University Hospitals Dorset NHS Foundation Trust

# Implementation of gammaCore™ at University Hospitals Dorset


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## BACKGROUND

Cluster headache is a highly debilitating primary headache disorder which is widely described as the most painful condition a human can experience[1] and is reported to affect 0.1% of populations studied[2].

Cluster headache has a major negative impact on personal life, self-perceived health, and societal costs[3].

It is a life-long condition with treatment taking on two main forms: abortive and preventative.

The main acute treatment is triptans (nasal spray or injection), but they are expensive, not always effective, and can only be used a limited number of times per day. Breathing high-flow oxygen during an attack can help some patients but not all and is not safe for smokers. Preventive treatments such as verapamil, topiramate, lithium, prednisolone, can all have quite marked side effects and each of these is only effective in a subset of patients.

Treatment will therefore take a trial-and-error approach[4] and some patients will not find an effective treatment.

## WHAT IS THE INNOVATION

gammaCore is a non-invasive vagus nerve stimulator which offers a non-pharmacological option for the treatment and prevention of cluster headaches.

It is a hand-held device designed to be self-administered by the patient or their carer.

After applying conductive gel, gammaCore is held against the neck (over the cervical branch of the vagus nerve) and delivers a small electric current for about 2 minutes. By stimulating the vagus nerve the aim is to block the pain signal causing the attacks[5].

Studies have shown that gammaCore can reduce the frequency of cluster headache attacks as well as the intensity of pain during an attack, but gammaCore is not effective in everyone with cluster headaches[6].


Credit: electroCore, Inc.

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gammaCore is currently the only technology that uses non-invasive stimulation of the vagus nerve to treat cluster headache, and is a device provided by electroCore https://www.electrocore.com/.

Recognising that it is not effective in everyone with cluster headaches, it is currently provided free of charge for the first 3 months (93 days) to allow patients to trial it.

NICE recommends the use of gammaCore to treat cluster headache in the NHS[6] as existing medications for cluster headaches are often only partially effective and may cause serious side effects. Additionally, there are no published reports of serious adverse events with gammaCore and evidence suggests that the device is well tolerated and easy to use[6].

## ADOPTION JOURNEY

The Dorset Headache Service is an NHS clinic service based at University Hospitals Dorset (UHD) to treat refractory migraine and give support for doctors and patients with headache. This service is part of Dorset Neurology and is the only specialist headache treatment centre in Dorset.

gammaCore has been a treatment option available from the Dorset Headache Service since 2021. As mentioned above, currently the initial 3-month gammaCore trial is provided free of charge and it is only any subsequent refill cards which require funding. Treatment delivery is facilitated by electroCore who, once patient consent is in place, liaise directly with the patient to supply the product and provide patient training on the use of the gammaCore device.

Implementation of gammaCore has been assisted through the inclusion of the device as a supported innovation under NHS England's Med Tech Funding Mandate (MTFM) policy[7]. These programmes being designed to support faster and wider adoption of proven, cost-effective innovations by removing financial and procurement barriers. This funding being present only to the point where the goal of incorporation in business as usual (BAU) has been reached.

## HOW HAS IT SCALED AND WHAT WERE THE ENABLERS

### Spread and Scale

The Dorset Headache Service is the centralised specialist service for the county and therefore there are no additional units/centres for this device to be spread to, but the challenge will be to ensure all patients who may potentially benefit from gammaCore are referred to the Dorset Headache Service for review and consideration.

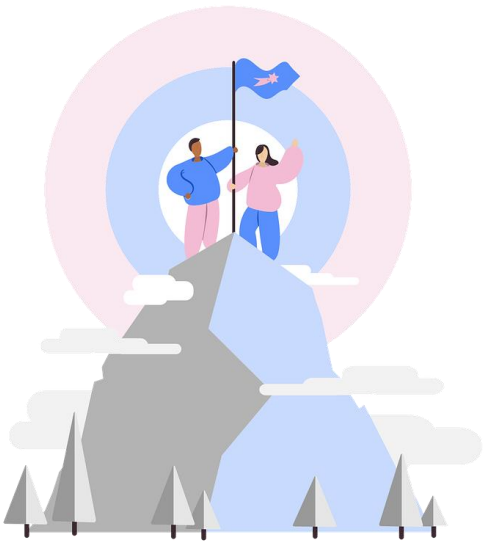
As cluster headaches affect 0.1% of the population, patient numbers will be relatively small, but the individual patient impact and wider benefit of successful cluster headache treatment should not be underestimated. Scale will therefore entail promotion and raising awareness within primary care so potential patients can be referred. This element of the work is in progress.

### Enablers

- National programmes: MTFM
- Senior clinical leadership and support
- Free 3-month trial of device
- Supplier support with training
- Supplier support with prompt patient access to device

## KEY CHALLENGES & LEARNING

- As device is provided direct to the patient by the supplier, there have been challenges experienced with the procurement process and ensuring invoices are processed and paid in a timely way.
- Lack of baseline data collected pre implementation has meant the reliance on patient recall for the measurement of impact.
- Due to capacity and resourcing restrictions, the outpatient pathway for this patient group is based on patient-initiated follow-up (in person and telephone). This means, therefore, that NICE guidance for patient review and follow-up cannot be met and there is limited formal review data in the patient medical notes to draw upon for evaluation.
- A key challenge will be moving gammaCore to part of BAU service delivery once implementation support under the MTFM programme ceases. It is hoped that the benefits realisation analysis completed will support any required business cases with conversations started with the operational and clinical teams within Neurology.



## WHAT WAS THE IMPACT

At February 2024, 11 patients had trialled the gammaCore device with 10 patients having completed the trial.

*Demographics*

Age: range 28 to 71 years, average = 50yrs
Gender: male 8 (73%); female 3 (27%)

Of the 10 patients who had completed the trial, 4 (40%) had continued use of gammaCore beyond the trial period. Nationally reported expected rate of response being 25% to 50%[6].

Cluster headache medication at the time of consent to trial of gammaCore

| Medication | No. of patients |
|---|---|
| Sumatriptan | 11 (100%) |
| Oxygen | 9 (82%) |
| Verapamil | 5 (45%) |
| Steroids | 3 (27%) |
| Indomethacin | 1 (9%) |
| Melatonin | 1 (9%) |
| Co-codamol | 1 (9%) |
| Topiramate | 1 (9%) |
| Amitriptyline | 1 (9%) |

*Clinical Audit*

The clinical audit standards reviewed concerned with the selection and consent of patients to a gammaCore trial were all met with 100% compliance.

The area of clinical practice which was found not to achieve compliance with best practice standards, as set by NICE[6], was around patient review and follow-up.

## WHAT WAS THE IMPACT

Compliance with follow-up standards:

- Patients prescribed gammaCore reviewed at 3 months by doctor = 0%
- Patients continuing gammaCore after the 3-month review, should be reviewed again by a doctor at 12 months of treatment commencement = 33%

*Patient Experience Questionnaire*

Given the enormous patient burden and quality of life impact that cluster headaches present, a patient questionnaire was a vital component of this evaluation. 11 patients were sent a copy of the questionnaire, with 5 (45%) returned.

| Medication | Before using gammaCore (Patient numbers) | Since using gammaCore (Patient numbers) |
|---|---|---|
| Triptan nasal spray | 1 | 0 |
| Triptan injection | 4 | 2 |
| Oxygen | 5 | 4 |
| Verapamil (tablet) | 4 | 1 |
| Topiramate (tablet) | 3 | 0 |
| Lithium | 0 | 0 |
| Other | 1 | 1 |

4 of the questionnaires returned were for patients who had completed the trial and had continued to use gammaCore.

A summary of responses related to some of the quality-of-life metrics used are presented in the table below.

Regarding side effects from gammaCore:

- 2 patients reported no side effects
- 2 patients reported 1 side effect
  - Local pain (face/head/neck)
  - Application site discomfort
- 1 patient reported 2 side effects
  - Muscle twitching (face/head/neck) and Other

At the end of the questionnaire patients were asked if there was anything else they you like to tell us about using gammaCore.

*"I have been liberated from the purgatory that is cluster headaches by the use of the gamma core device. This should be the primary treatment for this disease. I am now free to go to work, take holidays and participate in life again!"*

*"Havent experienced a cluster since using GammaCore this time around. I don't tolerate using it as an abortive as it can aggravate headaches and so stick to Oxygen and Injections as abortives. I like GammaCore as a treatment option as it is not pharmaceutical".*

*"Just to say thank you, gammacore has been amazing - headache free".*

**Impact of gammaCore on quality-of-life metrics**

| | No. of medications used | | No. of cluster headaches (CH) a day during an attack | | Frequency CH limit ability to do usual daily activities | |
|---|---|---|---|---|---|---|
| | Before using gammaCore | After using gammaCore | Before using gammaCore | After using gammaCore | Before using gammaCore | After using gammaCore |
| Patient 1 | 5 | 0 | 6+ a day | < 1 a day | Always | Never |
| Patient 2 | 2 | 2 | 6+ a day | < 1 a day | Always | Sometimes |
| Patient 3 | 4 | 1 | 6+ a day | < 1 a day | Always | Never |
| Patient 4 | 3 | 3 | 6+ a day | < 1 a day | Always | Sometimes |

## WHAT WAS THE IMPACT

*Benefits Realisation – Use of Sumatriptan*

Cost modelling[6] suggests a potential cost saving of £450 saving per patient over 1 year if gammaCore is used with standard treatment due to reduced sumatriptan use. Sumatriptan also being associated with significant side effects.

Of the 4 patients continuing to use gammaCore post-trial, 2 patients had a 100% and 1 patient had a 43% reduction in sumatriptan use. The remaining patient was not using sumatriptan pre gammaCore.

## NEXT STEPS

Although the patient numbers within the evaluation were small, the impact, where patients respond to gammaCore, has been found to be enormous as the associated economic and societal burden of this condition is significant.

Following review of this findings from this evaluation, the following actions have been agreed:

- To formalise the annual review process for patients continuing to use gammaCore.
- To link in with primary care to raise awareness of gammaCore as a treatment option for cluster headache patients.
- To prepare over the next 6-month period to move gammaCore to be part of standard BAU service provision and planning, ensuring sustainable treatment availability once the period of funding under the MTFM policy[8] ceases.
- Re-audit of gammaCore service delivery to monitor activity and assess the impact of service changes made.

## REFERENCES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