Lowering Cholesterol.

Saving Lives.

Health Innovation East

Part of the Health Innovation Network

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NHS

Tackling Cholesterol Together

Exemplar delivery models proving to be significantly effective for patients and the NHS

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GP Primary Choice

Healthy Hearts Project

Background

- GP Primary Choice (GPPC) have been commissioned to work in collaboration with East Suffolk North Essex Foundation Trust (ESNEFT) to significantly improve the health of its residents, with an aim to reduce cardiovascular events.
- This will be delivered through improved management of cholesterol and hypertension in patients on an existing pathway, as well as a programme of work to identify those not known to be on a cholesterol and hypertension pathway, with a view to introduce the required interventions.
- Based on a programme run in Bradford called ‘Bradford Healthy Hearts’ and ‘West Yorkshire and Harrogate Healthy Hearts’ GPPC are focusing on the following clinical workstreams

Cholesterol Management Task

1. Switching statin medication in line with NICE guidelines and Accelerated Access Collaborative (AAC) localised Suffolk North East Essex (SNEE) Lipid Pathway

2. Initiate cholesterol management in patients with a QRISK2 score of over 10%

3. Working with patients who have previously been prescribed a statin and are no longer taking it (establishing the reason – cost, intolerance, reputation etc.)

4. Identifying potential FH, review and consider onward referral to community or secondary care

Identification of patients

How did we identify patients?

Patients have been identified for the Colchester and Tendring Healthy Hearts project based on the West Yorkshire written Healthy Hearts system searches. Below are the high-level numbers identified in each category in North East Essex:

Query No	Criteria	No of Patients
01	Statin Switch – Primary Prevention	4512
02	Statin Switch -Secondary Prevention	1142*
03	Offer Statin - QRisk 10-20% - Never had a statin before	17554
04	Offer Statin - QRisk 10-20% - Previously tried a statin	1861
05	Offer Statin - QRisk >20% - Never had a statin	7772
06	Offer Statin - QRisk >20% - Previously tried a statin	2088
07**	Deprescribing – Patient Over 80 no CVD	6167
08	Potentional FH – Consider review and onward treatment	740

**We do not believe this number to be correct, we think there are coding issues in patients records which are being reviewed as we go. The number is thought to be less.*

***** This cohort of patient is currently excluded from the programme of work as more clinical decisions need to be made prior to commencement***

Support primary care to tackle cholesterol

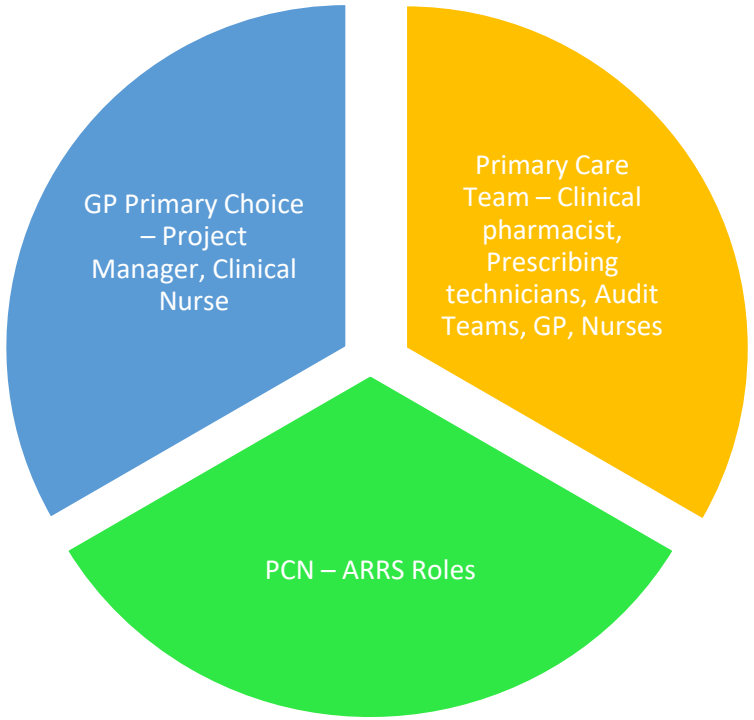
Delivery model = Primary care/PCN with or without support

1. Document suite of how to guides, searches, local pathway, letter templates
2. Clinical support
3. Administrative support
4. Pilot practices
5. Peer support for patients

Who is involved

Be flexible and use staff at all levels to suit practice/PCN needs

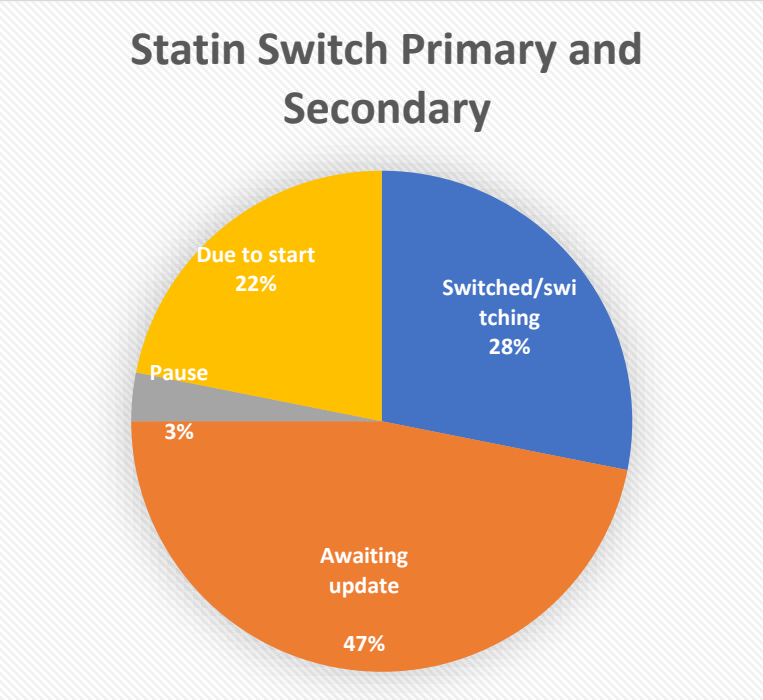
- Identification of patients – Administrative task
- Medication switches – Administrative task (adding medication templates)or clinical dependent on staff role and practice/PCN protocols
- Initiation of medication – Administrative task (adding medication templates) or clinical dependent of staff role and practice/PCN protocol
- Letters - Administrative staff
- Clinical review – Clinical pharmacist, Nurses, GP



What have we achieved so far

Statin switch

Primary Prevention on low intensity switched to Atorvastatin 20mg Secondary Prevention Atorvastatin 80mg where appropriate. We successfully piloted statin switch in 2 practices. 9 further practices have switched with 7 due to switch shortly.



Practice	Total Number of Primary >4 serum cholesterol >2 LDL	Total Number of Secondary >4 serum cholesterol >2 LDL	Total Primary & Secondary	Statin Switched Primary - cholesterol within the last 6 months	Statin Switched Secondary - cholesterol within the last 6 months	Total Switched	% of total switched	LDL 2<	Reduction in LDL
1	226	23	249	180	21	201	80.72	65	107
2	148	20	168	60	0	60	35.71	Due soon	Due soon
3	129	37	166	51	9	60	36.14	Due soon	Due soon
4	131	15	146	42	5	47	32.19	Due soon	Due soon
5	116	21	137	39		39	28.47	Due soon	Due soon
6	21	1	22	21	0	21	95.45	Due soon	Due soon
7	265	50	315	108	19	127	40.32	Due soon	Due soon
8	26	14	40	12		12	30.00	Due soon	Due soon
9	96	7	103	42		42	40.78	Due soon	Due soon

What did we learn

Not to bulk switch all patients

Why?
The searches we use look for patients who had a cholesterol test in the past 18 months. However, we did not want to switch patients who had not had a cholesterol test in the past 6 months.

Why search for them then?
Because it gave us an idea of the work to come and those that were overdue i.e. not had a test in the past 12 months but who needed one.

Initially we switched everyone with a cholesterol in the past 6 months and tried to get a baseline for all the others. We started with a large practice who had around 250 people on the list. This soon got a bit messy with lots of blood test requests and results. The last thing we wanted to do was create more work!

Continued

Now we advise practices to switch those who have had a cholesterol test in the past 6 months and request bloods for those that are overdue their annual test. We naturally wait for the others to fall into the 6 month timeframe. This makes the work bitesize and easier to work with. 3 months after a switch the bloods are reviewed, and the next batch of patients switched.

Do not switch Secondary patients directly to Atorvastatin 80mg

Why?
We decided to take a gentler approach and either reviewed patients on the secondary prevention list on behalf of practices, with recommendation made or advised practice to review this cohort of patients. Some patients may not tolerate Atorvastatin 80mg or may have contraindications to the dose. As a result we find that this reduces queries and complaints of intolerance.

Issues and concerns and how to overcome

Issues/Concerns	Mitigation
Increase in Bloods Tests	• Not doing the switch in bulk. • Providing additional clinics in practices and through the GPPC hubs to support an increase in demand.
Increase in activity for practices	• Not doing the switch in bulk. • GPPC supporting practices where possible.
Lack of medication availability	• Not doing the switch in bulk. • Patients do not collect the prescription at the same time – available for next issue. • Communicate closely with LPC to keep them aware of work being done.
Competing Demands e.g. QOF, Clinical System Changes, Staff Changes	• Work with practices to establish a good time to support and work up a plan with them.
Practices not engaging	• Continue offer of support. • Attend practices manager meetings. • Continue to send communication and positive outcomes. • Escalate to ICB Primary Care and Medicine Management team to support.
Coding Issues – incorrect coding, lack of coding (free text), historic Lloyd George notes not coded for CVD	• Work through the patients' records (particularly for secondary prevention). Where errors are found a task sent to clinical team to review and update the record. • A separate team in GPPC support practices with coding issues and training support.

Next for us

1. To continue working with practices that have started the statin switch and support practices to commence where they have not started.
2. Identify potential FH. Our clinical nurse or practices to review and treat each patient identified in line with the SNEE FH pathway. Referring to secondary care if appropriate.
3. Identify a pilot practice to start the initiation of statin with those with a Qrisk of >10%.
    - The patient will receive information to say it is recommended they take a statin. If they wish to do so they should contact their practice and a prescription will be issued
    - Focusing on patients with a QRisk score of over 20% first.
    - GPPC Nurse and Admin to support the practices with this work.
    - Identify patients from Healthy Heart Searches
4. GPPC Nurse to focus on the patients with a QRisk Score of over 20% who have previously had a statin - working through patients with the highest scores as a priority. Establish the reason why the patient has stopped taking the statin (cost, reaction, reputation, etc.) and see if we can support them to re-introduce the medication to support them to have a managed cholesterol reading.
5. Work with Health Innovation East on communication, literature, and website to signpost clinical staff and patients.

What else

As a result of the work that is carried out, we/practices identify patients that cannot tolerate statins, still are unmanaged or potential Familial Hypercholesterolaemia.

We have obtained funding from our ICB for the following pilots, to further support practices to tackle cholesterol:

Community Lipid Support Clinic

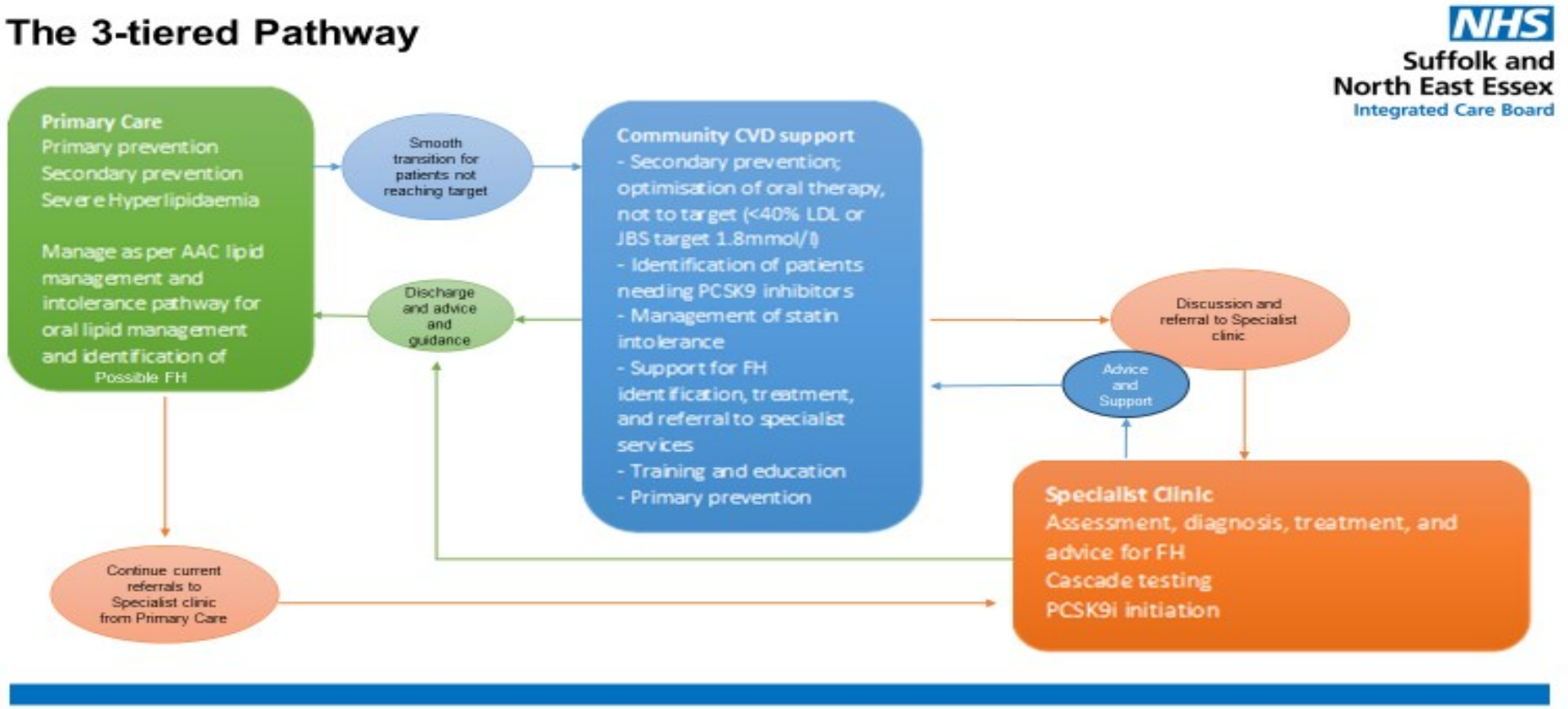
Inclisiran pilot

Community Lipid Support Service

- In North East Essex there is currently a 12+ month wait to see a Lipidologist.
- The community support clinic will be able to offer another layer of management and advice whilst waiting for an appointment.
- Management of patients who are complex for primary care +/- referral to secondary care lipid clinic.
- GPPC have strong links with the specialist secondary care clinic for onward referral if needed. The aim is to realign appropriate referrals to secondary care.

Please note this service is not in place of the Secondary Care Lipid Clinic. Referrals for probable FH, assessment, genetic testing and diagnosis continue to be directed to the service.

3-tiered pathway of Lipid management in NEE



Patient Case Study 1: Male 56

Medical/social history:

- Hypertension 2021 (159/89)
- Hyperlipidaemia on statin since 2022 (primary prevention)
- Increased BMI (31.07kg/m^2)
- Smoker (stopped 2022)
- No alcohol
- Regular exercise

Family History:

- Father died of MI at 49yrs

Baseline lipid levels :

TC = 4.28mmol/l (5.26 2021)
LDL= 3.02mmol/l (3.06 in 2021)
QRISK3 2022 = 25.2%

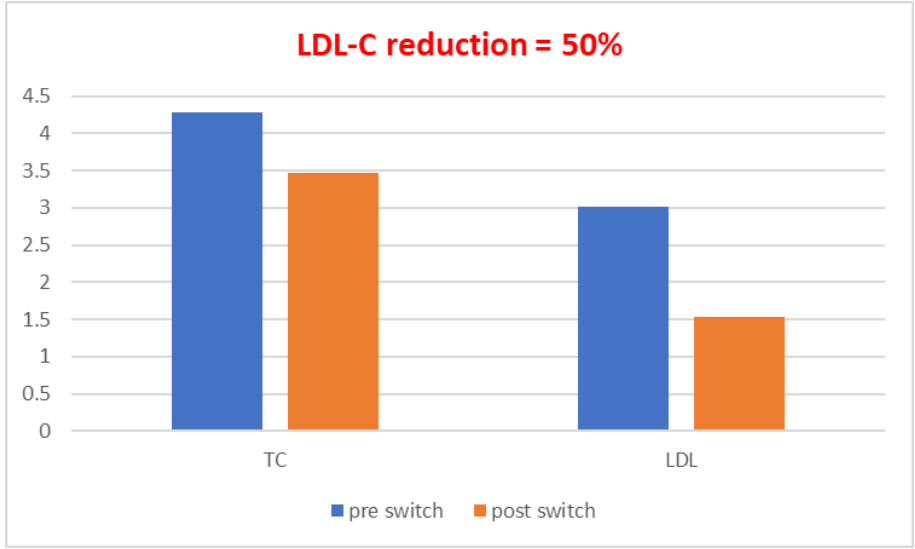
Current medication:

Amlodipine 5mg od, Simvastatin 20mg on
Statin switch June 2023 to Atorvastatin 20mg

Review of management:

- ✓ Adherent to medications
- ✓ Tolerated change to high intensity statin therapy
- ✓ Continued with lifestyle advice – stopped smoking – BP managed (now 130/82) – BMI the same.

Repeat lipid profile after 3 months:
TC = 3.47mmol/l; LDL = 1.53mmol/l
QRISK3 now 10.5%



Patient Case Study 2: Male 79

Medical / social history:

- **Cardiovascular Disease - Angina (2020)**
- 2 Vessel Disease (LAD, circumflex)
- CABG x2 Jan 2021, good LV function
- Increased BMI (31.33kg/m^2)
- Ex smoker, no HTN, no CKD
- Active: swimming, walking, tennis, sailing
- Alcohol 28units per week
- No family history recorded

Current medication:

Aspirin 75mg od, Bisoprolol 2.5mg od.
Currently not on any LLT
Has tried Atorvastatin 20mg; Rosuvastatin 10mg; Pravastatin 10mg; Ezetimibe 10mg; Rosuvastatin 5mg; Fluvastatin 20mg.

Review of management:

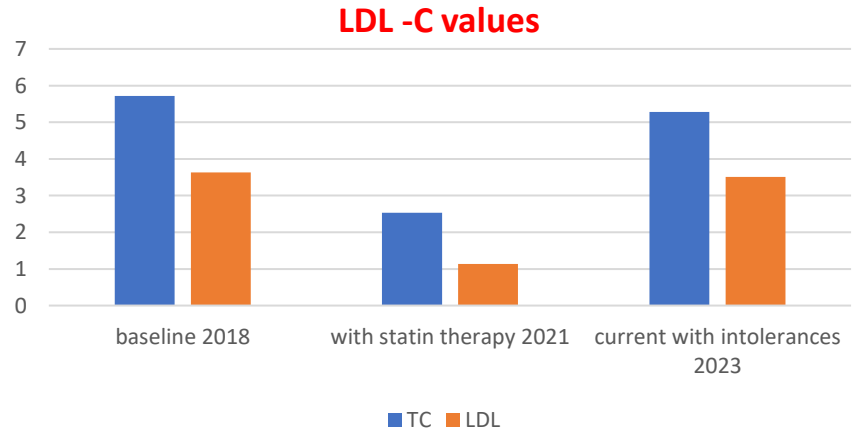
✓ Dietary and lifestyle advice

✓ Review intolerances to statins and Ezetimibe

Possibly see in community support service

LLTs options:

1. Re-challenged with Rosuvastatin 5mg 3x weekly – aim to titrate as per patient tolerance. CK if issues.
2. Re trial Ezetimibe 10mg – monotherapy or with rosuvastatin
3. Inclisiran – within pilot project ?



Please refer to the respective SmPCs of these therapies for full information.

Patient Case Study 3: Male 67

Medical / social history:

- **Cardiovascular Disease – Inf STEMI, pPCI to RCA 2020**
- Hypertension
- Diabetes type 2 (HbA1c 46mmol/mol)
- Increased BMI (28.7kg/m^2)
- Ex smoker
- Mechanic
- Light exercise
- No family history recorded

Current LDL level: 2.64mmol/l (reduction of 31% needed to get to target of 1.8)

Current medication:

Aspirin 75mg, Bisoprolol 2.5mg, GTN spray
Ramipril 10mg, Felodipine 5mg, Metformin 1g
Atorvastatin 80mg (previously taking low intensity statin)

Review of management:

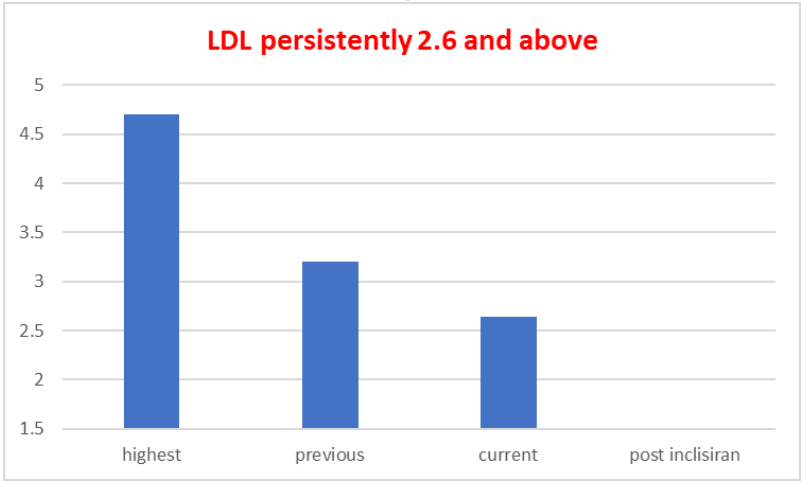
✓ Dietary and lifestyle advice

✓ Check adherence and tolerance of statin treatment

Has LDL reduction of >50% from highest LDL

LLTs options:

1. Add Ezetimibe 10mg (will give a further 6% reduction = LDL 2.48)
2. Inclisiran (LDL reduction of ~ 50%)
3. Shared decision making



Please refer to the respective SmPCs of these therapies for full information.

Inclisiran

Inclisiran is Green on the SNEE Formulary. Practices in NEE have been offered £100 to initiate 10 patients on Inclisiran.

Support made available to practices:

- Clinical advice available from nurse specialist
- How to guides, including instructions on how to create PSD's, letter invitation templates.
- Advice on setting up AAH account.
- Evaluation log so they can review the effect.
- Working collaboratively with Novartis to deal with queries and questions relating to the drug.

Enquires have been received from practices to help with administrative tasks and verifying eligible patients.

Novartis CVD team have also been contacted by practices. GPPC and Novartis catch up to share issues and solutions.

Clarity has been sought from a Lipid specialist and ICB medicines management team.

- Fasting blood only required if triglyceride above 4.5mmol/L
- LDL-C concentrations are persistently 2.6mmols/L or above (this meaning 2 results that are at least 3 months apart)

3 practices have completed the initiation of 10 patients. We are aware of at least 4 other practices that are currently working through their search results. 2 practices have expressed that they do not wish to participate.

The pilot aims to provide confidence to initiate the medication and follow the local lipid pathway in full (next slide)

NEE INCLISIRAN PROJECT DELIVERY FLOW CHART

NEE Primary Care Practices
Run initial searches based on step 1 and 2 below or identify patient from consultation/caseload
Add patients to Inclisiran project GP inclusion criteria list

Pre-Delivery Checks and counselling

STEP 1: Known CVD (with or without FH)

Is there a history of any of the following cardiovascular events:
- Acute coronary syndrome (such as myocardial infarction or unstable angina needing hospitalisation); Coronary or other arterial revascularisation procedures; Coronary heart disease
- Ischaemic stroke or Peripheral arterial disease

IF YES

NO → **Patient not eligible for Inclisiran**
Up titrate primary prevention lipid lowering therapy

STEP 2: LDL-C (2.6 mmol/L or higher) or non-HDL-C (3.4mmols/L or higher), if this is non fasting -

Need to confirmed with a fasting LDL-C – is this 2.6mmol/L or higher?

IF YES

NO → **Patient not eligible for Inclisiran**
Up titrate secondary prevention lipid lowering therapy

Maximum tolerated statins with or without other lipid-lowering therapies or, other lipid-lowering therapies when statins are not tolerated or are contraindicated See page 2

IF YES

NO → **Patient not eligible for Inclisiran**
Up titrate secondary prevention lipid lowering therapies See page 2

Patient counselling:
Agrees to have twice yearly injections and is aware that treatment will not be continued if the target LDL-C is not achieved (30% reduction)
Patients should be informed that the effect of Inclisiran on cardiovascular morbidity and mortality has not yet been determined discussion should include stopping criteria.
Patient aware that in the unlikely event of side effects (the most common being around the injection site) these will need to be reported via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.
Ensure that the patient has access to "A patient's guide to Inclisiran information":
https://www.health.novartis.co.uk/sites/health.novartis.co.uk/files/inclisiran-patient-leaflet.pdf

NO → **Patient does not agree to Inclisiran**
Up titrate Secondary prevention lipid lowering therapies

Yes agrees
continue to 1st delivery

1st Delivery

Invite for first appointment:
Consent and shared decision making
Prescribe 284mg SC Inclisiran
Deliver injection subcutaneous (single use prefilled syringe) Injection sites: Abdomen, upper are or thigh
Counsel patient on side effect reporting (MHRA yellow card)

Give patient blood form for fasting LDL-C in 3 months

Appointment for 2nd injection 3 months post 1st dose (not before)

2nd Delivery and Follow up

2nd appointment:
Consent and shared decision making
Prescribe 284mg SC Inclisiran
Deliver injection subcutaneous (single use prefilled syringe) Injection sites: Abdomen, upper are or thigh

Give patient blood form for fasting LDL-C for at least 3 months (?3-5months)

Follow up/ongoing care

Ongoing care

LDL-C 3 - 5 months post 2nd dose
Is there a reduction in LDL-C by 30% ?

YES → Continue with 6 monthly doses (from 2nd dose) with 12 monthly lipid profile

NO → **Discuss with GPPC/project group**
Continue secondary prevention lipid lowering therapies, revisit lifestyle advice and adherence.

Conclusion

e.g.

- Lipid optimisation targets included in Year 23/24 QoF and PCN CVD
- Pharmacy team in PCN can lead on lipid optimisation
- Involve the matrix team in your PCN and practices to collectively engage and manage patients' lipids,
- Making every contact count
- Collaborate with your local experts and partners
- NEE patients have access to a comprehensive range of lipid therapies with the lipid treatment pathway

Next steps

How can you action something similar in your practice/PCN or ICB

- Visit the West Yorkshire Healthy Hearts website to access searches
- Run the searches, identify cohorts to understand the work needed
- Reach out or keep an ear out for opportunities for funding
- Create how to guides and resource support including a clinical lead to offer guidance
- Understand the National/local Lipid pathway
- Statin intolerance pathway
- Inclisiran knowledge

e.g.
Resources: Heart UK, West Yorkshire Healthy Hearts

References

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Thank you
Any questions?

GP Primary Choice

Suffolk and North East Essex Integrated Care Board (ICB)