Health Innovation Manchester

Developing the Greater Manchester Lipid Management Pathway

July 2023

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Background

Background

Cardiovascular disease (CVD) causes a quarter of all deaths in the UK and is the largest cause of premature mortality in deprived areas.

Risk factors that contribute to CVD, such as a high cholesterol, are more prevalent in groups of lower socio-economic status, and there is a clear link between societal inequality and poorer CVD outcomes.1 2

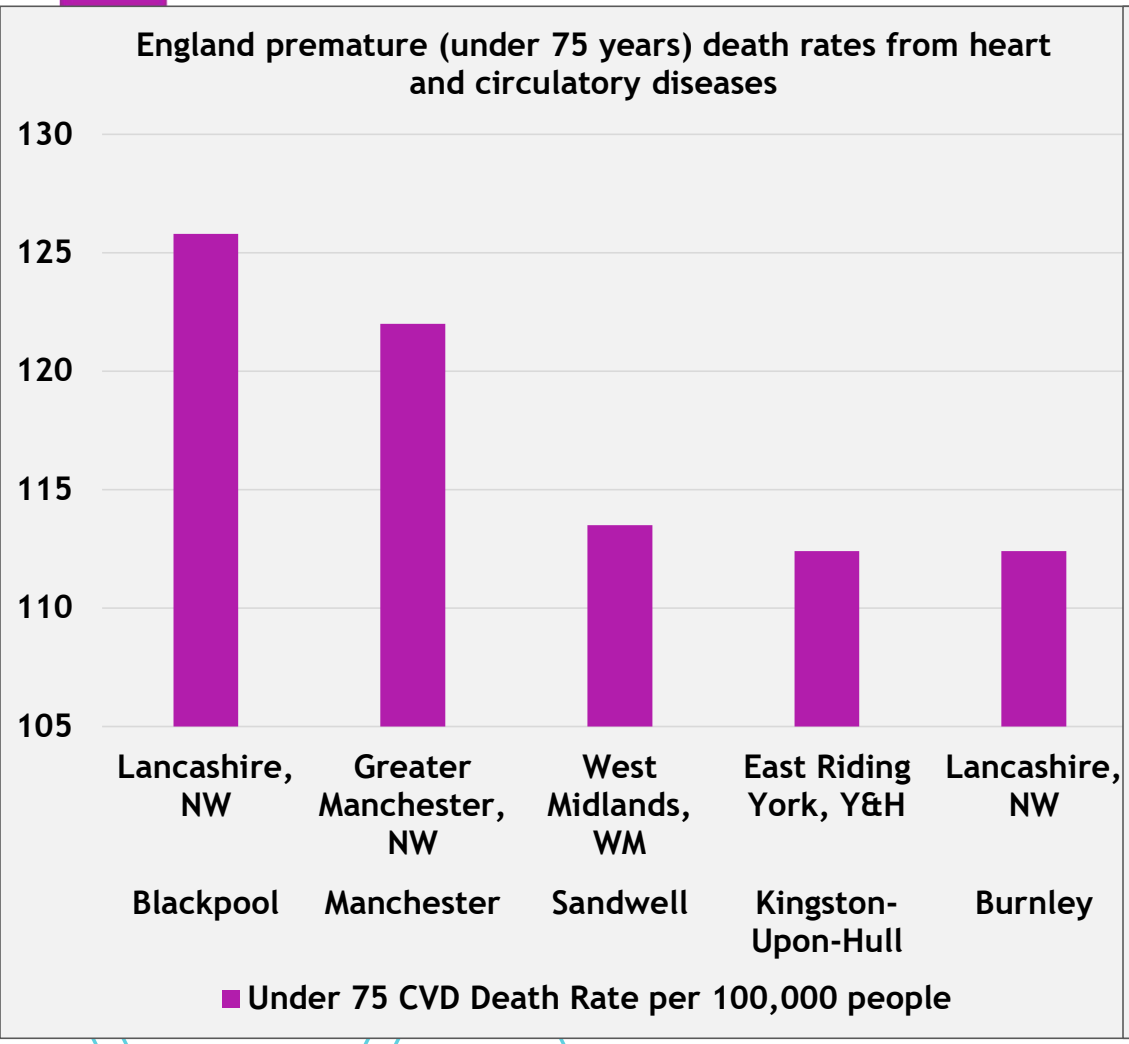
The biggest area where the NHS can save lives over the next 10 years is in reducing the incidence of CVD, through targeted approaches to reduce the widening of health inequalities. 3

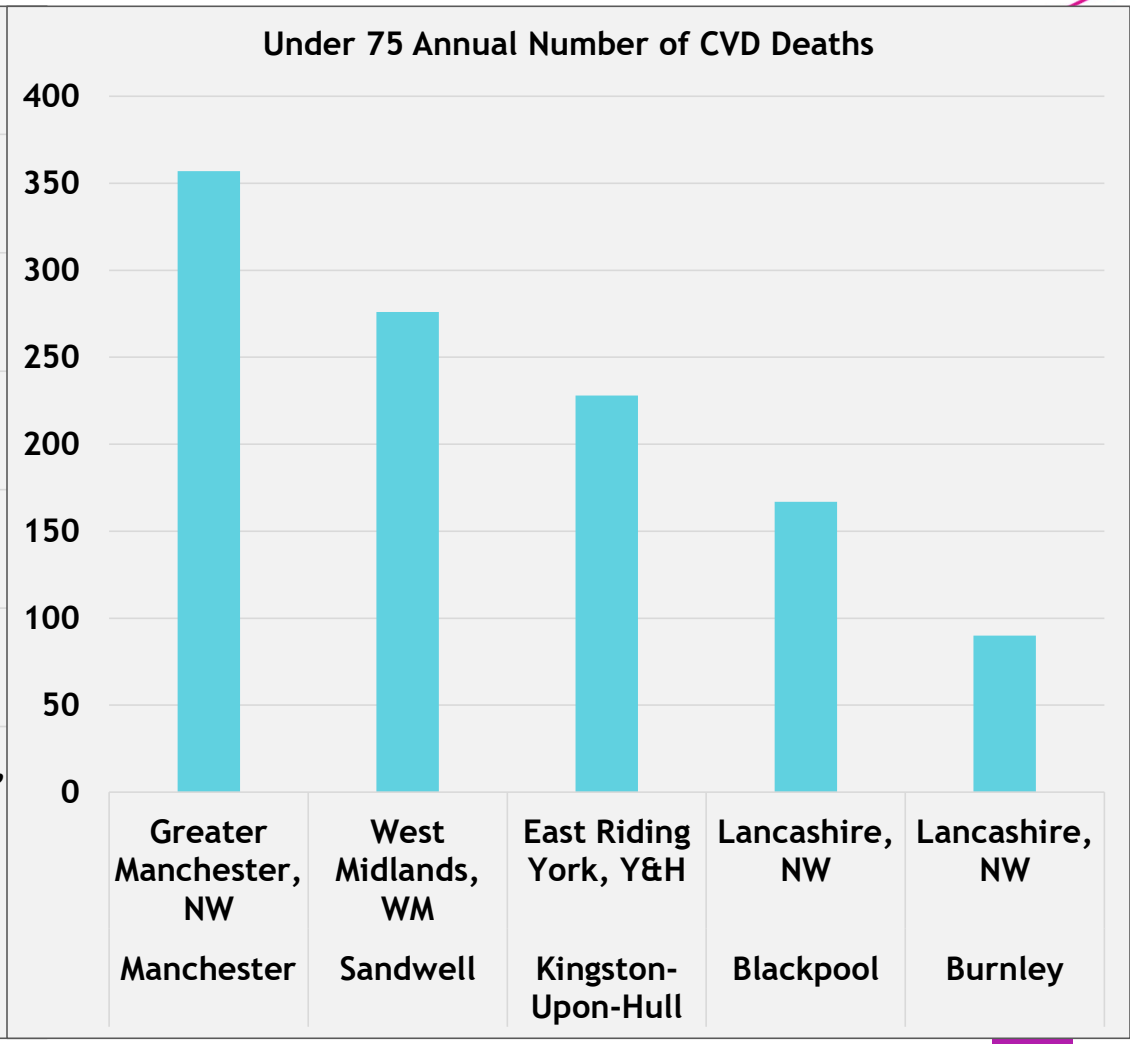
Hypercholesterolaemia (high blood cholesterol) is a significant risk factor for CVD, and evidence suggests that improving the detection of those with hypercholesterolaemia and ensuring they received effective treatment will have significant benefits

Background

- The AHSN Network is delivering a 3-year National Lipids Optimisation Programme 4 , which aims to improve the management of cholesterol, increase the detection of those with Familial Hypercholesterolaemia and optimise the use of all medicines for patients on the cholesterol management pathway.
- Improving cardiovascular health and reducing cardiovascular motility is important for Greater Manchester (GM). GM has the highest death rate (2018-20) of <75yo cardiovascular disease (CVD) in England (56.5/100,000), which is significantly above national average (39.1/100,000) 4. Chronic Heart Disease (CHD) prevalence in GM is 3.1%, which is above National average (3.0%) 5, consequently CHD admissions for GM (476.8/100,000) are also significantly above national average (367.6/100,000).

Why Lipid Management is important in Greater Manchester





Reference: BHF 2022

National Lipid Programme- The Ask

Optimisation of lipid lowering therapies

- Access to high intensity statins, ezetimibe and PCSK9i's.
- Systematic application of both primary and secondary prevention principles

Delivery of a novel therapies (Inclisiran)

- National roll out of inclisiran
- Primary care delivery

Case-finding

- Develop identification tool for people requiring lipid optimisation (secondary prevention)

The challenge

Nov 2021- May 2022

- BMA/ RCGP inclisiran position statement was a barrier for engagement in the programme
- Mixed messages around lipid pathway and implementation tools- and focus being on just one drug in this pathway
- Unclear on how to take this forward as a system
- Influential stakeholders questioned the drivers and challenged the delivery
- Primary care workforce capacity – combined with lack of financial incentives in primary care for lipid management (QOF/ IIF)

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The approach

What we have done through HInM

October 2021 – Sept 2022

Team

We established a project team with experienced individuals drawing on capabilities from HInM, GM system and industry.

System engagement

We worked through multiple task & finish groups for specific purposes, ran workshops and worked with the complex GM system governance and advisory groups

Delivery models

We initially developed 2 delivery models with detailed guidance, tailored for our localities.

- PCN hub
- Practice level

Resources

We coproduced

- GM lipid management resources
- Inclisiran prescribing toolkit
- interactive GM CVD Toolkit for primary care

Tools

We developed the case finding tool, integrated with all GP practice records.

Searches are replicated in GMCR enabling GM level data & real time performance metrics.

Approvals

All pathways, procedures and materials were approved by relevant governance fora, including Greater Manchester Medicines Management Group

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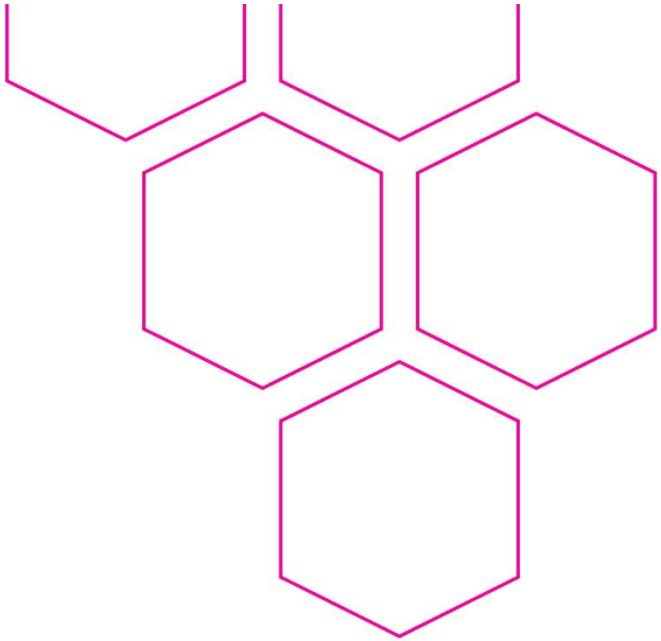
Initial stakeholder workshop

June 2022

Initial stakeholder workshop

Aim

To engage and collaborate with our key primary and secondary care stakeholder colleagues across Greater Manchester to initially design a ‘what good looks like’ for lipid management, enacting the NICE pathway across Greater Manchester



Workshop content

Hybrid 1.5-hour workshop with clinicians from primary care, including pharmacists, secondary care cardiologists and lipidologists and three patient representatives.

Initial stakeholder workshop

Agenda

Item	Information
1	Patient experience video
2	Open from HINM Chief Exec- importance of implementing innovation well through the lens of patients and with clear evaluation principles
3	Clinical consequences of not implementing lipid pathway guidelines optimally
4	Patient experience video
5	Primary Care Lipids pathway and where and how novel therapies fit
6	Case Finding for lipid patients
7	Q & A on presentations
8	Possible models of care
9	Group discussion
10	Actions and next steps

What went well

- Patient videos were effective, had great feedback from attendees and starting with a patient video was useful for giving context for the importance of the workshop. These have been circulated across AHSN's
- Delivery models slides needed to be created to use widely so useful & feedback was these wanted to be expanded on by attendees
- Key barriers were highlighted which has given focus/ clear aim for the task and finish group to resolve
- There was a multi-disciplinary attendance from across primary and secondary care
- Open and honest discussion

Initial stakeholder workshop

What did not go well

Timings

- Ambitious timing- workshop over-ran- we didn't get to the small group workshop session on delivery models
- Concern if making it longer than 90 mins no one would be able to attend

Audience

- There was a clear benefit of being in-person. We did try to reduce the numbers of attendees joining remotely by only sending the MS teams link to specific attendees

Lessons

- Longer workshop 120/150 minutes
- Ensure all speakers introduce themselves clearly to those who joined remotely
- Do a run-through on MS teams to test audio for remote users

Actions

- To mitigate that the workshop over ran we developed a task and finish group to deliver tasks over 6-8 weeks to produce a model of care for GM and develop implementation tools
- A post-workshop survey was sent to attendees to gather feedback and interest in joining the task and finish group

Lipids task and finish group

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July-Aug 2022

Problem statement- July 2022

Implementation of the secondary prevention NICE/AAC lipid management pathway across GM remain low with only 13% of PCNs initiated implementation of the pathway. Key barriers influencing this low uptake have been identified from the initial stakeholder workshop

These include:

- Low awareness of additional lipid treatments across primary care.
- Lack of clarity of pathways for referral and management of individuals who are identified as applicable for injectable lipid lowering treatments.
- Lack of concise implementation resources to support delivery

Purpose

- To raise awareness of lipid lowering treatments across primary care and to enable application of identified patients from case finding
- To develop a model of care for delivery of additional lipid lowering treatments across Greater Manchester
- To develop a one-page summary to support implementation for practices

Methods

An agile methodology was used for the task and finish group.

- The group had a 6 week sprint to achieve the aims and objectives.
- This involved weekly one hour meetings. This meeting was the main point of contact for the group to discuss and agree the weekly outcomes and actions.
- Any key actions were then allocated to smaller project groups as needed, to ensure the action was met for the next meeting.
- The meetings were recorded and disseminated with the meeting notes to group members, this ensured input from those who could not attend the weekly meeting.

Methods- roles and responsibilities

- The group secretariate was the HINM lipid project manager and the chair was the CVD lead for GM.
- It was felt to be appropriate for the group to be chaired by the CVD lead, rather than HInM, to ensure system collaboration and engagement in the group.
- The group membership included multidisciplinary clinicians from across Greater Manchester, including: cardiologists, lipidologists, GPs, nurses and pharmacists
- Having a collective membership ensured the decisions made were collaborative and agreed as a system.
- The key aspect of the T & F group was the co-creation of these resources with equal influence in the decision making.

Lipids task and finish group: outcomes

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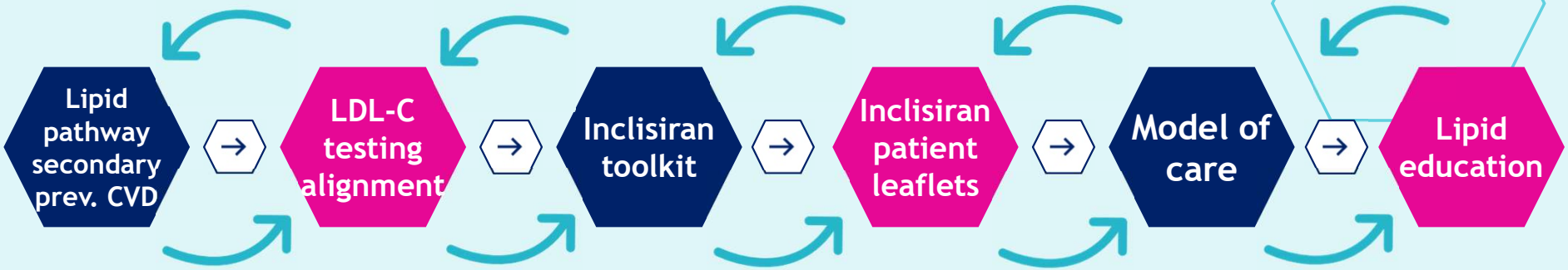
Aug- Nov 2022

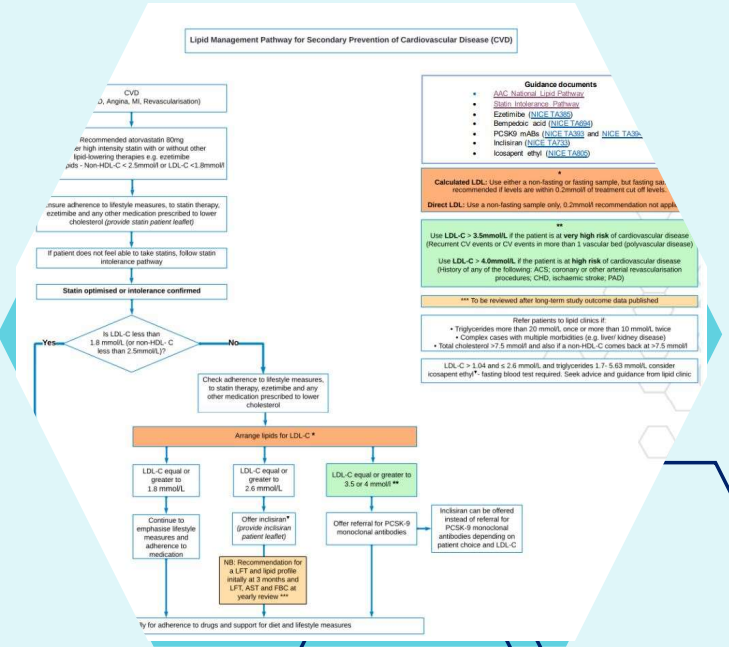
Task and finish group- outcomes



Lipid pathway secondary prev. CVD	LDL-C testing alignment	Inclisiran toolkit	Inclisiran patient leaflets	Model of care	Lipid education
• GM pathway agreed. Simplified version of NICE/ AAC pathway • Additional GM recommendations • Approved by GMMMG, published on their website	• South/ central Manc can do direct LDL-C testing using non-fasted samples • North Manc labs agreed to start doing calculated LDL using non-fasted samples to align pathway	• Inclisiran prescribing and ordering information agreed by GMMMG- went through consultation after the inclisiran workshop	• HInM branded • Clinicians ask: concise & clear information about statin adherence & outcomes data • Input from patients • Easy read & translation	Developed two models of care 1. PCN hub model 2. GP fed model Aimed at pharmacists but also HCP competent in sub-cut injection	• Pre-recorded lipid education webinars 1. Lipid management pathway (primary & secondary prevention) 2. Inclisiran 3. FAQ (clinicians and patients)

Lipid management pathway for secondary prevention of CVD

Document available on GMMMGs website here and HInM resources page



A key barrier identified in the stakeholder workshop was the lack of clarity in the lipid management pathway for secondary prevention of CVD. There was no system agreement for which pathway to implement.

To agree an evidence-based GM secondary prevention lipid management pathway and develop a simple, one page flow-chart.

The group agreed to follow the NICE/AAC lipid management pathway for secondary prevention lipid management.

This was a co-produced simplified version of the NICE/AAC pathway and included specific criteria for Greater Manchester that fitted our system need and to ensure clinicians are confident in prescribing the treatments.

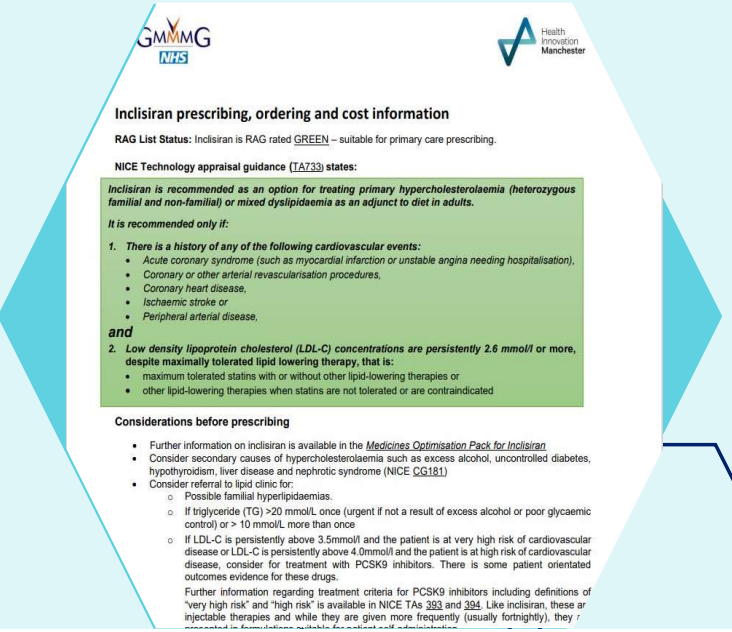
The document was co-produced with GMMMG. The pathway was presented at the Sept. 2022 meeting, amends were requested and it was approved by GMMMG in Nov. 2022.

The final version was approved by the GM Clinical Effectiveness Group in January 2023.

Following the pathway approval, the GM Cardiovascular Prevention Plan was published, detailing secondary prevention lipid management as a priority for GM.

Inclisiran prescribing, ordering and cost information

Available on GMMMGs website and HINM Lipid Resources Page



GMMMG NHS

Health Innovation Manchester

Inclisiran prescribing, ordering and cost information

RAG List Status: Inclisiran is RAG rated GREEN – suitable for primary care prescribing.

NICE Technology appraisal guidance (TA733) states:

Inclisiran is recommended as an option for treating primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia as an adjunct to diet in adults.

It is recommended only if:

1. ***There is 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,*

and

2. ***Low density lipoprotein cholesterol (LDL-C) concentrations are persistently 2.6 mmol/l or more, despite maximally tolerated lipid lowering therapy, that is:***
   - maximum tolerated statins with or without other lipid-lowering therapies or
   - other lipid-lowering therapies when statins are not tolerated or are contraindicated

Considerations before prescribing

- Further information on inclisiran is available in the *Medicines Optimisation Pack for Inclisiran*
- Consider secondary causes of hypercholesterolaemia such as excess alcohol, uncontrolled diabetes, hypothyroidism, liver disease and nephrotic syndrome (NICE CG181)
- Consider referral to lipid clinic for:
  - Possible familial hyperlipidaemias.
  - If triglyceride (TG) >20 mmol/L once (urgent if not a result of excess alcohol or poor glycaemic control) or > 10 mmol/L more than once
  - If LDL-C is persistently above 3.5mmol/l and the patient is at very high risk of cardiovascular disease or LDL-C is persistently above 4.0mmol/l and the patient is at high risk of cardiovascular disease, consider for treatment with PCSK9 inhibitors. There is some patient orientated outcomes evidence for these drugs.

  Further information regarding treatment criteria for PCSK9 inhibitors including definitions of "very high risk" and "high risk" is available in NICE TAs 393 and 394. Like inclisiran, these ar injectable therapies and while they are given more frequently (usually fortnightly), they r

Previous inclisiran implementation toolkits were lengthy and clinicians did not find them user-friendly or simple to follow. This was highlighted as a barrier to inclisiran understanding and prescribing.

Develop a simple, easy to follow, implementation toolkit for inclisiran containing prescribing and ordering information.

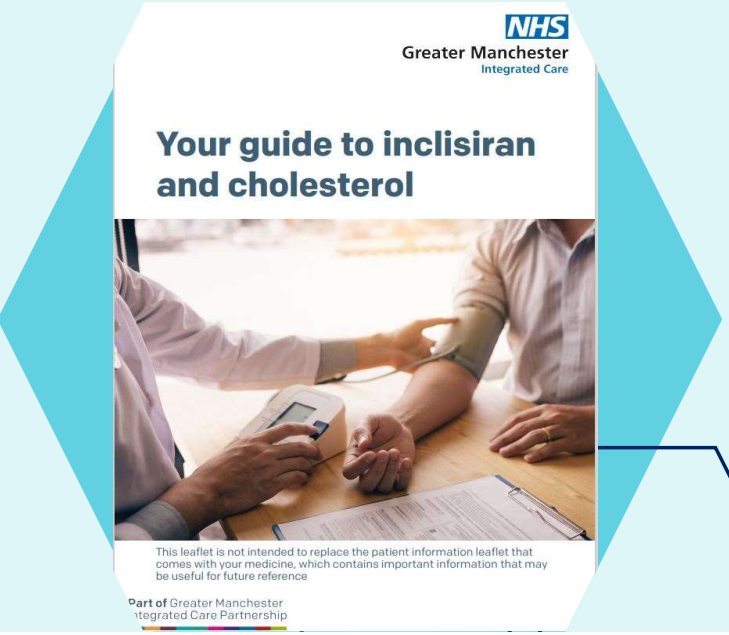
GMMMG had already drafted ordering and prescribing information which had been approved in their consultation process.

This sped up the process of developing the toolkit as the group agreed with the wording used by GMMMG and we incorporated the lipid management secondary prevention flowchart into this document.

There was specific wording about patient consent and clinicians were more comfortable with recommendations for clinicians to document patients has been informed about the lack of long terms outcomes data. This was to ensure the RCGP recommendations were implemented.

Inclisiran patient leaflet

Available on GMMMGs website and HINM Lipid Resources Page



There was feedback from clinicians to create a GM leaflet to highlight additional information e.g. importance of lifestyle factors, taking statin medication and long-term outcome data.

Develop a GM inclisiran patient leaflet.

To produce clear and concise inclisiran information for patients and make it very clear about continued statin adherence and lack of long-term outcomes data.

To co-produce the leaflet with GM citizens.

GM inclisiran patient leaflet which can be used across GM and embedded into primary care clinical systems.

Patients provided comprehensive feedback to the leaflet. Over 30+ responses.

Published on HINM website and GMMMGs website.

Lipid Management Resources

Resources page here

Engagement with primary care showed education gaps in lipid management for secondary prevention CVD.

Limited availability of clinicians to host regular, monthly education sessions.

Lots of information for lipid management on different websites led to confusion.

To develop pre-recorded lipid education sessions led by primary and secondary care clinicians.

Work with GP excellence to disseminate these across primary care and tailor to clinical groups.

Produce a website for these resources as a single point of information for GM clinicians.

GM lipid management resources page

- Webinars on the lipid management pathway, treatments and case finding.
- Guidance document for GM lipid management case finding tool
- FAQ page

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Lessons learnt & overview

Lessons learnt

What went well

- Agile approach meant all perceived and unknown outcomes were achieved in the 6 weeks
- Roles and responsibilities- chair was CVD lead for GM
- Multi-disciplinary group membership meant pragmatic outcomes achieved that are realistic for primary care with support of secondary care
- Meetings were recorded & disseminated out same day after the meeting so those would could not attend could provide feedback
- Aligned system collaboration

What did not go well

- Some key stakeholder groups attendance was not consistent each week. The group ran over summer holidays so impacted attendance
- When the resources went to GMMMG it was clear we had missed key stakeholders who should have been included in the group, this delayed approval of the lipid pathway

Lessons learnt

What can do next time

- Thorough stakeholder mapping before the task and finish group to ensure we have comprehensive membership

Next steps

- Record and launch lipids education webinars- published Nov 2022
- Launch case finding tools for EMIS, SystmOne and Vision across GM- published Nov 2022
- GMMMG approval of lipids pathway and inclisiran implementation toolkit- published Jan 2023
- Develop delivery plans for GM, locality, PCN and practice level based on case finding numbers

Aligning with our values

People

- Importance of a coordinated and multi-disciplinary approach to development of guidelines and tools to support a co-designed delivery
- Involvement and support for secondary and primary care & key buy-in from GMMMG (formulary) on producing the lipid management pathway and inclisiran implementation toolkit

Culture

- Agile delivery approach meant actions and outcomes achieved at pace with input from stakeholders across GM
- Unknown barriers which arose could be resolved at pace with input from key/ expert GM stakeholders
- Patients, service providers, commissioners, industry and innovation expertise as equal partners

Process

- Rigorous analysis to define priorities, activities and operating procedures
- Secondary prevention lipid management agreed as a priority for GM in the GM CVD Prevention Plan, including LDL-c 1.8 as a standard