NICE advice

Neon EEG electrode for EEG monitoring in newborns

Medtech innovation briefing
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Summary

- The **technology** described in this briefing is Neon EEG electrode. It is used for electroencephalogram (EEG) monitoring in newborns.
- The **innovative aspects** are that EEG electrodes can be placed on a newborn, without extra preparation or an EEG technician.
- The intended **place in therapy** would be in the neonatal intensive care unit in newborns with suspected perinatal brain injury.
- There is **no published evidence** for this device.
- **Key uncertainties** around the evidence or technology are that there are no published studies showing the accuracy, ease of use or reliability of the device.
- The **cost** of the Neon EEG is £50 to £60 per unit (exclusive of VAT). The **resource impact** would be greater than standard care.

The technology

The Neon EEG (Incereb) is a device which fits over the scalp of a newborn, like a cap. The device contains a passive electrode array for the purpose of recording an EEG when connected to a suitable recording system.

The Neon EEG needs a compatible EEG multichannel recorder and is available as an 8- or 12-lead option. Each single-use device is individually packaged with all 8 or 12 leads contained in a single ribbon cable. The cable has touch-proof, labelled connectors for universal connectivity, or a D-type electrode cap connector, which is designed for ease of connection in a single movement to the multichannel recorder.

The company claims that when the Neon EEG is applied to the scalp, which takes about 2 to 3 minutes, the electrodes are automatically positioned symmetrically. It is designed to be in accordance with the international 10 to 20 placement system.

Innovations

Neon EEG differs from current electrodes used for multichannel EEG recording in newborns. It is designed to be applied, after minimal training, by any member of neonatal clinical staff with minimal training and without needing an EEG technician.

Current care pathway

EEG is used if there is a risk of a newborn having seizures, for example if there has been a lack of oxygen to the brain during delivery. Newborns born between 32 weeks gestation and term, and aged up to 9 weeks post expected due date, at risk of seizures or hypoxic-ischaemic encephalopathy would have an EEG done typically in a neonatal intensive care unit (NICU). Current options for recording neonatal EEG are:

- Multichannel EEG: A trained EEG technician places the adhesive electrodes on the scalp for multichannel EEG monitoring. This is considered to be the gold standard of neuromonitoring, but may not be indicated, or available. Specialist commentators have suggested that most babies will only need routine EEG monitoring (single or dual channel amplitude integrated EEG monitoring).
- Single or dual channel amplitude integrated EEG (aEEG): A non-EEG expert such as a

neonatal nurse or a neonatologist can record single or dual channel EEG using 3 to 5 adhesive or invasive subdermal needle electrodes. The output from aEEG needs less interpretation but is less informative than the multichannel gold standard. Specialist commentators have stated that this is the most widely used method in the NHS.

Population, setting and intended user

This device would be used in the NICU by neonatologists and neonatal nurses on babies at risk of seizures or hypoxic-ischaemic encephalopathy. Newborns with mild to severe oxygen deprivation during delivery, or those with underlying neurological, metabolic or vascular disease will have an increased the risk of neonatal seizures needing monitoring by EEG. Some seizures are sub clinical and therefore not witnessed, and are only detected on multichannel EEG monitoring.

The Neon EEG device is designed to be used by non-expert EEG users after minimal training, which is provided by the company in a short instructional video.

Costs

Technology costs

The Neon EEG devices (Neon8 and Neon12) are supplied in individual sealed plastic trays complete with skin preparation gel at a cost of £50 to £60. The devices use standard 1.5 mm touch proof or D-type connectors (not supplied) to attach to existing compatible multichannel EEG recorders.

Costs of standard care

Single or dual channel amplitude integrated (aEEG) monitoring is usually done by a trained doctor or nurse and can take between 5 minutes (needle electrodes) and 30 minutes (gel electrodes) to fit the electrodes. The cost of standard care is expected to be around £30 for a gel electrode and adapter set or around £35 for needle electrodes, not including clinician time.

Resource consequences

Neon EEG would be an additional cost compared with standard care. Other than the need for a compatible multichannel recorder, there are no infrastructure or practical barriers to using the Neon EEG device. The device is suited to doing EEG recordings out of hours, when a trained EEG technician is not available.

The device is not currently used in the NHS.

Regulatory information

The Neon EEG electrode was CE marked as a class I device in 2015.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to: promote race and disability equality and equality of opportunity between men and women, eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

There are no equality considerations for the Neon EEG device.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the interim process and methods statement. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

No publically available evidence was found on the use of the Neon EEG.

Overall assessment of the evidence

Evidence of clinical effectiveness would allow for informed clinical or commissioning decisions on the Neon EEG electrode. Studies are needed describing its use in the NHS and specific assessments of use in babies with suspected brain injury compared to EEGs recorded using technician placed electrodes. Technical studies showing equivalence with existing electrodes, and on durability, would be useful, both in healthy babies and those with confirmed neurological conditions.

Recent and ongoing studies

No ongoing or in-development trials were identified.

Specialist commentator comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

One of the 4 specialist commentators had used this technology before.

Level of innovation

All specialist commentators stated that the design of the device is novel but is based on existing EEG concepts.

Potential patient impact

One specialist said the device could be quicker to apply causing less disturbance to the newborn and result in a faster result. It could also be less invasive but the integrity and quality of the signal produced and its stability over prolonged periods (up to 72 hours) would need to be proven. One specialist stated that adhesive electrodes are likely to be

more comfortable for the baby than needle electrodes. One specialist noted that Neon EEG may save time for staff if the electrodes stay in place better and do not need to be adjusted. The commentators agreed that this device would be used on babies in intensive care who may have had hypoxic-ischaemic encephalopathy, seizures, strokes and babies who are critically unwell and are muscle relaxed.

Potential system impact

Specialist commentators thought there could be lower staff costs but only where multichannel EEG is routine. In units using multichannel EEG, this would be a useful addition to existing methods. One specialist noted that non-invasive EEG monitoring often provides a lower quality signal than invasive needle electrodes. One specialist noted that babies will usually need aEEG monitoring for a minimum of 72 hours, there are no data on how Neon EEG performs over prolonged periods and the instructions for use for Neon EEG state that it is single use only (12 hours).

General comments

One specialist noted that, although multichannel EEG is the gold-standard for monitoring brain function, because of the lack of devices and expertise in interpretation, most NICUs in the UK adopt aEEG monitoring. One specialist said reliability of the Neon electrodes will be important, as will evidence of the signal quality performance in cases of high impedance, such as with hairy babies. One specialist noted that Neon EEG is a fixed size whereas the head size of newborn babies is highly variable, they concluded that the device may not be suitable for every baby.

Specialist commentators

The following clinicians contributed to this briefing:

- Dr Ela Chakkarapani, consultant senior lecturer neonatology, University of Bristol and University Hospitals Bristol NHS Trust. Did not declare any interests.
- Prof Marianne Thoresen, professor of neonatal neuroscience, University of Bristol. Did not declare any interests and has contributed to NICE guidance on therapeutic hypothermia in 2010.

- Dr Sharon English, lead clinician neonatal service, Leeds Teaching Hospitals NHS Trust. Did not declare any interests.
- Dr Paul Clarke, consultant neonatologist and honorary professor, Norfolk and Norwich University Hospitals NHS Foundation Trust. Has received payment and equipment from a competitor company.

Development of this briefing

The interim process and methods statement sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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