

Kent Surrey Sussex
Academic Health Science
Network

Next Level

gammaCore
Spread and Adoption

Presenter /
Dr. Charlotte Roberts

Date /
8 June 2022



Agenda

- Introductions
- Recap: cluster headache and gammaCore
- Spread through AHSNs and national programmes
- Innovator journey
- What next
- Summary



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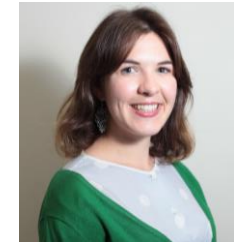
Mike Howard
IT Product Manager



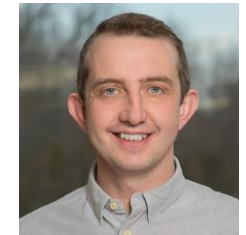
Rebecca Stuckey
Specialist Headache Nurse
Derriford Hospital



Dr. Charlotte Roberts
Senior Programme
Manager/AHSN Product Lead
2019-date



Iain Strickland PhD
Senior Vice President,
Global Sales & Strategy



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Recap: Cluster headache and gammaCore

Mike's experience

*'Really interferes
with my day-to-
day life'*

*'Punch me,
scratch me'*

*'Cumbersome
oxygen tank, not
practical'*

*'Tried many
solutions –
official and
unofficial'*



Cluster headache: a severely debilitating condition



Mainly behind or around the eye⁷

Often at the same time of day or night²

Typically lasting between 15 to 180 minutes⁷

Often at the same time of year²

Reddening and tearing of the eye

Droopy / puffy eyelid

Tinnitus and a feeling of pressure or fullness in the ears

Constricted pupil

A runny or blocked nostril

Flushing and facial sweating

Can be episodic or chronic⁴

Profoundly affects a person's quality of life⁵

Costs the NHS over £40,000,000 per year to manage⁶

1. Ouch UK Cluster Headache – The Basics. 2. Rozen, T., Fishman, R. Cluster Headache in the USA: Demographics, Clinical Characteristics, Triggers, Suicidality, and Personal Burden. Headache; 52: 99-113. 3. Torelli. Pain and behaviour in cluster headache. A prospective study and review of the literature. Funct Neurol. 2003 Oct-Dec;18(4):205-10. 4. OUCH UK Cluster Bout. 5. NHS Choices. Cluster Headaches. 6.MTFM policy guidance. 7 OUCH Uk. Cluster Attack. 8. Wei DY, et al. Managing cluster headache. Pract Neurol. 2019 Dec;19(6):521-528. 9 OUCH UK What is Cluster Headache



Challenge & solution

- **Current standard care:**
 - Prevention: lithium, corticosteroids, verapamil. Treatment: triptans, O₂
 - Invasive treatments; occipital nerve stimulator implant, deep brain stimulation
- **For up to 25% of patients, standard care will not work/be unsuitable**
 - Many limited by side effects and contraindications
 - Significant health burden, cost and distress to patients and families
- **gammaCore: non-invasive vagus nerve stimulator for preventing and treating cluster headaches**
 - Small, portable, handheld, patient-controlled
- **Applied to the neck to deliver a small electric current for 2 mins**
 - Modifies pain signals by stimulating vagus nerve
 - Used daily to help prevent headache or when a headache begins, anywhere, as many times/day as needed
- **An option before invasive options/lithium considered**
 - Avoids invasive treatments
 - Avoids use of unlicensed medications (ECG/blood) with serious side effects



Key benefits



- Safe, well-tolerated, non-pharmacological licensed treatment for reducing frequency, severity, duration
- Used preventatively/acutely, multiple times/day
- Non-invasive, handheld, self-administered, portable, reloadable, rechargeable
- No clinical monitoring required, can be used alongside existing medications



- Reduces triptan and O₂ use
- Cost-savings; reduced monitoring (ECG/blood), A&E/hospital, neurosurgery
- Financial model dependent on how individual is treated locally.
- Anecdotal evidence; staying in employment, coming off benefits
- >80 IFRs pre-ITP; real life examples £2000 → £18000/yr.



- Reduced monitoring associated with other medications (ECGs, blood)
- No additions to the way current services are organised / delivered.
- Training by supplier



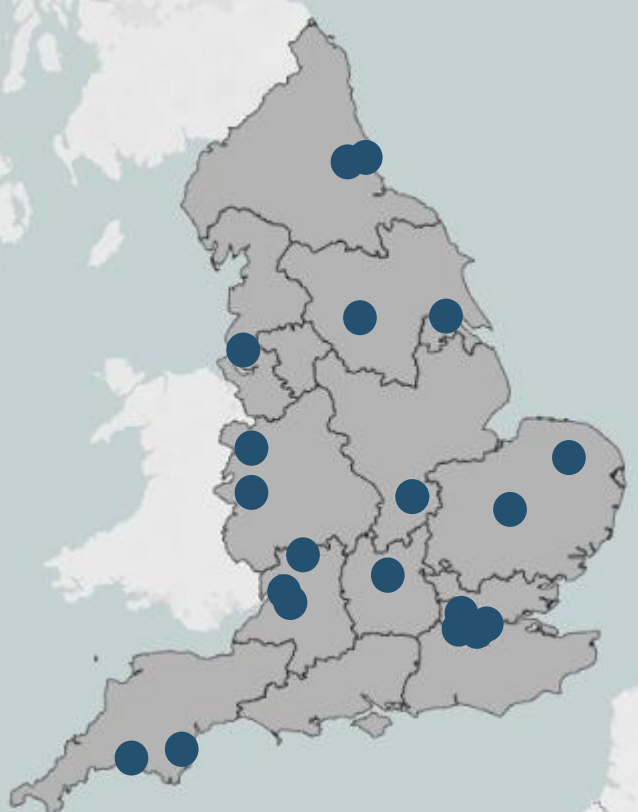
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**Spread through AHSNs
and national programmes**



2019 baseline uptake:



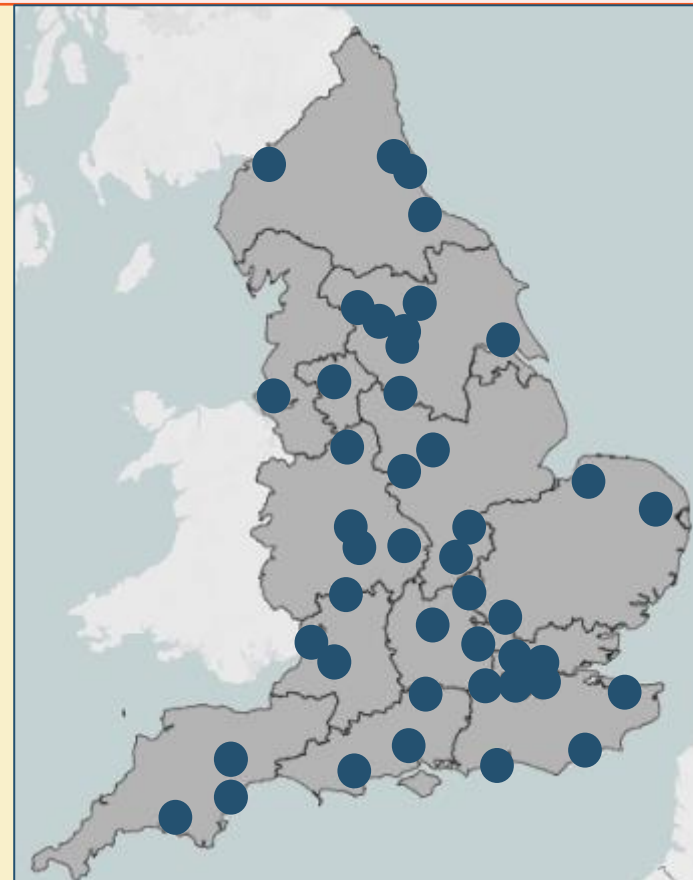
Nationally		UK and Internationally
<p>Cambridge University Hospitals NHS Foundation Trust City Hospitals Sunderland NHS Foundation Trust Gateshead Health NHS Foundation Trust Gloucestershire Hospital NHS Foundation Trust Guy's and St Thomas' NHS Foundation Trust Hull & East Yorkshire Hospitals NHS Trust Imperial College Healthcare NHS Trust Kings College Hospital NHS Foundation Trust Norfolk and Norwich University Hospitals NHS Foundation Trust North Bristol NHS Trust Northampton General Hospital NHS Trust Oxford University NHS Foundation Trust Plymouth Hospitals NHS Trust Royal United Hospitals Bath NHS Foundation Trust St George's Hospital The Mid Yorkshire Hospitals NHS Trust The National Hospital for Neurology and Neurosurgery The Walton Centre NHS Foundation Trust Torbay and South Devon NHS Foundation Trust University Hospitals Birmingham NHS Foundation Trust University Hospitals of North Midlands NHS Trust</p>		<p>Scotland USA Germany (licensed in EU, Australia & Canada)</p>

2022 ITP/MTFM uptake:

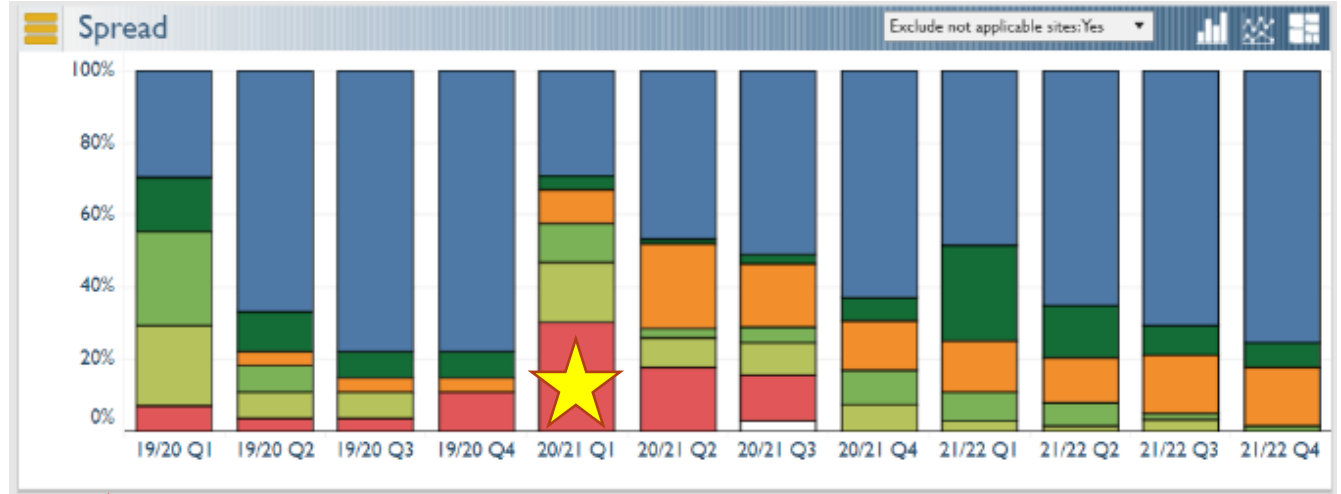
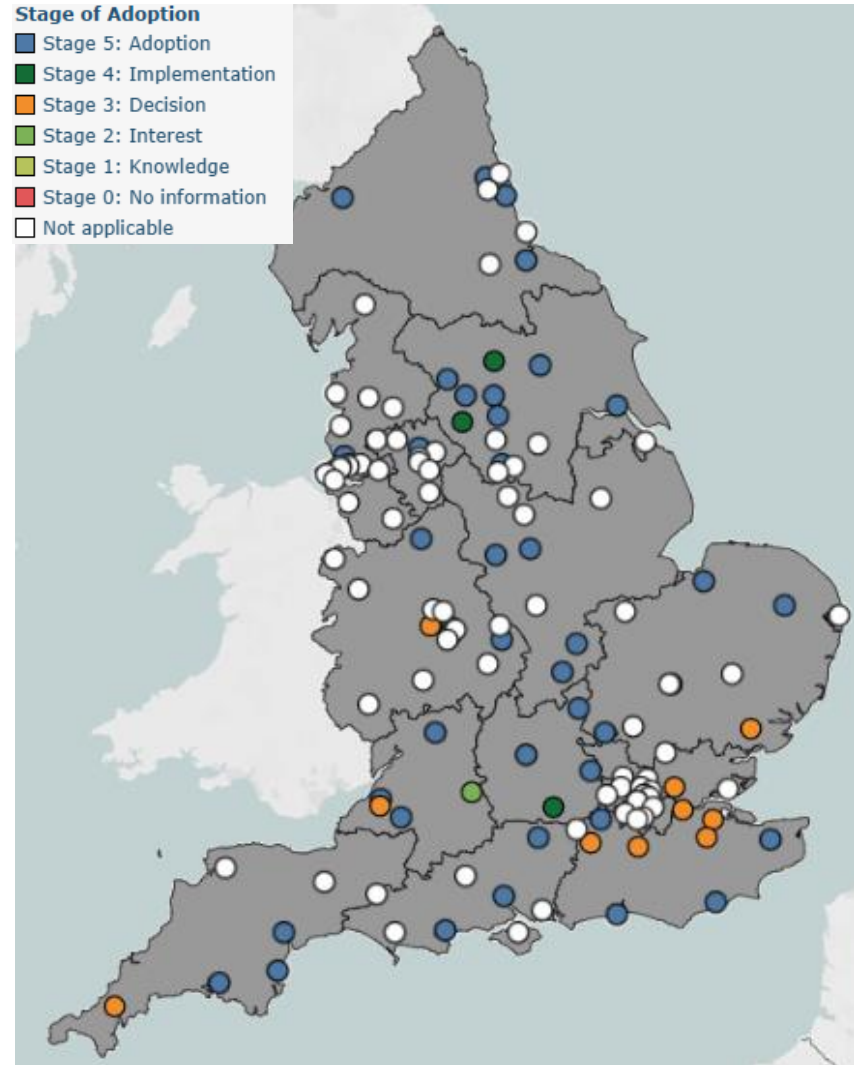
(as of 1st June 2022)



Nationally		UK and Internationally
<p>Ashford & St Peter's Hospitals NHS Foundation Trust</p> <p>Bedfordshire Hospital NHS Foundation Trust</p> <p>Bradford Teaching Hospitals NHS Foundation Trust</p> <p>Buckinghamshire Healthcare NHS Trust</p> <p>Cambridge University Hospitals NHS Foundation Trust</p> <p>City Hospitals Sunderland NHS Foundation Trust</p> <p>East Kent Hospitals University NHS Foundation Trust</p> <p>Exeter Headache Clinic</p> <p>Gateshead Health NHS Foundation Trust</p> <p>Gloucestershire Hospital NHS Foundation Trust</p> <p>Guy's and St Thomas' NHS Foundation Trust</p> <p>Hampshire Hospitals NHS Foundation Trust</p> <p>Hull & East Yorkshire Hospitals NHS Trust</p> <p>Imperial College Healthcare NHS Trust</p> <p>Kings College Hospital NHS Foundation Trust</p> <p>Leeds Teaching Hospitals NHS Trust</p> <p>Mid Yorkshire Hospitals NHS Trust</p> <p>Norfolk & Norwich University Hospitals NHS Foundation Trust</p> <p>North Bristol NHS Trust</p> <p>Northampton General Hospital NHS Trust</p> <p>Nottingham University Hospitals NHS Foundation Trust</p> <p>Oxford University NHS Foundation Trust</p> <p>Queen Elizabeth University Hospital</p> <p>Royal Cornwall Hospitals NHS Trust</p>	<p>Royal Devon and Exeter NHS Foundation Trust</p> <p>Royal United Hospitals Bath NHS Foundation Trust</p> <p>St George's University Hospitals NHS Foundation Trust</p> <p>Salford Royal NHS Foundation Trust</p> <p>Sandwell and West Birmingham NHS Foundation Trust</p> <p>Sheffield Teaching Hospitals NHS Foundation Trust</p> <p>South Tees Hospitals NHS Foundation Trust</p> <p>South Tyneside NHS Foundation Trust</p> <p>The Newcastle Upon Tyne Hospitals NHS Foundation Trust</p> <p>The National Hospital for Neurology and Neurosurgery</p> <p>The Queen Elizabeth Hospital King's Lynn NHS Foundation Trust</p> <p>The Royal Wolverhampton NHS Trust</p> <p>The Walton Centre NHS Foundation Trust</p> <p>Torbay and South Devon NHS Foundation Trust</p> <p>University College London Hospitals NHS Foundation Trust</p> <p>University Hospitals Birmingham NHS Foundation Trust</p> <p>University Hospitals Coventry & Warwickshire NHS Trust</p> <p>University Hospitals of Derby and Burton NHS Foundation Trust</p> <p>University Hospitals Dorset NHS Foundation Trust</p> <p>University Hospitals of North Midlands NHS Trust</p> <p>University Hospitals Plymouth NHS Trust</p> <p>University Hospitals Southampton NHS Foundation Trust</p> <p>University Hospitals Sussex NHS Foundation Trust</p> <p>York Teaching Hospital NHS Foundation Trust</p>	<p>Scotland</p> <p>Wales</p> <p>USA</p> <p>Germany</p> <p>Canada</p> <p>Lithuania</p> <p>Romania</p> <p>Latvia</p> <p>Belarus</p> <p>Kazakhstan</p> <p>Ukraine</p> <p>Belgium</p> <p>Luxembourg</p> <p>The Netherlands</p> <p>France</p> <p>Australia</p> <p>Qatar</p> <p>Cyprus</p> <p>United Arab Emirates</p> <p>Oman</p> <p>Saudi Arabia</p> <p>Bahrain</p>



Spread heatmap: gammaCore



★ NB: 20/21 Q1= trust eligibility categorisation changed



QART data nuances (up to 21/22 Q4)

133



- **46/137 reported as 'stage 5: adopted'**
 - 18/46 → 'commissioner funded'
 - 28/46 → 'provider funded'
- **4/137 reported as 'stage 4: implementation'**
 - Royal Berkshire Hospitals confirmed intent to adopt w/ internal processes to confirm finance route
 - Harrogate and District NHS FT prescribing (invoicing arrangements finalised)
 - Calderdale and Huddersfield NHS FT prescribing (invoicing arrangements finalised)
 - Imperial College Healthcare NHS Trust
- **1/37 reported as 'stage 2: interest'**
 - Great Western
- **77/137 reported as 'not applicable'**
 - 29/77 'refer to specialist centre in region'
 - 48/77 'no headache specialist at this trust'
- **10/137 reported as 'stage 3: decision'**
 - 1 since adopted
 - 6 'alternatives in place' could be 'ineligible: refer to specialist centre in region'
 - 5 KSS who refer to London (out of region)
 - Dudley Group refer to Queen Elizabeth Hospital (QEH) Birmingham: waiting lists (MyPlannedCare; 33 wks, NHS: '75 wks')
 - Dudley Group considering own headache service recruiting headache specialist consultant (09/2022).
 - 1 'no clinical need'
 - UHBW's neurology headache service runs NBT → AHSN advised 'ineligible: refer to specialist centre'
 - 2 'adoption ceased'
 - Barking Havering & Redbridge financial special measures affecting MTFM → escalating
 - East Suffolk reported incorrectly, → stage 4



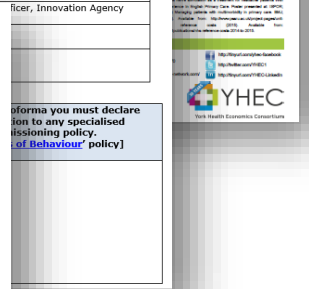
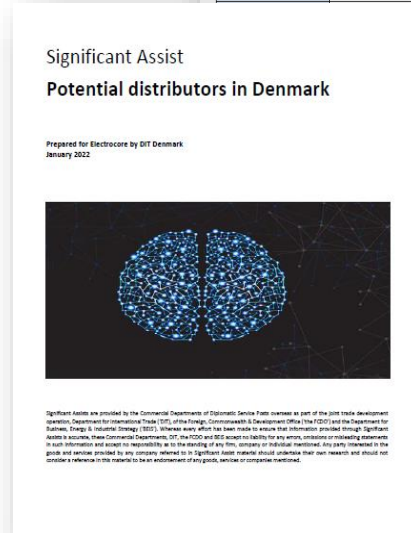
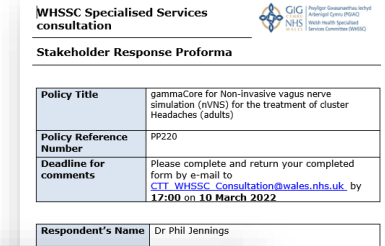
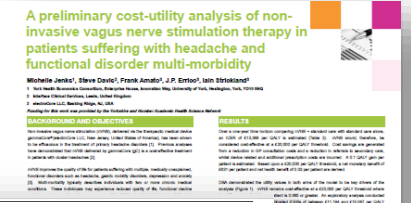


- **(MTFM related)**
- **‘Eligibility’ of sites**
 - ITP programme started with ‘eligible sites’ but after reviewing the policy/NICE guidance language we identified sites which should be engaged with (and reported on) to consider adoption.
- **‘Eligibility’ of prescribers**
 - During ITP/MTFTM multiple AHSNs reported hesitancy; *‘can I prescribe this? ‘What is ‘a headache specialist’*
 - ITP/ MTFM 21/22: *‘gammaCore™ prescribed by a **headache specialist** (in primary or secondary care)’*
 - NICE MTG 2019: *‘A doctor should decide if treatment has been successful after 3 months’*
- **CCG/finance concerns regarding savings**
 - Facilitating AHSNs/Finance Directors identifying savings; s/c vs oral triptans savings
- **Neurology outpatient waiting times and covid backlog**
 - Up to 75 weeks
- **Neurology workforce**
 - National shortage of neurology consultants



Other activity supporting gammaCore

- **Pre ITP; preliminary cost-utility analysis of non-invasive vagus nerve stimulation therapy in patients suffering with headache and functional disorder multi-morbidity**
 - Yorkshire & Humber AHSN funded study with YHEC
- **Proposed Policy Position Statement for gammaCore for Welsh residents**
 - Welsh Health Specialised Services Committee consultation; equity of access
 - AHSN and NHS E&I formal response arranged and submitted via AHSN Product Lead
- **Supporting gammaCore spread through international connections & networks**
 - ‘Significant Assist’
 - Trade Adviser, Technology & Health Innovation Lead’s report:
 - Suggestions for potential partner distributors in Denmark
 - Details on hospital neurology clinics
 - Links to Denmark’s public procurement system
 - Overview of tenders

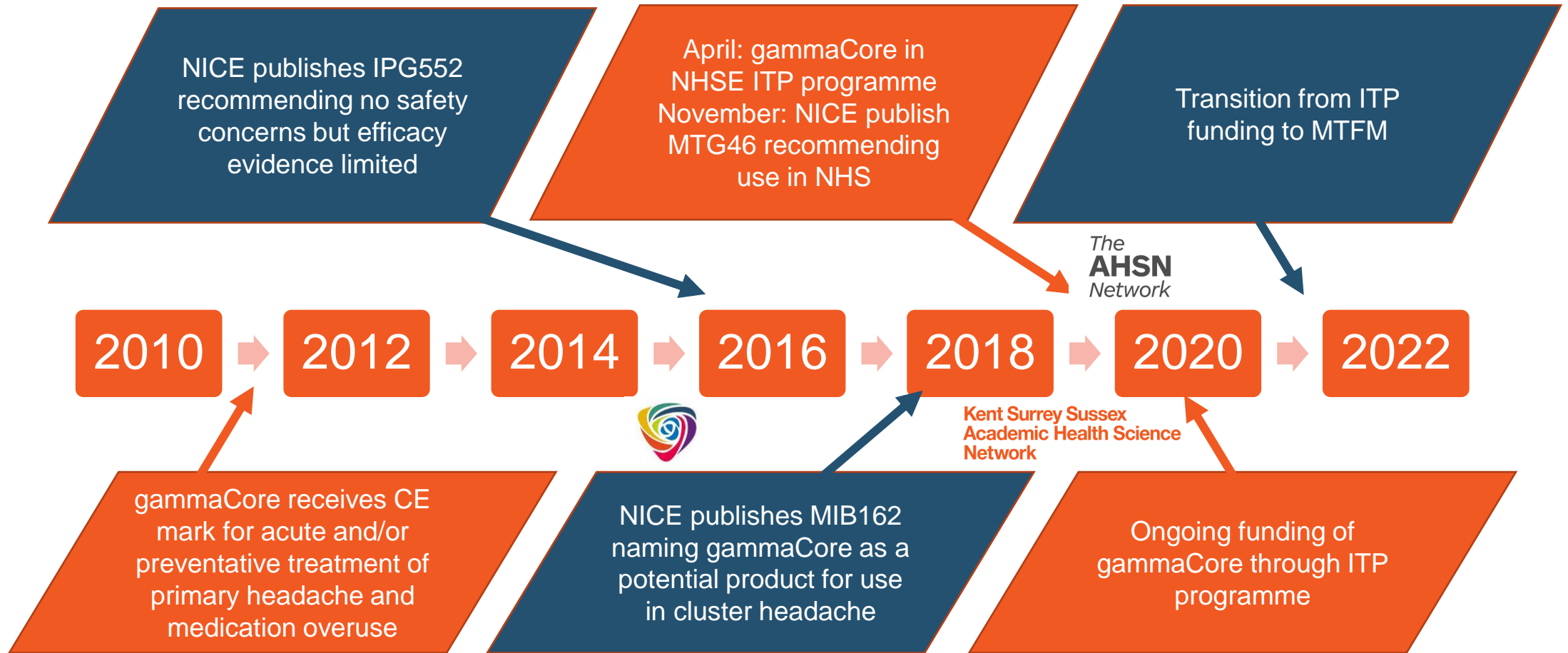


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Innovator journey

Innovator journey

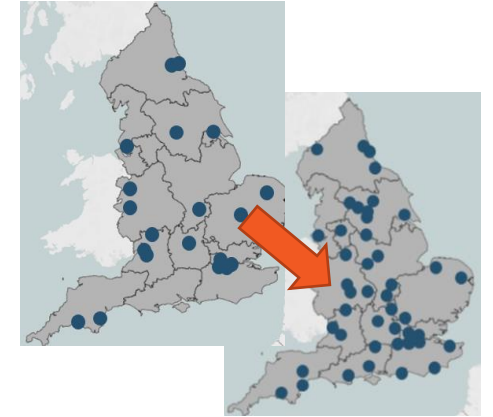


Improving access, reducing inequalities

138



- Lack of number of prescriber sites and travel → **increasing number of sites across England, remote training**
- Supporting older patients → **customer service team provide training for family and carers as well as patients**
- Digital exclusion → **non-digital training options**
- Accessibility → **training materials; video facilities and subtitle translations in different languages**



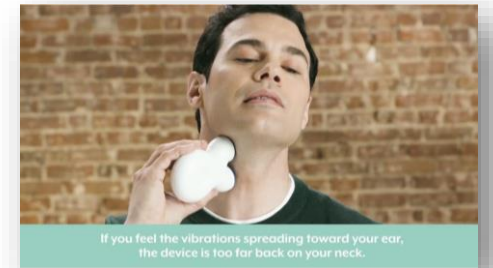
State of the Migraine Nation, September 2021:

- 1000s people unable to access headache treatment, forcing them to pay privately
- Very few people can afford this, leading to further inequalities
- Majority of Trusts **don't collect data** /have mechanisms to monitor local inequalities of access.
- A tiny fraction said they had any evidence of inequalities, though noted that it was likely **certain groups would experience worse care /health outcomes.**

Section 4: Inequalities

12. (a) Are you aware of local inequalities of access to headache specialist services amongst any groups (e.g. by gender, ethnicity, disability, socio-economic groups)?
- (b) If yes, please give details of the inequalities and any work you are doing or planning to address this.

- One NHS Trust highlighted **referrals to headache services from deprived areas were delayed**, but limited capacity to deal with this.
- Little research on if UK has ethnic or socioeconomic inequalities in **migraine** population or in migraine care → challenging to plan effective support or outreach strategies and to describe the impact that **migraine** has on individuals, communities, sectors and wider society.



the
migraine
trust

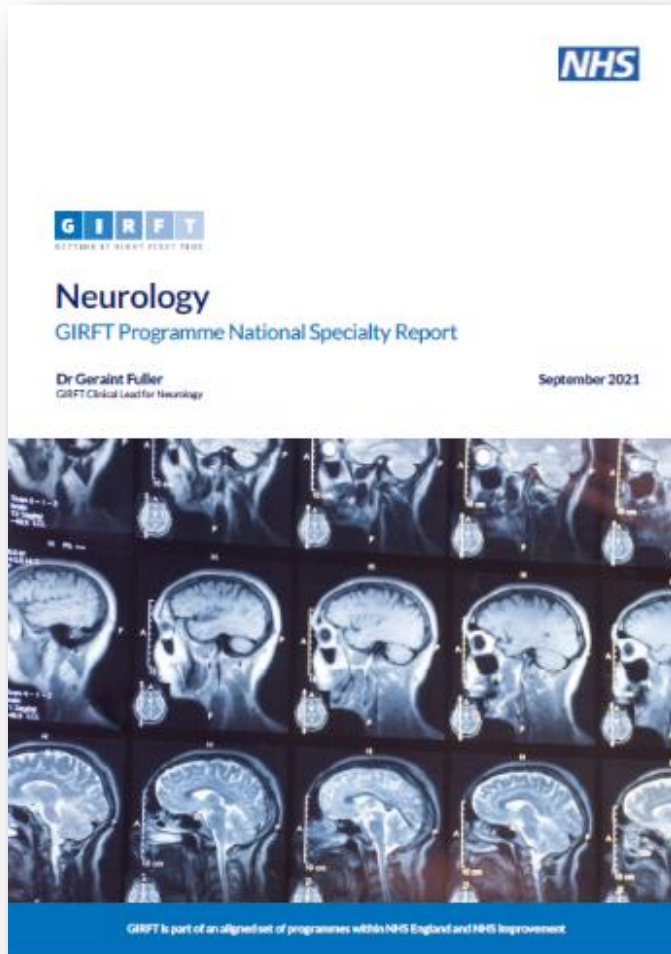


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What next...

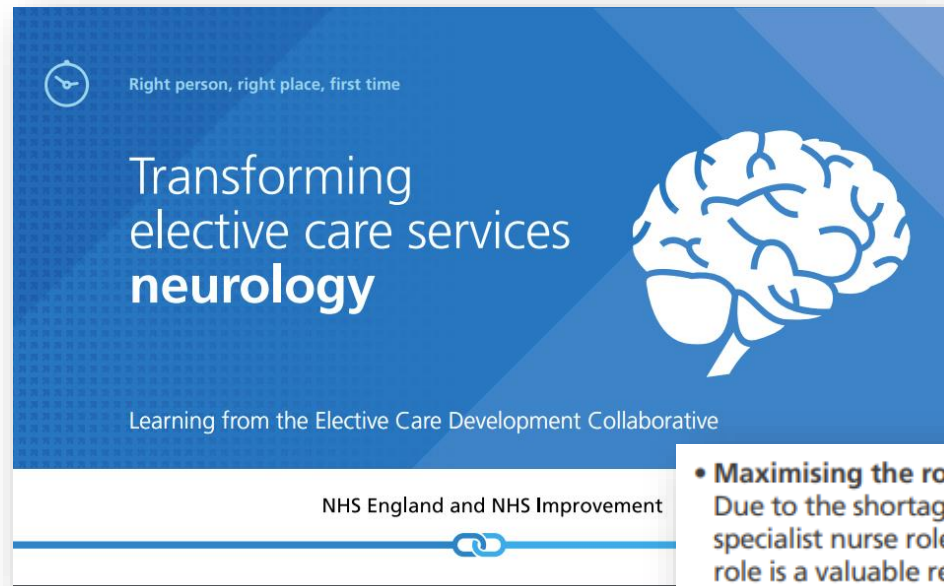
Getting It Right First Time: Neurology



Recommendation	Actions	Owners	Timescale
10. Ensure that patients with chronic neurological disorders have access to specialist nurses or other advanced practitioners working as part of an integrated multidisciplinary team, with appropriate administrative support.	a Integrate specialist nursing and advanced practitioner resource within the neurology service to enhance and maintain specialist skills. Trusts will need to consider any resourcing issues, and are encouraged to work with other providers within their ICS to establish shared arrangements if helpful. GIRFT will consider any resourcing issues with colleagues in NHS England and NHS Improvement at a national level if needed.	Trusts, GIRFT	For progress within 1 year
	b Develop credential proposals for consideration by HEE, with a view to standardising training for advanced practitioners (including specialist nurses) and covering both general neurology and disease-specific support.	Neurology associations	Proposals to be developed once the national credential approval process is launched in 2021/22

- Significant variation: acute headache management.
- **Recommendations to integrate clinical nurse specialists into services**
- Encouraged to use AHPs to improve continuity and plug staffing gaps; expand breadth of workforce



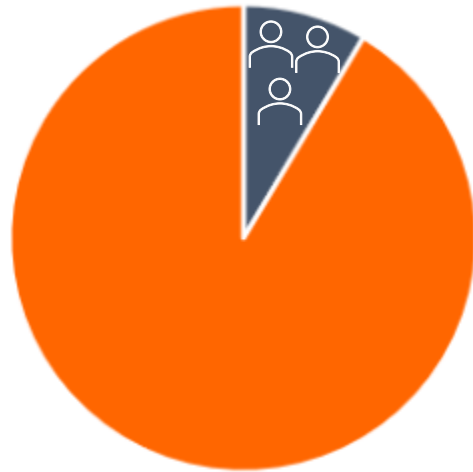


- **Maximising the role of community nurse specialists.** Due to the shortage of neurology consultants, the specialist nurse role and particularly a community nurse role is a valuable resource for increasing patient access to treatment. Access to a well co-ordinated multidisciplinary team is key to the provision of good care and maximising patient outcomes, particularly in a community setting ([The Neurological Alliance, 2018](#)). GPwERs and specialist nurses have the potential to improve care, reduce follow-up requirements and (re)admission rates ([Royal College of Physicians, 2011](#)).

- *‘Patient access is affected by variation in the number of neurologists working in small and medium acute trusts with some hospitals having no acute neurology service at all ‘*
- **‘Specialist nurses** *have the potential to improve care, reduce follow-up requirements and (re)admission rates’*

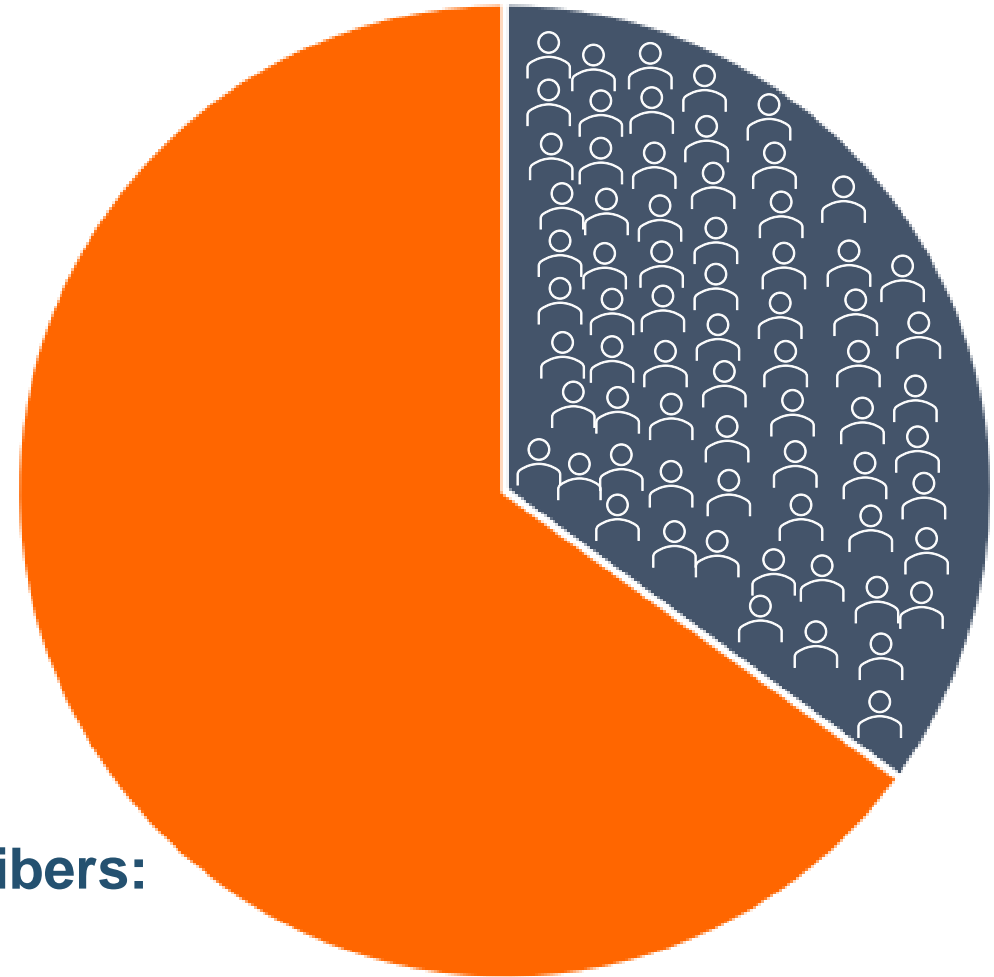


Prescribers: specialist nurses



2019

3/35 prescribers: nurses



2022

70/200 prescribers:
nurses



Specialist Nurse led services: Derriford Hospital

143



- Developed a 48-hour responsive service
- Offers counselling and support to patients, families and loved ones
- Really important to raise awareness of the condition, co-ran event with OUCH UK, to educate about what cluster headaches are, the services and treatments available, as well as to dispel myths and stigma around them
- Demonstrating local cost savings



Summary

- Cluster headaches are severely debilitating conditions
- 2019-2022 ITT/MTFM policies and AHSN support has led to significant spread with many more citizens benefitting
- Significant increase in prescribers and nurse prescribers
- Any questions?

