ACCELERATED ACCESS COLLABORATIVE

Introducing Innovation to the ***Lipid Management Pathway*** *using a Population Health Management approach*

23rd September 2021 | ***The meeting will start at 9:00 am***

ACCELERATED
ACCESS
COLLABORATIVE

1

Welcome to the latest Virtual Town Hall event from the Accelerated Access Collaborative (AAC) on lipid management

Matt Whitty

Director of Innovation Research and Life Sciences at NHS England and Improvement, and CEO of the AAC

Disclaimer: This meeting is part of a collaborative working agreement for lipid management between NHS England and Improvement and Novartis. Both NHS England and Improvement and Novartis have contributed resources in the form of skills, expertise, project management and administrative activity. Funding for the collaborative working programme and information about inclisiran▼(Leqvio®) have been provided by Novartis. NHS England and Improvement retained editorial control of the agenda and content for this meeting. Novartis has checked the associated materials against applicable codes and both parties are working within applicable codes

ACCELERATED ACCESS COLLABORATIVE

Agenda

Topics

Presenters

	Topics	Presenters
1	Welcome and introduction	Matt Whitty
2	Addressing the cardiovascular disease (CVD) prevention agenda and the NHS Long Term Plan	Dr Shahed Ahmad and Dr Kiren Collison
3	Live panel discussion	Dr Kiren Collison (Chair), Dr Tracey Vell MBE, Dr Jaimini Cegla, Dr Phil Jennings
4	Q&A	Matt Whitty, Dr Phil Jennings, Dr Kiren Collison, Dr Jaimini Cegla, Fiona Bride, Dr Tracey Vell MBE
5	Closing remarks	Matt Whitty

Objectives of today's event

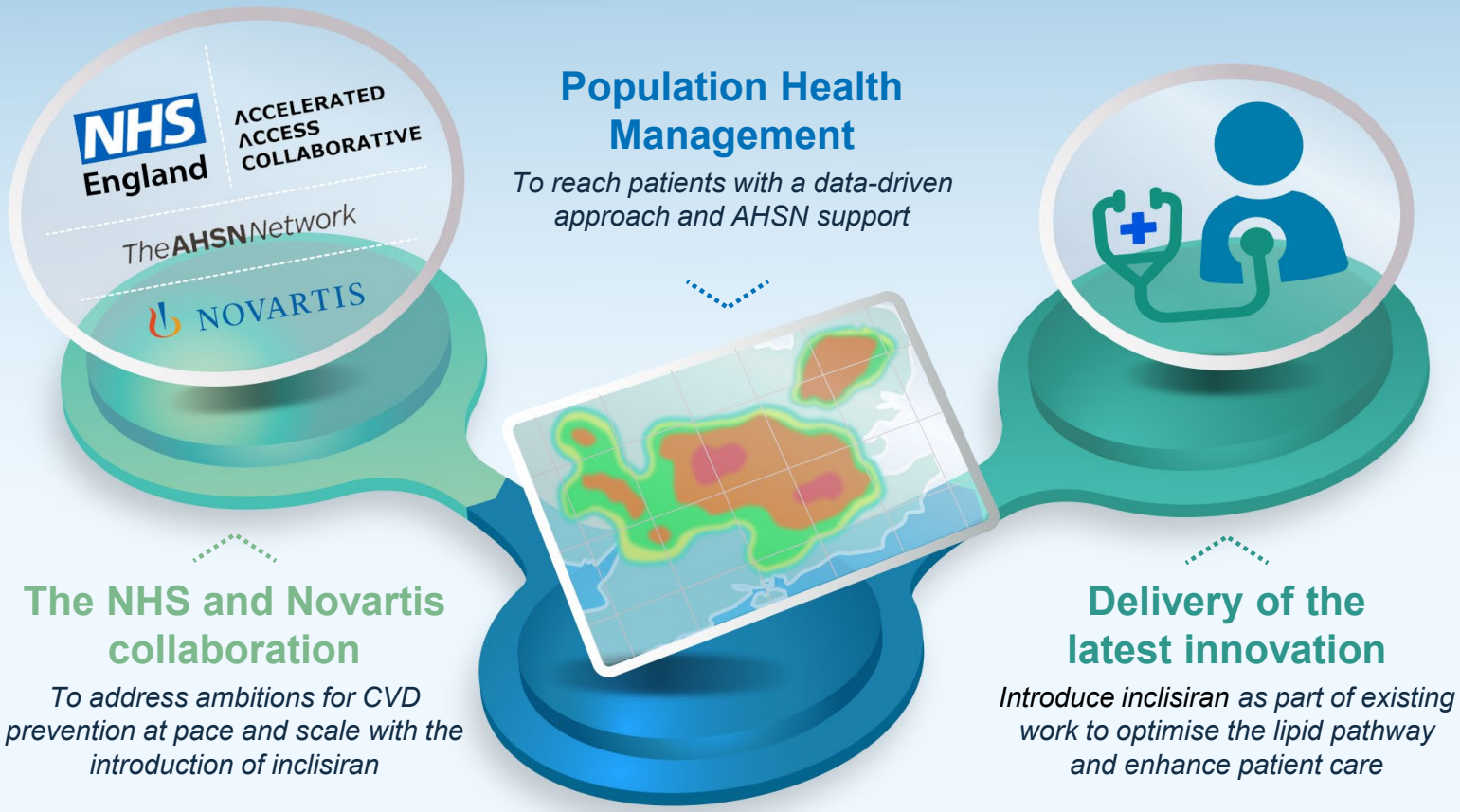
Discuss the opportunity presented by the collaboration on inclisiran to improve patient care

- in CVD prevention
- in delivering innovation into the NHS at pace and scale

Discuss how primary care, secondary care and Academic Health Science Networks (AHSN) can collaborate to bring inclisiran, as an innovation, to patients through a Population Health Management approach

Understand what the next steps could be within your organisation are, to embed this latest innovation in the lipid management pathway and deliver benefit to patients

NHS England and Novartis collaboration: delivering rapid access to innovation as part of the NHS Long Term Plan



Population Health Management

To reach patients with a data-driven approach and AHSN support

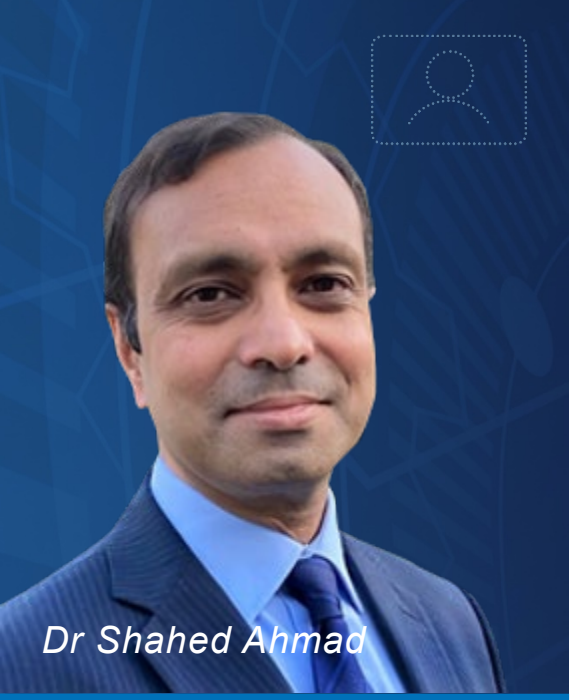
The NHS and Novartis collaboration

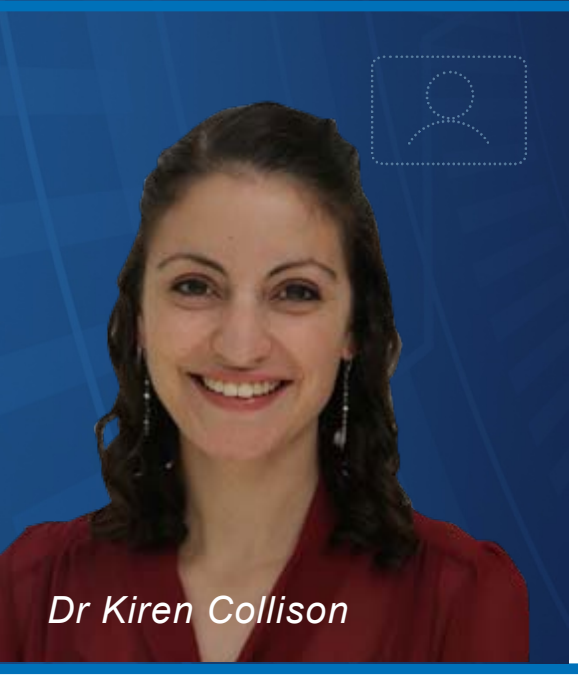
To address ambitions for CVD prevention at pace and scale with the introduction of inclisiran

Delivery of the latest innovation

Introduce inclisiran as part of existing work to optimise the lipid pathway and enhance patient care

This framework provides a blueprint for the launch of new treatments that meet the large-scale needs of health systems and patients





ACCELERATED ACCESS COLLABORATIVE

2

Addressing the NHS Long Term Plan ambitions for CVD prevention

Dr Shahed Ahmad

National Clinical Director for Cardiovascular Disease Prevention at NHS England and Improvement

Dr Kiren Collison

Deputy Medical Director for Primary Care, NHS England and Improvement

ACCELERATED ACCESS COLLABORATIVE

Why is CVD prevention a national priority?

CVD kills 136,000 people a year

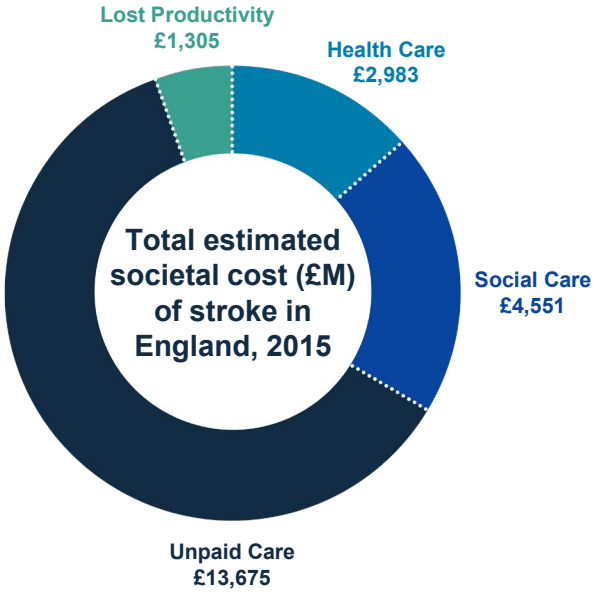
CVD differentially targets ethnic minority communities

CVD differentially targets deprived communities

As well as death, CVD can cause significant disability

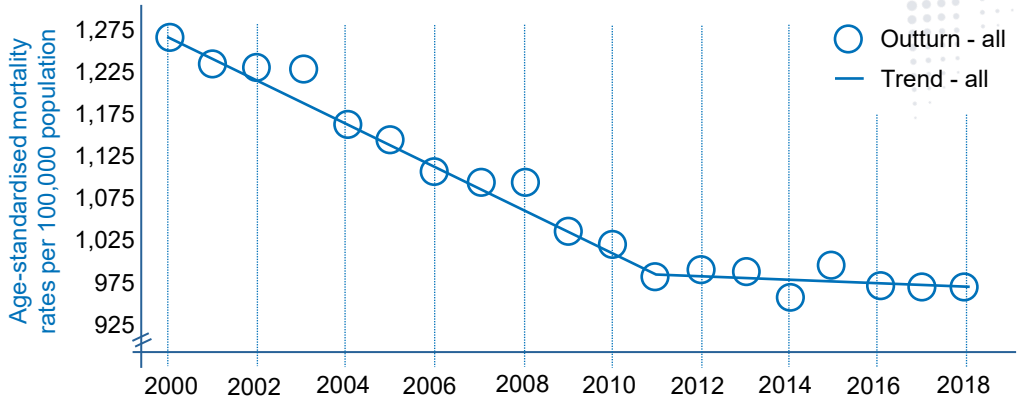
CVD can be prevented

Stroke is the largest cause of adult disability



Source: Stroke Association. Current, future and avoidable costs of stroke.

The changed trend in mortality rate improvements: England and Wales 2000-2018



CVD is expensive

£7.4 billion

CVD healthcare costs estimate

£15.8 billion

CVD economic costs estimate

Source: BHF analysis of European Heart Network (2017) European Cardiovascular Disease Statistics 2017.

ACCELERATED ACCESS COLLABORATIVE

Inclisiran works differently from other low density lipoprotein cholesterol (LDL-C) lowering therapies, by preventing the production of the PCSK9 protein in the liver, increasing hepatic LDL-C uptake and reducing LDL-C levels in the bloodstream

inclisiran "silences" the *PCSK9* gene

inclisiran prevents the PCSK9 protein from being made

Normal role of the PCSK9 enzyme:

- Binds to LDL-C receptors and blocks them from binding to LDL-C in the bloodstream
- Moves the receptors into the liver cell and decreases total number of LDL-C receptors

- LDL-C receptors are no longer blocked, and can clear LDL-C from the bloodstream
- The number of LDL-C receptors on the surface of the liver cell can increase again

ACCELERATED ACCESS COLLABORATIVE

NICE recommendation for inclisiran

On 1st September NICE has issued Final Appraisal Document (FAD) for inclisiran.

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:

- **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
- **LDL-C concentrations are persistently 2.6 mmol/L or more, despite maximum tolerated lipid lowering therapy**

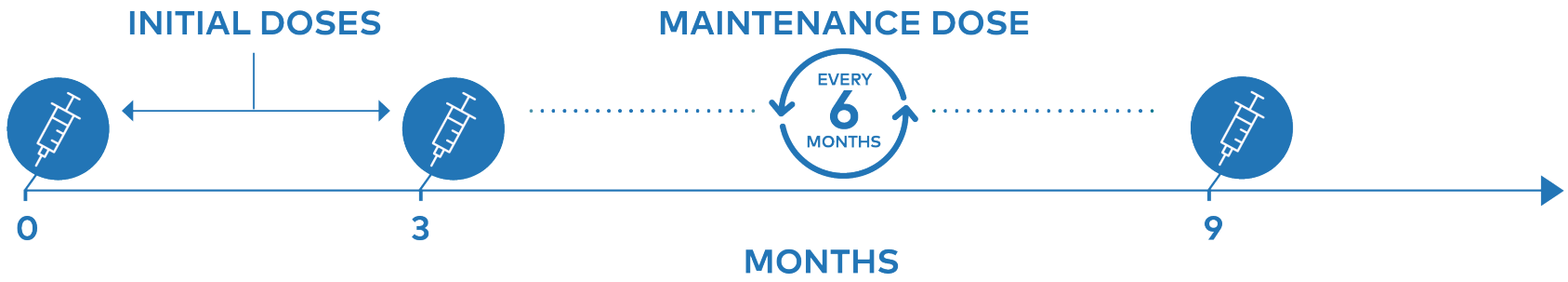
Inclisiran can be initiated in both primary and secondary care.

See slide 20 for prescribing information and adverse event reporting information.

ACCELERATED ACCESS COLLABORATIVE

Dosing and administration for inclisiran

- The recommended dose is 284 mg inclisiran administered as a single subcutaneous injection using a single-use, pre-filled syringe
- Inclisiran is administered via twice-yearly injections, administered by a qualified healthcare professional
- After an initial dose, inclisiran is administered again at 3 months, followed by every 6 months
- No dose adjustments are required for patients with mild or moderate hepatic impairment,* mild, moderate or severe renal impairment or end-stage renal disease,† or elderly patients
- Inclisiran has a 3-year shelf life
- It does not require any special storage conditions, but should not be frozen
- The solution should be clear, colourless to pale yellow and essentially free of particulates. If the solution contains visible particulate matter, the solution should not be used



* No data are available in patients with severe hepatic impairment. Inclisiran should be used with caution in these patients.
† There is limited experience with inclisiran in patients with severe renal impairment. Inclisiran should be used with caution in these patients. The effect of haemodialysis on inclisiran pharmacokinetics has not been studied. Haemodialysis should not be performed for at least 72 hours after inclisiran dosing.

Ordering and prescribing options for inclisiran

ACCELERATED ACCESS COLLABORATIVE

Prescriptions for inclisiran will be part-funded from a central NHSEI budget, enabling pro-active use in primary care

	Primary care FP34D (Proactive model)	Primary care FP10 (Reactive model)	Secondary care initiated: FP10HNC
Stock ordering	Stock ordered by general practice direct from wholesaler (AAH)	Retail chemist or dispensing GP practice order stock from AAH	Hospital pharmacy orders direct from Novartis Customer Care team
Patient identified for treatment	Patients identified through routine care and case finding in a primary care setting	Patient identified through routine care. Prescription generated in primary care	Patients identified through routine care by the hospital specialist team
Inclisiran administration	Administered by the primary care team	Administered by the primary care team or by community pharmacy	Administered in secondary care or via a request to the GP
Options for provider funding	Cost to primary care = £45. Drug tariff price = £55. Other fees may be claimable e.g. dispensing fee, personally administered item (PAI) fee	Cost to primary care = £45. Drug tariff price = £55. Other fees may be claimable e.g. dispensing fee	N/A
Budget impact	Drug tariff price added to commissioner and general practitioner (GP) prescribing budget	Drug tariff price added to commissioner and GP prescribing budget	Inclisiran negotiated confidential contract price is added to the Trust budget
Prescription charge	No patient prescription fee	Patient liable to pay for prescription	No patient prescription fee

FP34 route for ordering and reimbursement of inclisiran

ACCELERATED ACCESS COLLABORATIVE

Eligible patients are identified by primary care network (PCN) or General Practice in line with NICE guidance

Inclisiran is ordered directly to the practice at a cost of £45.* Pack size of one pre-filled syringe

Patients are called for assessment and treatment optimisation

A decision to administer the first dose of inclisiran† is taken in line with NICE guidance

At the end of the month, practice team adds inclisiran usage to the FP34D submission to NHS Business Services Authority and is reimbursed at the drug tariff price of £55‡

Inclisiran from Novartis, funded by NHS England, is available to all pharmacies and GPs for prescribed patients. Available to order for same day or next delivery from your local AAH branch, you can order inclisiran using AAH Point or your Patient Medication Record (PMR) system using the following codes:

Product Name	EAN Code	PIP Code
Inclisiran (Leqvio)	7613421044237	4174751

If you need any further support regarding inclisiran, please contact AAH Customer Care.
You can live chat with via AAH Point from 9am-5pm Monday to Friday or call us on 0344 5618899.

* Alternatively, inclisiran can be dispensed via an FP10
† After an initial dose, inclisiran is administered again at 3 months, followed by every 6 months
‡ Further information on FP34D can be found at https://www.nhsbsa.nhs.uk/nhs- prescription-services.

ACCELERATED ACCESS COLLABORATIVE

3

Live panel discussion

Dr Kiren Collison (Chair)

Deputy Medical Director for Primary Care, NHS England and Improvement

Dr Tracey Vell MBE

Clinical Director, Health Innovation Manchester (the AHSN for Greater Manchester)

Dr Jaimini Cegla

Consultant in Metabolic Medicine, Imperial College Healthcare NHS Trust

Dr Phil Jennings

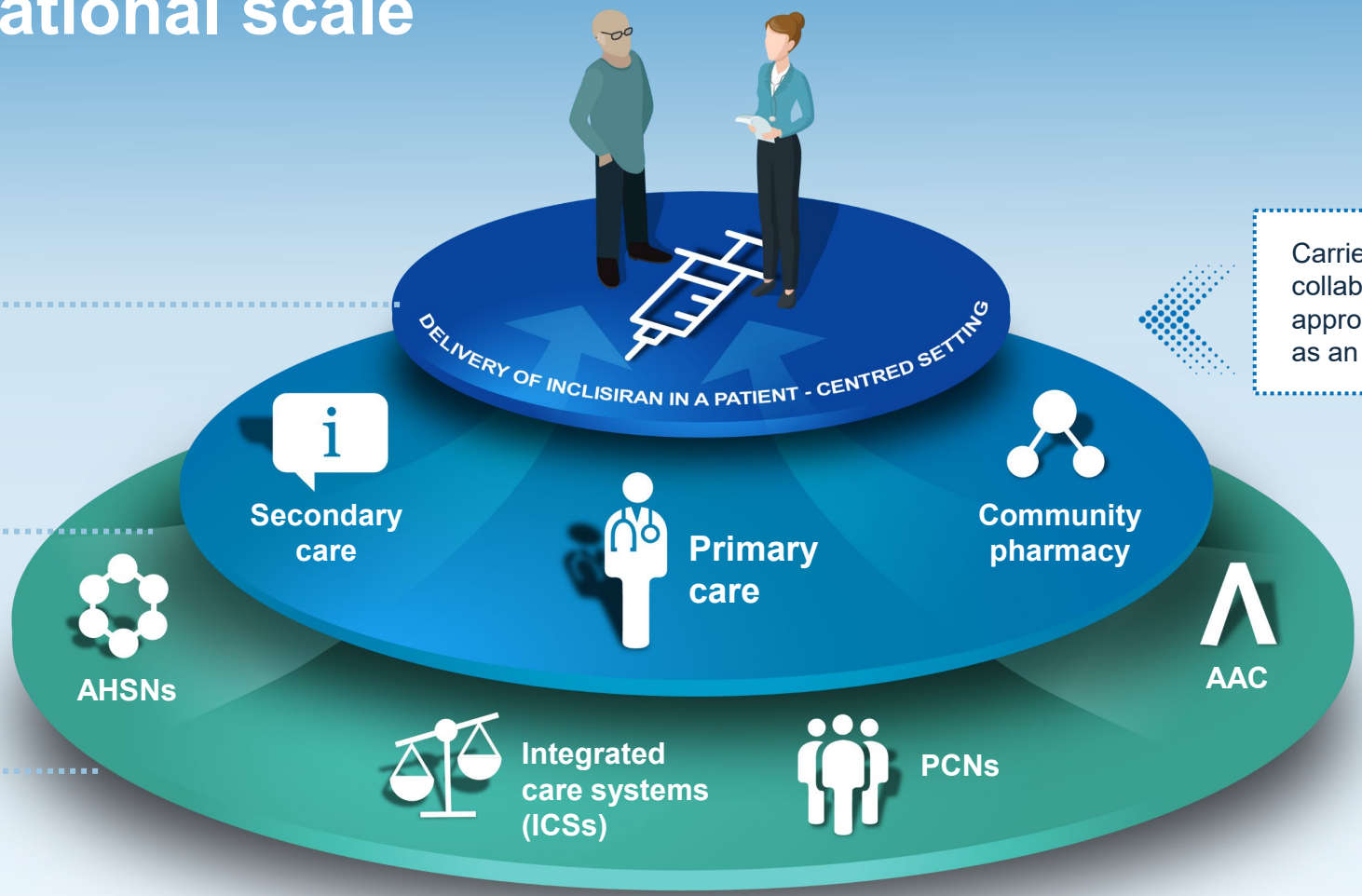
Chief Executive, Innovation Agency (the AHSN for the North West Coast) and AHSN Network Lead for the Rapid Uptake Products

A collaborative effort within each locality to implement inclisiran and deliver impact at national scale

Delivery to patients

Delivery partners

System enablers



Carried out through a collaborative cross-sector approach including inclisiran as an option

ACCELERATED ACCESS COLLABORATIVE

4

Q&A

Matt Whitty

Director of Innovation Research and Life Sciences at NHS England and Improvement, and CEO of the AAC

Dr Phil Jennings

Chief Executive, Innovation Agency (the AHSN for the North West Coast) and AHSN Network Lead for the Rapid Uptake Products

Dr Kiren Collison

Deputy Medical Director for Primary Care, NHS England and Improvement

Dr Jaimini Cegla

Consultant in Metabolic Medicine, Imperial College Healthcare NHS Trust

Fiona Bride

Director of Market Access, Novartis Pharmaceuticals UK Ltd

Dr Tracey Vell MBE

Clinical Director, Health Innovation Manchester (the AHSN for Greater Manchester)

5

Closing remarks

Matt Whitty

Director of Innovation Research and Life Sciences at NHS England and Improvement, and CEO of the AAC

ACCELERATED ACCESS COLLABORATIVE

Next steps after today's event

Find out more about the inclisiran Final Appraisal Document online here: https://www.nice.org.uk/guidance/gidta10703/documents/final-appraisal-determination-document

Speak to your local AHSN for more information on optimising the lipid management pathway in your region: https://www.ahsnnetwork.com/about-academic-health-science-networks

Start speaking to colleagues in your PCN and ICS to see what's happening locally on lipid management

ACCELERATED ACCESS COLLABORATIVE

Stay up to date – scan the QR codes below

Access the slides and a recording of this meeting

https://healthinnovationmanchester.com/resources-aac-lipid-management/

Access the Virtual Town Hall event survey and provide your feedback

https://forms.office.com/Pages/ResponsePage.aspx?id=kp4VA8ZyI0umSq9Q55Ctv4sjksTnxptCjNwaq0eiESRUN0ZMSFdCU0dXQVpGUlBLUk05UzcyMVFMNy4u

Access the Novartis website to find out more about inclisiran and sign up to receive email communications

https://www.health.novartis.co.uk/authentication/register

This link will take you to a Novartis promotional website which contains updates on inclisiran.

For more information email: england.lipidsPHM@nhs.net

ACCELERATED ACCESS COLLABORATIVE

Licensed indication

Inclisiran is indicated in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet:

- in combination with a statin or statin with other lipid-lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin, or
- alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated

Inclisiran is now available to prescribe in England.

LDL-C – low-density lipoprotein cholesterol

See slide 20 for prescribing information and adverse event reporting information.

ACCELERATED ACCESS COLLABORATIVE

Prescribing information

LEQVIO®▼ (inclisiran)
Important note: Before prescribing, consult the Summary of Product Characteristics (SmPC).
Presentation: Pre-filled syringe containing inclisiran sodium equivalent to 284 mg inclisiran in 1.5 ml solution. **Indication(s):** Leqvio is indicated in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet: - in combination with a statin or statin with other lipid lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin, or - alone or in combination with other lipid lowering therapies in patients who are statin intolerant, or for whom a statin is contraindicated. **Dosage and administration:** The recommended dose is 284 mg inclisiran administered as a single subcutaneous injection: initially, again at 3 months, followed by every 6 months. *Missed doses:* If a planned dose is missed by less than 3 months, inclisiran should be administered and dosing continued according to the patient's original schedule. If a planned dose is missed by more than 3 months, a new dosing schedule should be started – inclisiran should be administered initially, again at 3 months, followed by every 6 months. *Treatment transition from monoclonal antibody PCSK9 inhibitors:* inclisiran can be administered immediately after the last dose of a monoclonal antibody PCSK9 inhibitor. To maintain LDL C lowering it is recommended that inclisiran is administered within 2 weeks after the last dose of a monoclonal antibody PCSK9 inhibitor. *Special populations:* No dose adjustment required for patients with mild or moderate hepatic impairment, mild, moderate or severe renal impairment or end-stage renal disease (use with caution in severe renal impairment) or elderly patients. *Administration:* Subcutaneous injection into abdomen (alternatively, the upper arm or thigh). Injections should not be given into areas of active skin disease or injury such as sunburns, skin rashes, inflammation or skin infections. inclisiran is intended for administration by a healthcare professional. **Contraindications:** Hypersensitivity to active ingredient or any of the excipients. **Warnings/Precautions:** *Haemodialysis:* The effect of haemodialysis on inclisiran pharmacokinetics has not been studied. Considering that inclisiran is eliminated renally, haemodialysis should not be performed for at least 72 hours after inclisiran dosing. **Interactions:** inclisiran is not a substrate for common drug transporters and, although *in vitro* studies were not conducted, it is not anticipated to be a substrate for cytochrome P450. inclisiran is not an inhibitor or inducer of cytochrome P450 enzymes or common drug transporters. Therefore, inclisiran is not expected to have clinically significant interactions with other medicinal products. Based on the limited data available, clinically meaningful interactions with atorvastatin, rosuvastatin or other statins are not expected. **Fertility, pregnancy and lactation:** *Pregnancy:* No or limited data available from the use of inclisiran in pregnant women. Animal studies do not indicate any harmful effects with respect to reproductive toxicity. As a precautionary measure, it is preferable to avoid the use of inclisiran during pregnancy. *Breast feeding:* It is unknown whether inclisiran is excreted in human milk. Data in animals have shown excretion of inclisiran in milk. A risk to newborns/infants cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from inclisiran therapy, taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman. *Fertility:* No data on the effect of inclisiran on human fertility are available. Animal studies did not show any effects on fertility. **Undesirable effects:** Common (≥1/100 to <1/10): adverse reactions at injection site including site reaction, pain, erythema and rash. All reactions were mild or moderate in severity, transient and resolved without sequelae. *Other Adverse Effects:* Please consult the Summary of Product Characteristics for a detailed listing of all adverse events before prescribing. **Legal classification:** POM **Marketing Authorisation (MA) number, quantities and price:** EU/1/20/1494/001 Leqvio 284mg pre-filled syringe £1987.36 (ex. VAT) per pack (1 pre-filled syringe). **Date of last revision of prescribing information:** January 2021 (ID 105123) **Full Prescribing Information available from:** Novartis Pharmaceuticals UK Limited, 2nd Floor, The WestWorks Building, White City Place, 195 Wood Lane, London, W12 7FQ. Telephone: (01276) 692255.

Adverse Event Reporting: Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Novartis via uk.patientsafety@novartis.com or online through the pharmacovigilance intake (PVI) tool at www.report.novartis.com
If you have a question about the product, please contact Medical Information on 01276 698370 or by email at medinfo.uk@novartis.com

ACCELERATED
ACCESS
COLLABORATIVE

6

Thank you for your time

This meeting has now finished

For additional support, please contact:
england.lipidsPHM@nhs.net

Today’s slides and FAQ will be shared with you after the event