

**Joint Working Project between Sandwell and West Birmingham NHS Trust and Sanofi to improve identification and management of high-risk cardiovascular patients with cardiovascular disease and primary hypercholesterolaemia / mixed dyslipidaemia in a primary care setting with associated triage of other high-risk groups to existing services.**

## **End of Project Evaluation Report**

### **1.0 Project Aim**

The overall aim of the Joint Working Project is to implement a Community Lipid Clinic to provide a clear pathway between primary care and secondary care to support the identification and management of high-risk cardiovascular patients with cardiovascular disease and hypercholesterolaemia/mixed dyslipidaemia in Sandwell and Birmingham, West Midlands.

### **2.0 Project Objectives**

The specific objectives of the project were to:

- Create a nurse led community lipid clinic within The Modality Group with clinical supervision provided by Consultant Chemical Pathologist at Sandwell and West Birmingham NHS Trust
- Create and undertake a computer search which identifies high risk cardiovascular patients with elevated LDL-C to identify patients with cardiovascular disease and primary hypercholesterolaemia / mixed dyslipidaemia
- Triage patients, with the support of the Consultant Chemical Pathologist, to direct them to the most appropriate clinic (Lipid, FH, Community Lipid or Cardiology) thus creating a clear integrated pathway for Primary Care
- Provide proof of concept and reproducibility of a Community Lipid clinic

### **3.0 Project Outcomes and Benefits**

The expected project outcomes and benefits of the project were to:

#### Patients:

- Increase diagnosis rate and improve management of high-risk cardiovascular patients with elevated LDL-C
- Optimise treatment and lipid management
- Improve access to a specialised lipid service
- Bring care closer to home

- Enable patient empowerment and engagement in terms of their diagnosis and subsequent clinical management plan.

#### The NHS:

- Development of a primary care service that could be commissioned elsewhere/across other PCN's
- Increase capacity of lipid service
- Reduce waiting time
- Support alignment with NHS Long term plan <sup>(2)</sup> and CVD Prevent Audit in Primary Care.
- Support implementation of NICE CG181 <sup>(1)</sup>

#### Sanofi:

- The project aims were to increase the diagnosis rate and improved management of high-risk cardiovascular patients with elevated LDL-C, thus enabling patients diagnosed with these conditions to be then treated with cholesterol lowering medicines which may include Sanofi medicines for suitable patients in line with NICE TA393 <sup>(3)</sup> /TA394 <sup>(4)</sup>, and or, local / national guidelines
- Demonstrate collaborative working and enhanced reputation with the NHS to the benefit of patients that identifies scalable solutions

#### The NHS and Sanofi:

An opportunity to document how joint working between Sandwell & West Birmingham Hospital Trust, Modality and Sanofi has improved the identification and management of patients with cardiovascular disease and primary hypercholesterolaemia / mixed dyslipidaemia. Potential scenarios for sharing best practice may include:

- Case Studies to share best practice with the NHS
- Presentations to various NHS organisations
- Conference abstracts, posters, and presentations
- Publications

All parties (Sandwell & West Birmingham Hospital Trust, Modality and Sanofi) to seek each other's permission to use the information from the Programme and associated outcomes data with any external party.

## **4.0 Project Implementation**

The Community Lipid Clinic was set up within the Modality GP federation. At the time, this super-GP federation consisted of 13 GP practices within the Sandwell and Birmingham portion of its footprint, servicing 91,000 patients respectively.

This was supported by the arrangement of a project steering group committee that included Consultant/Deputy Medical Director, Directorate Lead for Community Services, Finance Director, GPwSI, GP Partner & Community Cardiology Lead, West Midlands FH Lead, Specialist Lipid Nurse and Associate Specialist Chemical Pathology, Divisional General

Manger Community and Secondary Care and two Sanofi representatives. This committee aimed to meet once a month to review progress of this project.

A Band 7 lipid specialist nurse was appointed to operate the Community Lipid Clinic for 2x session per week over a period of 52 weeks within the Modality group, and more specifically the Glebefields Health Centre and Enki Medical Centre. However, as this project coincided with the COVID pandemic, the clinic could not be set up during the assigned timeframe and therefore extended well into 2022 and 2023 – without impacting the allocated funding for this project.

Initially, to understand the number of patients impacted by cardiovascular disease and hypercholesterolaemia/mixed dyslipidaemia, three searches were conducted. These searches included (1) primary prevention, (2) secondary prevention, (3) direct referral to lipid clinic, which resulted in roughly 6,000 patients being flagged as possible recipients of this newly formed service.

The criteria for each search were as follows:

**1. Primary Prevention**

- QRisk  $\geq$  10% **OR** cholesterol  $\geq$  7.5 mmol/L **OR** Triglyceride  $\geq$  4.5 mmol/L

**2. Secondary Prevention**

- Either Post ACS, MI, stroke, TIA, PVA **AND** cholesterol  $\geq$  4.5 mmol/L **OR** LDL  $\geq$  2.3 mmol/L **AND**  $\leq$  85 years old

**3. Direct referral to lipid clinic**

- Cholesterol  $\geq$  8.5 mmol/L **OR** triglyceride  $\geq$  10 mmol/L **AND**  $\leq$  85 years old

Logistically, the clinic began at 1 x per week at Enki Medical Centre virtually where the identified patient cohort were scored from lowest to highest risk, enabling priority access for the latter first. However, during this time, the clinic suffered from slow patient uptake due to Covid-19 and its restrictions (March 2020 – January 2022). This meant that the clinic did not expand to 2 x face to face clinics per week at both sites until March 2021. From here, the clinic experienced full capacity and data collection from search-identified cohorts and referrals from locally associated surgeries – reaching a 50:50 blend of appointment type.

The Joint Working Project commenced in September 2020. The key milestones delivered in implementation of the Project were:

- **September 2020**

- Development of Project Plan to monitor delivery of the aims and objectives of the project.
- Recruitment of Specialist Nurse for desired clinic.
- Search tool utilised to risk stratify patient groups.
- Steering Group gained access to Teams site where project plan and other relevant documents were stored.

- Project metrics agreed.
- **October 2020**
  - Clinic opened at the Enki Medical Centre site (first site)
  - Data collection process agreed.
  - Covid-19 creating barriers to clinic usage.
- **March 2021**
  - Data collection period commenced.
- **May 2021**
  - Glebefields Health Centre clinic initiated.
  - Both Clinics at the Modality group running at capacity
- **October 2021**
  - Business case proposition required for additional funding.
- **February 2023**
  - Data collection period completed (22 months)
  - Results gathered and analysed.
- **March 2023**
  - Evaluation report produced.
- **August 2023**
  - Business cased approved. Specialist Nurse funded internally
- **October 2023**
  - Evaluation report agreed by Steering Group
  - Project close

## 5.0 Outcomes and Benefits Achieved

The table below outlines the key objectives and outcomes the project set out to achieve and provides a summary of how the project has performed against these.

Objectives	Outcomes and benefits achieved
Create a nurse led community lipid clinic within The Modality Group with clinical supervision provided by Consultant Chemical Pathologist at Sandwell and West Birmingham NHS Trust	<ul style="list-style-type: none"> <li>• A Community Lipid Clinic was set up in the Modality group between primary and secondary care, utilising a Specialist Lipid Nurse</li> <li>• 487 appointments conducted within the Community Lipid Clinic therefore establishing its presence</li> </ul>
Create and undertake a computer search which identifies high risk cardiovascular patients with elevated LDL-C to identify patients with cardiovascular disease and primary hypercholesterolaemia / mixed dyslipidaemia	<ul style="list-style-type: none"> <li>• Roughly 6000 patients identified via a computer search.</li> <li>• 43.8% of all appointments (487) were attended by patients that were identified to have high-risk cardiovascular disease with hypercholesterolaemia</li> </ul>
Triage patients, with the support of the Consultant Chemical Pathologist, to direct them to the most appropriate clinic (Lipid, FH, Community Lipid or Cardiology) thus creating a clear integrated pathway for Primary Care	<ul style="list-style-type: none"> <li>• 1 patient referred for FH screening</li> <li>• 5 patients referred to Sandwell Lipid service</li> </ul>
Provide proof of concept and reproducibility of a Community Lipid clinic	<ul style="list-style-type: none"> <li>• Clinic showcases the simplicity of introducing this type of resource and service as an intermediary between primary and secondary care is possible. It also demonstrates the positive reception in addressing the local population lipid need.</li> </ul>

## 6.0 Results and Key Achievements

### General

Over 22 months (80 session), there were 487 planned appointments (first and second appointments), but only 349 of appointments were delivered resulting in a 4.4 patient average per session, rather than the estimated 6.1. This was propelled by a subsequent 153 did not attend (DNA) appointments over this time at various points of a patient's journey (31.4%).

Project period	March 2021 – Feb 2023 (22 months)	No. of sessions actioned during project period	80
Appointments booked during project period	487	No. of patients expected per session	6.1
Actual Appointments delivered	349	No. of patients actually seen per session	4.4
First appointment	232	Second appointment	117

### Patient Profile

Due to the constantly evolving referral process, the patient population seen contained a patient profile of 53.8% primary hypercholesterolemia and 43.8% high-risk cardiovascular disease sub-sets. However, this still leant itself well to focusing on the latter as originally intended.

Patient Profile	First Appt Patient Type	Second Appt Patient Type
Primary Hypercholesterolemia +/- Diabetes	128	60
Primary Hypercholesterolemia	112	53
Primary Hypercholesterolemia + Diabetes	16	7
High Risk Cardiovascular Disease	104	49
Hypercholesterolemia + Pre event (CHD, HT, AF) +/- Diabetes	70	39
Hypercholesterolemia + Post event (CHD, HT, AF) +/- Diabetes	34	10
Undisclosed	0	8
<b>Total</b>	<b>232</b>	<b>117</b>

CVD = cardiovascular disease, CHD = coronary heart disease, HT = hypertension, AF = Atrial Fibrillation

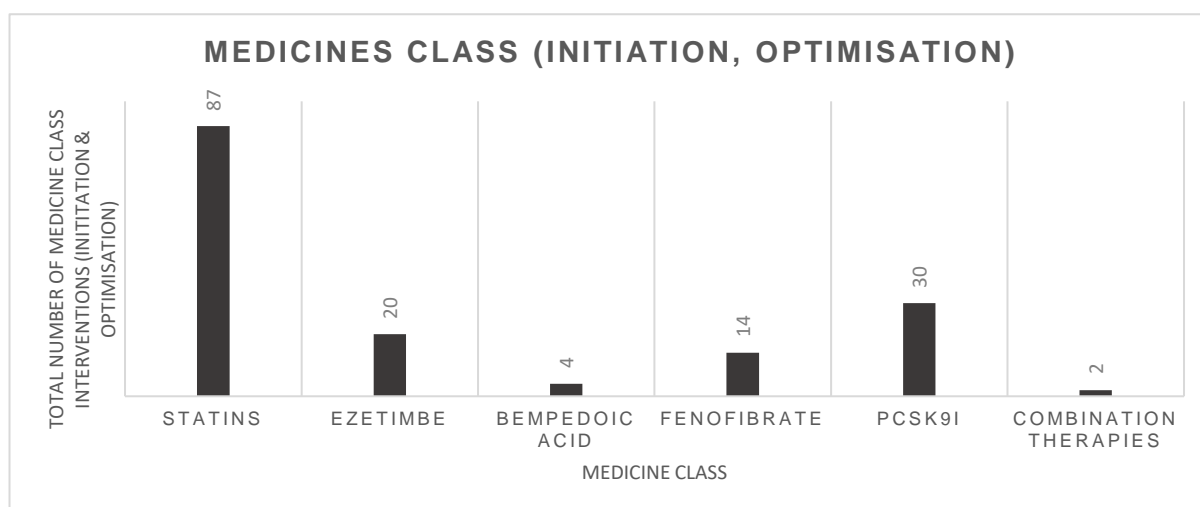
## Overall Intervention

Intervention	First Appointment	Second Appointment	Total
Lifestyle Advice	42	13	55
Medication Intervention	143	55	198
Add Treatment	127	19	146
Optimise treatment	16	11	27
Monitor Therapy	0	25	25
Blood sample	34	30	64
Monitor Patient	9	0	9
FH screening	1	0	1
Refer to Sandwell	5	0	5
Other	11	19	30
<b>Total</b>	<b>245</b>	<b>117</b>	<b>362</b>

89.2% of patients that entered the clinic (both First and Second appointments) required some form of intervention that included lifestyle advice, medication intervention, blood sampling, familial hypercholesterolaemia (FH) screening and referral. The category 'Other' included unrecognisable data, or mistaken referrals, resulting in the remainder 8.3%.

Peering further into the data, it can be seen 62.9% of these patients required some level of medication intervention, whether that was additional medication and/or optimisation. This further breaks down to 61.6% and 35% of patients requiring this type of intervention in their First and Second appointments respectively.

The medicines classes that were utilised most during this type of intervention included statins and PCSK9i at 56% and 19% respectively.



As a result of these interventions, the following results were obtained:

Measurement	Total Patient Count	Average Reduction	Single Maximum Reduction	Single Minimum Reduction
Triglyceride	72	2.4	4.7	0.3
LDL	59	2.0	5	0

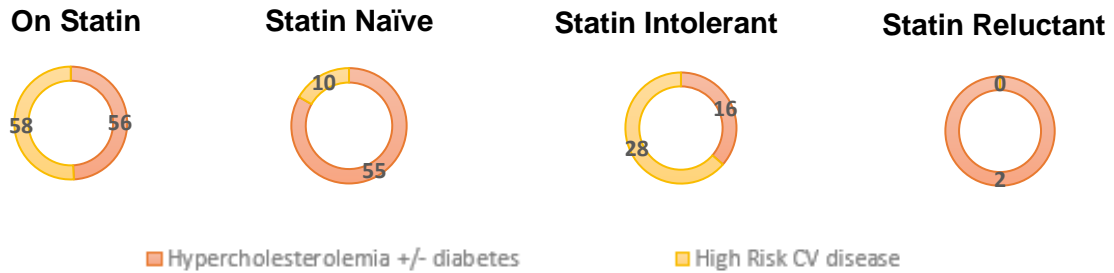
Please note that the total number of patient results were not captured due to the following reasons:

- The clinic is still chasing patients to complete the remainder blood tests post optimisation.
- Certain patients, once treated, have completed their post intervention blood measurement out of clinic.



## First Appointment

Statin Status	Patient Population	%
On statin	114	49.1%
Statin naïve	65	28.0%
Statin intolerant	44	19.0%
Reluctant to start statin	2	0.9%
Undisclosed	7	3.0%
<b>Total</b>	<b>232</b>	<b>100%</b>



Intervention	On Statin	Statin Naïve	Statin Intolerant	Reluctant to start Statin	Undisclosed
Lifestyle Advice	20	10	10	2	
Medication Intervention					
<b>Add Treatment</b>					
• Statins		28	9*1		
• Bempedoic Acid			3		
• Ezetimibe	9		7		
• Fenofibrate	9		1		
• PCSK9i	10	1	16		
• Combinations			2		
<b>Optimise treatment</b>					
• Statins	41				
<b>Continue Therapy</b>					
Blood sample	16	15	3		
Monitor		5	1		3
FH screening	1				
Refer to Sandwell	2	2	1		
Other	3	4			4
<b>Total</b>	<b>114</b>	<b>65</b>	<b>44</b>	<b>2</b>	<b>7</b>

\*1 9 patients were switched from one statin to another as clinician felt it may not be a medicinal class allergy

Of the 232 first appointment pool, it can be seen that 114 (49.1%) of patients were already on a statin. Where roughly over half belonged to the high-risk cardiovascular disease patient profile, thus reflecting the correct stream of patients entering the clinic for its intended purpose. As expected, the majority of this type of patient profile benefited from statin optimisation (41) predominantly, and then initiation of a PCSK9i (10).

The statin intolerant subgroup totalled 44 (19.0%) and were mainly made up of high-risk cardiovascular disease patient profiles (28). This cohort benefitted most from PCSK9i (16), where 15 were of a high-risk cardiovascular disease profile. This small sample size does suggest these patients had significantly uncontrolled lipid profile considering selected treatment choices. It also highlights the clinic actively providing an entry point and quicker route for intolerant statin patients to be treated sooner within the pathway, with more suitable therapies.

Only 65 (28.0%) patients were considered statin naive where only 28 received a statin. The remainder either mainly received lifestyle advice (10) or required a blood sample (15) for further testing, with the latter probably requiring greater intervention – again partially showcasing the right type of patient entering the service.


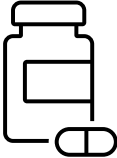
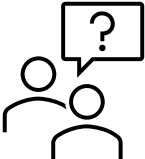
### Second Appointment

	Add Therapy	Optimise Therapy	Monitor Therapy	Reluctant to start Therapy
Statins	9	8	8	
Bempedoic Acid	1			
Ezetimibe	4		1	
Fenofibrate	1	1	1	
PCSK9i	4		11	4
Combinations			1	
Medication Adherence		2	3	
<b>Total</b>	<b>19</b>	<b>11</b>	<b>25</b>	<b>4</b>

Of the 117 second appointments, 41 (35.0%) patients required a further medication intervention and an additional 30 (25.6%) required a blood sample. The breakdown of medication intervention highlights therapy intensification and monitoring being the key activities conducting during this segment of the clinic.

It is important to note that at the time of collecting this data, not all second appointments, and therefore follow ups, were conducted thus limiting the amount of data collected.

## Key Achievements

 <p><b>The Clinic</b></p>	<ul style="list-style-type: none"> <li>• Specialist Lipid Nurse clinic established Glebefield Medical Centre and Enki Medical Centre for the duration of the project.</li> <li>• New touchpoint established within pathway linking primary and secondary care with Community Lipid clinic to accommodate moderate to high-risk patients, suffering from hypercholesterolemia and/or cardiovascular disease.</li> <li>• Clinic is looking to be retained as a staple within the locality, as it has demonstrated increased capacity within the system, better risk stratification through earlier triaging within the pathway</li> </ul>
 <p><b>The Results</b></p>	<ul style="list-style-type: none"> <li>• Roughly 6000 patients identified via search tool.</li> <li>• 232 new patients entered the clinic during the project.</li> <li>• 89.2% of these patients required some level of intervention to optimise lipid levels, where 62.9% required a medication intervention.</li> <li>• 117 patients returned to the clinic for a second appointment (follow up) for therapy intensification and/or further testing. This figure will continue to rise.</li> <li>• Average triglyceride and LDL reduction were 2.4 mmol/L and 2.0 mmol/L respectively.</li> <li>• 5 patients were referred into Sandwell and City specialist setting and 1 patient received FH screening</li> </ul>
 <p><b>Observations</b></p>	<ul style="list-style-type: none"> <li>• Clinic demonstrated an accessible and earlier entry point for patients to enter the pathway to receive second- and third-line therapies in accordance with local guidance to ensure optimised lipid levels, particularly in more complex cases.</li> <li>• The role of specialist lipid nurse is valuable to a primary care setting when made accessible via a Community Lipid Clinic.</li> </ul>

## 7.0 Challenges and Issues

- Covid-19 occurred during the initiation of this project, thus delaying the opening of the clinic, uptake and project timelines.
- 153 patient DNAs occurred during the project and accounted for 31.4% of the total number of appointments booked (487) therefore partially limiting the benefit received by the locality.

- Face to Face clinics isolated patients that were further away from the clinics or were worried about Covid-19 risks, increasing the number of DNAs.
- Patients not having recent blood test results meant further touchpoints were required within clinic to make a meaningful interaction.
- GP records not being update quick enough with blood results for clinic to utilise.
- When using the search criteria, roughly 6000 patients required lipid optimisation. This current need would not be met by the current use of the clinic due several factors that include patient DNAs, frequency of clinic sessions and days, logistics, and governance.

## 8.0 Lessons Learnt

A number of key lessons were learned that would be valuable for other hospitals to know if they were to explore a similar pathway transformation:

- The importance of having dedicated Project Management time devoted to co-ordinating the implementation of the project.
- The benefit of having a Project Steering Group to oversee and monitor implementation of the project as this has helped to keep the project on track and has supported the management of issues and risks in a timely manner. Monthly meetings worked well in co-ordinating the project.
- The importance of setting out at the start of the project the outcomes to be achieved and the outcome measures to be used to evaluate the benefits of the project.
- The value gained by obtaining Specialist Lipid Nurse clinic as an intermediary between primary and secondary care to address local lipid population need (easier access, more opportunities for second and third-line therapies earlier within the pathway)
- Being very specific of patient profile requirements when setting up a lipid clinic within a pathway to ensure it delivers the most impact it can, i.e. moving away from statin naïve patients or statin/tablet optimisation
- Enabling both face to face and virtual options to reach wider patient population.
- Modifying introductory patient letter to help patients understand the importance of attending this clinic (the why) to reduce DNA.
- Offering fewer appointment dates and times to patients to minimise DNA.
- Discharging patients from service if DNA on more than two occasions.
- Provide formalised recommendations to the GP if patient requires tablet optimisation and discharge from service, thus freeing the capacity of the service.
- Provision of admin time to increase efficiency of service and maximise clinic impact.

## 9.0 Next Steps

The project has delivered mostly on its aims and objectives of the collaborative working project. The only discrepancy being the type of patient entering the clinic due to the issues highlighted in the Project Implementation section. Securing the funding from the Hospital Trust for continued use of the Specialist Lipid Nurse post on an-ongoing basis will support with embedding and sustaining the changes and improvements made through this project.

Now that the project has concluded, some next steps have been identified to build upon the work of the project are as follows:

- Continue developing clinic to optimise results by increasing the number of patients seen per session, reduce the number of patient DNAs, and increase frequency of sessions to address local need.
- Consider adding additional resource such as admin staff or additional healthcare professional time to meet the above point and further develop governance and logistical efficiency of the service.
- Ensure only complex patient profiles are entering the clinic, by reducing the number of patients that only require statin initiation or optimisation entering the clinic.

## 10. References

1. <https://www.nice.org.uk/guidance/cg181>
2. <https://www.longtermplan.nhs.uk/wp-content/uploads/2019/08/nhs-long-term-plan-version-1.2.pdf>
3. <https://www.nice.org.uk/guidance/ta393>
4. <https://www.nice.org.uk/guidance/ta394>