Design for Dysphagia: a new hardware-and-software mobile system to monitor patients’ swallowing

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Abstract: Dysphagia - the medical term for the symptom of difficulty in swallowing - can lead to serious health problems and psychosocial issues. Swallowing disorders impact the health and quality of life of millions of people around the world, which results in significant management and labour costs for the welfare sector. In this paper, we describe the concept for a new hardware/software mobile system to monitor patients’ swallowing. The system, designed by a user-centred approach and an interdisciplinary team of clinicians, industrial designers, and engineers, will help patients with dysphagia deal with their rehabilitation at home, safely and autonomously. The intent is to provide an application and a device for healthcare professionals to aid them in managing the care of dysphagic patients, as well as providing support for both caregivers, and patients themselves. Through this interactive system, patient and doctor are in constant contact and the application informs the doctor, or therapist, etc., about the imminent risk factors, in order to be able to act immediately in risky situations.

This paper presents the study and the realisation of a suitable and ergonomic design, able to integrate technological features useful to the detection of salient parameters, taking into consideration the psychological repercussions on users and how easily they would accept the solutions offered.

This research tries to define, through the form and the functions of hardware and software, a new category of wearable devices, that are easy to use and useful for all involved with this pathology.

Keywords: Dysphagia, Usability, Ergonomics, Wearable device
1. Introduction
The present study aiming to develop an application and a device for the prevention of dysphagia, started in 2016 with the work of an interdisciplinary research team combining competences in design, engineering and medicine. Both the application (software) and the enabling wearable device to be developed, share as targets the healthcare staff working with dysphagic patients as well as the patients themselves and their caregivers. The research aims to provide an interactive system, thanks to which patients and medical staff can maintain constant contact. In fact, the application signals imminent risk factors to doctors, speech therapists, etc., enabling them to act promptly and accordingly.

2. Epidemiology of swallowing disorders
2.1 Background and research rationale
The epidemiological survey of swallowing disorders is not thoroughly exhaustive and it undoubtedly underestimates the actual diffusion of these disorders.

The literature reveals that every year around 10 million Americans consult a doctor due to a swallowing disorder (Segun, 2008).

Unfortunately, the literature does not provide any recent epidemiological data about Europe, and Italy in particular, as highlighted in the study by Kuhlemeier, 1994; AHCPR, 1999; Reilly, 2005.

Swallowing disorders can manifest at all ages and can be correlated to congenital anomalies, structural damage (occurring after surgery performed on body areas used in swallowing) and/or pathologies of various origins (neurological, bronchopulmonary, gastroenteric, infective, etc.) (Logemann, 1983). The main complications of dysphagia are tracheo-bronchial aspiration, globus, aspiration pneumonia, malnutrition and dehydration. The last two aspects can be associated with behavioural disorders and a decrease in immune defences.

There is a high occurrence of dysphagia in the adult population – in acute-care centres, rehabilitation centres for post-acute stages, and residential structures or at home - which is likely to increase in parallel to higher life expectancy and the improvement in resuscitation techniques. It has been estimated that dysphagia affects 13-14% of acute-care patients, 30-35% of patients in rehabilitation centres, and 40-50% of those in centres for long-term patients.

In neurology, dysphagia often occurs as a symptom in patients suffering from Acquired Brain Injury (42-45%), ALS (80-100%), Multiple Sclerosis (33-43%) as well as Parkinson’s (50-90%) and Alzheimer’s disease (84%). Additionally, around a third of the patients who have had a stroke suffer from dysphagia. According to the data by the Agency of Health Care Policy and Research, 75% of acute users hospitalised for stroke suffer from dysphagia and, 91% of the time, this can persist up to three months after the acute episode. 43-54% of this population manifest the symptom of inhalation, which becomes more severe in 40% of the cases of aspiration pneumonia. 4% of these patients die in the short or long term because of respiratory complications.

The risk of aspiration of food of varying consistency in the lower airways, with the potential consequence of high-mortality aspiration pneumonia, makes dysphagia a critical problem, which is not easy to tackle on a local level, especially because it is difficult to diagnose and monitor as well as carrying out a precise follow-up of the rehabilitation process. Additionally, a point which is often overlooked is the social restriction dysphagic patients must face with a consequential decrease in their quality of life (Gustafsson et. Al., 1992). Dysphagia is a real disability and its connection with the
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Reduction of psychological and social activities is becoming more and more evident. This results in a decrease in patients’ quality of life and a decrease in self-esteem, safety, work skills and leisure (Ekberg et al., 2002). Besides being a socially debilitating and expensive issue for patients and their families, dysphagia is also the cause of numerous hospital admissions (sometimes recurring) with consequently high costs for the community (Martin-Harris, 1999).

3. Goals

The present project aims to increase the level of autonomy and safety of patients suffering from dysphagia and to improve their quality of life. The research team sought to create a system able to remotely monitor the dysphagic patient during meals (whether the patient is autonomous or helped by a caregiver). In this way, the medical staff specialised in treating dysphagia (phoniatrists, otolaryngologists, physiatrists, speech therapists, physiotherapists, etc.) can identify, through the system, potential risks arising during meals that could become harmful for the patient.

The parameters that the system must be able to monitor are the following:

1. behaviour: alertness during meals, collaboration, attention, capacity to control physiological secretions;
2. motor skills: posture control, adoption of compensating postures or manoeuvres, fatigue;
3. coughing: presence and effectiveness;
4. oxygen saturation: assessing changes during meals or signs of possible inhalation (reduction of 2-3% alertness, 5% meal suspension);
5. variation of voice timbre (i.e. gurgling voice signalling inhalation);
6. food habits, and water and calorie intake: assessment during meals to avoid dehydration and malnutrition.

4. State of the art: survey on feasibility

4.1 State of the art on patented products

The patent concept of the present research is a device for the screening of dysphagia, a smart system to be used in domestic environments and able to acquire parameters such as: alertness, coughing, oxygen saturation levels, neck and head posture, and calorie intake during meals. Whenever the recorded parameters exceed the threshold, the system will remotely issue an automatic alert to the doctor.

The patent research focused on application and acquisition of the abovementioned parameters. Additionally, in developing the device, the research team used commercial technology, therefore, the patent concept refers to a set of technologies and not to one single sensor.

In the preliminary survey, the patents containing (in the title or abstract) a combination of the following terms were taken into account: dysphagia, screening, telemedicine, physical parameter control, medical device, device, sensors, cough, fever, head posture, neck posture, calories, oxygen and carbon dioxide. The keyword research was carried out using the international database: https://worldwide.espacenet.com/. The patent research led to the detailed analysis of 35 patents, 5 of which were partially relevant but not noteworthy.
The result of the analysis confirmed concrete grounds for the team to develop a project for the device.

**Table 1. Keyword research results**

| Research criteria                                      | Number of results | Potentially relevant          |
|--------------------------------------------------------|-------------------|--------------------------------|
| **Keyword 1 (in the title or abstract)**               |                   |                                |
| Dysphagia and screening                                | 6                 | JP2014224133                   |
| Dysphagia and telemedicine                             | 0                 |                                |
| Dysphagia and physical parameter control               | 0                 |                                |
| Dysphagia and medical device                           | 4                 |                                |
| Dysphagia and device                                   | 41                | WO2010082986 (A1)              |
| Dysphagia and sensors                                  | 1                 |                                |
| Dysphagia and cough                                    | 11                |                                |
| Dysphagia and fever                                    | 5                 |                                |
| Dysphagia and head and neck posture                     | 0                 |                                |
| Dysphagia and calories                                 | 0                 |                                |
| Dysphagia and oxygen and carbon dioxide saturation     | 0                 |                                |
| device and cough and fever and head and neck posture and calories and oxygen and carbon dioxide | 0                 |                                |
| Sensor and cough and fever and head and neck posture and calories and oxygen and carbon dioxide | 0                 |                                |

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### 4.2 Analysis of mobile devices and applications

The term “dysphagia” refers to all difficulties or impossibility to correctly carry out autonomous oral nutrition. Dysphagia is a swallowing disorder occurring in several neurological pathologies and after surgery - both on the nervous system as well as on other body areas involved in swallowing.

- Lips
- Tongue
- Mandible
- Teeth
- Pharynx
- Larynx
- Oesophagus

The function of swallowing requires complex coordination of areas involved in the passage of food, from mouth to stomach. There are different types of dysphagia that require specific assessment,
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treatment and precaution. Once the assessment is completed, doctors must decide whether the patient can eat orally. When this solution is not possible, an alternative nutrition option must be decided on, for instance the use of a nasogastric tube (NGT) or through percutaneous endoscopic gastrostomy (P.E.G.) .

Managing dysphagia when oral nutrition is possible, involves the help of medical staff (specialised doctors, speech therapists, nutritionists, dieticians, professional nurses, physiotherapists), and other assistance staff (caregivers, healthcare sanitary workers) and family.

The devices for dysphagia currently used in medicine are for nutrition via nasogastric tube or through PEG. (i.e. the Compat Ella® device, produced by Nestlé Health Science) However, the functions of these tools do not apply to the purposes of the present research project.

On the other hand, to re-educate dysphagic patients, devices based on neuromuscular electric stimulation (NME) are sometimes used. Several studies (Humbert- Poletto, 2006) observed how transcutaneous neuromuscular electric stimulation can facilitate swallowing. An example of this category of devices is the device called Synchrony, produced by ACP.

The survey on the status of the art on devices revealed a lack of systems for monitoring and treatment able to gather data and issue alerts in the case of imminent risks of inhalation.

A part of the research focused on the study of mobile applications currently available on the market. In particular, the nine mobile applications available in Apple Stores and Android (on the 30th August 2016) were examined. These are recent applications, released between 2013-2016.

The functions developed in the Apps deal with the following themes:
• Divulging information about issues connected with dysphagia and how swallowing works (with animated videos and tutorials)
• data collection and management on dysphagic patients
• motor exercises for rehabilitation
• advisory database on equipment, diet, medicine and useful techniques

Figure 2. Analysed mobile applications (released on the 30th August 2016).

5. DayD Specifications

The present experimental project falls into a branch of research started by the research team a number of years ago that focuses on weak users. Two fields in which friendly design excelled with a defined approach are the following: “Human Centred Robotic Design” and “Enabling Design”.

The Smart system, which the present research aims to realise, is targeted to medical staff working with dysphagic patients as well as the patients themselves and caregivers. It is an Interactive system allowing patients to maintain contact with the doctor/ speech therapist and that, through the Application itself, can help the medical staff to identify potential anomalies, in order to immediately tackle potentially risky situations.

The project, called DayD (Daily Dysphagy) aiming to aid daily activities, starts from the shared belief that the environment (meaning a set of spaces, objects, services and relationships) in which dysphagic patients live, plays a fundamental role in their psycho-physical welfare and quality of life. In particular, it is necessary to highlight the importance of designing and realising a smart system for dysphagia, that is accessible and acceptable for its potential users.

The discipline of Design can provide concrete answers to the challenge set by both the study and design of the DayD device.
5.1 Concept
The first stage of the study/design of the wearable device focused on identifying the adequate sensors to monitor the five parameters and their correct anatomic positioning. The study on sensor collocation aimed to achieve both the correct data acquisition and the least anatomic impact possible (invasivity) on the final users.

Table 2. Analysis chart of the monitoring parameters and sensor choice.

| Parameters | What to survey | How          | Tool          |
|------------|----------------|--------------|---------------|
| 1. Behaviour | Alertness-fatigue | Heartbeat – O₂ | Pulse oximeter |
| 2. Motor skills | Posture | Neck movement | Gyroscope      |
| 3. Coughing | Intensity-quantity | Decibel      | Microphone    |
| 4. Oxygenation | Level | Oxygen       | Oximeter      |
| 5. Voice | Timbre | Decibel      | Microphone    |

During all the stages of designing the device a User-Centred Design (UCD) approach was utilised, which focuses on the user and his needs and takes into consideration factors such as usability, adaptability and ergonomics.

Bearing in mind that the main purpose of the device is to survey data to aid the management of the pathology, the concept of the wearable device is also targeted at potential users and therefore it aims to achieve high levels of comfort with particular attention to hygiene and safety. For this reason, great importance was placed on the choice and use of pleasant and biocompatible materials. The technical, formal and ergonomic characteristics of the proposed concept, were dependant on these choices.

DayD is a daily accessory, conceived to adapt to different lifestyles and uses, which vary on the basis of the user’s personal routine, age, and psychophysical condition. The device aims to be discreet and easily accessible for operators (or family members).

Size constraints, and the positioning of sensors and the hardware in general led to the concept in Figure 3.

The goal of the research, developed within a multidisciplinary team, was to design all aspects of this new system-product: design, interface, ergonomics, study of hardware and software, and interaction/test with users.

The tools of Design contributed in identifying the needs of patients and developing innovative solutions, which also had to be financially affordable, in order to meet the abovementioned
5.2 Software design concept

The design of both the physical and graphic interface were based on criteria of accessibility and interaction.

The smart system utilises a piece of Software, to be used by the medical staff to monitor and collect data, as well as an advisory mobile Application (intended mainly for users). The architecture of the system is summarised in Figure 4.

The system is made up of five main sections, one of which can be utilised after the second access ("monitoring" section):

1. Patient’s data
2. Tests
3. Protocol
4. Device configuration
5. Monitoring

The first three sections are compiled by the doctor or therapist and help creating a user profile, as accurate and exhaustive as possible.

The configuration section of the wearable device has the main function of calibrating the smart device to the specific needs of its user: personalised threshold values are inserted for the parameters that need to be monitored (voice, coughing, heartbeat, temperature, oxygenation).

Once the setting has been correctly selected, the medical staff can consult the collected data in the “Monitoring” section.
In the DayD project great importance was placed on identifying the optimal characteristics related to the system’s interfaces.

The importance of an approach centred on the person in the project for ICT (Human Centered Robotic Design) was motivated by the need to design advanced mechanisms for interaction, that are however easy to use for all users, with particular reference to weak users.

Designing the system’s interface took into consideration not only the aesthetics of the device, but in particular the page design and layout rules for usability. The use of colour, shape, and font, had the user in mind. The research team tried to elaborate a graphic interface that was hierarchically structured depending on the user’s perception, making reading and browsing easy and clear.

In order to guarantee the utmost usability, directions and browsing options were limited, using a hierarchy with a clear path divided in levels and constantly offering a link to the main menu.

Moreover, adopting intuitive interfaces allowed inexperienced users, without particular experience or knowledge in using these devices, to use and interact with both the software and the Application in a simple and safe way.

6. Conclusions

In order to successfully manage swallowing disorders, patients and families become precious allies. Their awareness that the problem exists or that it could occur, their knowledge of the basic swallowing mechanism and of the most evident symptoms of dysphagia, and information on simple, effective preventive behaviours, are just as essential in the rehabilitation process as the medical staff involved in the treatment programme.

DayD aims to become an ally for patients, families and operators. Its design integrates technological features useful in retrieving salient parameters. It is the result of a study that took into great consideration the psychological repercussions on users and how easily they would accept the solutions offered.
References

Arizona Health Sciences Library. (2013, Dec 9). AHSL Guide: Mobile Apps & Resources [Online]. Available: http://azhin.org/evaluating-apps.

Benyon, D. (2012). Progettare l’interazione. Metodi e tecniche per il design di media interattivi, (a cura di Riva G.). Pearson editore.

Burkhead, L.M., Sapienza, C.M., Rosenbek, J.C. (2007). Strength-training exercise in dysphagia rehabilitation: principles, procedures, and directions for future research. Dysphagia, vol. 22, no. 3, (pp. 251-265).

Cairo, A. (2013). L’arte funzionale. Infografica e visualizzazione delle informazioni. Pearson editore.

Center for Excellence in Universal Design. Retrieved March 25, 2014, from http://www.universaldesign.ie/exploreampdiscover/the7principles.

Falcinelli, R. (2011). Guardare, pensare, progettare. Neuroscienze per il design. Editore: Stampa alternative.

Fridler, N., Rosen, K., Hertzberg, O., Lev, A., Kaplan, D., Hildesheimer, M., Menahemi-Falkov, M., Feldman, Y., Grosberg, D. & Shani, M. (2012). Tele-Rehabilitation Therapy vs. Face-to-Face therapy for Aphasic Patients. The Fourth International Conference on eHealth, Telemedicine, and Social Medicine.

Gamberini, L., Chittaro, L., et al. (2012). Human-computer interaction. Fondamenti teorici e metodologici per lo studio dell’interazione tra persone e tecnologie. Pearson editore.

Happtique App Certification Program. Happtique Inc. Mobile Health Source. mHIMSS App Usability Work Group. (2012, July 11). Selecting a Mobile App: Evaluating the Usability of Medical Applications (v1. July 2012) [Online]. Available: http://www.mhimss.org

Howden, C.W. (2004). Management of acid-related disorders in patients with dysphagia. American Journal of Medicine, vol. 177, no. 5A, (pp. 44S-48S).

Humbert, I.A., Poletto, C.J., Sassone, K.G., et al. (2006). L’effetto della stimolazione elettrica di superficie sul movimento hyolaryngeal in individui normali a riposo e durante la deglutizione. J Appl Physiol.; 101:1657-63

Lizarondo, L., Kumar, S., Hyde, L. & Skidmore, D. (2010). Allied health assistants and what they do: a systematic review of the literature. Journal Multidiscip Healthc, 3, 143-53.

Murray, J.H. (2011). Inventing the Medium, Principles of Interaction Design as a Cultural Practice. Mit Press.

Saffer, D. (2008). Designing Gestural Interfaces: Touchscreens and Interactive Devices. O’Reilly Media, Inc.
Saffer, D. (2013). Microinteractions: Full Color Edition: Designing with Details. O’Reilly Media, Inc.

Schindler, O., Ruoppolo, G. & Schindler, A. (2011). Deglutologia. Omega edizioni.

Steele, C.M., Bennett, J.W., Chapman-Jay, S., et al. (2012). Electromyography as a biofeedback tool for rehabilitating swallowing muscle function, applications of EMG in clinical and sports medicine. Dr. Catriona Steele (Ed.), ISBN: 978-953-307-798-7, InTech.

Tan, C., Liu, Y., Li, W., Liu, J., Chen, L. (2013). Transcutaneous neuromuscular electrical stimulation can improve swallowing function in patients with dysphagia caused by non-stroke diseases: a meta-analysis. Journal of oral rehabilitation. 2013;40(6):472-80.

Thimbleby, H. (2007). Press On, Principles of Interaction Programming. Mit Press.

Ward, E. C., Sharma, S., Burns, C., Theodoros, D. & Russell, T. (2012). Managing patients in the assessment of swallowing via telerehabilitation. International Journal of Telemedicine and Applications.

Ward, E. C., Sharma, S., Burns, C., Theodoros, D. & Russell, T. (2012). Validity of conducting clinical dysphagia assessment with patients with normal to mild cognitive impairments via telerehabilitation. Dysphagia.

Zhou, X., Appel, L., Gerhardstein, B., et al. (2012, May 10). Getting clinicians involved: Testing smartphone applications to promote behaviour change in health care [Online]. Available: http://www.ics.uci.edu
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Acknowledgements: the authors would like to thank all the other members of the DayD Project for their invaluable help and in particular Dott. Giulia Massazza (Speech therapist), Prof. Bruno Fattori (Associate Professor of Otorhinolaryngology, ENT - Audiology and Phoniatrics Unit, Department of Internal and Experimental Medicine, University of Pisa), Prof. Cecilia Laschi (Professor of Biorobotics, Scuola Superiore Sant’Anna, Pisa), Prof. Marco Raggio (Electrical, Electronics and Telecommunication Engineering and Naval Architecture Department – DITEN, University of Genoa).