated that 20 million people in England have elevated cholesterol levels, and the national prevalence of familial hypercholesterolaemia (FH) is approximately 1 in 250 (BHF, 2022).¹ Cholesterol levels can be lowered through lifestyle changes, and medicines initiation and optimisation. There is a need to ensure those at risk are identified and offered effective treatment, and clinicians are supported in identifying and managing patients. Previous studies and modelling have indicated estimated benefits from identification and treatment:

- statin therapy, to reduce cholesterol by 1mmol in people with a 10-year risk of CVD where the risk is greater than 10%, reduces risk of CVD events by 20-24% (Kearney, 2017). After the first year of statin use, each 1mmol/l reduction in LDL-C leads to 20-25% relative reduction in CV risk, including 20% decrease in coronary mortality (Cardoso, *et al.*, 2018); and
- modelling shows that if 90% of people with CVD were prescribed a statin and 70% were put on an optimal dose, >800 strokes and heart attacks could be prevented in five years (UCLP, 2022).

In 2023, through the National Implementation Agreement, Health Innovation North East and North Cumbria, NHS England, and Novartis (The Tripartite) funded successful applicants to build on approaches to delivering lipid management optimisation through The Collaborative Lipids Fund (CLF). The CLF projects were designed and delivered over 12 months from April 2023 to March 2024 to help improve and build services and models, implement best practice, and develop cross-organisation working in local geographies.

Somerset Context and Lipid Service Model

In Somerset, with a population of 571,600, around 82,000 people are living with circulatory diseases, 23,000 are living with coronary heart disease, and there are around 14,000 stroke survivors in the Somerset area (Somerset Intelligence, 2021) (BHF, 2023). Heart and circulatory diseases kill more the 1 in 4 people in the Somerset Area (BHF 2023).

Somerset detection and treatment of hyperlipidaemias (including FH) in primary care is low, putting a significant proportion of the population at increased risk of cardiovascular disease (CVD). Detection rates (as of September 2021) of a genetic diagnosis of Familial Hypercholesterolaemia were 0.7% of the anticipated individuals affected, which is significantly under the national average, and short of the NHS Long Term Plan of 25% diagnosed and treated optimally.² In early 2023, of those aged 40-74 in Somerset, only 27% had a QRISK score recorded in the previous five years, 17% recorded QRISK score more than five years ago, and 56% had no score recorded.³⁴ The NHS Long Term Plan CVD ambitions are for 75% of people aged 40-74 to have received a formal validated CVD risk assessment and have their cholesterol reading recorded. Of those detected as having a 20% or greater risk of developing CVD in primary care, 45% are to be treated with statins (NHS England, 2019).

¹ Familial hypercholesterolaemia (FH) is a condition caused by a defective gene that causes high levels of cholesterol in the blood. Commonly inherited from one parent but in rare instances can be more serious and inherited from both parents.

² CVD Prevent 2023; PHE 2023 Lipid Service Redesign Workshop. Unpublished.

³ CVD Prevent 2023; PHE 2023 Lipid Service Redesign Workshop. Unpublished.

⁴ QRISK is a prediction algorithm for cardiovascular disease

In addition, there was a limited provision of lipid clinics and specialists within the region in 2021, with one consultant-led clinic a month in secondary care. There was a growing waiting list and lengthy waiting times from referral to appointment for patients (waiting time above 79 weeks for some patients and a 92nd percentile waiting time of 77 weeks for those referred in 2021) due to limited service provision and capacity.

To address these challenges, Health Innovation South West, in partnership with the regional teams and leads, developed a phased approach to designing, delivering, and deploying an innovative lipid service in Somerset and Devon (with the ambition to spread more widely across the peninsula). The Somerset Lipids Project has been developed to work across primary (64 practices / 13 PCNs) and secondary care to transform primary care pathways, improve identification, and optimise treatment for familial hypercholesterolemia, and cholesterol (primary and secondary prevention). Additionally, it is seeking to increase service provision through specialist care service capacity and new ways of working and collaborating with primary care.

The core components of the service redesign model included:



building knowledge, skills, resources, and capacity in primary care;



building capacity and capability in secondary care;



building approaches to support collaboration and coordination between primary and secondary care; and



building a team, a vision and implementation plan.

Evaluation of the project

An evaluation was commissioned as part of the Collaborative Lipids Fund project to support Somerset and Devon. Health Innovation South West has worked collaboratively with Somerset and Devon lipid service teams to both build the foundations for evaluation and learning within the teams as the project developed and capture early insights on implementation and early outcomes achieved from the model. A mixed methods process evaluation was designed to understand implementation insights and the short-term outcomes of the project in Somerset from April 2023 to February 2024.

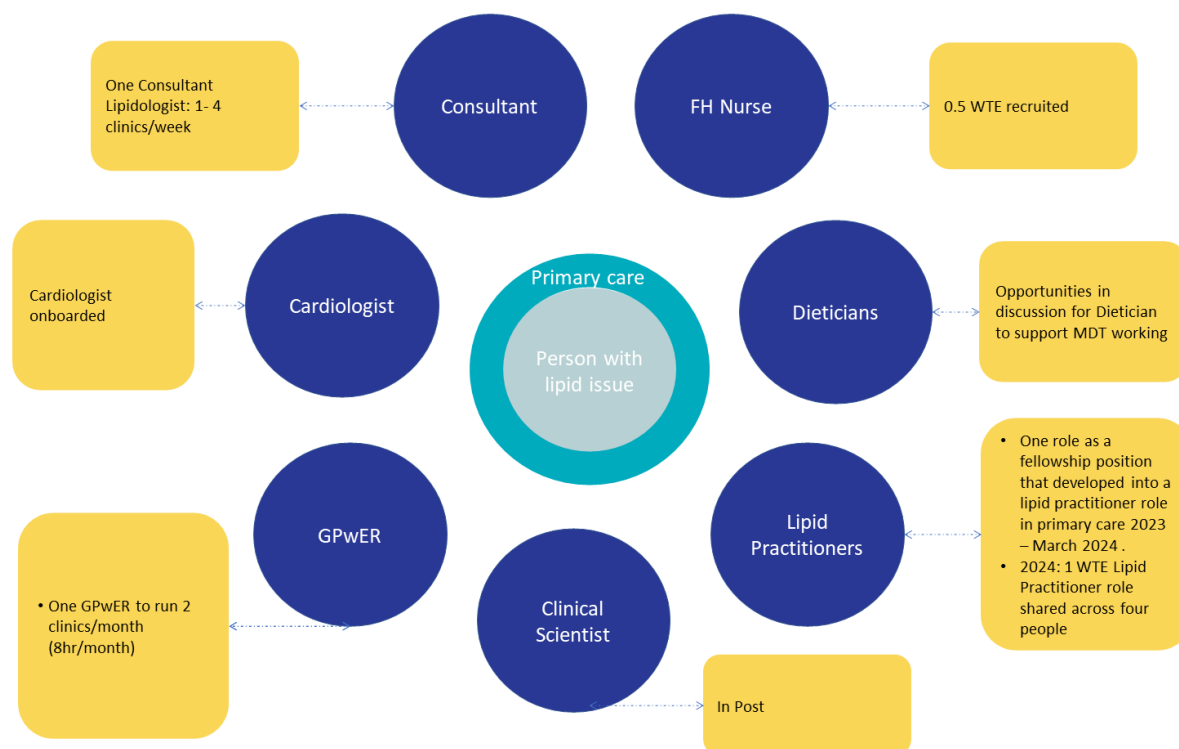
Results

The main findings from the evaluation are as follows:

- the model is seen as acceptable and appropriate at this early stage amongst key staff;
- the education and resource arms are improving access to resources with nearly half of Somerset practices accessing resources on TeamNet (29 of 64 practices), and more than 621 health care professional attending education sessions;
- the education sessions are increasing perceived knowledge and confidence of the primary and secondary care workforce attending education sessions;
- the new lipid practitioner role has been positively experienced and perceived to be influencing role development and satisfaction for the lipid practitioner;
- there is progress at primary care level with implementation of targeted lipid management through the embedded role with 323 patients reviewed, and patient feedback is positive; and
- the number of specialist lipid clinics run each month has increased from one to four per month, and there are indications that the lipid clinic waiting times are reducing.

Workforce

There is increased capacity, with new roles in primary and secondary care supporting a more targeted and joined up service. There has been a range of roles recruited or receiving training to support the project as seen in the figure below.⁵



The practitioner supporting primary care has had positive experiences of implementation. They feel they have **greater knowledge in the lipids field and operating in primary care**, and greater **satisfaction within their role**. The opportunity to develop their clinical role within an area of interest, and opportunity to work in more detail with primary care has been an enabler to their motivation and role development as a clinical pharmacist. The personal development and learning structure have **increased their knowledge and capability to manage patients with lipids in primary care**, and the practical and technical learning within the practice system has grown their technical skills and communication skills in primary care. The mentorship offered psychological safety to develop in the role and empowerment to take initiative.

"A really positive input. It's been really satisfying... I feel like I have a positive contribution. It certainly led to more satisfaction, and understanding of my own role and how I fit in primary care."

Lipid practitioner

⁵ GPwER: General Practitioner with Extended Role



Resources, education, knowledge and confidence

A core part of the project involved the steering team developing accessible resources about lipids management and pathways, as well as delivering education sessions to primary and secondary care. **The Somerset Lipids Project has reached more than 71 healthcare organisations over 11 months.** The health organisations reached have been in primary care (55), and across secondary care hospitals, trusts, urgent care, and research institutes in the South West Region, not only Somerset. Further details are below, along with feedback from a survey administered after the education sessions.

- 21 education sessions have been run across Somerset, and 621 people from various clinical roles in primary and secondary care have attended education sessions.
- 45% of practices in Somerset have accessed the new lipid service page and resources on the TeamNet. Resources and tools have been accessed 137 times by 29 (of 64) practices.
- 18 education sessions were evaluated and had n131 responses to the evaluation survey:
 - 99% of survey respondents strongly agreed or agreed that the session had **improved their understanding** of lipid management (figure 7);
 - 98% of survey respondents strongly agreed or agreed that they felt that they **had more confidence to manage patients** with lipid disorders, including FH; and
 - 96% of survey respondents strongly agreed or agreed that they felt **better able to implement** or support the implementation of the lipid pathway within their role.

Survey participants from across the clinical workforce attending education sessions felt that the sessions were clear and interactive, with useful and new information as seen in the quotes:

"A refreshing reminder of the rationale for statin use."

"New information regarding management."

"Excellent first principles-based teaching. Now have a good understanding."

"Good overview of a generally neglected area in secondary care."

"New agents for lipid lowering therapy. Learning how to identify genetic causes of hyperlipidaemia."

Education sessions survey respondents



Primary care site and patients

The lipid management targeted approach at two case study practice sites was implemented successfully by the lipid practitioner working one day a week. **Across two primary care sites the lipid practitioner was able to review 323 patients** across Quality and Outcomes Framework (QOF) indicators CHOL001/2, DM022/3, and QRISK>20%. Searches for those at risk of FH were conducted in site 1.

- 88 patients started statins or lipid lowering therapy (LLT).
- 30 patients had therapy increased or changed to HIST.
- 93 patients declined statins or LLT.
- 50 patients declined escalation of therapy.

- 40 patients were exception coded.
- Following the SMS invitations at both sites, 10% of patients declined the invitation at site 1 and 11% at site 2. The uptake rate of the lipids reviews was 12% at site 1 and 34% at site 2 and lessons can be learned to understand what engagement methods with patients would increase uptake, including uptake from those most deprived and digitally excluded.
- The lipid practitioner will not be an embedded post, which is a risk to the continuity and sustainability of the targeted lipid management approach at the practice. Increasing the days per week that the four lipid practitioners focus on searches and reviews once they are in post would support progress and enable practitioners to test engagement methods.

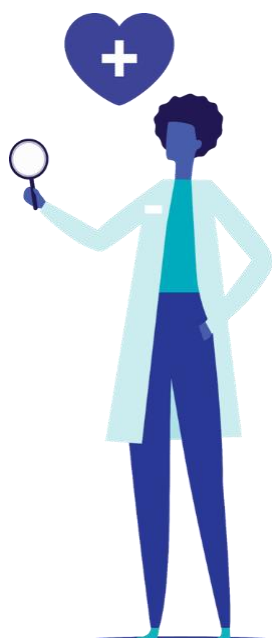
Early insights from a small number of patients (n7) suggest that the targeted service is **acceptable and accessible** but there is room to improve the information and support with lifestyle changes. There were mixed responses from the seven patients about how confident they felt about managing their own cholesterol following the review. The patients indicated that information and support with lifestyle changes such as diet and exercise, having regular annual meetings with the cardio nurses, and having more information on managing cholesterol, including what the medications, do would help them feel more confident in managing their cholesterol and health.

“Friendly & informative”

“Explained perfectly”

“Very helpful service, informative & encouraging.”

Patient feedback



Lipid Clinic

The lipid clinic enhanced service is still being established but early insights suggest that there has been an increase in the number of patients who have had a lipid clinic appointment after their referral, from n26 in 2021, to n46 in 2022, and n108 in 2023, while the average number of referrals has remained at 11 per month from 2021 to 2023. Not captured in the formal referrals and referral to treatments per month is the informal advice and guidance that is given via emails and phone calls, that would have otherwise been a formal referral but still requires resource from the consultant. The enhanced service model will be fully established in 2024 as three new roles start, which will increase the number of clinics to more than six per month. Currently in the early development of the service, the consultant-led clinics have increased from one to four per month, and there is a reduction in the average and median waiting time from referral to treatment that can be seen. The **median wait** for those who have a **completed pathway was 59 weeks** (half the patients were seen within 59 weeks). The **92nd percentile waiting time was 75 weeks** (table 4). Of the current patients waiting to start treatment (n145) (**incomplete pathway**), the **median wait time is 37 weeks** and the **92nd percentile waiting time is 49 weeks** (table 5).

Implementation insights

Implementation science research suggests that implementation strategies should be tailored to address the multiple contextual levels of the project: the individual level behavioural change, the collective level change (team, organisation, meso), and the structural/socio-political level (macro level) (Damschroder *et al.*, 2009). The key to setting up and implementing a redesigned lipid service model in Somerset involved several important factors within the wider context, external conditions of influence and opportunity, inner dynamics of the team and individual behaviour change areas, and implementation setting in primary care.

Designing and adapting for context

The project team highlighted the health challenges and needs in the region, particularly concerning cardiovascular disease (CVD), and lipid services. The challenges include:

- issues related to health services overall;
- workforce retention/recruitment;
- an aging population with a high CVD prevalence; and
- health inequalities faced by the population, especially unequal access to services and local access to specialist care (patients face difficulties accessing services due to the distance to clinics and long wait times).

Recruiting and retaining a suitable workforce in the region is a key challenge. To address this, the team considered roles beyond consultants in helping to deliver lipid clinics and lipid management. Initially, the project leaned towards a consultant-heavy model, but feedback and insights from team members led to a more diversified approach, considering various roles such as FH specialist nurses and clinical pharmacists able to deliver lipid management in primary care, as well as support secondary care clinics. They also recognised the need for local delivery across the county and adjusted the model accordingly, by placement of a GP with an extended role in the north of the county and collaborations with neighbouring regions to expand service access.

External conditions and opportunity

The external conditions for change and timing were critical factors in enabling the service redesign and project. Policy, financial incentives for primary care to focus on cholesterol and familial hypercholesterolemia, FH genetic testing becoming available as a nationally commissioned service, and wider policy attention being placed on CVD prevention programmes were influential in setting up the opportunities for change to take place. During this time, a driver for change was ensuring there was cross organisational and system communication of the issues in the service, and the risks with a growing waiting list. The challenges were placed on risk registers in the Trust, and the then Clinical Commissioning Group was made aware.

Capability, motivation, and ways of working

The capabilities and motivation of the core project team have been a key driver in initiating change, developing the model, and adapting for implementation. A team with experience in service development and clinical knowledge was seen as critical to early success in building the foundations and developing a pathway and full-service vision and outcomes to work toward:

- clear leadership and partnership across the team and organisations;
- adaptability and learning culture that has been built in;
- good communication processes and networks with regular meetings and sharing; and
- clarity of vision and shared motivation to improve patient health outcomes.

Implementation in primary care

The key enablers in the implementation at practices included:

- priority and tension for change and existing support for change at the practice;
- good compatibility between the lipid practitioner role and existing site functions and processes and people, enabling targeted lipid management in practices;
- incentives for primary care (QOF points), influencing motivation to adopt targeted lipid management approaches in primary care and work with the lipid practitioner; and
- access to knowledge and information from the clinical team for the lipid fellow/practitioner's, which was essential for the new role to build confidence and capability as a lipid practitioner.

The implementation process at the primary care site has benefited from familiarity with the practice and system, tailoring the approach to target at-risk patients effectively, and working closely with practices to meet their needs, including supporting QOF points.

Challenges

- Initial buy-in for the model was a challenge. Despite the existing external opportunities and policy drivers, ultimately the waiting list was the critical driver in receiving funding.
- Core team capacity is an ongoing challenge as service design and steering group membership are not necessarily inside their usual roles.
- Pace of working on service design is slow and takes time to work across organisations.
- Ensuring patient representation was built into the steering group early was a challenge, and early follow up and clear guidance is needed from the start of projects.

Barriers to implementation and patient engagement

- Reaching patients via SMS, and digital access barriers for patients was a key challenge.
- Uptake of the pathway can be improved.
- Managing time per patient and understanding capacity needed is a challenge for lipid practitioners testing the approach.
- Implementation at the first practice has been seen as easier to embed due to past/current experience that the lipid practitioner has with the practice. Time to adopt and embed could take longer for new postholders who are not familiar with the practice system or practice staff (knowing who to book an appointment with, names of the healthcare assistants).
- Ability to prescribe, and ability to navigate ethical challenges with FH, will be potential barriers for future roles.

Conclusion

The early insight from the evaluation shows that the project has progressed between April 2023 and February 2024, with core elements developed and implemented as planned. The evaluation activity alongside the project implementation has supported embedded learning and data collection for service improvement. Evaluation and ongoing monitoring should continue as the programme matures and the new roles across primary and secondary care begin and embed in 2024. The successful design and early implementation of the model, coupled with early adoption success, position the project well for further implementation.

- The next phase of the project will move from early adoption to embedding, and further spread into other practices which will benefit from ongoing evaluation and learning. A key challenge will be ensuring the model utilising lipid practitioners is sustainable and that lipid management approaches continue in practices, beyond any initial targeted work. Patient uptake of the consultations will be an area the project can focus on, and learn what

engagement approaches support higher uptake. This will help ensure patients most at risk and facing health inequalities, including digital exclusion, are actively engaged with and have access to treatment and support. The project has embedded tools and approaches to evaluation, including working closely with Somerset Public Health on a cardiovascular disease (CVD) dashboard, which will support the further evaluation of patient health outcomes and system benefits in time.

- There are early indications that the model will support the reduction in lipid clinic waiting times. The consultant and team are being further supported to test a demand and capacity model for the service.
- While the education sessions have positively influenced how the workforce perceive their knowledge and confidence in lipid management, and the resources on TeamNet are being accessed by nearly half of the practices in Somerset, application of that knowledge and use of resources will need to be assessed.
- For others developing lipid management approaches or a service redesign, clear and effective steering is critical, alongside leadership and co-ownership of the change and processes. Importantly, diverse representation within the project development team is central to the successful development of the project and system thinking. Cross system collaboration, early engagement, and ongoing coordination support are equally important for the change process and have been central to the Somerset Lipids Project service redesign approach and its early success.

1. Background

Cardiovascular disease (CVD) causes a quarter of all deaths in England and is the leading cause of premature mortality in deprived areas (Raleigh, *et al.*, 2022). Heart attacks and strokes can be prevented, and the NHS has made CVD prevention a priority, committing to preventing 150,000 heart attacks and strokes in the next 10 years (Ahmad, *et al.*, 2022). The NHS Long Term Plan (2019) sets out commitments across atrial fibrillation, blood pressure and cholesterol to support early detection and treatment, improve effectiveness of approaches, and ensure timely preventative treatments are offered.

It is estimated that 20 million people in England have elevated cholesterol levels, and the national prevalence of familial hypercholesterolaemia (FH) is approximately 1 in 250 (British Heart Foundation, 2022).⁶ Cholesterol levels can be lowered through lifestyle changes, and medicines initiation and optimisation. There is a need to ensure those at risk are identified and offered effective treatment, and clinicians are supported in identifying and managing patients. Previous studies and modelling have indicated estimated benefits from identification and treatment:

- statin therapy, to reduce cholesterol by 1mmol in people with a 10-year risk of CVD risk greater than 10%, reduces risk of CVD events by 20-24% (Kearney, 2017). After the first year of statin use, each 1mmol/l reduction in LDL-C leads to 20-25% relative reduction in CVD risk, including 20% decrease in coronary mortality (Cardoso, *et al.*, 2018); and
- modelling shows that if 90% of people with CVD were prescribed a statin and 70% were put onto an optimal dose, over 800 strokes and heart attacks could be prevented in five years (UCLP, 2022).

The NHS, through the Accelerated Access Collaborative, published an updated version of the NICE-endorsed lipid management pathway, including newer treatment options. The revised pathway brought multiple NICE guidance and technology appraisals into a single document to aid decision-making for clinicians and reduce treatment variation. The Health Innovation Networks have worked on the adoption and spread of the revised pathways since 2021, aiming to improve access to education and resources for the workforce, and improve FH detection, lipid management, and access to appropriate lipid treatment. Health Innovation South West has supported the three-year lipid management programme (2021-2023) through increasing awareness of the NICE lipid pathway, collaboratively planning training opportunities with education hubs, supporting prioritisation of CVD prevention measures and improving identification and service provision to those with FH.

In 2023, through the National Implementation Agreement, Health Innovation North East and North Cumbria, NHS England, and Novartis (The Tripartite) funded successful applicants to build on approaches to delivering lipid management optimisation through The Collaborative Lipids Fund (CLF). The CLF projects were designed and delivered over 12 months from April 2023 to March 2024 to help improve and build services and models, implement best practice, and develop cross-organisation working in local geographies.

⁶ Familial hypercholesterolaemia (FH) is a condition caused by a defective gene that causes high levels of cholesterol in the blood. Commonly inherited from one parent but in rare instances can be more serious and inherited from both parents.

1.1 Somerset Context and Somerset Lipids Project

In Somerset, with a population of 571,600, around 82,000 people are living with circulatory diseases, 23,000 are living with coronary heart disease, and there are around 14,000 stroke survivors in the Somerset Area (Somerset Intelligence, 2021) (BHF 2023). Heart and circulatory diseases kill more the 1 in 4 people in the Somerset Area (BHF 2023).

Somerset detection and treatment of hyperlipidaemias (including FH) is low, putting a significant proportion of the population at increased risk of cardiovascular disease (CVD). Detection rates (as of Sept 2021) of a genetic diagnosis of Familial Hypercholesterolaemia were 0.7% of the anticipated individuals affected, which is significantly under the national average, and short of the NHS Long Term Plan of 25% diagnosed and treated optimally.⁷ In early 2023, of those aged 40-74 in Somerset, only 27% had a QRISK score recorded in the previous five years, 17% recorded more than five years ago, and 56% with no score recorded.⁸ The NHS Long Term Plan CVD ambitions are that 75% of people aged 40-74 to have received a formal validated CVD risk assessment and have their cholesterol reading recorded. Of those detected as having a 20% or greater risk of developing CVD in primary care, 45% to be treated with statins (NHS England, 2019).

In addition, there was a limited provision of lipid clinics and specialists within the region in 2021, with one consultant-led clinic a month in secondary care. There was a growing waiting list and lengthy waiting times from referral to appointment for patients (waiting time above 79 weeks for some patients and a 92nd percentile waiting time of 77 weeks for those referred in 2021) due to limited-service provision and capacity.

Health Innovation South West in partnership with the regional teams and leads developed a phased approach to designing, delivering and deploying an innovative lipid service in Somerset and Devon (with the ambition to spread more widely across the peninsula). Health Innovation South West has been delivering the phased CLF project through:

- continuing the co-development of the lipid service model in Somerset including capturing early learning;
- co-designing and supporting adaptation and adoption of the Somerset model in Devon (Torbay and South Devon Foundation NHS Trust); and
- spreading best practices across the region with partners.

⁷ CVD Prevent 2023; PHE 2023 Lipid Service Redesign Workshop. Unpublished.

⁸ CVD Prevent 2023; PHE 2023 Lipid Service Redesign Workshop. Unpublished.

2. Evaluation

An evaluation was commissioned as part of the CLF project to support Somerset and Devon. Health Innovation South West have worked collaboratively with Somerset and Devon Lipids Project teams to both build the foundations for evaluation and learning within the teams, and capture early insights on implementation and early outcomes achieved from the model.

2.1 Evaluation aims and questions

A mixed methods process evaluation was designed to understand implementation insights and the short-term outcomes of the CLF project in Somerset from April 2023 – February 2024. The aims of the evaluation were to:

- develop a logic model, measurement strategy and data collection tools for Somerset;
- capture early learning from Somerset to support adoption in Devon, including embedding evaluation tools; and
- conduct a process evaluation during the stages of design and implementation in Somerset.

The evaluation questions were informed by the Medical Research Council (MRC) guidelines for process evaluations (image 1) (Moore *et al.*, 2015). The evaluation questions are in table 1. This report captures the methods and early insights from Somerset.

Image 1. MRC process evaluation

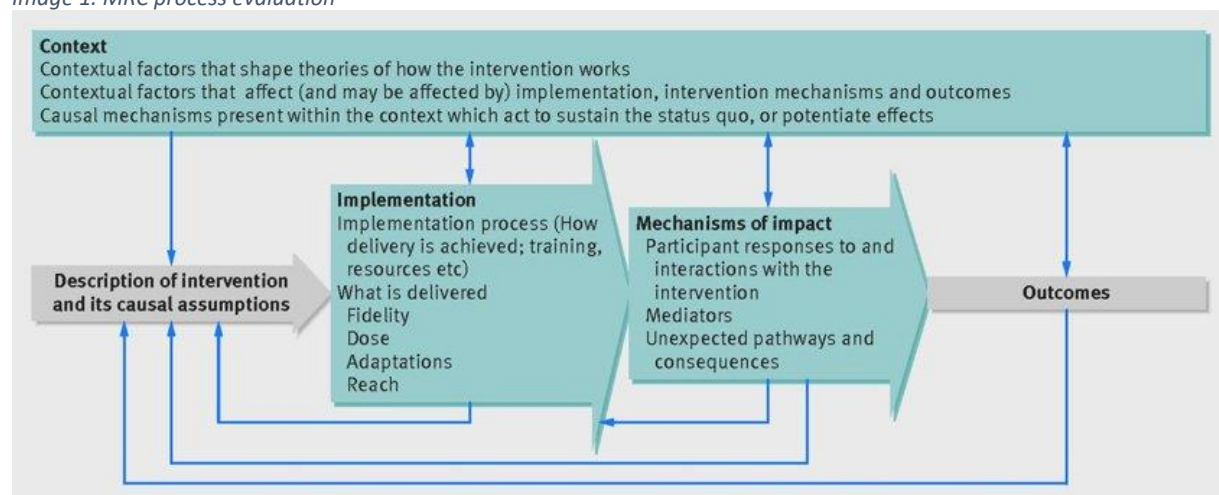


Table 1. Evaluation questions

Context, mechanisms	Process, Exposure(dose), Reach	Outcomes
• What are the contextual factors and influences that shaped implementation, including enablers and barriers and success factors? • Were there unanticipated or unintended consequences or pathways?	• What were the core components to implementing the change and was it delivered as intended? • How many staff have been recruited/brought on to support lipid clinics? • How many organisations/practices have been supported (access to resources, educational support and training, full support from Lipid Practitioner)? • How many patients access the lipid management care pathway at case study practices? • How many lipid clinics were run compared to before the enhanced service?	• What are the patient experiences of the pathway? Is it acceptable and accessible? • Do core implementing staff recruited for the enhanced roles in the project feel they have improved role development and satisfaction? • Do primary care staff feel more capable and confident to engage patients in the lipid pathway? • Has there been a reduction in waiting time at the lipid clinic?

2.2 Methods

The following mixed methods were used to capture early insights from Somerset:

- document review, and logic modelling workshops with key stakeholders;
- monitoring data on education session reach and attendance, and access to online resources (views on TeamNet);
- semi-structured interviews or surveys with core project and steering group members (n8);
- semi-structured interviews with implementing staff (i.e., Lipid Practitioner and other practitioner roles) (one practice implementing full model so far) (n1);
- quantitative data analysis on pathway uptake (numbers of patients identified, invited, reviewed, on LLT at case study practices implementing full model so far) (n2);
- analysis of CVD Prevent data relevant to cholesterol indicators at case study practices to establish baselines for the interim report (CHOL003, 009, 007);
- quantitative data analysis of lipid clinic waiting list data undertaken, to understand how many people are on the waiting list, how long they are waiting between referral and appointment and if there is a reduction in the waiting time for patients;
- workforce participants receiving direct education sessions with Consultant Lipidologist* or clinical champion or lead invited to participate in an evaluation survey to understand whether the session had improved their knowledge and confidence in lipid management and the experience of the session. N21 education sessions were held, n18 were evaluated and had n131 responses April – 1 February 2024); and
- patients who had a consultation with the Lipid Practitioner from the two practice case study sites received a patient experience survey to complete. The patient survey was developed to understand experience on access, acceptability, and person-centred care. Seven patients

*Consultant in Diabetes, Endocrinology and Lipids

responded from one site between August and December (8% response rate).¹⁰ The Theoretical Framework of Acceptability (TFA) was used to understand general acceptability of the lipid management approach for patients under seven constructs: affective attitude, burden, perceived effectiveness, opportunity costs, ethicality, intervention coherence, self-efficacy (Sekhon, *et al.*, 2022). The person-centred coordinated care experience questionnaire (P3CEQ), an 11-item measure designed to assess patient experiences of person-centred coordinated care, was used to understand the extent to which the service is providing person centred coordinated care (Lloyd, *et al.*, 2019).

All quantitative data were analysed using descriptive analysis, to understand pathway uptake in primary care, lipid clinic waiting data, and patient experience. All qualitative data were coded in NVivo and thematically analysed. The Consolidated Framework for Implementation Research (CFIR) was used as an analytical framework to understand the key factors that have influenced the project, and the enablers and barriers to implementation (Damschroder *et al.*, 2009). The CFIR is based on a systems approach and covers a range of factors with different levels that influence implementation (e.g., factors within the individual level, intervention level, contextual and outer level, process level).

¹⁰ The low response rate (n7 from a estimated 83 patients [8% response rate]) is a limitation to the analysis and conclusions. There was a lack of consistency in offering the patients the survey to complete via an SMS invite which further limited who of the 83 patients received an invite to the survey.

3. Findings

3.1 Process

3.1.1 The Somerset Lipids Project: core components and development

The Somerset Lipids Project has been developed to work across primary and secondary care to transform primary care pathways, improve identification, and optimise treatment for familial hypercholesterolemia, and cholesterol (primary and secondary prevention). Additionally, it is seeking to increase service provision through secondary/specialist care service capacity and new ways of working and collaborating with primary care. Images 2 and 3 show the overarching programme theory and logic model of the project.

The core components of the project included:

- **building knowledge, skills, resources and capacity in primary care;**
- **building capacity and capability in secondary care;**
- **building approaches to support collaboration and coordination between primary and secondary care; and**
- **building a team, a vision and implementation plan, by**
 - coordinating and forming as a team (including a service redesign workshop);
 - defining service needs and project approach, defining the vision and outcomes;
 - developing the foundational elements of the service and best practice to support management of the redesign;
 - developing a staffing model and recruitment strategy;
 - designing an education strategy and plan for primary care and secondary care;
 - developing regional resources and portals for accessing them; and
 - developing the foundations for evaluation and learning.

Somerset Lipids Project

Programme Theory

It is estimated that 1 in 250 people in the UK population have FH, of whom less than 8% are currently identified (92% undiagnosed).¹ Somerset detection and treatment of hyperlipidaemias (including FH) is low putting a significant proportion of the population at increased risk of cardiovascular disease (CVD). This is due to the limited provision of lipid clinics and specialist within the region, and a need for prioritisation of lipid management in primary care. Current detection rates (as of Sept 2021) of a genetic diagnosis of Familial Hypercholesterolaemia were 0.7% of the anticipated individuals affected, which is significantly under the national average and short of the NHS Long Term Plan of 25% diagnosed and treated optimally.² Currently only 27% of those aged 40-74 in Somerset have a QRISK score recorded in the last 5 years, with 17% older than 5 years, and 56% not recorded, and current detection rates of those at risk of non-FH CVD on sub-optimal treatment is low.² The NHS Long Term Plan CVD ambitions are that 75% of people aged 40-74 to have received a formal validated CVD risk assessment and cholesterol reading recorded. Of those detected as having a 20% or greater risk of developing CVD in primary care, 45% to be treated with statins.³ There is an opportunity to design a coordinated service to reduce the risk of CVD and CVD related deaths in Somerset by increasing service provision and enhancing patient care beyond that currently provided in routine practice, improving identification, management and optimisation of patients.

Redesign, support, capacity, capability

Support to primary and secondary care around full lipid pathway (FH and non-FH CVD on suboptimal treatment)

Education and knowledge materials, resources, upskilling, support from GP extended role to primary care

Secondary care staffed, have more clinics operating, are more joined up across departments

Primary and Secondary care coordinated and collaborating

New governance structure and lipid service management

Implementation

Enables region to identify and treat patients with (FH and non-FH CVD not on suboptimal treatment) in a consistent, timely, and coordinated manner between primary and secondary care

Primary care are supported in case finding, identification, and referral

Secondary care able to reduce current waiting list, and support new referrals from primary care

Secondary care collaborate with primary care, and run MDTs

New governance structure and lipid service management supports design, operation, system coordination, communication, and data/insights

Improved pathway and access

Leading to improved capability, capacity and collaboration in primary and secondary care, and greater access to testing, diagnosis, treatment and management for patients

Primary care have greater understanding, confidence, and capability to deliver the full care pathway (FH and non-FH CVD on suboptimal treatment)

Improved systematic identification, optimisation, referral and diagnosis

Improve waiting times for lipid clinics

Better regional communication, collaboration, and insights

Improved outcomes

Contributing to:

People at risk of FH, and at risk of CVD not on suboptimal treatment achieving improved health outcomes

A reduction in premature CVD mortality in Somerset

Reduction in incidence of stroke and MI

A more integrated system

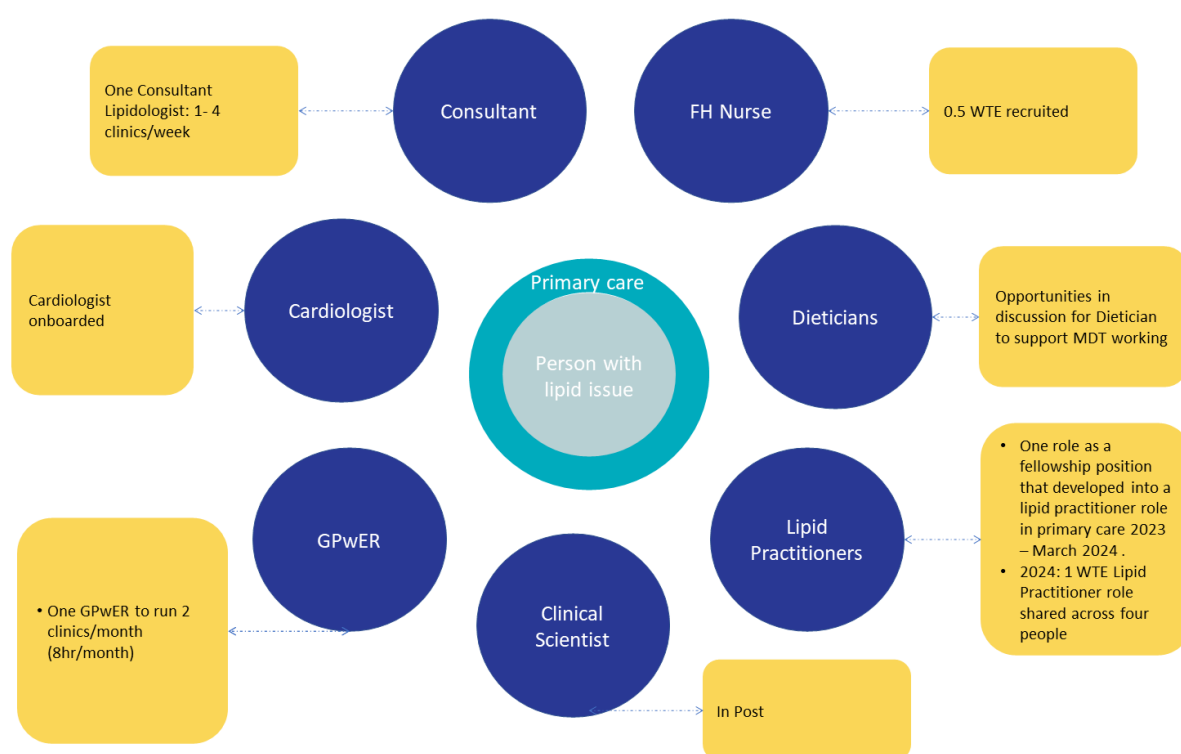
1. NHS England — London » Familial Hypercholesterolaemia (FH)
2. Orla Dunn, PHE, 2023. Lipid Service Redesign Workshop and CVD Prevent data. Unpublished
3. NHS England — South West » Cardiovascular prevention



3.1.1 What is the workforce model for the service?

The Somerset Lipids Project and workforce has been built over time, with early problem definition work in Somerset in 2022, building on the keen energy from the service lead and different groups in the system and funding opportunities emerging through wider CVD pathway work. The problem was defined through bringing in local knowledge and experiences about the challenges, building strong collaboration with multiple stakeholders across the system, and developing examples of different models, including the workforce needed. This early phase gave the foundations that allowed the lipid service lead to develop a business case. As a result of the foundational work and business case, the Somerset Lipids Project was able to create a workforce model that has a multidisciplinary team approach and enables primary and secondary care to work more closely together to support each other and patients. The workforce model is visualised in image 4.

Image 4. Workforce Model



Primary Care:

Progress: Primary care work has been piloted in two practices in Somerset with one Clinical Pharmacist/Lipid Practitioner recruited (starting as a fellowship position and growing into a Lipid Practitioner role between 2022-2023) covering one day per week. The role has included learning and development in lipidology and genetics, and patient management, and involved the active design and development of the structures to implement a lipid management pathway and consult with patients in primary care. The aim was for the role to develop resources and test the case-finding and management approach at four practices in a Primary Care Network (PCN) by March 2024. However, due to the post only being one day a week, the practitioner will only be working in two practices and

further supporting the onboarding of four new Lipid Practitioners once recruited.

Planned: Recruitment is underway (Autumn 2023 – March 2024) for new roles to support primary care in the same capacity as the current Lipid Practitioner position - four part time Lipid Practitioners supporting Primary Care Networks (PCNs) in the delivery of lipid detection and management (equivalent to 1 WTE). PCNs or practices will be offered targeted or rotating support across the region to implement the lipids pathway and support patient management. Consideration for initial targeting will be based on population need, deprivation, and equal access across each section of Somerset. Core to the role will be receiving support from the Consultant Lipidologist– ensuring primary and secondary care are more joined up, and that the workforce in primary care have access to specialist knowledge support through work with the Consultant.

Secondary Care:

Progress: An additional post was recruited to support the Consultant in secondary care – one GP with extended role (GPwER) (from 2022 – January 2023). The GPwER ran additional clinics monthly, as well as supported the Clinical Pharmacist in development of the pathway.

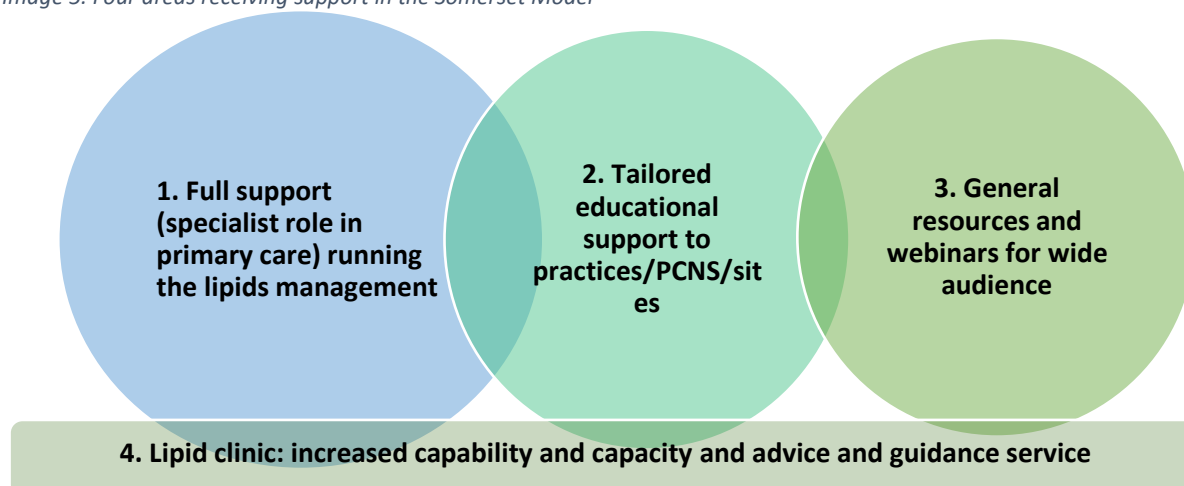
Currently, the Consultant has increased the number of clinics being run to four per month, from one per month. An advice and guidance service has been launched for primary care, to directly communicate with secondary care before referrals or with any queries to support appropriate referrals and less time spent on vetting.

Planned: Following recruitment and/or six months of shadowing and learning, there will be more capacity to run additional clinics with support from a Cardiologist (two clinics per month - eight hours per month) and GPwER (two clinics per month - eight hours per month), an FH Nurse Specialist (one clinic per week), and Dietician to support multidisciplinary working in clinics.

3.2 Reach and Exposure

The project aims to support practices and patients across Somerset over time. There are several categories of *reach and exposure* in this model that show how many practices/PCNs/ secondary care organisations are being reached, and to what extent they are receiving support through the lipid project model, as seen in image 5. Programme set up and early implementation insights were captured between April 2023 and February 2024 and show the programme making progress to deliver across all planned components. Sections 3.2.1 to 3.2.4 detail the reach across the four components.

Image 5. Four areas receiving support in the Somerset Model



11

Across the education sessions, the TeamNet access, and the full support at case study sites, the Somerset Lipids Project has reached more than 71 healthcare organisations over 11 months. The health organisations reached across the South West (not only Somerset) have been in primary care (55), and across secondary care hospitals, trusts, urgent care, and research institutes like the British Heart Institute within the Bristol Royal Infirmary (table 2).

Table 2. Organisations reached (education sessions, TeamNet access to resources, case study sites)

Organisation type	Total Reached
Education (deanery), British Heart Institute	2
Hospital, Trust, Urgent Care ¹²	14
Primary Care	55
Total	71

11

1. Practices that have had education sessions run with them and have a clinical pharmacist/lipid practitioner supporting implementation and lipids management. The proportion of patients taken up the pathway as a result.
2. Practices that have only had a practice or PCN tailored education session for their staff.
3. Practices or PCNs that have only received access to resources and webinars for education and lipid management support.
4. Lipid clinics increased with more capacity, and advice and guidance service.

¹² British Royal Infirmary, Derriford Hospital Plymouth, Gloucestershire Hospitals NHS Foundation Trust, Great Western Hospital, Herts Urgent Care, Musgrove Park, North Bristol NHS Trust, North Devon District Hospital, Barnstaple, Royal Cornwall Hospital Trust, Royal Devon University Hospital Trust, Somerset Foundation Trust, Southmead Hospital, University Hospitals Bristol and Weston, Yeovil District Hospital.

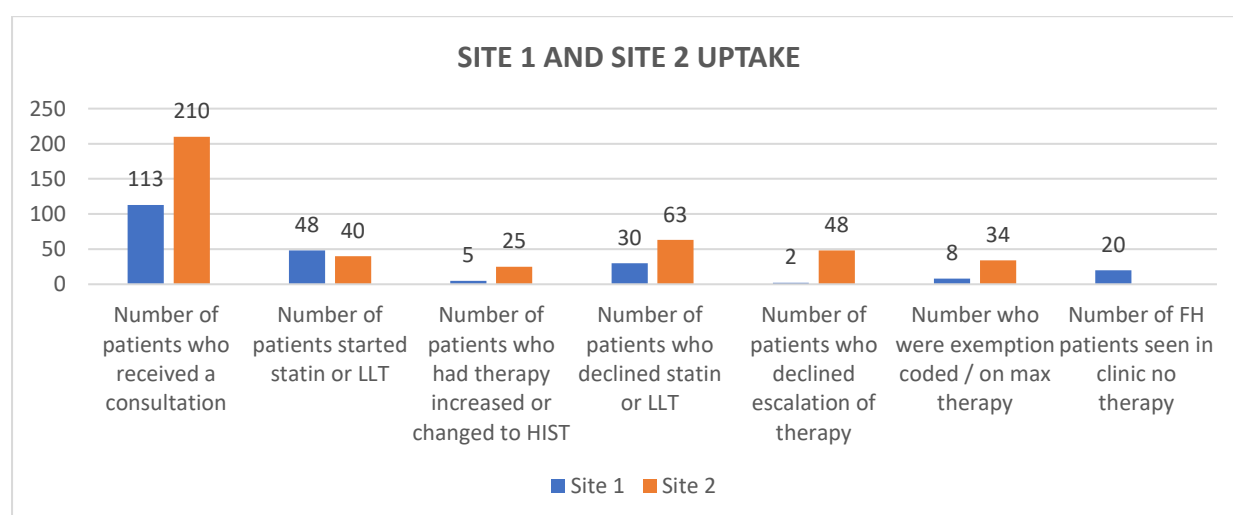
3.2.1 Full support

Currently one Clinical Pharmacist (Lipid Practitioner) supports the Somerset Lipids Project in two practices (the two case study sites in primary care). It is a unique role that was developed through a fellowship and focussed on supporting the development of resources and searches for the project rather than exclusively delivering lipid management services to patients. Four new part time Lipid Practitioners will be recruited in early 2024 (1 WTE shared across the four practitioners) and carry out full lipid management support to practices across Somerset.

Two practices, case study *sites 1 and 2*, received the embedded support from a Lipid Practitioner conducting searches and developing approaches to case finding, carrying out reviews with patients, and medicines management one day a week. The intention is to spread this model of full support further when the four new Lipid Practitioners are recruited and can rotate across practices. Across two primary care sites the lipid practitioner was able to review 323 patients across QOF CHOL001/2, DM022/3, and QRISK>20% (figure 1). Searches for those at risk of FH were conducted in site 1. Across the two sites a total of 88 patients started statins or lipid lowering therapy (LLT), 30 patients had therapy increased or changed to HIST, 93 patients declined statins or LLT, 50 patients declined escalation of therapy, 40 patients were exception coded. Following the SMS invitations at both sites, 10% of patients declined the invitation at site 1 and 11% at site 2. The uptake rate of the lipids reviews was 12% at site 1 and 34% at site 2. Lessons can be used to understand what engagement methods with patients would increase uptake, including uptake from those more deprived and digitally excluded.¹³

Increasing the days per week that lipid practitioners support the practices would enable progress. The lipid practitioner will not be an embedded post with the practice, which is a risk to the continuity and sustainability of the lipid management approach at the practice.

Figure 1. Primary care sites 1 and 2 uptake



A case study of site 1 is detailed below and shows the embedded approach was adopted successfully at the practice by the lipid practitioner.

¹³ Using patient postcode, the lipid practitioners can use a postcode look up to attain index of multiple deprivation (IMD) score for patients. IMD scores are widely used within the UK to classify the relative deprivation of small areas (Lower Super Outer Area in England). Multiple components of deprivation are weighted with different strengths and compiled into a single score of deprivation.

Somerset case study site 1: Utilising lipid practitioners to support primary care lipid management.

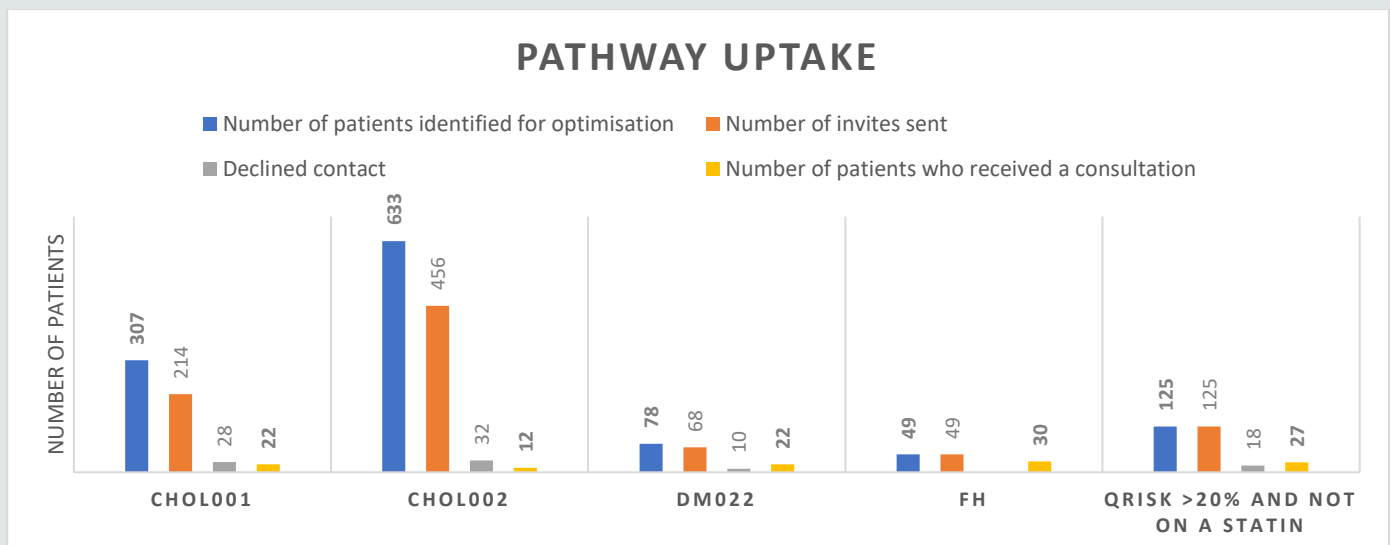
Practice 1 Size: >12,000. Fourth least deprived decile.

Four searches were conducted at one practice that piloting the full support approach: FH, CHOL001, CHOL002, DM022, (QRISK >20% TBD).¹⁴ The searches and lipid management reviews are currently being conducted at a second practice, January – March 2024 (case study site 2), and will report on final progress in March 2024. The CHOL and DM searches were conducted to support the practice work toward their QOF targets and support an embedded lipid management approach.

Across the searches at case study site 1 between August –December 2023:

- 1,192 patients were identified for optimisation;
- 912 invitations were sent via SMS (300 could not be sent as some did not have a valid mobile number or SMSs failed to deliver), 88 declined the review and consultation;
- 113 patients received a consultation (figure 2);
- of the 113 who received a consultation, 48 started statin or lipid lowering therapy (LLT), 5 had their therapy increased or changed to high intensity statin, 32 patients declined statin or LLT or declined escalation of therapy (figure 3); and
- it takes approximately 15 minutes per patient from case finding to consultation (Note: at site 2 the lipid practitioner took 10 days to review 210 patients and create searches, contact patients and code non-responders).

Figure 2. pathway uptake



¹⁴ **CHOL001:** Percentage of patients on the QOF CHD, PAD, Stroke/TIA or CKD register who are currently prescribed a statin, or where a statin is declined or clinically unsuitable, another lipid-lowering therapy.

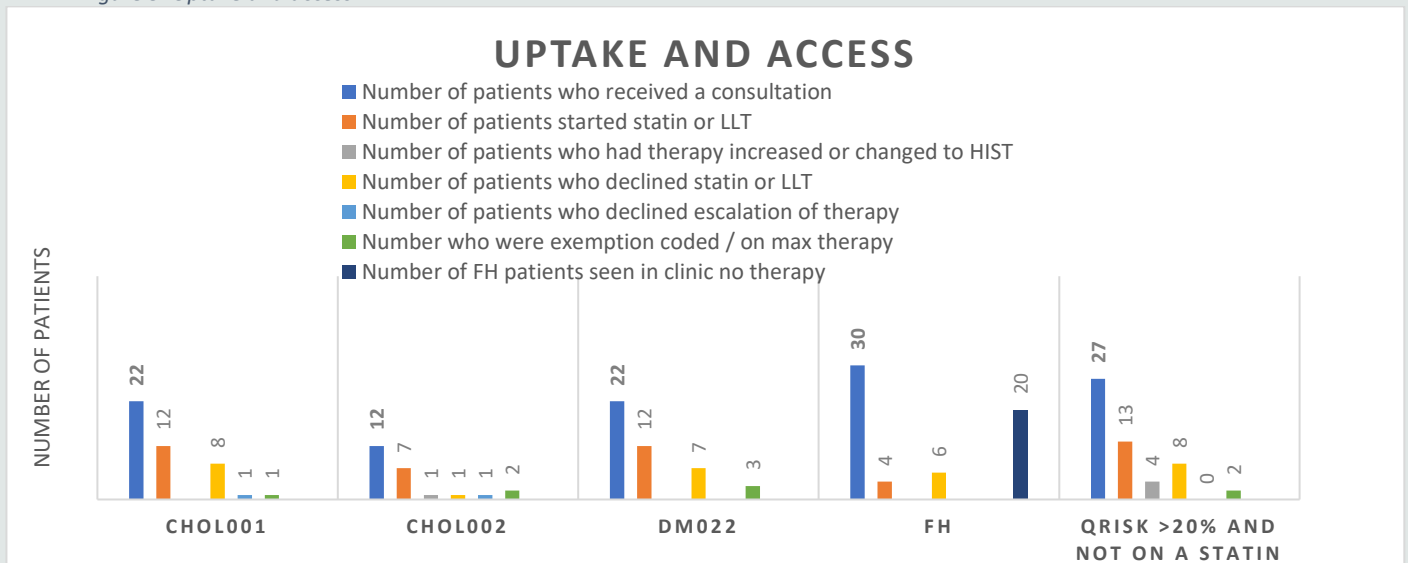
CHOL002: percentage of patients on the QOF CHD, PAD, or stroke/TIA register, who have a recording of non-HDL cholesterol in the preceding 12 months that is lower than 2.5mmol/L, or where non-HDL cholesterol is not recorded a recording of LDL cholesterol in the preceding 12 months that is lower than 1.8mmol/L.

DM022: the percentage of patients with diabetes aged 40 years and over, with no history of CVD and without moderate or severe frailty, who are currently treated with a statin (excluding patients with T2D and a CVD risk score of <10% recorded in the preceding 3 years).

QRISK>20%: Patients that have a QRISK >20% not currently on a statin.

FH: Patients at risk of familial hypercholesterolaemia

Figure 3. Uptake and access



The SMS invitations for the CHOL and DM searches required patients to respond confirming contact or declining (88 declined contact). Some patients could not reply and would need to be contacted another way (by phone or letter). The FH invitation process differs from the non-FH process, as a family history questionnaire needs to be sent and filled in, and then an invitation for review is sent, which adds to the engagement drop off rate at each step.

Reasons for non-engagement from patients: declined invitation due to personal circumstances; further tests not possible due to needle phobia; method of contact a barrier, i.e., not able to post family history questionnaire or respond to SMS; non-response to questionnaire or SMS.

Reasons for declining treatment: the lipid practitioner reflected that some patients who were not on medication yet consider it a big step to start a statin and acknowledge they have high cholesterol in the first place. Patients also consider implications of having high cholesterol and being on medication, such as increased insurance rates when they go on holiday and declaring they have high cholesterol/ are on medication.

Detailed lessons from implementation can be seen in section 3.4, including patient experience.

The key lessons include:

- **Adoption enablers at the site**
 - There was existing support for change to take place at a senior level.
 - The opportunity for a funded post to conduct active lipid management became available.
 - Compatibility of the role and processes with existing site functions and processes (EMIS, SMS function).
- **What went well in the approach**
 - The lipid practitioner had familiarisation with the practice, staff and system already.
 - The approach to targeting patients was tailored in a way that also supported practices achieve QOF points/incentives.

- The lipid practitioner actively looked to make blood testing efficient for the practice and patients by ensuring lipids tests were scheduled with other tests.
- A key success for the lipid practitioner was the access to knowledge and training and mentorship that was designed as part of the role.
- **The FH search effectiveness**
 - The FH search resulted in 74 identified as potentially having FH, 49 contacted, and 30 who had a consultation, but 0 patients were eligible or referred for FH testing.
 - To understand if targeted FH searches are effective, the stratification/exclusion/contact model will need to be assessed (24 patients were excluded of the 74; 22 did not reply to the initial SMS; the initial inclusion criteria may need to be broadened such as considering maximum triglyceride level).
- **Barriers and potential barriers**
 - Reaching patients and overcoming access barriers for patients was a key challenge.
 - Managing time per patient and understanding capacity needed is a challenge.
 - Implementation at first site has been seen as easier to embed due to past/current experience that the lipid practitioner has with the practice. Time to adopt and embed could take longer for new postholders who are not familiar with the practice system or practice staff (knowing who to book an appointment with, names of the healthcare assistants).
 - Ability to prescribe, and ability to navigate ethical challenges with patients presumed to have FH will be potential challenges for future roles. Lipid practitioners could be faced with ethical challenges of contacting patients who may have been given a presumed clinical diagnosis of FH but not had a genetic test for FH. Patients may face personal decisions following a diagnosis of a genetically inherited condition.
- Without a formal role embedded in the practice after the lipid practitioner finishes in post, the active case finding and reviews will reduce, or not actively continue in the practice and PCN beyond routine care, or unless a yearly plan is in place to support lipid management alongside the QOF work.
- While the lipid practitioner did not feel they were isolated in working in the practice, there is a need for new roles to embed and belong within primary care or the PCN to coordinate lipids and CVD work and practice approaches, rather than isolated tasks.
- Patient uptake following the targeted SMS invitations was relatively low at 12%. Methods of engagement with patients to increase uptake should be explored, including behaviourally informed messaging and utilising other methods of contact beyond SMS, to ensure those most at risk do not face exclusion if they do not have a mobile or smart phone to receive SMS and respond using the internet.

3.2.2 Tailored education sessions

A core part of the programme involved the project and steering team developing resources about lipids management and NICE guidance on pathways, as well as delivering education sessions to primary and secondary care staff, so they have access to information and tools for lipid management. The education sessions were conducted by the Consultant Lipidologist and an expert member of the lipids team.

There have been n21 education sessions delivered as part of the project (three of those sessions between June 2022 and March 2023 were pre-CLF, but still part of the early development of the Somerset model with Health Innovation South West). Participants from n18 of the CLF sessions responded to an evaluation survey (see section 3.3.3). Across the education sessions, the TeamNet access, and the full support at case study sites, the Somerset Lipids Project has reached an estimated 71 healthcare organisations, consisting of practices, PCNs, foundation trusts, hospitals in Bristol, Somerset and Devon, Heart Institutes, urgent care services, and Deanery (table 2, page 20) (table 3 details the education sessions).

About **621 people from various clinical roles in primary and secondary care have attended education sessions** with the Somerset Lipidologist between June 2022 and February 2024.

Table 3. Somerset Education Sessions Delivered

Date of session	Title of session	Target audience	PCN/Trust/Site	Attendance
21/06/2022	The Familial Hypercholesterolemia and New Lipid Medications	GPs	Yeovil	19
04/03/2023	Lipid Management	GP Practice Fellows	Primary care	20
24/08/2023	Assessment and initial management	Junior docs - YDH	Yeovil District Hospital	20
08/09/2023	"Let's talk about.....Lipids and Diabetes"	GPs	French Weir	5
14/09/2023	"Let's talk about.....Lipids and Diabetes"	GPs	Wells Health Centre, Buttercross, Symphony Healthcare Services, Glastonbury Surgery	12
26/09/2023	Lipid Management	GPs and patients	Langport Surgery	n/a
27/09/2023	Overview of lipids and management related to stroke	Stroke nurses + therapists	Somerset Foundation Trust Musgrove Park Yeovil District Hospital	40
27/09/2023	Assessment and initial management	Registrars, Hospital GPs from across the SW	Including but not limited to: University Hospitals Bristol and Weston Locum Doctor Gloucestershire Hospitals NHS Foundation Trust Royal Devon University Hospital Great Western Hospital Bristol Royal Infirmary Derriford Hospital Plymouth Southmead Hospital Taunton North Bristol NHS Trust North Devon District Hospital, Barnstaple Royal Cornwall Hospital Trust Somerset Foundation Trust	146

			Bristol Heart Institute Musgrove Park Severn Deanery Yeovil District Hospital	
09/10/2023	Lipid Management	GPs, Clinical leads	Oaklands	5
09/10/2023	Lipid Management	GPs	Taunton Vale	35
11/10/2023	Lipid Management	Diabetes nurses in the community	Somerset Foundation Trust, Preston Grove Medical Centre	5
18/10/2023	Lipid Management (Diabetes)	Whole of Somerset - all practice staff - GP, GPSE, Nurses	Including but not limited to: Langport Surgery, West Somerset Healthcare, Redgate Medical Centre, Penn Hill Surgery, Symphony Healthcare Services, Hendford Lodge, Quantock Medical Centre, Bruton Surgery, Lister House Surgery, Millbrook Surgery, Summervale Surgery, GP training surgery, Locums not organisation specific.	154
16/11/2023	"Lipids -Everything you need to know ...but were afraid to ask"	GPs	North Sedgemoor PCN (Axbridge Surgery, Brent Area Medical Centre, Burnham Medical Centre, Cheddar Medical Centre, Highbridge Medical Centre), South Petherton Surgery, Symphony Healthcare Services, Martock Surgery	6
20/11/2023	Fresh looks	GPs across Somerset	Including but not limited to: Crewkerne Health Centre, Creech, Lyngford park, East Quay Medical Centre, Polden, Taunton Vale, Summervale Surgery, NHS Somerset, Wells Health Centre, North Petherton Surgery, Taunton Road Medical Centre	60
30/11/2023	Lipid Management	Primary care - all staff	Vine Surgery	10
09/01/2024	Lipid Management	GPs	Grove House	8
16/01/2024	Lipid Management	Primary care - all staff	Wellington	23
17/01/2024	Lipid Management	Primary care - all staff	Millborn Port	7
18/01/2024	Lipid Management	YDH	YDH - junior docs	13
06/02/2024	Lipid Management - case based discussion	Primary care - all staff	Preston Grove	20
20/02/2024	Lipid Management	Bridgewater and Taunton Primary Care Group	Warwick House Medical Centre, Polden medical Practice, Quantock Medical Centre, French Weir Health Centre, College Way Surgery, Taunton Road Medical Centre, Burnham Medical Centre, French Weir Health Centre, North Sedgemoor PCN	13

3.2.3 General access to resources and wider webinars

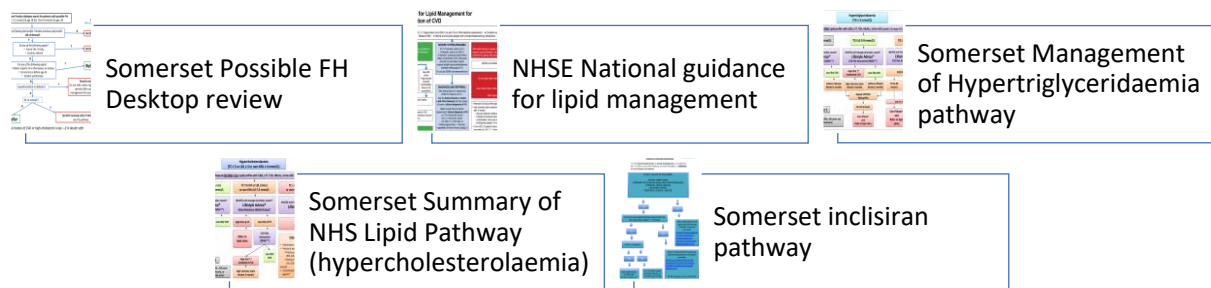
Lipids management resources for the project have been developed at two levels:

- Project and evaluation level to support the development of the Somerset Lipids Project.
- System level guidance and resources to support lipid management in Somerset.

The **system level resources are accessible to all practices in Somerset**, developed by key stakeholders and steering group members. The resources were designed to help primary care understand NICE guidance and pathways, access approaches and tools to lipid management such as tools to support patient identification, invitation, review, and management those at risk of CVD/with CVD/at risk of FH in primary care. The project aims to improve adherence to the pathway and processes across the region, by improving access to resources and guidance.

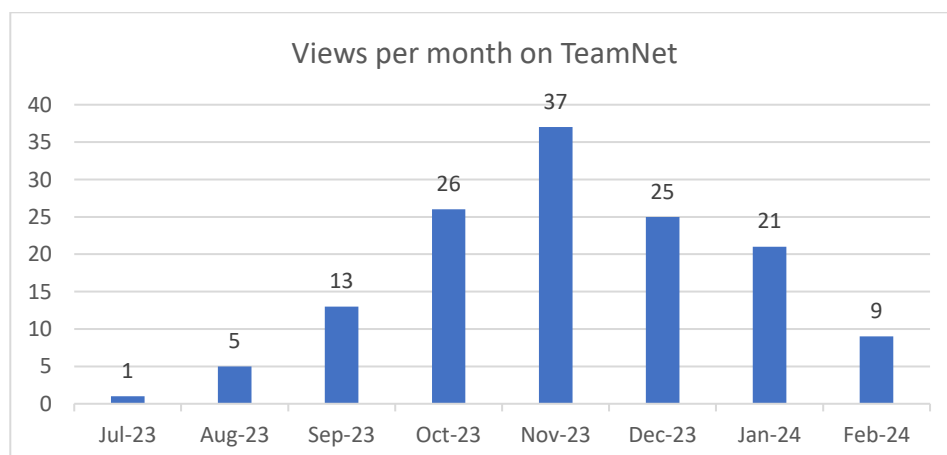
A TeamNet page has been developed as part of the programme, to give access to the resources. Numerous resources have been developed and uploaded, of which five key resources can be seen in image 6. TeamNet is an online platform that supports knowledge sharing and collaboration in primary care. The TeamNet resources were launched online at the start of August 2023, and **all 64 practices in Somerset have access to lipid management resources and guidance**. Alongside the downloadable resources about lipids pathways and management, the materials on TeamNet include guidance on who to refer to, what to do before referral, and how to refer. The resources can be viewed through Cardiology, Endocrinology, and Stroke/TIA sections in TeamNet – enabling teams from across specialities to access the same information.

Image 6. Resources on Somerset TeamNet



The Somerset Lipids Project **resources on TeamNet have been viewed 137 times across 29 practices** between August 2023 and February 2024 (45% of practices in Somerset). Access has increased monthly from 1 view to 37 views (figure 4).

Figure 4. Views per month on TeamNet



3.2.4 *Lipid clinics increase capability and capacity*

The fourth component in the lipid project is focused on increasing the capability and capacity in the secondary care lipid clinics. Previously the Somerset lipid service had one consultant running one clinic per month in Yeovil, and one clinic per week in Taunton before leaving the service in 2021. Currently, the consultant has been able to run four lipid clinics a month compared to the initial service he took over. A GP with an extended role and an FH nurse specialist are being recruited to support with additional clinics, and a Cardiologist is being trained and mentored to support additional clinics. The aim is for at least six clinics to be run each month, with each member able to run clinics in a part of the region to support local access to the service. An advice and guidance service has begun, and is supporting primary care with queries before referrals.

3.3 Outcomes

Early outcomes and progress toward outcomes are presented below across four areas:

1. patient experience 2. staff role development and satisfaction, 3. capability and confidence, 4. reduction in lipid clinic waiting times.

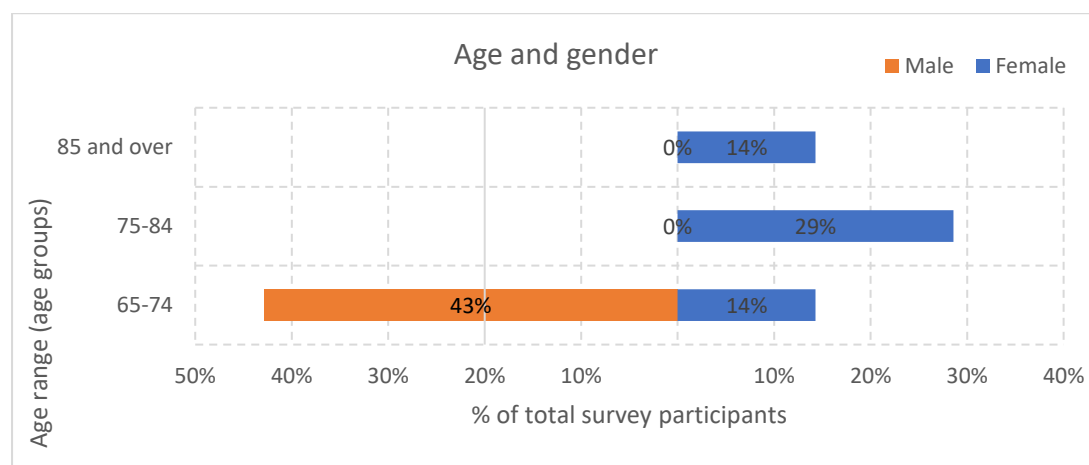
3.3.1 Patient experience

Patients who had a consultation with the Lipid Practitioner from the case study sites received a patient experience survey to complete. N7 patients responded between August – February 2024. All patients who responded were from case study site 1 only. The low response rate (n7 from an estimated 83 patients [8% response rate]) is a limitation to the analysis and conclusions. There was a lack of consistency in offering the patients the survey to complete via an SMS invitation, which further limited the numbers who received an invitation to the survey.

The survey included questions about patients' accessibility, acceptability, and personalised care, including ability to self-manage their condition. The Theoretical Framework of Acceptability (TFA) was used to understand general acceptability of the lipid management approach for patients; the seven TFA domains include: affective attitude, burden, perceived effectiveness, opportunity costs, ethicality, intervention coherence, self-efficacy (Sekhon, *et al.*, 2022). Additionally, the Somerset Lipids Project offers patients a more person-centred approach to their care, as they are actively being case-found and invited for reviews by the Lipid Practitioner. The person-centred coordinated care experience questionnaire (P3CEQ) was used to understand the extent to which the service is providing person-centred care (Lloyd, *et al.*, 2019).

Three patients were contacted by phone call, three by SMS, and one by SMS *and* phone call. Four patients responding were female and three were male. The ethnicity of all seven was white: English, Welsh, Scottish, Northern Irish or British Irish. Participants were aged over 65 (n4 65-74, n2 75-84, n1 85 and over) (figure 5).

Figure 5. Age and gender of survey participants

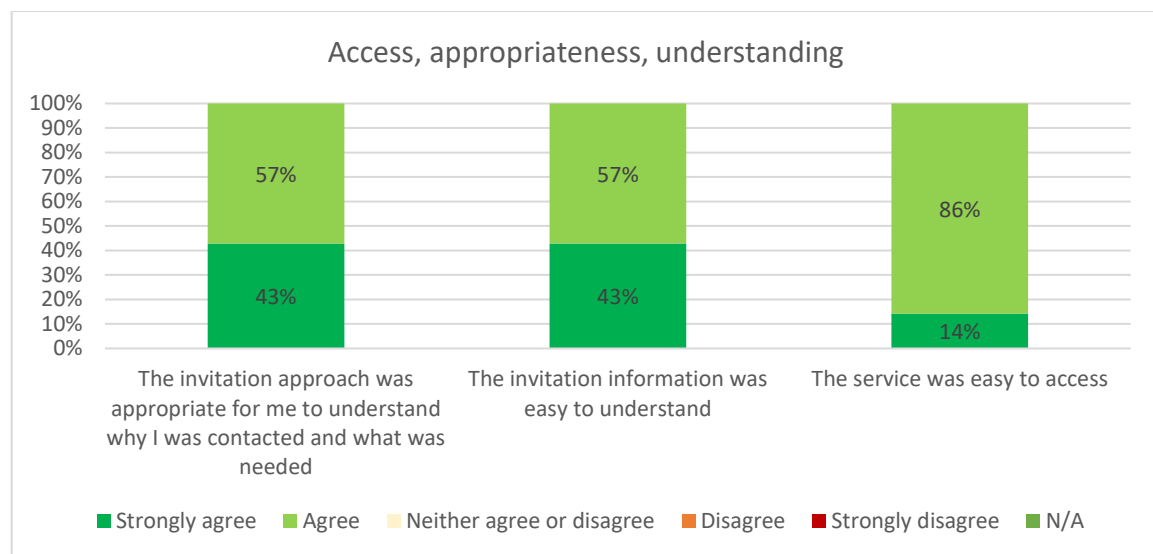


Early insights indicate positive responses to acceptability, accessibility and experiences of person-centred care.

Accessibility

- All seven agreed or strongly agreed that they found the *invitation method (SMS or phone call) appropriate* to understand why they were being contacted, the *information is easy to understand*, and the *service easy to access* (figure 6).

Figure 6. Access, appropriateness, understanding



Acceptability

- All seven said that overall, they found the care approach acceptable (with a general acceptability mean score of 4.7 out of 5).
- All seven agreed or strongly agreed that it made sense how the advice and treatment will improve their health, and felt confident managing their cholesterol following the review.
- Some (n2) felt less comfortable engaging with the lipids care pathway, and n2 felt there were moral issues to engaging with the service, even though they gave high overall acceptability scores.
- Textual comments included that it was “*explained perfectly*”, “*friendly advice*”, “*friendly and informative*”, “*very helpful service, informative and encouraging*”.

Person-centred care

- Overall, the seven patients responding had a good experience of person-centred care. The mean total score was 19.6 out of 24 (range of 12 – 24) (with the higher the score, the better the experience).¹⁵
- The seven participants felt that they were *involved in decisions about their care* and *considered a whole person* with these two questions having higher mean scores (2.7 / 3).
- The question with the lowest total mean score related to patients feeling that they had *enough support from staff to manage their cholesterol* (mean score of 2.1/3).
- The responses were mixed about *how confident they felt in managing their own cholesterol* (mean score of 2.3) (3 very confident, 3 somewhat confident, 1 not too confident). The responses contrast to the same question in the previous acceptability section where all seven agreed or strongly agreed that they felt confident managing their cholesterol following the review. They indicated that: “*diet and exercise*” [*information and commitment to lifestyle changes*], “*understanding what the medication will do*”, and “*annual conversations with the cardio nurse*” would help them feel more confident in managing their cholesterol and health.

¹⁵ The person-centred care subscale was used for the survey and the total score excludes P3CEQ questions 6 and 7a-d making the maximum total out of 24 rather than 30.

3.3.2 Role development, satisfaction and experience

A core aspect of the project is the support from enhanced roles. The project initially recruited a GP with an extended role to support the clinics and support primary care education, and a clinical pharmacist role as a lipid practitioner in primary care to develop the pathway tools and implement the lipid management pathway. The team will be recruiting more lipid practitioners and roles, as outlined in section 3.1. The project is seeking to understand if the staff in enhanced roles have improved role development and satisfaction in the role, and with the service delivery. The lipid practitioner was interviewed for interim insights. Further interviews will take place with practitioners recruited to the new roles for the final report. The interim insights show that the role has enabled the individual greater opportunity to develop skills, supports them with motivation and offers satisfaction in work, and has built their capability in a clinical role in primary care compared to their usual work as a clinical pharmacist.

The Lipid Practitioner interviewed felt a greater sense of motivation in this practitioner role compared to their usual role as a clinical pharmacist, as it offers more detailed clinical work and the opportunity to operate in primary care. The opportunity to assume a more clinical role and the motivation for such development influenced the respondent's positive attitudes about the role. The key motivating factors included: more in-depth learning; understanding clinical aspects of the work including interpreting blood work; and clinical decision-making. A motivating factor of the work in the future would be a permanent role, or role with more time than 1 day per week.

"I found it quite frustrating working in primary care having access to all these blood tests, and people saying, 'Oh, can you tell me what the results are', I'm reading off a set of numbers, and then I don't know what this means. So it's been really satisfying to know more about the lipid bloods, and knowing more about the NICE criteria, like say, Okay, if my triglycerides are this, how does that meet or not meet a NICE criteria? And what do I do about it? So, I think more in-depth knowledge that was also going to complement my current role."

A core part of the role has been capability building through learning, application, development opportunities, and mentoring. The respondent felt the learning aspect was critical to feeling they were developing and growing their knowledge, as well as providing them with the capability to design and implement the work. Specifically, the work within the role has enabled more in-depth knowledge and experience managing patients, building knowledge of a clinical area, building tools for primary care, and tools to enable communication and referral to secondary care, joining up with wider professions in the project team, and developing peer support/presentation skills. Having a mentor to support conversations and empower decisions and ideas has been a benefit. The respondent indicated they were very satisfied in the role and where they fit in primary care.

"A really positive input. It's been really satisfying... I feel like I have a positive contribution. It certainly led to more satisfaction and you know, understanding of my own role and how I fit in as primary care as much as anything else."

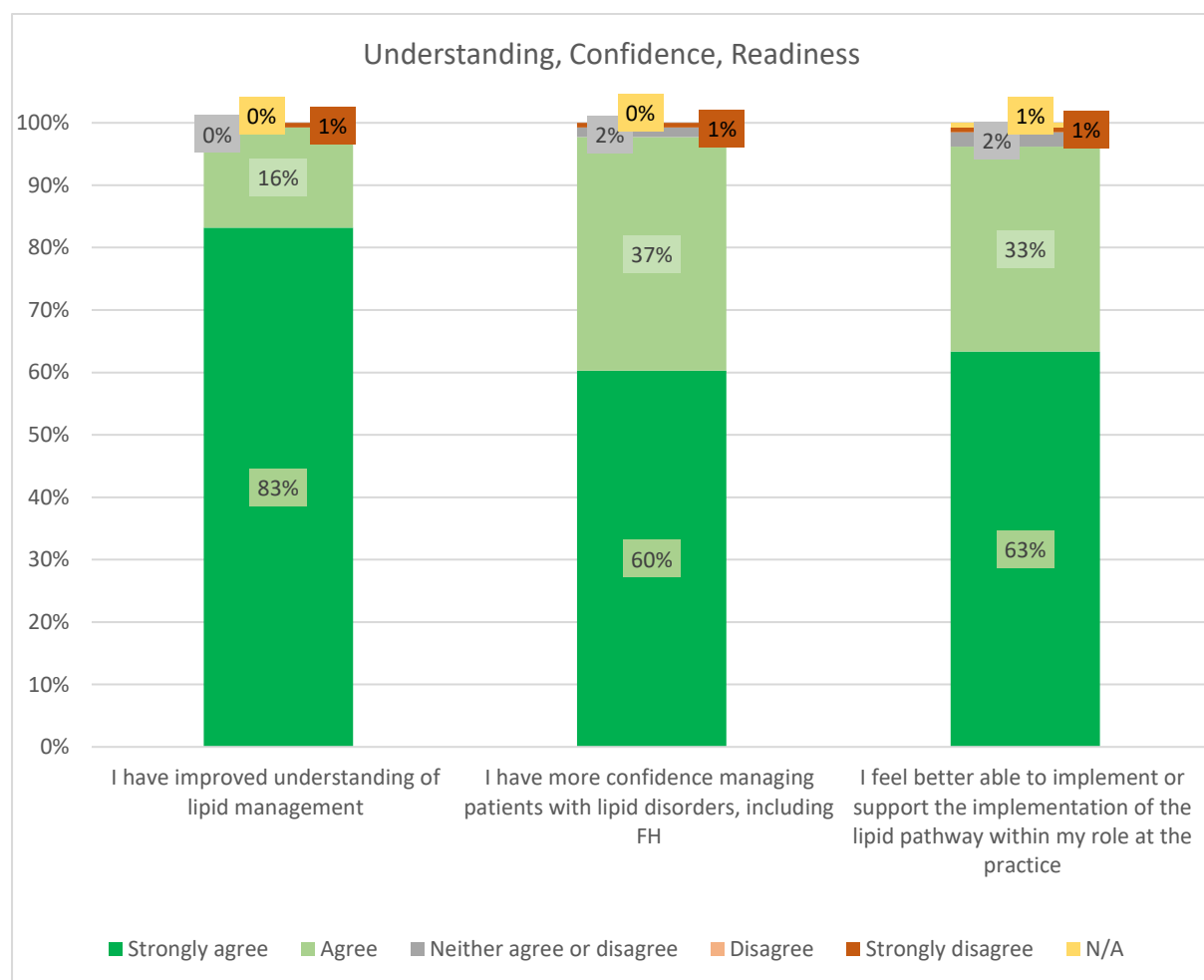
"It's actually exceeded my expectation. Because I thought what was going to be needed or required of me was literally bash it out, you want to see results as quick as possible for as many people as possible. If you don't tick these boxes, you know...But it's been really focused on my learning and development as well, which has been fantastic."

3.3.3 Education sessions outcomes: knowledge, confidence

The education sessions delivered across primary and secondary care from April 2023 were evaluated to understand how the workforce experience the session and if it improved their understanding and confidence with lipid management. N21 education sessions were run, and n18 of those sessions were evaluated as they were delivered after April 2023, and the survey had n131 responses.

- 99% of survey respondents strongly agreed or agreed that the session had **improved their understanding** of lipid management.
- 98% of survey respondents strongly agreed or agreed felt that they **had more confidence to manage patients** with lipid disorders, including FH.
- 96% of survey respondents strongly agreed or agreed felt **better able to implement** or support the implementation of the lipid pathway within their role.

Figure 7. Workforce education survey



Survey participants felt that the sessions were clear and interactive, with useful and new information. Three core themes capture the positive aspects highlighted by participants in the teaching sessions, emphasizing detailed medication knowledge, a focus on familial hypercholesterolaemia and physiology, and effective teaching strategies that enhance the learning experience. The teaching strategies such as utilising case-studies for real-life context and application, and signposting to resources, was effective in helping the participants engage with the content and learn.

A few participants commented on what could be done better or differently next time. They highlighted areas that could be emphasised more in other sessions: having longer sessions; more cases presented; interactive work where participants can work through a case together in the session; understanding prioritisation approaches from others; having a recap of guidance on referrals; complexity of drugs; and lifestyle aspects to support dietitians/MDT working.

"It was interactive and straight to the point."

"Excellent first principles-based teaching. Now have a good understand."

"A refreshing reminder of the rationale for statin use."

"New information regarding management."

"The systematic approach to treat high lipids."

"Good overview of a generally neglected area in secondary care."

"Working through the case study was useful, overall great session, really helpful."

"Good, clear teaching well presented."

"New agents for lipid lowering. Learning about how to identify genetic causes of hyperlipidaemia. Reminder to check all parts of a lipid profile."

3.3.4 Lipid clinic

The aim of the enhanced service at the lipid clinic is to manage demand more effectively and reduce the waiting time from referral to appointment to within 18 weeks.¹⁶ The Somerset Lipid Service identified a three-pronged approach to improving the service: increase service provision to manage the backlog from May 2021; increase service provision to meet increasing demand from new referrals as primary care; and work closely with primary care, offering advice and guidance to support appropriate referrals. The lipid project is further being supported to co-develop a model to understand demand, capacity and sustainability going forward.

In May 2021 there was the departure of the only consultant lipidologist running clinics for Somerset, leaving one lipid clinic a month running for the whole county with the new consultant. There was a need for increased service provision following the consultant changes in May 2021, together with the lengthy waiting times once referred to the lipid clinic, and the increased (expected increase) in demand due to more awareness and incentives in primary care around lipid management, and active case finding that is occurring with the lipid project. The Somerset Lipids Project is being set up and delivered to address those needs by increasing capacity to provide more clinics per month, increasing from the current one to greater than six when new recruits are in post. Currently the clinics are being run by the lipidologist (1 clinic/week) until recruits are in post after April 2024.

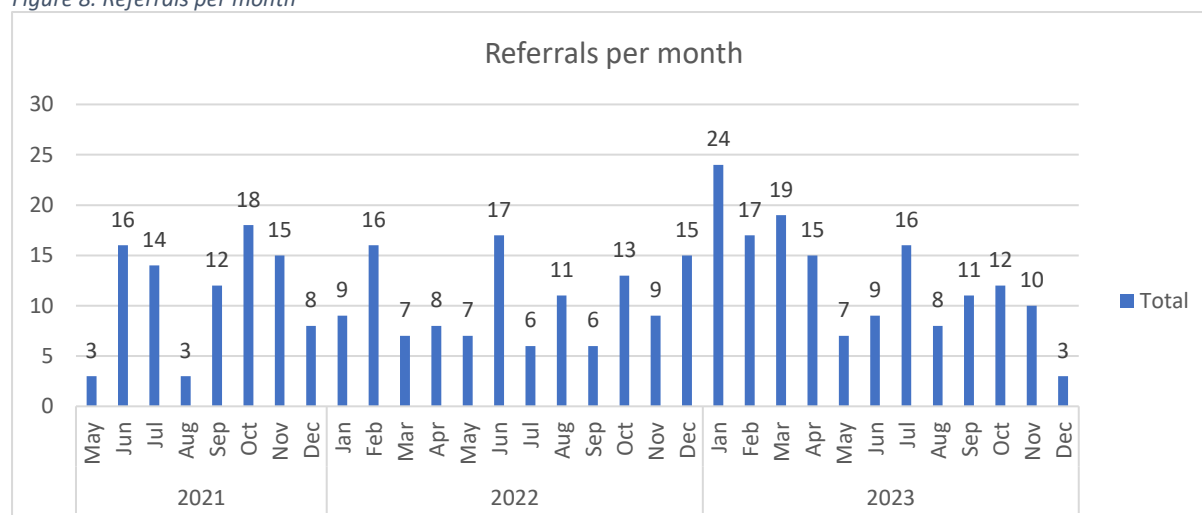
From 04/05/21 – 31/12/23 there were n364 patients on the referral list. The clinics and new service provision is still being established but early insights suggest that there has been an increase in the number of patients who have had a lipid clinic appointment from n26 in 2021, to n46 in 2022, and

¹⁶ NHS providers and commissioners also need to use this information to ensure they are meeting their patients' legal right to start consultant-led non-emergency treatment within a maximum of 18 weeks from referral – and to identify where action is needed to reduce inappropriately long waiting times.

n108 in 2023 while the average number of referrals per month has been 11 per month from 2021 – 2023. The enhanced service model will be fully established in 2024 as new roles start and increase the number of clinics run monthly. Currently in the early development of the service there is a reduction in the average and median waiting time from referral to treatment that can be seen.

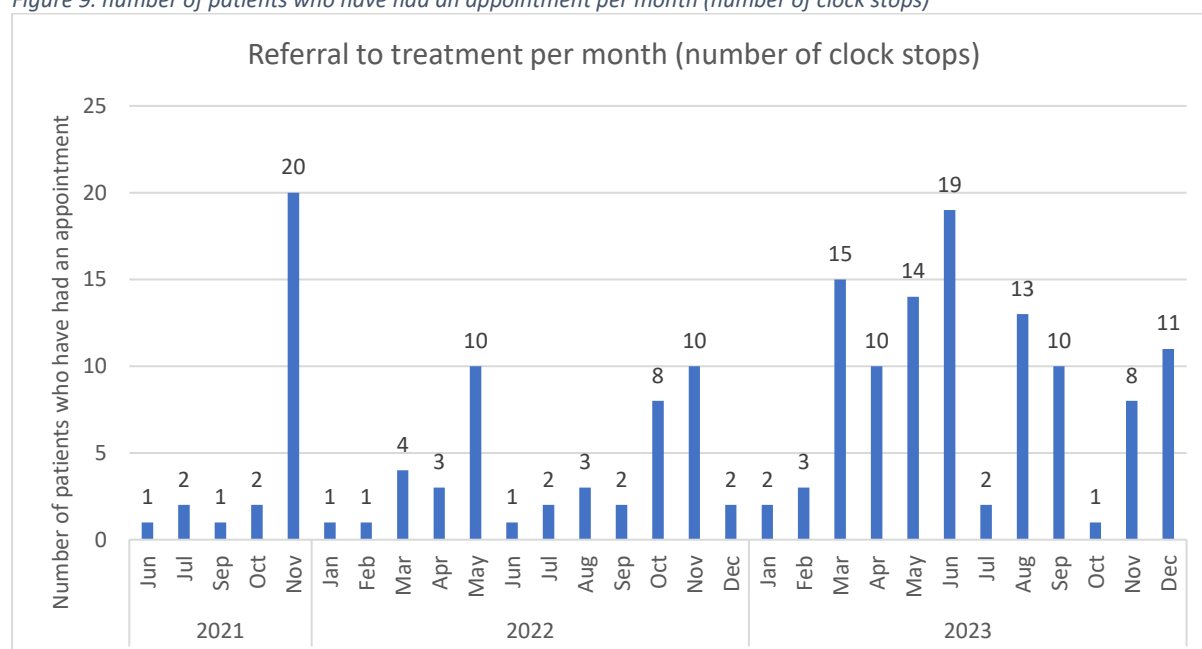
Overall, between May 2021 and December 2023 there is **an average of 11 referrals per month**, with an average of 11 per month in 2021, 10 per month in 2022, and 12 per month in 2023 (figure 8).

Figure 8. Referrals per month



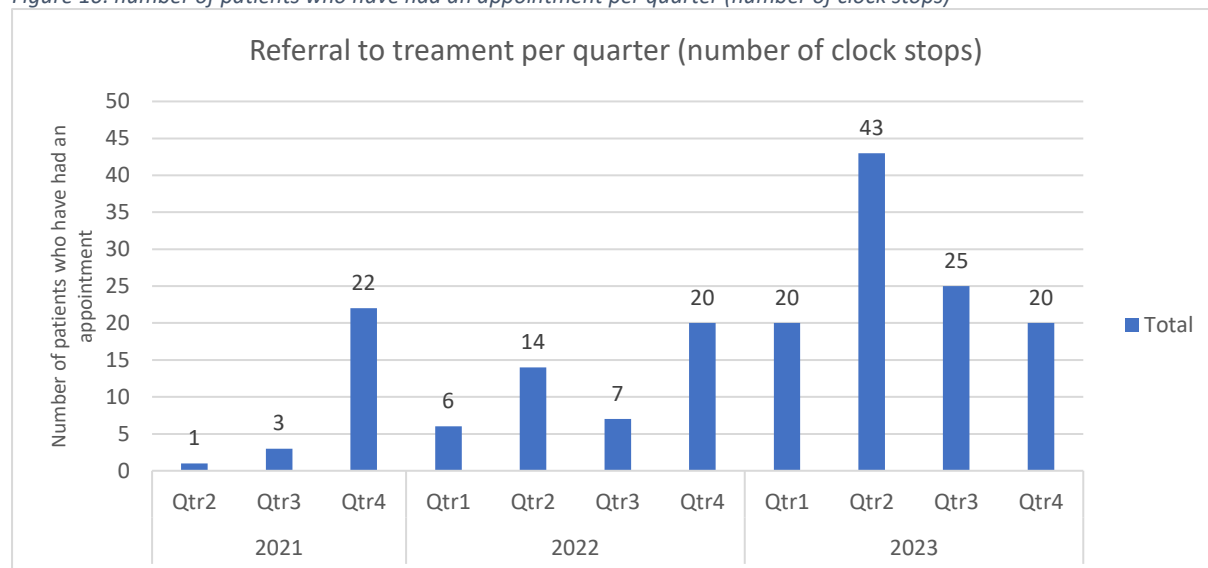
The **referrals to treatment per month** (number of people who have had an appointment following referral) (number of clock stops per month) **ranged from 1 to 20 per month**, with a total average across the years of 6 per month (an average of 5 per month in 2021, 4 per month in 2022, and 9 per month in 2023) (figure 9). Not captured in the formal referrals and RTTs per month is the informal advice and guidance that is given via emails and phone calls that would have otherwise been a formal referral, but still require resource from the consultant.

Figure 9. number of patients who have had an appointment per month (number of clock stops)



N219 people have had appointments (referral to treatment clock stop). The number of people receiving an appointment quarterly is increasing as more clinics can be run monthly (26 clock stops from Q2-Q4 in 2021, 47 clock stops Q1-Q4 in 2022, and 108 clock stops in Q1 – Q4 in 2023) (Q1 of 2024 is excluded here but contains 38 patients who have an appointment date booked and are counted toward the total n219) (figure 10).

Figure 10. number of patients who have had an appointment per quarter (number of clock stops)



The **median wait** for those who have a **completed pathway was 59 weeks** (half the patients were seen within 59 weeks). The **92nd percentile waiting time was 75 weeks** (table 4).

Of the current patients waiting to start treatment (n145) (**incomplete pathway**), the **median wait time is 37 weeks** and the **92nd percentile waiting time is 49 weeks** (table 5).¹⁷

Table 4. Completed pathway wait in weeks

Completed pathway wait time in weeks	
Average	52
Median	59
Percentile 95 th	77
Percentile 92 nd	75

Table 5. Incomplete pathway wait in weeks

Incomplete pathway wait time in weeks	
Average	32
Median	37
Percentile 95 th	48
Percentile 92 nd	47

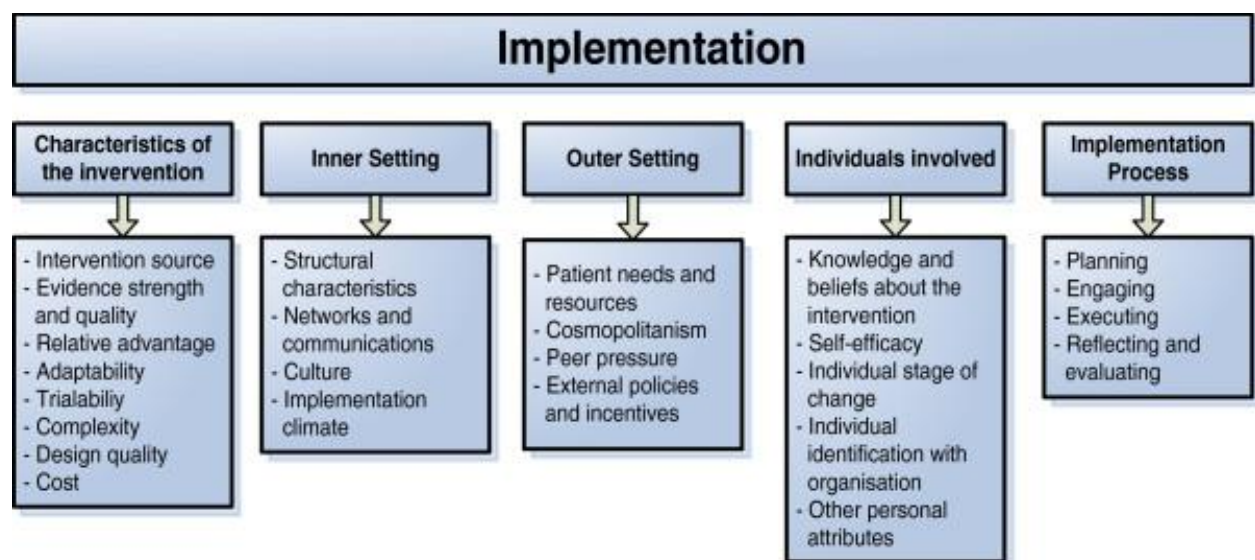
¹⁷ [Recording-and-Reporting-guidance-April_2021.pdf \(england.nhs.uk\)](#)

3.4 Context and Implementation Insights

Members of the project and implementation team (n8) participated in semi-structured interviews or a qualitative survey to share their experiences and learning across the project phases (development to early implementation). The quotes referenced below represent a diversity of voices from the team such as the lead consultant, lead programme manager, clinical pharmacist, FH specialist Nurse, programme manager for the Genomic Medical Service Alliance, and Somerset CVD Clinical Champion; the quotes do not have participant titles against them to retain anonymity. The responses were thematically analysed, and the Consolidated Framework for Implementation Research (CFIR) was used as a framework for secondary coding to understand core factors influencing implementation.

The CFIR is based on a systems approach and covers a range of factors that influence implementation. Enablers (3.4.1) and challenges (3.4.2) to implementation are themed under the five CFIR domains **a) innovation domain b) outer setting domain c) inner setting domain d) individuals domain e) implementation process domain** (image 7).

Image 7. CFIR domains



3.4.1 Enablers:

a) Intervention: designing for context, system, patient, and workforce needs

The project team highlighted the health challenges and needs in the region that have influenced how they designed the service model. The challenges included:

- issues related to health services overall;
- workforce retention/recruitment in the South West;
- an aging population with a high CVD prevalence in Somerset; and
- the health inequalities faced by the Somerset and South West populations, especially barriers to access to services and local access to specialist care (patients face difficulties accessing services due to the distance to clinics and long wait times).

The need for an increased lipid service in secondary care was evident from the growing referral list and the length of time patients are waiting from referral to appointment, with only one consultant running clinics for the whole region. The team feel the new model and the service will improve equity of access to a lipid and FH service in Somerset.

“Somerset will have gone from having no real lipid service and just one consultant picking this work up for the whole county, without the capacity to actually deal with it, to having not only a lipid service but also an FH service. This will significantly increase equity of access to care and improve inequality in outcomes as regards cardiovascular morbidity and mortality for Somerset population.

This is a huge achievement.”

“The problem is that there's no local service. It's all based in Yeovil which if you're in West Somerset takes an hour and a half to get there. The accessibility is a problem, not just in terms of distance, but also in terms of waiting time to get through to clinic of 72 weeks [waiting time from referral to appointment], there's that sort of problem. For a lot of people, though, this isn't just about patients, this is about workforce.”

Recruiting and retaining a suitable workforce in the region is a key challenge. To address this, the team considered roles beyond consultants in helping to deliver lipid clinics in secondary care and lipid management in primary care. Initially, the project leaned towards a consultant-heavy model, but feedback and insights from team members led to a more diversified approach, considering various roles such as FH specialist nurses and clinical pharmacists able to deliver lipid management in primary care, as well as support secondary care clinics. They also recognised the need for local delivery across the county and adjusted the model, placing the GP with an extended role in the north of the county and collaborating with neighbouring regions to expand service access.

“The trouble was my initial thoughts were very consultant heavy, because that's what everybody else does, and then speaking particularly to [X] and the others, my eyes were open to thinking more about other roles, which also made me think, we do live in a rural area, and people don't like to travel, even 10 miles, let alone 40. So that is now part of the model, thinking about how we deliver locally, which is, again, one with a GP with extended role, I was really keen that person will be working in the north of the county, because I cover the South, but there was nothing much at all in the north. I have had support and help from the neighbouring areas.”

The service redesign is a complex, system-wide change and thus involves multiple stakeholders and from primary care to secondary care and ICB and Public Health teams. The design of the model is based on NICE-approved pathways and best practice from lipid services in other regions in the UK. There are aspects to the project implementation that are adaptable, such as how much education and engagement is delivered, as well as the configuration of the workforce that is recruited for primary care implementation support, and the multidisciplinary teams that are supporting secondary care lipid clinics.

B) Outer setting: system need, external drivers and opportunity

There was a significant unmet need in the lipid service for the region as it was being previously delivered, demonstrated by the growing waiting list. There was one lipid specialist left in the region running one clinic a month and the service was not sufficient to meet the needs of the region. Additionally, there was concerns that the waiting list was increasing as a result of the communication and championing of lipids in the region, and the growing incentives for primary care to manage patients at risk. The lipid project model was designed after consultation with colleagues in other regions, understanding the models in operation in the UK, and the population and workforce needs for Somerset.

“[following departure of the second lipid specialist in the county] I was then the only lipid specialist for the whole of Somerset... and then [it became] clear very rapidly, that there was a significant unmet need. At that point, I was doing one lipid clinic a month for basically the whole county. I could

see about 10 patients a month. So, it became very clear very quickly that that was an insufficient service.”

“Within that timeframe genetic testing for FH became available as a nationally commissioned service. So up until that was available, I was doing a little bit of genetic testing for FH, but Taunton was doing none because they had not managed to identify any funding stream. It then became nationally available and consequently, I think that pushed referrals a bit as well. Certainly, in this area, because I was telling people it was available. The result of that is that my waiting list grew to the point where I think it was 110 weeks.”

The changes in the external context (policy and financial) were a critical factor in enabling opportunities for the service redesign and securing opportunities for funding. External factors such as:

- financial incentives for primary care to focus on cholesterol and familial hypercholesterolemia,
- FH genetic testing becoming available as a nationally commissioned service,
- and wider policy attention being placed on CVD and prevention programmes nationally and locally.

During this time of heightened policy and financial motivations, a driver for change was the lead ensuring there was cross organisational and system communication of the issues in the service and the risks with a growing waiting list. The challenges were placed on risk register in the Trusts and the then CCG was made aware of the priority.

“I think that because of the various national priorities that have come along it has been quite timely to raise the profile of lipids and CVD prevention. But I guess you make your own luck. Recognising that those priorities are there and shouting about them is really important.”

In addition to the needs, the CVD policy and financial drivers, there were also local opportunities where funding was available to focus on lipid related work locally. The initial local funding enabled the project to begin as a FH fellowship role in primary care which has further been developed into the broader commissioned lipid service.

Overall, external influences played a role in driving change, with a series of opportunities that emerged at similar times that propelled the programmes’ development. These included:

- wider prevention strategy and incentives,
- funding opportunities,
- need for redesign of a lipid service to respond to greater/unmet need,
- opportunity for workforce development and role development,
- and motivated and capable individuals in the region who were being connected by a champion.

C) Inner setting

There are two inner settings within this work: the **project steering team**, and the **implementation case study sites** in primary care. The dynamics within the inner settings highlight the conditions that have enabled positive working as a service design and steering team, and implementation in two case study sites.

There are elements of how the **project steering team** came together are enabling the redesign and implementation process, namely:

- clear leadership and partnership across the team,
- adaptability and learning culture that has been built in,
- good communication processes and networks with regular meetings and sharing,
- and clarity of vision and motivation to improve patient health outcomes.

“Good communication between participants aided by a structured minute taking and agenda. Regular meetings which again have been chaired well and kept the group focused on working through agenda items as needed.”

“We're really good at connecting, both internally and externally, I think that's been one of the big enablers in this work.”

“This group can hold the uncertainty well. The teams that thrive are those that have that permission to try and permission to fail. It's that shared responsibility that we're in this together, stronger together kind of approach.”

Collaboration was effective across the participants from various sectors and relied on good communication, clear vision, good understanding of roles and strengths within the team, structured meeting agendas, and minute-taking. The collaboration between primary and secondary care was driven by a shared focus on patient outcomes and benefits. The team in Somerset has evolved as more opportunities developed and a clear vision and service design emerged. The programme management and coordination support of the group and team is a core component of successful design and implementation and keeping up delivery momentum.

“Effective collaboration between participants from many different spheres (primary care, secondary care, AHSN & public health etc). Drawing on individual expertise relevant to each aspect of the implementation.”

“Good collaboration between primary and secondary care with patient outcomes and benefit at its heart.”

“Collaborative approach bringing in expertise from across the region to develop a robust and sustainable patient pathway/lipid service. AHSN co-ordination and bringing the project perspective has been excellent and will ensure the learning is shared.”

“The support from the AHSN has been great. The engagement from secondary care endo and all the relevant teams i.e., dieticians, biochem etc.”

The second inner setting is the **site of implementation within two case study sites in primary care who are** working with the extended roles/lipid practitioners. The key enablers in the inner implementation setting include:

- priority and tension for change and existing support for change at the sites,
- compatibility with site functions and processes,
- financial incentives,
- and the lipid practitioner's access to knowledge and information.

The two implementation sites were chosen based on existing relationships with the General Practice Health Care Group. There was existing work occurring around CVD with this PCN (supporting public health with a CVD dashboard), and there was buy-in for a fellowship role with the PCN that would utilise their clinical pharmacist for the lipid practitioner role. There were additional incentives with the work directly supporting points for the Quality and Outcomes Framework (QOF).

"The start was looking at the use of to the UCL searches. [Now] I'm trying to think what QOF boxes that those would tick, because [the lead] is really keen to do the UCL searches, but to pitch it to a surgery we need to be able to say, these are the things, this is why we want to do it. Of course, we want to look after patients, but we want to make sure we're getting paid for it at the same time."

The implementation process involved developing appropriate templates and patient invitations, letters, questionnaires and referral letters, and then beginning to see patients. These tools and materials were developed in collaboration with the lipid practitioner in primary care and key members in the steering group. The materials and tools fit within the existing EPR system (case finding, sending invitations via AccuRX, tracking uptake). The lipid practitioner manages the pathway one day a week and the approximate time from case finding to consultation is 15 minutes per patient.

The project had a steering member working closely with the role and offering guidance and mentorship, and the lipid practitioner was attending courses and training. Access to knowledge and support was important for the lipid practitioner and helped develop their clinical confidence.

"[the role] has been really focused on my learning and development as well, which has been fantastic... I'm so grateful for the support [steering member] has given me... wouldn't have been able to do this without [that member]. Partly because working one day a week is quite challenging for me, and without having [steering member] to bounce things off it would have been difficult."

D) Individuals

The capabilities and motivation of the core project steering team have been a key driver in initiating change, developing the model, and adapting for implementation. A team with experience in service development and clinical knowledge was seen as critical to early success in building the foundations and developing a pathway and full-service vision and outcomes.

"Think it's been a little bit serendipitous, driven by key people like [Health Innovation South West team], and others and people who have experience of service development, has been really helpful to just make useful suggestions and direct my efforts."

"The team that have come around this have done as most people do, in these kinds of situations, going over and above. They're so passionate about their topic, and patient care, that they are devoting time to it, where it's not necessarily even in their job description. And then a particular group has these magic ingredients that just drives it along almost by itself. But the key part of that is the lipid service lead."

"The stage [the team were involved] was when thinking 'what is the right model'... There aren't lots of consultant lipidologists waiting looking for a job. Initially, when I got the funding, I did try and get some help, and there wasn't really anyone out there. So that also made [us] start thinking about 'what could be a better model'. That turned into all the work that we've done. It turned into that initial pathway meeting, that eventually evolved into the model that we now have, along with the logic model, which started out just thinking about FH and now includes the whole lipids service. It's actually a really good way of visualising and driving forward so that we know what we want to achieve, and what how we can measure that in the long term."

Participation and stakeholder representation and engagement were core enablers in the development and support from the system. People across multiple organisations were involved in the development or understanding of the changes such as: secondary care, primary care and the PCNs, the Local Medical Committee, Integrated Care System, Public Health, Genomics, patient

engagement, specialist pharmacist, Health Innovation South West, and the CVD board. The team's ability to collaborate, work toward a shared vision, and create a culture of learning was key to the set up and early implementation success. The way the team functions in a collaborative way has resulted in the pathway and resources being seen as co-produced across the stakeholders, and enabled a sense of joint ownership of the work.

"We're just trying to get all the stakeholders involved... if they're all engaged and involved, that will hopefully result in success. And it's actually also really useful way of refining the pathway."

"I really hope people do feel it is joint ownership, because that's really what I'm trying to drive. Because I really feel very passionately, that if I design this, and it's all mine design, nobody will buy in."

"What [x] did really well was as a team director almost brought people into the room to make things happen."

Leadership and the ability to drive the vision, and bring people together to work with their strengths was a central enabler for the project and regional working. Having a lipid service lead who could advise and work with team members and their strengths was valuable in the design and delivery of the project. In addition to a lead, a coach or coaching role has been useful for the team in ensuring the appropriate support and future-forward questions are built in.

"Having a lipid service lead has been really critical to the process."

"I look around the team that we have and I think who are we missing from this conversation? Who would bring a different perspective that we don't have? I think team working for instance, should bring diversity with it and all sorts of diversity. But typically, that leads to different experiences and that different knowledge will bring in diversity of thought."

"I see this as a pretty high performing team."

"I think having someone to hold it has been really helpful."

E) Implementation process

Implementation can be understood at four levels as seen in Image 4 section 3.2 (full support from lipid practitioner in primary care, tailored educational support to sites, general resources access and webinars, and building capacity and capability in secondary care lipid clinics).

There have been specific enablers to the **'full support' level of implementation within the first case study site** by the lipid practitioner: familiarisation with the practice and system, tailoring the approach to targeting patients in a way that also support practices achieve QOF points/incentives, and actively looking to make blood testing efficient for the practice and patients by ensuring lipids tests are scheduled with other tests.

Implementation at the first case study site has been seen as easier to embed due to past/current experience that the lipid practitioner has with the practice. Time to adopt and embed could take longer for new postholders who are not familiar with the practice system or practice staff (knowing who to book an appointment with, names of the healthcare assistants).

"I wonder if somebody who is not familiar with EMIS or not familiar with the surgery would find that more difficult, because I know them, so when I go to book an appointment, I know the names of the healthcare assistants."

An approach to targeting at-risk patients in the practice and timing searches, invitations, and consultations is important to tailor to the needs of the practice and capacity needs. Additional time is needed to review patients following searches, to include those more suitable for invitation, and exclude those who are not suitable for various reasons such as having other illnesses. Exclusions are manual and require subjective clinical judgement.

“...quite a lot of people I excluded [following the searches] was subjective. If somebody's going undergoing cancer treatment, they're not going to want to talk about benefits, which I think is reasonable. But some of the things were subjective exclusions that I thought were not the right time [for the patient to come in].”

Working with practices and their needs when developing the approach to targeting searches and reviews is beneficial for buy-in, and supports the practice with wider incentives. For instance, including QOF searches CHOL001/2 and DM002 will support financial benefits as well as lipid management. There were considerations of the extra costs, such as extra blood tests that needed booking. One way to overcome the need for additional tests was to ensure the blood test was scheduled alongside other upcoming bloods, for example thyroid.

“I don't think surgery willingness to have people do this would be a barrier, because even just in the 20 minutes I've spent so far, there's a lot of QOF boxes to tick, I think they'd be really pleased to have us on board with it. And it's not as if it's not costing them anything, although the potential would be a repeat blood test might be needed.”

Implementing the **educational** arm of the programme has been enabled through co-developing materials, resources, and sessions. Having a clear engagement and education strategy has been critical to start and focus sessions, ensuring primary care and secondary care teams across the county have access to resources and sessions.

3.4.2 Challenges

A) Intervention

The core programme includes lipid practitioners supporting primary care to deliver the lipid management or supporting primary care with the tools and knowledge for their staff to improve the lipid management at their practices. There are challenges with both elements.

Currently the lipid practitioner is an embedded role as part of the PCN, but the newly recruited practitioners will be rotating or external to the practices. The approach taken on deploying the newly recruited lipid practitioners in primary care will require flexibility to adapt, depending on the needs and operations of the practice. Additionally, running the case finding searches can be rapid; the resource challenges appear at the next stage of the process, for instance when considering how to send invitations, track responses and attendance, and manage consultations and follow-ups with all the patients.

The educational element of the programme that aims to improve knowledge and confidence of primary care staff to deliver improved lipid management services will require resource and capacity in the practices to follow through beyond education sessions.

The educational component of the program aims to enhance the knowledge and confidence of primary care staff in delivering improved lipid management services. Staff motivation and capacity in

the practices will be required in order to ensure lipid management approaches are implemented in primary care, following access to resources and education sessions.

B) Outer setting

Contextual factors have influenced the timing and pace of the project. There were system challenges after COVID19 that meant staff were managing the burdens and changes, and the lipids project was difficult to prioritise. Additionally, there were organisational mergers and internal organisational changes that delayed progress at times. Further, the team found that communication with the system about the problem and the project opportunity was complicated due to difficulties in identifying the right stakeholders, during the shift towards more integrated working.

Gaining acceptance from the system took a significant amount of time, with buy-in primarily driven by concerns over lengthy waiting times for lipid clinic referrals.

"You don't see benefit in a system straight away. In systems, we're often getting over one event and thinking 'what's the next event coming?' We don't design well."

"It took a long time to get the whole thing moving. It is unsurprising, but still disappointing, that the only thing that really got this moving was the fact that people were having to wait two years. And having pointed out all the reasons why – not just the data but all the reasons why you need a lipid service - none of that really seemed to have any traction until it got to the point where the wait was long and then the hospital is essentially being penalised for that. And that's the thing that moves things."

After receiving funding, initiating the project has been time-consuming and slow at times, partly due to NHS structural processes and decision-making timeframes.

"Once we had the money, it was quite difficult to get things moving to the point of spending... We've got a load of money and we can't actually spend it because the way the NHS is structured and the way the decisions are made. It took a year and a half to free up the necessary amount of time for me, honestly, actually still not quite enough time, but it's still better than it was. So that's really frustrating, just takes a really long time to get things moving."

C) Inner setting

Some of the challenges within the project itself are:

- the capacity of the steering group who drive the project;
- time commitment to work collaboratively at pace; and
- ensuring patient and public involvement is built into the process.

The involvement of multiple individuals from different regions and organisations extended the time required for project design, delivery and decision-making in the early stages of development. Participation in the project often occurs outside of participants' regular roles, which made consistent attendance at earlier meetings difficult, and necessitated revisiting topics. Administrative or project support for the core team was essential to help coordination.

"Things often take longer to achieve than expected because of the number of people from different areas (geographical, as well as departmental such as primary care, secondary care and public health) who may need to contribute, and workload demands on participants. Obviously, with people's work commitments, not everybody can attend meetings when needed in order to move things along. I think this is just the nature of the beast and there is not really any way around this."

Balancing additional clinical work with service development is challenging, and the NHS often requires running both existing and new services concurrently.

“What you're often doing in the NHS, you run two things at the same time. You run your usual service, and you try and run your new service at the same time.”

“I do still have a capacity issue. Because one of the things that's happened is I've gone up to one clinic a week, which is great, but it has also increased the clinical workload and the implications of that. So trying to fit in the additional clinical work, as well as the service development is difficult.”

Integrating patient participation into the steering group took considerable time due to limited administrative support, and time constraints from participants. The patient perspective could have been included earlier for more effective decision-making.

“I think it would have been good if the patient participation had happened earlier so that we had a patient perspective and input earlier on in the process.”

“Unifying Patient and Public Involvement policies- still unpicking this.”

D) Individuals

Capacity, leadership and team formation, and future thinking are challenges to consider for the next stage of implementation. The motivations of the steering group members, and their capabilities, have been a key driver in initiating the change, but this has meant that time committed to the project was outside of their usual work. The project requires various roles to support project formation, implementation, and management, leaderships and mentoring of team members. This includes a coach and mentor to guide steering and delivery members, a strong leader to drive the project, and clarity on management roles, especially concerning extended roles like the lipid practitioners. These factors have emerged in the project and contribute to how it is seen to be functioning well, but they are also factors that needed additional time and effort to deliver and sustain, and will need clarity around how that can continue in the future.

“What does that mean in terms of sustainability? Where are the gaps? Does that mean that there's going to be a major coordination program management gap?”

“The other thing that is important is handover... for some assets there isn't a shared platform. We tried to get a SharePoint together, so we all have the stuff in one place, and it's not one person holding everything... that needs some significant time to do properly.”

“If you chunk up the system into teams, then you've got a real format by which we know retention is improved. We know the system is dynamic and agile as a result of teams where they're working well. So from top-down exec board, you need to be a high performing team.”

“...because he needs to then be the coach to this team, which will be quite disparate, because of their clinical pharmacists, they might even be working with the service one or two days a week, and you bring them together? How do you keep them together? I think I think there's a lot of work potentially.”

E) Implementation process

The barriers or potential barriers to implementation at the primary care level with lipid practitioners include ability to navigate ethical challenges with FH, familiarisation and training the new roles with the practice and system and their ability to prescribe, and patient engagement methods.

Part of the FH work is to understand how many patients have been coded as having FH but have not had a genetic test. This could mean at least 50% of those coded with FH could be incorrectly coded without that genetic test to have aided the clinical decision.

“The people that the clinicians would pick up on during the searches might already have had their bloods marked as normal by a GP, and that might have already been communicated to a patient. In the context that I've been doing it, because FH is a genetically diagnosed condition, it's been easy to say to people, ‘we've more modern medicine techniques’, we're looking at different ways that safety is established. So I can have a conversation without undermining the GP's comments. Whereas it might be a bit more difficult if the doctor's written ‘everything's fine’, and it isn't fine. A barrier could be how we have the conversations with the patients without undermining the GP's comments.”

“If new roles are not prescribers, that would pose a barrier to surgeries and increase workload.”

“Ensuring there is time to train the roles not just clinically, but with the specifics of the template and with the practice systems.”

Reaching patients for pre-invitation information or inviting patients has several barriers. A family history questionnaire is required by the patients who appear in the FH search. The questionnaire is an essential step in gathering the appropriate information. Those questionnaires were sent via text message, and some people did not consent to receiving the survey or did not reply. Additionally, approaches to contacting patients for the non-FH lipids pathway (text, phone, email) based on preferences, phone access, and non-responses will need consideration to ensure patients facing inequalities are not excluded from accessing the targeted support. Best practice and implementation protocols for new roles will support them in this regard.

While the lipid practitioner did not feel they were isolated in working in the practice, the project would benefit from the new lipid practitioners engaging with the practice and PCN staff, and coordinating lipids and CVD work and approaches.

4. Conclusion

In Somerset, with a population of 571,600, around 82,000 people are living with circulatory diseases, 23,000 are living with coronary heart disease, and there are around 14,000 stroke survivors in the Somerset Area (Somerset Intelligence, 2021) (BHF 2023). Somerset detection and treatment of hyperlipidaemias (including FH) is low, putting a significant proportion of the population at increased risk of cardiovascular disease (CVD). The Somerset population did not have access to a suitable lipid service at secondary care level, with only one clinic a month operating from 2021, and a growing waiting list with lengthy waiting times from referral to appointment.

The Somerset Lipids Project was established to address the challenges across the system, to ensure patients have greater access to lipid reviews, treatment, and timely access to secondary care clinics. The early insight from evaluation shows that the project has progressed with core elements developed and implemented as planned. The evaluation activity alongside the project implementation has supported embedded learning and data collection for service improvement. Evaluation and ongoing monitoring should continue as the programme matures and the new roles across primary and secondary care begin and embed in 2024. The early process evaluation has shown that the model and approach is relevant and valuable to the system and patients:

- the model is seen as acceptable and appropriate at this early stage amongst key staff;
- access to resources is improving with nearly half of Somerset practices accessing resources on TeamNet (29 of 64 practices), and more 621 health care professional attending education sessions;
- the education sessions are increasing knowledge and confidence of the primary and secondary care workforce attending education sessions;
- the lipid practitioner role has been positively experienced and perceived to be influencing role development and satisfaction for the lipid practitioner;
- there is progress at primary care level with implementation of targeted lipid management through the embedded role, and patient feedback is positive; and
- the enhanced service is increasing specialist lipid clinics each month and seeing indications that the lipid clinic waiting times are reducing.

The model has been successfully designed and implemented, with early adoption in primary care going well. The targeted lipid management work and the increase in access to treatment aim to improve the monitoring and reviews of those with, or at risk of CVD in primary care, increase the number of patients who are on the appropriate treatment, and improve patient health outcomes in the next year. CVDPREVENT data and QOF data can be assessed by the project team going forward to understand system level changes at sites implementing targeted approaches, alongside evaluation tools embedded within the project. Additionally, the Public Health team in Somerset have been key partners in the project and are leading the development of a CVD dashboard for the county, which will support both the project and the Long-Term Conditions team at the ICB to monitor and evaluate patient health outcomes across Somerset in time. The next phase of the project will move from early adoption to embedding, and further spread into other practices, and will benefit from ongoing evaluation and learning. A key challenge will be ensuring the model utilising lipid practitioners is embedded and sustainable, and that lipid management approaches continue in practices beyond any initial targeted work. Patient uptake of the consultations will be an area the project can focus on, and learn what engagement approaches support higher uptake, ensuring patients most at risk and facing health inequalities (including digital exclusion) are actively engaged with and have access to treatment.

Patient experience was captured for the process evaluation and showed positive experiences of the pathway and personalised care. The findings are limited due to the low response rate, and there is a need for the project to continue to build patient engagement in at the primary and secondary care level. There is a patient and public involvement and engagement representative on the steering group to support further adoption of PPIE.

There are early indications that the model will support the reduction in lipid clinic waiting times. The Consultant and team are testing a demand and capacity model for the service.

While the education sessions have positively influenced how the workforce perceive their knowledge and confidence in lipid management, and the resources on TeamNet are being accessed by nearly half of the practices in Somerset, application of that knowledge and use of resources will need to be assessed. Use of the resources, and active work in primary care and adherence to the lipid management pathway, should be assessed in the next phase of the project.

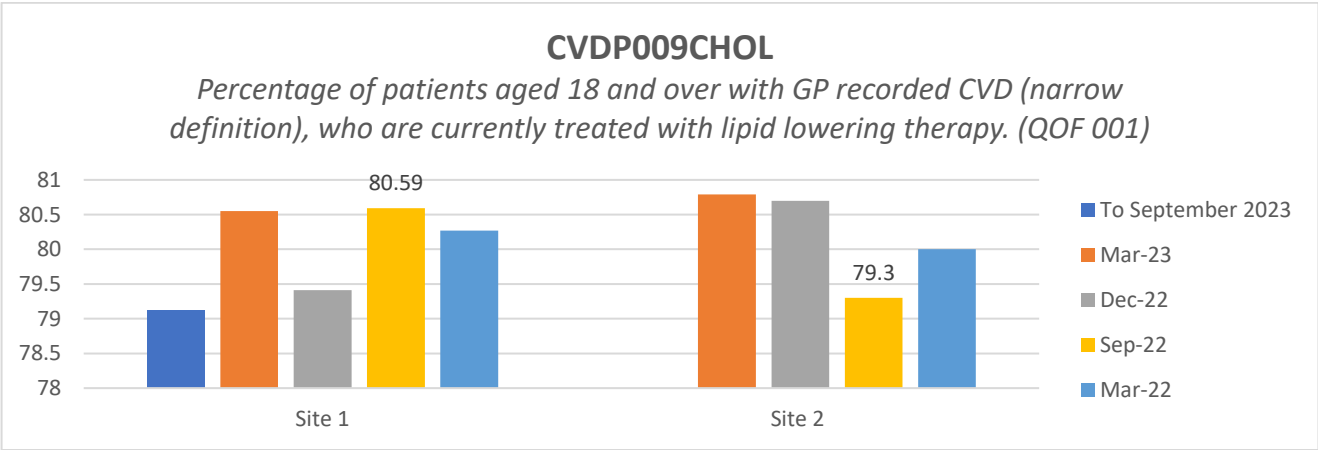
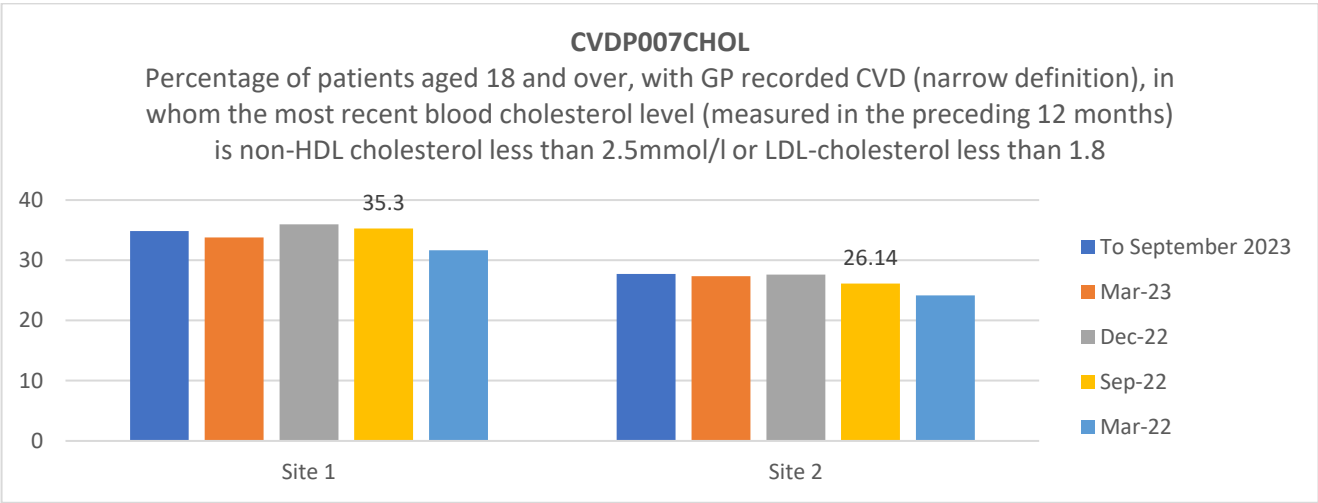
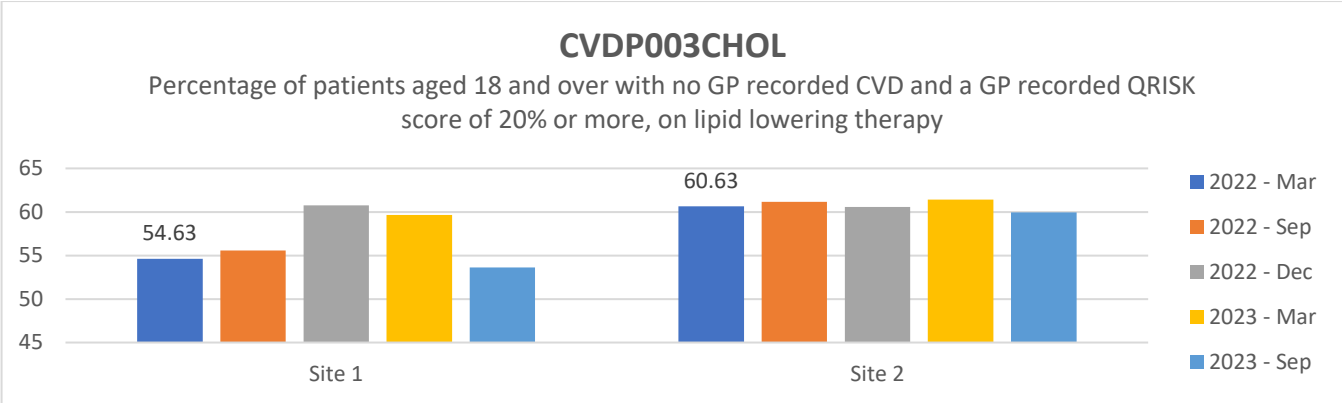
For others developing lipid management approaches or a service redesign, clear and effective steering is critical, alongside leadership and co-ownership of the change and processes. Ensuring that programme coordination and evaluation, and data analytics support, are planned into early business cases and budgeted for is essential. Importantly, diverse representation within the project development team was central to the successful development of the project and system thinking. Cross system collaboration, early engagement and ongoing coordination support are equally important for the change process and have been central to the Somerset Lipids Project service redesign approach and success.

Appendix 1: Baseline CVD prevent data

Somerset:

CVD indicators	Area Value to March 2023	System Median	National value
CVDP010CHOL: Percentage of patients aged 18 and over with GP recorded CKD (G3a to G5), who are currently treated with lipid lowering therapy.	56.72%	63.38%	61.97%
CVDP009CHOL: Percentage of patients aged 18 and over with GP recorded CVD (narrow definition), who are currently treated with lipid lowering therapy	79.19%	82.77%	82.17%
CVDP003CHOL: Percentage of patients aged 18 and over with no GP recorded CVD and a GP recorded QRISK score of 20% or more, on lipid lowering therapy	56.99%	59.68%	59.96
CVDP006CHOL: Percentage of patients aged 18 and over with no GP recorded CVD and a GP recorded QRISK score of 10% or more, on lipid lowering therapy	46.06%	49.75%	49.64%
CVDP007CHOL: Percentage of patients aged 18 and over, with GP recorded CVD (narrow definition), in whom the most recent blood cholesterol level (measured in the preceding 12 months) is non-HDL cholesterol less than 2.5mmol/l or LDL-cholesterol less than 1.8mmol/l	26.98%	29.17%	27.88%
CVDP008CHOL: Percentage of patients aged 18 and over, with no GP recorded CVD and a GP recorded QRISK score of 10% or more, CKD (G3a to G5), T1 diabetes (aged 40 and over) or T2 diabetes aged 60 and over, who are currently treated with lipid lowering therapy.	46.58%	51.45%	51.17%

Case study sites:



Appendix 2: key learning for others

Key messages for others based on what has gone well or learning from challenges:

- **Effective steering and leadership:** Clear and effective steering is critical, alongside leadership and ownership of the change and processes.
- **Team diversity:** Ensure diverse representation of skills, roles, perspectives, lived experience within the project development team.
- **Administrative support:** Adequate administrative support and time allocation are crucial.
- **Collaboration:** Collaboration among stakeholders, including primary care, secondary care, public health, Health Innovation South West, and patient voices, is essential.
- **Champion leadership:** Strong leadership and expert clinical guidance are vital.
- **Infrastructure for support:** Develop infrastructure to support patients' at-risk relatives.
- **Early engagement of stakeholders:** Involve stakeholders from the project's outset and maintain their involvement throughout.
- **Vision and planning:** Develop a clear vision supported by a robust business case.
- **Longer timelines for change:** Be prepared for prolonged efforts when making changes while maintaining routine services.
- **Wider learning about place-based care and services:** learn from the lipids approach about place-based care through a hub and spoke model linking community practitioners to specialists.

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- *working with 264 companies;*
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