IQoro and GERD – COST BENEFITS and IMPROVED PATIENT OUTCOMES

A Carter, T.W. Morris. MYoroface AB
www.iqoro.com

Purpose of document

Many NHS managers and clinicians are seeking ways to fund IQoro deployment in their institutions. There is often a need to present a business case at department or institutional level to fundholders and procurement departments. This document presents cost benefit data and rationale to support such applications. It is more focussed on the cost and savings arguments for IQoro use than on improved patient outcomes which are well documented elsewhere.
It is focussed more on the case for treating the conditions related to GERD than to those associated with dysphagia, the latter are addressed in a parallel paper.

Introduction

IQoro is a NICE-recognised treatment for reflux-based diseases, – usually as a result of Hiatus hernia [1] and is referenced by brand name in the relevant NHS care pathway guidelines for treating GERD in both adults and children [2, 3].

It is also an effective treatment for patients with dysphagia caused by a range of aetiologies. NICE reference IQoro in the relevant NHS care pathway guidelines for treating dysphagia [4]. This document does not focus primarily on this patient group.

IQoro's adoption has increased over the past 5 years with approx. 100,000 people in Europe using it at the time of writing. The majority of these IQoro devices have been self-purchased by individuals to treat GERD and similar conditions, with a smaller proportion purchased by healthcare institutions, often to treat dysphagia-related conditions.

IQoro can be prescribed by hospital consultants for patients under their care via the use of hospital prescriptions. IQoro devices procured in this way are issued by hospital pharmacies and funded from the hospital prescription budget.

IQoro: treatment of both reflux-based conditions and dysphagia

This document is one of two produced simultaneously by the manufacturers: this one focussing on the treatment of reflux-based diseases, and the other on dysphagia. Many patients may have difficulties in both condition areas, in which case both documents should be considered as being relevant. Both conditions are caused by muscular and / or neurological dysfunction [5,6], IQoro addresses the underlying causes of both with the same device and training regime.

What IQoro, is and what it treats

IQoro is a simple handheld neuromuscular training device. It can be self-administered by the patient in three daily training sessions of 30 seconds each when they are self-treating a condition [7]. Almost all individuals treating reflux conditions self-treat without HCP assistance; except for counselling and guidance on safe reduction of medication as their symptoms reduce.
In the case of dysphagia treatment, it is more normally used by or under the direction of an SLT.

Treatment with IQoro successfully addresses the underlying cause of reflux-based diseases – a Hiatal hernia [5], IQoro is shown in scientific studies [8 - 12] to be equally effective in treating patients whether at the onset of their condition or for those that have experienced their

symptoms for many years. Other studies [13] show that IQoro is equally effective in treating Hiatal hernia and reflux irrespective of patients' Body Mass Index (BMI). Costs of treating long-term reflux sufferers with existing traditional methods and medications can accumulate huge recurring costs.

It is not the purpose of this document to explain in detail how IQoro works [14], but in essence it stimulates the sensory nerves present in the oral cavity to activate a sensory motor reflex arc in the brainstem that in turn causes the efferent motor nerves to exercise the 148 muscles in the swallowing chain. Included in these muscle groups are the outer longitudinal muscles at the side of the esophagus which attach beneath the diaphragm. As these flex, they stimulate and strengthen the weakened diaphragm muscle around the Hiatal canal and promote reduction of the hernia.

Suitability of IQoro for use in NHS and clinical settings

At the current time, IQoro has been purchased for deployment in more than 30 NHS Trusts in varying numbers: a range of roughly a minimum of 5 in one to a maximum of 100 in the largest. In all but a few cases, the primary focus of these deployments is to treat patients with dysphagia; sometimes this includes reflux symptoms, but it would be misleading to purport that this was the main reason for this NHS use.

A recent service evaluation conducted in the Royal Devon and Exeter NHS Foundation Trust, *"IQoro Dysphagia Therapy within an NHS SLT Caseload: A Service Evaluation"* [15 § 7.1.1.5] which was funded by the South West Academic Health Science Network, looked at IQoro deployment in three Speech and Language care settings: acute, rehab and community. A direct quotation from this report is:

> *". . .it also shows that IQoro can be successfully introduced into the National Health Service setting."*

Once again, the primary focus of this evaluation was the treatment of dysphagia, with only some patients having reflux symptoms.

Cost saving opportunities

1. Quantifiable savings in the IQoro treatment of GERD

Reflux based diseases are widespread in the western world affecting 15 – 20% of the population [16]. NICE say that in the UK, "*The prevalence of dyspepsia depends on the definition used and is estimated to be between 12 and 41% of the general population*" [17].

In the UK there are large costs associated with treating it. According to the NICE Guidance Costing Statement:

> "2.5 *Dyspepsia accounts for between 1.2% and 4% of all consultations in primary care* (NICE guideline 184). *As a result, the management of dyspepsia continues to have a significant burden in primary in the UK*." [18]:

1.1 Avoided Laparoscopic Fundoplication operations

NICE guidance is for the GP to reduce the symptoms by prescribing Proton Pump Inhibitor medication, initially for a limited amount of time. The reality is that as the underlying cause of the problem is not being treated, such prescribing will often continue for many years. PPI drugs are linked to many unwanted side effects and health authorities in most countries advise that clinicians should minimise their use where possible.

For this or other reasons, some people are unwilling or unsuitable for continued PPI treatment and will instead be referred for a specialist opinion in secondary care to consider a surgical operation. According to the NICE guidance [3] the prescriber should:

> *"1.10 Laparoscopic fundoplication*
> *1.10.1 Consider laparoscopic fundoplication for people who have:*
> - *a confirmed diagnosis of acid reflux and adequate symptom control with acid suppression therapy, but who do not wish to continue with this therapy long term*
> - *a confirmed diagnosis of acid reflux and symptoms that are responding to a PPI, but who cannot tolerate acid suppression therapy [new2014]"*

This surgical operation targets the underlying cause of the condition by compensating for the muscular weakness in the diaphragm - Hiatus hernia - that allows the reflux to occur. Muscular competence can instead be restored by IQoro training. IQoro is recognised by NICE as an alternative to either medication or surgery in their Medtech Innovation Briefing [1].

> *"The intended place (for IQoro) in therapy would be as an alternative to long-term proton pump inhibitor (PPI) treatment or laparoscopic fundoplication surgery in people with hiatus hernia."*

Treatment guidelines recently released by NICE reference IQoro as a treatment in two relevant pathways: "Managing gastro-oesophageal reflux disease in adults" [2], and "Managing gastro-oesophageal reflux and reflux disease in children and young people" [3].

If IQoro were used by patients who were being considered for referral to surgery, most would regain their Hiatal competence without ever needing an operation [10, 13, 18].

An LF surgical intervention for an adult costs the NHS £4,434 [20].

> *"£4,434 (HRG code FF04D major, esophageal, stomach or duodenum procedures 19 years and over with CC score 0 – 1. National Schedule of NHS Costs 2019/20"*

The list price one-off cost of a IQoro device to the NHS is £121, it is warranted for 7 months and has an expected life of 2 years. In the referenced scientific studies [10, 13, 18] treatment periods were not usually more than 6 months, ongoing 'maintenance' training at a lower level of intensity may be required for some years and the need for a replacement device at some stage cannot be ruled out. The cost saving per each avoided LF surgical intervention is £4,313 if only one IQoro is needed.

All amounts in £

	cost
LF procedure	4,434
IQoro	(121)
potential saving	**4, 313**

Table 1

Potential cost savings from LF avoidance

The EC estimates [21] that in the UK, 26.7 people per 100,000 citizens will have a Laparoscopic Fundoplication in any year. This gives an annual figure of 18,052 operations in England, and at £4,434 per procedure the annual bill is more than £80 million.

Patients who have been successfully treated either by LF operation or by IQoro intervention do not incur future costs for PPI medication or repeat NHS visits to the same degree as if not treated, if at all.

Children can be treated with IQoro once the stomach has descended below the diaphragm around the age of 18 months. An LF surgical intervention for a child over the age of 2 costs the NHS between £3,736 and £6,834 depending on whether the CC score is or 1 or above (*HRG costs/ HFG FF04E Major, Oesophageal, Stomach or Duodenum Procedures, between 2 and 18 years*) [22].

1.1.1 Improved patient outcomes

Treatment with IQoro as an alternative to referral for LF would give the following patient benefits:

- treatment could begin immediately before referral for further examination and potential admission for operation.
- Many patients would prefer a natural non-invasive way to repair the weakened muscle to a surgical operation.
- Post LF operation patients need to live with a stomach that can no longer intrude through the diaphragm to allow vomiting or belching.
- LF does not always have lasting benefits. More than 50% of patients anyway become long-term PPI users 10–15 years post anti-reflux surgery. See "Conclusions" in the following: [23]
- Additionally, the NIHR say [24] that,

"People who take proton pump inhibitors for digestive disorders such as stomach ulcers and acid reflux may be up to 24% more likely to experience hip fractures . . ."

IQoro can thus bring patient benefits compared with either existing medication or surgical intervention recommendations.

1.2 Avoided endoscopic examinations

If, instead of waiting for a routine endoscopic examination to be scheduled and carried out, IQoro treatment were to commence immediately, symptom reduction can be expected in many cases to be evident within a few weeks. In the referenced customer survey, more than 45% of 3,995 respondents reported a positive change in their condition which they attributed

to IQoro training within eight weeks. This in itself provides assurance that the underlying cause was indeed a Hiatus hernia and may allow an endoscopic examination to be avoided or cancelled.

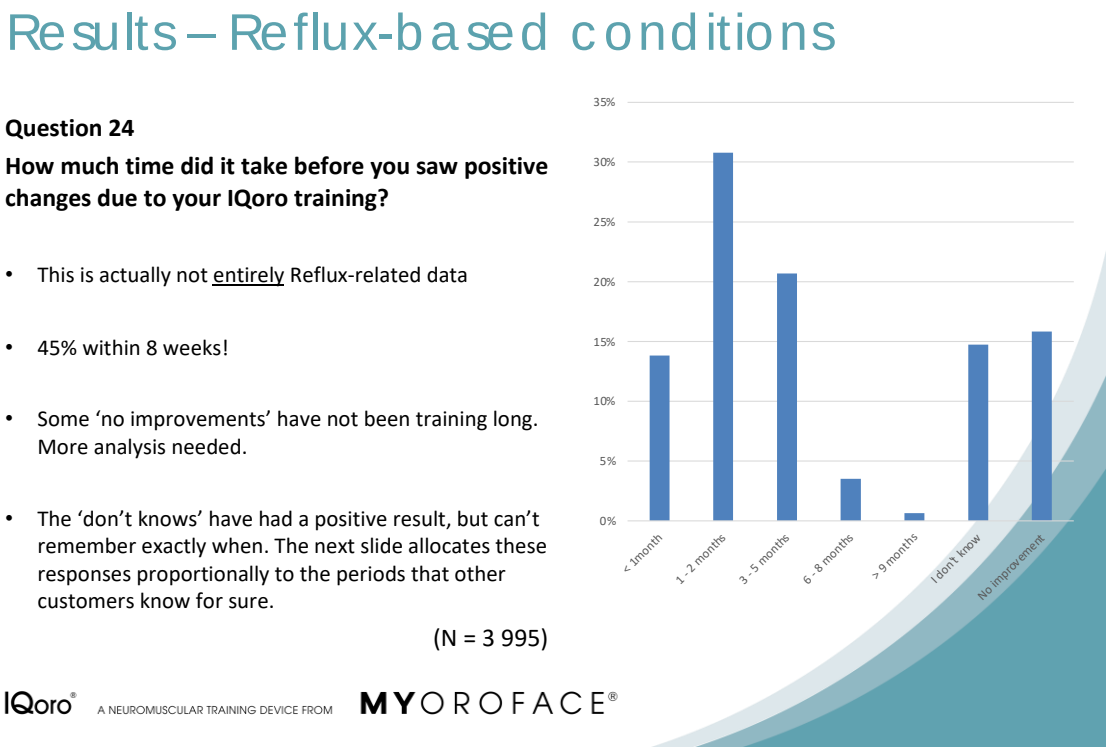

Fig. 1 IQoro Customer Survey

Where an endoscopic examination can be avoided because IQoro treatment has already successfully addressed the reflux symptoms, savings can be realised*:*

> *HRG code FE22Z 'diagnostic endoscopic upper GI tract procedures 19 years and over', 2014/15 national schedule of NHS costs 2019/20. Cost £500.* [52].

A similar procedure carried out on a child of 5 – 18 years old is more than twice as expensive at £1,087[25].

All amounts in £

	cost
Endoscopic procedure	500
IQoro	(121)
potential saving	**379**

Table 2.

Potential cost savings from avoiding Endoscopic examination

1.2.1 Improved patient outcomes

Patients referred for internal examination will often be aware that part of the reason for this is to rule out cancer as a possible cause, this can lead to a harrowing period of worry that could be avoided if treatment with IQoro were started and seen to be having a positive effect on the suspected Hiatal hernia.

2. Unquantifiable savings in the IQoro treatment of GERD

In addition to the cost savings that we have attempted to quantify above there are other, very real, costs that can be avoided. It is currently beyond our scope to quantify these accurately.

2.1 Reduced patient visits to GPs

There are 300 million GP visits p.a. in the UK. NICE says:

> *"Dyspepsia accounts for between 1.2% and 4% of all consultations in primary care (NICE guideline 184)* [17].

There are therefore between 3.6 million and 12 million GP consultations p.a. related to reflux-based diseases. Resolving the Hiatal hernia that is the underlying cause of these visits could provide huge reductions in GP time and cost.

2.2 Reduced PPI costs

PPI medication is prescribed in the UK to the tune of £425 million p.a. [26]. Where a Hiatal hernia can be successfully treated by IQoro treatment, PPI medication can be ceased [1].

Conclusion

Use of IQoro in NHS institutions continues to grow as better patient outcomes and reduced costs are being achieved, but overall take up is a small percentage of the cases where clinicians would like to use IQoro. The most frequent reason for this is the lack of an existing budget for such a device, this document supports the financial benefits of IQoro deployment in hospital and other departments.

NHS clinicians are routinely provided with support in adopting and deploying IQoro on a free-of-charge basis, including demonstration devices, feasibility / assessment kits and training sessions. A clinical team provides help with queries from professionals about patient cases, suitability and usage.

Similarly, the company provides comprehensive customer support services via web, chat, telephone and email to individuals as required.

References

Ref no	1	Item	NICE MIB - Hiatus hernia
		Source	NICE
		Author	
		URL	https://www.nice.org.uk/advice/mib176/chapter/summary
		Year	2019
Ref no	2	Item	Managing gastro-oesophageal reflux disease in adults
		Source	NICE
		Author	
		URL	https://pathways.nice.org.uk/pathways/dyspepsia-and-gastro-oesophageal-reflux-disease/managing-gastro-oesophageal-reflux-disease-in-adults
		Year	2021
Ref no	3	Item	Gastro-oesophageal reflux disease and dyspepsia in children and young people: investigation and management
		Source	NICE
		Author	
		URL	https://pathways.nice.org.uk/pathways/dyspepsia-and-gastro-oesophageal-reflux-disease#path=view%3A/pathways/dyspepsia-and-gastro-oesophageal-reflux-disease/managing-gastro-oesophageal-reflux-and-reflux-disease-in-children-and-young-people.xml&content=view-index
		Year	18th October 2019
Ref no	4	Item	Stroke rehabilitation: therapy
		Source	NICE
		Author	
		URL	https://pathways.nice.org.uk/pathways/stroke#path=view%3A/pathways/stroke/stroke-rehabilitation-therapy.xml&content=view-node%3Anodes-swallowing
		Year	2021
Ref no	5	Item	Introducing an Innovative Neuromuscular Treatment of the Underlying Reason for Reflux: Hiatus Hernia
		Source	InTechOpen
		Author	Hägg M., Franzén T
		URL	https://www.intechopen.com/chapters/75980
		Year	Apr 7th 2021
Ref no	6	Item	Introducing IQoro: A Clinically Effective Oral Neuromuscular Treatment for Dysphagia
		Source	InTechOpen
		Author	Hägg M., Morris. N.R.
		URL	https://www.intechopen.com/online-first/79510
		Year	2021
Ref no	7	Item	How to train with IQoro
		Source	MYoroface AB
		Author	
		URL	https://www.iqoro.com
		Year	2016
Ref no	8	Item	Effects of oral neuromuscular training on swallowing dysfunction among older people in intermediate care — a cluster randomised, controlled trial
		Source	Age and Ageing, Volume 48, Issue 4, July 2019, Pages 533–540, https://doi.org/10.1093/ageing/afz042.
		Author	Patricia Hägglund, Mary Hägg, Per Wester, Eva Levring Jäghagen
		URL	https://academic.oup.com/ageing/article/48/4/533/5486389
		Year	43592
Ref no	9	Item	Effect of IQoro® training on impaired postural control and oropharyngeal motor function in patients with dysphagia after stroke
		Source	Acta Otolaryngol 2016; 136 (7):742-
		Author	Hägg M., Tibbling L
		URL	https://pubmed.ncbi.nlm.nih.gov/26924256/
		Year	2016
Ref no	10	Item	Esophageal dysphagia and reflux symptoms before and after oral IQoro® training
		Source	World J Gastroenterol 21(24): 7558-7562
		Author	Hägg M, Tibbling L, Franzén T.
		URL	https://www.wjgnet.com/1007-9327/full/v21/i24/7558.htm
		Year	2015
Ref no	11	Item	Effects on facial dysfunction and swallowing capacity of intraoral stimulation early and late after stroke.
		Source	NeuroRehabilitation. 2015;36 (1):101-6
		Author	Hägg MK., Tibbling LI
		URL	https://pubmed.ncbi.nlm.nih.gov/25547771/
		Year	2015
Ref no	12	Item	Effect of oral IQoro® and palatal plate training in post-stroke, four-quadrant facial dysfunction and dysphagia: A comparison study.
		Source	Acta Otolaryngol. 2015 Sep;135(9):962-8
		Author	Hägg MK., Tibbling LI
		URL	https://pubmed.ncbi.nlm.nih.gov/25947252/

		Year	2015
Ref no	13	Item	Oral neuromuscular training relieves hernia-related dysphagia and GERD symptoms as effectively in obese as in non-obese patients.
		Source	Acta Oto-Laryngologica 138(11):1-5 DOI: 10.1080/00016489.2018.1503715
		Author	Franzén T., Tibbling L., Hägg M.
		URL	https://www.researchgate.net/publication/330300453_Oral_neuromuscular_training_relieves_hernia-related_dysphagia_and_GERD_symptoms_as_effectively_in_obese_as_in_non-obese_patients
		Year	43466
Ref no	14	Item	How does IQoro work?
		Source	Myoroface AB
		Author	
		URL	https://www.iqoro.com/what-is-iqoro/why-iqoro-works/
		Year	2016
Ref no	15	Item	"IQoro Dysphagia Therapy within an NHS SLT Caseload: A Service Evaluation"
		Source	Royal Devon and Exeter NHS Foundation Trust
		Author	Roseanne Exell, Hayley McBain, Sam Tuvey, Gill Hardy
		URL	
		Year	2021
Ref no	16	Item	Reflux prevalence
		Source	Annals of Laparascopic and Endoscopic Surgery
		Author	Colin P. Dunn, Tanu A. Patel, Nikolai A. Bildzukewicz, Justin R. Henning, John C. Lipham
		URL	https://ales.amegroups.com/article/view/5885/html
		Year	Jul-20
Ref no	17	Item	Dyspepsia prevalence
		Source	Dyspepsia and gastro-oesophageal reflux disease in adults: investigation and management
		Author	NICE
		URL	https://ales.amegroups.com/article/view/5885/html
		Year	Jul-15
Ref no	18	Item	Effect of IQoro® training in hiatal hernia patients with misdirected swallowing and esophageal retention symptoms.
		Source	Acta Otolaryngol.;135(7):635-9
		Author	Hägg M, Tibbling L, Franzén T
		URL	https://pubmed.ncbi.nlm.nih.gov/25963055/
		Year	2015 Jul
Ref no	19	Item	Costs of GERD treatment
		Source	NICE
		Author	
		URL	https://www.nice.org.uk/guidance/cg184/resources/costing-stathttps://www.nice.org.uk/guidance/cg184ement-pdf-193164877
		Year	
Ref no	20	Item	Cost of LF surgical operation
		Source	NHS England and NHS Improvement
		Author	
		URL	https://www.england.nhs.uk/national-cost-collection/
		Year	2019-2020
Ref no	21	Item	UK LF operations p.a.
		Source	EC
		Author	
		URL	https://ec.europa.eu/eurostat/statistics-explained/pdfscache/37391.pdf
		Year	
Ref no	22	Item	HRG costs / HFG FF04E Major, Oesophageal, Stomach or Duodenum Procedures
		Source	EC
		Author	
		URL	
		Year	
Ref no	23	Item	Use of proton pump inhibitors after anti reflux surgery: a nationwide register-based follow-up study
		Source	BMJ
		Author	
		URL	https://gut.bmj.com/content/63/10/1544
		Year	
Ref no	24	Item	PPI meds and osteoporosis Prevalence of hip fractures
		Source	
		Author	
		URL	https://evidence.nihr.ac.uk/alert/medication-to-reduce-stomach-acid-may-increase-risk-of-hip-fractures/
		Year	
Ref no	25	Item	Costs of endoscopic examination
		Source	NHS England and NHS Improvement
		Author	
		URL	https://www.england.nhs.uk/national-cost-collection/
		Year	2019-2020

Ref no	26	Item	Costs of PPI medication
		Source	NIH
		Author	
		URL	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6042351/
		Year	