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AAC Town Hall Event

Sharing early learning: a population health approach to innovation in lipid management

15 December 2021 | ***The meeting will start at 12:00pm and will be recorded***

See slide 24 for prescribing information and adverse event reporting information

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1

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

Jenny Turton

Deputy Director of Innovation Research and Life Sciences at NHS England and Improvement

Disclaimer: NHS England and Improvement is working with Novartis Pharmaceuticals UK Ltd as part of a collaboration which includes resources in the form of funding, skills, expertise, project management and administrative support. Ownership of the agenda and content of this meeting is the responsibility of NHS England and Improvement, and Novartis has had no input into its development. Novartis has checked the associated materials against the relevant guidance or codes, as applicable.

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1

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

Prof.Julia Newton

Medical Director, Academic Health Science Network for the North East and North Cumbria

Julia Newton

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Agenda

Topics

Presenters

	Topics	Presenters
1	**Welcome and introduction**	Jenny Turton and Prof.Julia Newton
2	**VICTORION-SPIRIT** **Early insights from the process evaluation**	Paul Wilson
3	**Affinity Care PCN: Adopting inclisiran▼* into primary care lipid management**	Dr Matt Fay, Dr Rani Khatib, Dr Mahmoud Khodadi
4	**AHSN Network: Early learnings on introducing a novel approach to lipid management**	Adele Bunch, Yorkshire & Humber AHSN Julia Reynolds, Innovation Agency (AHSN for the North West Coast) Nick Clarke, Eastern AHSN
5	**Q&A**	AHSNs, Paul Wilson, Sue Critchley, Dr Phil Jennings
6	**Closing remarks**	Julia Newton

*see Prescribing Information - slide 24

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Objectives of today's event

Learn the latest from the VICTORION-SPIRIT study – hear some early insights from patients

Hear from a PCN and the Academic Health Science Networks (AHSN) on their early experiences on introducing inclisiran, as an innovation to lipid management for patients through a Population Health Management approach

Provide you with an opportunity to reflect on these experiences and how you could embed these practices locally, to help embed this latest innovation in the lipid management pathway and deliver benefit to patients

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2

VICTORION-SPIRIT

Early insights from the process evaluation

Paul Wilson

Senior Lecturer, Centre for Primary Care and Health Services Research, University of Manchester

Implementation Science research theme lead, NIHR Applied Research Collaboration Greater Manchester

VICTORIAN -SPIRIT is a Novartis-sponsored implementation research study designed to provide and assess evidence for the implementation of inclisiran within a primary care setting in the NHS. See clinicaltrials.gov for further information https://clinicaltrials.gov/ct2/show/NCT04807400

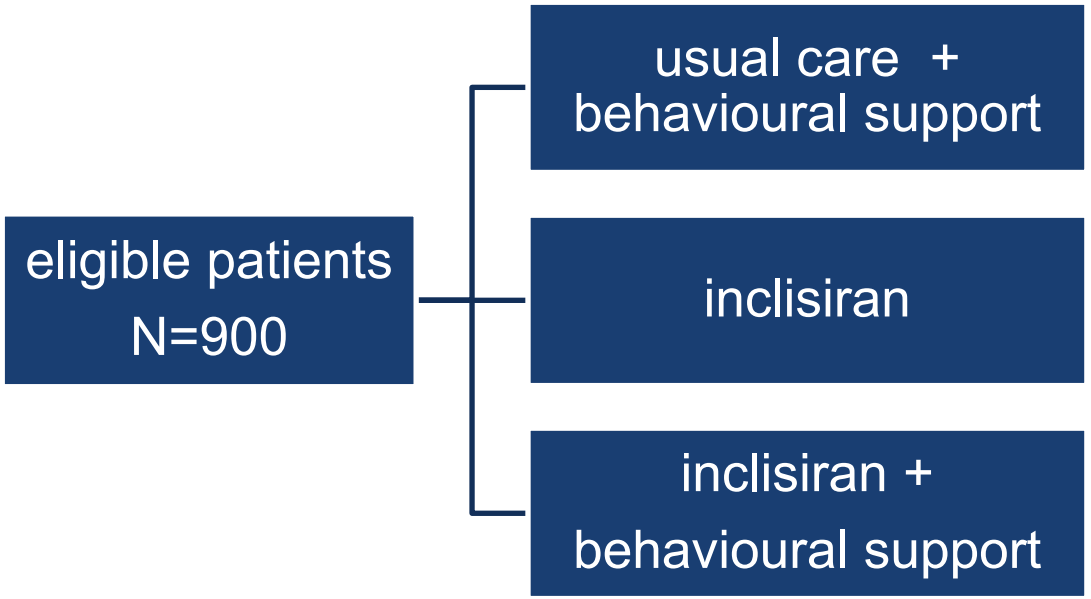
VICTORION-SPIRIT

Early insights from the ongoing process evaluation

Paul Wilson (Bec Elvey and Amy Mathieson)
Centre for Primary Care and Health Sciences Research , University of Manchester
NIHR ARC Greater Manchester

Contact: paul.wilson@manchester.ac.uk

Testing inclisiran +/- support vs enhanced primary care



Primary outcome
LDL cholesterol reduction

Secondary outcomes
Patient satisfaction, activation and empowerment, treatment burden

Process evaluation

Note: inclisiran is currently live in the health system and SPIRIT is intended to complement roll-out

Role of process evaluation in applied health research

- Better understand the effects of innovations within the real world conditions and populations
- Early identification of barriers and enablers to understand how innovations can be successfully implemented to inform wider uptake and spread
- Produce ‘actionable evidence’ to support decision making on the commissioning and uptake of innovations more widely

VICTORION-SPIRIT process evaluation

- What are the barriers and enablers to integrating inclisiran delivery within primary care
- What are the views and experiences of those delivering and receiving inclisiran
- Identify ‘core enabling ingredients’ to inform wider delivery of inclisiran across the NHS

Early insights ahead of outcomes

- Recruitment and engagement
- Treatment experience
- Treatment acceptability
- Experience of behavioural support

Recruitment & engagement

- Data derived from 32 patients from 10 GP practices across five localities in Greater Manchester
- All trial participants have consented to be contacted for interviews
- Only two have declined to take part in an interview.
- All have been engaged and willing to share their experience with the research team.
- 16 randomised to Group 2 and 16 to Group 3 (enhanced behavioural support)

Experience

- Arranging and attending appointments was straightforward and convenient
- Patients familiar with their GP surgery – know the staff, often live nearby so most convenient place to have the injection, and felt comfortable doing so
- Appointments mostly matched expectations
- For those patients concerned about receiving the treatment, most sought reassurance from the research nurses, trusted GPs, the internet, or PIS.
- Positive representation of NICE recommendations in the media

Acceptability

- Differing views on need for the intervention. Some people are happy to take statins and most said having high cholesterol has not affected them
- Experience of receiving the injection was good overall (no unexpected side effects, some discomfort but not as bad as feared) – similar to the flu and covid jabs
- Receiving blood test results immediately was helpful
- Most barriers highlighted relate to trial conduct - long appointments and often long waits; number of people in room
- Some patients think delivery would work better (quicker) as a practice nurse-led service

Enhanced behavioural support

- Most reporting very positive experiences and happy with the frequency/ length of calls
- Some initial apprehension about being ‘told what to do’ and ‘didn’t want to stop enjoying life’ but this was eased by the calls – find the approach flexible, not prescriptive
- Generally familiar with the concepts but appreciate the individual, tailored support
- Good rapport with coaches: “like talking to a friend” like having “a personal trainer” – moral support and “useful talking it through”
- Informative – printed materials are useful and coaches knowledgeable

Next steps

- Complete patient interviews
- Professional interviews with participating practice staff
  - perceptions about relative advantage of inclisiran
  - how delivery is understood and compares with existing practices
  - how delivery is locally adapted and translated into practice
  - acceptability and perceived sustainability of patient identification
  - barriers and enablers (and any unintended consequences) to implementation
- Interviews with implementation leads beyond the trial setting
- Capture and assess service costs

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Affinity Care PCN: Adopting Inclisiran into primary care lipid management

Prof.Julia Newton

Medical Director, Academic Health Science Network for the North East and North Cumbria

Dr Matt Fay

GP Principal,The Willows Medical Practice, and Clinical Chief Executive, Affinity Care PCN

Dr Rani Khatib

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

Dr Mahmoud Khodadi

Chief Pharmacist & Partner, Affinity Care PCN

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4

AHSN Network: Sharing early learnings on introducing a novel approach to lipid management

Prof. Julia Newton

Medical Director, Academic Health Science Network for the North East and North Cumbria

Adele Bunch

Programme Manager, Yorkshire & Humber AHSN

Julia Reynolds

Associate Director of Transformation, Innovation Agency (AHSN for the North West Coast)

Nick Clarke

Principal Advisor, Eastern AHSN

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Q&A

Prof. Julia Newton

Medical Director, Academic Health Science Network for the North East and North Cumbria

All previous speakers to be joined by:

Dr Phil Jennings

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

Sue Critchley

National Lipids Programme Education Lead (AHSN network)

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5

Closing remarks

Prof. Julia Newton

Medical Director, Academic Health Science Network for the North East and North Cumbria

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Next steps after today's event

See the inclisiran Technology appraisal guidance [TA733] online here:

https://www.nice.org.uk/guidance/ta733

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

Reflect on the experiences you have heard today and how you could start to translate this locally.
Start speaking to colleagues in your PCNs and ICSs to see what's happening locally on lipid management.

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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/r/FN0Zkar1aE

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

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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.

* See slide 24 for prescribing information and adverse event reporting information.
** LDL-C – low-density lipoprotein cholesterol

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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

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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