Improving the identification and treatment of patients with Familial Hypercholesterolemia in primary care

Evaluation Report

A joint working project between
Health Innovation Yorkshire & Humber and Sanofi

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Executive summary

Familial Hypercholesterolemia (FH) confers a high risk of cardiovascular disease (CVD). In untreated patients, lifelong elevated cholesterol levels lead to a higher risk of coronary heart disease. If patients with FH can be identified and treated earlier their risk of developing CHD can be reduced.

Identification of patients with FH can be difficult because the majority may be asymptomatic up until acute presentation with ischaemic heart disease. Using an effective clinical system search in primary care should enable patients to be identified, reviewed and triaged. Those who are likely to have FH are then referred to specialist teams enabling confirmation of diagnosis, treatment and genetic testing to take place. The genetic testing then allows for further patients to be identified and treated. The ultimate aim of identification of patients with FH is to reduce their risk of CHD and prevent premature death.

This project provides two examples of case finding for FH on primary care clinical systems and the outcomes achieved. It also demonstrates that although, in theory, this should be a straightforward and efficient process the steps taken to get to these outcomes were lengthy and further exacerbated by the COVID-19 pandemic. However, the learnings from this project can be implemented in future FH identification projects to enable a quicker route to identification of patients with FH.

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1.0 Introduction

The purpose of this evaluation report is to share the outputs and outcomes of a joint working project between Health Innovation Yorkshire & Humber and Sanofi which aimed to increase Familial Hypercholesterolemia (FH) identification and treatment. The project commenced in May 2018 and was expected to run for one year. The project was led by two specialist FH teams at Sheffield and Hull.

Due to the local clinical resource the two specialist teams approached the FH case finding in primary care in different ways.

Hull has a larger FH specialist nurse team who were keen to be upskilled in searching primary care clinical systems. Therefore, the specialist team reached out to primary care to run searches and triage patients.

In Sheffield FH specialist nurse capacity was limited and the CCG had a Primary Care Development Nurse (PCDNs) Team, whose role is to work on quality improvement projects, such as this. The PCDN team were upskilled by the FH Specialist Team at Sheffield and were key drivers in this case finding project.

Both approaches were reliant on GP practice engagement.

2.0 Background

FH confers a high risk of cardiovascular disease (CVD). Untreated the lifelong elevated lipid levels means a greater than 50% risk of coronary heart disease (CHD) by age 50 in men and a 30% risk of CHD in women by aged 60. It is well documented that FH is a preventable cause of CHD.

Raised cholesterol is present from birth in people with FH and may lead to early development of atherosclerosis and coronary heart disease. FH is caused by an inherited genetic defect. Siblings and children of a person with FH have a 50%risk of inheriting the gene.

Early identification of patients and their relatives enables proactive management, as a result patients are more likely to have a normal life expectancy.

It is believed that approximately 7-10% of the FH patients within Yorkshire and Humber have already been identified and the local team believe that a more realistic figure around FH mutation would be between 1 in 200 and 1 in 250 of the total population. Although a very effective specialist service exists, the localities are faced with a number of challenges in terms of identifying potential patients within primary care who have or may have FH and referring them to the specialist service for review.

Additional financial resource has been provided in order to increase the number of FH cascade tests, but these weren't being used as patients within many of the Clinical Commissioning Group (CCG) areas covered by Health Innovation Yorkshire & Humber aren't proactively being identified. In addition, there is limited specialist nurse resource within primary care to identify and refer potential patients for testing or treatment.

Health Innovation Yorkshire & Humber with the support of two of the specialist lipid teams within the area identified several opportunities to improve this scenario through a joint working agreement with Sanofi to allow for better patient identification and treatment of FH patients in primary care.

The clinical teams believed that the diagnosis of FH across the Yorkshire and Humber locality was significantly underreported but was better than the national average. A pilot project in 2014 run by NHS Medway CCG, demonstrated an approach to improving FH diagnosis, through the use of two interventions which increased the detection of FH. The first was an FH audit tool, the second intervention was a nurse-led programme to support FH diagnosis. The audit tool and nurse programme increased the proportion of patients diagnosed with FH from one in 750 (n= 343) to one in 357 (n=776) within the CCG.

The NHS Medway pilot project provided an example of an evidence based and cost-effective intervention. Both Health Innovation Yorkshire & Humber and the specialist clinical teams in the Yorkshire and Humber region wanted to implement an advanced version of the Medway project to improve the diagnosis and treatment of patients with FH.

At project inception there were no financial incentives or national programmes in place to support the identification of people with FH. However during the implementation of the project, the landscape changed considerably.

3.0 Aims and objectives

The aims of the project were to:

1. Develop an exemplar model of care for the effective identification and management of patients with suspected or diagnosed FH across the Health Innovation Yorkshire & Humber geographical area to show a measurable improvement in the number of patients diagnosed with FH and a measurable improvement in the management of FH (more patients achieving recommended lipid targets).

2. Through better patient identification, increase the utilisation of the genetic screening programme across the Health Innovation Yorkshire & Humber geography.

3. Provide more specialist care within primary care and ensure better utilisation and more appropriate referrals to the specialist service.

4. To deliver a greater awareness, knowledge and understanding of FH diagnosis in primary care and support primary care physicians to manage these patients more effectively.

5. Update the clinical guideline and pathway to include criteria for patients who can be treated in primary care and those that need to be referred up to the specialist team.

4.0 Project Implementation

Project delivery was initially agreed to be for one year from May 2018 until April 2019 with Sheffield Teaching Hospitals NHS Foundation Trust and Hull and East Yorkshire Hospitals NHS Trust. However, there were several factors which led to the delivery of the project being extended far beyond this initial timeframe.

There were two major amendments to the original delivery plan which resulted in the timelines for the project being extended.

1) The initial plan was based on using interface clinical systems, to undertake the identification work within primary care. However, it was recognised that this would not be a sustainable model, and therefore the approach was amended to establish local project teams with the relevant clinical leadership from the specialist teams within the trusts.

2) The initial plan was to use the validated familial hypercholesterolaemia case ascertainment tool (FAMCAT) search tool, on commencement of the project several months were spent trialling the search tool. Following these trials, the clinical teams believed that this search tool was not appropriate, therefore the scope of the project extended to include the development and testing of clinical system search criteria. This resulted in the implementation of the searches being delayed by several months.

Through the joint working agreement, a dedicated project manager was appointed to the project from Sanofi. This benefited the project in several ways. By having a dedicated project manager, it provided additional capacity across both sites to ensure relevant stakeholders were brought together. It allowed learning to be shared across both sites and with other projects further afield such as in Newcastle, this may not have happened without this post.

These initial delays resulted in the project still being underway when the COVID-19 pandemic struck in March 2020, which resulted in further delays.

A summary of the key deliverables and events which have been undertaken through the duration of the project are summarised below:

Phase 1 (Pre-COVID-19 Pandemic)

May to Dec 2018

- Set up of formal steering groups, terms of reference and quoracy.
- Discussed the experience of using FAMCAT and its limitations with sites that had already started using the tool, piloting of the tool was still underway in some areas. Linked up with Health Innovation North East North Cumbria (NENC) to share experiences with FAMCAT and ideas around possible alternative search criteria. Initial feedback was that it was not effective.
- Many meetings and testing on local clinical systems took place to understand if FAMCAT could be used as planned.
- Discussion on the use of external triage resource and undertook scoping to see if there was capacity within the CCG to undertake the triage work. Decision made to increase and utilise NHS Primary Care Development Nurses (PCDNs) resource for triage in Sheffield and FH specialist nurse time in Hull.

Early 2019

- Triage clinical resource agreed.
- Triage personnel training sessions;
  - Clinical systems training (for FH nurses)
  - FH training (for Primary Care Development Nurses (PCDNs)) with specialist clinicians from secondary care.
- Trial run within one practice to review FAMCAT tool and NICE search criteria search tools. Following review of the patient lists FAMCAT produced, it was concluded that the FAMCAT tool identified too many inappropriate patients.
- Decision made not to use FAMCAT, next steps to agree local search criteria to increase specificity of system searches, utilising the NICE patient identification guidance and local clinical and clinical systems knowledge.

Mid 2019

- Initial pathways designed collaboratively between the specialist team and PCDNs.
- Resources designed including patient invitation letters and practice invitation letter to participate in the project, family history request forms developed.
- Codes sourced from IT for capturing the review of clinical records and further interventions.
- Data capture form designed and reviewed.
- Time log commenced.
- Family History information request forms reviewed – several versions discussed including pictographic version reviewed before approved by group.
- Final version of pathway/triage agreed.

Nov 2019

- In Sheffield 20 practices contacted and invited to take part in the pilot phase of the project. At each of the practices, who opted in, meetings were arranged with clinical leads to discuss project, process and pathway.
- Patient record review process for PCDNs shared and approved by steering group and PCDNs including task process and timelines.
- GDPR forms sent to participating practices.
- First patient reviewed using new pathway and review process agreed by steering group.

Dec 2019 – March 2020

- 15 practices agree to sign up to pilot project.
- 5 practices decline due to competing priorities.
- FH questionnaires sent out to identified patients however, the team experienced difficulties in getting the forms returned or completed.
- First identified patients invited to attend GP practice for repeat lipid blood profile.
- First identified patients referred using agreed process to specialist team at the hospital.
- STH project registered with Information Governance and data capture spreadsheet approved.
- STH project approved and registered by Clinical Effectiveness Unit.

March 2020 - COVID-19 Pandemic

- All projects stood down in line with CCG and government guidelines.
- PCDNs redeployed to support COVID-19 swabbing programme and vaccination programmes, FH nurses redeployed within hospital trust.
- Project paused.

Phase 2 (Post height of COVID-19 pandemic)

October 2021 – Feb 2022

- In Sheffield initial discussions for restarting project.
- Virtual meeting held to consider how best project could be restarted with minimal impact on practice capacity.
- Further delays in restarting project due to roll out of vaccination programme.

Feb 2022 – April 2022

- Modified pathway designed and agreed with all assessments undertaken at Sheffield Teaching Hospitals NHS Trust (STH)
- Family history questionnaire, inhouse blood testing and GP discussion all replaced with simplified one stop invite to STH for assessment.
- Practice patient desktop review pathway for PCDNs modified and approved.
- Practices identified in phase one approached to gauge interest in restarting project.
- Search tools checked against University College London (UCL) search tool currently available in all practices for suitability and cross referencing.
- Investment and Impact Fund (IIF) launched by NHS England – CVD-04 of IIF encourages practices to identify possible cases of FH from general practice lists. Criteria used for CVD-04: Percentage of patients aged 29 and under with a total cholesterol greater than 7.5 mmol/l OR aged 30 and over with a total cholesterol greater than 9.0 mmol/l who have been referred for assessment for familial hypercholesterolaemia.
- Decision made to continue with modified NICE search tool designed in Sheffield and not to use UCL or Ardens as too many discrepancies.
- Exclusion criteria agreed.
- SMS messages and new invitation letters designed and approved for sending out to patients and GP practices.
- Embracing of new technologies used and perfected during COVID pandemic including sending of AccuRx and SMS messages to patients inviting referral.
- Pathway in practice for referral to STH agreed.
- Codes reviewed and identified that would support both the IIF requirements and those of the pilot project.
- Reviews restarted in practice late April 2022.

April – October 2022

- Reviews continue at practices approached during phase one of the pilot following simplified pathway.
- Staff shortages and competing workloads impact on capacity of team to support reviews in practice.
- Capacity at STH impacts on speed of review for identified FH patients.
- Agreement to close pilot project at the end of September 2022 and collate data.

5.0 Results

5.1 Identification and management of patients with FH

Hull

The clinical system searches in Hull resulted in 106 patients being highlighted as requiring review (see table below). Of those reviewed, 22 patients required referral to the specialist FH team, meaning more than 1 in 5 (22%) of the patients identified by the clinical system search was eligible for referral. This confirms that the search criteria used was an efficient route to identify potential patients with FH.

Total Practice Population: Hull	6,199	Percentage of total practice population	Percentage of those who met initial criteria
Over 30 with a TC >9	100	1.6%	
Under 30 with TC .7.5 mmol/l	6	0.1%	
Meets initial referral criteria	106	1.7%	
Already diagnosed with FH	2		
Needs family history or Request for further bloods	12 1		12.3%
Not to criteria	66		62%
Refer into FH service	22		21%
Unable to access/restricted	1		
RIP	1		

Sheffield

A modified search criteria was used:

- 18-30 years with a total cholesterol > 7.5 mmol/l and triglycerides < 2.5 mmol/l **OR**
- 30 years or older with a total cholesterol of > 9 mmol/l and triglycerides < 2.5 mmol/l

(Age range applies to age of the patient at time of cholesterol result).

The searches used in Sheffield identified 256 patients who met the search criteria of which, following a review of their notes 129 were suitable for referral to specialist team, most were females (70%). A relatively large proportion, 17% (43 patients) declined referral or didn't respond to invite to speak with a clinician. Of the 70 patients referred to lipid clinic by the PCDNs 65 patients were seen by the specialist team which equates to 25% of the patients identified by the clinical system searches. Almost half (49%) of the patients seen in lipid clinic were offered genetic testing for FH. Due to the COVID-19 pandemic the waiting time for results from the genetic tests is ~ 12 months. However, genetic tests are only requested which was primarily determined by the presence of a Welsh Genotype Score of 6 and above. A positive genetic test allows genetic testing for FH to be carried our within the patient's family to identify risk in others. This is particularly important if the patient has children as early treatment can result in the patient having their CHD risk lowered to 'normal' and prevent early CHD.

Total Practice Population: Sheffield	79,906	Percentage of population
No. of patients identified and reviewed using above search criteria	256	0.32%
No. of potential patients:	129	0.16%
No. of patients who already had an FH diagnosis	20 (3 diagnosed during phase 1)	0.03%
No. of patient's eligible patients who declined referral or who did not respond to invite	43	17%
No. of patients who had previously been referred and discharged without FH diagnosis	26	10%
No. of patients unsuitable for further investigation	31	12%
No. of patients referred onto lipid clinic	70	28%
No of "inappropriate" referrals	5	0.8%
Average age (years)	65	
Sex	49 F 21 M	70% Female, 30% Male
Did Not Attend Appointment (DNA)	5	7%
Total Patients included in data	63	25% (63 of 256 pts identified by search criteria)
No. of patients with WGS >5 (incl age adjusted)	26	41%
No. of patients with WGS >5 (incl age adjusted) and offered genetic testing	26	41%
No. of patients with WGS >5 (incl age adjusted) and offered genetic testing and had test done	18	
No. of patients with WGS >5 (incl age adjusted) and offered genetic testing and had test done and was positive for FH	5	
No. of patients with WGS <6 (incl age adjusted)	37	59%
No. of patients with WGS <6 and offered genetic testing	5	8%
No. of patients with WGS <6 and offered genetic testing and had test done	4	
No. of patients with WGS <6 and offered genetic testing and had test done and was positive for FH	0	
Total number of patients identified through the pilot	5	

Notes

- Patients were coded as declined if they failed to respond after three invitations.
- Codes were added for those previously referred to lipid clinic or with a confirmed diagnosis.

A number of patients were found to be unsuitable for referral for the following reasons:

- Already undergoing investigation or already been diagnosed with FH but not coded.
- Undergoing palliative care.
- Severe dementia.
- Additional blood testing or other information required.
- Secondary causes – nephrotic syndrome, hypothyroid, pregnancy.
- Lipids normalised without treatment.
- GP or consultant decision not to refer.
- Frailty.

- Introduction of the Impact and Investment Fund 2022-23 incentivised primary care networks to identify patients at high risk of FH using different search criteria. In order to achieve the IIF criteria the practices may choose to refer patients identified by the Ardens searches. Although through work done within this project, we feel that a number of these may be inappropriate adding to pressure on the secondary care team.

5.2 Provide more specialist care within primary care and ensure better utilisation and more appropriate referrals to the specialist service.

Both specialist teams developed materials to support the project such as locally tailored FH review protocols (see example in appendix 1), bespoke GP patient information / invite letter for GP practices and family history questionnaire.

Hull

The FH specialist nurse ran the system search in the GP practice, developed an educational slide deck to be presented to the general practice team, provided them with the background and knowledge to support the project. This increased education and awareness of FH to enable a longer-term legacy from this project. The education should mean that in future the clinicians refer appropriate patients to the specialist lipid service reducing the number of inappropriate referrals. Its currently too early to understand if this is the case.

Sheffield

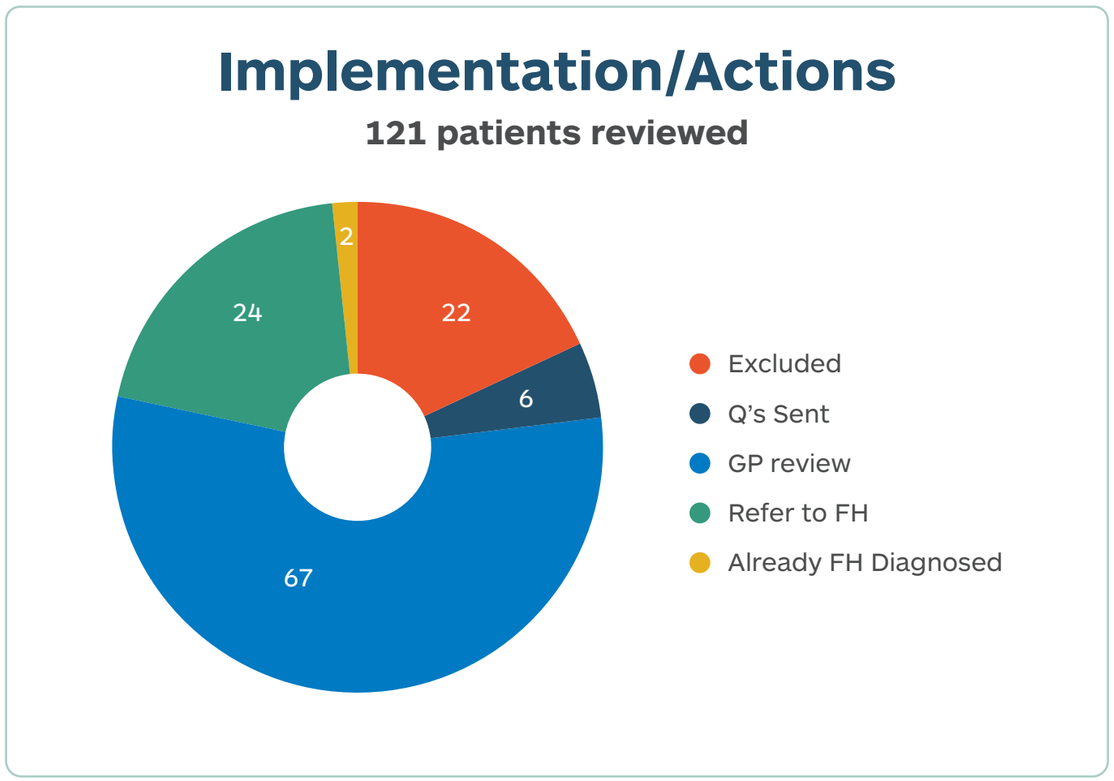
The PCDN team ran the system searches and triaged the list of patients, any patient that didn't meet the referral criteria but had sub-optimal lipid control was highlighted to the GP clinical team for optimisation. The approach was reviewed and amended post COVID-19 to reduce the amount of time required by GP practice personnel to ensure this was an absolute minimum.

5.3 To deliver a greater awareness, knowledge and understanding of FH diagnosis in Primary care and support primary care physicians to manage these patients more effectively. Update the clinical guideline and pathway to include criteria for patients who can be treated in primary care and those that need to be referred up to the specialist team.

Hull

As the FH Specialist Nurse or PCDN required the patient's own clinical team to make the referral to the specialist lipid service, the clinicians in the GP surgery were upskilled by having the identified patients flagged to them along with the reasons why a referral to the specialist lipid clinic was required.

The pie chart below shows the outcomes for the patients reviewed in primary care in Hull. 24 out of the 121 patients reviewed were referred to FH Nurses for review, equating to 20% of patients. An additional 67 patients were flagged for a review by their GP to optimise lipids.



6.0 Findings and Discussion

6.1 Findings

Hull

GP practice population of approximately 6,200 patients with an expected prevalence of 1 in 250 patients would mean approximately 25 patients should be identified with FH in this surgery. The project identified 22 patients that were eligible for testing. As the number of patients identified was in line with expectations this gave us confidence that the searches and triage were effective at identifying appropriate patients. The involvement of the GPs in the review of patients identified as requiring lipid optimisation but not referral to the specialist lipid clinic will mean that additional patients have potentially had their treatment optimised and potentially as a result will now have a lower risk of CVD.

Sheffield

The searches were run in 11 practices with a total population of 79,906 with an FH prevalence of 1 in 250 we would expect 319 patients with FH to be in this population. There was only 17 diagnosed at the start of the project. At the end of the project a further 31 patients had been sent for genetic testing and are likely to be diagnosed. Following FH diagnosis, we offered tests for family members which may result in further patients being diagnosed with FH as a result of the project over the coming months. The existing patients and the addition of the 31 patients identified through this project, will potentially result in 48 patients within the population of 79,906 having a diagnosis of FH, resulting in a rate of 1 in 1,664 down from 1 in 4,700 but still far from the expected prevalence of 1 in 250.

A particular challenge is that 1 in 4 patients identified by the search either declined investigation or did not attend (DNA) appointments (43 declined/no response 5 DNA patients). It is likely that many of these patients (and their family members) will have FH but will not benefit from diagnosis and cascade testing. DNA rate was low compared to standard clinics this may be an advantage of phone clinics.

To triage a patient once identified by the search the team estimate on average it takes 30 minutes to either rule a patient in or out. The time taken varies by patient, dependent on if more information is needed or to invite them in for further blood tests. It could be very time-consuming excluding secondary causes pre-referral.

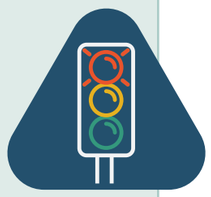
Many CCGs have GP surgeries utilising different clinical systems such as SytmOne or EMIS with a minority using Vision. The searches need to be accessible on each clinical system, this requires additional resource to write each search in the clinical system they cannot be shared across the different clinical systems.

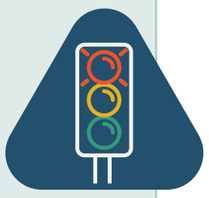
6.2 Discussion

The challenges experienced in the set up and implementation of this project were many and varied. They can be broadly categorised into three themes: data, clinical capacity and the environment.

Challenge		Detail	Learning
Data 	Access to data	As the FH Specialist Nurse or PCDN are not employed by the GP practice, data protection requirements mean that a data protection impact assessment (DPIA) has to be completed for each GP surgery. This resulted in delays to gaining access to the clinical data and additional workload for primary care clinicians.	Both these aspects required additional expertise from individuals external to the project team and were not fully appreciated when the project timelines were planned.
	Training	The clinical system used in GP surgeries is different to that used in secondary care and therefore training for the FH Nurses in Hull was required. Secondary care in Sheffield invested a huge amount of time in training PCDNs on FH itself, identifying secondary causes and assessing family history. The Consultant became the first point of contact for any queries from PCNDs which tended to be by email.	
	Data accuracy	The outputs of the searches are dependent on the coding in the clinical systems, cardiovascular family history, highest LDL-C, previous referral to lipid clinic or FH diagnosis are all often not coded in the clinical system.	The gaps in data meant that additional time was required to triage the patients, as additional bloods would need to be requested, a family history questionnaire sent to the patient or time spent trawling through the patients history looking at prior referrals.
Data 	System searches	The system searches that had been previously validated were not fit for purpose. The lists of patients that came from the initial search criteria were large, with a high proportion being deemed inappropriate. Many months was spent liaising with specialists to devise search criteria which would result in high specificity, without this specificity too much clinical time would be required to review large numbers of patients with few meeting the referral criteria, this would mean the project would not be an effective use of FH Specialist Nurse or PCDN resource and therefore not viable.	The need to create searches was not part of the original project scope, we assumed that the published and validated searches would be suitable for this project. It was disappointing that the project team had to invest so much time devising and testing new system searches. As a result, there was capacity to build searches in SystmOne only which means that practices (approx. a third of Sheffield CCG) who use the EMIS clinical system were unable to take part in the project. When setting up a project, if utilising a 'tool' from another area test the tool during project scoping to ensure that the tool can be utilised across clinical systems in your area.
Clinical capacity 	GPs	Through the triage process, patients that don't meet the criteria for possible FH, but who don't have optimal lipid control were identified. Once identified these patients would be flagged by the triage nurse to the GP practice team for a lipid review by the surgery team. The identification of these patients could put extra pressure on the GP clinical team however it will lead to improved outcomes for their patients and potential prevention of cardiac events for this cohort of patients.	Patients identified by the searches that are deemed to require referral to the specialist lipid service need to be referred by their clinical team member at the GP surgery. Contacting the patient and explaining the need for referral along with making the referral is additional workload for the GP clinical team. We knew at project scoping that this would be the case however we didn't fully appreciate how much of an issue and barrier this would be for GP practices. In order to reduce workload on GPs protected time is required or upskilling of other personnel to make the referral. Using available resources, such as, mail merge of referrals to reduce administration time. Ongoing improved coding, improved recording of family history will reduce the need for clinicians to ask patients for their family history. Alignment of clinical systems in Sheffield would improve efficiency currently there are multiple clinical systems being utilised, meaning visibility across Trust/CCG boundaries of blood results isn't possible.

Challenge		Detail	Learning
Clinical capacity 	Specialists	Excluding secondary causes pre-referral was time consuming for both PCDNs and secondary care. As a result of the project, there were increased referrals to the FH team, the teams had capacity for these referrals (if there was no capacity the project would not have been initiated). However, some of the workload for the project did not require clinical expertise, such as, checking if the patient had returned a family history questionnaire, if bloods had been taken, if the surgery had made the referral to specialist team etc..	These administrative tasks could have been undertaken by an administrative member of the team enabling the clinical staff to focus on the tasks that required their clinical knowledge. If we were to undertake a project like this again, we would have some administrative support built in.
	Clinical champion	The CCG commissioner was keen for the project to go ahead however there was a lack of a clinical champion in primary care to drive uptake of the project	A key takeaway from the project would be to ensure there is a clinical champion from primary care in the area impacted by the project (not just a specialist clinical champion) who pilots the project, writes up and shares the results to give reassurance to clinicians that the project is viable on top of 'business as usual'. We had this in Sheffield but not in Hull and it certainly made a difference in the engagement of primary care. Having a Project Owner within the practice to drive progress made a huge difference to project progress along with good communication about the project within the practice. Financial incentives would also likely drive engagement.

Challenge		Detail	Learning
Environment 		As a result of COVID-19 in March 2020 the FH specialist nurses were reallocated to other roles resulting in the project ceasing in Hull. Due to the delays in getting the project started due to the system search issues, training, DPIA etc already described above, only one practice was able to take part in the project.	Prior to project commencement use learning from other quality improvement programmes / joint working projects to build in realistic timelines. If the project is utilising a search 'tool' test the tool prior to commencement of the project or build in time for testing. Do not make assumptions that what has worked in one area can be lifted and shifted to another area.
		In Sheffield the PCDN team were tasked to deliver COVID-19 vaccinations, along with the (temporary) associated shift in focus away from non-urgent long-term conditions activity meant that the project was paused. Phase two started post the height of the pandemic. 15 practices invited 11 agreed to participate. The team approached practices with whom they had an established relationship. This was intended to reduce time frames. However, complications with obtaining GDPR data share agreements and identification of lead persons within the practices, setting up face to face meetings and agreeing the process with each practice added significant delays.	Did Not Attend rate was low, a potential advantage of 'phone clinics'. However, the uptake of genetic testing appears to be low (in those sent a form) as genetics lab only received a few samples back this could be a downside of telephone clinics. Patients have been sent a reminder and another form. Following up patients' multiple times uses Consultant time and creates additional administration. Genetics results taking approximately 12 months means a delay in processing data, still ongoing.

Challenge		Detail	Learning
Environment 		There are now (February 2023) several programmes and incentives to enable primary care to identify patients who have high Lipids. For example, Accelerated Access Collaborative (AAC) which means that the optimisation of patient's lipids in primary care is more of a focus and therefore if we were starting the project today there may have been greater GP engagement in the project. In December 2022 the NHS Accelerated Access Collaborative (AAC) provided and updated Summary of national guidance for lipid management for primary and secondary prevention of cardiovascular disease.	National programmes with additional funding help to make the disease area a focus for primary care clinicians and therefore improves engagement. If a project doesn't have a national driver behind it, greater thought needs to be given as to how to get engagement from already stretched clinical teams. The educational programmes and lipid management guidelines may mean that patients with FH are now more likely to be identified in primary care than at project inception. However, the changing priorities in the NHS often results in an area being in focus for a short period of time, potentially not enough time to achieve full impact.
		The Tackling Cholesterol Together education programme is a collaboration between the Health Innovation Network, Heart UK and AAC. The programme along with other organised workshops and webinars provides education to healthcare professionals on how to optimise lipid management for their patients.	

7.0 Conclusion

In the GP surgeries that took part in Sheffield CCG the project increased the proportion of patients diagnosed with FH from one in 4,700 (n= 17) to one in 1,664 (n= 48). In the Hull practice from 1 in 3,099 (n= 2) to 1 in 258 (n = 22).

If we take an average triage time of 30 minutes per patient per review. To either identify those appropriate for further investigation and those to be excluded, we can start to understand the cost implications of the triage part of the project.

- For Hull 30mins x 106pts = 53 hours. If we assume that the nurses undertaking the triage are band 6 and hourly rate of £16.52 (Hourly pay scales 2021/22 | NHS Employers) the cost for triage time is £875.56, which identified 22 patients likely to have FH. This equates to **£39.80** per patient found and eligible for referral (this doesn't include secondary care costs or costs related to the time taken educating the GP practice on FH and the project set up.

- For Sheffield 30mins x 256pts identified by the search = 128hrs. 128hrs X £16.52 = £2,114.56/ 70 pts referred = **£30.21** per patient referred.

To ensure the most cost-effective use of resources in the majority of cases DNA tests were not requested unless Welsh genotype score was > or equal to 6. On the basis of the latter, the Sheffield specialist team are looking at including Welsh genotype score (WGS) in the referral criteria from primary care for query FH patients.

Considering the burden on the individual and on the healthcare system of preventable CHD the identification of patient with FH via clinical system searches and triage in the community appears to be an effective use of resource.

Any future projects need to look at the accessibility of information, questionnaires, messaging and ensure availability in multiple languages if required so as not to further widen any existing health inequalities.

8.0 Recommendations

Based on our experience, outcomes and learning from this joint working project, the recommendations to inform future quality improvement work to improve the diagnosis of FH are:

- Communication and engagement with a broad range of stakeholders is critical, from those doing the implementation to everyone else who could be impacted by the project, from data protection personnel to GP administration staff. Ensure all people who are impacted understand the rationale for the project. This is particularly important when the project crosses organisational boundaries.

- Practice typology impacted on project engagement and the project worked better in some practices than others. General Practices can be categorised into types according to cultural, operational and business perspectives. Practices can be categorised as Traditional, Developmental, Entrepreneurial or Overwhelmed. Traditional and overwhelmed practices are unlikely to be able to provide the level of support needed for this project. Often traditional or overwhelmed practices will be self-excluding by not responding to expression of interest call outs but assessing practice type at initial engagement we may enable those that don't have the ability or will to devote the time to the project to opt out early to prevent any waste of resource. There is therefore a need to consider the typology of general practices in order to support GP practices to become engaged in quality improvement projects.

- It is important that, a clinician within each practice needs to 'own' the project (to be able to explain the project and answer any questions from patients), an administrative person (to arrange 'tasks', invite patients for bloods, request further information from GPs and to send out invite letters/ messages and then to send eReferral if appropriate) practices with high staff turnover or those 'overwhelmed' were unable to dedicate the time to progress the project.

- Data accuracy, the efficiency of any project utilising system searches is limited by the accuracy and completeness of data already in the clinical systems. If the area utilises different clinical systems, there is the need to build in capacity within the project to ensure searches can be built on all clinical systems to prevent exclusion of any practices.

- Patient engagement, is vital to ensure that patients identified by the searches respond to requests for further family history, attend for further bloods etc. Without this additional information it is impossible to accurately assess their risk. Some patients within the project did not wish to engage with healthcare professionals despite being advised that they could be at high risk of CVD. Further work is required to pilot interventions to improve patient engagement.

9.0 Appendices

Appendix 1

Phase 2 - FH Review Protocol and Initial Practice Discussion - 13/04/2022

Prepared by Tracey Turton – PCDN Project Lead

This guidance is to support conversations with practice teams and aid review of patients for the joint FH identification and cascade project in collaboration with STH.

The review pathway, FH searches and letters have been agreed by the FH group.

Pre-review

- Send invitation letter to practice with project overview (Appendix 1)
- Chase responses after seven days.
- Share modified NICE FH pathway and sample patient letter. (Appendix 2 and 3)
- Obtain consent to access clinical records and obtain GDPR if needed - save to practice folder on M drive.
- Obtain smartcard access.
- Record practice response on spreadsheet
- Arrange practice meeting (virtual or in person) if requested.
- Identify lead person to share reports and manage any queries.
- Agree processes e.g., performing repeat bloods if needed
- Ensure reception staff aware of project and referral process – referral letter to be attached to ESR referral.

Appendix 2

Sheffield FH Identification Pilot Project 2022
Primary Care Development Nurse, GP & Secondary Care

Box 1: Modified NICE Search Criteria

People 18 - 30 years, with a total cholesterol >7.5 mmol/l and triglycerides <2.5 mmol/l
and
People of 30 years or older, with a total cholesterol >9.0 mmol/l and triglycerides <2.5mmol/l

(Age applies to age at time of cholesterol result)

Run search of SystmOne & EMIS for each practise using modified NICE search criteria (see Box 1)

↓

Verify those already diagnosed with FH and under FHICC clinic and exclude.

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Send out standard letter to all patients inviting them to make appointment with Lipid Clinic via GP reception

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Refer to Lipid Clinic via eRS for telephone assessment and Genotype score

↓

No secondary cause identified
and
Genotype Score ≥6 or strong clinical suspicion

↓

Offer genetic testing