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IQoro® Early Adopters Programme - (IQEAP)

IQoro® has initiated the IQEAP programme as a required stage in the pursuit of NICE 'Guidance' status for the IQoro® device. The company anticipates that the programme will involve cooperating with a dozen willing and interested UK Speech and Language Therapy departments.

In early 2017, IQoro®, submitted a notification to NICE for advice / guidance status for the device. In summary, NICE seem satisfied with the clinical research undertaken as part of the product development and acknowledge that there is an unmet need for a self-administered, home-based treatment for dysphagia after stroke. The notification fell short of acceptance on its first pass though, on the following (summarized by us) points:

1. There was no large-scale study of existing users and their ease-of-use and satisfaction ratings. This has now been satisfactorily addressed by the company's PSEUD (Patient Satisfaction and Ease of Use Data) post-market survey undertaken late 2017.
2. The research submitted used therapy outcome measures familiar in Sweden but not widely known in the UK.
3. There was no evidence that the IQoro® treatment could be easily and effectively deployed in the NHS healthcare pathway without disrupting existing routines and methods. Proof that it is widely-adopted by Swedish healthcare institutions, was not sufficient.
4. There was no comparison with the Gold Standard of care for dysphagia after stroke in the UK, which is treatment by a Speech & Language Therapist (SLT) with the prevalent and accepted UK methods.
5. There was also mention of the desirability of 'imaging or mechanistic' data – FEES or Video Fluoroscopy - that could show the physiological improvements achieved.

What is an IQEAP and what would we like to achieve?
IQEAP is a service evaluation involving the use of IQoro® in patient treatment routines, it is envisaged this will take no longer than 6 months from planning, through deployment, end-of-treatment outcome measurement, and reporting.

One evaluation goal is to demonstrate how IQoro® fits into the existing clinical pathway for treating dysphagia after stroke. This will involve working with NHS SLTs to discover and document where IQoro® best fits in their clinical pathway, where it is best-used within the patient journey, and also show the outcome measures that are used by those SLTs.

How long will patients will be followed as part of the evaluation?
Published IQoro® studies show that, in cases of dysphagia after stroke, an improvement is seen within 5-13 weeks of commencement of treatment. Through IQEAP we want to be able to demonstrate this is also the case when used within the NHS SLT pathway, so would expect the patients to be followed for a similar time.

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What would we like to report back to NICE?
We would like to:

- Describe where and how SLTs have found in practice that IQoro® has fitted into their usual treatment pathways and the patient journey.
- Describe and report which outcome measures have been used: these will be required at baseline and ideally at end-of-treatment. The measures used will preferably be those already in use, in order to minimize extra work or disruption to existing routines and methods.
- Provide an anonymous view of the outcome data of those patients involved in the IQEAP, including any before and after Video Fluoroscopies, FEES, etc.
- Give an insight into any key learning gained from using IQoro® in real life treatment.

Differences between a service evaluation and a clinical study
IQEAP is not a clinical study but a service evaluation. The primary aim is to provide evidence of IQoro® acceptability and utility in existing NHS structures. Different hospitals may have different inclusion or exclusion criteria, different outcome measures or other local preferences. Some institutions may be able to follow a patient from acute through rehab and out to the community or his own home, others may not. These inconsistencies would render the exercise invalid as a clinical trial, but do not impact our ability to achieve the aims of a service evaluation.

What about patients with other reasons for swallowing difficulties?
Although the current NICE guidance application is in relation to dysphagia after stroke, there is clinical evidence that IQoro® successfully treats dysphagia caused by other conditions too. These may include ABI, COPD, degenerative diseases, aberrant jaw formation in the young, and more. As such, IQoro® welcome patients included in the IQEAP who have other diagnoses too. Relevant outcome data gathered by the SLT in relation to these will be of interest and add to the understanding of its use and deployment clinically and in the NHS.

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Taking Part in an IQEAP

Where an NHS institution sees the opportunity to investigate improved patient outcomes using IQoro® and wishes to be one of the 5 organisations taking part, the company are prepared to support the organisation with an IQEAP - through the provision of project support resource and IQoro® devices, with the following pre-conditions.

We will supply one device per patient in the evaluation provided that:

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- The entire evaluation is of sufficient scale to justify the company's involvement - maybe at least four SLTs or at least 15 patients: more would be welcome.
- The institution has cleared their own internal admin, ethical, regulatory, R&G and other approvals before the evaluation starts.
- All patient treatments start within an agreed period so that the evaluation has a fairly well-defined start and end.
- The SLT responsible for the patient has met with IQoro® and has understood a little of the theory and all of the practice of deploying the IQoro®.
- The patient meets the institution's agreed inclusion and exclusion criteria.
- The IQoro® introduction to the patient is performed according to the institution's agreed IQEAP process.
- A baseline test / tests (as decided by the institution) is performed before start-of-training.
- The patient use is checked within a couple of weeks of starting training so that its use is known to be correct.
- The same therapy outcome test is performed at end-of-training.
- The SLT and patient results are shared with us, anonymised, as agreed as part of the IQEAP.
- The institution prepares a brief report at the end of the evaluation that addresses the issues of ease-of deployment, fit for existing work practices, utility in the patient journey, perceived comparison or advantages over usual, existing treatment methods. For those institutions that can, any FEES or VF evidence would be gratefully received too.

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