User-Centered Design of a computerized HRQoL questionnaire
Qualitative analysis of user needs and prototype evaluation
Author: Nikolaos Syropoulos
Affirmation

I hereby affirm that this Master thesis was composed by myself, that the work contained herein is my own except where explicitly stated otherwise in the text. This work has not been submitted for any other degree or professional qualification except as specified; nor has it been published.

Stockholm, 31.08.2014

__________________________________________________________
Nikolaos Syropoulos
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Abstract

**Background:** The digitalization of Health-Related Quality of Life instruments as well as the design of computerized systems according to user needs can improve the usability and fulfil the expectations of the end-users.

**Objective:** The purpose of this study is to identify the features that a computerized Health-Related Quality of Life questionnaire, which has been designed through Questionnaire Service, should support, when it is being used from the patients and the healthcare providers. These features come from the needs of a specific group of healthcare providers

**Methods:** In this exploratory three-phase study, qualitative methods were used. Firstly, observations and individual semi-structured interviews were used to elicit the user needs and identify the features of the computerized questionnaire. Subsequently, content analysis was used to analyze the data and a wireframe prototype was developed. Finally, the prototype was evaluated with the use of a
scenario and semi-structured interviews, covering the all the levels of use of the computerized HRQoL questionnaire by the patients and the health providers.

Results: The qualitative methods that provided useful information regarding the current use of a paper-based Voice Handicap Index questionnaire service by Speech and Language Pathologists. Problems elicited that the users face by using a paper-based HRQoL instrument and which are related to process complexity, data reliability, as well as environmental issues. Additionally, important features for these types of tools were identified, related to enabling flexibility in completing the questionnaire, instant accessibility to the data produced, as well support for the follow-up processes and integration with EHR. Also, concerns regarding the new way of handling the data were expressed. The research also provided with a wireframe prototype of the computerized HRQoL questionnaire, designed according its use by the patients and the healthcare providers.

Conclusion: The user-centered design as well as the user-based evaluation identified the needs of the users towards a HRQoL instrument and also suggested general features that can applied in a computerized HRQoL questionnaire used from patients and different healthcare professionals in similar clinical contexts.

Keywords: HRQoL, User-Centered Design, Design Science, User needs, Wireframe prototype
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List of abbreviations

ASHA: American Speech-Language-Hearing Association
CLINTEC: Clinical Science, Intervention and Technology
CVHI-10: Children Voice Handicap Index-10
EHR: Electronic Health Record
HRQoL: Heath-Related Quality of Life
QoL: Quality of Life
QS: Questionnaire Service
pVHI: Pediatric Voice Handicap Index
SLP: Speech & Language Pathology/Pathologist
STEEEP: Safe-Timeless-Effective-Efficiency-Equal & Patient-Centered
SVHI: Singing Voice Handicap Index
SVHI-10: Singing Voice Handicap Index-10
UCD: User-Centered Design
VHI: Voice Handicap Index
VHI-10: Voice Handicap Index-10
VoISs: Voice Symptom Scale
VRQoL: Voice-Related Quality of Life
WHO: World’s Health Organization
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1. Introduction

This thesis describes a design science study exploring Speech Language Pathologists’ needs of a digital HRQoL questionnaire and identifies features that can be used in the design of a HRQoL questionnaire service. In section 1.1, concepts like Quality of Life (QoL) and Health-Related Quality of Life (HRQoL) are being given. The evolution of paper-based HRQoL questionnaires into computerized versions is described, depicting disadvantages of the former type and the advantages of the new versions. In section 1.2, User-Centered Design (UCD) is introduced, focusing on its significance in design as well as UCD techniques. An introduction in STEEEP is added in section 1.3, while section 1.4 includes information regarding the Swedish National template platform for HRQoL questionnaires. Section 1.5 includes a short introduction to the field of Speech and Language Pathology (SLP), with a focus on the use of HRQoL questionnaires. Finally, the Voice Handicap Index is described (see 1.6) and also its use from the SLP clinic at Karolinska University Hospital (see 1.7). The next sections (1.8-1.10) include the problem definition, the aim of the study as well as the relative objectives and the research questions respectively.

1.1. Computerized Health-Related Quality of Life questionnaires

The World’s Health Organization (WHO) defines QoL as “individual’s perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns” (1). In other words, QoL conveys an overall sense of well-being, encompassing aspects of happiness and satisfaction with life (2).

In healthcare, QoL is mentioned as Health-Related Quality of Life (HRQoL) and constitutes a subjective, multidimensional concept related to physical, psychological (or mental) and social issues (3). HRQoL is being considered as a measurable outcome, including questions that reflect health (both physical and mental), contributing to health surveillance, indicating service needs and intervention outcomes and finally demonstrating scientifically the impact of quality of life on health (2).
HRQoL constitutes a concept that refers to the same domain as “health” (4). Since the boundaries of health range from negative valued aspects of life (like death), clinicians measure HRQoL even when a patient is ill or diseased (5). HRQoL is measured typically by questionnaires, which are called instruments and either elicit reports or rating from patients (6). These instruments consist of a number of items or questions, which belong to different domains (or dimensions), referring to the area, behavior or experience that is going to be measured (5).

Generally, many HRQoL questionnaires have been developed and validated in order to measure the quality of life in various illnesses (7), (8), (9). A HRQoL questionnaire can either measure the general health, or a specific disease (6). The HRQoL questionnaires generally can be used in two ways; either to be administered by interviewers; or to be self-administrated (5), i.e. to be completed by the patient without direct control. There are various strengths and weaknesses that appear when it comes to different types of administration. Particularly, a questionnaire that is being administrated by an interviewer provides advantages, like maximizing the respond rate, decreasing the possibility of missing items and minimizes potential errors of misunderstanding. On the other hand, when a questionnaire is administrated, the measurement requires many resources (like time and energy) as well as training of the interviewers (5). The self-administrated questionnaires are a way of HRQoL measurement where potential errors may occur, like misunderstanding or missing items (10). However, they are less expensive, requiring minimal resources (5).

Traditionally, the instruments that are used to collect HRQoL data consist of paper-based patient self-report questionnaires. This means that these questionnaires are printed on a paper form, where the patient has to fill in them with or without administration. The patient’s responses in the questionnaire are usually entered manually into a database or mark-recognition systems are used to transfer the data immediately, processing of large amounts of data (11). However, the use of paper-based systems in HRQoL questionnaires imply potential risks, like missing data (11), selection of more than one option in multiple choice questions where only one answer is required, or editing the questions (10). The
The fact that the staff should monitor the paper-based questionnaires, makes the procedure time-consuming (12). It has also been proved that sometimes physicians overlook the results of the HRQoL assessment due to time pressure and clinical constraints (11). Furthermore, the use of paper in these procedures, require special paper forms, as well as verification and examination of the database for potential errors (11). Another disadvantage of the paper-based HRQoL questionnaires is the fact that the sum scores are being calculated manually, which is time-consuming and can be a potential source of error (12).

As a solution to the limitations that were describe above, interactive computerized HRQoL questionnaires were designed in order to improve high quality data collected from the patients (12). Preliminary work has shown that the computerized HRQoL questionnaires are easily administered, efficient, both patients and healthcare providers accept them, easy to use and also constitute reliable and valid alternatives of paper-based HRQoL questionnaires (13), demonstrating the following advantages:

- They provide the collection of high quality data, without missing or problematic patient responses (11), enabling high quality control of actual patient’s response, since the computer is programmed to proceed only after a question is answered (12) and only one appropriate choice can be given (accept in the multiple-choice questions) (10).
- Each question can be presented as a self-contained entity being separated from the others and be answered on its own merits (10), whereas the subject can see a number of items at once if they are completing a paper-based HRQoL questionnaire (13).
- Data handling is benefited (10) since the forms from the process of data collection are removed (12) and consequently both data entry and editing are eliminated and data are transferred to the final database directly (11).
- The sum scores from the instruments can be calculated immediately and with no errors and they can be compared automatically with other scores (like norm scores) (11), (14).
They can produce standardized documentation of the assessment for future reference

- The date and the time can be recorded
- They can provide help to patients regarding their use (11)

All these advantages can improve both the quality and the validity of the patient data, as well as faster data throughput and reduced workloads (11).

1.2. User centered design

User-centered design (UCD) is an informatics framework that includes the users in software development (15). In other words, it describes these processes, where the users of a software influence in its design. These processes compose a spectrum of ways in which the user can be involved the design (16). The involvement of users assures that the design of the software will fit in the environment in which it will be used, but also, that its design will make it suitable for the users that will use it (17). UCD approach places the user in the center of the design, facilitating the tasks, which the design is made for, for the user and making sure that the user will learn easily how to use it without spending a lot of energy (16).

The ISO standard for Human-centered design for interactive systems\(^1\) describes six key principles that ensure that a design is user-centered:

1. The design is based upon an explicit understanding of users, tasks and environments.
2. The users are involved throughout design and development
3. The design is driven and refined by user-centered evaluation
4. The process is iterative
5. The design addresses the whole user experience
6. The design team includes multidisciplinary skills and perspectives

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\(^1\) ISO9241-210, 2010
Preece et al. (18) mentions various techniques to involve users in the design and development of a software artefact, which are summarized in the Table 1-1 below.

<table>
<thead>
<tr>
<th>Technique</th>
<th>Purpose</th>
<th>Stage in the Design Cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Background interviews and</td>
<td>- To collect user needs</td>
<td>At the beginning of the</td>
</tr>
<tr>
<td>questionnaires</td>
<td>- To evaluate the design alternatives, prototype</td>
<td>design process</td>
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<tr>
<td></td>
<td>and the final artefact</td>
<td></td>
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<tr>
<td>Sequence of work interviews and</td>
<td>- To collect data related to the sequence of work by</td>
<td>Early in the design process</td>
</tr>
<tr>
<td>questionnaires</td>
<td>using the artefact</td>
<td></td>
</tr>
<tr>
<td>Focus groups</td>
<td>- To discuss issues and requirements with the stakeholders</td>
<td>Early in the design process</td>
</tr>
<tr>
<td>On-site observation</td>
<td>- To collect data for the context that the artefact is going to be used</td>
<td>Early in the design process</td>
</tr>
<tr>
<td>Role playing, walkthroughs and</td>
<td>- To evaluate alternative design and prototype</td>
<td>Early in the design process</td>
</tr>
<tr>
<td>simulation</td>
<td>- To elicit information for user’s needs</td>
<td></td>
</tr>
<tr>
<td>Usability testing</td>
<td>- To collect data related to usability criteria</td>
<td>Final stage of the design process</td>
</tr>
<tr>
<td>Interviews and questionnaires</td>
<td>- To collect data regarding the user satisfaction from the artefact</td>
<td>Final stage of the design process</td>
</tr>
</tbody>
</table>
making them human-centered. However, a number of different disadvantages have been reported regarding the use of UCD approach:

- A UCD can be a less efficient approach, since it requires a lot of resources like money and time, requiring both finances and human at the same time
- Sometimes it is difficult to translate some types of gathered data into design, leading to misunderstandings and consequently to negative results
- The final UCD-driven artefact may be too specific for more general use, since it has been developed according the user needs of a specific context. (16)

1.3. STEEEP

According to Crossing the Quality Chasm: A New Health System for the 21st Century, (22), a landmark report by the Institute of Medicine (IOM), there are six aims to improve the health care system and which form the word STEEEP.

1. Safety – A healthcare system must be safe
2. Time – The healthcare system must be timely
3. Effectiveness – It should match science and not overuse or underuse any the best available techniques
4. Efficiency – A healthcare system should constantly seeking to reduce the waste of resources
5. Equality – A healthcare system should be the same for everybody
6. Patient-Centered – A healthcare system should be respectful of and responsive to individual patients.
1.4. The “My Care Pathways” project and the Questionnaire Service

This thesis is related to the Swedish National project My Care Pathways\(^2\) (MCP). This project is founded by the Swedish Governmental Agency for Innovation Systems – Vinnova (23) and one of its objectives is the creation of services that can allow patients to follow, control and manage their care process related information (24), being able to track their health. The goal is to create a prospective possible critical path between the patient’s health past events to his future health events (25). Another objective of this project is to provide an open platform, where software developers, even outside of the sector of healthcare (25), can use a Health Innovation Platform\(^3\) for designing applications that are interoperable with current health information systems (24).

One of the services that will be developed within the MCP project, is the Questionnaire Service (QS). Via this service, the healthcare providers will have the chance to design their own HRQoL questionnaires using a certain template. The created questionnaires will be sent out to patients and returned digitally to the healthcare provider once the patient has completed the form. The patient will be able to access the questionnaires through the national platform My Healthcare Contacts\(^4\) (MHC) (24), alongside other e-services such as appointment booking and online access to health records. Through MHC, the questionnaires that will be designed from through the QS, will integrate directly with current electronic health record systems, facilitating administration for health care professionals and administrators within the care provider organization. The vision is that the questionnaires that are being created can be local to a specific provider, or shared and reused between providers. The service will also support the administration of the questionnaires for healthcare providers. In this thesis, the QS includes all the procedures, from the design of the HRQoL questionnaire from the health provider, till the administration of the completed questionnaire and its integration with the EHR. So far, the QS is in pilot, since research is being conducted to explore the future features of its

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\(^2\) Mina Vårdflöden in Swedish
\(^3\) www.healthinnovationplatform.se
\(^4\) Mina Vårdkontakter in Swedish
design. The Health Informatics Center (HIC) at Karolinska Institutet in Sweden is leading the research within the project and is focusing on needs and requirements analysis (24). In the initial phase of MCP project, the design of end-user e-services was based on research related to three patient groups; stroke, lung cancer and hip surgery patients. As a result of the initial research, a number of basic e-services were included (25). This study contributes to this research, focusing on how the computerized HRQoL questionnaires that have been created by the QS, should look like when they are being used from the patients and the health professionals, according to the feedback from a specific field (see 1.9)

1.5. HRQoL questionnaires in SLP field

According to American Speech-Language-Hearing Association (ASHA), Speech and Language Pathology (SLP) constitutes the healthcare discipline which focuses on the assessment, diagnosis and treatment of speech, language, social communication, cognitive-communication, and swallowing disorders in children and adults. These healthcare professionals that act in the field of SLP are called Speech and Language Pathologists (SLPs) and work in many different research, education, and health care settings with varying roles, levels of responsibility, and client populations (26).

QoL research in SLP field was limited until recent years and QoL instruments were used infrequently in clinical practice (27). Nowadays, this area of research is rapidly evolving and various studies have been conducted in developing QoL instruments for diseases that are related to the SLP field (26). These studies concern QoL instruments that are being used in Communication (28), in Hearing Loss (29), Dysphagia (30), in Stuttering (31), in Dementia (32) in Autism (28), etc. These instruments are mostly questionnaires that measure the HRQoL and have been developed and validated through research, covering aspects related to the SLP field. However, despite the fact that SLPs have been provided with QoL instruments, the majority of them are being used in a paper-based form, where related problematic issues occur (see 1.1). Limited computerized solutions have been used for these instruments (33) which are not designed according the user needs, in other
words, are not UCD-driven and consequently they do not include the advantages of a UCD artefact (see 1.2). As a result, SLPs’ needs are not included in any research regarding QoL instruments, creating a need of further investigation.

1.6. The Voice Handicap Index

In 1997, Jacobson et al. developed and validated a psychometrically robust voice disability-handicap inventory, in order to evaluate the psychosocial consequences of voice disorders. This inventory was a new QoL instrument (34) and was called Voice Handicap Index (VHI) (35). It was designed to assess all types of voice disorders, even those encountered by tracheoesophageal speakers (36).

The preliminary form of this VHI consisted of eighty-five items. These items were derived from the daily experience of Speech and Language Pathologists and otolaryngologists within seven years. After three investigation procedures, the items have been reduced to thirty, and the instrument has been validated using different coefficients (35). The current VHI form’s items are represented as statements that are grouped in three domains of aspects that voice disorders are related to; functional, emotional and physical (35). These domains which are considered as subscales, describe three different impacts of the voice disorder to the patient. The functional subscale consists of statements that describe how the voice disorders affect the patient’s daily routine. The emotional subscale describe how the patient responds to a voice disorder. The physical subscale describe the patient’s self-perceptions of laryngeal discomfort and the voice output characteristics (36). It should be noted that the actual VHI form includes the statements, not organized according each subscale, but as a mix of these three subscales. Each subscale is indicated with a code Fx, Ex or Px, for functional, emotional or physical statements respectively, where x is the number of the statement Table 1-2.

<table>
<thead>
<tr>
<th>TABLE 1-2</th>
<th>Codes of Statements for each subscale group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Code in the form</td>
<td>Related subscale</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>Subscale</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fx</td>
<td>Functional subscale</td>
</tr>
<tr>
<td>Ex</td>
<td>Emotional subscale</td>
</tr>
<tr>
<td>Px</td>
<td>Physical subscale</td>
</tr>
</tbody>
</table>

For each statement, a five-point scale is used, according to the perception of the patient; never (no points), almost never (one point), sometimes (two points), almost always (three points), always (five points). For the Voice Handicap Index form see Appendix A.

Other instruments for the measurement of QoL in voice disorders are the Voice-Related Quality of Life (V-RQOL), the Voice Symptom Scale (VoiSS) and the Voice Handicap Index 10 (VHI-10) (37), (38), (36). Some of them were developed and validated using the scientific basis of the original form of VHI, satisfying different groups of patients. Some other examples of different forms of VHI include the Singing Voice Handicap Index (SVHI), which consists of 36 items and is used for patients with singing problems (39), its shortened version Singing Voice Handicap Index 10 (SVHI-10), which includes 10 items and is used also for patients with singing problems (40), the Pediatric Voice Handicap Index (pVHI), a pediatric version of VHI, which includes 23 items for a parental proxy (41) and the Children Voice Handicap Index 10 (CVHI-10) used for children, which consists of 10 items (42).

Furthermore, VHI and its different forms have been validated in different languages, using cross-cultural adaptations and as a result is currently being used to subjects from different countries (43), (44), (45), (46), (47), (48). It is also important to mention that the VHI has been used as the main instrument for various scientific projects related to voice disorders (49), (50), & (51).

1.7. Use of VHI in SLP clinic at Karolinska University Hospital

The division of Speech Language Pathology is part of the department of Clinical Science, Intervention and Technology (CLINTEC) in Karolinska Institutet, at the Huddinge campus in Stockholm. This division deals with both education and research in the context of
speech, language, voice and swallowing disorders (52). The education is provided either in undergraduate (four-year program) or in postgraduate level (master and PHD programs) with twenty-eight students to be accepted to each study program annually (52).

Except from the research and education, the SLP division provides professional SLP services to patients with various pathology, at the two SLP clinics at Karolinska University Hospital in the area of Solna and of Huddinge, in Sweden. The staff at the division consists of ten employees and about 90 affiliated teachers and supervisors, at the Karolinska Hospital clinics, at other hospitals and divisions within the County of Stockholm or at private clinics (52).

Several of the research projects that have been published during the year 2013 in the SLP division are related to the voice sector (53). For many of these research projects, SLPs in the division use the VHI for evaluation of the patients with voice disorders. VHI is also used for evaluation of patients in the SLP clinics by the SLP professionals. Furthermore, SLP clinic, as part of the Karolinska University Hospital, uses TakeCare as the main EHR for the documentation of patients’ health data. TakeCare constitutes a record system which represent thousands of active users, whereas it is used by various health professionals and patients (54). It consists of different modules: all health care documentation, patient administration through “patient records”, health care planning, booking, electronic prescriptions, electronic referrals and replies (55). TakeCare is also an information source, providing health information data to Stockholm EPR Corpus which constitutes a source for research that is conducted at Stockholm University (56).

Paper-based VHI questionnaires are currently used by the SLPs of the SLP clinic of Karolinska University Hospital in Huddinge. Typically, SLPs use this instrument two times for each patient; one time during the first voice examination; and one time after the treatment, as a follow-up. Before both examinations, the patient is prepared and informed for the VHI examination, regarding both the VHI procedure and the nature of the results that are being elicited from the instrument.
The VHI examination is conducted during the session with the patient. The patient is asked to fill-in the questionnaire as long as the SLP waits for him to finish. After the VHI is filled out, the session continues. After the patient leaves, the SLP transfers the patient’s answers (responses) to a Microsoft Excel spreadsheet one by one, where the scores are calculated automatically through functions. The SLP double-checks if all the answers have been transferred and then the SLP transfers the scores to a paper and then accesses the patient’s directory in the EHR journal system (in this case, TakeCare is used). The SLP transfers the results to TakeCare and then the VHI process is considered as completed (see 3.1 for more details regarding the current VHI process).

1.8. Problem Definition

Research has proven that the use of paper HRQoL questionnaires is related to a number of limitations (11), (10), (12) and also that the adoption of their computerized versions has given plenty of advantages, which were reflected by either the patient’s or and the healthcare provider’s point of view (10), (11), (14), (13), (12). Furthermore, various studies have demonstrated UCD approach as an effective way to design artefacts that are more suitable to the users as well as adapted to the certain environment that they are designed for (19), (20), (21). However, it is a fact that the majority of the design of these computerized QoL tools does not follow this approach (16), (17), ending up with technologically-driven design, excluding the user from the design process, since UCD approach is related to disadvantages (16) that makes the process not attractive to follow.

At the same time, the Swedish National project MCP is currently running, planning to provide a questionnaire service, allowing healthcare providers to create their own HRQoL questionnaires, send them to the patients, allowing also the integration with EHR as well as their administration (23), (24), (25). According to the previous paragraph, it is crucial for this service, which target to a wide range of healthcare contexts, to follow a UCD approach by providing features that are designed with UCD techniques and reflect the user’s needs. Since services like these are used by healthcare providers from different fields and specialties, it is important to take into consideration needs from a variety of
different health professionals. However, providing examples or case studies from specific clinical contexts exploring needs for HRQoL instruments is imperative to ensure that the design of a Questionnaire Service tool becomes useful and meets the requirements of the clinical context. SLP, as such a clinical context, constitutes a field with limited research regarding UCD design and extended use of HRQoL instruments and therefore qualifies as an important case for exploring needs.

1.9. Aim and Objectives

Given the problem described in 1.7, this study aims to identify the features that a computerized HRQoL questionnaire, which has been designed through the QS, should support, when it is being used from the patients and the healthcare providers. This research will elicit knowledge that will provide:

1. Information that will enrich a clinical context with limited research regarding user needs
2. Basic knowledge regarding a novel tool, used by health professionals for administrating the questionnaires sent to patients in the day to day clinical practice
3. A scientific basis for exploring user needs in computerized HRQoL questionnaires
4. Information regarding generalizable features of a computerized HRQoL questionnaire should provide based on a specific clinical context.

In order for the aim of this study to be reached, the following objectives are required:

1. To investigate the user needs from SLPs regarding the use of a computerized VHI
2. To design a prototype of the computerized VHI according the SLPs needs
3. To formatively evaluate this prototype

1.10. Research Questions

The main research questions addressed in this study are:
1. What are the user needs of SLPs regarding the design of a computerized HRQoL instrument?

2. Which features should be supported from a computerized HRQoL questionnaire in order to meet the needs elicited from a specific clinical context, when it is being used from the patients and the health professionals?
2. Methods

In this chapter, the study design of this thesis is analyzed (see 2.1) as well as the approach that was followed is mentioned (see 2.2). Section 2.3 includes information regarding the setting that this study took place as well as the process that was used to identify and select the participants. Sections 2.4 and 2.5 include the methods used to collect and analyze the data of this study, respectively. Then the technique in which the artefact was developed is described step by step (see 2.6) and also related ethical considerations of this study are mentioned in the last section (see 2.7).

2.1. Study design

A research design constitutes a set of decisions that construct a general plan, which includes the methods and the procedures for collecting and analyzing the data in the research (57). Depending on the purpose of the research, a study can be characterized as exploratory, descriptive or explanatory (58). The choice of a research design depends on how much we know about a problem. The less we know, the more likely is to use the exploratory design (57). The exploratory research is used more in new areas with no or limited research and according to Bhattacherjee (58) its goals are “(1) to scope out the magnitude or extent of a particulate phenomenon, problem or behavior, (2) to generate some initial ideas (or “hunches”) about that phenomenon, or (3) to test the feasibility of undertaking a more extensive study regarding that phenomenon”.

In the introduction of this study, it has been stated that the aim of this research is to elicit knowledge about designing a computerized QoL questionnaire according the collection of user needs for SLPs. This tool is based on the VHI protocol for patients with voice disorders which is currently used in paper-based form. The outcome of this study constitutes new knowledge, where the collected user needs and from a field with limited related research, are transformed into a novel artifact, solving a practical problem, which can be generalized into basis-knowledge for creating similar artifacts. Taking this into consideration, the strategy used in this study is the exploratory inductive research design,
since the improvement of the VHI process will be explored by the use of a new solution, providing generalized knowledge.

According to Maguine & Bevan (59), the user needs and requirement analysis is a complex process which is composed of four tasks, which are illustrated in the Figure 2-1. Each of these tasks, can be executed by the use of different methods (59). Furthermore, according to Johannensson & Perjons (60), “Design science is the scientific study and creation of artefacts as they are developed and used by people with the goal of solving practical problems of general interest”. The roots of design-science paradigm come from engineering and sciences of the artificial and constitutes a problem-solving paradigm. It seeks a solution to a real world problem of interest to practice, to create innovations that define the ideas, practices, technical capabilities and products through which the analysis, design, implementation, management and use of information systems can be effectively and efficiently accomplished (61), (62) &
Design science is actually a study approach, a study framework which includes five different activities, reflecting the different steps of creating an artifact (60). Figure 2-2 illustrates the five activities of the design science framework.

According to this research study, the aim required the development of a solution, an artifact, which would solve the defined problem, by collecting the user needs. These are the two main reasons that the researcher decided to use the design science approach in order to fulfil the study purpose.

Taking into account the user needs and requirements analysis by Maguine & Bevan (59), as well as the design science framework by Johannesson and Perjons (60), a general study design framework was defined, which is illustrated by the Figure 2-3.

![Figure 2-3. The study design framework](image)

The study design framework includes three phases which reflect the aim of this research. Each of these phases, consists of tasks, which are described in detail later in this chapter.

The **first phase** concerns the user needs collection, by using two methods for data collection as well as a method for analysis of this data. The methods were used for the data collection were observations and semi-structured interviews (see 2.4). For the data analysis, content analysis method was used (see 2.5).
In the second phase, an artefact was created, using a certain design methodology (see 2.6)

The third phase constitutes the formative evaluation of the artefact, by using two methods for demonstration, as well as a method for data collection and a method for analysis of the data. The demonstration methods included a wireframe prototype and a scenario (see 2.6). For the data collection of this phase, semi-structured interviews were used (see 2.4), whereas content analysis was used for the analysis of the data (see 2.5.)

2.2. Research approach

According to Creswell (65), research approaches “are plans and the procedures for research that span the steps from abroad assumptions to detailed methods of data collection, analysis and interpretation”. Depending on the type of research that is chosen, there are two main different approaches to research: The qualitative and the quantitative approach (66).

Qualitative research is an approach that assist the researcher to investigate the quality of relationships, activities, situations, or materials, giving emphasis on activities of holistic description, like describing in detail what is going on in a particular process, by describing the attitudes or behaviors of the people (67). The process of a qualitative research includes emerging questions and procedure, data collection from the participants and analysis, which is done by using emerged themes and interpretation by the researcher (65).

On the other hand, quantitative research is an approach that enables the researcher to assess objective theories, by examining the relationship among variables (65). This approach generates data in quantitative form that can be subjected to rigorous quantitative analysis in a formal and rigid fashion (66). This data is numerical and can be measured, by using instruments that analyze using statistical procedures (65).

Considering the problem, as well as the aim and the objectives of this study, the researcher decided to use a qualitative approach, in order to identify and analyze
qualitative data, like the user needs for the design of an improved system, as well as their opinion and beliefs for the current systems and for the new improved one.

2.3. Study setting and selection of the participants

2.3.1. Study Setting

The main setting where this study was conducted was the SLP clinic of the Karolinska University Hospital in Huddinge in Sweden. The SLP clinic also extents at the Karolinska University Hospital in Solna, as well as the Astrid Lindgren Children’s Hospital and the Roselunds Hospital in Stockholm. The clinic works in a close collaboration with the SLP department of Karolinska Institutet, which is part of CLINTEC\(^5\).

Many SLPs that work in the clinic are also active researchers, working partly at Karolinska Institutet. They specialize in evaluation and treatment of patients with multiple diseases, affecting their language, speech, voice, as well as the swallowing function.

The clinic also collaborates with a large number of clinics at Karolinska University Hospital including Pediatrics, pediatric surgery and pediatric neurology (Astrid Lindgrens Children’s Hospital), Geriatrics, Hearing and Balance clinic, Clinic for reconstructive plastic surgery, Neurology, Department of Neurosurgery, Department of Rheumatology, Thoracic and Cardiovascular Clinic, Ear/Nose/Throat Clinic (68).

The observations as well as the majority of the interviews were conducted at the Karolinska University Hospital in Huddinge. However, some of them were done at the Karolinska University Hospital in Solna as well as the Roselunds Hospital.

2.3.2. Selection of the participants

One of the most important steps in the research process is the sampling, which is the process of selecting those individual that will participate in the study (67). There are

\(^5\) Department of Clinical science, Intervention and Technology
different methods of sampling, which reflect on the different ways that the researcher
defines and selects his participants. The most common methods for sampling in
qualitative research are the purposive sampling, the quota sampling and the snowball
sampling (69).

In the purposive sampling the researcher sets a number of criteria, selecting those
participants that fulfil them. Quota sampling can be considered as a purposive sampling,
however, this method is “more specific with respect to sizes and proportions of
subsamples, with subgroups chosen to reflect corresponding proportions in the
population” (69). The snowball method is used when the desired sample is “hidden”, in
other words, difficult to be found. In this case, the sample can be identified through a
social network, where one or more participants can refer to the others (69) and for this
reason is also known as “chain referral sampling” (67).

For the purpose of this study, the researcher used both purposive and snowball
techniques in order to select the participants. Particularly, certain criteria were defined
before the selection in order to find out the first participant. These criteria have been
selected in order to satisfy the research questions and are presented in Table 2-1 below.

<table>
<thead>
<tr>
<th>Type</th>
<th>Criterion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Occupation</td>
<td>SLP</td>
</tr>
<tr>
<td>Special skills</td>
<td>• Experience with patients with voice disorders</td>
</tr>
<tr>
<td></td>
<td>• Use of VHI within the clinical practice</td>
</tr>
<tr>
<td></td>
<td>• Use of TakeCare within the clinical practice</td>
</tr>
</tbody>
</table>

The first participant that fulfilled these criteria was identified at the Karolinska University
Hospital. Consequently, this participant led to the identification of the rest of the
participants that fulfilled the criteria. In this study, all the available subjects that fulfilled
the criteria in the Karolinska University Hospital, participated in this study. Totally, six
female participants that work as SLPs in the Karolinska University Hospital took part in the
study, being involved in several tasks. The characteristics of the participants are summarized in the Table 2-2 below.

Two of them [I2 & I3] were observed during their sessions with patients while they were conducting VHI examination. One of the participants confirmed the data collected from the observations and also confirmed the content of the interview [I1]. All of the participants took part to the initial semi-structured interviews and finally, five of the participants [I2 - I6] were involved in the evaluation of the prototype, providing the qualitative data that were analyzed in this study.

<table>
<thead>
<tr>
<th>Informant/Interviewee</th>
<th>Gender</th>
<th>Age</th>
<th>Years of experience</th>
<th>Participated in</th>
</tr>
</thead>
</table>
| I1                    | Female | >41 | >10                 | • Initial semi-structured interview  
|                       |        |     |                     | • Validation of observation data  
|                       |        |     |                     | • Validation of interview content |
| I2                    | Female | 36-41 | 7-9                 | • Observation session  
|                       |        |     |                     | • Initial semi-structured interview  
|                       |        |     |                     | • Evaluation of prototype |
| I3                    | Female | >41 | >10                 | • Observation session  
|                       |        |     |                     | • Initial semi-structured interview  
|                       |        |     |                     | • Evaluation of prototype |
2.4. Data collection methods

In qualitative research, these three are the most common methods for eliciting data; the observation; the interview; and the focus group. The observation is used when data is collected by observing behaviors in their usual contexts that they occur naturally, the interviews are used in order for certain information to be elicited from the participants (especially sensitive information) and focus groups are used when collecting data from a certain group in order to generate generalizations. (69)

In this study, two methods for data collection were used, which are summarized in the Table 2-3.

<table>
<thead>
<tr>
<th>Data collection method</th>
<th>Short description</th>
<th>Goal</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

TABLE 2-3

The data collection methods used in the study
Observation | Observation of the current use of VHI in a real voice examination session | To gain information regarding the current use of VHI in the selected setting

| Semi-structure interviews | Conduct of two semi-structured interviews to participants | The first semi-structured interview focused on collecting information concerning the user needs and the second one focused on collecting information concerning the participant’s opinion regarding the computerized VHI

2.4.1. Observations

As part of the first stage of the design science process; to explicate the problem, the researcher decided to conduct an observation. According to the literature, the observation constitutes a method that can give a nuanced understanding of the context, which comes only from personal experience (69) The observation that was conducted was direct, nonparticipant and naturalistic. This means that the process was done directly from the researcher in real time, there was no interference between the observer and the subjects during the observation and the events that have been recorded, occurred in the normal environment (67).

During this study, two different observations of the same procedure were conducted. This happened in order to identify any differences between different examinations. Both of these observations took place at the Karolinska University Hospital in Huddinge and were conducted in the context of a real first voice examination.
For the observation, the researcher discussed with one participant the current process of VHI in order to collect the initial information for constructing the observation protocol. Then, the protocol was prepared, which was used by the researcher in order to collect the observation data. This observational protocol (see Appendix B) had been organized using modules defined by the researcher. These modules focused on the tasks that take place, the time needed to be executed, as well as general information regarding the VHI conduct (means, place in the session, etc.). This was validated, before the observation, by one participant of this study, who claimed that the structure of this observation protocol was reflecting the VHI procedure.

Before the observation, both the examiner (the assigned SLP) and the patient were informed regarding the observation as well as its goal. Each observation lasted about 45’-60’ which was the duration of the whole examination session. During the observation, the observer was observing the VHI conduct behind a one-way mirror, taking notes from the procedure, using the observation protocol. The information gathered from the observations was validated and confirmed by the same participant that validated the structure of the observational protocol and were used to support the section which described the current use of VHI, as well as to be used for the structure of the initial semi-structured interviews.

2.4.2. Semi-structure interviews

The second data collection method used in this study was interviews. The main purpose of the interview is to find out “what people have in their minds” (69). During the interview method, the interviewee is considered as the expert, while the interviewer is considered as the student (66). In this research, there were three reasons for using interviews.

- To identify how the participants feel about the current VHI process
- To figure out what they actually need from an improved VHI procedure
- To discover what their opinions about a computerized VHI designed according their needs.
There are four different types of interviews; the structured and semi-structured interviews (the questions that the interviewer follow a formal protocol or are just structured by the researcher respectively); the informal interviews (which resemble casual conversations without the use of any specific type or sequence of questions); and the retrospective interview (which can be structured, semi-structured or informal, but their goal is to recall something that happened in the past) (70). In this study, semi-structured interviews were used, since the questions were defined and organized by the researcher, with a non-standardized method.

The semi-structure interviews were conducted for two different parts of this study. The initial semi-structure interviews were conducted to identify the user needs of the participants, whereas the second semi-structure interviews were conducted to identify the participant’s opinion about the new VHI system designed from the needs.

The Table 2-4 below summarizes the characteristics of the semi-structure interviews that were conducted in this research.

<table>
<thead>
<tr>
<th>Semi-structure interview</th>
<th>Context</th>
<th>Number of interviews</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial semi-structure interview</td>
<td>Karolinska University Hospital (Huddinge)</td>
<td>3</td>
<td>35’</td>
</tr>
<tr>
<td>Second semi-structure interview</td>
<td>Karolinska University Hospital (Solna)</td>
<td>3</td>
<td>45’</td>
</tr>
</tbody>
</table>
The interview guide for the first semi-structure interviews (see APPENDIX C) was organized into seven main categories, reflecting four general topics:

- The results of the observations
- The technological background of the participants
- Improvement issues

The interview guide for the second semi-structure interviews (see APPENDIX D) were organized into two categories reflecting the following topics:

- The six STEEEP aims
- The design of the prototype

One of the major advantages of this data collection method, was the fact that personal information that could not be collected through the observations, was elicited. However, a potential disadvantage was the fact that this information was mostly filtered by the interviewer, affecting the reliability to some extent (70).

It should be also mentioned, that pilot interviews were conducted before the actual interview sessions with a person in the context of informatics, in order to identify if the questions were understandable and followed a logical order. Furthermore, the content of the interview questions were validated by one of the participants before they were used for the interviews. All the interviews were also recorded with voice recording software in order to be analyzed afterwards.
2.5. Data analysis methods

There are numerous approaches for analyzing qualitative data (71). Qualitative content analysis is one of them, which is defined by Mayring (72) as “an approach of empirical, methodological, controlled analysis of texts within their context of communication, following content analytical rules and step by step models, without rush quantification”.

In this study, content analysis was used to analyze the data collected from the semi-structured interviews. This method enables the researcher to analyze the context of a text in an unobstructed way, i.e. that a researcher can observe the content without influencing it by his presence. Furthermore, the use of this method, does not restrict the researcher in time and space (67).

Elo & Kyngäs (71) suggest a certain content analysis process to analyze the qualitative data of an inductive research. Table 2-5 describes how this process has been applied in this study, step by step.

<table>
<thead>
<tr>
<th>Phase</th>
<th>Task</th>
<th>Short description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preparation</td>
<td>Selecting the unit of analysis</td>
<td>Decide what is going to be analyzed and in which detail</td>
</tr>
<tr>
<td>Organizing</td>
<td>Making sense of the data and whole</td>
<td>Gain an holistic data comprehension</td>
</tr>
<tr>
<td>Organizing</td>
<td>Open coding</td>
<td>Notes and headings are written in the text while reading it.</td>
</tr>
<tr>
<td></td>
<td>Coding sheets</td>
<td>The notes and the heading are transferred to coding sheets</td>
</tr>
<tr>
<td>Organizing</td>
<td>Grouping</td>
<td>The headings are being grouped under higher order headings</td>
</tr>
<tr>
<td>Organizing</td>
<td>Categorization</td>
<td>Creating categories according the content of the heading</td>
</tr>
</tbody>
</table>
Abstraction

<table>
<thead>
<tr>
<th>Reporting the analyzing process and the results</th>
<th>Model, conceptual system, conceptual map or categories</th>
<th>The results are being reported in a conceptual system according the final abstraction</th>
</tr>
</thead>
</table>

According to the Table 2-5, the content analysis process conducted for this study included the following steps:

1. During the preparation phase, the researcher decided the data that would be analyzed. In this study, this data was the information collected from the semi-structured interviews. Furthermore, the interviews were transcribed into text and were read multiple times until a holistic comprehension of them could be gained.

2. In the organizing phase, the text was being read by adding notes and headings on the margins, according to the content. These notes and headings were transferred in other paper, where the researcher grouped the headings into categories. These categories used, afterwards, to structure a categories Figure, where small categories were combined into main ones.

3. The main categories, which constitutes the emerged themes of the interviews, were reported in the study (see Results section)

It should be mentioned that this procedure was conducted by using paper and pen, without the use of any computer software.
2.6. Creating the artefact

2.6.1. Design science artefact activities

As it has been described in the 2.1, the design science framework includes five different activities which are presented in the Figure 2-4 (refers to table in the design science framework process). These activities concern the creation of the artefact, which is the proposed solution to the defined problem that was explained in the introduction of this thesis. So far, the problem has been explicated and the methods for the collection of user needs have been described in previous parts. According to the design science framework, the artefact should be designed and developed using the needs that have been selected, then demonstrated to the end-users and then to be evaluated (60). Figure 2-4 presents the place of the design science artefact activities in the study design framework used in this study.

![Figure 2-4. The placement of the design science artefact activities into the study design framework](image)

According to the Figure 2-4 above, the methods for designing and developing the artefact as well as the demonstration of the artefact are included in the phase 2 of the study design framework, whereas the methods for evaluation of the artefact are included in phase 3.
2.6.2. Development process

For the purpose of this study, the researcher decided to develop a prototype as the artefact in this design. The word prototype comes for the Greek word “πρωτότυπο” (International Phonetic Alphabet [IPA]: /pro’totipo/) which literally means “first type”.

Merriam-Webster dictionary defines a prototype as:

- An original or first model of something from which other forms are copied or developed
- Someone or something that has the typical qualities of a particular group, king, etc.
- A first or early example that is used as a model for what comes later (73)

Another definition of a prototype which reflects more the actual purpose of this study, has been given from Bill Verplank: “Prototyping is externalizing and making concrete a design idea for the purpose of evaluation” (74). As it has been described in the problem definition part, this study has the purpose to solve a problem which is related to design of a software solution. More specifically, in this study, the problem’s solution requires the collection of the user needs that will use a certain software artefact. The analysis of these needs will lead to a design idea which has to be illustrated and evaluated. Subsequently, the evaluated solution is going to improve the current procedure and be used as a paradigm for the design of similar solutions, by using the certain methodology that this study uses. Prototype constitutes a tool for solving problems. When a design concept is identified, then a prototype can be built in order to illustrate it (75).

Arnowitz et al (75) suggest a certain methodology to design and create a prototype, by using user needs. Figure 2-5 illustrates this prototype design process, which consists of four phases.
Each phase is composed of different tasks and each task is composed of different sub-tasks. This methodology, which is presented as “Effective prototyping” (75), reflects effectively the scope and the design of this study for the following reasons:

- It involves the user needs in the prototype design process
- Its structure of tasks allows the designer to plan the already collected data, to specify the characteristics of the prototype regarding these data, to design the prototype according the needs and finally to evaluate it through certain criteria.

In other words, this methodology seems to “fit” to the study design that has been described above and illustrated by the Figure 2-2.

Furthermore, it is important to mention that for the final design of the prototype, two different designs were created, referred as “first design” and “second design”. The first design includes the execution of the tasks which take place in the prototype design process and the second design includes the corrections after the user’s feedback during the evaluation of the artefact.

2.6.2.1. Applying the Effective Prototyping methodology

For the first design and development of the artefact, the researcher executed the tasks and the sub-tasks of the first three phases of the Effective Prototyping methodology. The fourth phase is related to the evaluation of the prototype and its results led to corrections within the prototype, forming the second design and development of the artefact.
Phase 1: Plan

During this phase, the user needs that have been collected after the qualitative analysis of the first semi-structured interviews were listed and prioritized. Then, these needs were combined into tasks, by creating task flows. Finally, the level of the content and the fidelity of the prototype were decided, according the needs of the study. For this study, the researcher chose to design and develop a low-fidelity prototype, since one of its major benefits is that they are usually rapid to produce (75) and this satisfies the short timeframe of the study.

Phase 2: Specification

Afterwards, certain characteristics of the prototype were defined, like the audience (internal or external), the stage (early, midterm or late), the speed (rapid or diligent), the longevity (short, medium or long), the expression (conceptual or experiential), the style (narrative or interactive), the medium (physical or digital) and the fidelity (low, medium or high) (75). These characteristics helped to define the type of prototype that was designed. According to the characteristics that have been chosen by the researcher, the creation of a wireframe prototype was decided.
According to Brown’s D. (76) wireframe definition: “Wireframes are Figures based on the simple idea that you can best describe the interactions of screen-based products by removing any aspects of the design incidental to its behavior”. Using this definition, choosing wireframes as the prototype method can provide a tool in order to demonstrate the functions of the artefact for this study, in a simply way. In this study, the purpose of the artefact is to focus on the different features that reflect the three major tasks of the computerized VHI, as they emerged from the initial semi-structured interviews (completing the questionnaire, access to data and follow-up). The limits of this study exclude the use of completed visual design and for this reason the wireframe prototyping was selected as the most appropriate method. An alternative solution would be the selection of paper prototype, which constitutes an interactive prototype using paper mockups of the user interface (75). However, the fact that there are many web-based wireframe tools\(^6\) on the internet led the researcher to exclude the paper-prototyping and choose creating wireframes.

UXPin\(^7\) UX tool is the one which selected by the researcher in order to design the wireframe prototype using in this study. The reasons that this tool was chosen were related to its structure and its functions, since it provides a simple and understandable interface, allowing the user to design without any training as well as a variety of functions that were satisfying the needs of this study.

Phase 3: Design


\[\text{http://uxpin.com/ [accessed on 25/07/2014]}

\(^6\) http://www.webdesignerdepot.com/2013/08/30-essential-ux-tools/ [accessed on 25/07/2014]

\(^7\) http://uxpin.com/ [accessed on 25/07/2014]
Arnowitz et al (75) suggest the establishment of certain criteria for the design of a prototype. These criteria reflect on how the design looks, that is how the information will appear and organized in the wireframe prototype, the rhythm and pattern of the design, as well as other criteria of interaction design. Because of the limited time of this study, the researcher decided not to use these criteria for the design of the wireframe prototype. Instead, the design has been done according to the user needs only, structured the data in a logical way, using partly the criteria that are described in the “Effective prototyping” design process. The creation of the design was done according to the following criteria:

- Adding all the GUI elements that had been emerged after the qualitative analysis of the initial semi-structured interview
- Organized them in a way that reflect the three major emerged tasks of the computerized VHI process (completing the questionnaire, access to data and follow-up)
- Keep it simple in order to avoid training sessions, in order the users to use it directly
- Allow users with different needs to use it effectively
- Make it flexible in order the users to navigate themselves easily
- Design it in a way that the user can interact with the system, not being a passive user

Phase 4: Results

The phase 4 of the “Effective Prototyping” describes three steps in order to review, validate and deploy the design. In this study, the researcher decided to skip the first and
third step which is to review the design and deploy it respectively. According to Arnowitz et al (75), the review of a design requires a team behind the design process that will review it before its validation. The reason that no review has been done in this study, was that the study timeframe for this research was limited and included only one researcher who played the role of the designer at the same time. Furthermore, the deployment step describes the procedure where the prototype turns into a software application ready for use. The limits of this study, does not include the transformation of this prototype into a working artefact, but it focuses on the user needs as well as the design elements of the prototype.

2.6.3. Evaluation of the artefact

Since the first design of the wireframe prototype was executed according the phase 1, 2 and 3 of the “Effective Prototyping” process, the next step was the evaluation of this design. The evaluation process was comprised by two parts (see Table 2.8).

<table>
<thead>
<tr>
<th>Part</th>
<th>Short description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demonstration</td>
<td>The wireframe prototype was demonstrated in combination with a scenario</td>
</tr>
<tr>
<td>Semi-structured interview</td>
<td>The second semi-structured interview in this study followed after the demonstration of the artefact.</td>
</tr>
</tbody>
</table>

Firstly, the artefact was demonstrated to the users and subsequently, the second semi-structure interview was conducted, in order to collect data that the researcher used as feedback for the second design.
According to Arnowitz et al (75), a very appropriate way to validate a wireframe prototype are the cognitive walkthroughs. This method is based on predefined user task goals and involves walking through these tasks in order to evaluate each step of them (75). In this study, three major tasks were emerged from the initial semi-structured interviews and for this reason, cognitive walkthroughs were selected to evaluate the design. In order to enrich the evaluation, making the process more fruitful, an additional scenario was used for this case. Walking through the tasks step by step with a running scenario of potential future users of the system, constituted the first part of the evaluation procedure that was used in this study.

In the context of the demonstration part of the evaluation, the researcher set 40’ sessions with each one of the participants. During these sessions, the researcher, using a laptop, was describing a scenario of a potential user of the future system. This scenario included two different users; a patient and an SLP, using the system, covering the three major tasks one by one. Table 2-7 summarizes the role of the scenario’s users in relationship with the three major tasks.

<table>
<thead>
<tr>
<th>User</th>
<th>Role</th>
<th>Task</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient</td>
<td>Used the system by providing data to SLP through completing the computerized VHI questionnaire</td>
<td>Completing the questionnaire</td>
</tr>
<tr>
<td>SLP</td>
<td>Used the system in order to access the VHI results from the first examination and the follow-up.</td>
<td>Access to data Follow-up</td>
</tr>
</tbody>
</table>
The researcher was demonstrating the wireframe prototype to the participants, using a presentation in Microsoft Power point, as long as the potential users were using the system in the scenario. During this procedure, there was no active participation by the study participants but only observation, while some of them were taking notes during the session. After the end of the scenario, the researcher conducted the second semi-structured interview (see 2.4) to receive the participants’ feedback regarding the artefact, completing the second part of the formative evaluation. Table 2-8 describes the steps of the artefact demonstration that took place in the evaluation session.

<table>
<thead>
<tr>
<th>Steps</th>
<th>Short description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Giving instructions</td>
<td>The procedure was explained to the participants.</td>
</tr>
<tr>
<td>2. Introducing the scenario</td>
<td>The first part of the scenario was described, introducing the participants to the potential scenario’s users and their roles.</td>
</tr>
<tr>
<td>3. Describing the three major tasks together with the demonstration of the wireframes</td>
<td>The three major tasks (completing the questionnaire, access to data and follow-up) were being described and analyzed, as long as the wireframes were being demonstrated to the participants</td>
</tr>
</tbody>
</table>

The method for the second part of the evaluation is described in 2.4 part of this chapter.

2.6.3.1. Second design after formative evaluation

After the formative evaluation of the first design, the data that have been collected, were analyzed and interpreted into formative design changes. Subsequently, these changes

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8 http://office.microsoft.com/sv-se/powerpoint/ [accessed on 25/07/2014]
were applied to the first design, providing with a second design for the three different tasks of the computerized VHI. Because of the limited time of this study, the second design was not validated again from the researcher.

2.7. Ethical considerations

Because of its nature, qualitative research relates to and is affected by a number of ethical concerns. Fraenkel & Wallen (67) mention some points of ethical issues that should be taken into account when qualitative research is being conducted:

- Confidentiality of the results should be maintained, by protected the participants of the qualitative study
- The participants should be respected and get informed regarding the research processes, by giving their permission
- The participants should ensure that no psychological or physical issues will affect negatively the participants
- The results of the research should not please only the researchers, but also the participants.

In this study, the research was conducted in a way to avoid these ethical concerns described above, by taking measures during all the study stages. The participants were informed regarding the aim of the study as well as the role that would play in this. Voluntary on-line consent form was used in order to ensure that the participants agreed to join the research. Furthermore, the participants were informed and regarding the use of voice record in this study, before every interview. The information collected during the observation and the interviews, was anonymized and process as such and the audio recordings were permanently deleted after the data analysis.

No ethical approval was required for the completion of this study, since no patients were involved, but only healthcare professionals.
3. Results

The results of the different phases of this study are presented in three different parts. Table 3-1 presents the parts that are included in this chapter.

<table>
<thead>
<tr>
<th>Section</th>
<th>Part</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1</td>
<td>Results from the Phase I – User needs elicitation</td>
</tr>
<tr>
<td>3.2</td>
<td>Results from the Phase II – Creation of the wireframe prototype</td>
</tr>
<tr>
<td>3.3</td>
<td>Results from the Phase III - Formative evaluation</td>
</tr>
</tbody>
</table>

3.1. Results from the Phase I – User needs elicitation

This section includes an overview of the results derived from the observations (see Appendix B) as well as the initial semi-structured interviews (see Appendix C) that were used in order to collect data regarding the user needs.

3.1.1. Observation

The observations led to the definition of a certain process which describes the current VHI conduct. Table 3-2, below, summarizes the most important elements of the procedure.

<table>
<thead>
<tr>
<th>Element</th>
<th>Short description</th>
</tr>
</thead>
<tbody>
<tr>
<td>General information</td>
<td>General information regarding the examination process</td>
</tr>
<tr>
<td>Time</td>
<td>Information about the time consumed in the process</td>
</tr>
</tbody>
</table>
Workflow

The flow of the different tasks that took place in the process

Interaction with the patient

The level of interaction between the SLP and the patient during the process

Use of tools

Information about the tools that are being used in the process

Information about the patient

Information regarding the patient in the process

Data analysis/Transfer

Information regarding the procedure of data analysis and data transfer in the process

**General Information**

The VHI examination constitutes part of the examination session that is conducted by the SLP. Whereas, only one SLP is involved in the process.

**Time**

Each task required time in the examination. The most time-consuming task was completing the questionnaire, which is the process where the patient fills in the questionnaire. The whole procedure takes about 10-15 min.

**Workflow**

During the VHI conduct, a number of different activities take place:

1. The SLP explains the patient regarding the process
2. The patient fills in the questionnaire, while the SLP is either with him, or out of the examination room.
3. The SLP reviews the VHI checking if the patient has answered all the questions
4. After the patient has left, the SLP transfers the answers to a Microsoft Excel spreadsheet one by one.
5. The SLP checks if all the answers have been transferred correctly.
6. Microsoft Excel calculates the results and the SLP transfers the results to a paper.
7. The SLP accesses the patient’s EHR directory (in TakeCare).
8. The SLP transfers the results from the paper to TakeCare.
9. The SLP either saves the VHI paper or throw it away.
10. After the treatment period, the activities 1-7 are repeated (Follow-up).
11. The SLP compares the results from the first VHI conduct to the second one.
12. The activities 8 and 9 are repeated.

**Interaction with the patient**

During the completing the questionnaire task, the SLP can interact with patient, by explaining items that are being misunderstood or are considered as difficult by the patient. There is not interaction with the patient during the data analysis and data transfer.

**Use of tools**

During the VHI conduct, paper and computer are used as the main two tools of the procedure.

**Information about the patient**

The patient usually fills in the VHI questionnaire in the same room with the SLP as well as is informed regarding the purpose of the examination.
Data analysis/Transfer

The data are being analyzed in TakeCare directly after the examination session. Microsoft Excel is used in order to calculate the VHI and also the data are transferred immediately after the calculation to TakeCare.

3.1.2. Semi-structured interviews

Table 3-3 summarizes the themes and the sub-themes that have emerged after coding the interview results.

<table>
<thead>
<tr>
<th>Theme</th>
<th>Sub-theme</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure complexity</td>
<td>Task flow</td>
</tr>
<tr>
<td></td>
<td>Time</td>
</tr>
<tr>
<td>Process reliability</td>
<td>-</td>
</tr>
<tr>
<td>Environmental issues</td>
<td>-</td>
</tr>
<tr>
<td>Familiarity with technology</td>
<td>-</td>
</tr>
<tr>
<td>Improvement by technology</td>
<td>Flexibility in completing the questionnaire</td>
</tr>
<tr>
<td></td>
<td>Data analysis</td>
</tr>
<tr>
<td></td>
<td>Integration with EHR</td>
</tr>
<tr>
<td></td>
<td>Follow-up</td>
</tr>
<tr>
<td>Requested features</td>
<td>Features in completing the questionnaire</td>
</tr>
<tr>
<td></td>
<td>Features when accessing the data</td>
</tr>
<tr>
<td></td>
<td>Features for follow-up</td>
</tr>
<tr>
<td>Concerns</td>
<td>Therapeutic relationship</td>
</tr>
<tr>
<td></td>
<td>Usability</td>
</tr>
<tr>
<td></td>
<td>Data quality</td>
</tr>
</tbody>
</table>
A number of questions during the initial interviews focused on the SLPs’ perspective regarding the complexity of the current paper-based procedure of the VHI conduct. Table 3-4 summarizes the subthemes that are included in this emerging theme as well as a short description for each one of them.

The most of the participants reported issues regarding the task flow that the paper-based VHI requires in order the results to end-up in the EHR system.

According to the participants, the most important negative factor is the fact that the results should be transferred in different places until they finally are transferred to EHR.

“…of course, if you use the protocol [refers to VHI] for years, then the process looks more simple. But it’s not funny at all to transfer the data from paper to Excel and back to paper and back to TakeCare […] Sometimes you need to use this time more effectively. [I3]

Another factor that can make the process complex is the fact that the SLPs should search for and scan the statements from the first VHI examination in order to compare them to the results of the second one (Follow-up process).
“It’s obviously a problem. Since I do not save the papers all the time, I have to speculate the progress according the results saved in the EHR. It is difficult to compare statements with numbers. It is not effective and makes it complicated” [1]

Regarding the time that is required to complete the paper-based VHI process almost all the participants claimed that the current procedure is not generally time-consuming, focusing on their experience.

“I use it [refers to VHI] from the first time I started working with voice patients. I like this protocol […] of course some parts need to be improved, but I think I could easily continue with that. It feels I know every aspect of it after so many uses […] I do everything automatically like a computer, fast. No problem for me. [12]

On the other side, some of the participants stated that the length of the completing the questionnaire part [the part where the patient fills in the questionnaire] of the process depends on the performance and the type of the patient.

“Oh…actually I have never thought about this before, but I guess I spend a lot of useful time and energy to complete it [the VHI examination]. I always do it when the patient leaves. Neither they nor I have the patience to interrupt [the examination] for a couple of minutes. And it is not polite, right? I did not say that it takes forever, but still it is annoying. [16]

“[…] as long as I can remember, there are patients that fill the questionnaire for hours […] of course not for hours, but it takes time. People can be stressed and they can think a lot before they check the box. It goes slow often”. [16]

“Some patients, particularly the older ones consume a lot of time to complete the test […]. They ask a lot of questions and sometimes correct, but not that often. This, yes, takes time. But not with all the patients”. [15]
Process reliability

TABLE 3-5

Emerging theme 2: Process reliability

<table>
<thead>
<tr>
<th>Theme</th>
<th>Short description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Process reliability</td>
<td>Reliability of the paper-based VHI concerning mistakes that may occur</td>
</tr>
</tbody>
</table>

An important issue that emerged from the initial semi-structured interview was the reliability of the process. Table 3-5 gives a short description of this emerging theme.

The human involvement in this certain procedure in combination with the particular task flow, can lead to potential mistakes which can give erroneous results.

Almost all the participants declared that they had identified mistakes in the past during the entry control.

“Some mistakes, yes [...] I remember myself double-checking the Excel I found ... it was ... at least three wrong numbers. I guess I jumped one entry or something like that...” [11]

According to the participants, the presence of these mistakes implicates factors like the task flow and the human nature generally.

“No, it’s not always safe. Even if you think that you are unerring. I always check all the time. The results travel from paper to computer and back again ... and that is risk” [12]

“ [...] I am generally really careful with the transfer of the data, but you never know ... when you are tired [...]” [14]

“Every time I have to double check them [refers to the answers of the patients] before I calculate the final results in Excel. Sometimes it feels that I miss something ... especially when I am in hurry ...” [15]
Environmental issues

<table>
<thead>
<tr>
<th>Theme</th>
<th>Short description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Environmental issues</td>
<td>Issues regarding the impact of the paper-based VHI to environment</td>
</tr>
</tbody>
</table>

As it was expected, environmental issues emerged, since the current procedure is based on paper. Table 3-6 presents a short description of this emerging theme.

Many study participants mentioned that the use of paper can provide advantages regarding its usability. However many claimed that the use of paper in this procedure, affects the environment negatively.

“I think is pretty handy [refers to paper]. He [refers to the patient] can use it easily and can handle it better. [...] Of course it’s not so environmental friendly, but it is only one page. But still ...” [15]

“[...] I try to save the paper after the patient leaves. I use it anyway in the future for the follow-up. Why to spend it?” [13]

“I am ...I throw away the paper after the test. Of course it would be better to avoid it. But I do not need it.” [14]

“Our department promotes recycling. Our chief has adopted certain practices to avoid the thoughtless use of paper. But in this case, we have to use it paper. At least our journal system [refers to TakeCare EHR] is digital. But the tests we use are in paper.” [16]
Familiarity with technology

TABLE 3-7
Emerging theme 4: Familiarity with technology

<table>
<thead>
<tr>
<th>Theme</th>
<th>Short description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Familiarity with technology</td>
<td>The level of familiarity that SLPs have concerning the use of technology at work</td>
</tr>
</tbody>
</table>

All the study participants seem to be familiar with the use of technology in the context of their working environment. Table 3.7 gives a short description of this theme. All of them use personal computers for different reasons like the management of their appointments as well as the access and management of patients’ health data through the EHR system. Also, the majority of the participants use more electronic tools related to certain groups of patients, like recording systems for the collection and management of voice samples for patients with voice disorders. Generally, all the participants claimed that the use of technology can improve their outcome results and can make the process easier, depending on the nature of the system.

“I feel quite familiar with the use of technology at work. It’s mandatory. Now technology is everywhere. I am not a super user, but I do work effectively here at work.” [I1]

“I think a new technological tool can help us a lot. But only if it is simple to use. I use technology, but I would appreciate something easy and straight-forward. In any case, I think I would be able to be familiar with it.” [I3]

“[…] because time is valuable for me, I need something that is easy to learn. I am used to paper tests because are handy. But I believe a digital solution would be handy as well … maybe faster, maybe not. […] depends on the solution.” [I6]

“[laughing] I am not like my daughter that can use tablet without having her eyes open. But I try to learn more and more. If you stay stable on traditional practices, you are out-of-fashion and maybe not so effective […] Technology can provide a lot.” [I]
Improvement by technology

<table>
<thead>
<tr>
<th>Theme</th>
<th>Subtheme</th>
<th>Short description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improvement by technology</td>
<td>Flexibility in completing the questionnaire</td>
<td>Needs and suggestions regarding the process where the patient fills in the VHI</td>
</tr>
<tr>
<td>Data analysis</td>
<td>Needs and suggestions regarding the way that the VHI data are analyzed</td>
<td></td>
</tr>
<tr>
<td>Integration with EHR</td>
<td>Needs and suggestions regarding the integration of VHI with EHR</td>
<td></td>
</tr>
<tr>
<td>Follow-up</td>
<td>Needs and suggestions regarding the follow-up process</td>
<td></td>
</tr>
</tbody>
</table>

One of the most important emerging themes that occurred from the semi-structured interviews was the **improvement by technology**. Here, the participants expressed their ideas, associating the limitation of the paper-based VHI that have been described above, with their actual needs. Table 3-8 summarizes the subthemes that the main theme includes, as well as a short description for each of them.

A number of questions focuses on the use of technology in the different parts of the paper-based VHI. Here the participants contributed by giving their ideas regarding the way that this process could be done.

Some participants suggested that the **Completing the questionnaire task** should be done through an electronic questionnaire instead of paper. According to them, this could save time since the patients could fill in the questionnaire out of the examination session.
(either from home or before at the waiting room). This solution could save valuable time, providing the patient the timeframe to fill in the VHI questionnaire by being more focused and less stressed.

“I would prefer the patient to do it from home. By computer. And then all the results to come directly to me. [...] Some clicks and then... done. Easier, isn’t it?” [I2]

“[...] or to fill in it outside the examination room. For example at the waiting room. The secretary can provide him with a tablet and do it there. [...] and if the patient is not able, maybe can do it here with me from the computer.” [I1]

“Some patients ask a lot and are stressed. Stressful patients give wrong answers. But if they would fill it out from home through internet, they would have enough time to review their answers” [I6]

As it has been mentioned above, one of the major emerging themes regarding the paper-based VHI conduct, is the process reliability which is associated with mistakes during the data analysis in the VHI. The most of the participants suggested a direct connection between the Completing the questionnaire task and the data analysis in order to avoid this problem, expressing their positive feeling regarding a digital calculation of the results.

“I don’t think it’s important to analyze the data by myself. And of course I trust a digital tool to do this task instead of me. Human can make mistakes, but computer can calculate better. Anyway, we use Excel for this. And works nice!” [I2]

“[...] if, for example, a patient could fill in the VHI and the results come directly to me, it would be super interesting! I would like to use it for sure.” [I5]

“[...] so much time would be saved and energy. Less mistakes, I bet.” [I1]

One of the parts of the paper-based VHI process in the certain context that the study has been conducted, is the transfer of the results to the EHR system which is used there. According to 3.1.1, this is part of the complexity of the process and the most of the participants suggested also a connection of the Completing the questionnaire task to the
transfer of data to EHR, after the automated data analysis. In other words, they suggested a VHI integrated with the EHR that they use.

“I face some complications with the use of TakeCare generally. But generally I believe it’s not that complicated to write the results in the journal system. But if a system could do it automatically, it would be better” [I3]

“[…] let’s think a scenario. A patient fills in the questionnaire at home and then I see the results and then I send them to EHR. […] Enkelt? [It means “simple” in Swedish]! […]” [I1]

According to the observation results, one of the main parts of the VHI examination is the follow-up. All the participants mentioned the significance of a technological solution that would assist them in order to identify the potential therapeutic improvement. Specifically, they suggested the use of a tool that could provide them with comparative results between the first and the second VHI examination.

“When I do the follow-up, I am looking for the old papers or I just look for the numbers in EHR. I do the test again and I compare. But if a system can handle all the other processes, why not this as well?” [I4]

“[…] and then the system can somehow give you the old results and make a smart comparison. That’s would be perfect!” [I1].

Requested features

<table>
<thead>
<tr>
<th>Theme</th>
<th>Subtheme</th>
<th>Short description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Requested features</td>
<td>Completing the questionnaire</td>
<td>Requested features in the Completing the questionnaire task of the digitalized VHI</td>
</tr>
</tbody>
</table>
During the semi-structured interviews, the participants expressed their needs regarding the way that the digitalized VHI should be designed. These needs, as well as some of the problems they face when using of the current paper-based VHI constitute the important features for the different tasks that have emerged and take place in the system. Table 3-9 summarizes the subthemes of the main theme and includes also a short description for each subtheme.

Some of the participants expressed their needs regarding the process where the patient fills in the questionnaire. Table 3-10 below presents the Requested features of the first task “Completing the questionnaire”, formed by the participants’ needs as well as a short description for each requested feature.

<table>
<thead>
<tr>
<th>Emerging task</th>
<th>Requested features</th>
<th>Short description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completing the questionnaire</td>
<td>Adjusting view</td>
<td>Provides to patients the assisting view, like adjusting the size of the font and listen to the text</td>
</tr>
<tr>
<td></td>
<td>Clear instructions</td>
<td>Clear and thorough instructions at the beginning of the test</td>
</tr>
<tr>
<td>Feature</td>
<td>Function</td>
<td></td>
</tr>
<tr>
<td>-----------------------------</td>
<td>--------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Limited view</td>
<td>Allows the patient to view the test questions one by one and not all them together</td>
<td></td>
</tr>
<tr>
<td>Navigation and skipping</td>
<td>Provides to patient the ability to navigate himself in the different questions as well as to skip questions and answer them later</td>
<td></td>
</tr>
<tr>
<td>Responses’ correction</td>
<td>Provides to patient the ability to correct his answers</td>
<td></td>
</tr>
<tr>
<td>Results notification</td>
<td>Explains the patient that the results will be given by the assigned SLP during the first examination</td>
<td></td>
</tr>
</tbody>
</table>

**Requested feature 1: Adjusting View**

The participants believed that a feature can provide to patients an assisting view, is required, like adjusting the size of the font and listen to the text.

“[...] but some patients cannot use it like your people. Some have visual problems and listening to the instructions and the statements is better than reading” [13]

**Requested feature 2: Clear instructions**

According to the participants, clear and thorough instructions at the beginning of the test are important for the patient to understand the test more.
“One of the biggest problems is that the patient does not understand that this test does not include questions like questions, but statements. Every time I say “these are statements” because otherwise they do not know which response should choose [...] a digital system should make it clear” [I2]

Requested feature 3: **Limited view**

The participants stated that the patient should view one question per time in order to avoid confusion.

“If I would change something, this would be to make provide the statements one by one and not altogether. The patients can mix the answers. I have seen it many times in the past” [I1]

Requested feature 4: **Navigation and skipping questions**

The participants believed that the patients should be able to navigate themselves in the test, as well as to be able to skip questions that do not desire to answer immediately.

“[...] some patients cannot decide which response fits better to them. I suggest them to continue and come back later [...]” [I5]

Requested feature 5: **Response’s correction**

The participants stated that the patient should be able to correct his answer if he thinks that it was not the one that desired.

“[...] and this [refers to the waste of time] happens actually when they [refers to the patients] change their mind and check another box [refers to the response choices]” [I2]
Requested feature 6: **Results notification**

The participants stated that the patients should be notified regarding the results, i.e. that the results will be announced after the examination session.

“Sometimes I am able to reveal the results...but this happens because of my experience. It’s not a hundred-per-cent correct, but I still can explain which aspect [refers to the different aspects that the VHI examines] is better or not. But sometimes I cannot do that [...] yes, they are stressed and they ask me to give the results. But again I explain it’s better to be done afterwards ... after the result analysis” [12]

The results of the first interview revealed a second task of the desired system, which is related to the way that the SLP accesses the already filled questionnaire and reviews the patient’s responses. Table 3-11 summarizes the emerging requested features and their short descriptions that the task “**Access to data**” includes.

<table>
<thead>
<tr>
<th>Emerging task</th>
<th>Requested features</th>
<th>Short description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access to data</td>
<td>Statistics</td>
<td>Statistic information about the patient’s responses in the test</td>
</tr>
<tr>
<td></td>
<td>Subscale scores</td>
<td>The score of each subscale separately</td>
</tr>
<tr>
<td></td>
<td>Categorized responses</td>
<td>View of the responses for each subscale</td>
</tr>
<tr>
<td></td>
<td>Additional notes</td>
<td>Free text notes regarding the results</td>
</tr>
<tr>
<td></td>
<td>Connection to EHR</td>
<td>Send the results directly to EHR</td>
</tr>
<tr>
<td></td>
<td>Resend the test to patient</td>
<td>The test is sent again to the patient when the</td>
</tr>
</tbody>
</table>
Requested feature 7: Statistics

According to the participants, the health professionals should be able to have an impression of how the patient filled the test as well as a quick view of the statistics of the responses.

“[…] and also it would be perfect to have a system that gives you analytical results … I mean … not only the subscales score, but also the type of the responses, like … 4 responses were ‘never’, 10 were ‘always’ and so on. […] this would help me to create an image for my patient for the impact, you know, of the disorder to him.” [16]

Requested feature 8: Subscale scores

It should be mentioned that all the participants asked for this feature during the first interview. According to this, the professional should be able to see all the scores immediately without further calculation

“[…] this is actually the goal, for me! I want the scores immediately. This would solve many problems” [11]

Requested feature 9: Categorized responses

According to the participants, the healthcare professional should be able to have a view of the responses filtered by different categories.

“What I can think right now … is that I would like to see the answers after the analysis […] I mean to see what the patient answered for every subscale. That would be fantastic to have in a tool” [13]
Requested feature 10: **Additional notes**

The ability to add notes regarding the results, was also one of the requested features of the participants.

“[…] I always write notes. Before the patient leaves and after I analyze the results. I need to remember. It helps me for the diagnosis and the treatment.” [16]

Requested feature 11: **Connection to EHR**

The participants requested an instant transfer of the results from the questionnaire to the EHR after the review of the test results.

“[…] let’s think a scenario. A patient fills in the questionnaire at home and then I see the results and then I send them to EHR. […] Enkelt? [It means “simple” in Swedish]! […]” [1]

Requested feature 12: **Resend test to the patient**

The participants desired to be able to resend the test to the patient in the case that they judge that the test is not reliable.

“I am afraid sometimes that the patient does not understand the instructions. And I remember a patient answering the almost everywhere ‘never’. We had to do the test from the beginning. We had to be sure” [13]

The last task that emerged from the analysis, was the one that is related to the “Follow-up” procedure from the SLP. The table 3-12 summarizes this task in relation with the Requested features that emerged from their answers, as well as a short description of them.

<table>
<thead>
<tr>
<th>Emerging task</th>
<th>Requested features</th>
<th>Short description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Requested feature</td>
<td>Description</td>
<td></td>
</tr>
<tr>
<td>-------------------</td>
<td>-------------</td>
<td></td>
</tr>
<tr>
<td><strong>Follow-up</strong></td>
<td><strong>Comparison results</strong></td>
<td>The scores of the subscales of the first and the second examination together</td>
</tr>
<tr>
<td></td>
<td><strong>Comparison chart</strong></td>
<td>A diagram that visualizes the progress in each subscale</td>
</tr>
<tr>
<td></td>
<td><strong>Total responses comparison</strong></td>
<td>The scores of the first and the second examination for all the statements</td>
</tr>
<tr>
<td></td>
<td><strong>Statistics</strong></td>
<td>Statistical information regarding the progress of the test per response</td>
</tr>
</tbody>
</table>

**Requested feature 13: **Comparison results

The participants suggested a feature that could make it possible to compare the results of the first examination to the results from the follow-up examination.

“A nice surprise for me would be to be able to compare the first test and the second one [...] it is extremely handy to have all the results together” [I4]

**Requested feature 14: **Comparison chart

The use of a comparison chart was suggested as well in order to provide the health professional with more visual information regarding the results.

“[...] it could be like numbers, it could be like diagrams, it could be anything” [I1]
Requested feature 15: **Total responses comparison**

The participants expressed their interest to a feature that could make it possible to review the results from the two examinations statement by statement.

“[…] I have to search for the old test and compare the responses one by one. This is the way I do it. Some others [refers to SLPs] just compare the results … the numbers. For me the most critical is to see the progress exactly statement by statement […]” [12]

Requested feature 16: **Statistics**

An extra statistics feature was suggested from the participants, in order to have a quick view of the results of the follow-up examination in contrast to the first examination.

“[…] and not only this [refers to the statistics of the ‘Access to data’ task] but also the results for the future examination […]” [16]

**Concerns**

<table>
<thead>
<tr>
<th>Theme</th>
<th>Subtheme</th>
<th>Short description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concerns</td>
<td>Therapeutic relationship</td>
<td>The therapeutic relation between the care-giver and the patient</td>
</tr>
<tr>
<td></td>
<td>Usability</td>
<td>The level of convenience that the users use the system</td>
</tr>
<tr>
<td></td>
<td>Data quality</td>
<td>The quality of the VHI outcome</td>
</tr>
</tbody>
</table>
The final results of the initial semi-structured interviews are related to the concerns that the participants expressed regarding the implementation of a new digital VHI. Table 3-13 summarizes the subthemes that are included in this emerging theme as well as a short description for each one of them.

Some of the participants raised the issue of the therapeutic relationship between the SLP and the patient. According to their responses, a system that would allow the patients to fill in a questionnaire from their home, would affect the familiarity between the health professional and the patient.

“[…] I like that the patient is with me when fills in the questionnaire. He feels closer to me and we can communicate more […]” [I5]

“Of course this [refers to the digital system] will affect the relationship between me and the patient to some extent. But it is a risk that you have to take anyway” [I1]

On the other hand, the majority of the participants believed that this new way of filling out the questionnaire using a digital VHI would not affect the therapeutic relationship.

“Oh… of course not! It is quite irrelevant. No … I will meet that patient anyway during the examination. I will get to know him there. The other thing [refers to the use of the digital VHI] is different … more practical” [I3]

“No, it’s not so important. Anyway, when the patient fills the questionnaire normally does not interact with the speech therapist. I don’t believe that if he would do it with me this would strengthen our relationship. Totally disagree…” [I4]

The usability of the new system was also a factor that has been emerged from the participant’s answers. Regarding this, they seem to be concerned about the level of computer knowledge in order to fill in the questionnaire from home.

“Ok … if you ask from my mother to do it right now, she will find it impossible. Older people find it difficult when it comes to new technology and computer. My daughter for example can do it. I can do it. But what about the others?” [I1]
“Yes, it is something you cannot avoid. People that know about internet and computers will manage to send the questionnaire. [...] If it’s easy, they will learn it of course” [15]

Some other participants expressed concerns regarding the quality of the data that the digital VHI examination will give to the SLP because of the fact that the patient fills in the questionnaire alone, without any help and control of the SLP.

“I have second thoughts, it’s true [...] and what happens when the patient needs help? The therapist will not be there to help” [14]

“[…] yes, you cannot see what he [refers to the patient] does ... how he answers. Maybe he has no idea. And maybe this give unreliable results. Not good!” [16]

3.2. Results from the Phase II – Creation of the wireframe prototype

After the initial semi-structured interviews, the information that emerged after the analysis of the collected data, led to two results:

1. The fact that the participants believe that a computerized VHI can improve the procedure comparing to the current paper VHI.
2. These Requested features that a computerized VHI should include in order to satisfy their needs.

The use of these Requested features in the creation of the wireframe prototype subsequently led to the representation of a new computerized VHI tool which is presented extensively in this part.

3.2.1. The three major tasks in the prototype

As it has been described previously, three major tasks emerged from the first interviews. Figure 3-1 illustrates these tasks.
The “Completing the questionnaire” task constitutes the task where the patient fills in the questionnaire. After the completion of the questionnaire, the SLP accesses it and sends its results to the EHR, executing the “Access to data” task. After the treatment period, the SLP reviews the second VHI results and saves the comparative results to EHR through the “Follow-up” task.

3.2.2. The prototype limits

The wireframe prototype that is described here, covers exactly the three major tasks of the computerized process (see 3.2.1), excluding any other process before and after. Specifically, the process in order to login the system, as well as more features that can be connected to the system are not being described here. Furthermore, no information is provided regarding the context (medium, bigger system or project) of the computerized VHI. It is also speculated here that the patient logins from his house, either from the waiting room of the healthcare context (the clinic in this case).
3.2.3. The wireframe prototype mockups

In this part, the wireframe prototype mockups are presented, organized according to the three major tasks as described in section 3.2.1. Every function of the computerized VHI is connected to the related requested feature emerged in the section 3.1.5. In the wireframe mockups, the reader can identify a sentence which indicated the provision of help. In this design, the help button does not appear, since its content has not been defined by the initial interviews. Also, it is important to mention that the following mockups constitute the first design. A second design of some of these mockups is included in the 3.3 section.

Completing the questionnaire

The patient logins the system and firstly accesses the instructions for completing the computerized VHI (Figure 3-2).

The patient can adjust the view [Requested feature 1] by changing the size of the font and listening to the text. After he reads the instructions [Requested feature 2], he starts filling the questionnaire by clicking on the “Start the test” button.

Then the patient moves to first statement of the VHI [Requested feature 3] (Figure 3-3), where he can either click on the desired response, or skip it [Requested feature 4]. Either clicking on the “Next” button or “Skip” button, he moves to the next question.

![Figure 3-2. The VHI instructions](image-url)
In the screen of the second statement (Figure 3-4), the patient can move forward clicking either the “Next” button or the “Skip” button or move to the previous question clicking on the “Previous” button [Requested feature 4].

The patient conducts the same procedure for the all the statements. At the screen of the last statement (Figure 3-5), the patient can finish the test, either by clicking on the “Finish the test” button or by clicking the “Skip” button. Then he moves to the skipped statements which he should answer one by one [Requested feature 3].
When the patient moves to the last skipped statement (Figure 3.6), he can click on the desired response and then finish the test by clicking on the “finish the test” button.

After this, the patient moves to the review screen (Figure 3-7), where he can review and change his previous responses [Requested feature 5]. Here, he can click on the “Reset” button to undo the changed and return to the previous ones, or submit the results by clicking on the “Submit the results” button.

After the patient submits the results, he moves to the notification screen (Figure 3-8), where he receives a notification about the upcoming results [Requested feature 6].
Access to data

The SLP logs into the system and moves to the review screen (Figure 3-9), where he can review the VHI questionnaire completed by the patient. In this screen, he can also see the statistics [Requested feature 7] regarding the Completing the questionnaire task, gaining an image of how the patient filled in the questionnaire. From here, the SLP can see the VHI results by clicking the “See the results” button.

Afterwards, the SLP reviews the first test results (Figure 3-10) according to each subscale [Requested feature 8]. In this screen, he can execute four tasks; he resends the test to the patient [Requested feature 12], add notes regarding the results [Requested feature 10], send the results to EHR [Requested feature 11] and review the patient’s responses according to each subscale [Requested feature 9].
**Voice Handicap Index**

Review the patient’s answers

1. My voice makes it difficult for people to hear me  □ Sometimes
2. I run out of air when I talk  □ Almost always
3. People have difficulty understanding me in a noisy room  □ Sometimes
4. The sound of my voice varies throughout the day  □ Almost always
5. My family has difficulty hearing me when I call them throughout the house  □ Sometimes
6. I use the phone less often than I would like  □ Sometimes

<table>
<thead>
<tr>
<th>Statistics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration: 05:03</td>
</tr>
<tr>
<td>Skipped questions: 2</td>
</tr>
<tr>
<td>No of Never:</td>
</tr>
<tr>
<td>No of Almost never:</td>
</tr>
<tr>
<td>No of Sometimes:</td>
</tr>
<tr>
<td>No of Almost always:</td>
</tr>
<tr>
<td>No of Always:</td>
</tr>
</tbody>
</table>

See the results

**Figure 3-9. The SLP’s review screen**

**Voice Handicap Index**

Test results

<table>
<thead>
<tr>
<th>SUBSCALE SCORES</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical subscale</td>
<td>Score:</td>
<td>See the responses</td>
</tr>
<tr>
<td>Emotional subscale</td>
<td>Score:</td>
<td>See the responses</td>
</tr>
<tr>
<td>Functional subscale</td>
<td>Score:</td>
<td>See the responses</td>
</tr>
</tbody>
</table>

**Figure 3-10. The first test results**

**Voice Handicap Index**

The responses according to certain subscales

<table>
<thead>
<tr>
<th>Physical subscale</th>
<th>Score:</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. I run out of air when I talk</td>
<td>□ Almost always</td>
</tr>
<tr>
<td>4. The sound of my voice varies throughout the day.</td>
<td>□ Sometimes</td>
</tr>
<tr>
<td>10. People ask, “What’s wrong with your voice?”</td>
<td>□ Almost always</td>
</tr>
<tr>
<td>13. My voice sounds creaky and dry</td>
<td>□ Sometimes</td>
</tr>
<tr>
<td>14. I feel as though I have to strain to produce voice</td>
<td>□ Sometimes</td>
</tr>
</tbody>
</table>

Back to results

**Figure 3-11. The categorized responses**
The SLP clicks on the “see the responses”, and then he moves to the categorized responses screen (Figure 3-11). From here, the SLP can go back to the results [Requested feature4] by clicking on the “Back to the results” button.

**Follow-up**

The SLP can login and review the results (Figure 3-9). From that point, he can see the results by clicking on the “See the results” button. Then he moves to the second test results screen (Figure 3-12), where he can also execute five tasks like in the figure 3-9, plus he can compare the results [Requested feature 13].

If the SLP clicks on the “compare the results” button, then he moves to the comparison results screen (Figure 3-13).

From here, the SLP can compare the results of the first and the second examination [Requested feature 13] as well as a comparison chart [Requested feature 14].

The SLP can also add notes regarding the comparison [Requested feature 10] and view the comparison of all the responses [Requested feature 15] (Figure 3-14) by clicking on the “View all responses” button. From this screen the SLP can view also statistics [Requested feature 16] regarding the progress of the patient.

---

**Figure 3-12. The second test results**

<table>
<thead>
<tr>
<th>Voice Handicap Index</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test results</td>
</tr>
<tr>
<td>SUBSCALE SCORES</td>
</tr>
<tr>
<td>Physical subscale</td>
</tr>
<tr>
<td>Emotional subscale</td>
</tr>
<tr>
<td>Functional subscale</td>
</tr>
</tbody>
</table>

**Additional Notes**

- Resend the form to patient
- Send results to EHR
- View comparison results
Voice Handicap Index
Comparison results

<table>
<thead>
<tr>
<th>SUBSCALE SCORES</th>
<th>1st examination (20-03-2014)</th>
<th>2nd examination (20-08-2014)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical subscale</td>
<td>Score:</td>
<td>Score:</td>
</tr>
<tr>
<td>Emotional subscale</td>
<td>Score:</td>
<td>Score:</td>
</tr>
<tr>
<td>Functional subscale</td>
<td>Score:</td>
<td>Score:</td>
</tr>
</tbody>
</table>

COMPARISON CHART

Additional Notes

Figure 3-13. The comparison results screen

Voice Handicap Index
Total responses comparison

1. My voice makes it difficult for people to hear me
   - Sometimes
   - Almost always
   - Almost never
   - Never

2. I run out of air when I talk
   - Sometimes
   - Almost always
   - Sometimes

3. People have difficulty understanding me in a noisy room
   - Sometimes
   - Sometimes
   - Almost always
   - Almost never

4. The sound of my voice varies throughout the day
   - Sometimes
   - Sometimes
   - Almost always
   - Almost never

5. My family has difficulty hearing me when I call them throughout the house
   - Sometimes
   - Sometimes
   - Almost always
   - Almost never

6. I use the phone less often than I would like
   - Sometimes
   - Sometimes
   - Almost always
   - Almost never

Statistics
Beter responses: 19
Worse responses: 2
Same responses: 9

Figure 3-14. Total responses comparison
3.3. Results from the Phase III – Formative evaluation

This section includes an overview of the results derived from the evaluation of the wireframe prototype that is described in the section 3.2. The evaluation consisted of two parts; the demonstration of the wireframe prototype with a scenario and the second semi-structured interview. In this section, the results of the second semi-structured interview presented. Table 3-14 summarizes the two major subjects that the second semi-structured interview covered.

<table>
<thead>
<tr>
<th>Subject</th>
<th>Short description</th>
</tr>
</thead>
<tbody>
<tr>
<td>STEEEP evaluation</td>
<td>Participants’ perspective on whether the prototype satisfies the STEEEP aims of improvement</td>
</tr>
<tr>
<td>Prototype design evaluation</td>
<td>Evaluation of the design of the prototype</td>
</tr>
</tbody>
</table>

3.3.1. STEEEP evaluation

The first major subject of the second semi-structure interviews concerns if the STEEEP aims are satisfied from the computerized VHI that has been presented as a wireframe prototype to the participants.

Safety

All the participants claimed that the safety of the data used in the system depends on the security level of the system, which is how the system is constructed in order to keep the information safe. Furthermore, it had been stated that the limits on this prototype do not cover security structures.
Time

The majority of the participants mentioned that the new system can surely make the process faster, providing advantages like instant connectivity between different parts of the procedure.

Effectiveness

According to the participants, the new system can produce reliable results that can be used to support a successful treatment plan. However, some participants expressed their worries about the fact there is no control during the Completing the questionnaire task and maybe this lead to mistakes and misunderstandings, affecting the quality of data. Also, the participants believe that this system do not overuse or underuse information, providing the user with useful features, handling the data effectively.

Equitable

The only inequity factor mentioned was the age of the patients, using the system. According to the participants, this system can be used effectively by people that are more familiar with technology, and consequently, older people maybe face problems in use.

Efficiency

All the participants claimed that this system requires resources that the majority of people have at the moment. It does not use more equipment than any other computerized system require.
**Patient-centered**

A majority of the participants claimed that this system can be considered patient-centered, since it is made for the patient and includes the patient in the process. Of course it does not allow the patient to be involved in his own therapy, but it includes him in one of the early stages of the treatment plan, as an information provider.

### 3.3.1. Prototype design evaluation

The second part of the second semi-structured interviews concerned the evaluation of the design of the demonstrated wireframe prototype and its goal was to collect the participants’ opinions in order to move to corrections that may lead to a second design.

Generally, all the participants described the design as easy to understand with logical task flow, avoiding overuse of information that may lead to misunderstandings. However, some participants identified certain aspects of the design that needed improvement, and suggested possible solutions that could be applied on a second design and which are summarized in the Table 3-15.

<table>
<thead>
<tr>
<th>Related task</th>
<th>Feature/Requested feature</th>
<th>Problem description</th>
<th>Suggested solution(s)</th>
</tr>
</thead>
</table>
| Completing the questionnaire| Mandatory responses       | Some of the questions cannot be answered by the patients, since they are not relative to them. | 1. Explain on the instructions that if a statement is not relevant to them, they can choose to click on the “Never” response.  
2. Add an extra response called...|
<table>
<thead>
<tr>
<th>Access to data/ Follow-up</th>
<th>Total score</th>
<th>The system should give the total score as well and not only the scores according the different subscales</th>
<th>Add the total score at the Total results screen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Follow-up</td>
<td>Total comparison results</td>
<td>The system should give the total comparison results as well and not only the comparison results according the different subscales</td>
<td>Add the total comparison results at the Comparison results screen</td>
</tr>
</tbody>
</table>

**Second design**

A second design of some of the wireframe mockups are provided here, according the results of the Table 3-12.

In the context of the Completing the questionnaire task, a new button added in every statement (Figure 3-15), representing a new response called “Not relevant to me”. This response gives the same result as clicking the “Never” response.
In the context of the Access to data task, a “Total score” box has been added under the scores of the different subscales (Figure 3-16). The same change has been done for the Total score in the Follow-up task.

In the context of the Follow-up task, a “Total score” box has been added in the comparison results screen (Figure 3-17).
### Voice Handicap Index
Comparison results

<table>
<thead>
<tr>
<th>SUBSCALE SCORES</th>
<th>1st examination (20-03-2014)</th>
<th>2nd examination (20-09-2014)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical subscale</td>
<td>Score:</td>
<td>Score:</td>
</tr>
<tr>
<td>Emotional subscale</td>
<td>Score:</td>
<td>Score:</td>
</tr>
<tr>
<td>Functional subscale</td>
<td>Score:</td>
<td>Score:</td>
</tr>
<tr>
<td>Total</td>
<td>Score:</td>
<td>Score:</td>
</tr>
</tbody>
</table>

**COMPARISON CHART**

- White: 1st examination
- Purple: 2nd examination

**Additional Notes**

Send comparison results to EHR

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*Figure 3-17. The comparison results screen (second design)*
4. Discussion

In this section, the major findings of the study are discussed and a reflection is made on their significance. Furthermore, the most important study results are being discussed and being connected to other related studies (see 4.1) and the generalizability and the significance is reflected (4.2). The methods that were used in this study are also discussed, as well as alternative methods (see 4.3). Finally, limitations of the study are presented (see 4.4) and recommendations are given for further research (see 4.5).

4.1. Discussion of the results

The first phase of this qualitative, explorative study, provided results related to the identification of needs and expectations of SLPs, regarding the use of a computerized interactive version of a VHI HRQoL instrument for voice disorders. This phase is strongly related to and answers the first research question of this study, while also as well as it contributes contributing to the second research question, which is related to the exploration of the features that a HRQoL questionnaire should support in order to fulfil the user needs.

The results of the observations were very important, since they were used as the basis for constructing the rest of the study, providing input to e.g. the construction of interview guides and creation of test scenarios. The major findings from the observations were related to the workflow of the current procedure of the paper-based VHI used by SLPs in Karolinska University Hospital in Huddinge. The complexity of the activities revealed a continuous transfer of sensitive data from paper to computer and vice-versa. Other findings in the observation showed that the interaction between the SLP and the patient is focused only on a certain activity of the VHI process, which is the filling process, i.e. the process where the patient fills in the questionnaire. The observation findings correspond highly to the findings of the semi-structure interviews of the first phase. The other findings of the observation were also valuable, giving an overview of how the paper-based VHI is used from by the SLPs.
The results of the semi-structured interviews of the first phase provided insight into the SLPs perspective regarding the current use of the VHI, as well as the definition of the needs and expectations of a computerized version of VHI. The task flow that was observed before was included a complicated transfer of the sensitive data and as it was expected, this complication was also reflected on in the interview results. The SLPs defined it as a major limitation, making the current process both complex, and less reliable, since data can be missed or changed accidentally. This finding is totally supported by related studies, where limitations of paper-based questionnaires were identified and discussed (11), (10) and (12). At the same time, the issue of required time for the completion of the current process is something that does not affect negatively the SLPs. This finding is also important, since it explains why the matter of time does not constitute a limitation, according the studies reviewed from the researcher (11), (10) and (12). According to SLPs, the level of experience can make a process feel less time-consuming, since the increased familiarity with this process moderated this issue.

Another important finding of the initial interviews was the fact that the needs of SLPs are actually recommendations of an improved system, rather than characteristics that require the immediate replacement of a current process. In other words, according to the interviews, SLPs identified limitations in the current process, but at the same time, they stated that the can work effectively using it. Their needs and expectations are related to suggestions to improve a new system, expressed as answer to a question like “What would you suggest as a better tool”. The SLPs’ made these suggestions in contrast with the limitations of the current process, providing advantages of a potential computerized tool, which are similar to advantages in other studies (10), (11), (14), (13). [12].

The participant’s suggestions were finally considered as requested features of a computerized tool, and three major tasks emerged; the “completing the questionnaire” process; the access to data; and the follow-up. According to Preece et al (18), the methods that were used to elicit these features constitute UCD methods and consequently the requested features, as products of the UCD methods, are considered as UCD-driven features as well. The definition of the UCD features of a computerized HRQoL contributed
to the second research question, which is related to the identification of the UCD features that should be supported by a computerized HRQoL questionnaire. In the thesis, it has been mentioned that VHI has been transformed into a digital version before (32). That design was technologically-driven, focusing on the functions of the paper-based VHI and occurs differences comparing the UCD digital VHI that has been design in this thesis. One of the major differences is that the non-UCD digital VHI does not support the three major tasks that were emerged by the UCD VHI process, indicating that when a design is conducted by involving the users in its development, the result is quite different and different aspects, features and tasks emerge.

An important finding from the initial interviews was the concern regarding the therapeutic relationship that is the relationship between the SLP and the patient. This concern is totally explained by the observed results, since the patient and the SLP interact during the filling process of the VHI conduct. This concern is a potential risk, which cannot be avoided and is acceptable from SLPs.

The requested features were defined from the interview, but they should be evaluated by the SLPs. The second phase was actually the medium that was used to reflect the features elicited of the first phase and allow the SLPs to evaluate them in order for the second research question to be answered. Particularly, prototyping the requested features in the second phase, provided visual demonstration of them to SLPs, giving them the chance to see how a computerized VHI based on their own needs can be used, through a scenario during the second phase. The results of the first phase led to a structured, straightforward design, where both patients and SLPs have their own interface and interact differently with the system.

Finally, after the third phase (formative evaluation), it was interesting that the SLPs stated that the prototype of the new tool met their expectations, saying that the design was simple, understandable and concrete and followed the STEEEP aims. Some additional recommendations were given, contributing to the creation of a second design, where some of the features were changed to some extent, supporting the iterative nature of the
design. These changes affected only a few parts of the initial design, which reflects their satisfaction about the new tool.

4.2. Generalizability and significance of the results

Despite the fact that the results come from a limited number of participants, from a specific context and for a very specific tool, many of the problems are similar to other clinical settings (10), (11) and (12). As a consequence, the features that were elicited from the research can be transferred in these settings, since they concern actually general technical requirements. Table 4-1 presents these requirements.

<table>
<thead>
<tr>
<th>Technical requirements</th>
<th>Short description</th>
</tr>
</thead>
<tbody>
<tr>
<td>View</td>
<td>Features related to how the user can see the questionnaire and the answers</td>
</tr>
<tr>
<td>Text</td>
<td>Features that provide additional information through text</td>
</tr>
<tr>
<td>Navigation</td>
<td>Features that enable the user to navigate himself within the questionnaire items</td>
</tr>
<tr>
<td>Correction</td>
<td>Features that enable the user to change his answers in the questionnaire</td>
</tr>
<tr>
<td>Statistics</td>
<td>Features that provide statistic information to the user</td>
</tr>
<tr>
<td>Score calculation</td>
<td>Features that calculate the scores of the questionnaire immediately</td>
</tr>
<tr>
<td>Notes</td>
<td>Features that allow the user to add notes regarding the questionnaire</td>
</tr>
<tr>
<td>EHR integration</td>
<td>Features that transfer the results of the questionnaire to the EHR</td>
</tr>
</tbody>
</table>
Comparison Features that provide comparison among the results of the first and the follow-up examination

Resending test Features that allow the user to resend the test to the users that fill it out

The QS, as a prospective service of Mina Vårdflöden project, should take into account these technical requirements in order to be designed as a useful tool, providing a UCD computerized HRQoL questionnaire that can satisfy the various users from similar contexts and use HRQoL instruments in their clinical experience. In the context of this application, several issues will be emerged and should be evaluated:

- How easy will be for the healthcare professionals to create a questionnaire service themselves? If these features are going to be applied, how the users will be able to create new instruments easily, using the QS?

- What challenges can somebody envision based on the needs for visualizations and automatic calculations? A system that needs to provide visual information regarding sensitive data as well as to calculate automatically the scores, may carry on challenges like security and reliability. These challenges should be taken into account.

- What challenges the sharing of questionnaires would imply? Again, security is also again the major challenge, when the questionnaires that include personal health information is distributed among different healthcare contexts and different systems.

- How can the comparisons of data can be done over time? Will the tool need to be able to access old test data stored in the medical record, or should there be a separate storage for the questionnaire service?

- What challenges the reusability of the QS would imply? Could different healthcare professionals use the same service to create various HRQoL questionnaires?
Different clinical contexts as well different instruments may involve different characteristics and require different features, as a consequence. The technical requirements that are being described in Table 4-1 can be considered as general, but they come from research coming from a specific group (SLPs).

4.3. Discussion of the methods

According to the study design framework (see 2.1), the first phase of this study included two different data collection methods; observations and semi-structured interviews. Observation, as the first method, was considered a fruitful method, fulfilling its purpose i.e. the understanding and description of the SLP's current work-flow with the paper-based VHI. This method, in combination with a structured observation protocol, gave clear information regarding the procedure, a basis for the researcher to “build” the next methods on. Generally, no difficulties were identified during the conduct of the method and measures were taken to reduce any potential negative risk as much as possible (inform both the SLP and the patient regarding the observation and use of one-way mirror). Despite these measures there were some disadvantages:

The method was time-consuming since it required three phases of constructing the protocol (discussion of the current process, development of the observation protocol and finally validation of the protocol) as well as the use of a whole voice examination session plus time after the end of the examination, in order to record all the phases of the VHI procedure (in total about 70’ per session).

The examination session was in Swedish. This was a limitation since the observer was not proficient in Swedish. Because of this, the VHI procedure was not completely comprehensive for the observer, particularly during the interaction between the SLP and the patient. Any misunderstandings or blanks in the observations were corrected or completed during the validation phase after the observation phase. However, the workflow of the observed procedure was pretty clear, since no understanding in Swedish language was required, but only observation of the activities.
An alternative way of collecting similar data, would be the use of a questionnaire to SLPs, where the same structure as the observation protocol (see APPENDIX B) could be used. This method would save time, since it would give directly the required answers. However, because of the significance of the collected data, the researcher chose not to rely on the SLP to recall details of the process, but to record everything observing the natural context.

The next method of the first phase was the semi-structured interview. This method provided the researcher a lot of useful results, using a structured interview guide (see APPENDIX B & C). Despite the structure of the interviews, they were flexible, allowing the participants to express themselves better and the researcher to gain the required information. However, the large amount of data was also disadvantageous, since the analysis was so excessive, required a complex content analysis, threatening the final results. Again, questionnaires could be used instead, to limit the size and the number of the participants’ responses. But finally this method was not used, since some subjects needed further discussion and therefore open questions, driven by the interviewer.

Content analysis was used during the first phase, in order to process the qualitative data and give the results in order to answer the research questions. This method was quite useful and simple, since it was structured, consisting of certain clear steps (see 2.5). Alternatively, this method can be used with the use of a computer software. A technique like this could save more time when organizing the data, but for an unexperienced user it would require time and energy to learn how to use it. Therefore a manual, paper-based process was chosen for the analysis.

The second phase of this study (see 2.1) included the development of the wireframe prototype. The selection of this tool to visualize the results of the first phase as well as to demonstrate during the third phase, was considered as the best choice for the limited time of the thesis, since its development was fast and not complicated and could support all the requested features elicited from the first phase. Alternatively, paper or high-fidelity prototypes could be used to visualize the artefact. The reasons that the researcher chose the wireframe was that on the one hand, the paper prototype requires design on paper, which would require more time, since many wireframe tools for easy and fast design are
provided for free on the internet now. And on the other, although a high fidelity prototype would provide more details and a product for a cooperative evaluation, it requires a number of resources (time, energy and money) that could not be supported in the context of this study.

Finally, the user scenario was used to support the demonstration of the artifact, worked well, accepting positive reaction from the participants. Because of the simple scenario, the participants were able to understand completely the features of the design and reflect on them, using the actors of the scenario for this. Instead of the scenario, a simple description of the features could be used, which would be less time-consuming and require less effort from the researcher. Despite this, this method proved quite fruitful, contributing to the collection of useful feedback from the participants.

4.4. Study limitations

The study design imposed limitations which need to be acknowledged when considering the results:

Regarding the participants, only SLPs contributed to this study. Patients were excluded from the research, whose involvement may have led to a different design as well as different features, like access to their own filled questionnaire and the comparison results.

The interviews were conducted only in English language, which was not the native language of the participants or the researcher. Despite the fact that no difficulties were reported in the communication during the interviews, it is speculated that maybe the answers would be different if they would be given in the native language of the participants (Swedish), since the participants would, maybe, express themselves differently.
Furthermore, the limited time of thesis restricted the analysis to only the expressed needs of the participants and not further to complete requirements specification, as it suggested by Maguire (59)

Also, the wireframe prototype was evaluated only one time during the study, due to the limitation of time. If more iterations would be done, maybe different results would be elicited regarding the design.

4.5. Future research

This study has provided some results, answering specific research questions. Despite the fact that a number of limitations were identified (see 4.3), this study could be used as a starting point and a knowledge base for related future research.

The same study design used for this research could be used, including also patients, in order to explore their user needs and design an artefact that would be patient-centered, rather than driven by the health professionals’ needs. Another recommendation is to further this study by creating a high-fidelity artefact. In this case, the potential users would have the opportunity to use it during the actual examinations and therefore more detailed and complete usability testing would be provided.

A similar research could be conducted using different healthcare professionals, except from SLPs in order to produce more generalized results. Particularly, a certain study design is recommended, where the main research question could be related to the user needs and requirements elicitation for HRQoL instruments. The results of the different studies could be compared and common characteristics could be extracted and used to form a questionnaire platform with certain features that could be evaluated by users from different fields.
5. Conclusion

This study aimed at yielding knowledge about identifying the features that a computerized HRQoL questionnaire, which has been designed through the QS, should support, when it is being used from the patients and the healthcare providers.

The main findings of the study indicate that the current procedure of paper-based VHI used by SLPs in Karolinska University Hospital is related to a number of limitations concerning the complexity of the procedure and the risk of producing unreliable data. The SLPs stated that a new computerized system could eliminate these issues, by improving the VHI examination procedure, suggesting a number of features which would improve its three main activities; the process where the patient fills the questionnaire; the process where the SLP analyzes and transfers the data to EHR; and the follow-up process. These features were visualized through a wireframe prototype evaluated by the SLPs of the particular context and they can be used as features supported by a computerized HRQoL questionnaire service.

Although the use of computerized solution in QoL finds more and more application, this study provides user needs within a field with limited research in computerized HRQoL instruments, contributing in the development of UCD-driven solutions.
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Appendices

Appendix A. The Voice Handicap Index (VHI)

Instructions: These are statements that many people have used to describe their voices and the effects of their voices on their lives. Circle the response that indicates how frequently you have the same experience.

<table>
<thead>
<tr>
<th>Code</th>
<th>Statement</th>
<th>0=Never</th>
<th>1=Almost Never</th>
<th>2=Sometimes</th>
<th>3=Almost Always</th>
<th>4=Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>F1.</td>
<td>My voice makes it difficult for people to hear me.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>P2.</td>
<td>I run out of air when I talk.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>F2.</td>
<td>People have difficulty understanding me in a noisy room.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>P4.</td>
<td>The sound of my voice varies throughout the day.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>F5.</td>
<td>My family has difficulty hearing me when I call them throughout the house.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>F6.</td>
<td>I use the phone less often than I would like.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>E7.</td>
<td>I'm tense when talking with others because of my voice.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>F8.</td>
<td>I tend to avoid groups of people because of my voice.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>E9.</td>
<td>People seem irritated with my voice.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>P10.</td>
<td>People ask, &quot;What's wrong with your voice?&quot;</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>F11.</td>
<td>I speak with friends, neighbors, or relatives less often because of my voice.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>F12.</td>
<td>People ask me to repeat myself when speaking face-to-face.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>P13.</td>
<td>My voice sounds creaky and dry.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>P14.</td>
<td>I feel as though I have to strain to produce voice.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>E15.</td>
<td>I find other people don't understand my voice problem.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>F16.</td>
<td>My voice difficulties restrict my personal and social life.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>P17.</td>
<td>The clarity of my voice is unpredictable.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>P18.</td>
<td>I try to change my voice to sound different.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>F19.</td>
<td>I feel left out of conversations because of my voice.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>P20.</td>
<td>I use a great deal of effort to speak.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>P21.</td>
<td>My voice is worse in the evening.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>F22.</td>
<td>My voice problem causes me to lose income.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>E23.</td>
<td>My voice problem upsets me.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>E24.</td>
<td>I am less outgoing because of my voice problem.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>E25.</td>
<td>My voice makes me feel handicapped.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>P26.</td>
<td>My voice &quot;gives out&quot; on me in the middle of speaking.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>E27.</td>
<td>I feel annoyed when people ask me to repeat.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>E28.</td>
<td>I feel embarrassed when people ask me to repeat.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>E29.</td>
<td>My voice makes me feel incompetent.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>E30.</td>
<td>I'm ashamed of my voice problem.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>
Appendix B. The observation protocol

1. General Information

   A. General Information (name, date, setting, aim, place of examination)
   B. Is the VHI examination included to the general voice examination session?
   C. Are more than one SLP involved in this process?
   D. If (C) is “Yes” how many SLPs are involved?

2. Time (in minutes and seconds)

   A. Preparation
   B. Examination
   C. Data Analysis
   D. Data transfer
   E. Total length

3. Interaction with patient

   A. Interaction before the examination
   B. During the examination
   C. After the examination

4. Information about the patient

   A. Did the patient know about the VHI examination in advance?
B. Did the patient fill in the test in the same room with the SLP?

C. Additional information

5. Data analysis/Transfer

A. Did the SLP analyze the data directly after the examination?

B. If (A) is “No” then when did he do it?

C. Did the SLP use any scale/tool/guide to analyze the data? If yes, what?

D. Did the SLP transfer the data to EHR directly after the examination?

E. If (D) is “No” then when did he do it?

F. Did the data interact with other data after their transfer and how?

6. Workflow (List with the tasks)

7. Use of tools (Paper, electronic systems, etc.)
Appendix C. The initial interview’s guide

1. Time

A. How do you evaluate this process, concerning its length?
B. Do you need more time to prepare the test for the patient?
C. The patient fills in the questionnaire. How do you evaluate this task?
D. How do you evaluate the procedure of data analysis?
E. Do you believe that you need more time to make the data analysis?
F. How do you evaluate the task of data transfer?
G. Do you want to add anything else regarding the length of the whole process?

2. Use of paper/Technology

A. In your opinion, how effective is to use paper in this procedure?
B. Could you suggest other means to do the same procedure?
C. Do you think that you could use technology instead?
D. If (C) is “Yes” then how could technology assist you in this procedure?

3. Computer and Internet literacy

A. Do you use technology in your work environment? Give examples
B. How much familiar do you feel with the use of technology at work?
C. Do you think that a new technological tool at work could make the tasks more complicated?
D. Do you think that a new technological tool at work would require more time from you at work?
E. Do you think that the use of technology can improve the quality of your outcome at work?
F. Do you believe that the use of paper at work works better for you?
G. Do you believe that a patient can use easily a digital system on his own in order to do tasks, like filling in an electronic questionnaire?
4. Interaction with patients
   A. Do you think that is important to interact with the patient during all the stages of the procedure?
   B. Do you believe that the patient can trust a digital tool for assistance instead the physical interaction with you, during the different stages of the procedure?
   C. Do you think that a digital tool that interacts with the patient during the procedure, would affect you relationship with him?

5. Data analysis
   A. Do you find that the use of Excel makes the data analysis more complicated?
   B. Do you believe that is important for an SLP to analyze the data on his own?
   C. Would you trust a digital tool that analyzed the data automatically?

6. Data transfer
   A. How do you evaluate the process of transferring data to EHR?
   B. Do you find important for an SLP to transfer the data to EHR on his own?
   C. Would you trust a digital tool that transfers the data to the patient’s EHR?

7. Improvement
   A. Which do you think is the hardest part of this procedure?
   B. Are you satisfied from the current process?
   C. If (B) is “No” then what would you change and
Appendix D. The second interview’s guide

A. STEEEP

1. SAFETY

- Do you think that this procedure keeps the patient’s data safe? If not, why?

2. TIME

- Compare this procedure with the one that is being currently done, according the time. Do you think that it makes the process faster, slower or the process length the same?

- Do you think that this procedure offers advantages regarding the waiting time?

3. EFFECTIVENESS

- Do you think that this procedure produces reliable results that can be used to support a successful treatment schedule?

- Do you think that this procedure uses more information than it is actually needed? If yes, justify

- Do you think that this procedure uses less information than it is actually needed? If yes, justify

4. EQUITABLE

- Do you think that this procedure can be used for all kinds of people, regarding gender, age, socioeconomic level, ethnicity and geographic location? If not, justify
5. EFFICIENCY
- Do you think that this procedure wastes equipment and energy? Do you think that in order this procedure to be completed, a lot of resources are being used? If yes, justify

6. PATIENT CENTERED
- Do you think that this procedure respects the patient? If not, justify
- Does this procedure gives the patient the ability to be involved in his own therapy plan? If not, justify

B. DESIGN
- How do you evaluate the design of this procedure, regarding its content and task flow? (Easy, difficult) For patient and SLP.
- Do you think that the filling process is understandable from the patient? If not, which parts are difficult and why?
- Do you think that the access to data is understandable from the SLP? If not, which parts are difficult and why?
- Do you think that the follow up is understandable from the SLP? If not, which parts are difficult and why?
- Which part would you change and how?
- Do you think this design lacks important aspects of the process? If yes, justify.