Academic Health Science Network
North East and North Cumbria

Northern Lipid Forum

20th October 2022, 6.30-8pm
Crowne Plaza Hotel, Newcastle upon Tyne

This meeting has been sponsored by Sanofi, Daiichi-Sankyo, Amarin, Amgen and Novartis who have had no input into the arrangements & educational content of the programme.

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North East and North Cumbria

Welcome

Dr Pete Carey

Consultant in Diabetes and Endocrinology

South Tyneside and Sunderland NHS Foundation Trust

Chair, Lipid Specialist Advisory Group

Housekeeping

- No fire drill scheduled
- Please turn mobile phones onto silent
- Toilets are located just off the mezzanine
- Information will be circulated following the event
- Our exhibitors are outside the main room
- Speaker Questions
- Delegate survey
- Certificate of Attendance

Programme

Overview of the work of the AHSN NENC on Lipids

Professor Julia Newton, Medical Director, AHSN NENC

The increasing role of Pharmacists in Lipid Management

Dr Rani Khatib, Consultant Pharmacist in Cardiology & Cardiovascular Research, Leeds Teaching Hospitals NHS Trust

Sponsors Disclosure

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Since we last met….

- Publication of the NHS Long Term Plan
- Successful FH Primary Care Project
- AHSN-NENC National Lead for FH / Lipid Optimisation
- Several Pharmacist Led Lipid Optimisation Projects (ACC PTF / AHSN)
- 3 new drugs
- Development of regional NEELI Guideline

https://ntag.nhs.uk/wp-content/uploads/2022/09/NEELI-edit-v2022.2-FINAL-NTAG.pdf

Northern England Evaluation and Lipid Intensification guideline

Section Description	Primary Secondary prevention	Statin Intolerance	Severe Hypercholesterolaemia	Severe Hypertriglyceridaemia	Pregnancy	FH in Children and Young People	Supplementary information
Section Guideline			Simon Broome criteria for diagnosis of Familial Hypercholesterolaemia		Lipid management and medication issues in pregnancy		Frailty Guidelines Common drug interactions Lipid Clinic referral criteria Lipoprotein (a) Regional Lipid clinics Inclisiran FAQs
Flow charts	National Guidance for lipid management Secondary prevention treatment beyond standard therapy	Statin Intolerance flow chart	Assessment pathway	Assessment pathway		Assessment pathway	

Professor Julia Newton

Julia joined the AHSN NENC as Medical Director in 2017.

Julia graduated from Newcastle University Medical School in 1990. Since then she has worked in a range of roles in the North East of England. She became a Consultant Physician with an interest in Geriatric Medicine in 2000 and Professor of Ageing and Medicine at Newcastle University in 2008.

She was Dean of Clinical Medicine in the Faculty of Medical Sciences until 2015 and more recently Director of Newcastle Academic Health Partners.

She has a PhD in physiological sciences from Newcastle University and her research focusses upon understanding the causes of fatigue in chronic diseases.

Dr Rani Khatib

Consultant pharmacist in Cardiology & Cardiovascular Research at Leeds Teaching Hospitals NHS Trust and Associate Professor at the University of Leeds.

He leads several CardioRenalMetabolic innovative clinical services in Leeds.

A national clinical champion for Lipid Management at NHSE / AHSN NENC.

He is a member of several national and international bodies including NICE Heart Failure Quality Standards, European Society of Cardiology, and UK Clinical Pharmacy Association, Cardiology Group.

Well published and leads several applied research projects.

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Overview of the Work of the AHSN NENC on Lipids

Professor Julia Newton
Medical Director
AHSN NENC

The AHSN Network

Delivery of The AAC/AHSN Lipid and FH National Programme in England

Prof Julia Newton

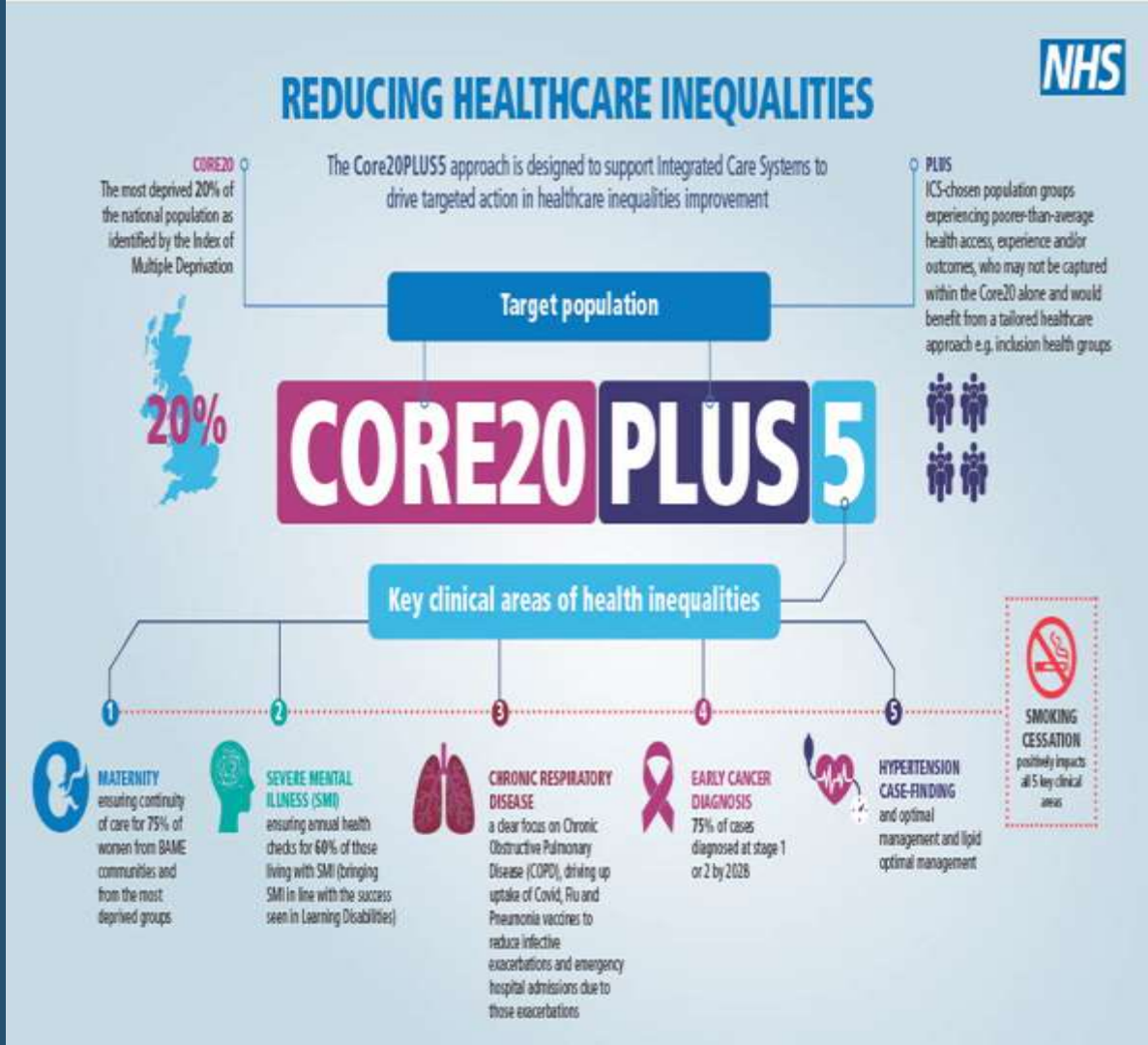
Executive Lead for the AAC/AHSN Lipid and FH National Programme

20 October 2022

A connected "network of networks"

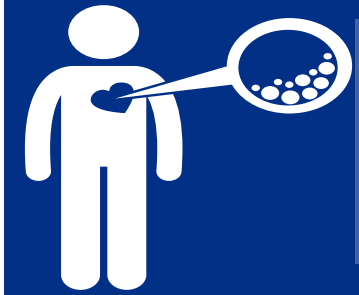
- 15 **AHSNs** make up the **AHSN Network**
- Established to transform how the **NHS** identifies, adopts and spread innovation
- Operates simultaneously as a single network, but individually as 15 locally embedded and integrated organisations
- Funded by the **NHSE/I**, **OLS** and partner contribution
- For the lipid and FH programme - commissioned by **NHSE/I** to deliver a national programme across England aimed at improving detection and treatment
- Delivery is led by **NENC AHSN and a national team** overseen by **Prof Julia Newton** as Executive Lead

Policy Drivers to Tackle Health Inequalities



Why cholesterol management is so important in CVD prevention?

In the UK
~25-28% of CVD
death is due to
elevated cholesterol[5]



High cholesterol is the second most significant medical risk factor after blood pressure[5]

For every 1 mmol/L reduction in LDL-C there is a

23%

REDUCTION IN MAJOR VASCULAR EVENTS[6]

Interventions that lower LDL-C can **significantly reduce** the incidence of coronary heart disease and other major vascular events in a wide range individuals[6]

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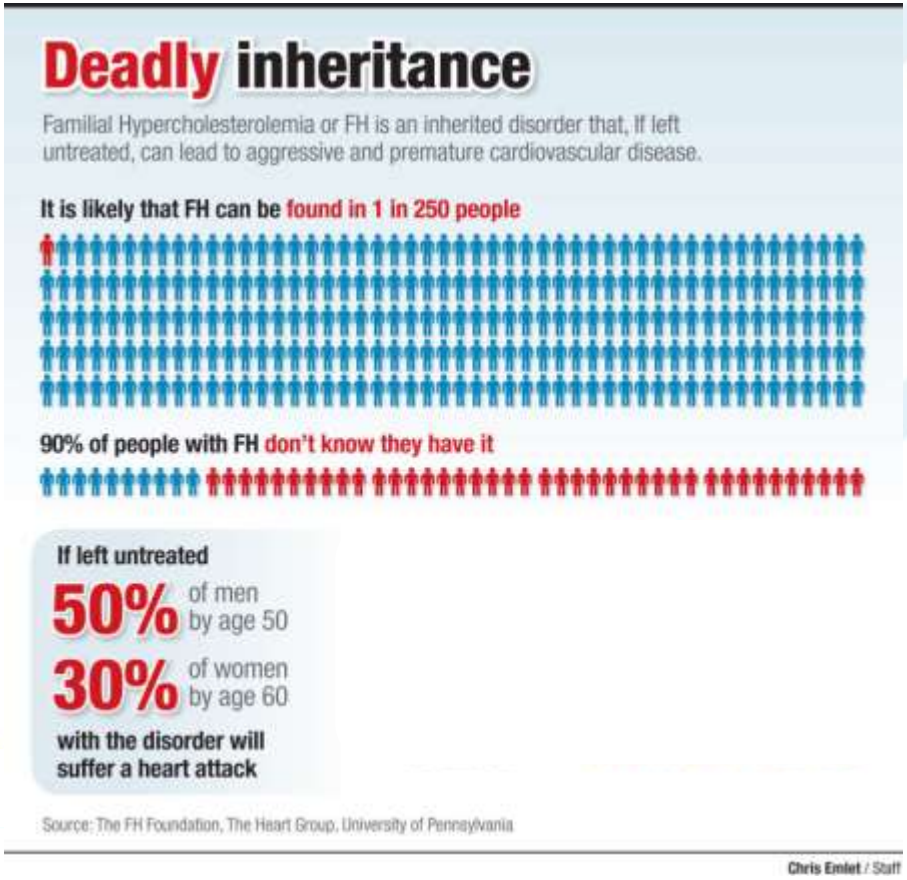
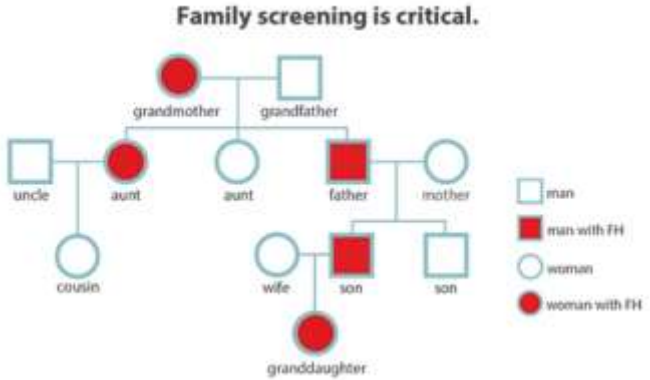
CVD, cardiovascular disease; LDL-C low density lipoprotein cholesterol

Familial Hypercholesterolaemia (FH)



NHS LTP ambition 25% by 2025



What is the National Lipid and FH Programme?

Aims and Objectives

The AAC/AHSN Lipids & FH National Programme is an innovative approach aimed at improving patient care and outcomes by effectively identifying and treating patients with hypercholesterolaemia including those with the genetic condition familial hypercholesterolemia (FH).

The objectives are:

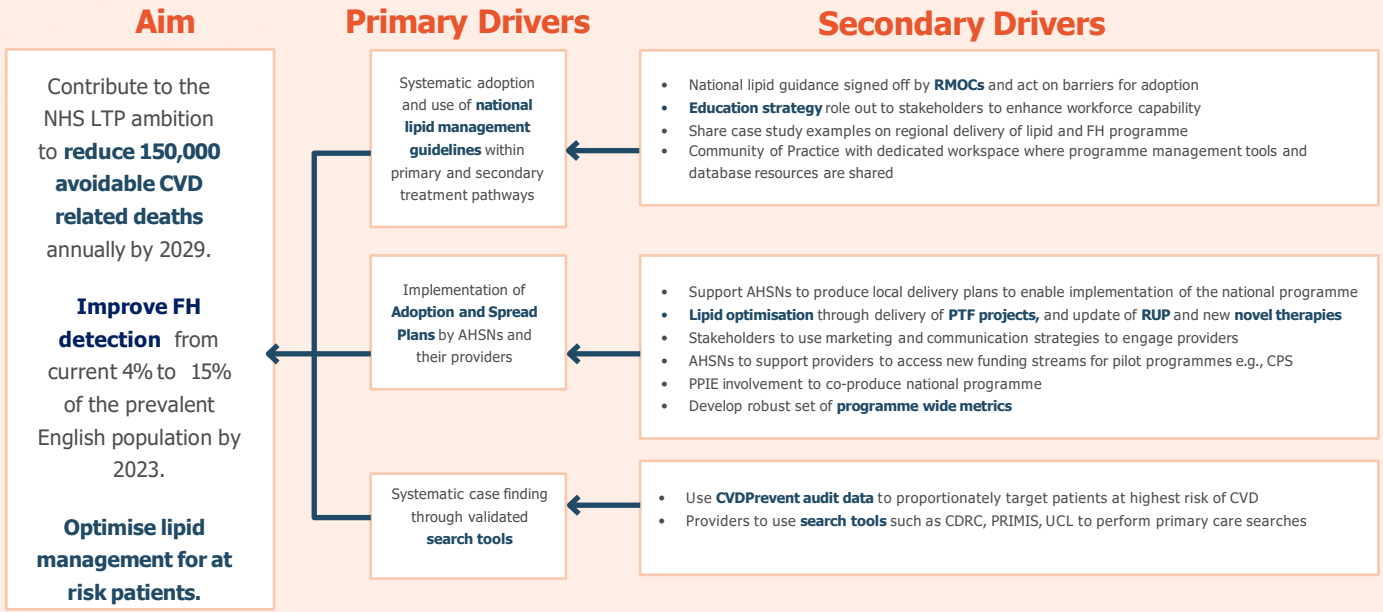
- To **reduce the risk for heart attacks** and strokes occurring.
- To **reduce the risk of admissions and** re-admissions associated with cardiovascular disease.
- To provide a pathway to **optimise the identification of those with the genetic condition familial hypercholesterolaemia (FH),** and
- To provide more treatment options to high-risk patients who remain at risk **despite maximum tolerated statin therapy** (through NICE approved Novel Therapies);
- To **reduce health inequalities** by ensuring a consistent, national approach to lipid management, **using a NICE approved clinical pathway**.

AAC/ AHSN National Programme Driver Diagram

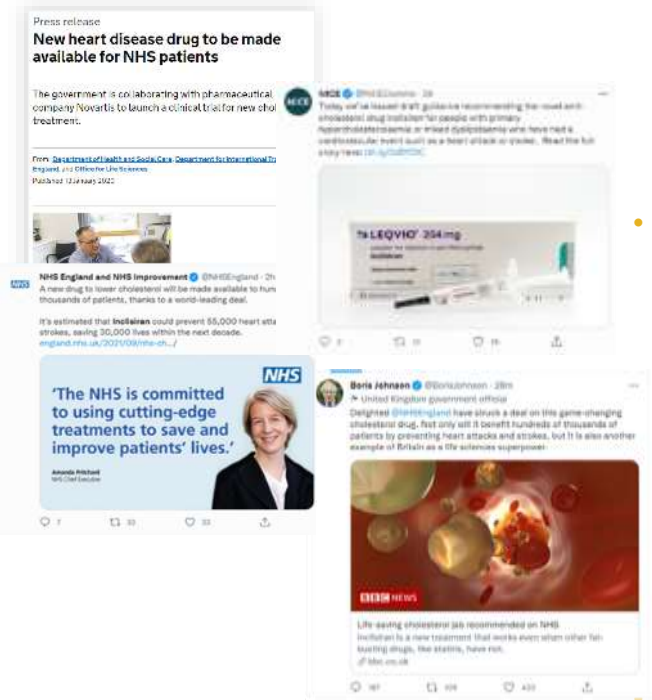
Aligned to our NHS LTP ambitions

Key Enablers:

- Tackle CVD health inequalities
- **Development of a CoP**
- Workforce capacity & capability
- **PPI/E programme** coproduction
- Programme wide metrics
- **Clinical leadership**



Population Health approach to lipid management

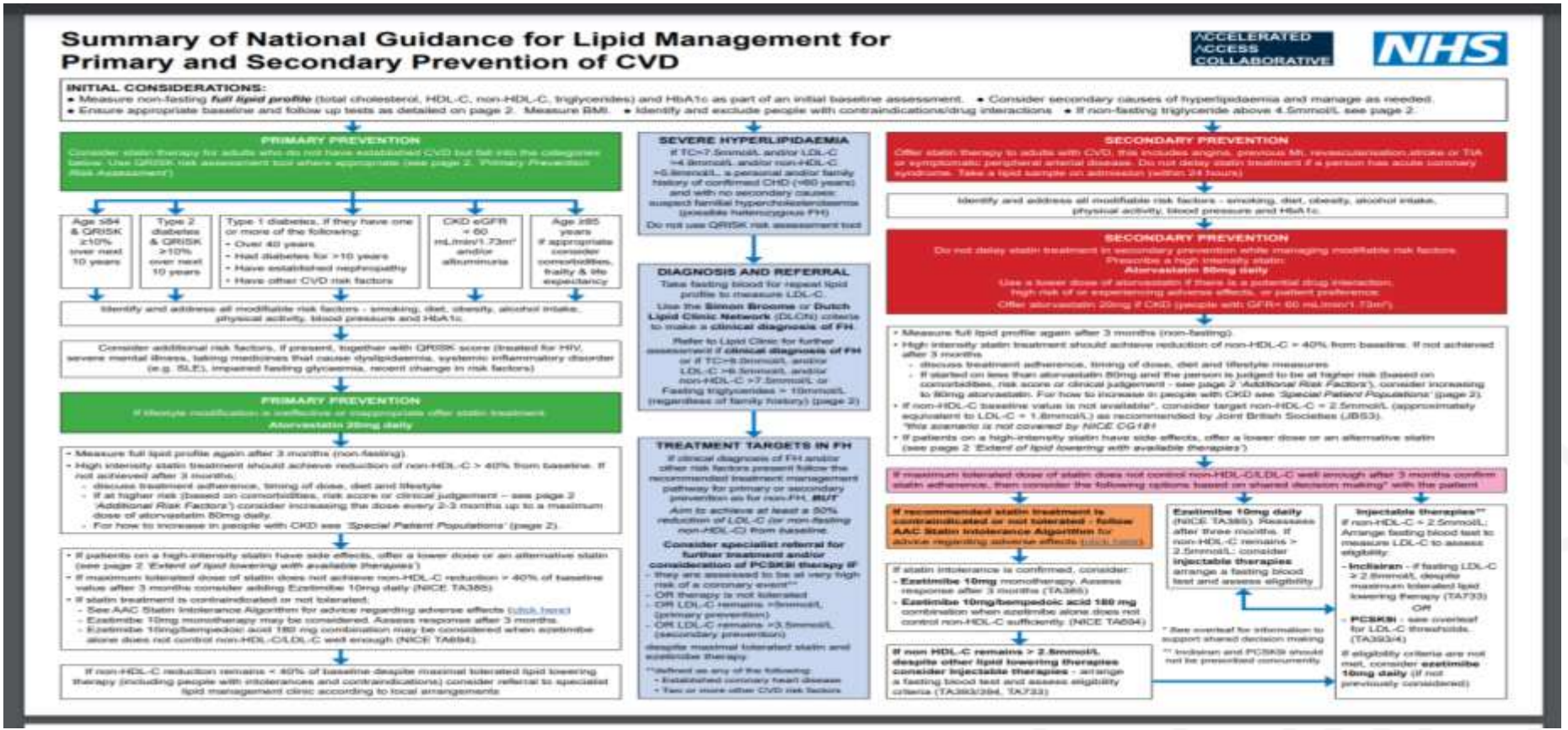


- Cardiovascular disease is a top preventable cause of death as set out in the NHS Long Term Plan, and a huge driver of inequalities. Prevention is key, and a local approach that is accessible to many people is likely to be the most effective way of tackling the inequalities associated with CVD.
- NHS and Government undertook a 'population level' agreement to introduce Inclisiran, subject to NICE approval, as an option in the lipid management pathway, enabling access to this therapy option at greater scale.

Inclisiran was approved by NICE on 1 September 2021 and made available as an additional option within the secondary prevention lipid management pathway, as set out in TA733.

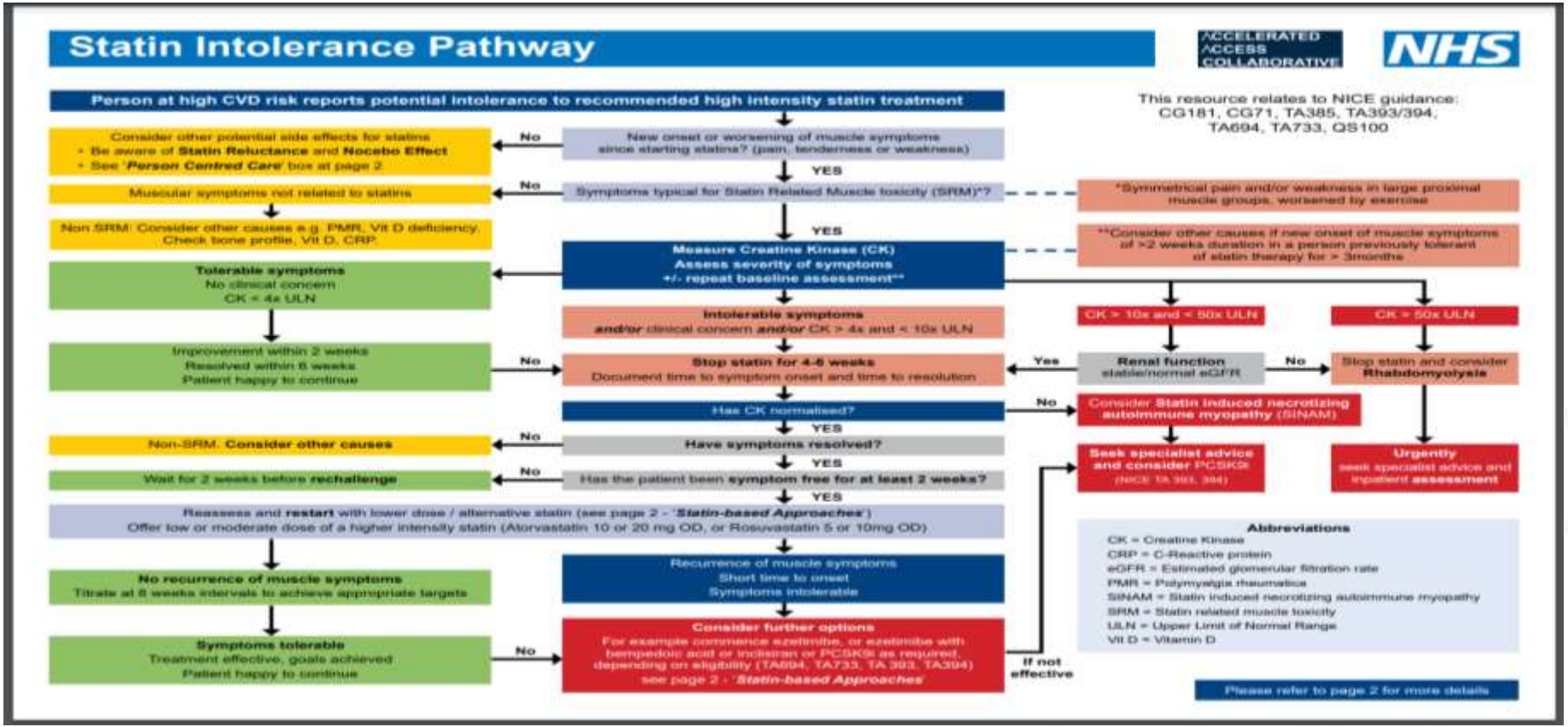
- Additional 'tool in the toolkit' for clinicians and an exemplar of how interventions could help address large scale health needs such as CVD.

NICE Endorsed Lipid Guidance (Two Pager)



https://www.england.nhs.uk/aac/wp-content/uploads/sites/50/2020/04/Summary-of-national-guidance-for-lipid-management-for-primary-and-secondary-prevention-of-cardiovascular-disea.pdf

NICE Endorsed Statin Intolerance Pathway (Two Pager)

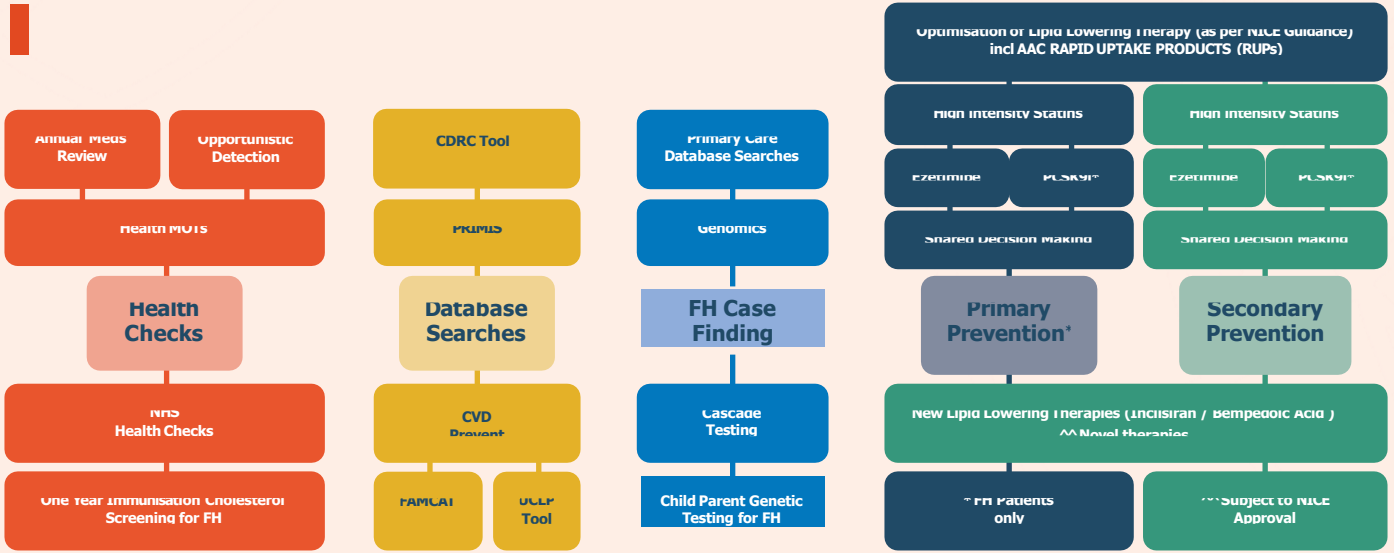


https://www.england.nhs.uk/aac/wp-content/uploads/sites/50/2020/08/Statin-intolerance-pathway-January-2022.pdf

National Programme Delivery Model

- To ensure consistency with how the programme is delivered, the full NICE endorsed pathway is depicted in this national delivery model.

  It's imperative to note that as new therapies and evidence emerge, this delivery model is flexible and amended to accommodate any changes in practice, in collaboration with our Clinical Advisory Group recommendations.



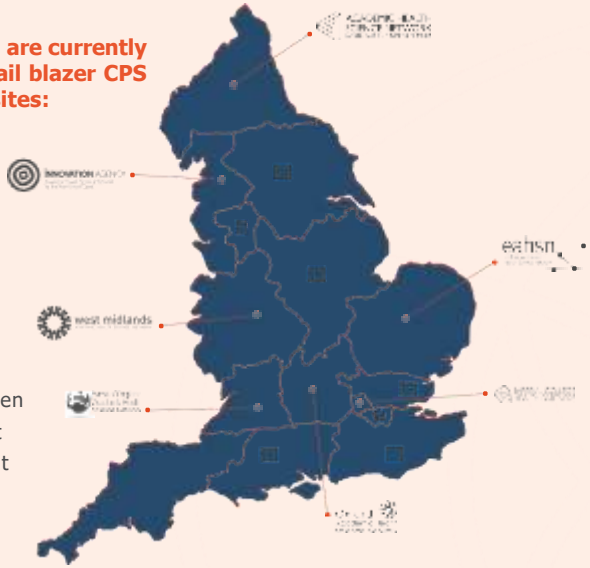
Delivery Case Examples: Child Parent Screening Service

The Child Parent Screening Pilot Programme

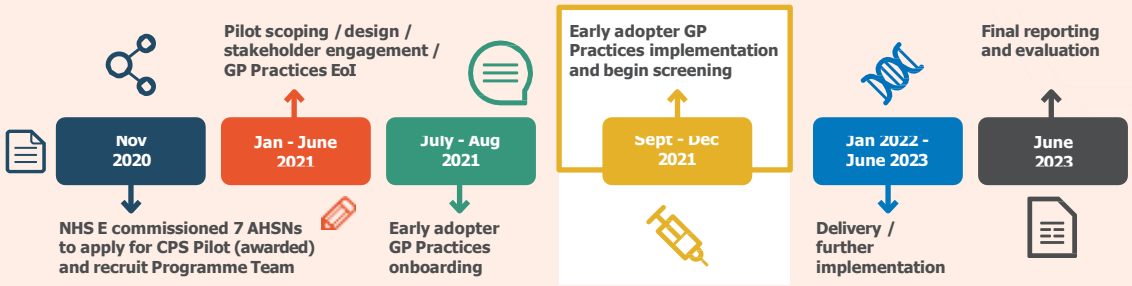
In June 2021 we heard that our business case to NHSE to support the implementation of a Child Parent Screening Service aimed at detecting those with FH was successful. In November 2021, this project began with the first child screened in Warrington.

The Child-Parent Screening Service (CPSS) is a service development programme aiming to identify children and their families with Familial Hypercholesterolemia (FH) to support the NHS Long term ambition to increase the identification of FH. In the programme, testing sites have been set up in partnership with seven AHSNs and the aim is to screen 30,000 children over the next 24 months with a view to a national roll out across the whole AHSN Network over the subsequent 12 months.

These are currently our trail blazer CPS pilot sites:



CPSS Timeline



Delivery case example:

Pathway Transformation Funding (PTF)

The PTF funding has been made available for providers to deploy innovative ideas and solutions to overcome barriers in the deployment and adoption of lipid Rapid Uptake Products (RUPs). Delivery included:

- Training and accreditation for staff on how to use new equipment (we would expect to leverage support from the supplier)
- Care pathway redesign
- Business support expertise
- Provision of specialist nurses/clinical staff needed to implement a new part of the procedure
- Covering double running costs
- Backfilling of posts
- Quality improvement programmes
- Coaching to address change management challenges
- Piloting of new roles
- Capital equipment

HEART UK has partnered with the NHS Accelerated Access Collaborative (AAC) and the Academic Health Science (AHSN) Network to provide a comprehensive and varied education programme for healthcare professionals.

- Deliver a range of webinars around lipid optimisation, statin hesitancy, novel therapies, NICE CG181 Guidance, cholesterol frameworks, evaluating CVD risk, patient searches and a focus on FH
- HeartUK hosting eLearning resources including identification of FH in Primary Care, Lipid Optimisation and interpreting lipid results
- Podcast resources with case studies of FH cascade testing and Child Parent Screening featuring GPs with a special interest in CPS
- A primary care resource centre page with information on managing patients with altered lipid profiles
- Lipid educational videos from Clinical Champions around England aimed at UK healthcare professionals

Delivery case example:

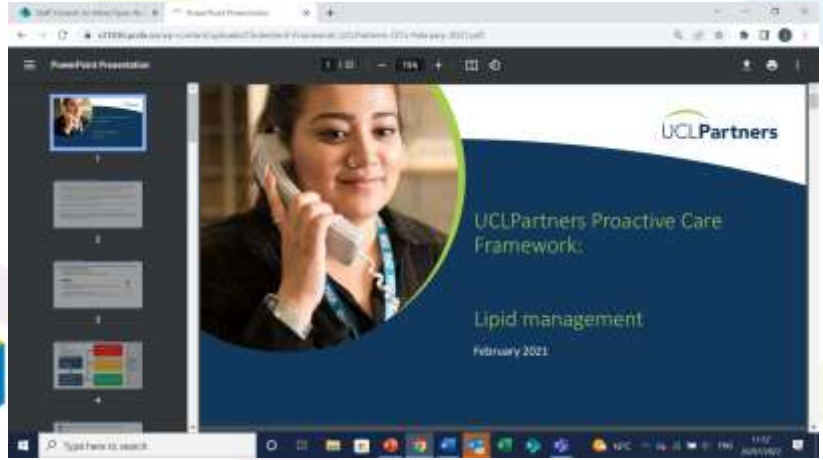
Tackling Cholesterol Together Educational Programme

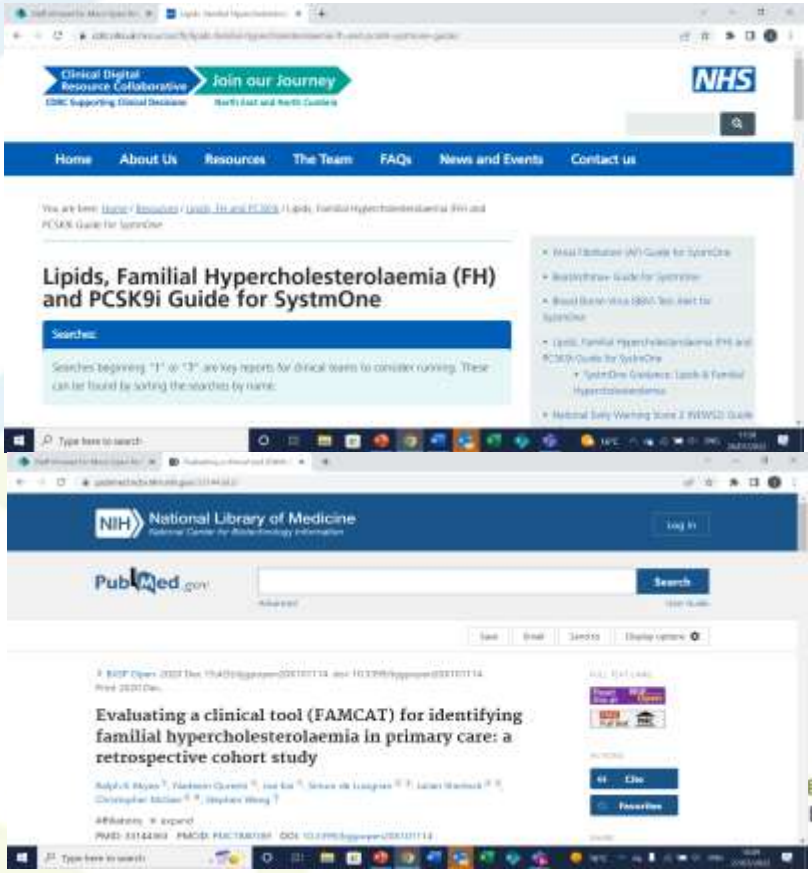
Delivery case example:

Regional Implementation (NENC AHSN)

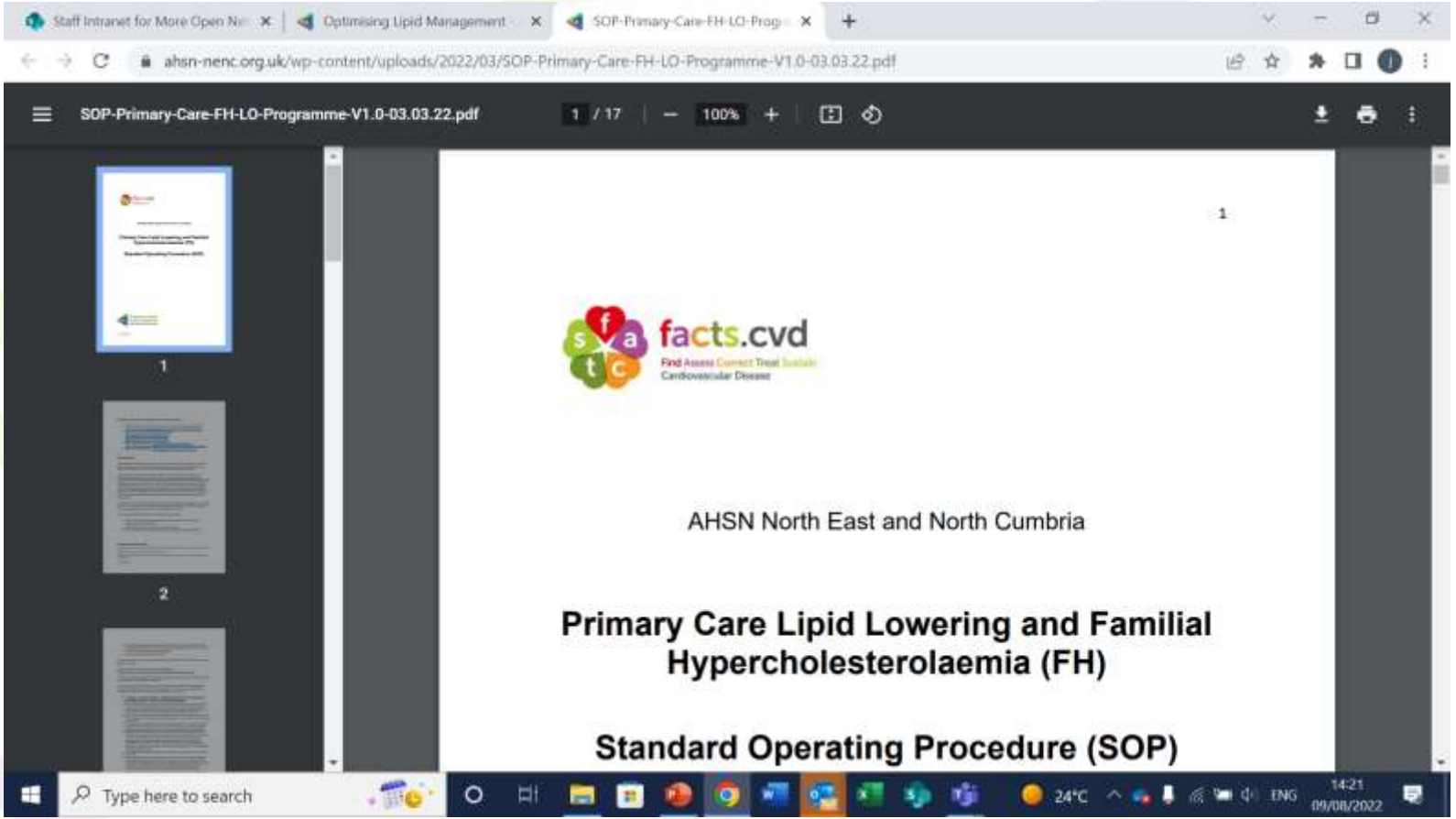
- **Built upon experience with FH pilot work but lipid optimising was unknown and untried.**
- **Clinical pharmacists & FH specialist nurses, working with the AHSN NENC, tested new ways of working during Covid 19 using virtual and remote approaches with willing practices, plus piloting CDRC searches in primary care systems (S1 & EMIS) for lipids and FH.**
- **After 9 months, held 2 process mapping events pulling together those working in the field to pool knowledge and agree ways of working.**
- **Adopting the national lipid guidance locally: NEELI (Northern England Evaluation and Lipid Intensification Guideline).**
- **Process mapping highlighted barriers, developed solutions & ideas.**
- **Development of Lipids and FH Standard Operating Procedure (SOP) – a 'how to' step-by-step guide with handbook and template resources to support primary care to find and manage patients with disordered lipids. This was co-produced with input from:**
  - **GPs**
  - **Clinical pharmacists**
  - **CDRC Team (development of searches for primary care systems)**
  - **LSAG (Lipid Specialist Advisory Group)**
  - **Northern Genetics Service**

Primary care searches





g.uk
ENC



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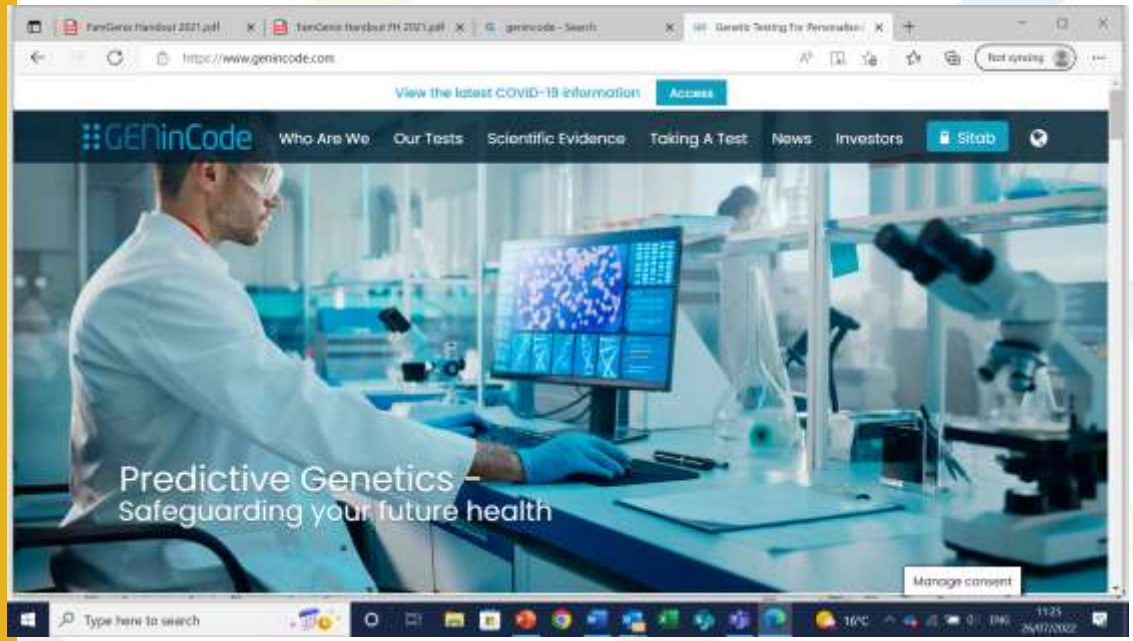
https://ahsn-nenc.org.uk/what-we-do/improving-population-health/cardiovascular-disease-prevention/disordered-lipids

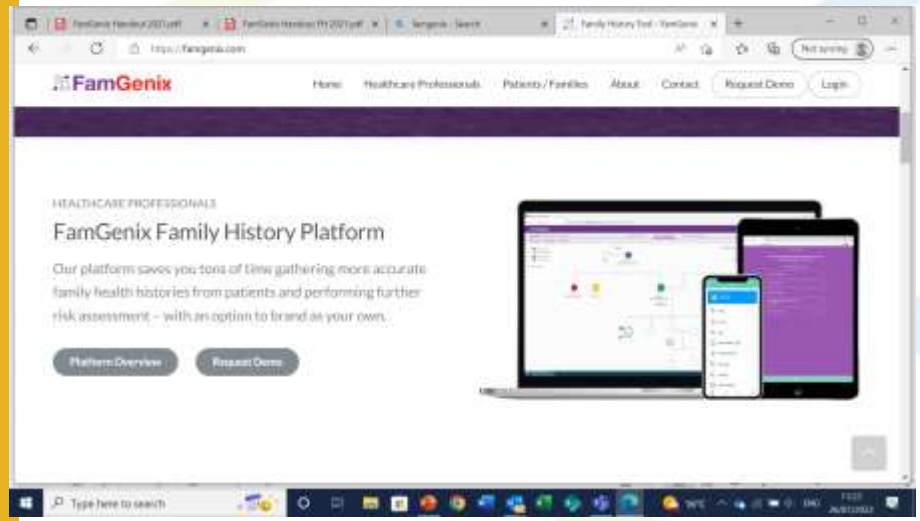
www.ahsn-nenc.org.uk
@AHSN_NENC

Genincode



- Qualitative evaluation in lipid clinic – complete
- Implementation in PCN in Darlington

Digital platform to support cascade testing



- NENC, Eastern, South West
- Implementation and evaluation across 7 sites
- Supported by Sanofi

Familial Hypercholesterolemia

19th September 2022, 16th January 2023 | Half Day per week over 5 weeks (1-4pm each Monday)

Register your interest

AHSN Name	Primary Care Units	Secondary Care Units	PCNs
East Midlands	176	13	32
Eastern	103	10	32
Health Innovation Mancheste	107	7	25
Health Innovation Network	49	53	21
Imperial College Health Part	286	312	36
Innovation Agency	104	2	30
Kent, Surrey & Sussex	169	3	48
North East & North Cumbria	217	53	36
Oxford	160	3	46
South West	208	3	40
UCLPartners	25	11	12
Wessex	59	6	19
West Midlands	145	428	44
West of England	1007	20	57
Yorkshire & Humber	229	65	51

Since the launch of the lipid & FH programme we have seen

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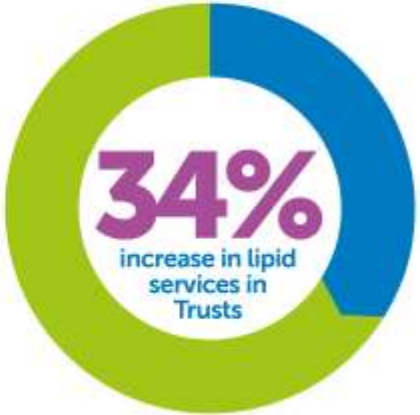
in the number of Trusts reporting a functioning lipid management pathway between primary and secondary care



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Since the programme began:

835
more FH cases were added to the FH national database (PASS)

1,335
more people benefitted from PCSK9i treatment

177,560
people now taking statins and

116,079
people are now on High Intensity Statins which is a 3 % increase

Those additional 116,079 people on high intensity statins have reduced their risk of having CVD incidence like heart attacks or strokes by at least

14%

9,284
more people have benefited from ezetimibe

Key take home messages

- There is still a lot to be done …..

- We need to ensure we target the most at risk populations where we can make the biggest difference

Connect with us

Web: www.ahsnnetwork.com

Email: joe.Chidanyika@ahsn-nenc.org.uk

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The Increasing Role of Pharmacists in Lipid Management

Dr Rani Khatib
Consultant Pharmacist in Cardiology & Cardiovascular Research
Leeds Teaching Hospitals NHS Trust

Northern Lipid Forum

in association with

HEART UK
THE CHOLESTEROL CHARITY

The increasing role of Pharmacists in Lipid management

Dr Rani Khatib

Consultant Pharmacist in Cardiology & Cardiovascular Research

Leeds Teaching Hospitals NHS Trust

Visiting Associate Professor, University of Leeds

Hear Failure Quality Standards Committee Member, NICE

National Clinical Champion for PCSK9i & Lipid Optimisation, AAC, AHSN NENC

Co-Chair Cardiology Group, UKCPA

Member of Science Committee European Society of Cardiology, ACNAP

@DrRaniKhatib | khatib@leeds.ac.uk

W: https://medicinehealth.leeds.ac.uk/medicine/staff/507/rani-khatib

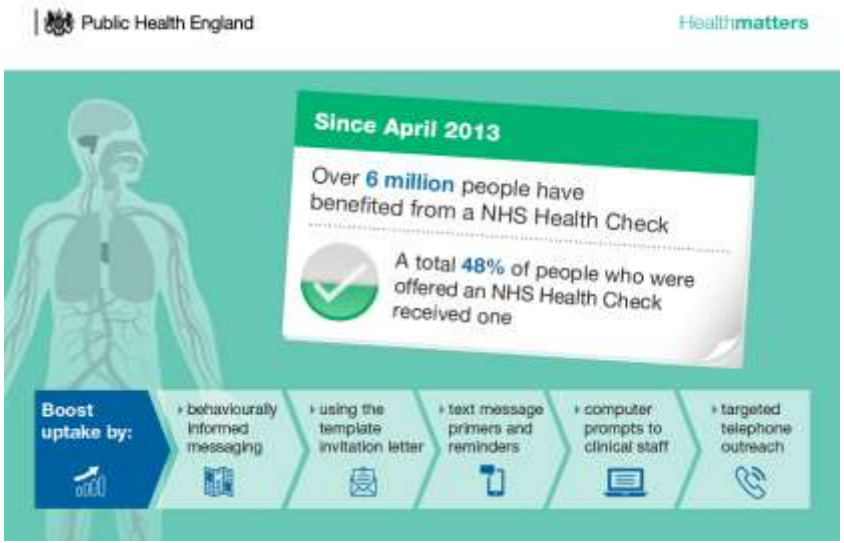
Objective

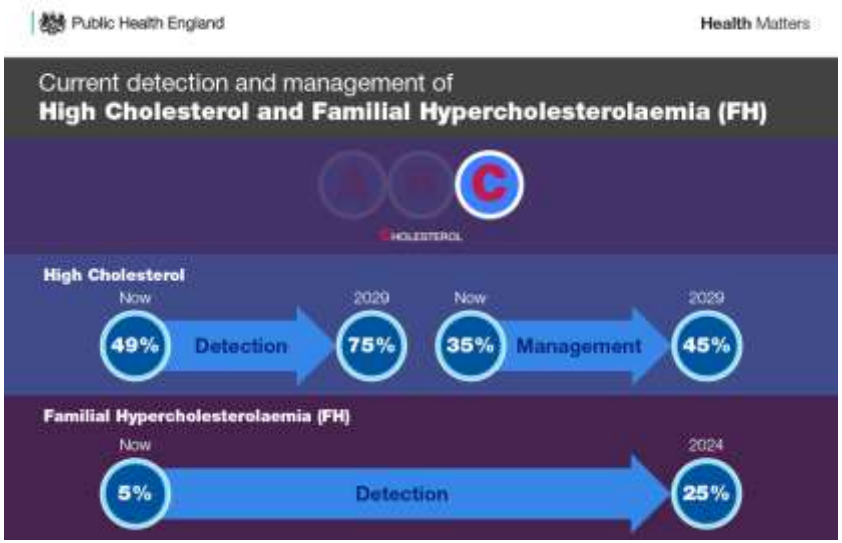
- To explore the role of pharmacy in tackling cholesterol across the healthcare continuum

The role of Pharmacy in Tackling Cholesterol Together

- The Pharmacy profession across the healthcare continuum
- Detection & Prevention
- Supporting design of pathways and guidance
- Optimising Lipid Management in primary and secondary care
- Leading Lipid Management Clinics
- Improving access to new lipid lowering therapies
- Supporting adherence
- Tackling statin intolerance

Unmet needs in lipid management

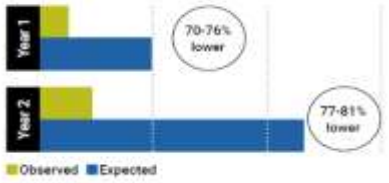




7.6 million people in England with CVD[1] - Of these:

- 25% are not lipid lowering therapies (at least a statin)[2]
- 40% are on low or medium intensity statin[3]

Access to new lipid lowering therapies e.g. PCSK9i



1. https://www.bhf.org.uk/what-we-do/news-from-the-bhf/contact-the-press-office/facts-and-figures
2. UCLP data on file
3. Openprescribing: https://openprescribing.net/measure/statinintensity/national/england/

The Patient - Patient-Centered Outcomes Research (2022) 15:473–483
https://doi.org/10.1007/s40271-021-00566-4

ORIGINAL RESEARCH ARTICLE

Will the Public Engage with New Pharmacy Roles? Assessing Future Uptake of a Community Pharmacy Health Check Using a Discrete Choice Experiment

Gin Nie Chua[1] · Christine Bond[2] · Terry Porteous[3] · Mandy Ryan[1]

Accepted: 7 December 2021 / Published online: 24 January 2022

Conclusion

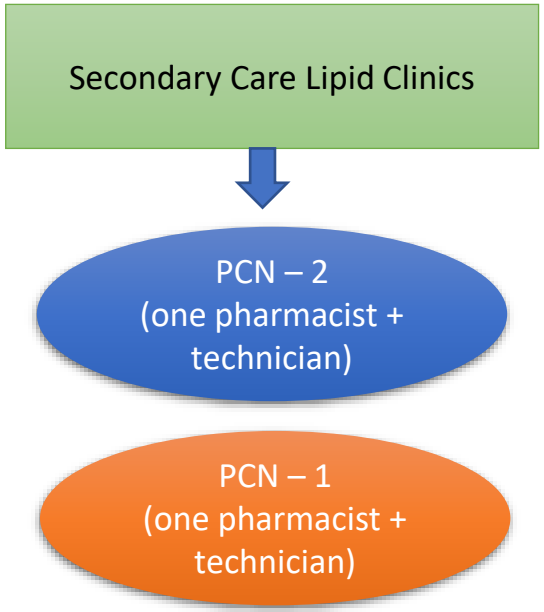
Findings affirm the public's acceptance and value of a pharmacy-led CVD health check. The findings can inform pharmacy-based screening services before they are introduced, guide new service design and support resource allocation decisions.

Community/PCN Pharmacist role

- System 1 & EMIS searches
- Case finding
- Optimisation of lipid lowering therapy
- Identification of potential FH cases
- Tackling Statin Intolerance
- Supporting adherence

Screening for CVD risk factors is highly cost-effective for the NHS (around £3000 per QALY)

The Leeds PCN Lipid Optimisation Project

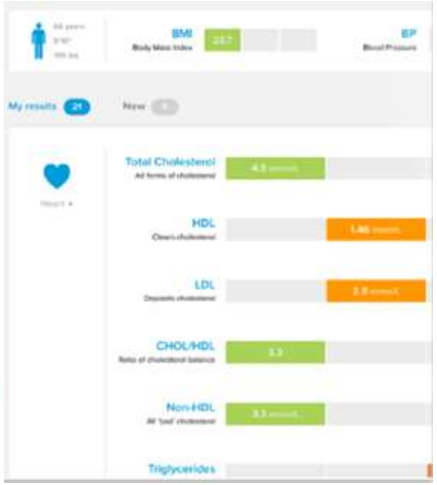


- Searches for patients with CVD
  - Established CVD > 5000
  - On HI statins 58%
  - On HI statin + ezetimibe 3%
  - 25% with non-HDL-C > 2.5 or LDL-C >2.6
    - 25% of those are not on any lipid lowering therapy
    - 21% Despite HI statins
    - 26% Despite HI statins + Ezetimibe
  - Underway

HealthTab
Know better. Live better.

The Evolution of Point of Care Testing

- Proven point-of-care screening system, designed to support pharmacists evolving role.
- Empowers patients to be proactive about their health by directly measuring and monitoring key safety tests and biomarkers of chronic disease.
- Simple, fast, lab-accurate, and requires just a few drops of blood from a finger stick or nasal swab.
- Results can be printed in-store or accessed securely online.
- Robust QA program utilized by leading conventional labs.



Preliminary Data

Pilot performance....

3300+ total tests Completed since the pilot began

25 pilot stores participating

28 days

Of the tests completed....

22 patients were **newly identified** as being diabetic

21% of patients were at high-risk of having an MI or death in the next 10 years

18% of patients had A1C results in the "high" range

40% of patients had high triglycerides

To date, all patients with repeat readings, saw an improvement in A1C and / or Lipid during their 2nd test

Patient Flow

Patient Feedback

263 patients responded to the post-service survey collected throughout the pilot

214 of the 263 said they learned something new from their pharmacist about managing their health

Over 60% of patients said they have not seen their GP in over a year

Majority of patients indicated they were extremely comfortable discussing their test results with their pharmacist

Majority of patients found it convenient to receive access to these tests at their pharmacy

Source: A lecture by John Papastergiou (Toronto (Canada)) at the the EUROHEARTCARE 2022 Congress

We are not good at treating to target after myocardial infarction

Profile and treatment of chronic coronary syndromes in European Society of Cardiology member countries: The ESC EORP CICD-LT registry

9174 patients with previous ST-elevation myocardial infarction (STEMI), non-STEMI or coronary revascularisation, or other CCS

"Poorly controlled cardiovascular risk factors were common across all cohorts"

Current smoking (18.5%)

Obesity (33.9%)

Diabetes (25.8%)

Raised low-density lipoprotein cholesterol (73.3%)

Persistent hypertension (24.7%)

European Journal of Preventive Cardiology, Volume 28, Issue 4, April 2021, Pages 432 445, https://doi.org/10.1177/2047487320912491

Adherence issues

Among 500 patients with coronary artery disease in West Yorkshire, 43.5% were found to be non-adherent with at least one SPM

Statins contributed to **66.7%**

Aspirin to **61.7%**

of overall non-adherence

identified by the Single Question tool.

A number of modifiable barriers to adherence were identified in the 219 non-adherent individuals, including:

- Forgetfulness (84.9%)
- Worry that medicines will do more harm than good (33.8%)
- Feeling hassled about taking medicines (18.7%)
- Feeling worse when taking medicines (14.2%)
- Not being convinced of the benefit of medicines (9.1%)

Consequences?

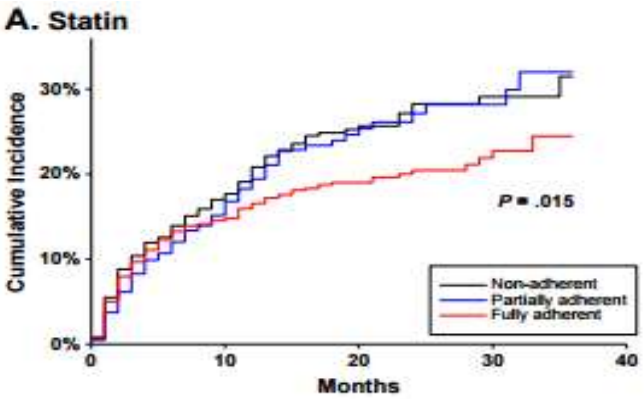
Untangling the relationship between medication adherence and post–myocardial infarction outcomes: Medication adherence and clinical outcomes

Background Patients who adhere to medications experience better outcomes than their nonadherent counterparts. However, these observations may be confounded by patient behaviors. The level of adherence necessary for patients to derive benefit and whether adherence to all agents is important for diseases that require multiple drugs remain unclear. This study quantifies the relationship between medication adherence and post–myocardial infarction (MI) adverse coronary events.

Methods This is a secondary analysis of the randomized MI FREEE trial. Patients who received full prescription coverage were classified as adherent (proportion of days covered ≥80%) or not based upon achieved adherence in the 6 months after randomization. First major vascular event or revascularization rates were compared using multivariable Cox models adjusting for comorbidity and health-seeking behavior.

Results Compared with patients randomized to usual care, full coverage patients adherent to statin, β-blocker, or angiotensin-converting enzyme inhibitor/angiotensin receptor blocker were significantly less likely to experience the study's primary outcome (hazard ratio [HR] range 0.64-0.81). In contrast, nonadherent patients derived no benefit (HR range 0.98-1.04, $P \leq .01$ for the difference in HRs between adherent and nonadherent patients). Partially adherent patients had no reduction in clinical outcomes for any of the drugs evaluated, although their achieved adherence was higher than that among controls.

Conclusion Achieving high levels of adherence to each and all guideline-recommended post-MI secondary prevention medication is associated with improved event-free survival. Lower levels of adherence appear less protective. (Am Heart J 2014;167:51-58.e5.)



Non-adherence to SPM was associated with a
10–40% relative increase in risk of cardiac hospitalisations and a 50–80% relative increase in mortality

ACE=angiotensin-converting enzyme; ARB=angiotensin-receptor blocker; MI=myocardial infarction; SPM=secondary preventive medicine.

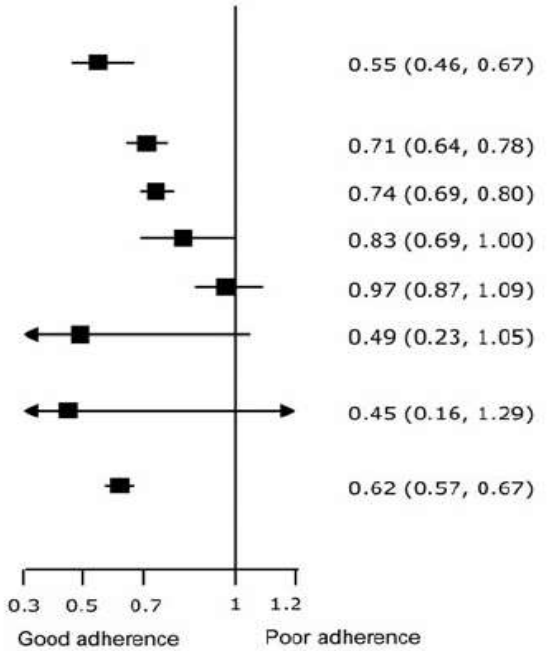
1. Choudhry N Am Heart J 2014;167:51-58

2. Ho P, et al. Am Heart J. 2008;155:772 – 779.

Relative risks for all-cause mortality for good vs poor adherence to major cardiovascular medications

9% of all CVD events in Europe could be attributed to poor adherence to CV medications

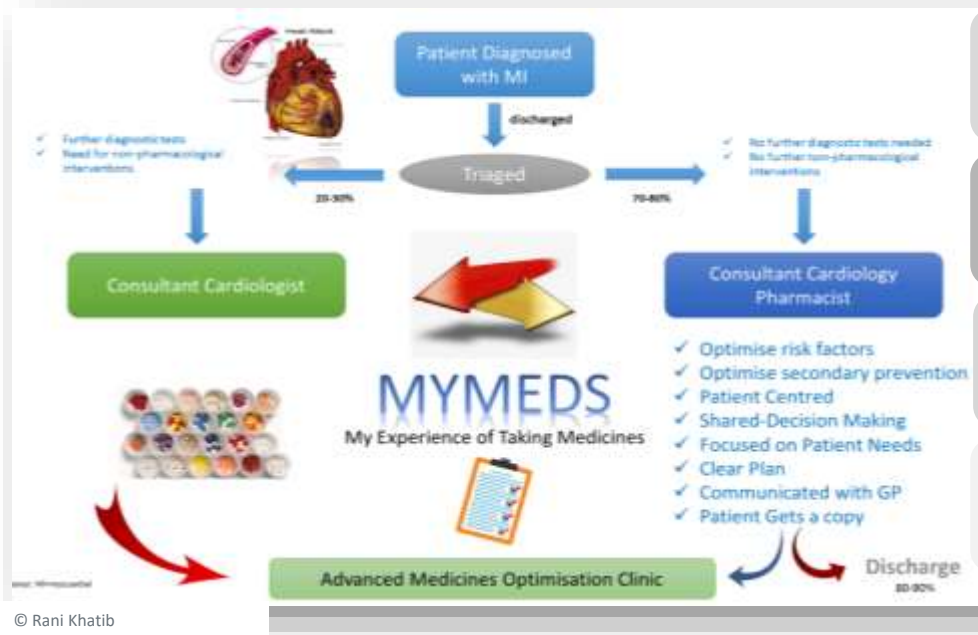
	No. of studies	No. of participants	No. of deaths	Proportion (95% CI)
(1) Adherence to statins	11	291,864	29,605**	0.55 (0.46, 0.67)
(2) Adherence to antihypertensive agents	11*	205,598	12,288**	0.71 (0.64, 0.78)
ACE inhibitors/Angiotensin receptor blockers	4	62,196	886**	0.74 (0.69, 0.80)
Beta-blockers	7	67,991	5,441**	0.83 (0.69, 1.00)
Calcium channel blockers	1	9168	2696	0.97 (0.87, 1.09)
Multiple agents	3	81,342	2978	0.49 (0.23, 1.05)
(3) Adherence to aspirin	3	12,980	1573	0.45 (0.16, 1.29)
(4) Adherence to any CVD medication	23*	533,381	94,126**	0.62 (0.57, 0.67)



ACE=angiotensin-converting enzyme; CV=cardiovascular; CVD=cardiovascular disease.

1. Chowdhury R, et al. *Eur Heart J*. 2013;34:2940–2948.

Pharmacy-led innovations in the Post MI Medicines Optimisation Pathway



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Increased capacity and reduced Waiting Time

44% ↓ in mean waiting times from discharge to first outpatient cardiology review

Improved secondary prevention medicines Adherence

Up to 70% ↓ in non-adherence to SPMs at 3-6 months post clinic

Provisional data shows reduction in Re-admissions

40–55% ↓ in ACS readmissions at 30, 60 & 90 days post-discharge *vs* previous year

Improved compliance with NICE Recommendations*

90% of patients were on good optimal SPM at 12 months

Analysis of the feedback showed full Patient Satisfaction

100% found the clinic valuable and would recommend for patients with heart disease

BMJ Journals
openheart
Re-engineering the post-myocardial infarction medicines optimisation pathway: a retrospective analysis of a joint consultant pharmacist and cardiologist clinic model

NICE National Institute for Health and Care Excellence
Re-engineering the Post-Myocardial Infarction Medicines Optimisation Pathway

Khatib R, *et al. Open Heart* 2018;5:e000921. doi:10.1136/openhrt-2018-000921

Examples of Impact on Secondary Prevention Therapies

Table 4 Self-reported non-adherence to individual secondary prevention medicines before and after the medicines optimisation clinic

Secondary prevention medicine	Non-adherence rate prior to clinic	Non-adherence rate 3–6 months post-clinic	Relative reduction in non-adherence	P value
ACE inhibitor /ARB	27/178 (15.2%)	10/130 (7.7%)	49.3%	0.046
Beta blocker	23/169 (13.6%)	5/119 (4.2%)	69.1%	0.008
Statin	39/181 (21.5%)	8/127 (6.3%)	70.8%	<0.001
Clopidogrel/prasugrel/ticagrelor	32/173 (18.5%)	7/126 (5.6%)	69.7%	0.001
Aspirin	24/176 (13.6%)	10/128 (7.8%)	42.6%	0.112

ARB, angiotensin receptor blocker.ACE, Angiotensin-Converting Enzyme.

21 %

of patients had their statin dose optimised

(initiated a high-intensity statin, challenged intolerance or uptitrated in line with guidelines)

Khatib R, et al. Open Heart 2018;5:e000921. doi:10.1136/openhrt-2018-000921

Meds & Risk optimisation needs 12m post MI

- 12-month review was conducted with 201 post-MI patients
- 93 (47%) required LDL-cholesterol testing.

On admission : 83% had TC
68% had LDL-C

Post discharge: 73% had TC
54% had LDL-C

Achieving Targets - Lipid levels

	Patients (at admission) n/N (%)	Patients (at 12 months) n/N (%)	Absolute change, %
TC < 4.0 mmol/L	45/167 (26.9)	99/148 (66.9)	40.0
LDL-C < 1.8 mmol/L	18/137 (13.1)	60/108 (55.6)	42.5

Drug	Discharge, n (%) N=201	12 months, n (%) N=201
Statin	193 (96.0)	188 (93.5)
Ezetimibe	4 (2.0)	13 (6.5)
Neither	5 (2.5)	9 (4.5)

- At 12 months
  - **43%** patients were achieving the LDL-cholesterol target at 12 months compared with baseline (admission)
- The majority of patients, whether they achieved targets or not, were on high-intensity statin therapy
- Room for improvement – need primary care intervention.
- Community and PCN pharmacists have an important role to play here.

Summary of National Guidance for Lipid Management for Primary and Secondary Prevention of CVD

ACCELERATED ACCESS COLLABORATIVE

NHS

INITIAL CONSIDERATIONS:

- Measure non-fasting ***full lipid profile*** (total cholesterol, HDL-C, non-HDL-C, triglycerides) and HbA1c as part of an initial baseline assessment.
- Consider secondary causes of hyperlipidaemia and manage as needed.
- Ensure appropriate baseline and follow up tests as detailed on page 2. Measure BMI.
- Identify and exclude people with contraindications/drug interactions.
- If non-fasting triglyceride above 4.5mmol/L see page 2.

PRIMARY PREVENTION

Consider statin therapy for adults who do not have established CVD but fall into the categories below. Use QRISK risk assessment tool where appropriate (see page 2, 'Primary Prevention Risk Assessment')

- Age ≤84 & QRISK ≥10% over next 10 years
- Type 2 diabetes & QRISK ≥10% over next 10 years
- Type 1 diabetes, if they have one or more of the following:
  - Over 40 years
  - Had diabetes for >10 years
  - Have established nephropathy
  - Have other CVD risk factors
- CKD eGFR < 60 mL/min/1.73m² and/or albuminuria
- Age ≥80 years. If appropriate consider comorbidities, frailty & life expectancy

Identify and address all modifiable risk factors - smoking, diet, obesity, alcohol intake, physical activity, blood pressure and HbA1c.

Consider additional risk factors, if present, together with QRISK score (treated for HIV, severe mental illness, taking medicines that cause dyslipidaemia, systemic inflammatory disorder (e.g. SLE), impaired fasting glycaemia, recent change in risk factors)

PRIMARY PREVENTION

If lifestyle modification is ineffective or inappropriate offer statin treatment:

Atorvastatin 20mg daily

- Measure full lipid profile again after 3 months (non-fasting).
- High intensity statin treatment should achieve reduction of non-HDL-C > 40% from baseline. If not achieved after 3 months:
  - discuss treatment adherence, timing of dose, diet and lifestyle
  - If at higher risk (based on comorbidities, risk score or clinical judgement – see page 2 'Additional Risk Factors') consider increasing the dose every 2-3 months up to a maximum dose of atorvastatin 80mg daily.
  - For how to increase in people with CKD see 'Special Patient Populations' (page 2).

- If patients on a high-intensity statin have side effects, offer a lower dose or an alternative statin (see page 2 'Extent of lipid lowering with available therapies')
- If maximum tolerated dose of statin does not achieve non-HDL-C reduction > 40% of baseline value after 3 months consider adding Ezetimibe 10mg daily (NICE TA385)
- If statin treatment is contraindicated or not tolerated:
  - See AAC Statin Intolerance Algorithm for advice regarding adverse effects (click here)
  - Ezetimibe 10mg monotherapy may be considered. Assess response after 3 months.
  - Ezetimibe 10mg/bempedoic acid 180 mg combination may be considered when ezetimibe alone does not control non-HDL-C/LDL-C well enough (NICE TA694).

If non-HDL-C reduction remains < 40% of baseline despite maximal tolerated lipid lowering therapy (including people with intolerances and contraindications) consider referral to specialist lipid management clinic according to local arrangements.

SEVERE HYPERLIPIDAEMIA

If TC>7.5mmol/L and/or LDL-C >4.9mmol/L and/or non-HDL-C >5.9mmol/L, a personal and/or family history of confirmed CHD (<60 years) and with no secondary causes suspect familial hypercholesterolaemia (possible heterozygous FH)

Do not use QRISK risk assessment tool

DIAGNOSIS AND REFERRAL

Take fasting blood for repeat lipid profile to measure LDL-C.

Use the **Simon Broome** or **Dutch Lipid Clinic Network** (DLCN) criteria to make a ***clinical diagnosis of FH***.

Refer to Lipid Clinic for further assessment if ***clinical diagnosis of FH*** or if TC>9.0mmol/L and/or LDL-C >6.5mmol/L and/or non-HDL-C >7.5mmol/L or Fasting triglycerides > 10mmol/L (regardless of family history) (page 2)

TREATMENT TARGETS IN FH

If clinical diagnosis of FH and/or other risk factors present follow the recommended treatment management pathway for primary or secondary prevention as for non-FH, ***BUT***

Aim to achieve at least a 50% reduction of LDL-C (or non-fasting non-HDL-C) from baseline.

Consider specialist referral for further treatment and/or consideration of PCSK9i therapy IF

- they are assessed to be at very high risk of a coronary event*
- OR therapy is not tolerated
- OR LDL-C remains >5mmol/L (primary prevention)
- OR LDL-C remains >3.0mmol/L (secondary prevention)

despite maximal tolerated statin and ezetimibe therapy.

*defined as any of the following:
- Established coronary heart disease
- Two or more other CVD risk factors

SECONDARY PREVENTION

Offer statin therapy to adults with CVD: this includes angina, previous MI, revascularisation, stroke or TIA, or symptomatic peripheral arterial disease. Do not delay statin treatment if a person has acute coronary syndrome. Take a lipid sample on admission (within 24 hours).

Identify and address all modifiable risk factors - smoking, diet, obesity, alcohol intake, physical activity, blood pressure and HbA1c.

SECONDARY PREVENTION

Do not delay statin treatment in secondary prevention while managing modifiable risk factors.

Prescribe a high intensity statin:

Atorvastatin 80mg daily

Use a lower dose of atorvastatin if there is a potential drug interaction, high risk of or experiencing adverse effects, or patient preference.

Offer atorvastatin 20mg if CKD (people with GFR< 60 mL/min/1.73m²).

- Measure full lipid profile again after 3 months (non-fasting).
- High intensity statin treatment should achieve reduction of non-HDL-C > 40% from baseline. If not achieved after 3 months:
  - discuss treatment adherence, timing of dose, diet and lifestyle measures
  - If started on less than atorvastatin 80mg and the person is judged to be at higher risk (based on comorbidities, risk score or clinical judgement - see page 2 'Additional Risk Factors'), consider increasing to 80mg atorvastatin. For how to increase in people with CKD see 'Special Patient Populations' (page 2).
- If non-HDL-C baseline value is not available*, consider target non-HDL-C < 2.5mmol/L (approximately equivalent to LDL-C < 1.8mmol/L) as recommended by Joint British Societies (JBS3).
  *this scenario is not covered by NICE CG181
- If patients on a high-intensity statin have side effects, offer a lower dose or an alternative statin (see page 2 'Extent of lipid lowering with available therapies')

If maximum tolerated dose of statin does not control non-HDL-C/LDL-C well enough after 3 months confirm statin adherence, then consider the following options based on shared decision making** with the patient:

If recommended statin treatment is contraindicated or not tolerated - follow AAC Statin Intolerance Algorithm for advice regarding adverse effects (click here)

If statin intolerance is confirmed, consider:

- **Ezetimibe 10mg** monotherapy. Assess response after 3 months (TA385)
- **Ezetimibe 10mg/bempedoic acid 180 mg** combination when ezetimibe alone does not control non-HDL-C sufficiently. (NICE TA694)

If non HDL-C remains > 2.5mmol/L despite other lipid lowering therapies consider injectable therapies - arrange a fasting blood test and assess eligibility criteria (TA393/394, TA733)

Ezetimibe 10mg daily (NICE TA385). Reassess after three months. If non-HDL-C remains > 2.5mmol/L, consider **injectable therapies** arrange a fasting blood test and assess eligibility

Injectable therapies** If non-HDL-C > 2.5mmol/L, Arrange fasting blood test to measure LDL-C to assess eligibility:

- **Inclisiran** – if fasting LDL-C ≥ 2.6mmol/L despite maximum tolerated lipid lowering therapy (TA733)

OR

- **PCSK9i** - see overleaf for LDL-C thresholds. (TA393/4)

If eligibility criteria are not met, consider **ezetimibe 10mg daily** (if not previously considered)

* See overleaf for information to support shared decision making

** Inclisiran and PCSK9i should not be prescribed concurrently

Khatib R & Neely D. 2021. National Lipid Management Pathway. Available from https://www.england.nhs.uk/aac/publication/summary-of-national-guidance-for-lipid-management/. Accessed 17th Sept 2021

PRIMARY PREVENTION

If lifestyle modification is ineffective or inappropriate offer statin treatment.

Atorvastatin 20mg daily

- Measure full lipid profile again after 3 months (non-fasting).
- High intensity statin treatment should achieve reduction of non-HDL-C > 40% from baseline. If not achieved after 3 months;
  - discuss treatment adherence, timing of dose, diet and lifestyle
  - If at higher risk (based on comorbidities, risk score or clinical judgement – see page 2 *'Additional Risk Factors'*) consider increasing the dose every 2-3 months up to a maximum dose of atorvastatin 80mg daily.
  - For how to increase in people with CKD see *'Special Patient Populations'* (page 2).

- If patients on a high-intensity statin have side effects, offer a lower dose or an alternative statin (see page 2 *'Extent of lipid lowering with available therapies'*)
- If maximum tolerated dose of statin does not achieve non-HDL-C reduction > 40% of baseline value after 3 months consider adding Ezetimibe 10mg daily (NICE TA385)
- If statin treatment is contraindicated or not tolerated;
  - See AAC Statin Intolerance Algorithm for advice regarding adverse effects (click here)
  - Ezetimibe 10mg monotherapy may be considered. Assess response after 3 months.
  - Ezetimibe 10mg/bempedoic acid 180 mg combination may be considered when ezetimibe alone does not control non-HDL-C/LDL-C well enough (NICE TA694).

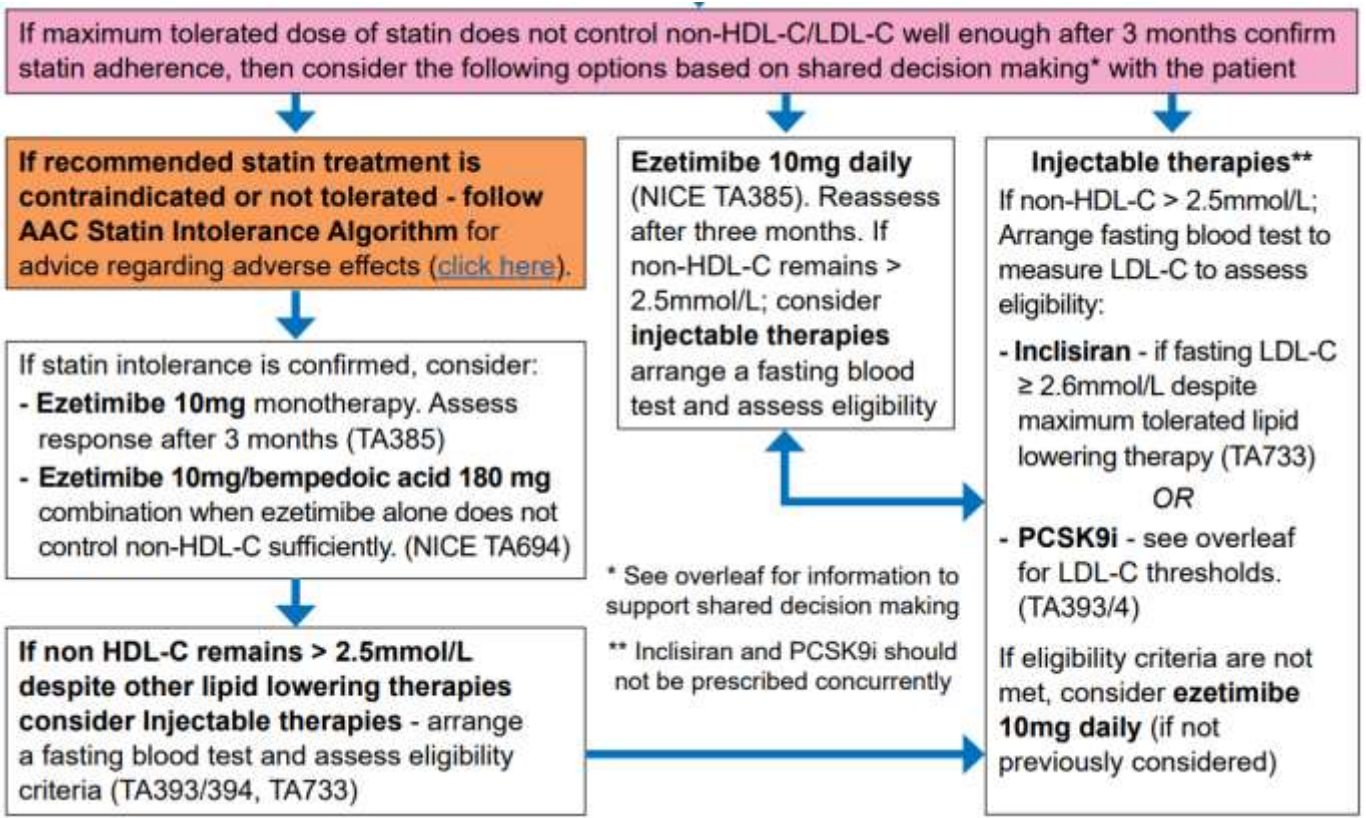
If non-HDL-C reduction remains < 40% of baseline despite maximal tolerated lipid lowering therapy (including people with intolerances and contraindications) consider referral to specialist lipid management clinic according to local arrangements

- Ezetimibe
- Bempedoic acid / Ezetimibe
- PCSK9i (if LDL-C >5)

NICE TA393 Alirocumab NICE TA394 Evolocumab	Without CVD	With CVD	
		High risk [1]	Very high risk [2]
Primary non-FH or mixed dyslipidaemia	Not recommended	LDL C > 4.0 mmoL/L	LDL C > 3.5 mmoL/L
Primary heterozygous-FH	LDL C > 5.0 mmoL/L	LDL C > 3.5 mmoL/L	

[1] History of any of the following: ACS; coronary or other arterial revascularisation procedures; CHD, ischaemic stroke; PAD. [2] Recurrent CV events or CV events in more than 1 vascular bed (that is, polyvascular disease).

Secondary Prevention



PCSK9i & Lipid Management Pharmacy-Led Services

Key questions

What is already known about this subject?

- Lipid optimisation is important to reduce the risk of cardiovascular disease.
- Although statins are central to lipid management, there are significant challenges; some patients report intolerance or reluctance, others poorly adhere to these medicines,and some do not achieve acceptable levels of lipid reduction on maximum tolerated therapy.
- Proprotein convertase subtilisin/kexin type 9 inhibitors (PCSK9is) offer another option to better manage hyperlipidaemia but are underused despite being recommended by the UK National Institute for Health and Care Excellence (NICE).

What does this study add?

- This paper describes an innovative, person-centred, centralised, multidisciplinary service that has been successfully deployed to improve PCSK9i utilisation in line with NICE recommendations, leading to improved lipid management.
- The service does not focus only on PCSK9is but also attempts to address other challenges in the optimisation of lipid management, such as statin intolerance and adherence. The model was found to be cost effective and was funded by the Clinical Commissioning Group.
- It also paved the way for multidisciplinary working and the implementation of more streamlined mechanisms for referring appropriate patients.

How might this impact on clinical practice?

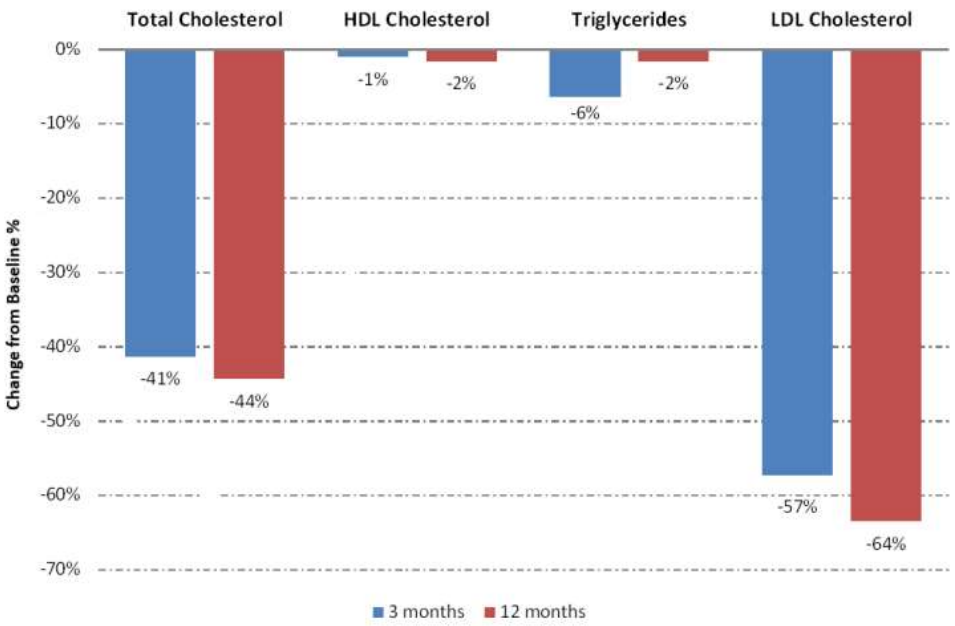
- This service improved access to PCSK9i among eligible patients—and can be duplicated in other centres to offer patients better optimisation of their lipid management.
- The model is flexible enough to allow the introduction of other novel medications for cholesterol lowering—and is multidisciplinary, thereby allowing all relevant healthcare professionals to contribute to lipid management.
- It can also bridge the gap for patients with statin intolerance.

Open access Cardiac risk factors and prevention

openheart

Innovative, centralised, multidisciplinary medicines optimisation clinic for PCSK9 inhibitors

Rani Khatib ,[1,2,3] Mutiba Khan ,[3] Abigail Barrowcliff,[3] Eunice Ikongo,[3] Claire Burton,[4] Michael Mansfield,[4] Alistair Hall[1,2]



87% of patients *agreed or strongly agreed* that their cholesterol is now better than before attending the clinic

100% of patients *agreed or strongly agreed* that after attending the clinic they fully understood their cholesterol lowering medicines and why they were prescribed.

All patients felt supported, listened to, and that all their questions about the medicine were answered

"Good advice given about my medicine. Management of the appointment moving from consultant pharmacist to research nurse to future appointment works extremely well. There is plenty of time to discuss any issues/concerns with experienced and knowledgeable people"

Khatib R, et al. Open Heart 2022;9:e001931. doi:10.1136/openhrt-2021-001931

Patient Feedback on Pharmacy-led clinic

Table 6 Results from the anonymous feedback questionnaire

	Strongly agree	Agree	Disagree	Strongly disagree
All questions and concerns about my medicines were answered (N=26)	19 (73)	7 (27)	0 (0)	0 (0)
I felt reassured by the consultant cardiology pharmacist (N=28)	20 (71)	8 (29)	0 (0)	0 (0)
I felt involved in the discussion and any decisions made were in agreement with me (N=29)	20 (69)	9 (31)	0 (0)	0 (0)
I was given enough time in the clinic to cover all we needed to discuss (N=29)	20 (69)	9 (31)	0 (0)	0 (0)
The consultant seems to know important information about my medical history (N=29)	21 (72)	8 (28)	0 (0)	0 (0)
The consultant provided me with clear plans and goals about my cholesterol-lowering medicines, any tests I needed and my health as a whole (N=29)	19 (66)	9 (31)	1 (3)	0 (0)
After attending the clinic, I fully understand my cholesterol-lowering medicines and why they were prescribed (N=30)	22 (73)	8 (27)	0 (0)	0 (0)
After attending the clinic, I feel less concerned about my cholesterol-lowering medicines (N=29)	17 (59)	10 (34)	2 (7)	0 (0)
I feel confident about using the cholesterol lowering medicines provided (N=29)	22 (76)	6 (21)	0 (0)	1 (3)
Overall, I think this was a valuable clinic that I would recommend for patients with high cholesterol (N=30)	26 (87)	4 (13)	0 (0)	0 (0)
I felt supported and listened to (N=31)	24 (77)	7 (23)	0 (0)	0 (0)
I am satisfied that my cholesterol is now better than before attending the clinic (N=31)	23 (74)	4 (13)	4 (13)	0 (0)
	Very satisfied	**Satisfied**	**Neutral**	**Dissatisfied**
Thinking of the overall service from this clinic, please rate your experience (N=31)	26 (84)	4 (13)	1 (3)	0 (0)

All data are n (%). Thirty-one individuals filled in the questionnaire, but they did not answer every question and hence N was <31 for some questions.

Khatib R, et al. Open Heart 2022;9:e001931. doi:10.1136/openhrt-2021-001931

How did the overall lipid management look like?

Table 4 Lipid profile among PCSK9i-treated patients

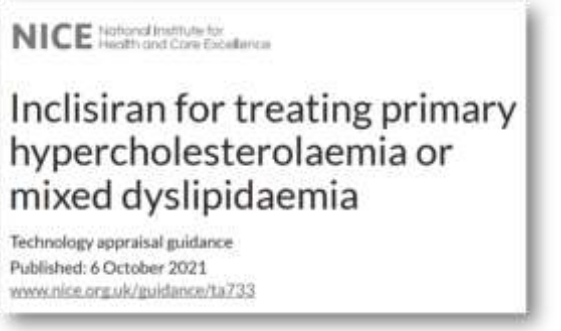
	Total cholesterol (mmol/L)	LDL-C (mmol/L)	TG (mmol/L)	HDL-C (mmol/L)
Baseline	7.7 (1.6, 5.1–12.2)	5.0 (1.6, 1.4–8.9)	2.9 (1.7, 0.4–7.4)*	1.4 (0.3, 0.8–2.2)
3 months	4.5 (1.4, 2.4–7.7)	2.1 (1.3, 0.5–5.2)	2.3 (1.0, 0.8–5.6)*	1.4 (0.3, 0.9–2.1)
12 months	4.3 (1.2, 1.9–7.4)	1.7 (1.1, 0.2–5.1)	2.6 (1.1, 0.7–5.7)*	1.4 (0.3, 0.9–2.5)

N=40. Data are mean (SD, range).
*One patient was on fenofibrate, discontinuation of fenofibrate led to significant elevation of TG at 3 months and, therefore, fenofibrate was reinstated before the 12 months reading. This result was excluded from the graph.
HDL, high-density lipoprotein-cholesterol; LDL, low-density lipoprotein-cholesterol; PCSK9i, proprotein convertase subtilisin/kexin type 9 inhibitor; TG, triglycerides.

Khatib R, et al. Open Heart 2022;9:e001931. doi:10.1136/openhrt-2021-001931

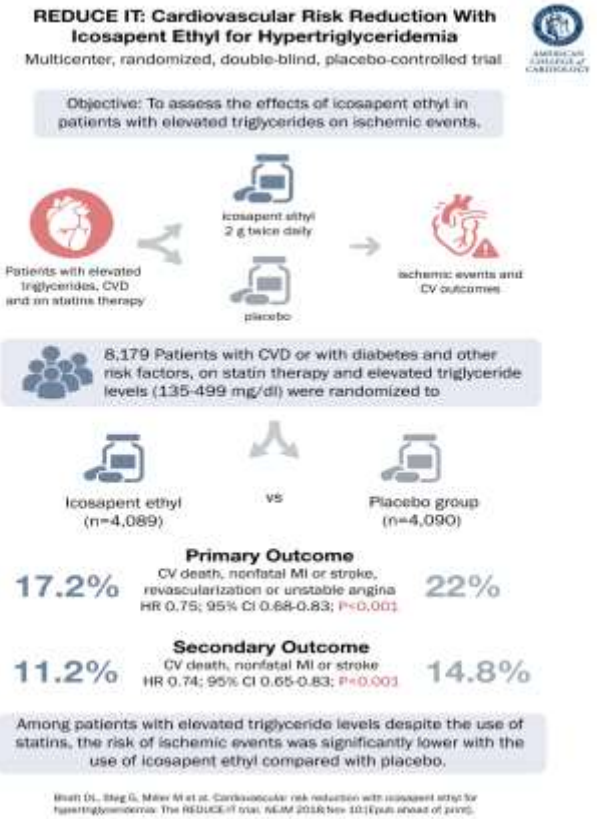
Bempedoic acid & Inclisiran

- Offering in clinic, as an option / alternative to PCSK9i
- More focused on inclisiran
- 30 patients so far
- Still no data to report as only initiated in the last 6 months
- We give 1st dose & GP continues
- More challenging when we do not initiate first dose of inclisiran



Icosapent ethyl

- Made from the omega-3 fatty acid eicosapentaenoic acid
- 8,179 patients
- Stable statin therapy, had elevated triglyceride levels (at least 1.5 mmol/L) and either documented CVD or diabetes with other CV risk factors.
- Well-managed LDL-C
- Side effects: Peripheral Oedema (6.5%), Atrial Fibrillation (5.3%), Constipation (5.4%).



2019 ESC Guidelines on Dyslipidaemias (Management of)

Lipid analyses for CVD risk estimation

Lp(a) measurement should be considered at least once in each adult person's lifetime to identify those with very high inherited Lp(a) levels >180 mg/dL (>430 nmol/L) who may have a lifetime risk of ASCVD equivalent to the risk associated with heterozygous familial hypercholesterolaemia.

Drug treatments of patients with hypertriglyceridaemia

In high-risk (or above) patients with TG between 1.5 and 5.6 mmol/L (135 - 499 mg/dL) despite statin treatment, n-3 PUFAs (icosapent ethyl 2 × 2g/day) should be considered in combination with statins.

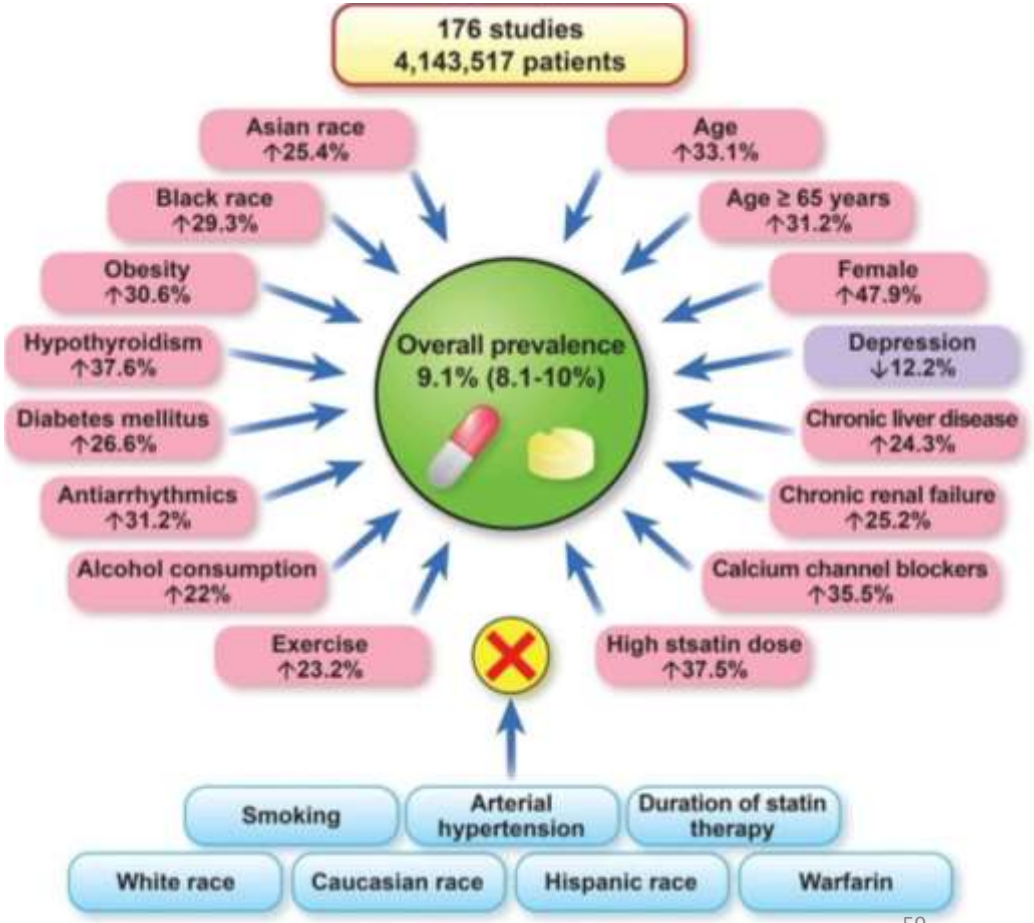
Prevalence of Statin intolerance – Meta-analysis[1]

- Prevalence of statin intolerance (according to international definitions) is 9.1% & lower

"Inability to tolerate a dose of statin required to sufficiently reduce an individual's CV risk, limiting the effective treatment of patients at risk of, or with, CVD." International Lipid Expert Panel

".. any adverse effects relating to the quality of life and leading to the decision to decrease or stop the use of an otherwise beneficial drug". The National Lipid Association

"an inability to tolerate ≥2 statins at any dose or an inability to tolerate increasing doses. Symptomatic criteria include intolerable muscle symptoms [with or without CK changes] or severe myopathy, and they must appear in the first 12 weeks after initiating treatment or following an increase in dose" The Luso-Latin American Consortium & the Canadian Consensus Working Group



1. European Heart Journal, ehac015, https://doi.org/10.1093/eurheartj/ehac015

Statin Intolerance Pathway

Person at high CVD risk reports potential intolerance to recommended high intensity statin treatment

This resource relates to NICE guidance:
CG181, CG71, TA385, TA393/394, QS100

New onset or worsening of muscle symptoms since starting statins? (pain, tenderness or weakness)

NO → Consider other potential side effects for statins
- Be aware of **Statin Reluctance** and **Nocebo Effect**
- See **'Person Centred Care'** box at page 2

YES

Symptoms typical for Statin Related Muscle toxicity (SRM)*?

NO → Muscular symptoms not related to statins

*Symmetrical pain and/or weakness in large proximal muscle groups, worsened by exercise

YES

Measure Creatinine Kinase (CK)
Assess severity of symptoms
+/- repeat baseline assessment**

**Consider other causes if new onset of muscle symptoms of > 2 weeks duration in a person previously tolerant of statin therapy for > 3 months

Non SRM: Consider other causes e.g. PMR, Vit D deficiency. Check bone profile, Vit D, CRP.

Tolerable symptoms
No clinical concern
CK < 4x ULN

Intolerable symptoms
and/or clinical concern and/or CK > 4x and < 10x ULN

CK > 10x and < 50x ULN

CK > 50x ULN

Improvement within 2 weeks
Resolved within 6 weeks
Patient happy to continue

NO → **Stop statin for 4-6 weeks**
Document time to symptom onset and time to resolution

YES ← **Renal function** stable/normal eGFR

NO → Stop statin and consider **Rhabdomyolysis**

Has CK normalised?

Consider **Statin induced necrotising autoimmune myopathy** (SINAM)

NO → Non-SRM. **Consider other causes**

YES

Have symptoms resolved?

NO → Wait for 2 weeks before **rechallenge**

YES

Has the patient been **symptom free for at least 2 weeks?**

Seek specialist advice and consider PCSK9i
(NICE TA 393, 394)

Urgently seek specialist advice and inpatient assessment

YES

Reassess and **restart** with lower dose/alternative statin (see page 2 - **'Statin-based Approaches'**)
Offer low or moderate dose of a higher intensity statin (Atorvastatin 10 or 20 mg OD, or Rosuvastatin 5 or 10mg OD)

No recurrence of muscle symptoms
Titrate at 8 weeks intervals to achieve appropriate targets

Recurrence of muscle symptoms
Short time to onset
Symptoms intolerable

Symptoms tolerable
Treatment goals achieved
Patient happy to continue

NO → **Consider further options**
(For example co-administering ezetimibe or as monotherapy)
see page 2 - **'Statin-based Approaches'**

IF NOT EFFECTIVE

Abbreviations

CK = Creatinine Kinase
CRP = C-Reactive Protein
eGFR = Estimated Glomerular Filtration Rate
PMR = Polymyalgia Rheumatica
SINAM = Statin Induced Necrotising Autoimmune Myopathy
SRM = Statin Related Muscle Toxicity
ULN = Upper Limit of Normal Range
Vit D = Vitamin D

Please refer to page 2 for more details

Management of Statin Intolerance in a Pharmacy led Cardiology Innovative Medicines Optimisation Lipid Clinic

To assess how many people reviewed in our pharmacy led clinic were re-challenged and successfully continued on a statin

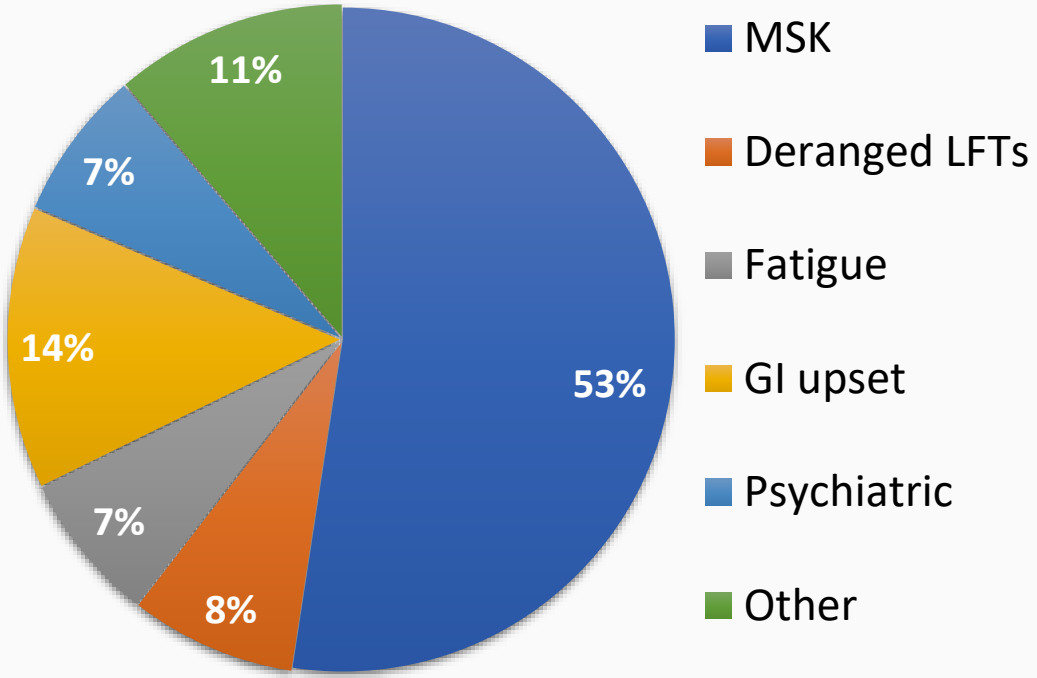
The Innovative Medicines Optimisation Clinic Team: Abigail Barrowcliff, Mutiba Khan, Kirsty Fox and Dr Rani Khatib.

Presented at ESC Congress: https://esc365.escardio.org/presentation/253172

Results

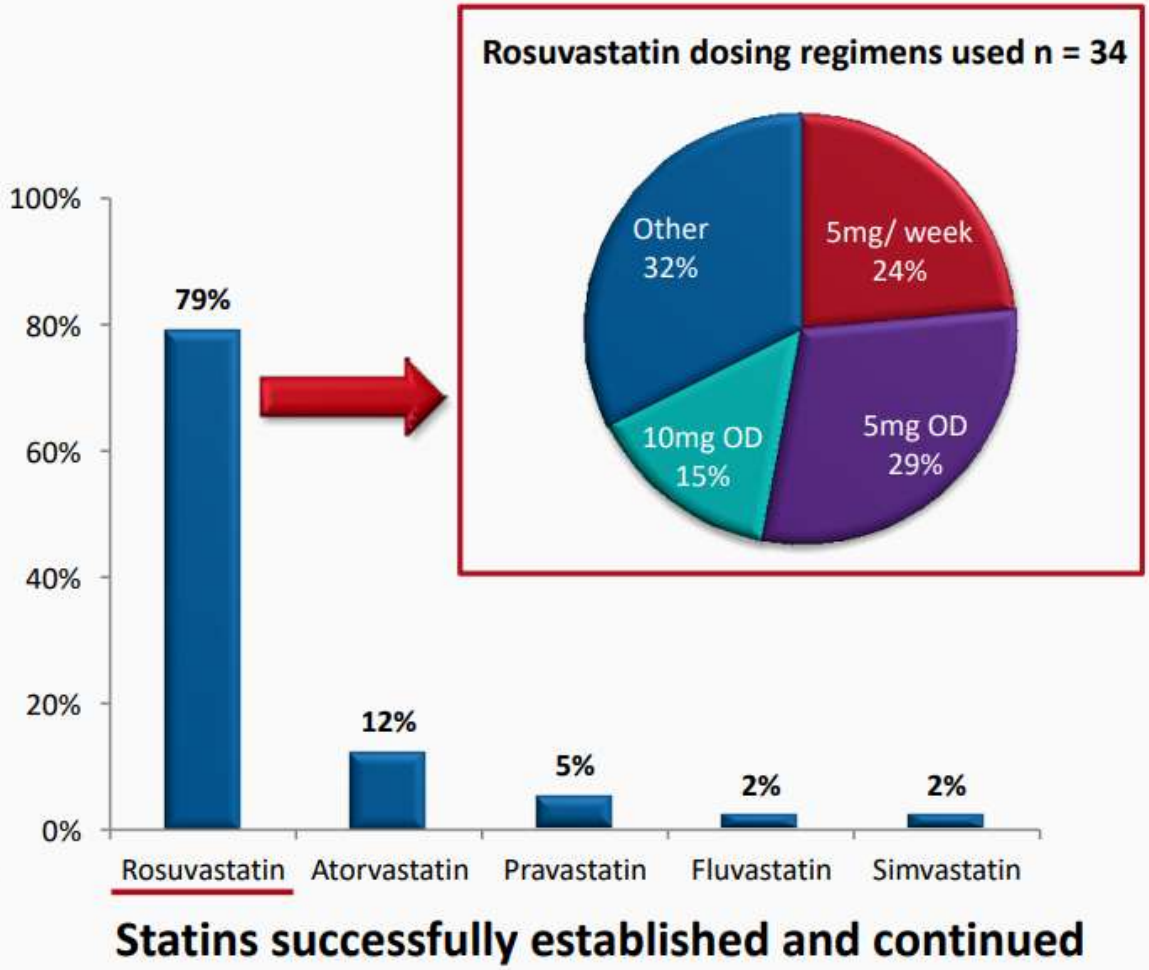
- Over 6 months 207 patients were reviewed
- Of those 152 (73%) were labelled as “statin intolerant”

Reported ADRs to statins n= 152



Results

- **69/ 152 (45%) patients accepted a re-challenge**
  - 44/ 69 (64%) qualified for PCSK9i
- **43/69 (62%) were successfully restarted on a statin.**
- **Of those who did not accept a re-challenge:**
  - 55/77 (71%) had previously experienced MSK reactions.
  - 62/77 (81%) qualified for PCSK9i
- **Patients who were eligible for PCSK9i were less likely to accept a statin re-challenge (p= 0.012)**



Results

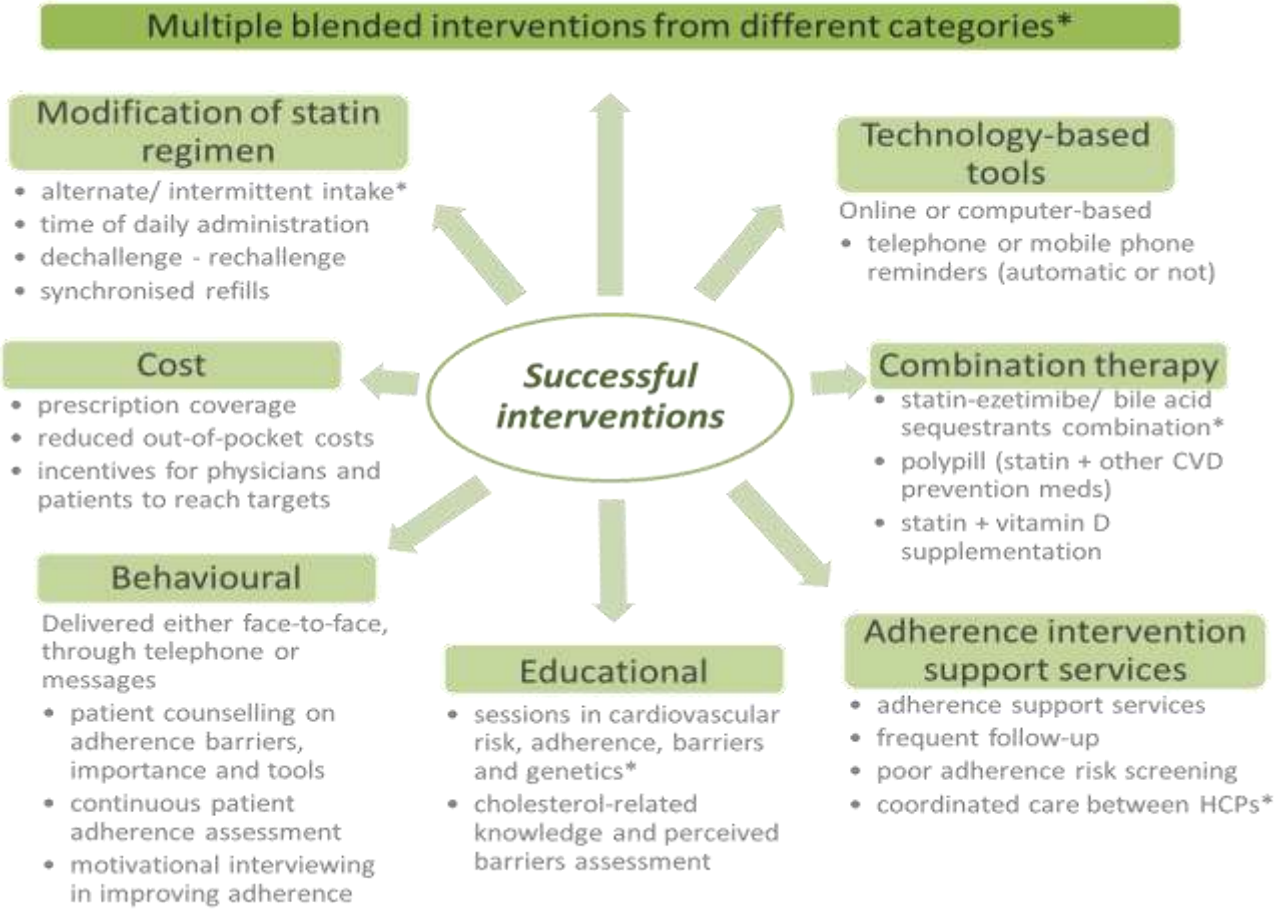
- At an average of 14 months post re-challenge, LDL-C (available for >80% of the sample) was reduced by an average of 31% (LDL -1.4± 1.5 mmol/L; 0.1-4.1mmol/L) in those not on PCSK9i.
  - Statin + ezetimibe 40% reduction (LDL -1.7± 1.4mmol/L; 0.1-4.1mmol/L)
  - Statin monotherapy 20% reduction (LDL -0.9 ± 1.5 mmol/L; 0.5-2mmol/L)

- Compared to a 62% reduction (LDL -3.3 ± 1.6 mmol/L; 0.3-7mmol/L) (sustained over an average of 40 months) in those on combination therapy with PCSK9i.

Conclusions

- By applying a person centred approach it is possible to re-establish patients on statins who were previously considered intolerant.
- Patients who qualify for PCSK9 inhibitors were less likely to consider a re-challenge with statins
- Combination therapy results in a better reduction of LDL-C

Strategies to address Statin intolerance & adherence



- KAMPOURAKI & Khatib et. al. Unpublished data. 2022

Conclusion

- The pharmacy work force has a huge role to play in tackling cholesterol
  - Detection
  - Optimisation of LLT
  - Statin intolerance
  - Supporting adherence
  - Better access to innovative therapies

- New therapeutic options provide more options to tackle cholesterol
  - More choice to meet patient needs
  - More chance to meet targets
  - Tackling variety of lipids

Thank you

Questions

Dr Rani Khatib

@DrRaniKhatib r.khatib@leeds.ac.uk

Thank You

Thank you for attending.

Please remember to complete your feedback forms and include your email address for your Certificate of Attendance.