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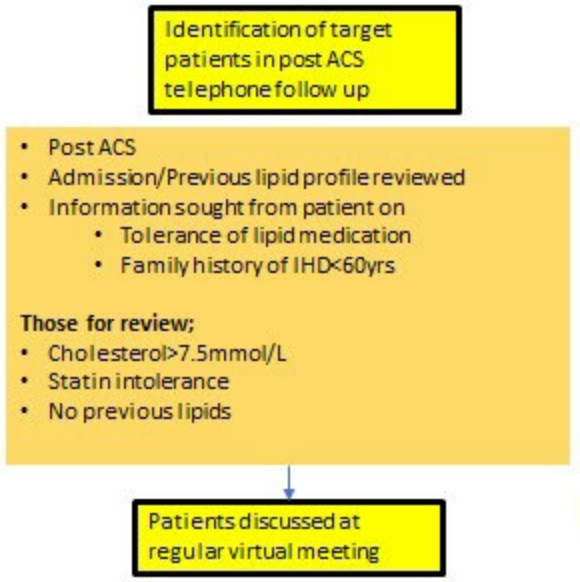
Implementation of an optimised lipid management pathway across primary & secondary care (Northumbria Healthcare and Northumberland CCG)

This Project was agreed as part of the Accelerated Access Collaborative (AAC). The AAC was formed in response to the independently chaired Accelerated Access Review published in October 2016. The AAC brings industry, government and the NHS together to remove barriers to uptake of innovations, so that NHS patients have faster access to innovations that can transform care.

The joint working project was completed at the end of 2021 following a number of delays due to COVID-19 pandemic.

Below outlines the outcomes against the original objectives for the project

Please briefly outline the key objectives and outcomes the project set out to achieve as stated in your application. How has the project performed against these?		
Proposed objective / outcome	Status *Achieved, Partially Achieved, Not achieved*	Narrative
1) Identification of patients (with lipid values above target) post Acute Coronary Syndromes (ACS)	Partially achieved	The original proposal to undertake a secondary prevention clinic face to face in all patients post acute coronary syndrome (ACS) was not able to be undertaken due to the COVID-19 pandemic. Alterations to this side of the pathway were significant and in order to simplify the pathway to allow multiple nurse specialists to identify the highest risk patients in the absence of face-to-face clinics, the following pathway was implemented. This allowed those with statin intolerance, total cholesterol >7.5mmol/L or no previously measured cholesterol to be assessed in a multidisciplinary team meeting. Advice specifically for those patients was passed back to the cardiology specialist nurse for communication to primary care. The pathway below was followed.

		
2) Identification of patients with atherosclerotic cardiovascular disease (ASCVD) in the community in whom non-HDLc > 4mmol/L.	Achieved	Within this project work has been undertaken with 14 General Practices, within 9 PCN's, across 2 CCGs - Northumberland CCG and North Tyneside CCG covering a total population searched of 188,000 from August 2020- August 2021. Within the search criteria for pilot practice reviews, the non-HDLc was adjusted to >5mmol/L to allow a smaller group of patients to be reviewed in whom the LDLc would likely exceed the NICE criteria for PCKS9i initiation. Using a quality improvement approach, the team subsequently adopted nationally available searches designed by the Clinical Digital Resource Collaborative (CDRC) which used a combined search for patients with LDLc >4 mmol/L, non-HDLc > 5mmol/L and/or total cholesterol >6mmol/L.

		<table><tr><td>Total Population searched (using CDRC digital searches in EMIS/S1 systems)</td><td>188,000</td></tr><tr><td>Number of patients commenced on PCSK9i</td><td>26</td></tr><tr><td>Number of patients recommended optimisation of oral medication</td><td>205</td></tr><tr><td>Number of patients commencing optimisation of oral medication</td><td>166</td></tr></table> A new model of working was created, piloted in two General Practices and then shared with a further 12 practices. Through use of online meeting tools, the Pharmacist and Consultant Chemical Pathologist met with individual practices/PCN representatives to agree their preferred model for involvement and responsibilities (e.g.intensification/prescription management), ensuring all activity and changes to repeat prescribing was consistent with practice policy (e.g. annual recalls, synchronised prescriptions). In a number of practices this was linked to an educational update about lipid therapies. With relevant permissions to directly access primary care records and using a pre-determined digital search, the prescribing pharmacist was able to identify patients with atherosclerotic cardiovascular disease (ASCVD)

		in each practice for whom cholesterol was above target. Following a desktop review of the primary care record, patients were then contacted by telephone to explain and offer options for lipid optimisation which may have included intensification of oral medications or assessing their suitability for PCSK9i medication (using a fasting lipid blood test as per NICE TA requirements). A large proportion of this group of patients had experienced side-effects with previous statins leading to their discontinuation without appropriate re-challenge. This model provided an opportunity to re-engage with those who had previously declined cholesterol lowering treatment and have a patient-centred conversation about their medication and lifestyle factors that could reduce their cholesterol. The pharmacist would then follow up the patients to ensure they showed a response in terms of their blood results and where appropriate titrate Lipid Lowering Therapy or refer for PCSK9i therapy. A clinical multidisciplinary group was set up to allow complex cases to be discussed with the Consultant Chemical Pathologist. Cases included those with statin intolerance/ allergy, patients requiring titration and those who required review and potentially further investigation for Familial Hypercholesterolemia.
3) Initiate a Pharmacist led PCSK9i initiation clinic	Achieved	Patients identified prospectively in project objective 1. or retrospectively for 2. and in whom PCSK9i initiation criteria were met in accordance with local / national guidelines, were trained, prescribed and followed up from this clinic with a PCSK9i medication. Patients meeting the criteria to commence on PCSK9i medication, as identified from the CDRC searches within the primary care systems and verified by pharmacist desktop review, were invited either to a virtual video clinic or an in-person clinic within hospital to explain, train and support their initiation of

		PCSK9i medication. Video clinic contact also offered the patients an opportunity to provide online feedback for the service at the end of the consultation. The pharmacist would then follow up the patients to ensure they had tolerated the new medication and demonstrated a satisfactory response defined as at least 20% reduction in non-HDLc from baseline. Further hospital-based prescriptions were then provided and patients were offered a homecare delivery service. 26 patients have been commenced on PCSK9i Very positive patient experience feedback was received from service users of pharmacist-led PCSK9i clinic.

What have been the key achievements and highlights of the project?

1) Secondary care – Identification of patients post ACS

a) Engaging with secondary care cardiology clinical colleagues
-Lipid consultant attends the bimonthly cardiology meeting
-Weekly lipid MDT meetings for case discussion

b) Raising the profile as lipid management in secondary care and sharing new options of treatment including facilitating access to new agents

c) Highlighting the need to look for and identify patients who may have Familial Hypercholesterolaemia
-Lipid MDT
-Linking to the NEELI Regional Guideline launched in 2021

d) Ensuring lipids are checked at appropriate points in the patient pathway in secondary care
-Changes to ICE requesting for bloods in chest pain pathway (lipids made as a pre -selected test in the computer system)

e) Support the decision making for secondary prevention at patient follow up
-Lipid MDT discussion and communication back to primary care

2) Primary care arm

Flexible approach: Despite COVID-19, the project was able to continue due to the pharmacist being able to remotely carry out searches and speak to patients on the telephone. Use was also made of video calling software - Attend Anywhere. There was flexibility in the way the pharmacist worked with each practice to minimise the impact of the project on surgery time. The work was carried out in the context of COVID-19 with a lack of capacity of blood test appointments at the GP surgeries, some reluctance among patients to attend appointments, additional demands on primary care workforce to deliver COVID-19 vaccination and the (temporary) associated shift in focus away from non-urgent long-term conditions activity.

The engagement of practices: Having completed pilots within the respective practices of the two CCG long-term conditions leads, we were able to demonstrate that the model was both effective and, crucially, not placing substantial further demands on the general practice workforce. This early pilot data was then used to support CCG communications to other practices to enable good engagement and interest from practices willing to take part in the project. The pharmacist worked with all members of the practice team: GPs/ Practice nurses/ Pharmacists/ Pharmacy technicians/ Administration staff to raise awareness of the different lipid therapy options, share resources and support them in their patient interactions. By working collaboratively with practices in this way, the pharmacist received additional direct referrals and queries which they were able to answer or bring to the lipid MDT. Furthermore, the agreed detailed clinical management plans for lipid optimisation were directly recorded by the pharmacist onto the patient's primary care record, allowing practices to efficiently follow these recommendations for seamless care.
The project was branded as 'Lipid Optimisation in Secondary Prevention'.

Networking and sharing information/ resources: The project information, background and lipid optimisation updates were shared directly with 14 practices using a presentation via MS Teams at the practice lunchtime meeting/ monthly education session. The project learning and clinical updates were also shared with the Northumbria pharmacy department to increase awareness of the PCSK9i medication as well as providing information to support conversations with inpatients requiring a lipid optimisation step.

The project was presented at Northumbria Healthcare NHS Foundation Trust Excellence in collaboration annual conference which is an event designed to share work with Trust and local primary care colleagues.

Resources created by the project team at Northumbria were shared with other PCSK9i PTF sites and key learning was shared at national meetings including the Combined Lipid Operational Group (CLOG), as well as individual meetings with organisations requesting information. The resources included a standard operating procedure for Primary Care Pharmacists: “Reviewing and managing elevated non-HDL cholesterol levels in Secondary prevention primary care patients”, a handbook to support training staff to provide a secondary care lipid optimisation clinic: “Lipid Optimisation in Secondary Prevention (LOSP) Handbook” and a case study to assist with national redcap database training.

Increased Accessibility to Specialist Advice

A weekly multidisciplinary team meeting was set up to discuss complex cases, those requiring a lipid optimisation step and / or those requiring further investigation. The meeting included a Consultant Chemical Pathologist, LOSP pharmacist, Familial Hypercholesterolemia pharmacist and Cardiology Specialist nurses. Between October 2020 and August 2021 there were 35 MDT meetings and 215 cases discussed.

Access to primary care systems has enabled the searches, as well as documentation of each consultation on the patient record using either EMIS or SystmOne. This includes a summary of the discussion and a plan of different options which is visible to all members of practice staff- raising awareness of the different options and also enabling the next member of staff who speaks to the patient- in a CVD annual review or whilst reviewing blood results, to know where the person is on their lipid lowering treatment journey and what options to try next, including a sign post to the Lipid clinic Advice and Guidance service if further advice is required.

3) Pharmacist-led PCSK9i initiation clinic

A Pharmacist led PCSK9i initiation clinic was set up to discuss and initiate PCSK9i medication, follow-up patients to monitor for adverse effects and response to treatment, as well as provide prescriptions for ongoing treatment in accordance with local and national guidelines.

A flexible approach to clinic appointments was used- either use of Attend Anywhere video calling appointments or in-person appointments. Video appointments allowed remote outpatient appointments to continue despite COVID-19 and provided greater access to clinic appointments for those who couldn't travel or those who live further away. Given the large geographical area covered by Northumbria Healthcare NHS Foundation Trust, this remote option was useful to support accessibility. Individuals opting for a video call were posted a placebo pen and leaflet, supplied by either Amgen or Sanofi, which enabled training in use of the injection devices to occur online and minimise any impact on the quality of the outpatient appointment when compared to a standard face-to-face discussion. People unable to use or access the technology for a video call were invited to an in-person appointment.
These appointments were initially delayed due to COVID-19.
PCSK9i clinic appointments:
Number of in-person appointments - 15 patients
Number of video call appointments - 11 patients

To assess the impact on quality as a result of the change to a remote outpatient appointment for PCSK9i initiation, an ongoing assurance measure for patient experience was incorporated into the model. Of the patients who responded, all rated the quality of care received as 'excellent'. This also provided assurance of the quality of care provided from a pharmacist-led PCSK9i clinic in place of the previous consultant-led model, with all respondents highlighting confidence and trust in the pharmacist.

4) Other

An abstract of the initial work was accepted by Heart UK conference 2021 and Great North Pharmacy Research Conference 2021.
An application was submitted for an AHSN Bright Award 2021 for the category "Demonstrating an Impact upon Patient Safety and/or Quality Improvement"
Participant in the NHCFT Quality Festival/ Ideas Hub 2021- poster, blog and video were accepted.
An application to the North of Tyne formulary committee was made by the project team to have the status of rosuvastatin updated to make it available to be prescribed within primary care, rather than initiated only on the advice of a secondary care specialist. This restriction for a water-soluble high intensity statin was identified as a barrier to its usage from a number of primary care

clinical staff involved with the project. As a trial with rosuvastatin is typically a required step before consideration for PCSK9i, this formulary update was a key enabler for practices to carry out optimisation for patients with intolerance to first line statins.
The NEELI regional lipid guidelines have been updated and shared regionally https://ntag.nhs.uk/wp-content/uploads/2022/09/NEELI-edit-v2022.2-FINAL-NTAG.pdf?UNLID=854670302022112516530

What challenges and issues were encountered and how did these impact on the project performance?

Secondary care arm changes

The original project plan for the secondary care case finding arm proposed a change to the NHCFT cardiology post-ACS pathway to incorporate a non-fasting lipids blood test to be carried out at 12 weeks during a face-to-face clinic appointment with a specialist nurse. A letter to the GP/patient would then follow depending on the non-HDLc level, referring eligible patients to the PCSK9i pharmacist as appropriate. As a result of the COVID-19 pandemic, restrictions to face-to-face appointments and blood tests within the Trust prevented this new patient pathway from going ahead as planned.
The process was changed to enable the additional cardiology input to continue without the originally proposed face-to-face contact.

Amendment to secondary prevention arm of LOSP

--Resource: MDT lipid 1hr per week to support the decision making for patients referred from Cardiac Nurse Specialist virtual clinic reviews B7 0.4WTE resource between Feb21 and June 21

A - Requesting changed for lipid profile for ACS

-At the point of requesting blood tests for those patients in whom chest pain is a presenting complaint, lipid profile is a panel of tests which can be selected. An audit found that <60% of those with subsequently diagnosed ACS had a lipid profile taken on admission. One action that was taken in light of this data was to make the lipid profile automatically part of the chest pain set rather than a selectable component.

B - Patient identification and referral to Lipid MDT process: 21 patients referred to Lipid MDT with the project period

-18 of those patients had a cholesterol>7.5mmol/L, 3 of them statin intolerant, 0 had no previous cholesterol measured

-12 patients either had action taken or plan communicated onto primary care which was the output of the MDT (out of these 7 had positive action taken, and this comprised either meds updated or blood tests taken and reviewed).

A total list of those 12 patients in whom action was taken is listed below including the action performed;

1 x possible Familial Hypercholesterolaemia, seen in clinic, commenced on statin
1 x achieved target of non HDLc <2.5mmol/l (2.3mmol/l actual value achieved)
2 x switched to rosuvastatin due to statin side effects
1 x switched to rosuvastatin and achieved target of non HDLc<2.5mmol/L
2 x escalation of treatment, added in ezetimibe 10mg
1 x advised to seek A+G from lipid clinic, referred through and commenced on Ezetimibe 10mg
4 x advice passed to primary care; no action seen via electronic records although likely too early to assess at point of notes review

-From the remaining 9 patients out of the 21, one had a plan communication, but no record of this being carried out and 8 did not have documented evidence of information passed onto primary care from MDT.

Challenges included ensuring the correct message got back to the team, often in primary care, who was responsible for that patient. Additionally, ensuring that recommendation was carried out was also a challenge.

2) For the Primary care arm of the project the following represented areas of challenge;

- Follow up/fasting lipids – with the reduction in face to face working in all areas of the health service there was a period of time in which blood tests were not being undertaken for more routine indications. This delayed the process of triaging patients. Later in 2021 blood tube restrictions also had an impact, albeit minor, as the project was mature at that stage and less new patients were being identified.
- Primary Care Workload / Buy-in – The project was proposed and designed prior to the global pandemic. At the point of project launch amidst a peak of COVID-19 infections and its many uncertainties, among the stakeholders there

were perceptions that the project was occurring at the wrong time. Even with adjustment for remote operation there was still a requirement for practices to engage with the new project and authorise access. As this was perceived as 'new' quality work for practices, it was understandably a difficult time for them to engage with the project team for fears this would result in further demands being placed on them for bloods or changes to prescriptions. This issue if not considered would have resulted in the primary care arm of the project stalling significantly for several months. The project team were able to mitigate this risk in developing a standard procedure which placed very few demands on the practice teams.

- Recruitment of practices – The project had originally proposed targeting of practices based on measures for optimisation of lipid lowering therapy (a 'heat map'). Following good stakeholder engagement even before project submission there was an expectation for significant practice engagement across both CCGs. Due to pressures associated with the pandemic, the strategy for project roll-out was altered to running two initial practice pilots from each CCG footprint linked to their respective long-term condition lead GPs. Following successful pilots, the team utilised CCG communications to welcome expressions from other practices. Although there was an initial delay in achieving these results, the strategy was successful in identifying other willing practices, significantly helped from endorsement from these two key stakeholders.
- PCSK9i clinics – a partial solution to the reduced number of outpatient appointments available during the COVID-19 pandemic was to utilise virtual Attend Anywhere video consultation software and offer to all patients who were able to access this technology. This reduced face to face contact and also avoided travel time and costs. A barrier to this was the lack of access to internet and technology among some of the patients requiring outpatient assessment. Upon easing of restrictions, more face-to-face appointments were made available to ensure equitability of service to all patients.
- Difficulty commencing PCSK9i – in the early stages of the COVID-19 pandemic, the ability to differentiate COVID-19 symptoms from side effects with new PCSK9i medication was difficult due to limited availability for PCR diagnostic testing. This resulted in delayed initiation of PCSK9i for new patients until more widespread PCR testing was available locally.
- Delay of national contractual incentives for lipid optimisation – Prior to project submission, there was an expectation for a national CVD prevention contractual target/incentive within primary care given its absence from current QOF domains. CVD Prevent is a national audit of primary care data in England which extracts pseudonymised patient

data from GP systems. Following analysis and publication of the findings at national, regional, PCN and CCG practice level, the audit report would then be used to identify gaps in treatment and opportunities for improvement. The postponement to the introduction of national CVD prevention initiatives removed a key enabler in what would have added significant momentum for the project.

- Quality of clinical coding – the secondary care arm was originally planned to deliver a significant number of prospective cases with high confidence of eligibility for PCSK9i i.e.a definite new diagnosis of MI and availability of recent bloods within thresholds. In contrast, the primary care case finding arm was reliant on the identification of secondary prevention cases through accurate clinical coding within primary care systems and the availability of recent lipid blood tests. In hindsight, the barriers to the secondary care arm created by COVID-19 meant that primary care 'historic' coded patients provided a regular list of candidates who were potentially eligible for PCSK9i and was the more successful arm of the project in terms of patients identified for PCSK9i. However, there were a number of cases who were incorrectly coded and this process required significant pharmacist time to review records to ensure eligibility for PCSK9i.

What are the key lessons learned that you think would be valuable for other adopting sites to know if they attempted a similar pathway transformation?

Stakeholder engagement

From the application stage of the LOSP project the team ensured good stakeholder engagement, particularly with key primary care contacts including representatives from North Tyneside and Northumberland CCGs and respective lead GPs for long-term conditions (LTCs). The team also reported to the Cardiology Collaborative to link in with other local CVD initiatives across North Tyneside and Northumberland. The team engaged with Northumberland County Council public health team to ensure awareness of familial hypercholesterolaemia case finding. This engagement proved invaluable in ensuring advocates for the project and its benefits across the different healthcare settings, supporting its roll-out despite the barriers presented through COVID-19.

Pilots and Roll-out

Having completed pilots within the respective practices of the two CCG long-term conditions leads, we were able to demonstrate that the model was both effective and crucially did not place further demands on the general practice workforce. This early data was then used to influence CCG communications to other practices to enable good engagement and interest from practices willing to take part in the project. Although this reassurance was especially important during the initial pressures of the global

pandemic, the approach would be helpful at any time to support project roll-out. Our experience with similar integrated projects and the barriers that can develop when adding significant workload to practice teams was a key factor in setting up the project to allow autonomous pharmacist working in practices wherever possible.

Engagement with secondary care
Maintaining key communications about the project with a small number of people is important, and especially so when changes occur to the project protocol. We did not employ any formal change management given the resources we had but this may also be useful to think about if the plan is more complex and changes are occurring to ensure the correct people have the most contemporary information. Using straightforward criteria to identify patients is also key to ensure standardisation and uptake of the process within clinical teams. More complex strategies risks a reduction in engagement or referrals which may not meet the criteria required.
Electronic requesting of bloods and profiles also are beneficial to standardise requesting within an organisation.

Remote working, flexible approach
Be aware that primary care practices will differ in how they work and an agreement initially in how bloods are requested, results reviewed, and actions undertaken is key so that there are no unexpected surprises or results or actions do not get missed. Patients also will have a preference in how they may be followed up, especially if being trained with PCSK9i - some may wish for face to face contact, others are happier with a virtual approach.

What are the next steps now the project has concluded? How will the change be embedded and made sustainable? Are you planning further developments to build on the work of the project

1. A business case to maintain the prescribing pharmacist role has been prepared and submitted. If successful, this proposal will allow continuation of the primary care case identification, initiation and following up of lipid clinic patients commenced on PCSK9i as part of the project. It will also add capacity within secondary care to enable further work in secondary prevention such as post ACS and post stroke.
2. Regional lipid guidelines have increased awareness of lipid management and ensure PCSK9i identification by the NICE TA is clearly listed.

3. Learning from the project will be further shared within the organisation and a publication will be prepared to summarise the key learning from the integrated model and PCSK9i pharmacist-led clinic developed.
4. A further audit of lipid optimisation in acute stroke inpatients at NHCFT has commenced to allow review of performance against local standards.This will provide a greater understanding on whether there is need to improve lipid management within the stroke pathway. This was highlighted as an unmet need in other PTF sites who specifically looked at stroke services.

In what demonstrable way has the project tackled health inequalities?

Both the primary care consultations and secondary care lipid clinic offered either face to face appointments or remote telephone / video consultations.
This allowed us to support all patients irrespective of their ability to travel. Patient experience questionnaires received have highlighted that the remote pharmacist clinic had a positive impact on accessibility of the service and that significant distances/costs of travel to secondary care sites were avoided.
The approach taken for primary case-finding was systems-based and led directly by the clinical data and prescribing criteria to seek out patients on potentially suboptimal therapy rather than relying upon patients to engage directly with the service which may have added to inequality. The direct utilisation of primary care data removed barriers that can be associated with the traditional identification and referral model to enable us to support patients experiencing inequality in health provision. The added capacity within primary care as a result of project funding ensured this.
The project embedded shared decision-making where patients were empowered to take an active role in their own lipid lowering management. Where discussing these complex prescribing choices, the pharmacist was able to adapt to the patient's needs to ensure they received all the necessary information in a way they could understand and supported the patient to make the right choice for them.

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Quantitative feedback

Metric / measure	Number	Comments
Number of secondary prevention patients who have had an adverse to statins	539	From 1011 patients identified from the CDRC searches and receiving desktop review from pharmacist, 539 had a recorded adverse reaction to one or more statins.
Number of secondary prevention patients who have accessed ezetimibe	23	Patients initiated by the pharmacist on ezetimibe intensification in addition to statin or as monotherapy
Number of secondary prevention patients who have accessed PCSK9i Alirocumab 75 mg Q2W	2	1x Initiated due to latex allergy 1x Initiated due to ADR with evolocumab
Number of secondary prevention patients who have accessed PCSK9i Alirocumab 150 mg Q2W	0	
Number of secondary prevention patients who have accessed PCSK9i Evolocumab 140 mg Q2W	25	
Number of secondary prevention patients who have accessed other drug/dose/frequency combinations	176	Includes patients who may still be eligible for PCSK9i, currently assessing response to intensification/re-challenge. Excludes patients who have had a consultation to discussion possible changes but declined.
Number of secondary prevention patients who had an adverse reaction to PCSK9 inhibitor drugs	2	2 patients from the 26 initiated by the pharmacist.

Percentage of secondary prevention patients who had their annual medicine review with a blood lipid profile		Not evaluated during project. Figure would be compounded by a significant proportion of intentionally delayed LTC bloods, either by practices' request or patients due to COVID-19 risks from attending practices.
Percentage of secondary prevention patients who had their annual medicine review without a blood lipid profile		
Number of secondary prevention patients not eligible for PCSK9i therapy	738	From 1011 patients identified from the CDRC searches and receiving desktop review from pharmacist, 273 patients were potentially eligible for PCSK9i and are either: a) Currently receiving PCSK9i therapy b) Currently being optimised with a view to initiating PCSK9i therapy c) Declined change to treatment at this time i.e. may be eligible after a future optimisation step

The outcome measures listed in the bid are as follows:

o Total number of patients reviewed: 413

o Patients with suboptimal lipid control reviewed: 348 (as 64 were discharged immediately after the first review and 1 passed away)

o Patients with changes to statin therapy and % patients who have been put on a high intensity statin: 311 and 62.95% respectively.

o Patients with addition of ezetimibe: 103

o Patients referred for PCSK9i eligibility: 10 (3 were initiated on PCSK9i)

o % patients whose cholesterol has been optimised: 17.92%