Patient, clinician and product designer perspectives on the design of a dysphagia rehabilitation tool

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Conventions

As this thesis was written for the consideration of the journal *Disability and Rehabilitation: Assistive Technology*, APA style referencing and formatting style have been adopted as per journal specifications.

Glossary of terms used in this thesis

Activity¹: the execution of a task or action by an individual.

Format²: “the particular way a device operates”.

Impairment¹: problems in body function and structure such as significant deviation or loss.

*Isometric tongue pressures*: tongue muscle contraction against constant resistance (Yoshida et al., 2006).

*OroPress*: a clinic ready prototype swallowing rehabilitation tool.

*Out-of-Box Experience*: the features associated with a specific experience / reaction that a user has when using a product for the first time after taking it out of its box (Ketola, 2005).

Participation¹: involvement in a life situation.

Primary user²: “the person that directly uses a device” (e.g. patients).

Primary user usability²: “how easy or difficult the primary user finds a product to use”.

Secondary users²: “any other people that have indirect use with a device” (e.g. clinicians, carers and family members).

User interface²: “the way in which the primary user interacts with a device”.

Wellbeing / Distress³: emotional level of upset or distress.

¹ International Classification of Functioning, Disability and Health (ICF) terminology (World Health Organisation, 2001).
² Reference/definition provided by co-supervisor.
³ UK TOMS terminology (Enderby & John, 1997).
Abstract

Background: There is an absence of available biofeedback tools for use in rehabilitation of people who have dysphagia. To create a suitable tool, ‘expert’ opinion from people such as clinicians and product designers is desirable to establish what may be achievable for a rehabilitation tool. More importantly, target clients are integral to any design process, as understanding their needs and potential patterns of use enhances the likelihood of a tool being designed to meet their needs.

Objectives: To determine: (i) whether a dysphagia tool would be useful for patients rehabilitation; (ii) how would a dysphagia tool be used; (iii) the preferred product format for a dysphagia tool; (iv) views about a specific clinic-ready prototype tool, called OroPress.

Method: Three focus groups were conducted with product designers, speech and language therapy clinicians, and post-surgical head and neck cancer patients. To facilitate discussion, a set of topic headings, photographs and models were introduced. Qualitative analysis was performed on the transcribed text using Glaserian coding principles to form open codes, selective codes and then themes.

Results: Examination of concordance, across and within groups, identified five main themes: user interface, out-of-box experience, format, primary user usability, and views about OroPress.

Conclusions: This study indicates that: (i) a tool was assessed as being useful and needed; (ii) a dysphagia tool would be used independently in the home, while connecting with a speech and language therapist electronically via the device; (iii) feedback was considered essential, with product designers and clinicians favouring visual, and patients preferring tactile. Preferred placement of the device varied; (iv) OroPress was considered to be bulky and unappealing. All groups agreed that it required reverse engineering.
Introduction

Swallowing is a complex sensorimotor activity that includes numerous meticulously timed events. Specifically, swallowing involves the peripheral and central nervous systems as well as more than 30 pairs of muscles and six cranial nerves (Humbert & German, 2013). A breakdown of swallowing results in dysphagia, defined as, “a difficulty in moving food from mouth to stomach” (Logemann, 1998, pp. 2). Reilly and Ward (2005, pp.15) state that, “dysphagia is not a single disease but a cluster of symptoms that occur as a result of an underlying disorder”. Symptoms of dysphagia include pneumonia, malnutrition and dehydration. Over 50% of people with dysphagia eat less because of the discomfort that co-exists with an unsafe or inefficient swallow (Ekberg et al., 2002).

Dysphagia results in clear physical consequences but its social and psychological effects are less well understood. Eating and drinking are social and pleasurable experiences for healthy people, and meals are often the focus of family celebrations or religious holidays. Ekberg et al. (2002) conducted a study with elderly people who had dysphagia in Germany, France, Spain and the United Kingdom. Eighty four percent of those surveyed thought that eating should be an enjoyable experience, but only 45% of them found it so. Dysphagia can limit and/or destroy the social opportunities and pleasures of mealtimes, negatively affecting the quality of a person’s relationship with family members. Dysphagia can also undermine health and confidence (Ekberg et al., 2002). People with dysphagia can become isolated, excluded by others and feel anxious and/or distressed at mealtimes. Dysphagia reduces a person’s dignity and self-esteem (Ekberg et al., 2002).

The causes of dysphagia vary and may include natural aging, neurological, degenerative and systematic diseases, head injury and/or auto-immune disorders (Murray & Carrau, 2012). This study was focused on a specific population in Ireland for whom dysphagia is prevalent - people with a diagnosed head and neck (HN) cancer. HN cancers are the eleventh most common set of cancers in Ireland, accounting for 2.8% of all cancers in men and 1.1% in women (National Cancer Registry, 2011). The majority of patients treated for HN cancer have some degree of swallowing difficulty; the severity of their dysphagia will depend on the location of the tumour, the extent of surgery and/or the provided treatments (Groher & Crary, 2010). Treatments destroy cancer cells through a combination of surgical
interventions, chemotherapy and radiation therapy, but survival is often associated with long term dysphagia (Van der Molen et al., 2009).

García-Peris et al. (2007) determined the prevalence of dysphagia in a sample of HN cancer patients treated with surgery and radiotherapy or chemoradiotherapy in Spain. Their research found that oropharyngeal dysphagia was present in 50.6% of these patients and that patients who had a total glossectomy and chemoradiotherapy had the highest rate (García-Peris et al., 2007). Patients receiving radiation therapy are at greater risk for dysphagia than are patients receiving surgical treatments without radiation (Groher & Crary, 2010).

**Interventions for dysphagia**

Swallowing is a complex mechanism involving higher brain centres of the cortex (Humbert et al., 2009). This is encouraging for the treatment of dysphagia because clinicians and patients can train, and/or modify the components of oropharyngeal swallowing that are volitionally initiated or modified. However, many swallowing treatments are compensatory (using strategies designed to improve swallowing safety by accommodating to the deficit, such as by modifying food consistencies) rather than rehabilitative (using oropharyngeal exercises to regain safe and efficient swallowing) (Ekberg et al., 2002). Compensatory strategies are often used in the short-term to maintain oral intake, while long-term management has a focus on rehabilitation (Daniels & Huckabee, 2008). Rehabilitation is a key aspect of managing dysphagia.

Current strategies used in dysphagia management include the effortful swallow (patients are instructed to ‘swallow hard’) and the Masako manoeuver (patients are instructed to hold their tongue between teeth when swallowing). These techniques were initially presented as compensatory mechanisms to facilitate swallowing efficiency; however they have since been applied during rehabilitation with the belief that these exercises result in tongue and pharyngeal muscle strengthening- despite the fact that no data is available to document this effect (Daniels & Huckabee, 2008).

In applying such techniques, tools for biofeedback may be added to these muscle exercises. Kasman (1996, pp.4) commented that biofeedback represents “instantaneous performance-contingent feedback”. Biofeedback tools allow for immediate (visual, auditory or both)
feedback of some aspect of swallowing and provide information to evaluate, teach and/or monitor the impact of performance (Daniels & Huckabee, 2008). Quantitative information provided by biofeedback tools may encourage patients and clinicians to persevere with treatment when progress has not yet begun to manifest clinically. The use of biofeedback may also enhance compliance with therapy programmes and increase fidelity to treatment (Daniels & Huckabee, 2008). Denk and Kaider (1997) used a fibreoptic endoscopic evaluation of swallowing (FEES) for ongoing biofeedback with a sample of patients with HN cancer. Those who received such visual biofeedback recovered more rapidly than those in the control group (without feedback). This exemplifies the advantages to be gained with the use of biofeedback. Nonetheless a FEES procedure is not without risks. Due to the invasive nature of this procedure, which may result in discomfort, gagging and/or vomiting or in mucosal perforation (Nacci et al., 2008), a less invasive biofeedback tool is required.

Surface electromyography (sEMG) is the best documented tool used for biofeedback in swallowing rehabilitation. Crary et al. (2004) reported the outcomes of 45 patients with pharyngeal dysphagia, secondary to either stroke or HN cancer, who participated in a structured swallowing programme supplemented by sEMG biofeedback. Results indicated that this approach improved swallowing in both groups but the addition of biofeedback increased the rate of motor learning and hence improved the time efficiency of therapy (Crary et al., 2004). Unique challenges are seen when applying sEMG to swallowing musculature because of the small size of the muscles in relation to sEMG site of detection and a lack of knowledge about exact innervation locations (Stepp, 2012). The specific outcomes from using this tool are not able to be measured as the area of change is unknown, meaning it is difficult to pinpoint what specific group of muscles were targeted and/or improved.

**Tongue strength as a predictor of swallowing efficiency**

Dysphagia researchers have more recently focused on the role of the tongue (Steele et al., 2013; Gingrich et al., 2012) as the ability to generate tongue-palate pressure has been documented as a good predictor of swallowing efficiency (Clark et al., 2003). Reduced tongue strength, measured during maximum isometric tongue-palate pressure tasks, has been observed in adults with dysphagia. Hori et al. (2013) state that tongue strength
represents a simple, non-invasive, and quantifiable method by which tongue activity can be evaluated. Oral tongue devices are used to measure contact pressure between the tongue and hard palate during isometric and swallowing tasks.

There are many tongue-strength measurement tools such as the Hori/Ono sensor sheet and the oro-lingual pressure array of the Kay Swallowing Workstation. However, only the Iowa Oral Performance Instrument (IOPI) and OroPress will be compared in this review because they are similar and both are clinically current. The IOPI and OroPress are similar as both involve measuring tongue pressures intra-orally (Adams et al., 2013). The anterior portion of the tongue presses against the sensor(s) and tongue strength at that contact point is measured.

The IOPI may be used for biofeedback using its liquid-crystal-display (LCD) of red and green lights presented vertically (Youmans et al., 2009). A green light indicates that the user is reaching a target pressure, but it does not allow the user to visualise the pressure change produced across time. Despite some positive research using the IOPI, there are significant shortcomings associated with its use including the intrusiveness of one large sensor, the high cost of single use sensors and the poor consistency of the recordings because of the hand-held intra-oral probe (Adams et al., 2013).

OroPress is a prototype clinical tool that employs a small sensor adhered to the hard palate, resulting in a stable positioning for pressure measurements during swallowing and isometric tasks. A user pushes their tongue directly against a flat sensor attached to the hard palate, allowing for lingual pressures to be reliably recorded (McCormack et al., 2013). OroPress may be used to measure lingual pressures in real-time and this information is displayed as an on-screen line graph. Although OroPress is designed for accurate clinical measurement, rather than for biofeedback, the screen may be shown to users to provide them with biofeedback as they can see the level of pressure they are producing, which rises or falls over time as they exert more or less force (Giggins et al., 2013). Features of the IOPI and the OroPress are compared and contrasted in Table 1 below.
Table 1: Comparison of IOPI and OroPress devices (McCormack et al., 2013)

<table>
<thead>
<tr>
<th></th>
<th>IOPI</th>
<th>OroPress</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comfort of sensor</td>
<td>X Intrusive: Large-air filled bulb</td>
<td>✓ Small flat sensor</td>
</tr>
<tr>
<td>Consistency of recordings</td>
<td>X Poor: Hand-held probe</td>
<td>✓ Good: Adhered to palate-static</td>
</tr>
<tr>
<td>Portability</td>
<td>X Wired: Sensor connected to control device</td>
<td>✓ Wireless</td>
</tr>
<tr>
<td>Visual display for biofeedback</td>
<td>✓ LCD of red and green lights vertically (not across time).</td>
<td>✓ On-screen line graph displaying pressure in real-time.</td>
</tr>
<tr>
<td>Home usage</td>
<td>X Clinical tool</td>
<td>X Clinical tool</td>
</tr>
</tbody>
</table>

*Note.* ✓ indicates concept applies; X indicates concept does not apply.

It can be seen from Table 1 that OroPress fulfils the requirements of a clinic-ready safe, portable, valid and reliable tool for assessing oral tongue pressures. However, there remains a need for a smaller biofeedback tool that patients can use during practise to enhance their dysphagia rehabilitation programmes. This tool needs to be designed and manufactured.

**Designing a suitable biofeedback tool for people with dysphagia to use**

People with dysphagia require continuous medical care and intensive rehabilitation, often as a one-on-one interaction with the speech and language therapist. Unfortunately, present demands and budget restrictions do not allow this intensive rehabilitation. Hence, there is an urge for new technologies improving the efficacy and effectiveness of dysphagia rehabilitation (Poli et al., 2013). To design a dysphagia biofeedback device, knowledge of user wants and needs is important (Bruseberg & McDonagh, 2003). Incorporation of user needs into a design may lead to commercial success, but it also leads to personal gains, such as social empowerment, for the users of new products. A user-centred approach also expands the product designers’ knowledge (Bruseberg & McDonagh, 2003). One of the primary barriers to be overcome by product designers is the acceptance that they need to
be aware of their own biases, as their views are distinct and may be different from their target users (Bruseberg & McDonagh, 2003). To achieve an ‘ideal tool’, collaborative design is essential. ‘Expert’ opinion from clinicians and product designers is required to ascertain what is possible to achieve from a rehabilitation tool, as well as what may be desirable. By making the potential device-users integral to the design process itself (which for the purpose of this project includes patients with dysphagia from HN cancer) a focus is placed on their ‘lived experience’ which enhances the likelihood of the tool being specifically tailored to meet their explicit needs (Pruitt & Adlin, 2010).

There are numerous methods of obtaining collaborative/consensus opinions. One approach is through the use of questionnaires. These are useful as information can be collected from a large number of people in a short period of time and in a relatively cost-effective way (Popper, 2005). However, a disadvantage is that questionnaires may not be adequate to understand some forms of information, such as opinions and feelings, especially without directing subjects, thereby introducing a bias (Popper, 2005). The use of focus groups is another method of collecting data. This approach can be used when the phenomena being researched requires a collective discussion in order to understand the topic being discussed. This method gives insights into particular groups’ opinions and allows for group dynamics to be developed (Bruseberg & McDonagh, 2003). A disadvantage of this method may be that personal opinions may be stilted due to group dynamics (Burlingame et al., 2011), which highlights the importance of having a skilled facilitator to manage each group session.

**Purpose of this study**

The aim of this study was to inform the design of a portable tool, OroPress (R), to augment therapy/rehabilitation with adults who have dysphagia, by determining: (i) whether a dysphagia tool would be useful for patients rehabilitation; (ii) how would a dysphagia tool be used; (iii) the preferred product format for a dysphagia tool; (iv) and views about a specific clinic-ready prototype tool, called OroPress.
Methodology

Study Design

Full ethical approval for this study was granted a priori by the University of Limerick’s Faculty of Education and Health Sciences research ethical committee and the Clinical Research Ethics Committee Cork.

As home-use rehabilitative tools are relatively unexplored, there were no hypotheses to test. This was an exploratory, vanguard study using a qualitative approach. The study was explored with as much openness and inquisitiveness as possible without formulating any assumptions. A qualitative research method was chosen because it was best suited to such an approach. In this way, the themes that were important to the participants of the study, and about whom this study is based, were captured, rather than directing subjects with questions influenced by the researchers own theoretical observations (Silverman, 2000).

Three focus groups (FGs) were held, where participants’ audiotaped data were collected and later transcribed and analysed, in order to develop a design brief for a new dysphagia rehabilitation tool.

Participant recruitment and sample

Inclusion criteria for participant recruitment included fluent English language skills and an ability to communicate to the FG orally. Exclusion criteria included an inability to give informed consent and cognitive impairment as participants needed to express views accurately at the FG. No remuneration or rewards were offered for participation.

Product designers (N=5, 3 female; 2 male) were recruited to take part in the FG by the student researchers. Recruitment was from staff members of the Department of Design and Manufacturing Technology at the University of Limerick, using email invitation. Participant’s age ranged from 18 to over 45 years. Three of the product designers had worked in product design for four to ten years, one had worked in it more than ten years and another less than one to three years (Appendix 1).

Speech and language therapy clinicians (N=4, all female) were recruited via an oral presentation at a Dysphagia Special Interest Group event. On the day of the clinician FG, only three participants participated due to a last minute cancellation. The FG was thus run...
with three clinicians and subsequently, another therapist was interviewed to ensure sufficient sample numbers were obtained. The transcripts were then merged together. Participant’s age ranged from 26 to 45 years. Two of the clinicians worked exclusively in an adult rehabilitation setting, one worked exclusively in an adult acute setting and one worked with a mixed caseload of adult acute and rehabilitation.

Speech and language therapists working in South Infirmary Victoria University Hospital, Cork were invited in writing to assist in the recruitment of head and neck cancer patients (N=4, 2 female; 2 male), who had attended the speech and language department, post-surgery and with experience of dysphagia. All head and neck cancer patients had radiotherapy treatment (while one patient had additional chemotherapy) and were aged between 46 and over 65 years.

**Procedure**

Information and consent forms were prepared for potential participants (Appendix 2). Consent to participate in the research and for audio-recordings of sessions was obtained from all participants. Confidentiality and anonymity were assured. Participants were informed that only the student researchers and their supervisor could access the data.

The dates and times of the FGs were organised to suit participants’ commitments. Sites included meeting rooms at the University of Limerick for the product designer group, the National Rehabilitation Hospital, Dublin for the clinician group, and South Infirmary Victoria Hospital, Cork for the patient group. Each room was arranged to encourage informal discussion.

All three FGs were run in a similar manner. All participants were welcomed to the group and introduced to each other at the start of each FG. The purpose of the session was explained by the moderator and participants were informed that the session would be audio-recorded on a tape recorder. Discussion was facilitated by a moderator who had no prior involvement with the participants. Participants were invited to talk frankly about topics that were relevant and to voice conflicting opinions. They were encouraged to provide both negative and positive comments. Equal participation was encouraged. Confidentiality on the part of the researchers and group members was stressed. An assistant was introduced as she was present in an unobtrusive position to make field notes and
capture additional aspects of any non-verbal communication, such as gesture and facial expressions.

To facilitate discussion a set of topics, based on a reading of the literature, were introduced at the meetings (Appendix 3). These included: (i) whether a dysphagia tool would be useful for patients; (ii) how might a dysphagia tool be used; (iii) any preferred product format for a dysphagia tool; (iv) and views about the clinic-ready prototype tool, called OroPress.

To facilitate discussion about possible product formats and the current OroPress prototype tool, images and alternate product format model forms were presented during FG (Appendix 4), although discussion was not confined to these images. At various points the moderator summarised points that had been discussed, seeking verification, expansion and any additional comments. In a few instances, direct questions were asked for the purpose of clarification and/or to elicit comments about specific issues. All FG participants took part in the discussion and appeared to be relaxed in the situation. Each session lasted approximately one hour and concluded when all participants indicated they had no further contributions to make.

**Rigour**

Rigour was established through prolonged engagement with data collection and analysis. A modified Delphi technique was applied to ensure data was rigorous, accurate and 'truly' representative of views expressed at each FG. This involved a summary report being sent out to all participants after the FG, requesting feedback from them regarding data interpretation. There was an option to amend and/or to agree that the content represented the views of the FG as expressed. All reports were then returned to the researchers via pre-paid envelopes. The amendments received by the researchers were minor, consisting of re-wording (e.g. ‘a representative should be trained in the locality’ changed to ‘a nurse should be specifically trained in the community’). Only a one-stage Delphi was undertaken as good FG concordance was reached in one round of feedback.

**Analysis**

Data from audio-recordings was transcribed orthographically and field notes - which included documented non-verbal behaviours - were added. A second research assistant
verified the transcripts against the recordings to ensure accuracy. Some content which was clearly irrelevant was discounted (e.g. a comment about the parking onsite).

Qualitative analysis was performed using Glaserian coding principles (Urquhart, 2013). This included extracting excerpts of verbatim data and grouping those of similar meaning together (e.g. tool usage; psychosocial considerations). Open codes, which involved attaching initial labels to the data, were applied line-by-line to characterise meaningful units within the data (e.g. tool usage: intrusiveness; discrentional use; psychosocial considerations: willingness; resignation). The open codes were subsequently grouped into larger categories known as selective codes, until these categories became saturated and there were no longer codes emerging (e.g. tool usage: place of use; concerns of use; psychosocial considerations: motivation; acceptance) (see example in Appendix 5). Data were independently coded by both researchers to reduce subjectivity and ensure rigour. Following coding of all data, patient contributions were initially characterised using classifications taken from the ICF (WHO, 2001) and UK TOMs (Enderby & John, 1997).

All three data sets were then thematically analysed and related topics were grouped together (e.g. user population, current rehabilitation, role of clinician, compliance and patient considerations as subthemes within a general theme of ‘primary user usability’). There were no pre-determined codes or themes. As with the conduct of the FGs, the analysis was approached without preconceptions. The topic headings used to stimulate discussion in the FGs were disregarded when analysing the data. Extracts were repeatedly examined and re-contextualised, including re-readings of the entire dataset.
Results

Top-Down Thematic Analysis
The patient data were primarily analysed using a top-down approach (i.e., beginning with a set of pre-determined codes and analysing the data for segments which matched those codes (Chi, 1997)). The ICF (WHO, 2001) and UK TOMs (Enderby & John, 1997) frameworks were applied to the data set to classify the issues central to the person with a disability (Appendix 6).

Group discussion centred on each patient’s individualised impairment, indicating impairment is of fundamental importance to patients and should be considered as central to the design of any rehabilitation tool. Patients also discussed how their impairment(s) cause difficulties for them in executing simple daily tasks and the compensatory strategies they implement:

“I know not to stand up and try to take a drink of water because it will automatically come down my nose. I would choke as well. I have to be sitting down to drink a liquid. Otherwise, I know I’m going to be in trouble” (P3).

Patients agreed that they would use any device which would improve their swallowing function as their collective ultimate aim was to return to ‘normal’:

“I would certainly use it during rehabilitation but my aim always is to get as near normality as I could so I’d be inclined to reduce it after awhile. Well, have it on hand in case I need it” (P1).

Patients recognised that their activity with a swallowing rehabilitation device might impact on their social participation (e.g. wearing a device whilst eating in a restaurant). Discussion regarding social participation generated conversation about feelings of distress/wellbeing which have impacted on their lives since the onset of their condition. In particular, they cited ‘motivation’ as a positive influencing factor on rehabilitation. However, they also cited multiple distressing factors negatively affecting their rehabilitation, such as fear and depression:

“I think it’s not as much depression now. Yes earlier on, but I think anyone that goes through surgeries has that. I would occasionally get to a point if I had a bad eating day, you know
what people are like, they look and they look and I think I’m so fed up with this. You can get, not depressed I would say, but a bit fed up with it” (P3).

**Bottom-Up Thematic Analysis**

All three data sets were analysed using a bottom-up approach (i.e., beginning with no predetermined codes and working closely with the data to determine the codes (Chi, 1997)). Analysis across and within the focus groups generated five main themes (which are defined in the Glossary on page 2): user interface; format; primary user usability; OroPress and out-of-box experience (emerged as a significant theme in clinician and product designer data only). Themes and related subthemes are shown as thematic maps in Appendix 7. Illustrative quotations from FGs are included below. Quotations were selected to ‘capture the essence of the point . . . without unnecessary complexity’ (Braun & Clarke 2006, pp.93).

Figures 1-3 are word clouds generated using Wordle.net showing the most talked about themes within each group (i.e., the larger the text, the more frequently it was discussed).

**User Interface**

All three groups considered the importance of user interface; however this theme dominated the product designer FG (Figure 1). Feedback was considered to be an integral aspect of user interface. There was discord among the product designers about the preferred mode of feedback. However, three members (of five) agreed that visual feedback was desirable, with auditory input to accompany it:

“The progress you are making could be on a visual screen but you could also have an auditory education to say 'create this action,' like bite into something. If a patient can actually visualise and also have a cognitive form of what are they actually doing, it would help them understand” (D5).

Figure 1: Word cloud for product designers indicating a FG dominance regarding user interface.
Clinicians highlighted the importance of having feedback as part of rehabilitation, making reference to it as being “paramount” to patients’ understanding of their own dysphagia and its influence in bettering therapy outcomes. Similar to product designers, all four clinicians agreed that visual feedback was preferable as it gives the patients a concrete concept: “As the old motto goes ‘seeing is believing’. Patients tend to trust visuals, even more so than us (their therapists)” (C3).

Clinicians likewise considered combining visual feedback with auditory instruction, suggesting that ‘a visual’ would represent progress whereas audio would count repetitions or instruct on the next action to complete. Unlike product designers or clinicians, all patients had a preference for tactile feedback as they believed this would be more discrete than a screen or a sound output.

All three groups agreed that a dysphagia rehabilitation tool should measure patient’s progress throughout the rehabilitation process. Product designers and clinicians agreed that a hierarchy of specific targets would be helpful as patients can often find software programmes difficult to follow. Both groups agreed that the goals should be based on a specified function, rather than unrelatable scales: “I mean just to track quantities, it that not a measure? Or last week I was eating banana and that’s soft but now I’m eating bread and that a little harder. It’s far more relatable to somebody than arbitrary numbers” (D4).

Patients also agreed that having a target to reach in previous therapy has been a motivating factor. Two of four participants expressed a fondness for a prescribed optimum number of trials as a target, contradicting the secondary users’ opinions of numbers being arbitrary.

Product designer and clinician groups both discussed conceptualisation and modes of measurement. Four of five product designers suggested that a tool should encourage patients to conceptualise their swallow by using mental imagery to go through the swallowing process sequentially, similar to the visualisation techniques used in sports. There was disagreement regarding this technique within the group due to the challenge of visualising an internal event:
“Would that not be really difficult though cause with a ball you can see but this is internal, like I can't see, when you say my voicebox is moving up, I don’t know what that looks like” (D4).

As with the product designers, clinicians agreed that previous rehabilitation programmes have been problematic due to patients being unable to conceptualise what was being asked of them. With respect to mode of measurement, all product design participants agreed that sensors would be required to recognise the movements of a swallow. All agreed that this sensor would preferably be placed externally and be in situ at all times so that compliance to rehabilitation is maintained.

Clinicians however, had a preference for the pharyngeal swallow being targeted in rehabilitation, and indicated that a sensor would need to be inserted internally during set rehabilitation exercises. Clinicians raised the concern that a measurement needs to be accurate and consistent.

Conceptualisation and mode of measurement were not factors raised by the patient group. Instead, they wanted a device that incorporated cautionary features. These features could include a warning signal that indicated when they were swallowing ‘wrongly’ and likely to aspirate or a reminder for when they had completed their rehabilitation for the day:

“You want to get back to the way you used to be. I might push myself too hard. I need something to mind me. If you do something wrong it could help you. I’m not saying I’m helpless but regardless, I can get carried away” (P4).

**Primary User Usability**

All three groups discussed the importance of considering the specific user population when developing a new tool, but primary user usability was the theme that dominated the patient FG (Figure 2).

![PU Usability](image)

**Figure 2: Word cloud for patients indicating a FG dominance regarding PU usability.**
Product designers deliberated issues such as reducing patient fears regarding choking and aspirating, whilst ensuring patient dignity is maintained. All members of the group agreed that a device must be a “comfortable experience” and non-disruptive to patient’s lives: “Just dignity you know, if someone has a load of devices attached to them; they might have oxygen, they might have other monitors. You don’t want to look like a machine. And you want people to live a little bit” (D4).

Clinicians postulated that a tool would be appealing to all patients going through dysphagia rehabilitation and it would encourage patients to get actively involved in their own therapy. However, the clinician group did consider that tools would have to be tailored to meet patient’s individual needs. Their concerns included the patient’s physical abilities, cognitive abilities and health status in being able to actively participate in rehabilitation:

“I think again that goes back to having a choice within devices. I think is really important because every patient is different and their ability even from a sensory feedback or visual or auditory, they could have problems with all of that. I don’t think one-size-fits all” (C1).

As the primary users, patients focused on their individual limitations and difficulties (as previously mentioned under the ICF and UK TOMs analysis). This highlights the importance of tailoring devices specifically to patients.

All three groups also considered the role of the clinician after a device has been implemented. All five product designers expressed an interest in a design feature that allowed patients to connect with their clinicians electronically via the device. This would allow a clinician to provide feedback and guidance to the patient without the patient having to attend a hospital appointment:

“(For example) the clinician gets an email to say ‘X is doing well’, then that clinician could email the patient and say ‘I got your readings, everything is fine and we won’t need you to come in this week, work away’. Or else, ‘we have a concern, can you come in’” (D1).

Patients agreed with the product designers regarding clinician involvement. The group discussed the excessive amount of hospital appointments they were expected to attend post-surgery, and two out of four patients agreed that an electronic link-in with clinicians would be beneficial:
“It would be helpful if you could record, in some way, a machine to link with the speech and language therapist so they can see what’s happening with patients in the times between appointments as well. Initially the amount of appointments, when you’re going for chemo, radio and the dental hospital, to the speech and language therapist, and physio. You don’t feel well. You’re feeling horrible. You don’t want people to necessarily see you after surgery” (P3).

Clinicians viewed their role as being more direct than the product designers and patients. All four clinicians agreed that they would like to be able to discharge patients with a prescriptive programmed device and then monitor their use by reviewing them in person. Clinicians approved of a prescriptive programme that they could prescribe to patients as they are resource and time effective:

“Things like LSVT and the McNeil programme are liked by the profession because it’s prescriptive. It’s a programme, it has rules, targets, it has ways to monitor, steps to go through and I think as a profession that’s appealing” (C2).

Clinicians also considered the importance of a device being simple and easy to use for patients so that it is easily transferable into treatment. This was also mentioned by patients as they reported previous rehabilitation to be problematic due to difficulty understanding instructions:

“Some of them (exercises) I have difficulty with. This one (the Mendelsohn) I have difficulty with because I have no feeling so I’m not sure what’s happening and to be honest, I’m not sure what it is I’m meant to be doing!” (P1). This also highlights the importance of feedback.

Both clinician and product designer groups discussed the importance of primary user motivation to ensure compliance with the device and rehabilitation regime.

Product designers raised the issue of patient compliance being a “massive problem” in the area of rehabilitation, whereas the clinicians all agreed that from their previous experience, introducing a device into rehabilitation programmes has increased compliance (e.g. using a TheraBite for patients with trismus (Singh et al., 2013)):

“If you give patients something that they can use themselves, I think it would definitely give them a better outcome or at least I think it gives them something substantial to work on other than just a few pages wrapped up in their pocket. Patients love technology and they
love being able to see something and they love being strapped up to something and they think it’s so much more valuable than us coming in all the time” (C1).

Patients themselves were motivated by their desire to return to “normal functioning”. A device that could aid in their recovery would be most appealing. Three of the four patients stated they would only use a device at home whereas one said that she wouldn’t care where she used a device, as long as it was helpful. Patients also declared a preference for a device that they could use as part of an exercise regime, rather than during meal times: “I would rather have it as part of the rehabilitation, not while I’m eating. I would find it to be just an additional clumsy thing in my mouth. I would certainly use it during rehabilitation but my aim always is to get as near normality as I could so I’d be inclined to reduce it after awhile” (P1).

Format

Format as a theme was generated from all three data sets; however clinicians discussed this issue more than the other groups (Figure 3).

![Figure 3: Word cloud for clinicians indicating an equalised discussion regarding format and PU usability.](image)

All three groups discussed device placement and sensor placement. Product designers reached a group consensus to move the device away from the head. Two of the five participants rejected the development of a tool in an environment which they considered to be ‘machine-heavy’ already. Instead these participants contemplated the use of a specially designed chewing gum that could be used to carry out specific tasks (e.g. manipulating the gum against the roof of the mouth). Three of the five product designers had a preference
for a device situated on the neck in the shape of a pendant or incorporated into a garment, with a wireless sensor into the mouth. A concern raised by one participant was that this device must then be lightweight, not to cause damage to the neck musculature. Physical considerations, such as the size and weight of the device, were also mentioned as race and gender factors would need to be incorporated. Three of the four clinician participants had a preference for a neck device:

“The one you hold against the neck is my favourite. It’s like patients with an electrolarynx; it can be quite discrete. You’re only using it when you’re swallowing I presume which is nice. You wouldn’t have to hold it there the whole time as opposed to the one that adheres to the neck. The only thing is if you have someone doing a supraglottic swallow or Mendelsohn that that wasn’t affecting it” (C4).

Clinicians all had a preference for a device that would be used sporadically during specific tasks, rather than an in-situ device, as this would be less intrusive in daily activities. Clinicians concurred that sensor placement is dependent on the specific target. Three of four clinicians stated that they wanted a device that targets the pharyngeal swallow as they believe there are already well-developed oral-stage swallowing tools available.

All patients agreed that a neck device would be desirable as it would be discrete and easy to hide. Patients were opposed to an oral device or an oral sensor because of their prior surgery:

“I’d rather keep my mouth clear. I think I’d be uncomfortable with something in my mouth. I’ve had enough surgery, and plastic in there and as Dr X said ‘nature never intended for a piece of plastic to be in there’” (P1).

OroPress

All three groups discussed the format of the current OroPress prototype tool (pictures of the OroPress prototype were presented to the group to facilitate this discussion).

The product designer group raised concerns regarding the size, weight and placement of the device. All participants agreed that the device should be made smaller and, ideally, be positioned on the body. Similarly, clinicians and patients expressed concerns regarding the weight of the device:
“My only concern with that would be the weight of the device itself and especially the ear pieces. I am hypersensitive with nerve damage all down that one side, so that will really irritate and hurt. If you’ve had a lot of head surgery, even little weights on your head initially hurt” (P3).

Product designers also stated that the size of the device makes the device-user very identifiable. The battery-pack attached to the device was considered an “over-kill.” Future recommendations included involving an electronic engineer to implement more suitable technology:

“I think that you could start reverse engineering this. So for instance from here over (indicating the head band) is not necessarily essential. This is sort of the guts (indicating the battery pack) and this you could look into what is the minimal size the device could be, then looking where it could be placed. I’d say that could be stripped right down” (D1).

In contrast to the product designers, the clinicians thought that the device would be appealing to patients as it isn’t too “foreign-looking” (e.g., appears similar to headphones). The patient group also stated that the device format was a familiar concept, being similar to a radio-headset. However, they said they would be reluctant to wear a headset device in public as it would be too discriminating.

Clinicians expressed concerns about the sensor piece travelling from the battery-pack to the mouth as it was considered to be very ‘discriminating.’ Individual patients had concerns about the intra-oral sensor as they had post-surgical complications such as trismus, (spasm of the jaw muscles, causing the difficulties with mouth opening) which could lead to difficulties in adhering the sensor.

Clinicians alone debated the purpose of the tool and agreed that it would possibly be more applicable as a device to target speech sounds (e.g. tongue positioning for alveolar sounds). Again, a discussion surrounding therapy goals was generated:

“We have patients on normal diets with no anterior tongue movement at all from nerve damage and are still on normal diets so we wouldn’t spend a huge amount of time working on that. It wouldn’t be a priority whereas the priority would be the pharyngeal stuff” (C1).

Clinicin’s suggestions for future developments were similar to those of product designers – i.e., reverse engineering and updating the technology:
“If you were going to run with this particular device and style, I think that if you could make it more compacted, the size of it itself, particularly the parts on the earlobes themselves. Like possibly if the sensor didn’t have to be attached, like wireless and there was some way to get feedback. And then the sensor, could that even be made more discrete?” (C1).

**Out-of-Box Experience**

A theme exclusively common to product designers and clinicians was ‘out-of-box experience.’ The product designer group were concerned with the health and safety considerations of a new device. They highlighted the importance of preventing infection, the elimination of discomfort and of any choking risks. The clinicians also stated that infection control was highly important. Environmental concerns were also discussed among the product designer group, such as having disposable packaging and batteries.

Both product designer and clinician groups discussed issues surrounding costs. Clinicians stated that a device must be cheap to buy, but also cheap to maintain. Product designers commented on researching the scale of the market to investigate how cheaply a new device could be manufactured. They also discussed the importance of investigating who has the ‘purchasing power’ (i.e., who will be buying the device- patients themselves, or health service managers) because they will be the target audience for whom the product should be directed.

Product designers stated that education regarding a new device is crucial. Three participants discussed training a local community representative (e.g., a member of the hospital team or a community SLT) to provide one-to-one training to patients acquiring the device. They also highlighted the importance of providing instructions to secondary users as well as to primary users.

The topic of education did not arise during the clinicians FG, however two of the four participants expressed how important it is to develop an evidence-base to support a new device:

“What’s empirical is your research to prove that it’s (the new swallowing tool) actually going to work. You need to be able to prove within a given population that it is going to help in order to get the SLT’s on board. Really all our practice should be evidence-based” (C4).
Discussion

Product designers were primarily concerned with user interface (how the primary user will interact with the device) and considered the development of a new tool through the lens of health and safety, resulting in them generating ideas cautiously and being overtly conscious of regulations.

Clinicians were predominantly concerned with PU usability (how easy or difficult the primary user finds a product to use) and the format of a new tool. Clinicians wished for a prescriptive tool to assist in current rehabilitation, to target swallowing directly at a pharyngeal level, although conscious of the challenges implied.

Head and neck cancer patients were driven by their desire to regain ‘normal’ swallowing functioning and were willing to ‘try anything’ in rehabilitation. PU usability was of utmost importance to the patient group as they were concerned about how a tool would impact on their social activity and participation.

The main findings from this study signify that although ‘expert’ opinion from people such as clinicians and product designers is desirable to ascertain what is possible and achievable in a rehabilitation tool, these opinions often do not reflect what is desired by the primary users (e.g. the two secondary user FGs both expressed a preference for visual feedback, but the primary users wanted tactile feedback). From this study, the importance of collaborative design between ‘experts’ and primary users has been demonstrated. Participation in design not only gives users more control in determining the technologies they might eventually use during rehabilitation but their opinions give insight into the ‘lived experience’ of the client group (Vines et al., 2013). Primary users should be recognised as a source of information and have certain types of expertise that should be inter-subjectively shared and exchanged. Researchers should establish ways for this knowledge to be shared, communicated and embodied in rehabilitative technology design (Vines et al., 2013).

Study strengths and weaknesses

This study has many strengths. The first is that this is the first time a study of this nature has been conducted; incorporating user opinions along with ‘expert’ opinion in rehabilitative tool design. The design and organisation of the FGs enabled good discussion around shared
themes. This study was rigorous in its design and applied a modified Delphi technique for ensuring veracity of data collected.

This study was limited by a small sample size (N=13) suggesting the reported findings may not be truly representative (Portney & Watkins, 2009; Fraenkel & Wallen, 2003). However, while acknowledging the small sample size, participants were purposefully recruited meaning a good exemplification of views occurred at each of the focus groups.

Ideally six to eight participants would have been recruited for each focus group (Tang & Davis, 1995) however recruitment was limited by time constraints of an FYP study. The clinician focus group consisted of only three participants as one failed to attend on the day. This group’s data was augmented by an interview with another therapist at a different site. Ideally, this therapist would have attended the FG as her opinions may have been changed by the group dynamics (Burlingame et al., 2011).

**Future Directions**

Recommendations posed by the product designers included that a design ethnography study is undertaken to understand how a rehabilitation tool could potentially fit into a patient’s environment. Clinicians recommended that a tool is required to target pharyngeal constriction, although considerations about how this could work is challenging. Future research to extend the FGs to participants from other populations, such as stroke patients, would obtain a greater breadth of perspective. Initially this FG was planned as part of this study but recruitment of a stroke population became impossible.

**Conclusion**

From this study, we have an indication that a dysphagia rehabilitation tool would be useful and is needed. A dysphagia tool would be used independently by patients in their homes, while linking electronically for assessment and feedback from a speech and language therapist. Suggested formats of such a tool were varied although some form of feedback was considered essential.

Any device needs to be population-specific to meet a patient’s individual needs (e.g. post-surgical head and neck cancer patients do not want a device that sits on the head as they commonly experience post-surgery discomfort in their head and neck anatomy). OroPress
prototype model was considered to be bulky and was unappealing. All groups agreed that it requires ‘down-sizing’ and/or reverse engineering.

If technically feasible, OroPress (R), a dysphagia rehabilitation tool, needs to reflect the collective and shared values of the collaborative team (that is primary users and secondary users) as presented in this paper. However, it is beyond the scope of this study to examine the technical feasibility of encompassing these values as they are stakeholders ‘perspectives’ rather than ‘directives’. By encompassing collaborative opinions a patient-centred care approach to design will be embraced. The tool needs to be easy-to-use, readily accessible, and ready for clinical application in dysphagia rehabilitation (Kaizer et al., 2012).
References


## Appendix 1: Participant Information

### Participant Details: Product designers

<table>
<thead>
<tr>
<th>Participant</th>
<th>Gender</th>
<th>Age (in years)</th>
<th>Years in product design</th>
<th>Years in medical devices product design</th>
<th>Education</th>
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<tr>
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<td>10 +</td>
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<tr>
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### Participant Details: Speech and language therapy clinicians

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<th>Participant</th>
<th>Gender</th>
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<th>Area of work</th>
<th>Demographic of employment</th>
<th>Years in area of dysphagia</th>
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<td>Adult acute/rehab</td>
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### Participant Details: Post-surgical head and neck cancer patients

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<th>Effect of dysphagia on everyday life</th>
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<td>Surgery, Radiotherapy</td>
<td>Plastic palate inserted. “Food/liquids often come down nose”</td>
<td>Slow eater, avoid eating out in public</td>
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<td>P3</td>
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<td>“Food left in throat and mouth, difficulty starting a swallow”</td>
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<td>Neck and palate</td>
<td>Surgery, Radiotherapy, Chemotherapy</td>
<td>“Food gets stuck at side of throat”</td>
<td>Socialising and eating out</td>
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Appendix 2: Participant information and consent form

OroPress Rehabilitation tool; Stakeholder perspectives

Study information

What are the purposes of this study?
The purpose is to inform the design of a new clinical tool called OroPress®, for use by adults with dysphagia (a swallowing problem) due to tongue weakness/incoordination.

Based on the views of likely users, clinicians (speech and language therapists or SLTs) and design engineers at a series of Focus Groups, a design brief for OroPress® will be developed.

What does this study involve?

1. If you are interested in taking part in this study, you will be asked to sign a consent form and we will arrange a date and time convenient for you to attend a one hour focus group session at the South Infirmary Victoria Hospital, Cork.

2. Each Focus Group will consist of 4-6 people who have experienced dysphagia as a result of a head and/or neck cancer and two researcher associates (RAs) - SLT final year students - who will organise and tape record the session.

The session should take no more than one hour and refreshments (tea, coffee, water) will be provided.

3. At the Focus Group we will ask for your views about using a tool for therapy/practising tongue movements and tongue strength. We will also ask you about what you would prefer to use in therapy (a mobile phone or a computer, or something else). There will be opportunity for question and discussion and all participants’ comments will be tape recorded and notes about the session will be made by one of the RAs.

4. The audiotapes will be transcribed and then sent to you for checking afterwards, as we want to ensure everyone’s views are correctly represented. You will have a pre-paid envelope to send back the report, with any amendments or comments, to one of the RAs.

Why is this research important?

This study will provide information about whether OroPress® can be effectively used for therapy; whether it might help you with a programme of tongue exercises and/or act as a bio-feedback tool. Such information is important when designing a new tool to help people to undertake tongue exercises, especially where reduced tongue pressure has been linked to swallowing difficulties.
What will the information I give be used for?

The information you provide will be recorded and written up as part of a larger study, the results of which will form the basis of the Final Year Projects of two SLT students at the University of Limerick. The results will help us to better design a new rehabilitation tool called OroPress®.

The results of this study may also be presented at a national conference and/or printed in a scientific journal but at no point will you be identified; all the information you may provide will be anonymised to everyone, except the two SLT researchers and their Supervisor, Prof Alison Perry.

Are there any risks associated with participating in this study?

No. There are no risks.

Do I have to participate in this study?

Your participation in the study is completely voluntary.

Will I receive any compensation?

No compensation can be offered to any of the study participants.

What about my confidentiality?

Good research practice involves maintaining confidentiality. You can be assured that the information you provide will be kept confidential at all times. Only members of the research team will have access to the information you give.

What if I want to leave the study?

You may withdraw from the study at any time without giving a reason and you will not be penalised in any way.

Has Ethical Approval been granted for this study?

Full Ethical approval has been given from the UL/EHS Research Ethics Committee and the Clinical Research Ethics Committee Cork.

What is the complaints procedure?

Complaints or queries about the study can be directed to the Principal Investigator (Prof Alison Perry) or to the UL/EHS Ethics Committee Chairperson.

Whom do I contact if I want further information about the study?

If you have any concerns or queries about the study please contact:

Principal Investigator: Professor Alison Perry (Dean, Faculty of Education and Health Sciences)

Address: Dean’s Office, Faculty of Education and Health Sciences, University of Limerick.

Phone: +353 61 234987 E-mail: Tara Hussey 13000616@studentmail.ul.ie

Nicole Wallace 13012134@studentmail.ul.ie
OroPress Rehabilitation tool - Stakeholder Perspectives

Informed consent

Consent Form

- I have read and clearly understand all the detail provided on the subject information sheet.
- I know that my participation is voluntary and that I can withdraw from the project at any stage without giving any reason.
- I understand what the project is about, and what the results will be used for.
- I am fully aware of all of the procedures involving myself, and of any risks and benefits associated with the study.
- I am aware that my results will be kept confidential.
- I agree to participate in this study.

If you agree with all the above statements please tick the box below to confirm your participation in the study.

I consent to participate and have my views documented at a Focus Group □
Signed: _____________________________ Date: _____________________

(Print Name): ______________________________________________________

I consent to have my data used for analysis and for the data to be written up in a way that will not identify me (for a professional publication or/and a student project) □

Signed: _____________________________ Date: _____________________

(Print Name): ___________________________ Phone Number: _____________

E-mail Address: _____________________________________________________
Appendix 3: Topic guides used at the focus group

**Topic Guide (Product designers)**

**Introduction**

“Morning everybody, welcome to our focus group today. Thank you for taking the time to come and join our discussion of swallowing tools. My name is X and this is Y. We are here from the Speech and Language Therapy department at the University of Limerick. We’re here today to chat to you about tools used in swallowing therapy. We have invited three different focus groups to be part of our study such as clinicians, head and neck cancer patients and yourselves. We are particularly interested in your views because you have lots of experience in design and we want to tap into those experiences. We’d like to point out that this discussion will audio-recorded. Anything you say will be kept completely confidential and you won’t be identifiable by your views. Today, we will be discussing your thoughts and opinions on swallowing tools. We want to know what you like and dislike about these tools and what could be done to improve them. There are no wrong answers but rather differing points of view. Please feel free to share your point of view even if it differs from what others have said. Keep in mind that we are just as interested in negative comments as well as positive comments. Before we begin let me suggest some things that will make our discussion more productive. Please speak up. Only one person should talk at a time. My role here is to ask questions and listen, I won’t be participating in the conversation but I want you to feel free to talk with one another.”

*(Recording)* “First, let’s find out a bit more about each other by going around the table. To help us identify you on the tape, could you just share your first name, a bit about yourself, and a bit about your experience in product design”.

- Can you each give us your name and a bit about yourself?

“So now you all know each other, we’re going to begin to discuss swallowing tools. What I mean by this is a tool used for swallowing rehabilitation. As you all know, swallowing is the process by which we take food or drink into the mouth. We then close our mouths and create a pressure. This pressure is usually made by our tongues lifting to behind our teeth. Our voiceboxes move up to protect our airway and the food then safely moves down to the stomach. A problem involving swallowing occurs when part of this process is impaired. For example, if you had a stroke you might have a weak tongue meaning you can’t create this pressure needed anymore. Swallowing tools are tools that could possibly assist patients with swallowing difficulties following stroke, head and neck cancer or neurological diseases, by helping them to identify and imagine their swallow”

- **Objective: Would they use a tool and if so how?**

“Can you imagine such a tool being useful? If so how?”

- **Objective: Preferred Product Format (models and photographs supplied)**

“I’m going to give you a few diagrams and models. These are just a few examples of how a swallowing tool might take shape but of course many others are possible. We want you to think about how they look, how they feel. Tell us what your thoughts about what might be important for a user?"
• **Objective: OroPress (photograph of OroPress in situ supplied)**

“Ok so if we’re looking at this particular tool what do you think? What sort of things do you like/dislike?”

• **Closing**

“So now we’ve designed the ‘perfect’ tool, is there anything else you think that is important in developing this product?”

Summarise session and close.
“Morning everybody, welcome to our focus group today. Thank you for taking the time to come and join our discussion of swallowing tools. My name is X and this is Y. We are here from the Speech and Language Therapy department at the University of Limerick. We’re here today to chat to you about tools used in swallowing therapy. We have invited three different focus groups to be part of our study such as product designers, clinicians and yourselves. We are particularly interested in your views because you have experienced swallowing difficulties and we want to tap into those experiences. We’d like to point out that this discussion will audio-recorded. Anything you say will be kept completely confidential and you won’t be identifiable by your views. Today we will be discussing your thoughts and opinions on swallowing tools, we want to know what you like and dislike about these tools and what could be done to improve them. There are no wrong answers but rather differing points of view. Please feel free to share your point of view even if it differs from what others have said. Keep in mind that we are just as interested in negative comments as well as positive comments. Before we begin let me suggest some things that will make our discussion more productive. Please speak up. Only one person should talk at a time. My role here is to ask questions and listen, I won’t be participating in the conversation but I want you to feel free to talk with one another”.

(Recording) “First, let’s find out a bit more about each other by going around the table. To help us identify you on the tape, could you just share your first name, a bit about yourself, and a bit about your swallowing difficulties”.

- “Can you each give us your name and a bit about yourself?”

“So now you all know each other, we’re going to begin to discuss swallowing tools. What I mean by this is a tool used for swallowing rehabilitation. As you all know, swallowing is the process by which we take food or drink into the mouth. We then close our mouths and create a pressure. This pressure is usually made by our tongues lifting to behind our teeth. Our voiceboxes move up to protect our airway and the food then safely moves down to the stomach. A problem involving swallowing occurs when part of this process is impaired. Swallowing tools are tools that could possibly assist patients with swallowing difficulties following stroke, head and neck cancer or neurological diseases, by helping them to identify and imagine their swallow”

- **Objective: Would they use a tool and if so how?**

  “Tell us how you think patients might use a swallowing tool for rehabilitation?”

- **Objective: Preferred Product Format (models and photographs supplied)**

  “I’m going to give you a few diagrams and models. These are just a few examples of how a swallowing tool might take shape but of course many others are possible. So maybe this is a screen, maybe this is a radio, this could be something you hold in your hand or something you put on your neck, this could be worn on the head or the neck. Tell us what your thoughts are on these options? We want you to think about how they look, how they feel. What might be important for a user?”
• **Objective: OroPress (photograph of OroPress in situ supplied)**

“Ok so if we’re looking at this particular tool what do you think? What sort of things do you like/dislike?”

• **Closing**

“So now we’ve designed the ‘perfect’ tool, is there anything else that could help you to use this?”

Summarise session and close.
Introduction

“Morning everybody, welcome to our focus group today. Thank you for taking the time to come and join our discussion of swallowing tools. My name is X and this is Y. We are here from the Speech and Language Therapy department at the University of Limerick. We’re here today to chat to you about tools used in swallowing therapy. We have invited three different focus groups to be part of our study such as product designers, head and neck cancer patients and yourselves. We are particularly interested in your views because you have lots of experience in working with dysphagia and we want to tap into those experiences. We’d like to point out that this discussion will audio-recorded. Anything you say will be kept completely confidential and you won’t be identifiable by your views. Today we will be discussing your thoughts and opinions on swallowing tools, we basically want to know what you like and dislike about these tools and what could be done to improve them. There are no wrong answers but rather differing points of view. Please feel free to share your point of view even if it differs from what others have said. Keep in mind that we are just as interested in negative comments as well as positive comments. Before we begin let me suggest some things that will make our discussion more productive. Please speak up. Only one person should talk at a time. My role here is to ask questions and listen, I won’t be participating in the conversation but I want you to feel free to talk with one another. “

(Recording) “First, let’s find out a bit more about each other by going around the table. To help us identify you on the tape, could you just share your first name, a bit about yourself, and a bit about your experience in working with people who have dysphagia”.

- “Can you each give us your name and a bit about yourself?”

“So now you all know each other, we’re going to begin to discuss swallowing tools. What I mean by this is a tool used for swallowing rehabilitation. Swallowing tools are tools that could possibly assist patients with swallowing difficulties following stroke, head and neck cancer or neurological diseases, by helping them to identify and imagine their swallow”

- **Objective: Would they use a tool and if so how?**

“Tell us how you think patients might use a swallowing tool for rehabilitation?”

- **Objective: Preferred Product Format (models and photographs supplied)**

“I’m going to give you a few diagrams and models. These are just a few examples of how a swallowing tool might take shape but of course many others are possible. So maybe this is a screen, maybe this is a radio, this could be something you hold in your hand or something you put on your neck, this could be worn on the head or the neck. Tell us what your thoughts are on these options? We want you to think about how they look, how they feel. What might be important for a user?”

- **Objective: OroPress (photograph of OroPress in situ supplied)**

“Ok, so if we’re looking at this particular tool what do you think? What sort of things do you like/dislike?”
• **Closing**

“So now we’ve designed the ‘perfect’ tool, is there anything else important in developing this product?”

Summarise session and close.
Appendix 4: Pictures and model forms presented during focus groups.

Figure 1. Format model forms presented

Figure 2. OroPress prototype model

Figure 3. Images depicting various formats (e.g. neck/head/oral)
Appendix 5: An example of coding and thematic analysis: open codes, selective codes and themes

Key: Blue – Activity; Yellow – Impairment; Green – Distress/Wellbeing; Orange - Participation

<table>
<thead>
<tr>
<th>Group</th>
<th>Participant</th>
<th>Transcript extracts</th>
<th>Open Codes</th>
<th>Selective Codes</th>
<th>Themes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>ICF Thematic Coding</td>
<td>1. Current treatment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P1:</td>
<td>We got exercises from ET. We got pages of those and we’re supposed to be still doing them. Some of them I am (still doing). I have difficulty with the one there (the Mendelsohn) because I have no feeling so I’m not sure what’s happening and to be honest, I’m not sure what it is I’m meant to be doing!</td>
<td>Current exercises; Uncertainty of exercises;</td>
<td>1a) Exercises</td>
<td>Activity</td>
<td></td>
</tr>
<tr>
<td>P1:</td>
<td>If I don’t do them I notice I stiffen up. I like to use, well this, the Megabite as I like to call it or the TheraBite.</td>
<td>incentives; tools;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P4:</td>
<td>Well I had some exercises and... yeah I had the little spoon things. But I still do the exercises, I still do. Well what works for me is really emphasising the alphabet. A, B, C. Because it keeps the tongue moving, and the jaw.</td>
<td>tools; self-monitoring</td>
<td></td>
<td></td>
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<tr>
<td>P2:</td>
<td>I don’t eat sort of very crusty stuff or stuff like that because I find that hard. I like soft food, well it likes me. Soft and plenty to drink and no spicy stuff, I can’t tolerate that or alcohol. It scalds it or anything sharp</td>
<td>restrictions;</td>
<td>1b) Diet modification</td>
<td></td>
<td></td>
</tr>
<tr>
<td>P2:</td>
<td>But swallowing the porridge, it comes down my nose.</td>
<td>surgical consequences</td>
<td></td>
<td>Impairment</td>
<td></td>
</tr>
<tr>
<td>P4:</td>
<td>But since 2 years ago I’ve been eating a lot</td>
<td>diet progress; obstruction;</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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better. In all fairness when it is going down, it’s kind of lodged. Eventually it will go down. I do my exercises and sometimes the food would lodge but I do eat a lot of soft food like a boiled egg and I drink milk and then I’d have tea like soft cheese and crackers and I’d drink milk. I’d have rice or porridge in the morning as well and I’m partial to a bar of chocolate as well.

When I chew. I can chew fairly well. But it’s the swallowing part I’d be afraid of. There’s always a fear there. But I can chew grand and then have a bit of milk.

I know not to stand up and try to take a drink of water because it will automatically come down my nose. I would choke as well. I have to be sitting down to drink a liquid; otherwise I know I’m going to be in trouble.

Yeah, I have a problem with the tongue because half of my tongue is numb and as P2 was saying it could be coming down the nose or coming out when you’re cleaning your teeth. I have had some corrective surgery but for instance I couldn’t suck through a straw. Even if I hold my nose. But I do find if I am having difficulty, if something is stuck, if I hold my nose and try...
<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>P1:</td>
<td>No that isn’t common to me. I can suck through a straw.</td>
<td>sucking ability;</td>
</tr>
<tr>
<td>P3:</td>
<td>I still have swallowing difficulties and I’m nearly 9 years down the line. I have problems positioning my tongue to be able to swallow. I also find if I talk too much, I find it very difficult to swallow. Food-wise I’m still experimenting with food really, you know you have to have quite soft food quite often with liquid with it, nothing dry. And I would still aspirate on occasion.</td>
<td>maintained difficulties; tongue positioning; fatigue; diet modification; aspiration;</td>
</tr>
<tr>
<td>P1:</td>
<td>So as regards swallowing, I have to go slowly because it’s narrow. I need lots of liquid.</td>
<td>self-monitoring;</td>
</tr>
<tr>
<td>P3:</td>
<td>That would depend on each individual, on their surgery wouldn’t it? Because I know for instance, I had problems with my bottom teeth sticking into the gum at the top, I had various things made at the dental hospital and a plate or anything in the roof of the mouth, means I then can’t swallow properly because the tongue can’t manoeuvre.</td>
<td>Individuality; under-bite; tongue manipulation difficulties;</td>
</tr>
<tr>
<td>P3:</td>
<td>Yeah I used that as well but I don’t use that anymore (TheraBite). I found it was beginning to loosen my teeth. And I’ve nothing there to</td>
<td>tool complications; dental complications;</td>
</tr>
</tbody>
</table>
P1: And I'd rather not have a tool.

P2: X, Y and Z, the follow up team were terrific. Initially yeah to get the opening to start but as I said I found it was starting to loosen the teeth. I’ve had to have the teeth all concreted at the back to stop them moving.

P3: It would be helpful if you could record, in some way, a machine to link with the speech and language therapist so they can see what’s happening with patients in the times between appointments as well. Initially the amount of appointments, when you’re going for chemo, radio and the dental hospital, to the speech and language therapist, and physio. You don’t feel well, you’re feeling horrible. You don’t want people to necessarily see you after surgery.

P3: I think it would be beneficial to the patient yes, because it gives them something to work towards like when you see something getting better you want to try a little harder, I think it would also be helpful if you could record in some way a machine to link with the speech and language therapist so they can see what’s happening with patients in the times between appointments as well.

P1: stop the movement. Initially yeah to get the opening to start but as I said I found it was starting to loosen the teeth. I’ve had to have the teeth all concreted at the back to stop them moving.

follow up care;

3. Clinician Involvement

Distress/Wellbeing

surplus appointments;
patient wellbeing;

3. Clinician Involvement

Participation

goal directed progress;
motivation; dual recordings; link in with SLT

Participation

unwanted;

4. Tool Use

Activity
<table>
<thead>
<tr>
<th>P1:</th>
<th>Now I’m not saying that it might not be useful. But of course we’re all different.</th>
<th>individuality; usefulness;</th>
<th>Impairment</th>
</tr>
</thead>
<tbody>
<tr>
<td>P1:</td>
<td>Well I wouldn’t care, really gone beyond all that (aesthetics) if it functioned</td>
<td>functionality</td>
<td>Distress/Wellbeing</td>
</tr>
<tr>
<td>P4:</td>
<td>I’d do them (exercises) at night-time especially.</td>
<td>compliance; night-time</td>
<td>Participation</td>
</tr>
<tr>
<td>P1:</td>
<td>I would rather have it as part of the rehabilitation not while I’m eating I would find it to be just an additional clumsy thing in my mouth. I would certainly use it during rehabilitation but my aim always is to get as near normality as I could so I’d be inclined to reduce it after a while. Well, have it on hand in case I needed it</td>
<td>rehab v daily activities; reduce over time</td>
<td>Activity</td>
</tr>
<tr>
<td>P3:</td>
<td>I would (in public). I wouldn’t care who saw it.</td>
<td>unself-conscious;</td>
<td>Participation</td>
</tr>
<tr>
<td>P1:</td>
<td>I would use it at home if it was helpful.</td>
<td>home use;</td>
<td></td>
</tr>
<tr>
<td>P3:</td>
<td>I think you’d feel a little too conscious in public, maybe in the house you’d use it yourself but I certainly wouldn’t think about wearing a head one like that outside (diagram of headset). It’s like making a fashion statement! If you want to use a device out like in a restaurant, you wouldn’t want to be carrying a screen with you or a radio while other people are there, very possibly something there (pointing to a neck device).</td>
<td>self-conscious regarding head device;</td>
<td></td>
</tr>
<tr>
<td>P3:</td>
<td>If you want to use a device out like in a restaurant, you wouldn’t want to be carrying a screen with you or a radio while other people are there, very possibly something there (pointing to a neck device).</td>
<td>discrentional use;</td>
<td></td>
</tr>
<tr>
<td>P3:</td>
<td>I would use something at home</td>
<td>home use;</td>
<td></td>
</tr>
<tr>
<td>P1:</td>
<td>I would use it at home as I felt I needed it but hoping that I could diminish the use</td>
<td>home use; reduction over time;</td>
<td></td>
</tr>
<tr>
<td>Speaker</td>
<td>Statement</td>
<td>Notes</td>
<td></td>
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<tr>
<td>P2:</td>
<td>I'm easy really on that, no hard opinion on that. I wouldn't have any problem using it at home. P4 concurs. (would use one) If it wasn’t negating what I was trying to do myself.</td>
<td>home use agreed; 4c: Concerns of Use</td>
<td></td>
</tr>
<tr>
<td>P1:</td>
<td>I would rather have it as part of the rehabilitation not while I’m eating; I would find it to be just an additional clumsy thing in my mouth. I would certainly use it during rehabilitation but my aim always is to get as near normality as I could so I’d be inclined to reduce it after awhile. Well have it on hand in case I need it.</td>
<td>non-disruptive; intrusive; rehab v daily life; normality driven;</td>
<td></td>
</tr>
<tr>
<td>P1:</td>
<td>Well at the moment, I don’t feel the need for a tool. I feel that I’m handling it with my own strategies at the moment. And I think if I became reliant on a tool, I may not pursue my own strategies and I would rather approach normality as best I could.</td>
<td>over-reliance of tool; unnecessary; normality driven; 5. Psychosocial considerations 5a) Social Impact Participation</td>
<td></td>
</tr>
<tr>
<td>P2:</td>
<td>Well eating out is something I tend to turn down now because...or if we’re in the restaurant I might face the wall, just in case it runs down my nose or whatever but C at home (his wife) she can chop up the food, chop up the meat, bit of beef or whatever and I can just munch that and gulp it down. I’m not chewing it as much as I would of liked to in the past. But in the restaurant, everyone’s finished their dinner and they’re looking at social limitations; compensatory strategies; self-consciousness</td>
<td>Activity</td>
<td></td>
</tr>
</tbody>
</table>
**P2:**

Does anybody, I suppose we all do to a certain degree, suffer from depression? There's an element of depression having had to have this surgery over the years, sometimes you feel low.

**P3:**

I think it's not as much depression now. Yes earlier on, but I think anyone that goes through surgeries has that. I would occasionally get to a point if I had a bad eating day, you know what people are, they look and they look and I think I'm so fed up with this. You can get, not depressed I would say, but bit fed up with it.

**P2:**

The important thing is to deal with it.

**P3:**

I don't know how many of you have aspirated, I have, my goodness it's the most scary thing.

**P2:**

Well I'm resigned to the fact, that with the nerve gone up here (near eye socket) and with the 7 teeth missing, I'll never be able to chew. I think I'm resigned to that. If I was 30/40 years younger maybe it would be a problem but at 73 it's not a problem.

**P1:**

No matter depression or being fed up, we have to get on with it. It bothers me a little bit but not too much.

**P3:**

It would depend on the situation, how you were initially told use it. And then on from

<table>
<thead>
<tr>
<th>5b) Psychological Impact</th>
<th>Distress/Wellbeing</th>
</tr>
</thead>
<tbody>
<tr>
<td>depression related to surgery; self-consciousness; fed-up</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5c) Acceptance &amp; Current functioning</th>
<th>Impairment</th>
</tr>
</thead>
<tbody>
<tr>
<td>resignation to swallowing disorder; acknowledgment of prognosis</td>
<td></td>
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</table>

<table>
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<tr>
<th>5d) Motivation</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>perseverance; willingness; instruction; ensuring achievements;</td>
<td></td>
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there, I would tend to be one of those people that if you told me to do it 7 x 7 x 7, I would do it 8 x 8 x 8, for the results, you know.

P3: Yeah, may I just say something there? I initially had a PEG feed, I had it for 3 years and I was told I would never get rid of the PEG and I would never eat by mouth ever again. I’ve now had PEG feed out for 3 years, or probably more. Sometimes I think it’s mind over matter. You know like I do that (push jaw over to right) if I want to chew something. So I think sometimes, if it’s something you can’t do. Just watch, it’s surprising what you can do. Like as I was told, I was told I would never orally take liquids or solids.

P4: If I find that it’s helpful I would and then if I found it was a hindrance, you know. It’s a good idea. I’d try it, I mean I wouldn’t have anything to lose.

P3: I think there’s always room for improvement. I’m still trying to improve. I say to myself every morning, I’m still trying. I’m still trying.

P2: None of you have trouble opening your mouths do you? Well they told me initially that before the surgery you could get 3 fingers in there (in your mouth) with normal opening. And that’s the target but I can sort of get 2 in. Yeah, this (TheraBite) gets me to about 2 fingers. But then you have to...
work up to it. But before I’m finished the days exercise, I can get that open fully. And I know when that hits that, it’s open fully but I wouldn’t get to that immediately. Second this: I’d be the same as P3. I do mainly my exercises and I was told that thing about that fingers. When I was measured I was 36. A gauge that’s it. It was 30 and then 34 and now 36. I done the exercises. I think if you incorporated how many times you actually swallowed in the day, because I found earlier on that if I get tired I find it hard to swallow. I tend then not to do it or I try not to do it so if there was some way of incorporating, well say everybody has to swallow X times a day, kind of like a counter. Yeah like a target, like the TheraBite. You know the target 7, 7, 7 if you have to swallow. We all know if you don’t do it the therapists can tell and you know they know that you haven’t been doing enough so incorporating a counter I think is a good idea.

I suppose there’s an optimum number of swallows one can do in an hour or half an hour and it could be percentages of those but I suppose it would need some research to find out the average numbers of swallows is in half an hour. Something like that to get normal.
| P3: | If it was to give you signals to say yes you’re swallowing right, no you’re not swallowing correctly that sort of thing you know. | warning system; encouragement; prevention |
| P3: | Both (for eating & exercises) really. So maybe you could incorporate both the swallows for preventative or just stop and think what you're doing before you go any further |
| P3: | So something like that (intra-oral) for me on the palate wouldn’t work because the tongue wouldn’t be able to move. | palate concerns; tongue difficulties; surgical implications; individuality; |
| P3: | The one inside the mouth again I just think it depends on the kind of surgery you’ve had. |
| P1: | Not for me. Like I’d rather keep my mouth clear. I think I’d be uncomfortable with something in my mouth. | intrusiveness; keep mouth clear |
| P2: | Well I have this already (rubber palate) and I’d prefer if I didn’t have it. I mean you guys don’t want to see it but it’s a big lump of plastic with a magnet on my palate, the lower part snaps up onto it. But I’d prefer if I didn’t have it. I’d have enough in my mouth as it is. I wouldn’t fancy any of that stuff. I’d rather keep my mouth clear. I think I’d be uncomfortable with something in my mouth. I’ve had enough surgery, and plastic in there and as Dr X said ‘nature never intended for a piece of plastic to be |
| P2: | | unnatural; foreign object; |

| 7. Mode of delivery |
| 7a) Oral Device |
| Impairment |

| Distress/Wellbeing |

| Intrusiveness; keep mouth clear |

| Impairment |

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<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>Feature</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>P3:</td>
<td><em>I wouldn’t be too sure on the head one either (headset device).</em></td>
<td>concerns;</td>
<td>Activity</td>
</tr>
<tr>
<td>P3:</td>
<td><em>Something against the throat or something on the throat, I wouldn’t have a problem with. Something that could be discrete and you could just put a scarf around it or something you know, like I wear a scarf already to hide the scar.</em></td>
<td>neck preference; discrete; hidden</td>
<td>Participation</td>
</tr>
<tr>
<td>P1:</td>
<td><em>If any of them it’s that one (external hand held neck device).</em></td>
<td>external, handheld, neck preference</td>
<td>Impairment</td>
</tr>
<tr>
<td>P4:</td>
<td><em>Yeah (would wear neck device) because that’s where I have all the tightness here (on neck).</em></td>
<td>neck tightness;</td>
<td>Activity</td>
</tr>
<tr>
<td>P3:</td>
<td><em>Again that hand held I would say would be a home use as well.</em></td>
<td>home use;</td>
<td>Participation</td>
</tr>
<tr>
<td>P2:</td>
<td><em>Hands-free? Oh yeah (all gesture in agreement).</em></td>
<td>hands free;</td>
<td>Impairment</td>
</tr>
<tr>
<td>P3:</td>
<td><em>You’d need something portable.</em></td>
<td>portable;</td>
<td>Activity</td>
</tr>
<tr>
<td>P2:</td>
<td><em>My hearing is bad, so when my battery goes low for my audio aids, I just get (beep beep) and that tells me to change the battery within 20 minutes.</em></td>
<td>beeping feature; battery level warning;</td>
<td>8. Design Features</td>
</tr>
<tr>
<td>P4:</td>
<td><em>Well for me anyway I think it's psychological, I was saying to yourself, you know you want to get back to the way you used to be (inaudible speech). I might keep going push myself too hard. I need something to remind me. If you do something wrong somebody could help you, I'm not saying I'm helpless but regardless, I can get carried away.</em></td>
<td>warning system; overworking; mind me;</td>
<td>Distress/Wellbeing</td>
</tr>
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</table>
P3: *Something when you are swallowing, obviously there is movement in the muscle in the throat. So if it could maybe give you a warning, like you're starting to swallow wrong, you're not doing it right, be careful because you're going to aspirate, choke, get it stuck. P1: I would second what P3 said.*

P2: A buzzer (buzz sound)

P3: I would think more an actual pulse or something.

P3: Well when I said to you maybe if you incorporate, I don't know how, but if there was some kind of sensor when you start to swallow correctly, to sort of just pulse that’s not right, try again.

P2: The only thing here is this woman can open her mouth like a whale (pointing to image of sensor placement) (group laughter)

P2: I couldn’t get it in (sensor in mouth)

P3: I would find that very hard to use because of the movement of the tongue against the sensor.

P3: I’d prefer something external

P3: My only concern with that would be the weight of the device itself and especially the ear pieces. I am hypersensitive with nerve damage all down that one side, so that will really irritate and hurt. If you’ve had a lot of head surgery and even little weights on your head initially hurts. I would still find it a problem (mouth weight; nerve damage; hypersensitivity; irritation; discomfort;
<table>
<thead>
<tr>
<th></th>
<th>Sensor connected to neck device) because it would inhibit any tongue movement in there at all.</th>
<th>It would be better light than heavy really.</th>
<th>lightweight; private use; familiar concept</th>
<th>Activity Participation</th>
</tr>
</thead>
<tbody>
<tr>
<td>P1:</td>
<td>(wouldn’t wear in public) unless I had to. Well you’d probably get away with it as a DVD player or radio or headset people walk around the streets with.</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>P2:</td>
<td></td>
<td></td>
<td>10d) Place</td>
<td></td>
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Appendix 6: Thematic map of patient data analysed using classifications taken from the ICF\(^1\) and UK TOMS\(^2\).

**Activity:** The execution of a task or action by an individual.

**Impairment:** Problems in body function and structure such as significant deviation or loss.

**Participation:** Involvement in a life situation.

**Wellbeing / Distress:** Emotional level of upset or distress.

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Appendix 7: Thematic maps of group data analysed using a framework derive from their data

Terms operationalised:

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Format:</td>
<td>The particular way a device operates.</td>
</tr>
<tr>
<td>Out of Box Experience:</td>
<td>The features associated with a specific experience that the user has when</td>
</tr>
<tr>
<td></td>
<td>using a product for the first time when taken out of its box.</td>
</tr>
<tr>
<td>PU or Primary User:</td>
<td>The person that directly uses a device (e.g. a patient group).</td>
</tr>
<tr>
<td>PU usability:</td>
<td>How easy or difficult the primary user finds a product to use.</td>
</tr>
<tr>
<td>User Interface:</td>
<td>How the primary user interacts with the device.</td>
</tr>
</tbody>
</table>

Figure 1. Thematic map of patient discourse, using a framework derived from their data.
Figure 2. Thematic map of clinician discourse, using a framework derived from their data (see key on page 54 for terms operationalised).
Figure 3. Thematic map of product designer discourse, using a framework derived from their data (see key on page 54 for terms operationalised).