



## Patient access to voice prostheses and heat and moisture exchangers: Factors influencing physician's prescription and reimbursement in eight European countries

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### ABSTRACT

**Objectives:** Patient access to the voice prosthesis and heat and moisture exchanger (HME) is not always guaranteed in Europe. Therefore, the aim of this qualitative study is to evaluate factors influencing physician's prescription and reimbursement of these devices in eight European countries, and to identify barriers of and facilitators to effective patient access.

**Materials and methods:** In this mixed methods study, we conducted a survey among stakeholders evaluating prescription (Part 1 of the survey), reimbursement (Part 2), and barriers of and facilitators to effective patient access (Part 3). Part 1 was completed by head and neck surgeons employed in France, Germany, the United Kingdom, Italy, Spain, Belgium, the Netherlands and Poland. Part 2 and 3 were completed by medical device company representatives in respective countries, followed by semi-structured interviews.

**Results:** Based on the survey, filled in by 36 surgeons, all prescribed the voice prosthesis. Four surgeons didn't prescribe the HME in Italy and Poland due to lack of both reimbursement and experience/training, and feeling uncomfortable with device use. Most restrictive factors (e.g. increased workload, insufficient staff) occurred in countries with decentralized healthcare systems including Spain and Italy.

**Conclusion:** Non-HME-usage was influenced by economical and physician-related factors. Restrictive factors were related to limited regional device reimbursement and provision. Nationwide reimbursement, guideline implementation, support for physicians by training/education and providing a rehabilitation team will increase device use.

### Introduction

As the survival rate of patients with head and neck cancer (HNC) continues to improve over the past years, attention has been growing towards survivorship and rehabilitation care [1]. After total laryngectomy, rehabilitation of HNC survivors focuses on restoration of functions such as the ability to phonate and the improvement of pulmonary function. Placement of a voice prosthesis, an internal valve which is implanted in the tracheoesophageal wall, gives optimal voice rehabilitation [2,3]. The heat and moisture exchanger (HME) minimizes pulmonary problems by providing stoma occlusion and ensuring humidification, heating and filtering of inhaled air [4–7]. In addition,

the utilization of voice prostheses and HMEs has contributed to the improvement of patients' quality of life (QoL) [3,5–8].

Yet, in spite of the valuable role of the voice prosthesis and HME, device access for laryngectomy patients, defined in this study as 'effective patient access', is not always provided in the European Union (EU) [9]. Effective patient access is enabled by reimbursement and prescription practices, which may be driven by the physician's knowledge as well as perceived ease of use and usefulness of the device [10–12].

Factors influencing device's ease of use and usefulness can be evaluated by the Technology Acceptance Model (TAM) described by Davis et al. [12]. TAM is commonly used to understand how the

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behavioral intention and actual usage of a device are influenced. This framework consists of the key elements that can properly facilitate the exploration of factors that affect physicians' decisions to prescribe the voice prosthesis and HME.

Evidence on the prescription of medical devices (in general) is scarce and dependent on the device type. Furthermore, information regarding reimbursement in different EU countries remains incomplete [11,13]. Publications specifically related to prescription and reimbursement of the voice prosthesis and HME mostly describe reimbursement issues (e.g. lack of reimbursement, restrictions to reimbursement dependent on a maximum amount or number of devices provided) in EU countries (see details in Appendix A) [9,14–18]. A comprehensive overview of prescription practices and reimbursement systems of the voice prosthesis and HME could bring forth insights to improve effective access.

Therefore, the aim of this mixed methods study is to evaluate factors influencing prescription and reimbursement of voice prostheses and HMEs, and to identify barriers to and facilitators of effective patient access in the EU.

**Materials and methods**

We performed a survey among head and neck surgeons and medical device representatives to study patient access in eight EU countries. Sequentially, we conducted interviews with the representatives to gather into-depth insights from the supplier perspective into the barriers and facilitators identified in the survey.

*Online survey*

An online survey was developed focusing on: physician's prescription (Part 1) and reimbursement (Part 2) of voice prostheses and HMEs, and barriers to and facilitators of effective patient access (Part 3). Part 1 was completed by head and neck surgeons who treated laryngectomy patients in Belgium, France, Germany, Italy, the Netherlands, Poland, Spain and the UK. As head and neck surgeons play a key role in the provision of both devices in the EU, we selected them to complete the first survey of the study. The contact details of the surgeons were obtained through the networks of some healthcare professionals employed at the Netherlands Cancer institute (NKI-AVL). All surgeons were sent an e-mail with information regarding the study including a survey link for participation. A minimum of three to four respondents per country was decided upon a priori. Part 2 and 3 were completed by representatives (managers) (n = 8) employed at a medical device company in the respective countries. Because the representatives are well-versed with policy- and practice-related matters regarding device use, it was assumed that they could provide a representative overview on device reimbursement and access at a national level.

In Part 1 of the online survey, various factors influencing prescription of both devices were questioned by applying the TAM (Fig. 1) [12]. TAM is considered to be a robust model and is often used in Information Technology (IT). According to TAM, two beliefs - the perceived usefulness and perceived ease of use - determine the attitude towards using the technology, thereby also affecting behavioral intention and use. These beliefs are influenced by multiple external factors [19]. Based on the available literature and input from a multidisciplinary panel, we identified important possible factors to consider and defined the questions [19]. The panel consisted of clinicians, experts in the field of health technology assessment and the head of clinical affairs of a device company. Also, the innovativeness was characterized by the diffusion theory of Rogers [20]. Five categories were distinguished within the external factors: organizational, economical, clinical, physician- and patient-related. Each category contains several factors, shown in Fig. 1, which were covered with at least one item in the survey. In addition, two items reflected the behavioral intention and actual use of the devices.

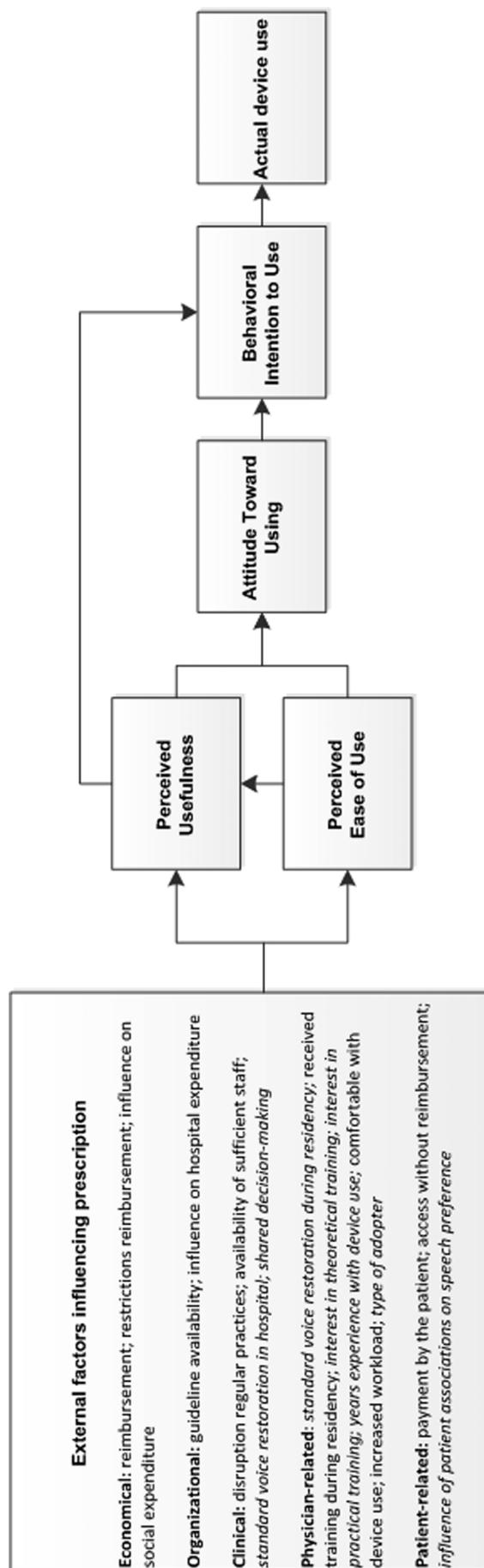


Fig. 1. Technology Acceptance Model (TAM) of voice prosthesis and HME utilization. Most external factors are outlined in Table 2. The remaining factors are stated in italic in the figure.

Multiple choice items regarding the reimbursement of voice prostheses and HMEs (Part 2) were developed based on publications included in a previous systematic literature review [11,21–26]. The items reflected key aspects of reimbursement described in the review. These aspects included: reimbursement scheme (e.g. hospital budget), level of reimbursement (e.g. national, regional), restrictions to reimbursement and type of payer (e.g. health insurer, out of pocket payment). Questions were addressed for both devices separately.

Part 3 of the survey comprised of open items concerning barriers to and facilitators of effective patient access to the voice prosthesis and HME, and asked at the reimbursement, physician's and patient's level.

Before dissemination, the survey was reviewed by a team of experts consisting of researchers specialized in the field of health technology assessment, speech-language pathologists (SLPs) and head and neck surgeons involved in laryngectomy rehabilitation prior to the start of the study. To prevent the occurrence of missing data, the online tool required completion of all questions in the survey.

#### Semi-structured interviews

Semi-structured telephone interviews were carried out with each representative of the medical device industry by both the first author and a research assistant. Part 2 and 3 of the survey, including a combination of multiple choice and open items, were used to perform a more in-depth exploration of the barriers to and facilitators of effective patient access reported in the survey. If necessary, data from the survey was confirmed and clarified with the respondents.

#### Analysis

Available data in the literature was compared across EU countries.

In Part 1, the external factors were interpreted as either having a facilitating or restrictive effect on the actual device use, in case the majority (> 50%) of the respondents indicated the factors to be favorable or unfavorable of device prescription respectively. The results of the survey were analyzed by utilization (users versus non-users) and country.

The semi-structured interviews were recorded and transcribed verbatim by two trained typists. Subsequently, the first author coded text fragments according to: type of factor (barrier/facilitator), type of device (voice prosthesis/HME) and level of access (reimbursement/physician/patient). Coding of the fragments, performed by the first author, was checked by the second author. Next, the coding was confirmed by the representatives. Results were compared among EU countries.

## Results

#### Survey and semi-structured interviews

##### Part 1: Physician's prescription of the voice prosthesis and HME

In total, 36 out of 110 head and neck surgeons employed in 30 different hospitals in Belgium (n = 4), France (n = 6), Germany (n = 5), Italy (n = 4), the Netherlands (n = 6), Poland (n = 5), Spain (n = 3) and the UK (n = 3) completed the survey. **Table 1** provides an overview of their demographics. Most respondents were male (83%) and employed in an academic center (89%). Of the surgeons, 81% performed > 10 total laryngectomies annually.

First, we analyzed the data focusing on the group of non-users compared to the users. All 36 surgeons were experienced in fitting voice prostheses. Four (11%) surgeons in Poland (n = 3) and Italy (n = 1) did not use HMEs in practice. Three of these surgeons had the intention to use HMEs, and one surgeon did not report his intention. Absence of reimbursement was reported by all non-users. Lack of training/experience and feeling uncomfortable with HME use were reported by Polish non-users. The non-users confirmed that these factors were restrictive on the actual use.

**Table 1**  
Demographics of respondents (head and neck surgeons).

Characteristics	Total no. (%)
Sex	
Male	30 (83)
Female	6 (17)
Country	
France	6 (17)
Netherlands	6 (17)
Germany	5 (14)
Poland	5 (14)
Belgium	4 (11)
Italy	4 (11)
Spain	3 (8)
UK	3 (8)
Hospitals	
No. of hospitals	30
Academic	32 (89)
Non-academic	3 (8)
Cancer center	1 (3)
No. of total laryngectomies per year	
5–10	7 (19)
> 10	29 (81)
Years experience (average (range))	
Voice prosthesis	17 (3–33)
HME	11 (0–30)

Abbreviations: HME, heat and moisture exchanger; UK, United Kingdom.

Second, we evaluated the effect of the factors across EU countries. In **Table 2**, the effect (restrictive or facilitating) of the factors on access to the voice prosthesis are displayed per country (complete overview including the HME is provided in Appendix B). Most notable results are outlined in this section. In the Netherlands and the UK, no restrictive factors were identified. The UK was the only country where responses regarding reimbursement were inconclusive, meaning answers varied (answered by respondents: 'yes', 'sometimes', 'no', or 'I don't know') and no majority was identified. In Belgium, reimbursement was available but restricted to five voice prostheses and 200 HMEs per patient yearly. Here, hospital guidelines for both devices were available for two of the four surgeons. Poor guideline implementation was the only restrictive factor mentioned by the majority of respondents in France (n = 5) and Germany (n = 3). Decrease of the social expenditure by HME implementation was expected in Germany (n = 3) [27]. In Italy, the reimbursement of voice prostheses was restricted to the number provided per year, and surgeons experienced increased workload through use of voice prostheses (n = 3) and HMEs (n = 2). In addition, the majority reported absence of guidelines. In Poland, the HME was not reimbursed but paid by the patient (n = 3). Furthermore, the HME was not available in their hospital. Increase in hospital and social expenditure by the HME was reported by 4 surgeons. With regard to Spain, no device guidelines were available. In addition, device implementation was thought to reduce societal costs, but increase hospital expenditure (n = 2). Insufficient staff, lack of HME training, and increased physician workload by device implementation were reported (n = 2).

Third, the remaining factors (in italic in **Fig. 1**) were analyzed. Most hospitals used tracheoesophageal speech as the standard care for voice restoration, whereas two hospitals in France and Italy applied standard esophageal speech. Standard care as taught during residency consisted of tracheoesophageal speech (n = 22) and esophageal speech (n = 14). Surgeons in Italy, Spain and Poland were interested in practical and theoretical device training. Innovativeness was questioned in the survey according to Rogers' diffusion theory. Most surgeons (n = 20) reported to be early adopters, 10 surgeons were late majorities, including the Polish non-HME-users, and six were innovators [20]. Thirty surgeons reported shared decision-making. In addition, most respondents in Germany, France, Italy and Poland indicated that patient associations (promoting either tracheoesophageal, esophageal speech or

**Table 2**  
Survey results: Factors influencing physician’s prescription of the voice prosthesis (n = 36).

		Voice prosthesis							
		B (n=4)	G (n=5)	N† (n=6)	UK (n=3)	F (n=6)	S (n=3)	I (n=4)	P (n=5)
ECONOMICAL	Reimbursement	Y*	Y*	Y*	IC	Y*	Y*	Y*	Y*
	Restrictions reimbursement	Y*	N*	N	N	N*	N*	IC	N
	Influence on social expenditure	IC	N	IC	IC	IC	N	NK	Y
ORGANIZATIONAL	Guideline availability	IC	N	Y*	Y	N	N*	N*	Y*
	Influence on hospital expenditure	IC	N	NK	IC	N	Y	IC	N
CLINICAL	Disruption of regular practices	N	N	N	N	N	N	N	N
	Availability of sufficient staff	Y*	Y*	Y*	Y*	Y	N	Y*	Y
PHYSICIAN-RELATED	Residency: Received training	Y*	Y*	Y*	Y*	Y	Y	Y*	Y*
	Comfortable with device use	Y*	Y*	Y*	Y*	Y*	Y*	Y	Y
	Increased workload	IC	N	IC	N*	N	Y	Y	N
PATIENT-RELATED	Payment by the patient	N*	N*	N*	N*	N*	N*	N*	N
	Access without reimbursement	IC	NA	NA	NA	NA	NA	NA	NA

Abbreviations: B, Belgium; F, France; G, Germany; I, Italy; IC, inconclusive; N†, Netherlands; N, no; NA, not applicable; NK, not known; P, Poland; S, Spain; UK, United Kingdom; Y, yes.

The abbreviations used in the table are explained below the table. The overview is based on answers that were given by the majority (> 50%) of respondents. When the respondents’ answers were uniform (e.g. all respondents answered ‘yes’), this is indicated with an asterisk (‘Y’). In case respondents’ answers to the question varied within a country and no majority could be identified, this was stated as inconclusive (IC).

Responses that are interpreted as facilitating to effective patient access are marked in green; responses that are interpreted as restrictive to effective patient access are marked in red. No influence is indicated without markings. Grey markings were given when answers were inconclusive, or in case the majority answered ‘I don’t know’ or ‘not applicable’.

‘Influence on social expenditure’ was defined as the impact of device implementation in practice on the societal costs (e.g. positive influence of device use on return to work reduces cash benefits for unemployed patients) derived from the definition stated by the Organisation for Economic Co-operation and Development (OECD) [27].

‘Influence on hospital and social expenditure’: ‘Y’ indicates that the device use results in an increase in the expenditure; ‘N’ indicates that the device use has no influence (not marked) or results in a decrease in expenditure (marked in green).

electrolarynx) have an impact on speech preference of patients.

**Part 2: Reimbursement systems**

Table 3 provides an overview of the reimbursement systems applied to the voice prosthesis and HME in the EU.

Belgium applies a lump sum in the inpatient sector. The lump sum is dependent on the maximum price per voice prosthesis and a fixed number of HMEs (regardless of the unit price). The sum is mainly funded by the Belgian National Health Insurance (NHI). In addition, a small contribution is made by the patient quarterly. Excess costs are paid by the hospital or the patient.

In France, the voice prosthesis and HME are funded by the NHI in the outpatient sector through a list of products and services qualifying for reimbursement (*Liste des Produits et Prestations Remboursable - LPPR*) under the generic line (existing categories) and brand name (innovative

devices) respectively.

Reimbursement in Germany is dependent on the type of insurance: the Statutory (SHI) or Private Health Insurance (PHI). The (first) devices applied postoperatively are included in the diagnosis-related group (DRG) of the laryngectomy. During follow-up, devices are reimbursed under the flat rate system. The system provides a monthly fixed amount covering (unlimited) rehabilitation care including nurses. The PHI insures through ‘itemized billing’: patients order at the medical device company and receive an invoice for the insurer.

In Italy, the voice prosthesis is paid through per-case tariffs (DRG-based) funded regionally through the Italian National Health Service (NHS). The HME is paid by the health districts or the patient.

In the Netherlands, the voice prosthesis is provided nationally using a DRG-based DBC (*Diagnose Behandel Combinatie*) system. The HME is incorporated in a reimbursement list and funded through itemized

**Table 3**  
Survey and interview results: Reimbursement of the voice prosthesis and HME (n = 8).

Country	Device	Reimbursement method	Funding by IP or OP	Payer
Belgium	VP	Lump sum	IP	NHI + contribution patient
	HME	Lump sum	IP	NHI + contribution patient
France	VP	Itemized billing <sup>b</sup>	OP	NHI
	HME	Itemized billing <sup>b</sup>	OP	NHI
Germany	VP	1. DRG + flat rate 2. DRG + itemized billing	1. IP + OP 2. IP + OP	1. SHI 2. PHI
	HME	1. DRG + flat rate 2. DRG + itemized billing	1. IP + OP 2. IP + OP	1. SHI 2. PHI
Italy	VP	Per case tariffs	IP	NHS (Regions)
	HME	None	NA	NHS (HD) or patient
Netherlands	VP	DRG-based	IP	PHI + contribution patient
	HME	Itemized billing <sup>b</sup>	OP	PHI + contribution patient
Poland	VP	Hospital budget <sup>a</sup>	IP	NHS
	HME	None	NA	Patient
Spain	VP	Hospital budget <sup>a</sup>	IP	MOH
	HME	Itemized billing <sup>b</sup>	OP	NHS
UK	VP	Hospital budget <sup>a</sup>	IP	NHS
	HME	Itemized billing <sup>b</sup>	OP	NHS

Abbreviations: DRG, diagnosis-related group; HD, health district; HME, heat and moisture exchanger; IP, inpatient; MOH, Ministry of Health; NA, not applicable; NHI, National Health Insurance; NHS, National Health Service; OP, outpatient; PHI, Private Health Insurance; UK, United Kingdom; SHI, Statutory Health Insurance; VP, voice prosthesis.

<sup>a</sup> No direct reimbursement but indirectly funded by the NHS/MOH.

<sup>b</sup> Reimbursement list.

billing. Patients pay an annual fixed amount, ‘the own risk excess’, after which the device costs are covered by the PHI.

The hospital budget pays for the voice prosthesis in Poland. The budget is funded by the NHS post factum. The HME is paid by the patients.

Spain and the UK also fund the voice prosthesis out of the hospital budget, which is provided by the Ministry of Health (MOH) and NHS respectively. The HME is incorporated in a reimbursement list funded through itemized billing.

#### Part 3: Barriers to and facilitators of effective patient access to voice prosthesis and HME

Barriers and facilitators are outlined in Table 4 per level of access.

Lack of reimbursement is a barrier to access the HME in Poland and Italy, resulting in out of pocket payment by the patient. Restrictions on budget and device provision were mentioned in Belgium (e.g. fixed lump sum) and Poland (e.g. hospital budget and incentives of health policy makers). In Germany, an unrestricted flat rate system is applied, whereas provision may be constrained when distributors are not profitable. The presence of reimbursement or access to a reimbursement list was mentioned as a facilitator in the Netherlands and the UK.

Positive opinions on the device as well as device support from hospitals (e.g. political lobby), patient associations, healthcare professionals (e.g. informing patients) and manufacturers were reported among Belgium, Italy and Spain. In Germany and France, absence of support by the physician and patient associations negatively affected prescription and utilization respectively.

Available clinical evidence on the device is a facilitator to access in the Netherlands and France. Guideline implementation has a positive influence on reimbursement in Italy, whereas guideline absence was reported in Poland.

Increased physician workload by device prescription (e.g. providing rehabilitation care, administration) and a lack of rehabilitation personnel was stated in France, Italy, Poland and Spain. In Spain, a rehabilitation team with SLPs is sometimes facilitated to support the physician.

(Lack of) education or experience of patients and healthcare professionals (SLPs and physicians) were mentioned either as a barrier or facilitator (France, Spain, Poland and the UK).

Positive device-specific features mentioned in the Netherlands and

the UK included quality of the device, ease of use, performance (e.g. improvement of voice quality and QoL) and device lifetime. Complications or negative experiences related to the device were hindering access in the Poland, Spain and the UK.

Other barriers to physician’s prescription or patient’s utilization that were mentioned: preferred esophageal speech (Italy), maintenance of traditions related to non-usage (Poland and Italy), isolation of and prioritization by patients (France), secondary puncture for voice prosthesis placement (Spain) and the requirement for hospitalization during voice prosthesis replacement (Poland).

#### Discussion

To our knowledge, this is one of the first studies in the HNC field presenting drivers to prescription and reimbursement of voice prostheses and HMEs in eight EU countries. In addition, this analysis included identification of barriers to and facilitators of effective patient access. Access to the voice prosthesis was established through (indirect) funding and prescription by all respondents. The HME was not reimbursed in Poland and Italy. At the individual level, four surgeons did not prescribe the HME. Compared to the HME-users, the four non-HME-users encountered specific restrictive factors including absence of reimbursement, lack of experience/training of the surgeons and feeling uncomfortable with the HME usage. At a country-based level, most restrictive factors were identified for Poland, Spain and Italy, and included - among the factors related to non-users - increased physician workload and insufficient number of staff. Guideline absence was stated by respondents from Germany, France, Spain and Italy. From the interviews, restrictions to reimbursement (e.g. fixed lump sum), lack of physician’s and patient’s education, increased workload and complications after device use were the most common barriers. Most common facilitators to effective patient access were providing education to healthcare professionals and patients, and support from healthcare professionals regarding the device.

Our results were in accordance with findings on device access in literature. In our study, absence of reimbursement applied to all non-users in Italy and Poland, although most of them had the intention to use HMEs. Thus, financial reimbursement is an important barrier in physician’s prescription, and the representatives stated this accordingly. This was also found in the study of Van der Houwen et al.,

**Table 4**  
 Survey and interview results: Barriers to and facilitators to effective access to voice prosthesis and HME according to the different levels (reimbursement/physician/patient). Further explanation on the barriers and facilitators is provided in Part 3 of the Results section (n = 8).

	Barriers	Facilitators
<b>Reimbursement level</b> <i>What are barriers of and facilitators to reimbursement of the voice prosthesis and HME?</i>		
Belgium	<ul style="list-style-type: none"> <li>● No reimbursement beyond the fixed amount of the lump sum</li> <li>● Provision by hospital pharmacies is dependent on the lump sum</li> </ul>	<ul style="list-style-type: none"> <li>● Support from patient associations and academic hospitals</li> </ul>
Germany	<ul style="list-style-type: none"> <li>● Healthcare provision is sometimes restricted under the flat-rate system when it becomes non-profitable for distributors</li> </ul>	
Italy		<ul style="list-style-type: none"> <li>● Development of a national guideline</li> <li>● Collaborations of manufacturers with the Health Ministry</li> <li>● Availability of clinical evidence</li> </ul>
Netherlands	<ul style="list-style-type: none"> <li>● Incentives of health policy makers: decision-making regarding reimbursement</li> </ul>	
Poland	<ul style="list-style-type: none"> <li>● Budget restrictions by the hospital<sup>a</sup></li> </ul>	
Spain		<ul style="list-style-type: none"> <li>● Positive opinion of physicians<sup>a</sup></li> <li>● Listing on the Drug Tariff<sup>b</sup></li> </ul>
UK		<ul style="list-style-type: none"> <li>● Availability of clinical evidence<sup>a</sup></li> </ul>
<b>Physician's level</b> <i>What are barriers of and facilitators to physician's prescription of the voice prosthesis and HME?</i>		
France	<ul style="list-style-type: none"> <li>● Physicians are not convinced<sup>a</sup></li> <li>● Lack of education of physicians<sup>a</sup></li> <li>● Workload of physicians: providing rehabilitation care<sup>a</sup></li> <li>● Lack of collaboration between physicians and SLPs after treatment<sup>b</sup></li> <li>● Voice teachersprefer esophageal speech<sup>a</sup></li> <li>● Workload of physicians: providing rehabilitation care<sup>a</sup></li> <li>● Lack of rehabilitation personnel<sup>a</sup></li> <li>● No reimbursement<sup>b</sup></li> </ul>	
Italy		
Netherlands	<ul style="list-style-type: none"> <li>● No national guideline available<sup>a</sup></li> <li>● Complications in the past<sup>a</sup></li> </ul>	<ul style="list-style-type: none"> <li>● Reimbursement of the device</li> <li>● Education of physicians<sup>a</sup></li> </ul>
Poland	<ul style="list-style-type: none"> <li>● Incentives of hospital directorates: maintaining traditional treatment regime<sup>a</sup></li> <li>● Workload: administration/documentation during replacements<sup>a</sup></li> </ul>	
Spain	<ul style="list-style-type: none"> <li>● No reimbursement<sup>b</sup></li> <li>● Workload of physicians: providing rehabilitation care<sup>a</sup></li> <li>● Lack of experience with rehabilitation by physicians<sup>a</sup></li> <li>● Complications in the past<sup>a</sup></li> <li>● Complications in the past<sup>a</sup></li> </ul>	<ul style="list-style-type: none"> <li>● Rehabilitation team with SLPs<sup>a</sup></li> <li>● Positive opinion of physicians<sup>b</sup></li> </ul>
UK		<ul style="list-style-type: none"> <li>● Education of physicians, SLPs and patients<sup>a</sup></li> </ul>
<b>Patient's level</b> <i>What are barriers of and facilitators to patient's utilization of the voice prosthesis and HME?</i>		
Belgium		<ul style="list-style-type: none"> <li>● Support from SLPs and physicians<sup>a</sup></li> <li>● Support from SLPs and patient associations<sup>b</sup></li> <li>● Education of patients on the device</li> <li>● Previous experiences of patients with the device</li> <li>● Unrestricted healthcare provision provided by flat rate system<sup>b</sup></li> </ul>
France	<ul style="list-style-type: none"> <li>● Social isolation of patients<sup>a</sup></li> </ul>	
Germany	<ul style="list-style-type: none"> <li>● Utilization is no priority to patients<sup>b</sup></li> <li>● No support from patient associations<sup>b</sup></li> </ul>	
Italy	<ul style="list-style-type: none"> <li>● Patient associations and voice teachers prefer esophageal speech<sup>a</sup></li> <li>● Tradition of patients not to wear a HME<sup>b</sup></li> <li>● Payment by patient<sup>b</sup></li> </ul>	

(continued on next page)

Table 4 (continued)

	Barriers	Facilitators
Netherlands		<ul style="list-style-type: none"> <li>● Perceived quality of the device</li> <li>● Improvement of quality of life of patients by using the device</li> <li>● Ease of use of the device</li> </ul>
Poland	<ul style="list-style-type: none"> <li>● Lack of education of patients<sup>a</sup></li> <li>● Hospital admission for VP replacement<sup>a</sup></li> <li>● Payment by patient<sup>b</sup></li> <li>● Secondary puncture<sup>a</sup></li> </ul>	
Spain	<ul style="list-style-type: none"> <li>● Complications in the past<sup>a</sup></li> <li>● Lack of education of patients<sup>a</sup></li> <li>● Negative performance of the device<sup>b</sup></li> </ul>	
UK		<ul style="list-style-type: none"> <li>● Support from manufacturers and healthcare professionals<sup>a</sup></li> <li>● Education of patients<sup>a</sup></li> <li>● Ease in speaking and voice quality<sup>a</sup></li> <li>● Long device lifetime<sup>b</sup></li> <li>● Improving breathing<sup>b</sup></li> </ul>

Abbreviations: HME, heat and moisture exchanger; SLP, speech language pathologist; UK, United Kingdom; VP, voice prosthesis.

<sup>a</sup> Related to only the voice prosthesis.

<sup>b</sup> Related to only the HME.

describing a large difference in adhesives utilization by laryngectomized patients between reimbursing and non-reimbursing countries [16]. In studies previously published on cardiac implantable devices and transcatheter aortic valve (TAVR) implants utilization, similar results were observed [28,29]. In addition, the frequency of prosthesis replacements is dependent on the country's reimbursement system, as DRG-based systems enable adequate device access (e.g. regular prosthesis replacements) in contrary to hospital budgets which are being led by restrictions on funding [18]. For instance, the voice prosthesis is replaced six times per year in the Netherlands, whereas in Spain this was reported to be only three times [30,31]. Within the EU, countries with regional autonomy such as Italy and Spain encounter more barriers to effective patient access. As a consequence, device utilization is lower in these countries than those with national reimbursement (data not shown). Decentralized healthcare systems are more susceptible to variations in device reimbursement (e.g. funding at the hospital level) and differences in provision between the regions, of which the latter is strongly dependent on physician-related factors [32]. In this study, physician-related factors for non-usage included lack of training during residency and feeling uncomfortable with using the device. Three of the four non-users tend to start using the device in a late stage of device diffusion, whereas most users were early adopters. At the physician level, Cappellaro et al. also described the cultural background of the physician as to impact device provision [11]. At an organizational level, absence of guidelines was a restrictive factor for device provision reported in four out of eight countries. This barrier was also described by Boriani et al. for cardiac device implementation [33].

Several limitations should be taken into account. To identify factors influencing device prescription, comparing data of users and non-users is inevitable. Although we believe that the responses of the 36 surgeons provided a good representation of current practices, a small bias cannot be excluded. We may not have captured all the possible variation within each country. This may be caused because we either did not identify non-users of the voice prosthesis in the sample of the study, or the non-users did not respond. For instance, we know that in most countries where utilization of the voice prosthesis is not optimal, (e.g. Spain and Italy) many patients still rely on esophageal speech. This selection bias may be caused by the fact that, although we achieved to include 30 hospitals in this study, most responding surgeons were employed in an academic hospital. Also, as the degree of concentration of HNC care differs among EU countries, some variation in the restrictive factors may not have been identified in countries with less concentrated care. A possible limitation of the study is that only representatives employed at one medical device company participated in the study. On the other hand, there are only two leading companies in the EU and no differences exist in device reimbursement and patient access. Some discrepancies were found in responses from surgeons and representatives. Regarding reimbursement-related issues, representatives focused on reimbursement systems, whereas surgeons' responses also included other financial support (e.g. health districts in Italy). Barriers and facilitators were partly obtained from device company representatives, who might be biased as they also represent other interests (e.g. device marketing). Several strengths of the study include applying the TAM framework to evaluate device use, and the involvement of various stakeholders in the survey. This study is unique because, to our knowledge, this is the first study in the field of HNC to provide insight on reimbursement as well as prescription of HNC-specific devices, and on facilitating and restrictive factors affecting patient device use in eight EU countries. Ultimately, these results can be used in optimizing access to these devices.

For further research, we recommend obtaining more data from non-users of the voice prostheses and HMEs, especially in (regions of) countries with lower device utilization, e.g. where esophageal speech is still standard of care. A larger sample size would also allow for the performance of statistical analyses of differences in reimbursement and

device use across EU countries or intercontinentally (e.g. EU versus North-America). Conducting semi-structured interviews with surgeons, particularly non-users, could be a next step to deepen drivers to device prescription. In addition, device-related factors should be included as external factors in the TAM, as suggested by Venkatesh et al. to identify the impact of the device and its outcomes on prescription practices [19].

Several implications for clinical practice come forth. Providing national reimbursement of HMEs in Poland and Italy is essential to increase utilization. In addition, introducing more flexibility in reimbursement systems such as the hospital budget and lump sum for the voice prosthesis in Poland and Belgium respectively could increase access to patients. Uniformity in device access and use in France, Germany, Italy and Spain could be achieved by national guideline implementation. At the physician level, increased workload during in the follow-up and rehabilitation phase could be alleviated by providing support from health professionals in countries such as Spain, Poland, France and Italy. Finally, physician's and patient's lack of training and experience with the device could be addressed during and after residency by means of continuous education.

## Conclusion

In this mixed-methods study, factors associated with non-prescription were, apart from the absence of reimbursement – a key driver to effective patient access –, lack of training/experience and feeling uncomfortable with device use. Restrictive factors to device access were identified often in decentralized healthcare systems in countries such as Spain and Italy leading to lower device utilization. From this study, we recommend nationwide reimbursement and guideline implementation on both devices, and the availability of a rehabilitation team to support the physician in healthcare provision. Furthermore, inexperienced physicians as well as patients should be trained and educated e.g. by competent professionals and supported by manufacturers. For further research, it is recommended to gain more data from non-users, investigate device-related factors, and conduct interviews with physicians to deepen causality between external factors and actual use of the voice prosthesis and HME.

## Role of funding source

Atos Medical AB had no involvement in the development of the study.

## Conflict of interest statement

This work was supported by a non-restricted research grant from Atos Medical AB contributing to the existing infrastructure for health-related quality of life research of the department of Head and Neck Oncology and Surgery. Atos Medical AB had no involvement in the development of the study.

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## Appendix A. Supplementary material

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.oraloncology.2019.02.017>.

## References

- [1] Gatta G, Botta L, Sanchez MJ, Anderson LA, Pierannunzio D, Licitra L. Prognoses and improvement for head and neck cancers diagnosed in Europe in early 2000s: the EURO-CARE-5 population-based study. *Eur J Cancer* 2015;51(15):2130–43.
- [2] van Sluis KE, van der Molen L, van Son RJ, Hilgers FJ, Bhairosing PA, van den Brekel MW. Objective and subjective voice outcomes after total laryngectomy: a systematic review. *Eur Arch Otorhinolaryngol* 2018;1–16.
- [3] Clements KS, Rassekh CH, Seikaly H, Hokanson JA, Calhoun KH. Communication after laryngectomy: an assessment of patient satisfaction. *Arch Otolaryngol-Head Neck Surgery* 1997;123(5):493–6.
- [4] Ackerstaff AH, Hilgers FJ, Balm AJ, Aaronson NK, van Zandwijk N. Improvements in respiratory and psychosocial functioning following total laryngectomy by the use of a heat and moisture exchanger. *Ann Otol Rhinol Laryngol* 1993;102(11):878–83.
- [5] Brook I, Bogaardt H, van As-Brooks C. Long-term use of heat and moisture exchangers among laryngectomees: medical, social, and psychological patterns. *Ann Otol Rhinol Laryngol* 2013;122(6):358–63.
- [6] Hilgers FJ, Aaronson NK, Schouwenburg PF, Zandwijk N. The influence of a heat and moisture exchanger (HME) on the respiratory symptoms after total laryngectomy. *Clin Otolaryngol* 1991;16(2):152–6.
- [7] Ackerstaff A, Hilgers F, Aaronson N, Schouwenburg P. Physical and psychosocial sequelae of total larynx extirpation and the use of a heat and moisture exchanger. *Ned Tijdschr Geneesk* 1990;134(50):2438–42.
- [8] Hilgers FJ, Ackerstaff AH, Aaronson NK, Schouwenburg PF, Zandwijk N. Physical and psychosocial consequences of total laryngectomy. *Clin Otolaryngol* 1990;15(5):421–5.
- [9] van der Molen L, Kornman AF, Latenstein MN, van den Brekel MW, Hilgers FJ. Practice of laryngectomy rehabilitation interventions: a perspective from Europe/the Netherlands. *Curr Opin Otolaryngol Head Neck Surg*. 2013;21(3):230–8.
- [10] Basu S, Hassenplug JC. Patient access to medical devices—a comparison of U.S. and European review processes. *N Engl J Med*. 2012;367(6):485–8.
- [11] Cappellaro G, Fattore G, Torbica A. Funding health technologies in decentralized systems: a comparison between Italy and Spain. *Health Policy* 2009;92(2–3):313–21.
- [12] Davis FD. Perceived usefulness, perceived ease of use, and user acceptance of information technology. *MIS Quarterly* 1989:319–40.
- [13] Schreyogg J, Baumler M, Busse R. Balancing adoption and affordability of medical devices in Europe. *Health Policy* 2009;92(2–3):218–24.
- [14] Betlejewski S, Ossowski R, Sinkiewicz A. Rehabilitation after total laryngectomy—vision and realization. *Otolaryngol Pol* 2007;61(3):344–8.
- [15] Ten Hallers EJ, Marres HA, Rakhorst G, Hagen R, Staffieri A, Van Der Laan BF, et al. Difficulties in the fixation of prostheses for voice rehabilitation after laryngectomy. *Acta Otolaryngol* 2005;125(8):804–13.
- [16] van der Houwen EB, van Kalker TA, Post WJ, Hilgers FJ, van der Laan BF, Verkerke GJ. Does the patch fit the stoma? A study on peristoma geometry and patch use in laryngectomized patients. *Clin Otolaryngol* 2011;36(3):235–41.
- [17] Wierchowska M, Burduk PK. Early and late complications after implantation of the Provox 2 voice prosthesis in patients after total laryngectomy. *Otolaryngol Pol* 2011;65(3):184–7.
- [18] Zimmer-Nowicka J, Morawiec-Sztandera A. Causes and indwelling times of multiple voice prosthesis replacements in patients after total laryngectomy—analysis of 184 replacements in 42 patients. *Otolaryngol Pol* 2012;66(5):322–7.
- [19] Venkatesh V, Bala H. Technology acceptance model 3 and a research agenda on interventions. *Decision Sci* 2008;39(2):273–315.
- [20] Rogers EM. Diffusion of innovations. Simon and Schuster; 2010.
- [21] Olberg B, Perleth M, Busse R. The new regulation to investigate potentially beneficial diagnostic and therapeutic methods in Germany: up to international standard? *Health Policy* 2014;117(2):135–45.
- [22] Martelli N, van den Brink H. Special funding schemes for innovative medical devices in French hospitals: the pros and cons of two different approaches. *Health Policy* 2014;117(1):1–5.
- [23] Parquin F, Audry A. Clinical evaluation of medical devices: main constraints and specificities. *Therapie* 2012;67(4):311–8.
- [24] Guillou J. Medical device reimbursement in France process of decision. [French, English] Remboursement des dispositifs médicaux en France processus de décision. *STP. Pharma Pratiques* 2011;21(5):425–32.
- [25] Loge P, Delalande F, Reymond MC, Germain S. Factors influencing reimbursement of medical devices in France. *Int J Technol Assess Health Care* 2015;31(6):399–406.
- [26] Schwander B, Krone FA, Walzer S. Clinical and health economic evidence requirements for obtaining health insurance coverage for innovative medical devices in Germany. *Value Health* 2013;16(7):A474.
- [27] Social Expenditure Last accessed: 28-1-2019. [updated 13-3-2003. Available from: <https://stats.oecd.org/glossary/detail.asp?ID=2485>.
- [28] Mylotte D, Osnabrugge RL, Windecker S, Lefèvre T, de Jaegere P, Jeger R, et al. Transcatheter aortic valve replacement in Europe: adoption trends and factors influencing device utilization. *J Am Coll Cardiol* 2013;62(3):210–9.
- [29] Mairese GH, Braunschweig F, Klersy K, Cowie MR, Leyva F. Implementation and reimbursement of remote monitoring for cardiac implantable electronic devices in Europe: a survey from the health economics committee of the European Heart Rhythm Association. *EP Europace* 2015;17(5):814–8.
- [30] Mayo-Yáñez M, Cabo-Varela I, Dovalo-Carballo L, Calvo-Henríquez C, Martínez-Morán A, González-Botas JH. Provox 2® and Provox Vega® device life-time: a case-crossover study with multivariate analysis of possible influential factors and duration. *Eur Arch Otorhinolaryngol* 2018;1–4.
- [31] Petersen JF, Lansaat L, Timmermans AJ, van der Noort V, Hilgers FJ, van den Brekel

MW. Postlaryngectomy prosthetic voice rehabilitation outcomes in a consecutive cohort of 232 patients over a 13-year period. *Head Neck* 2018.

- [32] Castro MF, Guccio C, Pignataro G, Rizzo I. The effects of reimbursement mechanisms on medical technology diffusion in the hospital sector in the Italian NHS.

*Health Policy* 2014;115(2–3):215–29.

- [33] Boriani G, Burri H, Mantovani LG, Maniadakis N, Leyva F, Kautzner J, et al. Device therapy and hospital reimbursement practices across European countries: a heterogeneous scenario. *Europace* 2011;13(suppl\_2):ii59–65.